OF THE NATIONAL ACADEMIES

Roundtable on Value & Science-Driven Health Care



March 14, 2012 Keck Center, The National Academies 500 Fifth Street, NW Washington, DC 20001



ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

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- Fendrick, Mark et al. Value Based Insurance Design: Maintaining a Focus on Health in an Era of Cost Containment. American Journal of Managed Care. 2009.
- Goldman, Lee et al. Improving Adherence Money Isn't the Only Thing. New England Journal of Medicine. 2011.
- Schaeffer, Leonard et al. Benefit Design Should Reflect Value. Institute of Medicine. 2012.
- Gabow, Patricia et al. A Broad And Structured Approach to Improving Patient Safety and Quality: Lessons From Denver Health. Health Affairs. 2011.
- Meyer, Harris. Life in the Lean' Lane: Performance Improvement at Denver Health. 2010.
- Clark, Steven et al. Neonatal and Maternal Outcomes Associated with Elective Term Delivery. American Journal of Obstetrics & Gynecology. 2009.
- Clark, Steven et al. Reduction in Elective Delivery at <39 Weeks of Gestation: Comparative Effectiveness of 3 Approaches to Change and the Impact on Neonatal Intensive Care Admission and Stillbirth. American Journal of Obstetrics & Gynecology. 2010.
- The National Priorities Partnership. National Priorities & Goals: National Priority Overuse. 2008.
- Oregon Health Leadership Council. Value Based Benefit Design Large Employers (50+). 2010.
- Patient Centered Outcomes Research Institute. Draft National Priorities for Research and Research Agenda (Version 1). 2012.
- Centers for Medicare & Medicaid Innovation. Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2: Stage 2 Meaningful Use Objectives and Associated Measures. 2012.
- Gold, Marsha. Identifying, Monitoring, and Assessing Promising Innovations: Using Evaluation to Support Rapid-Cycle Change. Commonwealth Fund. 2011.

SECTION 4: BIOGRAPHIES AND MEETING LOGISTICS

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- Location, Hotel, and Travel

Agenda

INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

♦ Members Meeting

MARCH 14TH 2012 KECK CENTER 500 FIFTH ST., NW |WASHINGTON, DC

Meeting Goals

- 1. Identify Roundtable Member views on issues and opportunities of priority in engaging the value proposition in health care.
- 2. Propose ways in which Member initiatives, within and across organizations, can foster cooperative progress for the changes necessary at both the societal and individual levels.
- 3. Present, discuss, and solicit Member insights, interests, and suggestions on the broader Roundtable agenda for collaborative action to accelerate progress toward a continuously learning and improving health system—and effective, efficient care.

8:30 am	Coffee and light breakfast available
9:00 am	Welcome and introductions
	Opening remarks <i>Mark McClellan,</i> The Brookings Institution and Roundtable Chair <i>Harvey Fineberg,</i> Institute of Medicine
9:15 am	Engaging the value proposition in health care
	Assessing the value of innovative delivery models William Shrank, Center for Medicare & Medicaid Innovation
	Innovations in value-based insurance design Mark Fendrick, University of Michigan
	Delivering value in the safety net <i>Patricia Gabow</i> , Denver Health
	Open discussion
10:30 am	Break

10:45 am	Engaging the value proposition in health care (cont.)
	Aligning value incentives in program design Rodney Armstead, Optum
	Clinical protocols and value improvement—an example <i>Jonathan Perlin</i> , HCA Inc.
	Mobilizing employers to seek value Roger Merrill, Perdue Farms Inc.
	Open discussion
12:00pm	Lunch & reflections on Patient-Centered Outcomes Research
	Joe Selby, Patient-Centered Outcomes Research Institute
	Open Discussion
1:00 pm	Roundtable update and observations
	Summary of opportunities identified in Member conversations Michael McGinnis, Institute of Medicine
	Open discussion
1:30 pm	Federal levers to enhance effectiveness and efficiency in health care
	Centers for Medicare & Medicaid Services
	Patrick Conway, Chief Medical Officer
	Office of the National Coordinator for Health IT Joshua Seidman, Director, Meaningful Use
	Comments
	 Peter Hussey, RAND Corporation Edward Shortliffe American Medical Informatics Association
	 Matt Wynia, American Medical Association
	Open Discussion
3:30 pm	Summary and next steps
	Comments from the Chair Mark McClellan, The Brookings Institution and Roundtable Chair
	Comments and thanks from the IOM Michael McGinnis, Institute of Medicine

Roundtable Update Materials

IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

Learning Health System Strategy Map

Assessing the progress

Stewarding the action

Describing the possible

Making the case



Advising the nation • Improving health

Roundtable High Level Overview

Phase 2006 Phase I Vlaking the case 2007 Phase 2	Goal Transformational capacity for clinical evidence generation and use A learning health system that delivers continuous improvement in health care and	Results-i • Patient Centered Outcome • Accelerated translation ac • 11 <i>Learning Health System</i> • Spread of lean process imp
2 ibing the possible	A learning health system that delivers continuous improvement in health care and health outcomes	 11 Learnin Spread of CMS Inno Value initi Meaningfi
009 hase 3 tewarding the action	Collaborative stakeholder activities to accelerate progress toward continuously learning health systems	 Best Pract Clinical R Digital Le Evidence Value Incompared
2011 Phase 4 Getting the word out	Rapid spread of proven innovation in value and science-driven health care	• IOM Di • IOM Cc
2012 Phase 5 Assessing the progress	Streamlined, harmonized, and reliable monitoring for better care, lower costs, and better health	• Natior • Why N • Triple

and sponsor creative communication strategies). **Opportunities for Roundtable members and staff:** Collaborative projects (propose, take lead for, participate in); Constituents (engage and recruit constituents to build involvement); Spread (disseminate and communicate, suggest

*Important related developments, fostered by multiple contributors and stakeholders

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Advising the nation • Improving health

Roundtable Action Phase

Innovation Collaboratives	Example Organizations	Collaborative Activities
Best Practices (professional societies)	American Academy of Nursing, American Academy of Nurse Practicioners, American Academy of Physician, Assistants, American College of Clinical Pharmacy, ACP, ACS, ADA, AMA, ANA, AAHC, AAMC	Team-based care: principles & expectations Clinical guidelines in co-occuring conditions
Evidence Communication (marketing experts)	AARP, AstraZeneca, Consumers Union, Foundation for Informed Medical Decision Making, Healthwise, Kaiser Permanente, Mayo Clinic, National Partnership for Women and Families, Research!America, Sanofi	Patient-clinician communication: principles Evidence messaging strategies Virtual electronic medical library
Value Incentives (payers, purchasers, systems)	Aetna, BCBS Association, General Electric, Group Health, Johnson & Johnson, Kaiser Permanente, Medtronic, National Business Group on Health, Leapfrog, ThedaCare, Virginia Mason, Wellpoint	CEO Checklist for High-Value Care Value incentive project inventory Value pilot evaluation working group Strategies for engaging people on value
Digital Learning (systems, CIOs, vendors)	Children's Hospital of Philadelphia, Cleveland Clinic, Geisinger, Google, Harvard, HCA, IBM, Intermountain, Kaiser Permanente, Mayo Clinic, Microsoft, Partners HealthCare, Vanderbilt	Digital data quality workshop Clinical data trust: privacy and governance Engaging the public on the clinical data utility
Clinical Effectiveness (<i>researchers</i> , <i>systems</i>)	AAMC, AstraZeneca, Bristol-Myers Squibb, Center for Medical Technology Policy, Duke, FDA, Harvard, Johnson & Johnson, Kaiser Permanente, NIH, Partners HealthCare, UPenn, Vanderbilt	Common Rule and the learning utility Large simple trials: better, faster, cheaper? System CEOs and the research-practice bridge CER field advancement discussion paper
Other (ad hoc)		

Funder forum on accelerating molecular-based diagnostics—DARPA, philanthropies, federal stakeholders Conflict of interest harmonization-NIH, CMS, FDA, societies, journals, others (Health care audit—CMS, AHRQ, payers, system stakeholders) (Triple Aim progress metrics: local, state, national-BSCAF, CMS, CDC, HRSA) (State exchanges, ACOs, and population health-CMS, ASTHO, CDC, Pew)

Possible Roundtable Projects: Member Suggestions

Achieving the vision	Speeding innovation	Determining effectiveness	Removing waste	Rewarding value	Improving decisions	Compelling Aim
 Tool kit and talking points on the learning health system Workshop on contributions of a learning health system in combatting health disparities Roles and perils of high capacity, triple-missioned Academic Medical Centers Greater clarity and consistency in definitions, roles, responsibilities in health care 	 Making the case for practice-based evidence Case studies on the use of clinical data sets for breakthrough insights Putting data privacy considerations into understandable context Exploring the path to a global digital data utility 	 Blueprint for path to broad clinical registry utility development and use Advance understanding and use of large simple trials for efficacy, effectiveness studies Implications of electronic records for regulatory streamlining 	 Spreading lean practice and culture Discussion paper on administrative simplification for cost reduction Exploring the glide path for care delivery consolidation Aligning digital health data reporting requirements 	 Identify and propose improved measures of high value care Working group on payer experiences exploring ACO models for high value care Identify approaches to incentives alignment Analytics/strategies targeting highest cost patients (non-outlier conditions) Analytics/strategies targeting highest cost patients (outlier conditions) 	 Guideline development and use streamlining and harmonization. Novel approaches to continuous population of the Electronic Medical Library Improving consumer tools and resources (e.g. EML consumer translation) Inventory of comparative risk communication reference points 	Sample Project Focus

Other Background Materials

Background Articles Engaging the Value Proposition in Health Care

Assessing the value of innovative care delivery models

William Shrank, Center for Medicare & Medicaid Innovation

This discussion will cover the work being done at the CMS Center for Innovation to assess innovative delivery models to move the country toward the three part aim of better health, better care and reduced costs. Included is a summary of the progress made by CMMI during its first year, including a summary of its ongoing initiatives.

• CMS Innovation Center. One Year of Innovation: Taking Action to Improve Care and Reduce Costs. US Department of Health and Human Services. 2012.

"Through specific transformative programs in the Affordable Care Act and programs launched by the Innovation Center, HHS and Centers for Medicare and Medicaid Services (CMS) are working hard to support physicians, nurses, hospital systems, and others who have accepted the challenge to develop a new, sustainable health care system."

Innovations in value-based insurance design

Mark Fendrick, University of Michigan

This discussion will cover innovative approaches to engaging consumers in health care value through insurance benefit design, including the need for clinical nuance in such programs. Articles cover principles behind value-based insurance design, a discussion of the finding that a rational health care system must go beyond financial incentives, and am IOM Commentary on the need to reflect value in benefit design.

 Fendrick, Mark et al. Value Based Insurance Design: Maintaining a Focus on Health in an Era of Cost Containment. American Journal of Managed Care. 2009.
 "The principles behind VRID on work supersistically with a range of patient, and provider original supersistical supe

"The principles behind VBID can work synergistically with a range of patient- and provider-oriented cost containment strategies to promote value."

• Goldman, Lee et al. Improving Adherence — Money Isn't the Only Thing. New England Journal of Medicine. 2011.

"A rational health care system must not only incorporate financial considerations but must also investigate and develop additional ways to improve adherence."

• Schaeffer, Leonard et al. *Benefit Design Should* Reflect Value. Institute of Medicine. 2012. "VBID shows promise as a key strategy to help move the nation toward a health care system that rewards value...The real promise of VBID is to mitigate tension between controlling health care costs and ensuring that patients get the care they need."

Delivering value in the safety net

Patricia Gabow, Denver Health

This discussion will cover Denver Health's approach to delivering value in the context of a safety net environment through the application of LEAN principles. Included are articles profiling Denver Health's experiences improving care quality and patient safety.

• Gabow, Patricia et al. A Broad And Structured Approach to Improving Patient Safety and Quality: Lessons From Denver Health. Health Affairs. 2011.

"The Denver Health experience demonstrates that care quality and patient safety can be advanced within America's health care institutions, even in organizations challenged by lack of resources and by socially disadvantaged patients."

• Meyer, Harris. *Life in the Lean' Lane: Performance Improvement at Denver Health.* 2010. "Denver Health, an integrated, public safety-net institution, has developed a multifaceted, structured approach to quality and safety improvement that has produced positive outcomes."

Clinical protocols and value improvement-an example

Jonathan Perlin, HCA Inc.

This discussion will cover HCA's approach to reduce neonatal morbidity by reducing elective preterm deliveries. Articles included cover the scientific evidence for the program, as well as a study comparing the effectiveness of institutional approaches to reducing preterm elective deliveries.

- Clark, Steven et al. Neonatal and Maternal Outcomes Associated with Elective Term Delivery. American Journal of Obstetrics & Gynecology. 2009.
 "Elective delivery before 39 weeks' gestation is associated with significant neonatal morbidity."
- Clark, Steven et al. Reduction in Elective Delivery at <39 Weeks of Gestation: Comparative Effectiveness of 3 Approaches to Change and the Impact on Neonatal Intensive Care Admission and Stillbirth. American Journal of Obstetrics & Gynecology. 2010.

"Physician education and the adoption of policies backed only by peer review are less effective than 'hard stop' hospital policies to prevent the practice of elective deliveries at <39 weeks of gestation."

Mobilizing employers to seek value

Roger Merrill, Perdue Farms Inc.

This discussion will include a discussion of health care value from the perspective of a large employer, including examples of evidence-based plan design, and reflections on future priorities for employers given the changing health care environment. Articles included cover the national priorities and goals of the National Priorities Partnership of the National Quality Forum, as well as a benefits summary from the Oregon Health Leadership Council for the Value Based Benefits Design for large employers.

- The National Priorities Partnership. National Priorities & Goals: National Priority Overuse. 2008.
- Oregon Health Leadership Council. Value Based Benefit Design Large Employers (50+). 2010.

Reflections on Patient-Centered Outcomes Research

Joe Selby, Patient-Centered Outcomes Research Institute

This discussion will cover the current state of play with the Patient-Centered Outcomes Research Institute (PCORI). Material included covers PCORI's recently released research priorities and agenda now open for public comment.

• Patient Centered Outcomes Research Institute. Draft National Priorities for Research and Research Agenda (Version 1). 2012.

"The five comparative clinical effectiveness research priorities developed in light of PCORI's statutory requirements are: assessment of prevention, diagnosis, and treatment options; improving

healthcare systems; communication and dissemination research; addressing disparities; and accelerating patient-centered outcomes research and methodological research."

Office of the National Coordinator for Health IT

Joshua Seidman, Director, Meaningful Use

This discussion will cover the recently releases proposed rule for Meaningful Use Stage 2, as well as ONC's programs and priorities going forward. Material included summarizes the stage 2 Meaningful Use objectives and associated measures.

Centers for Medicare & Medicaid Innovation. *Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2: Stage 2 Meaningful Use Objectives and Associated Measures.* 2012. Stage 2 Meaningful Use Objectives and Associated Measures.

Additional resources:

• Gold, Marsha. Identifying, Monitoring, and Assessing Promising Innovations: Using Evaluation to Support Rapid-Cycle Change. Commonwealth Fund. 2011.

"Timely evaluation that is targeted to important concerns can help identify the kinds of innovations likely to make a big difference and support policymakers to better structure the way they test innovations to enhance the ability to learn from such testing."

ONE YEAR OF

[Taking Action to Improve Care and Reduce Costs]









OVER THE PAST SEVERAL YEARS, there is one point on which policy makers, health care providers and patients have come to agree: if we want an improved and sustainable health care system, **we need to transform how we deliver and pay for health care**.



Through the Affordable Care Act, the U.S. Department of Health and Human Services (HHS) has been helping providers improve how they deliver health care services, through hospital value-based purchasing, realigned and increased primary care payments, and greater coverage for preventive care. The Center for Medicare and Medicaid Innovation (the Innovation Center), is an important new resource for health care providers dedicated to improving how our health care system works. Its mission is to move quickly to identify, test, and spread delivery and payment models to help providers improve care while cutting costs.

In the year since opening its doors, the Innovation Center's work is well underway. It has introduced 16 initiatives (see Table at end of report) involving over 50,000 health care providers that will touch the lives of Medicare and Medicaid beneficiaries in all 50 states and will continue to expand its partnerships and reach in the years to come. These initial efforts are focused on improving patient safety, promoting care that is coordinated across health care settings, investing in primary care transformation, creating new bundled payments for care episodes, and meeting the complex needs of those dually eligible for Medicare and Medicaid.

THE CASE FOR INNOVATION

The American health care system is, in many respects, the envy of the world. The United States is the global leader in developing new ways to prevent, diagnose, manage, and cure illness. Our academic institutions offer the finest education and training available. Our talented physicians, nurses, and clinicians work hard each day to deliver the highest quality care. Many of our hospitals are internationally known and admired. Yet despite having the world's best doctors and nurses, most advanced medical technology, and finest hospitals, Americans continue to live sicker and die sooner than citizens of many other nations. Our health care system is full of barriers, roadblocks, and red-tape—ranging from the way we pay for health care services to a lack of usable, reliable information for patients and clinicians alike—that often keep health care professionals from practicing medicine in a collegial, evidence-based, and patient-centered manner. Many doctors, nurses, and other providers have had great ideas, good intentions, and determined efforts, but have been thwarted by disincentives and other obstacles to innovation. The result is a health care system that is often disjointed, inefficient, and costly.

Yet we know improvement is possible. Dedicated clinicians and innovative entrepreneurs around the country have found ways to work with other providers and payers in their local communities to break down barriers and redesign care for the benefit of their patients, themselves, and their communities. For example, large employers and unions are working together to improve the health of their workers by investing in comprehensive primary care, which is decreasing the overall cost of healthcare.

Similarly, some health systems have demonstrated that by keeping people healthy in the first place, providing a coordinated care experience, and striving to get care right every time, they can achieve better outcomes and lower costs for their patients. From their efforts, we know what can and should be done. The current and crucial health care challenge is to bring the best of these approaches to every community in the country.

Through specific transformative programs in the Affordable Care Act and programs launched by the Innovation Center, HHS and Centers for Medicare and Medicaid Services (CMS) are working hard to support physicians, nurses, hospital systems, and others who have accepted the challenge to develop a new, sustainable health care system. It will be a system where providers work with engaged patients and are rewarded for keeping people well, not simply for delivering more services.

AN INNOVATIVE "MENU" OF OPTIONS FOR PARTNERSHIP

We know there is growing consensus that we must move from a volume-based and fragmented health care system to one more based on achieving value for patients and providers through better care, better health, and lower cost. Our strategy is to partner with the patients, providers, and other payers to test new payment and care models that support providers in transitioning to that new system.

To implement that strategy over the past year, the Innovation Center actively sought input from a broad array of stakeholders to identify some of the most promising ways to improve care and lower costs. The Innovation Center met with hundreds of outside innovators, held ten regional meetings with over 4,000 attendees, and received nearly 500 significant proposals for improving health care payment and delivery through the "Innovation Portal" on its website.

Incorporating this rich feedback, the Innovation Center launched an initial menu of initiatives that engage different types of providers and payers at varying levels of experience with care coordination. Each initiative holds the promise of reducing health care costs, improving quality, and improving health. All of these models are tests to help identify which care and payment models deliver greater value for our health system and then to rapidly spread what works.

Some of the new initiatives launched by the Innovation Center this year are described below, and a broader list of initiatives are described in the table at the end of this report:

Improving Patient Safety in Hospitals—The Partnership for Patients. Through the Partnership for Patients initiative, the Innovation Center is working with hospitals, physicians, nurses, other clinicians, consumer groups, and employers to reduce hospital-acquired conditions and preventable hospital readmissions. The program is a public-private partnership with over 7,100 organizations participating as of January 2012 including more than 3,200 hospitals. By joining the Partnership, these organizations have pledged to meet the Partnership's two goals—to reduce preventable harm in hospitals by 40 percent and readmissions to hospitals within 30 days of discharge by 20 percent in the next three years.

The Partnership is investing up to \$500 million in publicprivate engagement networks that will help hospitals adopt proven strategies to reduce hospital-acquired conditions in their own facilities and systems. The Partnership's second component, the Community-based Transitions Program, is a \$500 million initiative to reward hospitals, physicians, and others who partner together to keep patients out of the hospital after discharge. Taken together, the Partnership has the potential to save 60,000 lives, reduce millions of preventable injuries and complications in patient care and, by meeting its goals, save our health care system as much as \$50 billion over 10 years, according to the CMS Office of the Actuary.

Encouraging Care Coordination—Pioneer Accountable Care Organizations (ACOs) and Advance Payment Models. Today's system of paying on a perservice basis often discourages—and even financially penalizes—health care providers for working together to coordinate care and keeping patients healthy and out of the hospital or a nursing home. The Pioneer ACO Model tests the rapid transition to a new payment model where experienced organizations are paid according to their ability to improve the health of their patient population, rather than for each specific service they provide. Starting on January 1, 2012, 32 organizations are participating in the Pioneer ACO Model to test what can be achieved through highly coordinated care for more than 850,000 Medicare fee-for-service beneficiaries. Participating organizations must create similar arrangements with other private sector payers so that more patients have access to this highly coordinated care. According to the independent CMS Office of the Actuary, this model is projected to save Medicare up to \$1.1 billion over five years.

A closely related initiative, the Advanced Payment ACO Model, will test whether pre-paying a portion of future shared savings will allow more physician-based and rural ACOs to participate in the Medicare Shared Savings Program, to improve care for beneficiaries and generate greater Medicare savings more quickly. In the Shared Savings Program, groups of providers come together

"The Partnership for Patients is going to give us the ability, for the first time, to unlock the energy that's already there. We know when we look at some of the hospitals that we work with, that people are doing great stuff around really saving lives, around making patients lives better. So, for instance, one hospital in our membership, Stony Brook, has cut mortality from sepsis, from severe infections, by half. That's great news. But now the question is, how do we spread that, how do we make sure that that's not just exception, that everybody's doing that and everybody knows how to do that and has sort of the basic tools to make it happen? That's what the Partnership can really accelerate, can really create a breakthrough around." "The Pioneer ACO program provides an important opportunity for physicians who are ready to participate in an ACO now, while other groups can begin the process of forming a Medicare ACO in CMS' program throughout 2012."

PETER W. CARMEL, MD.

President, American Medical Association

"This (Pioneer ACO announcement) is a large step forward for Medicare, and for the entire health care delivery system."

DR. DON CRANE President, California Association of Physician Groups

as accountable care organizations to improve care coordination for Medicare beneficiaries and can share in savings they generate for Medicare if they meet certain quality improvement metrics. The Innovation Center is still accepting applications for Advanced Payment ACOs, which will start in April and July of this year in concert with the first two enrollment periods for the Shared Savings Program.

Matching Payment to the Patient Experience— Bundled Payments for Care Improvement. Patients experience care in episodes, often visiting multiple doctors' offices, hospitals, and laboratories as they seek treatment and recovery. But today's system of paying separately for each service often leads to disjointed care, poor outcomes, and a confusing and frustrating experience for many patients. The Bundled Payments for Care Improvement initiative builds on episode-based payment models pioneered in the private sector by redesigning payment to match the patient experience. It offers providers four patient-centered episode of care models to choose from, allowing providers the flexibility to choose the conditions they believe make sense to bundle, decide how best to work together to deliver high-quality, coordinated episodes-of-care, and determine participating providers' share of payment. Health care organizations will give Medicare a discount off the current cost of care for the episodes covered under the initiative, thereby ensuring Medicare Trust Fund savings.

Revitalizing Primary Care—The Comprehensive Primary Care Initiative and The Federally Qualified Health Center Advanced Primary Care Practice Demonstration. Communities with high-performing health systems share a common trait: a strong primary care backbone. Through various investments such as free Medicare Wellness visits and enhanced reimbursement for primary care as a result of the Affordable Care Act among other initiatives, CMS has made the commitment to strengthen the primary care system. However, general practitioners still often struggle to find time to spend with each patient due to the increasing demand from patients and lagging supply of primary care practitioners. The Innovation Center has launched multiple initiatives to strengthen primary care by supporting clinicians willing to comprehensively manage and coordinate the care of their patients, particularly those with serious or chronic diseases with the goal of reinvigorating the primary care system.

The Comprehensive Primary Care Initiative is a collaboration between public and private payers and primary care practices to support patient-centered primary care practices will receive new, public, and private funding for primary care functions not currently supported by fee-for-service (FFS) payments, including an opportunity to share net savings generated through this program. In return, participating practices will agree to give patients 24-hour access to care, create personalized care plans for their patients, and coordinate with other providers to ensure patients are getting healthy and staying well.

The Federally Qualified Health Center Advanced Primary Care Practice Demonstration tests whether advanced primary care practice at community health centers can improve care and patients' health, and reduce costs. In October 2011, 500 community health centers in 44 States were selected to receive approximately \$42 million over three years to reorganize as Patient Centered Medical Homes and improve the coordination and quality of care they give to people with Medicare and other patients.

"The Medicare Bundled Payment for Care Improvement Initiative has the potential to speed up bundled payment implementation by testing various models and giving providers a great deal of flexibility to design a model that works for them."

MARK ZEZZA, STUART GUTERMAN, AND JENNIE SMITH The Commonwealth Fund, January 2012 The Comprehensive Primary Care initiative "offers enormous potential to promote the kind of personalized and coordinated care that patients seek and that physicians want to deliver. The program will provide primary care physicians with the support needed to work hand-in-hand with patients toward a shared goal of ensuring high-quality care while making the most efficient use of health care resources."

DR. STEVEN WEINBERGER

Chief Executive Officer, The American College of Physicians

New Models of Care and Payment to Support

Medicare-Medicaid Enrollees. The Innovation Center is committed to working with other purchasers of health care—both private and public—to ensure care is improving across patient populations. Working with the CMS Medicare-Medicaid Coordination Office, the Innovation Center is empowering States to test new payment and service delivery models that will help improve quality of care, and reduce the costs of care, for the nearly nine million people enrolled in both the Medicare and Medicaid programs. While these Medicare-Medicaid enrollees represent a small percentage of the nearly 100 million people enrolled in the two programs, their care is complex and costly: they account for 21 percent of Medicare beneficiaries but 36 percent of Medicare spending, and 15 percent of Medicaid recipients but 39 percent of Medicaid cost. To date, 15 States have been awarded design contracts of up to \$1 million to develop new ways to meet the needs of this complex population. Additionally, the Innovation Center and the Coordination Office have offered States the opportunity to move beyond the design phase and test new models of payment and care coordination in their States. Thirty-eight States and the District of Columbia have expressed interest in working with CMS.

Engaging Local Innovators—Health Care Innovation **Challenge.** The Innovation Center recognizes that many of the best ideas will come from physicians, other health care providers, and innovative thinkers in communities across the country. Announced in November 2011, the Health Care Innovation Challenge will award up to \$1 billion in grants to applicants who put into practice the most compelling new ideas for rapidly delivering better health, improved care and lower costs to people enrolled in Medicare, Medicaid and CHIP, particularly those with the highest health care needs. The initiative is also looking for new models of workforce development and deployment to support the transition toward high-value care. Awards will range from \$1 million to \$30 million for a three-year period. Providers, payers, local government, public-private partnerships and multi-payer collaboratives may apply.

Supporting Individuals to Help Transform Health Care—Innovation Advisors Program. Crucial to the efforts of transforming the health care system is supporting individuals who can test and refine new models to drive delivery system reform. The Innovation Center seeks to deepen the capacity for transformation by creating a network of experts in improving the delivery system for Medicare, Medicaid, and CHIP beneficiaries. The Innovation Advisors will:

Utilize their knowledge and skills in their home organizations or communities in pursuit of the three-part aim of improving health, improving care, and lowering costs through continuous improvement;

- Work with other local organizations or groups in driving delivery system reform;
- Develop new ideas or innovations for possible testing of diffusion by the Innovation Center; and
- Build durable skill in system improvement throughout their area or region.

In December 2011, the CMS Innovation Center selected 73 individuals out of 920 applications through a competitive process to participate in the initiative. The first group of Innovation Advisors is starting their sixmonth intensive orientation and applied research period in January 2012.

LOOKING FORWARD

The Innovation Center is not only testing new models of care delivery and payment, it is also changing the way CMS partners with providers and conducts demonstration projects. Learning from previous CMS projects and feedback from the health care community, the Innovation Center is committed to providing participants more timely and useful data necessary to improve and coordinate care, rapid-cycle evaluations on their performance, and a new array of opportunities to learn from each other as they innovate. The Innovation Center is also piloting new ways to spread lessons learned, so that success is not just a report—but tangible to providers and patients across the country. That's why every Innovation Center initiative includes a "diffusion" element that matches participating organizations with experts in the field and peer organizations to discuss successes and learn from mistakes. Providers will have tools and resources available to them and will be expected to help diffuse best practices, lessons learned, and improved care strategies so that innovation is not limited to a demonstration site or only one particular community.

INNOVATION CENTER INITIATIVES

[2010 – 2011]

INITIATIVE	APPLICATION DEADLINE	INITIATIVE START DATE	LENGTH	PARTICIPANTS/ LOCATIONS	TOTAL FUNDING	NUMBER OF BENEFICIARIES AFFECTED	
PRIMARY CARE TRANSFO	RMATION						
Comprehensive Primary Care Initiative Demonstration	1/17/2012	2012	4 years	Plan for payers and states in 5–7 markets;	\$322 million	315,000 Medicare 15,750 Medicaid	
Public-private partnership to enhance primary care services, including 24-hour access, care plans, and care coordination				75 practices per market			
Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration	9/16/2011	11/1/2011	3 years ending on 10/31/14	500 FQHCs in 44 states	\$49.7 million	202,000 Medicare	
Care coordination payments to FQHCs in support of team-led care, improved access, and enhanced primary care services							
Multi-payer Advanced Primary Care Practice Demonstration	8/17/2010	Phased-in starting 07/01/2011	3 years	NC, ME, MI, MN, NY, PA, RI, VT	\$283 million*	332,000 Medicare	
State-led, multi-payer collaborations to help primary care practices transform into medical homes							
Independence at Home	2/16/2012	Summer 2012	3 years	Up to 50	\$15 million*	10,000 Medicare	
Home-based care for patients with multiple chronic conditions				practices with at least 200 high need beneficiaries.			
BUNDLED PAYMENTS FOR CARE IMPROVEMENT							
Bundled Payment for Care Improvement Initiative	Model 1: 11/18/2011; Models 2-4:	2012	3 years	To be determined	\$118 million	Not available	
Episodic payments around inpatient hospitalizations to incentivize care redesign	4/30/2012						

INITIATIVE	APPLICATION DEADLINE	INITIATIVE START DATE	LENGTH	PARTICIPANTS/ LOCATIONS	TOTAL FUNDING	NUMBER OF BENEFICIARIES AFFECTED
ACCOUNTABLE CARE OR	GANIZATIONS					
Pioneer Accountable Care Organization Model Initiative	8/19/2011	January 2012	3 years (with optional	32 ACOs—see link for full list of orgs	\$77 million	860,000 Medicare
Experienced provider organizations taking on financial risk for improving quality and lowering costs for all of their Medicare patients			extension)			
Accelerated Development Learning Sessions	Not applicable	June 2011	3 sessions completed	Open to leadership from	\$1.5 million	Not applicable
Public opportunities to learn from leading experts about successful ACO development				developing or existing ACOs		
Advanced Payment Accountable Care Organization Model Initiative	2/1/2012 for 4/1/2012 start date; 3/30/2012 for	4/1/2012 or 7/1/2012	Payments end June 2014	Physician-based and rural ACOs in the Shared Savings Program	\$175 million	650,000 Medicare+
Prepayment of expected shared savings to support ACO infrastructure and care coordination	date					
Physician Group Practice Transition Demonstration	Not applicable (open only to	1/1/2011	Up to 3 years	10 group practices started the demo: 3	\$500,000* in administration	87,700 Medicare
A precursor to the Medicare Shared Savings Program; rewards physician groups for efficient care and high quality	original PGP demo)			moved to the Pioneer ACO model		
MEDICARE-MEDICAID EN	ROLLEES	1	1			
State Demonstrations to Integrate Care for Medicare-Medicaid Enrollees	2/1/2011	April/ May 2011	18 months (with extension option)	CA, CO, CT, MA, MI, MN, NY, NC, OK, OR, SC, TN, VT, WA, WI	\$15 million	Not applicable
Assistance to help states engage stakeholders in redesigning care for Medicare-Medicaid enrollees						
Financial Alignment Model Demonstrations	Spring 2012	January 2013	3 years	38 States and DC have submitted	To be determined	2 million Medicare- Medicaid enrollees
Opportunity for States to implement new care and payment systems to better coordinate care for Medicare-Medicaid enrollees				letters of intent		

* Note: The budget for the Advance Payment Model was based on an estimated 650,000 Medicare beneficiaries. These beneficiaries would be assigned to Shared Savings Program ACOs.

INITIATIVE	APPLICATION DEADLINE	INITIATIVE START DATE	LENGTH	PARTICIPANTS/ LOCATIONS	TOTAL FUNDING	NUMBER OF BENEFICIARIES AFFECTED			
CAPACITY TO SPREAD INNOVATION									
The Partnership for Patients National campaign targeting a 40% reduction in hospital-acquired conditions and a 20% reduction in 30-day readmissions	Ongoing	4/12/2011	Ongoing	26 Hospital Engagement Networks supporting over 3,200 hospitals in all 50 states	\$500 million	Not applicable			
Innovation Advisors Program Training health care providers from around the country in achieving the three-part aim	11/15/2011	January 2012	Ongoing	73 Advisors selected and started January 2012 with up to 127 more in the next cycle	\$5.9 million	Not applicable			
Health Care Innovation Challenge A broad appeal for innovations with a focus on developing the workforce for new care models	1/27/2012	3/30/2012	3 years	To be determined	\$1 billion	Not available			
OTHER			1	1					
Medicaid Emergency Psychiatric Demonstration Expanding access to inpatient psychiatric services for Medicaid beneficiaries	10/14/2011	Spring 2012	3 years	Unspecified number of states	\$75 million*	Not yet available			
Medicaid Incentives for Prevention of Chronic Diseases (MIPCD) Program Collaborating with States to test the effectiveness of preventive services in Medicaid	5/2/2011	Sites awarded 09/13/2011	5 years	WI, MN, NY, NV, NH, MT, HI, TX, CA, CT	\$100 million*	Not available			

* Program developed and implemented by the Innovation Center, but funding based on other statutory authorities.

Value Based Insurance Design: Maintaining a Focus on Health in an Era of Cost Containment

A. Mark Fendrick, MD; and Michael E. Chernew, PhD

s private and public purchasers of healthcare struggle to constrain rising costs, they must also strive to maximize the clinical benefit achieved for the money spent. In contrast to highly-publicized, provider-focused initiatives to enhance value such as preferential selection or reimbursement of clinicians who score highly on value measures, episode-based payments and patient centered medical homes, Value Based Insurance Design (VBID) focuses on patient incentives. Specifically, VBID is based on the premise that patient cost sharing should more explicitly encourage patients to use high value services and avoid low value services (visit www.vbidcenter.org for more information).

VBID is not a panacea for the ills of the healthcare system, nor is saving money its principal objective. However, the principles behind VBID can work synergistically with a range of patient- and provideroriented cost containment strategies to promote value. For example, VBID strategies can be used to mitigate the likelihood of adverse clinical outcomes under high deductible health plans by allowing first dollar coverage for services identified as high value. Similarly, VBID programs can augment provider-oriented strategies to favor use of high value services by aligning patient and provider incentives.

In this essay, we discuss the influence of cost sharing on patient behavior, explain the VBID concept, describe some real world examples of VBID implementation, and summarize the evidence regarding its clinical and economic effects.

Central Role of Cost Sharing

Patient cost sharing is one of the fundamental levers for changing behavior and will, therefore, remain an important cost containment tool. It is widely accepted that higher across-the-board patient cost sharing reduces utilization of healthcare services and consequently lowers aggregate (and purchaser) healthcare spending. Evidence supporting this point dates back to the seminal RAND Health Insurance Experiment (HIE) begun in the 1970s¹ and many subsequent studies. A comprehensive review of this literature reports price elasticities for healthcare demand in the range of -0.04 to -0.75 and concludes that the most reasonable estimates tend to center around -0.17.² This implies that a 10 percent increase in price would cause utilization to fall by 1.7 percent. Although this is a modest effect, the ramifications can still be meaningful.

Ideally, higher patient copayments would discourage only the utilization of low value care. However, evidence from the HIE demonstrates that increased cost sharing reduces use of both high and low value services.³ Numerous recent studies that examine cancer screening and high value prescription drugs confirm that cost sharing affects the use of even potentially life-saving services.⁴⁻⁶

Value Based Insurance Design

By explicitly applying "clinically sensitive" cost sharing, VBID offers a way to preserve the demand-dampening advantages of higher cost sharing while lessening the adverse health consequences that can result when high out-of-pocket expenditures reduce the use of high value clinical services.^{7,8} VBID programs are based on three observations: 1) medical services differ in their clinical benefit; 2) the value of a specific intervention likely varies across patient groups; and 3) cost sharing discourages use of even high value, potentially life-saving services. We believe that more efficient resource allocation can be achieved when cost sharing is a function of the value of the specific healthcare service to a targeted patient group.

In practice, there are two general approaches to VBID programs. The first simply targets specific services and does not attempt to differentiate among patient groups that would benefit more or less from their use. Copayments would be lowered or eliminated for all users of services viewed as high value, and could be increased for low value services. The second approach targets patients with specific clinical diagnoses (e.g., coronary artery disease) and lowers copayments for specific high value services (e.g., statins, beta-blockers) only for those patient groups. This strategy, which requires more sophisticated data systems to implement, creates differential copayments based on patients' health conditions.

A number of factors will determine how VBID programs affect patients' health and purchasers' spending. These factors include the effectiveness of the services targeted, the level and precision of clinical targeting, the magnitude of the copayment changes, and patients' responsiveness to price changes. Programs that are better at identifying patients who will most benefit from the targeted service will have a higher likelihood of both improving patients' health and achieving a positive financial return since fewer individuals will be eligible for copayment reductions.

While copayment reductions and program administration expenses represent real costs to the healthcare purchaser, these costs can be offset by reductions in use of other services due to better patient health. For example, fewer emergency room visits for acute asthma exacerbations would offset, at least partially, the direct costs of lower copayments for asthma controller medications. Several studies have shown that changes in drug copayments led to fewer hospitalizations and emergency room visits, particularly among patients with chronic diseases.9 The likelihood of realizing such offsetting savings-and thereby improving the net financial benefit of the VBID program-is higher when the underlying risk of an expensive adverse outcome is high, when consumers are responsive to lower copayments, and when the service targeted for lower cost sharing effectively prevents the adverse outcome. Additional return on investment accrues if the non-medical benefits of improved health [e.g., reduced disability and absenteeism, enhanced productivity] are included.

Experience to Date With VBID

Several private and public sector employers, health plans and phar-

Figure.	Impact of	Copayment	Reductions	on	Medication	Adherence
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	Baseline MPR (Compliance)	Percentage Point Increase in MPR	Increase in Compliance	Decrease in Non-Adherence
ACE inhibitors/ARBs	68.4	2.59 (<i>P</i> <0.001)	3.8%	-8.2%
Beta-blockers	68.3	3.02 (<i>P</i> <0.001)	4.4%	-9.5%
Diabetes medications	69.5	4.02 (<i>P</i> <0.001)	5.8%	-13.2%
Statins	53.0	3.39 (<i>P</i> <0.001)	6.3%	-7.1%
Inhaled corticosteroids	31.6	1.86 (<i>P</i> = 0.134)	5.9%	-2.7%

MPR indicates Medication Possession Ratio; the percent of days in the quarter that the patient possessed the prescribed medication. Copayments were reduced by 50% for brand name drugs and eliminated for generic drugs. *Source:* Adapted from Chernew et al. (2008). "Inpact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment." *Health Affairs*, 27(1): 103-12.

macy benefit managers have implemented VBID programs. Notable early adopters include the city of Asheville, NC, Pitney Bowes, Marriott Corporation, Aetna, the state of Maine, United HealthCare (UHC) and the University of Michigan. Most typically, VBID programs simply lower copayments on classes of medications identified as high value. Other programs, such as the Asheville Project, University of Michigan's Focus On Diabetes program and UHC's Diabetes Health Plan, target patients with a particular clinical condition.

Evaluation of the impact of VBID programs is fairly nascent with most work focusing on understanding how changes in cost sharing affect medication adherence. Our recent evaluation of a program that lowered copayments for all users of five high value pharmaceutical classes demonstrated significant increases in medication compliance for four of the five drug classes, relative to a control group not subject to copayment reductions (Figure). Whether these improvements in adherence will translate into better health outcomes remains to be determined.

The financial impact of VBID programs depends on program design features including the direction and magnitude of copayment changes and the extent of targeting. Programs that raise cost sharing for low value services are most likely to save money. Those that lower copayments for high value services can also produce net savings, and reports in the popular press suggest this has been the outcome for some VBID programs.¹⁰⁻¹² For example, Pitney Bowes reported substantial savings after lowering copayments for prescription drugs for high-cost chronic illnesses, although the absence of an external control group in this study leads to questions regarding the generalizability of the findings.¹³ Simulations also indicate that VBID programs can save money if sufficiently well targeted.^{14,15} By and large, however, more rigorous examination of VBID programs is needed to determine their financial impact.

The Future of VBID

While barriers to VBID implementation certainly remain, private purchasers are increasingly adopting VBID programs as they acknowledge that efforts to control spending through patient cost sharing should not produce preventable reductions in quality of care. Interest has also spread to the Medicare program; legislation was recently introduced in Congress (S.1040) to require Medicare to test the impact of reduced cost sharing for medications used to treat 15 common chronic conditions. Moreover, as comparative effectiveness research identifies high value services and health information technology becomes more widespread, it is becoming easier to create and implement VBID programs.

Experience from the field indicates that VBID programs are feasible to implement, accepted by all vested stakeholders, and very well received by

beneficiaries.¹⁶ VBID can also support other initiatives such as high deductible health plans, disease management, patient centered medical homes, accountable care organizations and pay-for-performance programs. By allowing differential cost sharing, patient accountability is promoted and value of the system is enhanced.

We do not expect VBID alone to resolve our health system's inefficient use of resources. Although VBID programs cannot be designed immediately for all clinical conditions due to limited data, key VBID principles should be applied to services and patient groups

for which we predict that more rational cost sharing can produce higher value care. Ultimately, the alignment of financial incentives – for patients and providers – will encourage the use of high value care while discouraging the use of low value or unproven services, and produce more health at any level of healthcare expenditure. The quest for more efficient use of our healthcare dollars must continue, and we believe that VBID can play a role in achieving this goal.

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also other approaches to improving Treg numbers and function in autoimmune diseases and GVHD and inhibiting them in cancer. The design of these trials will need to take into account the challenge of interpretation of data in patients who are receiving complex therapies. Alternatively, combinations of interleukin-2 with other directed immunotherapies, such as the infusion of ex vivo expanded Treg cells, might be used. Finally, mechanistic studies must be included, notably signaling assays (such as signal transducer and activator of transcription 5 phosphorylation) coupled with immune phenotyping. These studies may identify populations of patients who will have a response to the therapy to ensure that the pleiotropic effects of the drug, and specifically its ability to promote effector and memory T-cell responses, can be precisely evaluated.

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Improving Adherence — Money Isn't the Only Thing

Lee Goldman, M.D., and Arnold M. Epstein, M.D.

Interventions that both improve outcomes and save costs are unusual, but the provision of lifesaving medications to survivors of myocardial infarction is one such example.1 In the past, physicians' poor compliance with evidence-based guidelines was a major reason for suboptimal use of such medications. Now, with help from the dissemination of quality metrics, cost-saving medications such as beta-blockers, aspirin, and angiotensin-converting-enzyme (ACE) inhibitors are nearly universally prescribed to eligible patients after myocardial infarction,^{2,3} so the focus has switched from physician prescribing to patient adherence. The concept of value-based insurance design,⁴ which is encouraged by the Patient Protection and Affordable Care Act of 2010, is to use lower copayments in order to encourage patients to adhere to high-value, potentially costsaving treatments.

In this issue of the Journal, Choudhry and

colleagues⁵ report their findings from a controlled trial, sponsored by Aetna, that assessed whether the elimination of copayments for statins, betablockers, ACE inhibitors, and angiotensin-receptor blockers for recent survivors of an acute myocardial infarction could improve adherence, reduce future cardiovascular events, and save costs. The elimination of copayments, which averaged about \$13 to \$25 per month per medication, significantly increased adherence, by 4 to 6 percentage points above the rates of 36 to 49% in the control group.

The elimination of copayments did not significantly reduce the risk of the primary end point, a first major vascular event or revascularization procedure (17.6 per 100 person-years in the full-coverage group vs. 18.8 per 100 personyears in the usual-coverage group; hazard ratio, 0.93; P=0.21). However, the incidence of two prespecified secondary end points, all major vascular events or revascularizations and the time to

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the first major vascular event, declined significantly by nearly 2 percentage points. All reductions were within a plausible range, given changes in adherence and the expected benefits of the medications.⁶ The 11% relative reductions in overall and cardiovascular-specific spending with free medications were not significant, although patients' out-of-pocket spending for prescription drugs was reduced (relative spending, 0.70; P<0.001).

Perhaps the most sobering findings were both the low baseline adherence and the small improvement in adherence in what should have been a highly motivated group of patients after myocardial infarction. Adherence to prescribed medications varies depending on the frequency of administration (a four-times-daily regimen is associated with a relative reduction of nearly 40% in adherence, as compared with a once-daily regimen), as well as on psychological problems, cognitive impairment, treatment of an asymptomatic disease, side effects, and cost.7 Strategies for improving poor adherence have addressed these issues but generally have reported baseline rates of adherence and changes in adherence similar to those in the study by Choudhry et al., regardless of whether the intervention eliminated copayments or was behaviorally focused.8,9

Because of the relative paucity of trials to assess the worthiness of value-based insurance interventions, the business community has been slow to adopt this approach. For example, a recent Mercer national survey of health plans sponsored by large employers showed that less than 20% of plans now have such value-based components, even though more than 80% say they plan to offer them in the future.¹⁰ The reduction in events and the trend toward lower costs in this study should foster great interest among employers and other payers, even if the business case does not yet indisputably confirm lower costs for them.

Value-based insurance design may be a useful complement to the health savings accounts and consumer-driven health plans that are increasingly being offered in the market. Employers have sought to shift health care costs to the beneficiary through higher deductibles or higher copayments at the time of service. The goal of these plans is to foster greater cost-consciousness by consumers, deter utilization, and lower the cost of care. The challenge is that patients are often poor judges about the relative or absolute benefits of different health care services. Valuebased insurance design can provide important signals that identify high-value services, as well as financial incentives to encourage their use.

Reducing or eliminating the costs of highly beneficial medicines is almost certainly one key component of increasing adherence, even if its absolute benefit is distressingly modest. More comprehensive insurance coverage also has appeal, but it is likely to raise the costs of care. For patients who have had a myocardial infarction, currently available generic formulations are already far less expensive than the average copayments faced by patients in the study by Choudhry et al. For example, generic statins cost \$4 per month,¹¹ as compared with their average copayment of \$25 per month. Pharmaceutical companies should not expect that the elimination of copayments for costly proprietary preparations will be considered a sensible alternative when lowcost generics are available.

In some instances, it surely makes sense to align financial incentives with high-value care. However, a rational health care system must not only incorporate financial considerations but must also investigate and develop additional ways to improve adherence. Since health insurers, both private and public, have a huge stake in the outcomes, their sponsorship of research should be a good investment, not only for them but also for the people whom they insure.

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Benefit Design Should Reflect Value

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January 2012

In 1965, when Medicare was enacted, spending for prescription drugs was less than \$4 billion—so low that no one thought to include a drug benefit as part of Medicare. By 2003, the cost and importance of drug therapy was so high that Medicare Part D was enacted.

Drug therapies have become one of the most important tools for managing chronic illness: they forestall complications, reduce attendant medical utilization, and help improve patients' productivity.^{1,2}

Unfortunately, the benefits of drug therapy are regularly undermined by the low rates of compliance—sometimes as low as 20 percent, and varying with complexity and duration of therapy.³ The reasons for noncompliance are myriad—including aversion to side effects and general forgetfulness and can be difficult to combat.

However, financial incentives can influence patient behaviors. We know, for example, that copayments exert a powerful influence on use of chronic medications.⁴ So why not lower them for certain patients to encourage better adherence to high-value drugs that are most effective?

Increasingly, payers are embracing value-based insurance design (VBID) that reduces copayments for patients who are most likely to benefit from a drug or service, as determined using available clinical evidence.^{5,6} Patients for whom the therapeutic benefit is modest—or the evidence is mixed—face higher cost sharing. For example, a plan might charge a

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Commentary

lower or no copayment for cholesterollowering drugs if a patient has another risk factor, like diabetes. To offset this cost, patients at low risk might face higher copayments.

Empirical studies-most focused on prescription drugs—suggest measurable benefits from a value-based approach to drug therapy.^{6,7,8} For example, VBID for cholesterol-lowering therapy alone would reduce patients' total health costs by 3-5 percent.⁹ Anecdotal evidence suggests even more dramatic savings. Pitney Bowes reduced copayments for several classes of chronic medications, including diabetes, hypertension, and asthma, in combination with other health initiatives. They found improved medication compliance, with the higher pharmacy costs more than offset by lower rates of emergency department visits and avoidable hospitalizations.¹⁰

Clearly, VBID could be a very useful tool for restraining health care costs by discouraging use of medical interventions with marginal value and by encouraging certain services for selected patients for whom there is clinical benefit. But VBID faces operational challenges that could limit

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broader application.

First, if guidelines aren't carefully drawn, they can lead to perverse incentives. For example, patients who feel relatively healthy might postpone medical care until they are sicker and/or get better coverage. Second, some anecdotal evidence suggests that offering more generous drug benefits makes a plan less competitive.¹¹ A health plan with a reputation for offering the most generous benefits may disproportionately attract the sickest patients. These concerns, however, can be mitigated through risk adjustment and incentives to stay healthy.¹²

The biggest challenge is that clinical data on efficacy for many services and procedures are lacking or expensive to collect, so VBID is not yet a widespread solution. However, the potential VBID has shown with medications suggests that payers may want to use it with those procedures—such as medical devices and imaging—that impact spending the most.¹³

VBID shows promise as a key strategy to help move the nation toward a health care system that rewards value. We must continue to test and establish financial incentives that steer patients toward the most appropriate levels of care for their conditions. The real promise of VBID is to mitigate tension between controlling health care costs and ensuring that patients get the care they need.

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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 improving and learning health system envisioned by the IOM. Statements are personal, and are not those of the IOM or the National Academies.

In this commentary, Leonard Schaeffer and Dana Goldman's discussion of value-based insurance design touches on several issues and lessons central to incentives for care that is effective, efficient, and continuously improving, including:

- The development and application of analytic tools that can improve both individual choice and personal awareness of the value of health care interventions.
- Closer attention to assessing the costs and outcomes of health interventions, e.g. pharmaceuticals, devices, imaging, and services delivered outside the health care setting.
- The development of analytics and incentives that drive attention, coverage decisions, and plan choices toward health care services that deliver the highest value to individuals and society.
- A strengthened level of communication between people and their clinicians on best practices, shared decision making, and tailoring care to conditions and informed personal preferences.
- Greater engagement in continuous feedback and improvement on the experiences with, services of established importance in the control of chronic diseases.

Information on the IOM's Learning Health System work may be found at www.iom.edu/learninghealthsystem.
By Patricia A. Gabow and Philip S. Mehler

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To Improving Patient Safety And Quality: Lessons From Denver Health

A Broad And Structured Approach

ABSTRACT America's health care systems have not achieved the desired level of quality and safety. This may be due, in part, to the lack of clear and robust approaches for institutions to follow. Denver Health, an integrated, public safety-net institution, developed a multifaceted, structured approach to quality and safety improvement that has produced positive outcomes. For example, in 2010 Denver Health ranked first of 112 US academic medical centers in terms of actual mortality observed relative to the national mortality rate. Given these results, we argue that regulatory bodies should refocus their oversight to consider an institution's overall structured approach to quality improvement and safety, instead of monitoring individual small outcomes, such as a patient's receipt of antibiotics for pneumonia within six hours of arriving in the emergency department.

atient safety and quality have been important objectives for American health care for more than a decade. Although gains have been made in some focused areas, such as compliance with hospital discharge protocols for patients with a myocardial infarction,¹ widespread improvements have eluded our health care system.² One factor that could inhibit quality improvement efforts is the lack of a defined and replicable approach for health care systems to follow to achieve institutional quality and safety.

It seems unlikely that either aspiration or a series of uncoordinated efforts can improve health care quality. We describe a structured, multifaceted approach to quality and safety at one safety-net institution, Denver Health. The efficacy of such an approach may have health policy implications, because it could move regulatory bodies away from measuring individual processes and outcomes and toward assessing the robustness and aggregate nature of an institution's approach to quality and patient safety.

The Organization

Denver Health is a public, academic health system and Colorado's principal safety-net institution. The system includes an emergency paramedic system; an acute care hospital; all eight of Denver's federally qualified health centers; twelve school-based clinics; the city's public health department; a health maintenance organization; a 100-bed nonmedical detoxification unit; correctional care; and a call center that includes a poison center, a help line staffed by nurses, and centralized appointment and translation services. The system serves one-third of Denver's adults and 40 percent of the city's children. Almost half of the system's patients are uninsured.

Although Denver Health's structured approach to quality and safety began approximately seven years ago, a number of foundational elements were already in place, including an integrated health care system. We believe that this integrated system is the foundation for quality and safety because it provides people with geographically convenient access

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to care; seamless continuity of care across a person's life and health care needs; and the right care, at the right time, with the right provider.

Another foundational element is that the system is staffed by 265 employed and salaried physicians, all of whom have academic appointments at the University of Colorado School of Medicine. This employed-physicians model promotes the alignment of goals across the enterprise and helps implement quality and safety interventions. There is no salary incentive plan that provides higher payments for more procedures, and that may reduce the overuse of resources and the use of unnecessary high-cost procedures.

An employed-physician model is not unique to Denver Health; such a model is used in academic health centers, many safety-net institutions, and other organizations. Moreover, although such an arrangement promotes the alignment of many goals and initiatives, there is nothing in Denver Health's structured approach that depends on salaried employment.

The delivery of safe, high-quality, and efficient health care depends on the provider's having comprehensive patient care information at the point of care. Denver Health is an advanced user of health information technology. The technology is also being used in other health care systems and will become more widespread in response to incentives in the Health Information Technology for Economic and Clinical Health (HITECH) provisions in the American Recovery and Reinvestment Act of 2009.

This foundation of an integrated system, employed academic physicians, and health information technology provided a springboard for Denver Health's structured approach to health care quality and patient safety. At the same time, as a safety-net institution, Denver Health faces clear disadvantages compared to other health systems.

These barriers include limited resources coupled with a population of socially disadvantaged and clinically complex patients. For example, in 2009 the Denver Health system provided more than \$100 million of care to patients classified as homeless. In 2010 the system provided approximately \$382 million of uncompensated care to patients with no insurance. Denver Health has been in the black every year since 1991, but its 2009 operating margin was only 0.4 percent, leaving few resources for quality and safety initiatives.

Although characteristics of the health care system are important in achieving high-quality, safe, and efficient care, health is the result of mutual efforts by the patient and the care system. A safety-net institution's patients are often society's most vulnerable, including the poor, the mentally ill, and many non-English-speaking members of minority groups. For example, the majority of Denver Health's patients have incomes below 185 percent of the federal poverty level. Three-quarters of the system's patients are ethnic minorities, and one-third do not speak English. These patient characteristics embody health care disparities that impede the intended outcomes of a system's quality and safety interventions.³

Denver Health's leadership was inspired to begin a quality improvement journey in part because of these substantial challenges that it faced as a safety-net institution. The system's leaders saw an opportunity to address the problem, and they were aware of new approaches that could be applied to health care.

The Structured Approach

Denver Health's quality improvement approach involved four steps: creating a comprehensive approach to patient care; appointing a person or creating a department to take responsibility for quality and safety; creating programs to manage high-risk and high-opportunity clinical situations; and implementing systems to reduce variability in patient care processes and outcomes.

This quality-of-care and patient safety initiative was embedded in the framework of an existing comprehensive patient care approach that began seven years ago with a grant from the Agency for Healthcare Research and Quality. Denver Health called this effort "Getting It Right: Perfecting the Patient Experience."⁴ Initially there were five linked components: the right environment for providing high-quality care; the right people to provide it; the right communication among providers and between patients and providers; the right reward for teams that took steps to address a financial or quality issue; and the right process. More recently, "right service" was added to reflect the need to consider the patients' perception of their care. Each component contained elements that advanced patient safety and care quality.

RIGHT ENVIRONMENT The "right environment" component focused on developing patient care spaces built for safety, quality, and efficiency. Examples include identical patient room layouts to avoid confusing the caregiver, particularly in an emergency; rooms to accommodate family members, including sleeping areas, to enable family involvement in patient care decisions; and distinct environments for high-risk, behavioral health, and correctional care patients.

RIGHT PEOPLE The "right people" component

focused on using talent-based hiring tools to select employees with values and work styles reflective of high performers. These tools have been validated by large, successful companies in their hiring processes. However, these tools are not widely used in health care, which is an industry that tends to focus on specific education and skill sets such as having a nursing, physical therapy, or medical degree along with specific experience. Denver Health uses a company that relies on talent-based screening tools to hire its employees; only 22 percent of that company's clients are in health care.

RIGHT COMMUNICATION The "right communication" component focused on structured communication such as a clearly outlined set of reasons for escalation and detailed processes for escalation; checklists; and so-called geographic clustering of similar patient types. As an example of escalation, a nurse who did not get a timely reply to a question from a senior resident would be encouraged to contact the chief resident or the staff attending physician.

The technique of geographic clustering represents a change from typical hospital practice. In the majority of hospital settings, patients are seen at different times by nurses, doctors, pharmacists, and others. With geographic clustering, coupled with "team rounding," the caregivers visit each patient as a team, which facilitates interdisciplinary communication. In addition, an anonymous online patient incident reporting system for reporting errors and near misses occasions when a patient's safety was almost endangered—was implemented. The system made it possible to track trends or system issues that were creating barriers to quality and safety.

RIGHT REWARD The "right reward" component featured monetary awards given to teams that substantively addressed a financial or quality issue. Of the 133 cash awards given to date, 57 were given for quality initiatives. These payments underscored that quality and safety were important, along with financial outcomes.

RIGHT PROCESS The "right process" component relied on the wide dissemination of the lean or Toyota Production Systems approach throughout the enterprise. Lean is a philosophy and tool set that focuses on reducing waste from the customer perspective.⁵ It is built on a philosophy of respect for people and continuous improvement, and it thus has a direct impact on organizational culture. The use of lean can dramatically improve and standardize processes and result in higher-quality, lower-cost care.⁶

The implementation of the lean approach at Denver Health relied on 8 full-time facilitators and 225 internally trained "lean black belts" people trained to lead process-improvement

We saw the need for a department of patient safety and care quality to facilitate changes in process, organization, and teamwork.

projects. There were sixteen areas of focus, called "value streams," across Denver Health, including recently added clinical processes such as those that focused on cancer screening and the prevention of blood clots in hospitalized patients. More than 300 "rapid improvement events"—mechanisms for making radical changes to current processes and activities within a very short time frame—occurred in these focus areas during the past five years.⁷

This comprehensive, broad, and multifaceted approach to "perfecting the patient experience" created the physical spaces and a culture on which specific quality and safety efforts could be built. Having the right people, and having them focused on doing work in the right manner to support each other and the patients, nurtured a culture of respect and commitment to improvement and quality.

Identifying Quality And Safety Leaders

The next step in Denver Health's approach to creating high-quality care and patient safety was to identify a responsible person and department to lead this effort (see the Appendix Exhibit).⁸ Although decentralizing and integrating these strategies into every clinical department is important, we saw the need for a centralized and distinct department of patient safety and care quality to facilitate the application of a broad array of changes in process, organization, and teamwork. An associate medical director position was created, with the responsibility of developing goals and leading the department. This arrangement drew on the quality improvement literature, which demonstrates the association between developing broad and shared improvement goals and achieving substantial quality improvement, through the provision of

administrative support to mine data fields for quality improvement purposes, having strong physician leadership, and using credible and timely data feedback.⁹

Key new personnel appointed included a manager of regulatory compliance, a director of medical biostatistics and data warehousing, and a director of medical education, as well as additional infection control personnel. The manager of regulatory compliance played a central role in the overall quality effort by focusing on linking regulatory standards to patient safety and quality initiatives. The director of medical biostatistics also served a vital function in meeting the need to constantly measure, monitor, and report the outcomes of interventions. Objectively comparing valid, consistent, timely, and transparent measurements with established benchmarks enabled quality initiatives to spread and be sustained throughout Denver Health's system.

The inclusion of a director of medical education within Denver Health's Department of Patient Safety and Quality reflected the deep need for oversight of medical education in bringing about improvement in health care quality. Physicians-in-training are at the hub of care delivery systems, especially in safety-net hospitals and academic medical centers; thus, they must work in concert with evidence-based quality initiatives. This coordination has been facilitated at Denver Health by team rounding, checklists, and computerized physician order entry with standard order sets. (Standard order sets are similar to checklists used to ensure the accuracy and completeness of prescriptions, standardize patient care, and guarantee clarity when communicating medical orders.)

The inclusion of infection control in the Department of Patient Safety and Quality reflected a growing recognition of the severity of hospitalacquired infections. An infectious disease physician with epidemiology training was appointed to head infection control and was supported by qualified nurses. The new appointments placed within this department fostered the implementation of interventions in the high-risk areas discussed below.

Managing High-Risk And High-Opportunity Areas

The third element in Denver Health's approach to creating high-quality care and patient safety included a set of programs to manage high-risk and high-opportunity areas. This reflected the notion that safety is not only freedom from injury or damage but also freedom from the risk of injury or damage. Some of the high-risk and high-opportunity areas identified in the relevant clinical literature were also identified at Denver Health (Exhibit 1). Each is discussed below.

FAILURE TO RESCUE "Failure to rescue" refers to failure to identify patients who are deteriorating and to intervene in a timely manner to prevent their deterioration. The recent study of postoperative mortality by Amir Ghaferi and coauthors stressed "failure to rescue," rather than the number of complications, as the key variable in explaining differences in mortality rates across hospitals.¹⁰

We were aware of hospitalized patients at Denver Health who gave evidence of clinical deterioration long before substantive interventions were activated. Thus, we opted to institute a rapid response system to identify such patients and intervene in their care. Given that the literature shows only modest evidence of success for common rapid response team approaches, we opted for a variation on those approaches.¹¹

We reviewed the literature and defined our own "clinical triggers." For example, a systolic blood pressure of less than 90 mm Hg would activate the response system.¹² Our system did not involve a separate team of responders. Instead, it used the patient's intern and resident teams, who were called by the patient's nurse in response to the presence of a clinical trigger. The

EXHIBIT 1

Approaches Used To Address High-Risk And High-Opport	tunity Clinical Settings At Denver Health
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Approach
Clinical triggers/rapid response system
Hospitalist co-management or consultation
Antibiotic stewardship program Mandatory consultation for specific conditions/situations
Checklists/posting of results
CPOE-embedded prophylactic therapy guidelines

SOURCE Denver Health internal document. NOTE CPOE is computerized physician order entry.

team members were expected to evaluate the patient at his or her bedside within ten minutes of the nurse's call.

Using this new rapid response system, Denver Health reduced its cardiopulmonary arrest rate from a median of 5.9 per 1,000 discharges to 2.2 per 1,000 discharges (p < 0.001). The number of patients who required transfer back to the intensive care unit within forty-eight hours after being moved to hospital floor units also decreased significantly, from 4.62 to 3.27 per 100 intensive care unit transfers (p = 0.03).

HOSPITALIST CO-MANAGEMENT We instituted hospitalist co-management or consultation for all patients on the orthopedic service, patients on low-volume inpatient surgical specialty services such as oral maxillofacial and urology, and patients on the psychiatric ward with concurrent medical conditions. This arrangement promoted the care of these patients' medical problems, such as diabetes or cardiac disease, by providers whose expertise was in these areas.

ANTIBIOTIC STEWARDSHIP Another Denver Health initiative was related to infectious disease care. Antibiotic use is considered one of the most important aspects of infection control. Overuse and underuse of antibiotics have been deemed by the Joint Commission to be an important barrier to quality improvement.

Almost 60 percent of Denver Health's inpatients were being treated with an antibiotic during their hospital stay. Therefore, a formal and robust antibiotic stewardship program was established to provide careful oversight and guidance to our clinical services. This approach spawned new programs, including mandatory infectious disease consultation for certain common and serious infections; concurrent and timely feedback to a prescribing team when multiple antibiotics were used for the same patient; new rules-driven guidelines embedded within our computerized physician order entry system for common inpatient infections such as pneumonia and cellulitis; and formal weekly infectious disease consultant rounds with intensive care unit teams.

As a result, Denver Health's antibacterial drug use, in days of therapy per 1,000 patient days, was the lowest of thirty-five US academic health centers reporting through the University Health-System Consortium.¹³ Moreover, proper treatment has increased and adverse consequences from illness have decreased for the highly prevalent *Staphylococcus aureus* bacteremia.¹⁴

CATHETER CHECKLISTS Nationally, central-line (intravenous catheter) infection is a common and costly hospital-acquired condition, which is associated with the deaths of 31,000 patients annually in the United States.¹⁵ The use of check-

lists has been demonstrated to dramatically affect this complication, and it therefore was a measure that Denver Health instituted.¹⁶ The use of checklists, strict measurement, and consistent posting of infection rates resulted in a dramatic decline in the rate of central line–associated bloodstream infections in all of the system's intensive care units. A median infection rate of zero was sustained for many consecutive months.

REDUCING POSTOPERATIVE BLOOD CLOTS Another high-risk hospital-acquired condition is venous thromboembolism, or blood clots occurring after surgery. These blood clots are the most common preventable cause of hospital deaths, and each blood clot that is prevented avoids \$25,000-\$40,000 in medical costs.

A lean rapid improvement event team focused on the proper and cost-efficient use of prophylactic anticoagulation—use of blood-thinning medication—with high-risk inpatients. Lowmolecular-weight heparin, a medication used to prevent postoperative blood clots, had become the most costly line item in the hospital pharmacy's budget. Yet our incidence of these postoperative blood clots was much worse than national benchmarks.

The team produced an evidence-based riskassessment tool and a clinical practice guideline, which were embedded into admission order sets in the computerized physician order entry system. Compliance with the guideline is now approaching 100 percent, the overall use of lowmolecular-weight heparin has decreased more than 60 percent, and the occurrence of these blood clots has decreased in frequency. Our performance in preventing venous thromboembolism is now in the top 10 percent of outcomes nationwide.¹⁷

Targeting Outpatients For Quality Improvement

The aforementioned interventions have all focused on hospitalized patients. Improving ambulatory care poses unique challenges.¹⁸ Despite the fact that there are currently 900 million outpatient visits annually in the United States, compared to 35 million hospital discharges,¹⁹ there has been less effort directed toward improving the quality of outpatient care.

However, with the growing focus on medical homes and health reform's emphasis on accountable care organizations, it is crucial that high-quality care is also delivered to outpatients. Denver Health has embarked on outpatient quality initiatives using its integrated health information technology system, along with a robust data warehouse and dynamic patient registries.

As a result of its structured approach to quality and safety, Denver Health was ranked first of 112 academic medical centers.

The system now has a mature immunization registry that enables Denver Health to achieve an 88 percent immunization rate among oneyear-old patients. The health system was awarded the prestigious Codman Award by the Joint Commission for this effort. There are similar registries for asthma, trauma, cancer screening, hypertension, diabetes, anticoagulation, and obstetric care.

These registries trigger improved quality by providing aggregated point-of-care (care delivered during an office visit) performance data by specific clinic site and specific clinician to make the data available for audit and feedback. The cancer registries' patient-specific data serve as a visual prompt to the physician during a patient encounter, reminding the physician to encourage the patient to comply with recommended breast, cervical, and rectal cancer screening. These registries are also tools for proactive management and outreach to patients between visits. As a result, 70 percent of patients with hypertension have their blood pressure controlled, and more than 50 percent of diabetic patients have their low-density lipoprotein cholesterol, or "bad" cholesterol, values at the target level.

Focusing On Process For Better Care

The fourth element in Denver Health's approach was more uniformity in patient care processes, such as the administration of preoperative antibiotics. This was achieved through both the meaningful use of health information technology and the implementation of lean's core concept of standard work, which states that there is one consistent way to do a process.

Despite the usefulness of computerized physician order entry systems,²⁰ only 17 percent of health care institutions have implemented them, and even fewer are using these systems with decision support—reminders and links for physicians about guidelines and best practices.²¹ Denver Health has had computerized physician order entry systems for almost five years and has linked these systems with standard order sets to enable evidence-based care as the standard approach. Computerized physician order entry systems eliminate handwriting errors; enable pharmacies to check doses, allergies, and drug interactions; and produce clinician alerts. Approximately 250,000 inpatient orders are entered each month into the Denver Health system.

As a result of this structured approach to quality and safety, Denver Health was ranked first of 112 academic medical centers, with the lowest (0.55) observed-to-expected mortality ratio the ratio of actual deaths at Denver Health compared to national death trends—in the 2010 University HealthSystem Consortium's Quality and Accountability Aggregate Score. In 2008 Denver Health was ranked twenty-eighth in this indicator. (The consortium is an alliance of academic medical centers and their affiliated hospitals, representing approximately 90 percent of US nonprofit academic medical centers.)

This improvement in the observed-to-expected mortality ratio occurred despite a progressive and sustained increase in Denver Health's case-mix index, which measures the severity and acuity of patients' medical conditions.

In addition, in January 2011 the Colorado Department of Public Health and Environment released the most current (2007-09) risk-adjusted trauma inpatient mortality for all level 1 trauma facilities in Colorado. The mortality rate for Denver Health was the lowest in the state, with a mortality odds ratio of 0.74. This means that the mortality rate at Denver Health was 26 percent lower than would be expected for a hospital in Colorado with its case-mix. Also, Denver Health's cesarean section rate has been the lowest of all consortium hospitals for two years, with no unexpected full-term fetal mortality. Moreover, the success of Denver Health's quality quest is evident in a marked reduction in the number of annual sentinel events (the most serious and preventable). In 2010 Denver Health had only two sentinel events across the entire system. In 2009 it had nine, and in 2008 it had thirteen.

Conclusion

The Denver Health experience demonstrates that care quality and patient safety can be advanced within America's health care institutions, even in organizations challenged by lack of resources and by socially disadvantaged patients. Denver Health demonstrates one pathway. Its integrated system of care, employed medical staff, and strong health information technology infrastructure has allowed the creation of a structured approach to patient safety and quality of care.

Our approach includes the designation of a responsible person and department for quality and safety that focuses on high-risk clinical areas, uses standardized care based on rigorous scientific evidence, and is supported by transparent and robust real-time performance data that can be used for peer comparisons. The Denver Health experience suggests that regulatory entities might achieve the substantial results in quality improvement that they desire by increasingly focusing their assessments on an institution's or organization's overall structured approach to improving quality and on broad outcomes, rather than by focusing on narrower outcomes related to the care of individual patients.

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REENGINEERING THE DELIVERY SYSTEM



Dr. Chris Colwell, right, director of emergency medicine at Denver Health, confers with Gary Witt, an emergency medicine technician, during the hospital's rapid-improvement event in July.

By Harris Meyer

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Life In The 'Lean' Lane: Performance Improvement At Denver Health

n unshaven young man in blue jeans, with a minor medical problem, hustles into the emergency department at Denver Health, a major urban safety-net hospital. If this were a normal day, he could expect a long wait. At the hospital's busy ED, which sees an average of 350 patients daily, it can take four hours or more for lower-acuity cases to be seen.

But today is a "rapid-improvement event" day at Denver Health, so a man behind the intake desk quickly thrusts out his hand. "Hi. I'm Dr. Colwell. What can I do for you?"

In the next moments, Chris Colwell gleans from the young man that he has a rash on his leg near his groin. Colwell hands the patient a pink folder that will get him expedited service, and ushers him off toward evaluation and registration.

Next.

It's not every day that a big hospital like Denver Health asks the chief of emergency medicine— Colwell—to function as a temporary greeter in the ED. But on this particular day, a team consisting of Colwell, nurses, technicians, and administrators is trying to determine how to improve overall efficiency by speeding up service to low-acuity patients. And this morning the "fast-track" experiment they've concocted seems to be working. Eighteen patients are waved into the expedited queue by Colwell and are quickly treated there by an attending physician and a nurse practitioner.

The effort is just one of more than 300 socalled rapid-improvement events that Denver Health has conducted during the past five years. They're a standard feature of the system's Toyotainspired "Lean" performance improvement program, in which management methods that have transformed manufacturing and service companies are being applied to the notoriously inefficient American health care system. So far, Denver Health has used Lean to improve processes in the operating room, billing, imaging, supplies, pharmacy, primary care, and other medical and business areas.

The effort has more than paid off: Denver Health has documented cost savings and revenue gains from Lean efforts totaling \$54 million, while also improving the quality of care. Thanks in part to these Lean-related savings, Denver Health is one of the few urban safety-net hospitals in the country operating in the black—with a margin of \$5.1 million on total operating revenues of \$642.7 million in 2009.

In all her career in health care management, says Patricia Gabow, Denver Health's chief executive officer (CEO), "I've never seen anything this powerful."

Health Care Systems' Embrace Of 'Lean'

With hospital and physician leaders facing growing pressure to control costs and improve the quality of health care, it's little wonder that a growing number of health systems are embracing Lean. ThedaCare in Wisconsin¹ and Virginia Mason Medical Center,² Group Health Cooperative,³ and Seattle Children's Hospital⁴ in Seattle, Washington, have emerged as national leaders in the movement. Other hospital systems such as Massachusetts General in Boston and Emory Healthcare in Atlanta, Georgia, are using Lean as one approach in a broader arsenal of performance improvement methods. Others seem likely to follow as state Medicaid funding cuts kick in, and as the Patient Protection and Affordable Care Act puts new constraints on Medicare payments.

It takes leadership for systems to go Lean, and in Denver Health's case, the inspiration came from Gabow. Now 66, she's a nephrologist who has worked at Denver Health for 37 yearsas a clinician, department chief, medical director, and then CEO for the past 18 years. Over that period, Denver Health has grown into a teaching institution that also runs the city's paramedic system, twenty outpatient and school clinics, the regional poison control center, the city's public health department, and Medicare and Medicaid managed care plans. Yet within the past decade, Gabow says, she had grown "frustrated that the medical community was doing things the same way as forty years ago. It was irrational."

In 2003 Gabow applied for and received a

federal planning grant to improve patients' experiences of care at Denver Health. She organized study visits to manufacturing and service companies using Lean tools in the United States and Denmark. The hospital also conducted focus groups with employees and surveyed patients.

Around the same time, Gabow hired an industrial engineer, who mapped some of the hospital processes. One stunning finding was that trauma surgery resident physicians walked eight and a half miles in the course of a single twentyfour-hour shift. "Tell me," Gabow recalls saying in horror, "this isn't what we do."

So Gabow and her leadership team turned to Lean, a system derived from the work of American quality expert W. Edwards Deming⁵ and used successfully by Toyota, Dell, FedEx, and other leading companies. (They chose Lean over an alternative performance improvement model, Six Sigma, because Gabow and her colleagues found it easier for everyone to understand.)

Eliminating Waste, Maximizing Value

Management experts estimate that up to half of the expenses of running a health care system are unnecessary.⁶ As a management discipline, Lean aims to eliminate this waste in production processes and maximize value to customers. Although typically mandated by top management, Lean projects are planned and carried out by line workers themselves, requiring continuous, rather than one-time, efforts to improve processes.⁷ That contrasts with the traditional approach in medical organizations, which tend to be institutions run from the top down. "We've tended to work on the model of individual perfection-that you can fix problems by writing policies and getting individuals to perform at a higher level," says William Bornstein, the chief quality and medical officer at Emory Healthcare. "But it doesn't get us anywhere."

To imbue Denver Health with the Lean culture, training was provided to selected staff, including all physician and administrative leaders. As of today, the hospital has intensively trained 225 staff in Lean methods, including medical department chiefs, head nurses, administrators, and technicians. These so-called Black Belts are authorized to carry out their own ad hoc cost reduction and quality improvement projects across the Denver Health system. As of last year, they were also required to use Lean and other techniques to improve their departments' bottom lines by at least \$30,000 apiece.

From the start, Gabow made clear to all that Lean work was not optional, even for the system's top physicians. Because Denver Health employs all of its doctors, physicians were assured that they would not lose income while working on Lean projects. However, a few old-school managers who didn't like the Lean methods were pushed out.

Success Of Rapid-Improvement Events

By 2005, Denver Health was ready to take on its first rapid-improvement event: an effort to reduce infections in the operating room. The goal was to increase the percentage of patients who received prophylactic antibiotics within an hour before undergoing surgery. The project initially achieved nearly 100 percent compliance and has been maintained at 96-100 percent ever since, Gabow says. Since then, additional Lean projects have reduced the average length-of-stay for the hospital as a whole from 4.5 days to 4 days since 2005; cut bed turnaround time from 150 minutes to 88 minutes, as a result of faster cleaning and better coordination; and increased total collections from uninsured patients from \$2,000 a month to more than \$40,000, through the adoption of financial counseling before discharge.

Besides saving money, Denver Health's Lean initiative also boasts some notable achievements in improving clinical quality. In 2008 the hospital ran a rapid-improvement event to improve prevention of deep vein thrombosis and pulmonary embolism in hospitalized patients. As a result, the hospital has reduced occurrence of this potentially fatal condition by nearly 80 percent. It has also saved about \$1.75 million by trimming hospital stays and by reducing the use of an expensive form of heparin for thrombosis patients, according to Philip Mehler, the hospital's chief medical officer.

Such savings represent a substantial return on a program that costs \$1 million a year in salaries for the seven full-time Lean facilitators and an outside Lean adviser from Simpler Consulting, an Iowa-based firm that works with a number of hospital systems using Lean. There are also modest financial incentives for the Black Belts they can receive up to \$500 for exceeding their targets on a given rapid-improvement project as well as for non–Black Belt staffers and teams who achieve savings.

For all of the benefits, though, living Lean isn't easy. Participants in Lean programs describe them as an often exhausting exercise of taking entire processes apart, step by step, while stripping out the unnecessary parts and reengineering the rest. A typical rapid-improvement event thus entails a hectic, challenging week for Denver Health staffers, who are also expected to get their regular work done while spending four solid eight-hour days on the improvement event. There is often spirited debate about the appropriate direction of a given experiment and when it's over, there is sometimes disagreement about the results. Often, it takes several tries over a period of months to achieve the desired outcomes.

Gabow reads the Lean project reports and statistics from the Black Belts and the departments closely. She occasionally sends out what she calls "love notes" to department chiefs who fail to achieve their Lean goals.

"Lean is hard work," says Denver Health's Paul Melinkovich, who oversees the system's primary health clinics. "There is a fatigue, with people saying they can do only so many Lean events in a year."

The satisfactions come over time, as a result of the intense teamwork and a feeling of ownership of the process of change. Lean "breaks down silos and creates incredible cohesion across the enterprise," says Gabow.

Transforming Denver Health's Emergency Department

The groundwork for the July 2010 ED rapidimprovement event was actually laid some months earlier, in February 2010. At that time, Denver Health held a broad, three-day analysis examining the emergency department as a "value stream." That's a broad category of services, such as pharmacy or human resources, and associated sets of activities. The analysis of the ED was one of sixteen such "value streams" at Denver Health that have so far come under the scrutiny of the Lean team.

The analysis revealed numerous inefficiencies in the ED and recommended that eight different rapid-improvement events be carried out. One was to be targeted on the wait time for loweracuity patients—a lengthy 143 minutes, on average, from "door to discharge." That's an increasingly typical experience at hospitals across the country, where EDs are being used more than ever by patients with nonemergent conditions.⁸

The study at Denver Health showed that when such patients showed up for care at the emergency department, they were typically pushed to the back of the line while staff treated more severely ill or injured patients. Because of the long waits, 5.4 percent of these patients gave up and "left without being seen," in standard ED parlance. That fact cost the hospital sizable sums in lost revenue.

What's more, with so many minor emergencies clogging the main emergency/trauma area, Denver Health was having to divert nontrauma

Testing and perfecting a new fast-track system in just four days can look like barely controlled chaos.

patients to other hospitals 9 percent of the time. This cost the system lost revenue. And with the long waits, there was always the risk of fatal incidents such as those experienced by other hospital emergency departments, where patients have died while waiting for care. The ED waits can also lower the system's quality ratings from the Joint Commission.

So the rapid-improvement event was set for July, with a goal of slashing the door-todischarge time for lower-acuity patients to 90 minutes. Additional goals were to reduce the percentage of left-without-being-seen patients to 1 percent, cut ambulance diversions to 5 percent, and boost net revenue \$250,000 a year by seeing more patients.

Key Players Central To 'Fast-Track' Launch

To an outside observer, testing and perfecting a new fast-track system in just four days can look like barely controlled chaos. Attempting to instill order was the man leading the exercise, Matt Beno, a fast-talking former cardiac unit administrator and now a full-time Lean facilitator for Denver Health.

Each day, Beno led the other team members in observing the busy ED process. They moved personnel around, scrambled to provide needed equipment, calculated costs, then stood back and watched the results.

Another key player on the team was Colwell, an earnest, empathetic Dartmouth Medical School grad who has practiced in this emergency department for twelve years. On the day he was stationed at the department's entrance, he began looking for patients who could be treated through the experimental fast-track process and "turned around" in ten to fifteen minutes.

Colwell screened the mother of a feverish baby, a woman with a broken arm, and a man on a oneday pass from jail seeking a prescription refill. For an elderly Hispanic man complaining of an ankle rash, Colwell walked around the desk to take a look at the leg and peppered the man and his son with questions in Spanish.

Colwell directed most of these patients into fast-track, as he had the young man with the rash whom he'd seen earlier in the day. More severely ill or injured patients were ushered straight to the main emergency/trauma treatment area. The rest were sent back to the waiting area with a promise that they'd be evaluated and registered soon.

Many patients that day turned out to be pleasantly surprised to receive a physician's attention at the front desk. "We had happy patients, family members, and staff," Robin Olson-Lovvorn, the interim associate nursing chief for the emergency department, recalls.

Learning From Day-One Experience

But the ten members of the rapid-improvement event team weren't satisfied. They thought it was too early to declare that the most efficient model would have a doctor screening patients at the intake desk.

Later that day, senior hospital officials questioned whether speedier treatment would encourage more patients to inappropriately seek care in emergency. On the other hand, no one had a good solution to the national problem of where else to treat these patients.

After the day's work was complete, the ED rapid-improvement team, along with others from the obstetrics and outpatient lab departments that were also running events the same week, gathered in the hospital's Lean conference room. The purpose was to report that day's results to Gabow and other senior executives.

Scott Nimmo, a clinical nurse educator who later admitted he was so nervous his mouth was dry, took the podium. He explained that the fasttrack process that day had cut patients' length-ofstay to about an hour and saved the trauma staff from having to treat low-acuity patients. "Patients were excited," he informed the gathering. "They expected to wait six hours, and they were out in an hour. And they were delighted to see a physician out front."

But Melinkovich, the physician who directs the primary care clinics at Denver Health, voiced his doubts. He was skeptical that the ED was the right place to treat low-acuity patients, such as those needing a prescription refill. He said he'd prefer to handle those patients in his primary care clinics, although he knows the clinics currently don't have sufficient resources. "I don't agree there is no other place these patients could be seen," he told the teams. Olson-Lovvorn, the interim associate ED nursing chief, spoke up. "The majority of these patients needed a resource, and it was an emergency to them," said Olson-Lovvorn, a twentyyear ED nursing veteran with a self-described "Type A plus plus" personality. "If we don't treat them, they'll be back later, and it will be more expensive."

Gabow challenged Olson-Lovvorn's assertion. "That's not true for all of them," she said. "I don't accept that without seeing more data."

The next morning, Wednesday, the ED team met to discuss revisions to the fast-track experiment and to start developing "standard work"— Lean lingo for protocol for the new system. Many implementation issues were raised, such as criteria for selecting fast-track patients, the cost of additional staffing, and the need to stock treatment supplies.

Refining 'Fast-Track' Criteria

Team members addressed each of these issues, then spent two hours drafting the selection criteria. They checked past discharge records to see how many patients were likely to qualify for fasttrack under the new criteria. They decided that suture removals would qualify for fast-track, but female abdominal pain wouldn't; for prescription refills, they were undecided. They also discussed the grumbling from staff in the adjacent adult urgent care unit that the ED's new fasttrack process had left their unit with fewer and lower-acuity—patients.

Next the team turned to another pivotal issue: who should decide which patients should be fasttracked, when the decision should be made, and who should treat the patients. Nancy Klock, one of two financial analysts on the team, pressed for answers so she could budget out the staffing cost. That was critical, since Denver Health generally requires that rapid-improvement events prompt changes with no net cost increase.

Olson-Lovvorn and the other nurses on the team favored having the ED nurses who normally handle patient triage make decisions about fasttracking some patients. They also argued that the fast-tracked patients should be treated by one or two nurse practitioners. An attending physician sitting in on the meeting, Richard Bynny, agreed. "It would be a huge source of dissatisfaction," he said, for him and his doctor colleagues to handle low-acuity cases.

Having reached agreement, the team decided to try out the nurse-centered approach that day. Just in case, an attending physician would also be on hand to provide treatment.

Wednesday proved to be a difficult day for the experimental team. In Lean terms, the "flow"

Patients who received expedited treatment seemed pleased.

was poor. At various points, the nurse out front wasn't referring enough potential patients to the fast-track area. A temporary nurse shortage at lunchtime led to a backlog of twenty-one patients in the central evaluation unit. As a result, fewer fast-track patients were treated than on Tuesday. And there was more grousing from the adult urgent care side.

At day's end, team leader Beno was frustrated. "Yesterday was an 8 or 9, today was a 4," he said. "Things work well one day, and not as well the next day."

Even so, patients who received expedited treatment seemed pleased. "I've been coming here for my psych meds for a year and a half, and I usually have to take a whole day off work. It's a nightmare," said one patient, 30-year-old Richard Abeyta. "But today was excellent. It was a shock."

On Thursday morning came a switch in signals. Mehler, the chief medical officer, nixed the plan to have two nurse practitioners treating fast-track patients. He preferred having the care provided by an attending physician paired with a nurse, and he passed out a journal article showing that's how other hospitals do it. The perceived advantage is that physicians can treat more types of problems and move patients more quickly. "I didn't envision this run by midlevels," he said. "They aren't trained to do suturing."

So the team changed the experiment once again. Beno instructed the two budget analysts to revise their spreadsheet to reflect the cost of 1.75 physicians working fast-track four days a week, twelve hours a day.

To everyone's relief, Thursday's flow proved much better. By 2:00 p.m., twenty-four fast-track patients had been treated, and there was no one else in the lobby waiting to be screened.

Weighing Initial Results

The next day, Friday, was the time for "reportout," the culminating event of the week for rapidimprovement teams. This was their chance to explain to senior executives the initial problem they tackled, their progress toward achieving targeted improvements, and their schedule for full implementation.

The fact that Lean's change processes are based on hard data also has innate appeal in health care.

Colwell and ED nurse Nicole Carnelli presented the mixed results of their team's experiment. "We played with a few ideas for fast-track," Carnelli said. "Hopefully, what we came up with will increase revenue, patient satisfaction, and staff satisfaction."

Gabow, Mehler, and Melinkovich immediately lobbed tough questions at them. Were separate fast-tracks needed in emergency and adult urgent care? Should low-acuity patients even be seen in the emergency department? Shouldn't there be a policy of no prescription refills there? Wasn't there a better way of getting these patients into primary care?

Carnelli fired back: "A lot of people are losing health insurance, there's a five-month wait for doctor appointments in the indigent care program, and people need their hypertension and diabetes medications. These people have nowhere else to go."

It was obvious to everyone in the room that even ED fast-tracking at Denver Health wouldn't solve the national problem of inadequate primary care. So the Denver Health executives ended their questioning and pronounced the rapid-improvement event a success. "This is the first step in a new paradigm," Mehler said, wrapping up. "There ultimately are issues that have to be dealt with. But you were successful in seeing so many patients."

Sitting in the conference room as people filed out, Colwell looked weary. His job and three young children hadn't allowed him much sleep lately. Beno shook his hand. "Good job," he said. Gabow, too, stopped by to compliment him for his "courage" in tackling this difficult experiment.

From that point on, it would be up to Colwell as emergency medicine director to work through the myriad details of implementing the fast-track plan. He anticipated challenges in funding and staffing it—and in getting attending physicians to accept a role in taking care of minor emergencies.

Assessing Lean's Strengths And Weaknesses

The rapid-improvement events, and the entire Lean approach, clearly aren't a panacea for all that ails US health care. But in the context of running a health care system, says CEO Gabow, they've proved far superior to traditional approaches—such as convening hospitalwide committees to attack a process problem.

For one thing, results come in a week, rather than over many months. Little time is wasted in an often futile attempt to reach consensus. "When we did the first rapid-improvement event in the operating room, I got e-mails from people saying they weren't consulted," Gabow says. "That's the old committee model, where everyone has a veto. So I told them, 'Yeah, you weren't asked, but your colleagues made a decision based on hard [data and] observation,' " so the process changes would proceed.

The fact that Lean's change processes are based on hard data also has innate appeal in health care. Gabow says she has found that physicians and other staff readily embrace Lean because it's a scientific approach based on data. Plus, they agree with the basic philosophy that rooting out waste shows respect for patients and employees.

At the same time, Lean also has its limits. Lean process improvement in individual health systems won't fix such industrywide problems as poorly designed catheters that contribute to infections and medical errors.

Peter Pronovost, a Johns Hopkins University medical professor who has spearheaded efforts across the country to reduce hospital-acquired infections, says that although Lean methods are very effective for improving specialized processes and attacking operational issues, they are less so for grappling with problems in the clinical quality of health care.

That's because entirely different processes than Lean are needed to develop valid clinical measures for adverse events and to address the attitudes and beliefs of clinicians that block helpful changes. "I think Lean has some role" in improving health care, says Pronovost, "but it's not the only hammer in the toolbox."

Employee relations can also be an issue in using Lean. Denver Health's workforce is not unionized, but many unionized organizations in health care and other fields have embraced the approach. Nonetheless, in Minnesota, the nurses' union has resisted Lean. In June the Minnesota Nurses Association held a one-day strike against six health care systems, in part to protest lower staffing levels that the union believes have resulted from Lean efforts.⁹

Mark Graban, a senior fellow at the Lean En-

terprise Institute in Cambridge, Massachusetts (which works with a network of twenty-four health care organizations in the United States and Canada that collaborate on Lean methods), says it's easier for a workforce to accept Lean if it's made clear from the start that those in jobs eliminated through process improvement will be transferred to other positions, not laid off. "If people lose their jobs, that will kill participation in Lean," Graban says.

Back at Denver Health, and just ahead of the start of flu season, the emergency department has now adopted the system for fast-tracking low-acuity patients. In August the emergency department started running a fast-track process on Mondays and Tuesdays. It is seeing nearly thirty fast-track patients each day. Two more rapid-improvement events in the emergency department are scheduled for 2010, including one on speeding up transfers of patients to obstetrics. After all, as quality guru Deming famously said, "It is not enough to do your best; you must know what to do, and then do your best." And in the rapidly changing world of health care, knowing what to do is a process that never ends. ■

NOTES

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Neonatal and maternal outcomes associated with elective term delivery

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OBJECTIVE: To quantify adverse neonatal and maternal outcomes associated with elective term delivery at less than 39 completed weeks of gestation.

STUDY DESIGN: Prospective observational study conducted in 27 hospitals over the course of 3 months in 2007.

RESULTS: Of 17,794 deliveries, 14,955 (84%) occurred at 37 weeks or greater. Of term deliveries, 6562 (44%) were planned, rather than spontaneous. Among the planned deliveries, 4645 (71%) were purely elective; 17.8% of infants delivered electively without medical indication at 37-38 weeks and 8% of those delivered electively at 38-39 weeks required admission to a newborn special care unit for an average of 4.5 days, compared with 4.6% of infants delivered at 39 weeks or beyond (P < .001). Cesarean delivery rate in women undergoing induction of labor was not influenced by gestational age but was highly

influenced by initial cervical dilatation and parity, ranging from 0% for parous women induced at 5 cm or greater to 50% for nulliparous women at 0 cm.

CONCLUSION: Elective delivery before 39 weeks' gestation is associated with significant neonatal morbidity. Initial cervical dilatation is highly correlated with cesarean delivery among women undergoing induction of labor in both nulliparous and parous women. Elective delivery before 39 completed weeks' gestation is inappropriate. Women contemplating elective induction at or beyond 39 weeks' gestation with an unfavorable cervix should be counseled regarding an increased rate of cesarean delivery.

Key words: elective delivery, induction of labor, repeat cesarean delivery

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elivery before 37 completed weeks of gestation has traditionally been defined as preterm, that between 37 and 41 completed weeks as term, and that at 42 weeks and beyond as postterm.¹ Much has been written regarding potential adverse newborn effects of preterm and postterm birth, but little attention has been given to differential neonatal outcomes of infants delivered within the 37-41 week interval.²⁻⁴ Several factors may have contributed to this lack of investigation. First, in an era when gestational age was often erroneously based on last menstrual period alone, such distinctions had little meaning. Second,

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most infants delivered within this age range clearly do well, and very large populations would be needed to document significant differences in newborn outcome. Finally, even if such differences were identified, the clinician has no influence over the exact timing of spontaneous term labor; thus ascertainment of differences in outcome would have little clinical significance if most women delivered spontaneously. However, at a time in which gestational age is generally confirmed by first- or second-trimester ultrasound and elective term delivery is increasingly common, an examination of neonatal and maternal outcomes between 37 and 41 weeks may be of importance.^{5,6}

MATERIALS AND METHODS

Between May 1, 2007, and July 31, 2007, we prospectively collected data variables in all women undergoing planned term delivery at 27 hospitals within the Hospital Corporation of America system. This larger system currently includes 114 hospitals with delivery services in 21 states. Facilities were selected before data collection to be representative of the population as a whole, both in terms of geographic location and delivery volume. Planned term delivery was defined as a delivery occurring at or beyond 37 weeks and 0 days by best clinical estimate in women who did not present either in labor or with ruptured membranes. This collection was part of a quality improvement project directed at determining the extent, if any, to which elective term delivery contributed to newborn morbidity in our health care system. Data were completely deidentified; however, institutional review board approval for data publication was obtained. Data were collected by a single designated experienced labor and delivery nurse on each unit. Planned deliveries were divided into indicated and elective procedures. Indicated deliveries were those in which the admitting physician stated an indication for delivery or in which the nurse performing data collection determined the

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Elective delivery and neonatal outcome			
Variable	37 wk	38 wk	39+ wk
Elective inductions	112	678	2004
NICU admissions	17	44	61
%	15.2 (<i>P</i> = .003)	7.0 (<i>P</i> < .001)	6.0
Elective repeat cesarean	105	696	776
NICU admissions	21	58	62
%	20.0 (<i>P</i> < .001)	8.3 (<i>P</i> = NS)	8.0
Elective primary cesareans	24	97	153
NICU admissions	5	16	12
%	20.8 (<i>P</i> = NS) ^a	16.5 $(P = NS)^{a}$	7.8
Total elective deliveries	241	1471	2933
NICU admissions	43	118	135
%	17.8 (<i>P</i> < .001)	8.0 (<i>P</i> < .001)	4.6

NICU, neonatal intensive care unit; NS, nonsignificant.

Statistical analysis represents a comparison of each gestational age to the subsequent gestational age category.

^a For 37 + 38 wk elective primary cesarean vs 39+ wk elective primary cesarean, P = .027.

Clark. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol 2009.

presence of an indication. No attempt was made prospectively to assess the validity of an indication stated by the admitting physician. Those without any such indication were deemed elective. Gestational age was recorded as completed weeks and days but is reported here according to weeks *completed* gestation (eg, 37 weeks 6 days is reported as 37 weeks.)

In addition to demographic data, the following were analyzed: initial cervical dilatation, initial blood pressure for women with hypertensive disease as the indication for delivery, agent used for induction, length of labor, route of delivery, weight of newborn, initial or subsequent admission to a newborn special care unit (defined as any unit other than the normal newborn unit), and length of newborn stay in the special care unit. Criteria for special care nursery admission were not determined by universal protocol, thus some interfacility variation in admission criteria certainly existed.

Data collection sheets were entered electronically into a web-based database (Excel; Microsoft Systems, Inc, Redmond, WA) and data were analyzed centrally. Statistical analysis was performed by using χ^2 with Yates continuity correction.

RESULTS

Twenty-seven hospitals in 14 states (Colorado, Florida, Georgia, Kansas, Kentucky, Louisiana, Nevada, New Hampshire, Oklahoma, South Carolina, Tennessee, Texas, Utah, and Virginia) participated. Thirteen hospitals had annual delivery volumes of < 2000, 9 facilities had annual delivery volumes between 2000-4000, and 5 hospitals had annual delivery volumes $> 4000.^{5}$ Total patient delivery volume in these 27 facilities during this 3-month period was 17,794.

Of 17,794 total deliveries, 14,955 (84%) occurred at term, that is, 37 weeks or greater. Of term deliveries, 6562 (44%) were planned, rather than spontaneous. Among the planned deliveries, 4645 (71%) were elective. Indications for the nonelective planned deliveries were as follows: 41 weeks or greater (6%), hypertension (6%), large for gestational age/macrosomia (6%), diabetes (4%), oligohydramnios (2%), IUGR (1%), abnormal antepartum testing (1%), and other (3%). Among deliveries for hyper-

tension, patients in 15 of 27 facilities (56%) had neither a mean admission systolic pressure > 140 mm Hg nor a mean admission diastolic pressure > 90 mm Hg. In only 3 of 27 facilities, was the mean admission systolic pressure > 145 mm Hg, and in only 1 of 27 facilities was the mean admission diastolic pressure > 90 mm Hg.

Sixteen percent of all deliveries (2794 deliveries) were elective inductions of labor at term (range, 8-40%.) Four facilities had elective term induction rates of < 10%, 15 had rates of 10-20%, and 8 had elective term induction rates > 20%. Two hundred seventy-four women (1.5%) underwent elective primary cesarean delivery at term (range, 0-5%). Only 2 facilities had an elective primary cesarean rate > 2%.

Among patients undergoing induction of labor, 72% were induced primarily with oxytocin, 15% with a prostaglandin E2-containing agent, 8% with misoprostol, and 4% with amniotomy.

For elective deliveries, neonatal outcome is expressed as a function of gestational age in the Table. Seventy percent of the infants requiring transfer to a special care unit were initially admitted to that unit; 30% of such infants were transferred later to such a unit. Of 2779 infants, 270 (9.7%) electively delivered at term required admission to a special care unit, compared with 252 of 3783 infants (6.6%) undergoing indicated planned term delivery (P < .001.) The mean duration of special care stay for infants admitted to a special care unit after elective delivery was 4.6 \pm 5.9 days.

Cesarean delivery rate in women undergoing planned induction of labor was not heavily influenced by gestational age; cesarean rates of 13.9%, 10.0%, and 13.5% were seen for women induced at 37, 38, and 39+ weeks, respectively. However, cesarean delivery rate was highly influenced by initial cervical dilatation in both nulliparous and parous women (Figure). The mean length of labor (start of induction to delivery) for women undergoing elective term induction of labor was 13.6 \pm 7.9 hours for nulliparous women and 8.2 \pm 5.0 hours for parous women.



Initial cervical dilatation and cesarean delivery rate among women undergoing induction of labor at term.

Clark. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol 2009.

COMMENT

Previous publications suggest that the population of women undergoing delivery in our facilities is similar to the delivery population in the United States as a whole.7,8 This analysis of almost 18,000 deliveries in 27 hospitals within a 3-month period in 2007, revealed that 44% of all deliveries are planned term deliveries and 71% of all planned term deliveries are elective. Elective term deliveries make up 31% of the total delivery population. A closer analysis of the listed indications for nonelective deliveries would suggest that at least 6-12% of these were performed for "indications" not generally recognized as such. In addition, a potential Hawthorne effect on the performance of elective delivery during this time frame cannot be excluded. Thus, the true magnitude of the practice of elective term delivery is probably even greater and appears to represent well over one-third of all deliveries.

We observed significant variation between facilities in the rate of induction even for accepted medical indications. We previously demonstrated similar variation in both primary cesarean and operative vaginal deliveries in the United States.⁷ As with these operative procedures, such variation is a reflection of a lack of unambigous guidelines for management of such cases or a lack of emphasis on existing guidelines. Reduction of such variation is essential to the provision of quality care in any high-reliability organization.^{9,10}

Although much attention has recently been focused on neonatal morbidity associated with the near-term premature infant, few data exist regarding outcomes for infants at different gestational ages traditionally classified as "term."11,12 We have clearly demonstrated increased neonatal morbidity for infants delivered at both 37 and 38 weeks, compared with those delivered at 39 weeks and beyond. Our practice of "rounding down" for the purposes of data analysis, as described previously, would tend to underestimate the degree of morbidity for any gestational age (ie, a newborn infant at 37 weeks 6 days would be expected to have less morbidity than 1 at 37 weeks 0 days, but outcomes for both groups are reported as "37 weeks"). In a similar manner, for purposes of statistical analysis, we accepted as valid any stated indication for delivery. These biases would lead to an underestimation both of the frequency and neonatal complication rates associated with elective term delivery. Short-term complications associated with intensive care admission in infants in this gestational age range are thoroughly described and have been demonstrated to be overwhelmingly respiratory in origin.¹³⁻¹⁶

For over 2 decades, the American College of Obstetricians and Gynecologists (ACOG) has advocated the restriction of elective term delivery to women with a confirmed gestational age of at least 39 weeks.^{17,18} Our data support the ongoing validity and importance of these recommendations, as well as the fact that they are disregarded in at least 10% of all deliveries. Noncompliance with these recommendations appears to represent a classic example of the "normalization of deviance," a term used to describe an unsound practice that continues because of anecdotally derived favorable experience.19 In the case of the elective, term pre-39 week induction, several things are clear. First, most infants delivered even at 37 weeks do not require special newborn care. Second, our observation that about one-third of such infants requiring special care are not immediately transferred to a special care unit from the labor suite suggests many obstetricians may not be aware of such transfers. This observation also suggests that any analysis of term or near-term neonatal infants that tabulates only initial special care admissions will underestimate the true morbidity seen in this group. Third, because gestational age-related adverse outcome in this group is, for the most part, confined to short-term morbidity, rather than long-term injury or death, long-term patient dissatisfaction is unlikely to be brought to the attention of the obstetrician. Finally, the above numerical analysis demonstrates that such morbidity could never be statistically demonstrated within the experience of any single obstetrician, group of obstetricians, or, in most cases, even an individual facility.

We observed a mean labor time of 14.5 hours in nulliparous women undergoing planned induction and 8.7 hours in parous women. This compares with 10-11 and 6-7 hours, for nulliparous and parous women in a recent series that included both induced and spontaneous labors.²⁰ This observation has important implications with respect to resource utilization, an important issue, because labor and delivery ranks behind only cardiovascular care in terms of total cost in the United States.²¹

Our data are not uniformly negative in terms of implications for elective delivery. Indeed, it would appear that for the parous woman with a favorable cervix at 39 weeks, induction of labor carries a rate of primary cesarean far lower than seen in the general population, with no increase in neonatal morbidity. Caughey and Musci⁴ also observed a nadir in both neonatal morbidity and cesarean delivery rate for all infants born at 39 weeks' gestation. Although the nature of our dataset does not allow the definitive conclusion that such women have a lower rate of primary cesarean delivery if induced at 39 weeks than if allowed to labor spontaneously, these data would suggest that elective induction at 39 weeks in parous women with a favorable cervix remains an appropriate option.

Elective primary cesarean at term represented only 1-2% of all deliveries over the study interval, although wide regional variation was seen. Because current standard of care allows a woman to choose elective primary cesarean delivery (an option with a 100% chance of cesarean), we cannot rationally argue against a standard that would allow induction of labor in a nulliparous woman with an undilated cervix (an option with a 50% chance of cesarean), assuming appropriate informed consent has been obtained. However, because health care costs would be incrementally higher both in women undergoing elective primary cesarean delivery and elective induction at term with an unfavorable cervix, both approaches represent suboptimal resource use that should be seriously considered by payers.²²⁻²⁴

Our data demonstrate increased neonatal morbidity associated with elective delivery before 39 weeks' gestation. This practice should be curtailed in accordance with ACOG guidelines. We are in the process of implementing strict protocols to end this practice within our health care system. An increased rate of cesarean delivery is also seen in women undergoing elective induction of labor with an unfavorable cervix. Induction of such women must be accompanied by appropriate informed consent regarding the risks of cesarean delivery.

Finally, the graduated pattern of neonatal morbidity seen in 37- and 38-week deliveries, compared with those at 39 weeks and beyond, coupled with similar data regarding morbidity in the nearterm infant (34-36 weeks), suggests that the use of the designations "term" to refer to a gestation that has reached 37 weeks 0 days and "preterm" to those at 36 weeks 6 days and below is anachronistic. Such a designation has no basis in maternal or fetal physiology and potentially leads to inappropriate care by suggesting to the clinician and patient that 37 weeks 0 days represents a valid physiologic threshold. One may extend this principle to the use of the descriptor postterm, because neonatal morbidity has been shown to increase incrementally beyond 39 weeks' gestation as well.^{4,25,26} The use of these older terms

may lead to both inappropriate attempts to prolong pregnancy in the presence of certain complications before 37 weeks, inappropriate elective delivery beyond this point in time, and an underappreciation of the well-defined risks of allowing pregnancy to proceed beyond 39 weeks.^{4,26} Given the near universal use of early ultrasound to establish or confirm fetal age, such a discontinuous classification of gestational age is no longer helpful. We suggest that both risks and appropriate management approaches in obstetrics should be precisely defined in terms of the gestational ages at which these risks have been demonstrated or management approaches have been validated.

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OBSTETRICS

Reduction in elective delivery at <39 weeks of gestation: comparative effectiveness of 3 approaches to change and the impact on neonatal intensive care admission and stillbirth

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OBJECTIVE: No studies exist that have examined the effectiveness of different approaches to a reduction in elective early term deliveries or the effect of such policies on newborn intensive care admissions and stillbirth rates.

STUDY DESIGN: We conducted a retrospective cohort study of prospectively collected data and examined outcomes in 27 hospitals before and after implementation of 1 of 3 strategies for the reduction of elective early term deliveries.

RESULTS: Elective early term delivery was reduced from 9.6-4.3% of deliveries, and the rate of term neonatal intensive care admissions fell

by 16%. We observed no increase in still births. The greatest improvement was seen when elective deliveries at <39 weeks were not allowed by hospital personnel.

CONCLUSION: Physician education and the adoption of policies backed only by peer review are less effective than "hard stop" hospital policies to prevent this practice. A 5% rate of elective early term delivery would be reasonable as a national quality benchmark.

Key words: elective delivery, patient safety, practice change

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The practice of elective delivery at <39 weeks of gestation is common in the United States and may account for 10-15% of all deliveries, despite long-standing recommendations by the American College of Obstetricians and Gynecologists against this practice.¹⁻⁴ Recent publications have demonstrated that this practice is associated with significant newborn morbidity and increased rates of primary cesarean delivery.^{1-3,5} This issue is of sufficient importance to warrant recent inclusion as a national perinatal quality bench-

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0002-9378/\$36.00 © 2010 Mosby, Inc. All rights reserved. doi: 10.1016/j.ajog.2010.05.036 mark both by the National Quality Forum and the Joint Commission.^{6,7} Although the morbidity that is associated with this practice is widely recognized, there has also been speculation about the potential for an increase in term stillbirths were this practice to be reduced significantly.⁸

We sought to investigate the comparative effectiveness of 3 types of policies that were directed toward the reduction of elective delivery at <39 weeks of gestation in a large, national hospital system and the effects of such policies on both neonatal intensive care admissions and stillbirths. To our knowledge, this approach has not been used previously and may have wider applicability to the examination of change in physician practice patterns beyond the question of elective early term delivery.

MATERIALS AND METHODS

In the summer of 2007, 27 pilot facilities of the Hospital Corporation of America in 14 states were chosen for an investigation into the frequency of elective delivery at <39 weeks of gestation and the impact of this practice on neonatal outcomes. Facilities were chosen for geographic and demographic representation of our larger system that is responsible for the delivery of approximately 220,000 babies annually in 21 states.⁹ Thirteen facilities had annual delivery volumes of <2000; 9 facilities had delivery volumes of 2000-4000, and 5 facilities had delivery volumes of >4000. This system has been shown previously to be roughly representative of the United States as a whole.¹⁰⁻¹² During a 3-month period, data were collected from >17,000 deliveries.

Based on the observed morbidity that is associated with this early term delivery, we then instituted efforts to reduce its frequency throughout our system. After a period of physician and nursing education that included the provision of published practice guidelines and our own internal data, medical staffs at all hospitals were informed of our intent to restrict this practice on the basis of patient safety considerations. However, medical staffs were allowed to choose 1 of 3 approaches to reduction of this practice: (1) a "hard stop" approach that involved the adoption of a policy that

TABLE 1

Elective deliveries at <39 weeks of gestation and newborn intensive care admission

Variable	2007	2009	P value
Deliveries, n	17,794	17,221	NA
Deliveries \geq 37 wk, n	14,995	14,863	NA
Planned + elective deliveries at 37.0- 38.6 wk, n	6562	4349	< .001 ^a
Elective deliveries at 37.0-38.6 wk, n (%)	1712 (9.6)	746 (4.3)	<.001 ^a
Group 1: 7 hospitals, n/N (%)	320/3886 (8.2)	65/3818 (1.7)	.007 ^b
Group 2: 9 hospitals, n/N (%)	403/4797 (8.4)	155/4646 (3.3)	< .025 ^b
Group 3: 11 hospitals, n/N (%)	989/9111 (10.9)	526/8757 (6.0)	.135 ^b
Neonatal intensive care unit admissions at \geq 37 wk, n (%)	1328 (8.9)	1119 (7.5)	< .001 ^a

For gestational age, days are expressed as decimals; elective deliveries are expressed as percent of total deliveries. NA. not applicable.

^a χ^2 with Yates correlation correction; ^b 2-way analysis of variance.

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would prohibit purely elective inductions and primary and repeat cesarean deliveries at <39 weeks of gestation. This policy would be enforced by hospital staff members who were empowered to refuse to schedule any such deliveries. Questionable "indications" would be handled in the standard manner by accessing chain of command. (2) A "soft stop" approach that would include adoption of a similar policy to that described earlier. In contrast to the "hard stop" approach, compliance would be left up to individual physicians, and elective deliveries at < 39 weeks of gestation would be allowed if ordered by the attending physician. However, all such cases would be referred to the local peer review committee for evaluation and potential action. (3) An "education only" approach that would involve the provision of available literature to attending physicians and both internal and professional association recommendations against this practice, which was also provided with the first 2 approaches. However, no formal policy prohibiting this practice would be adopted by the medical staff.

Data regarding physician compliance and neonatal outcomes were collected exactly 2 years later (2009) during the same 3 months of the year (May, June, July) and compared with the baseline data from these same 27 facilities in 2007. Analysis of identical facilities during identical months of the year within a 2-year period was necessary to minimize confounding effects of changes in patient or provider population or of scheduling concerns. Because of a concern regarding potential development of "creative" indications by staff physicians, we tracked rates of each type of planned delivery (elective and indicated) during these 2 time periods as an internal control. A planned delivery was defined as 1 in which the mother delivered after entering the labor and delivery suite not in labor and with intact membranes. An elective delivery was defined as a planned delivery without a recognizable medical or obstetric indication for delivery by either the attending physician or the nurse who collected the data.1 This included inductions and primary and repeat cesarean deliveries. Gestational age was assigned based on the best estimate of the attending clinician according to both menstrual history and prenatal sonography.^{1,2} For the overall reduction in rates of elective early term delivery and newborn intensive care unit admissions, the unit of analysis was the individual delivery.

For the comparison of departmental policy, facility rates were used as the unit of analysis. Statistical analysis for the

TABLE 2

Change in elective early term deliveries by facility

Facility	2007	2009
Group 1		
1	12.3	5.8
2	8.6	1.2
3	3.6	0.7
4	44.7	4.1
5	3.2	0
6	22.3	0.7
7	8.8	0.3
Group 2		
8	22.2	5.7
9	5.6	7.1
10	13.9	8.5
11	5.9	0
12	7.9	5.8
13	9.0	3.8
14	9.6	3.8
15	5.8	0.9
16	4.4	2.0
Group 3		
17	1.4	2.7
18	10.4	4.7
19	5.8	0.6
20	2.9	1.4
21	12.7	4.8
22	14.0	7.2
23	2.4	1.3
24	4.2	5.6
25	18.9	8.5
26	26.7	8.0
27	16.7	20.5

overall performance and neonatal outcome data was performed with the χ^2 test with Yates correlation correction. One-way analysis of variance and Friedman repeated measures analysis of variance on ranks with all pairwise multiple comparison procedures (Student-Newman-Keuls method) and 2-way analysis of variance with multiple comparisons vs control group (Holm-Sidak method) were used to compare sequential performance differences in the 3 study groups. Significance was set at a probability value of .05. This was a quality improvement project that used deidentified data for analysis. Exemption from institutional review board review was obtained based on 45CFR46.101(b)² and 46.102(f) and 45CFR164.514(a)-(c) of the Health Insurance Portability and Accountability Act. However, institutional review board approval had been obtained for the control data publication.

RESULTS

During the 3 study months in 2009, 17,221 deliveries occurred in these 27 facilities, compared with 17,794 deliveries during the same months of 2007. The rate of elective delivery between 37 and 39 weeks of gestation fell from 9.6% of all deliveries in 2007 to 4.3% of deliveries in 2009 (P < .001; relative risk [RR], 0.45; 95% confidence interval [CI], 0.41–0.49; Table 1) The rate of elective and indicated planned deliveries also fell significantly during this interval (36.9-25.3%; P < .001; RR, 0.69; 95% CI, 0.66–0.71).

Performance improvement by type of policy adopted and the effect of such changes on term newborn intensive care unit admission rates are detailed in Tables 1 and 2 and Figures 1 and 2. There were no differences in the initial (2007) rates of elective early term delivery among the 3 groups (P = .52) Both groups 1 and 2 demonstrated a significant decline in the rate of elective early term delivery over the study period; group 1 experienced twice as great a reduction as group 2 (Table 1). Although a decline was also seen in group 3, this change did not reach statistical significance.

Table 2 shows the individual facility rate of change by group. Facilities with initially high rates of elective early term delivery were found within each group. However, only groups 2 and 3 included facilities with no improvement over the study period. Additional demographic differences between groups were minor. As seen in Table 1, a greater number of larger hospitals were represented in group 3 (no policy adopted), although all groups contained facilities with deliv-







ery volumes in both the highest and lowest volume groups described in the "Materials and Methods" section. All study groups included facilities from geographically diverse states.

For all study facilities during this time frame, the rate of term newborn intensive care unit admission fell from 8.9-7.5% (P < .001; RR, 0.85; 95% CI, 0.79–0.92; Table 1). There was no change in the rate of system-wide stillbirth during this time frame (2007: 1522 stillbirths/222,084 births [0.69%]; 2009: 1497 stillbirths/211,467 births [0.71%]; P = .38; RR, 1.3; 95% CI, 0.96–1.11).

COMMENT

National interest in the practice of elective term delivery at <39 weeks of gestation was spurred by documentation of significant short- and long-term morbidity that was associated with near-term (34- to 37-week) deliveries and a realization of the absence of evidence for a biologic threshold at 37 weeks of gestation, which is the traditional definition of term.13-15 Subsequent investigations revealed significant morbidity that is associated with both 37- to 38-week and 38to 39-week elective deliveries, compared with those deliveries that occurred at >39 weeks of gestation.^{1-3,16} This finding pertains to elective induction of labor and elective primary or repeat cesarean delivery. Recent data suggest that such morbidity is seen even when lung maturity has been documented before delivery.3 Further, some studies suggest a contribution of elective induction to the rising cesarean delivery rate.^{1,5} Such data have led the Joint Commission to adopt elective early term delivery as a national quality metric beginning in 2010.7

Previous success in lowering rates of early elective induction has been reported.^{17,18} However, our data are unique both in the size and diversity of the population studied and in the inclusion of an ideal reference group of patients who delivered at the same facilities during the same months of the year before the initiation of efforts to change practice. In addition, the physicians involved were neither employed by the hospital nor a part of a closed insurance panel. Although we lacked these 2 powerful tools for encouraging physician compliance that was available in other settings, our results are more widely generalizable to practice in the United States where clinical policy changes must be approved by independent medical staffs. Thus, from the hospital standpoint, education, leadership, and recommended policy are the only tools that are available to change these deeply ingrained but flawed practice patterns.

Perhaps of greatest advantage of this study was our ability to compare the relative efficacy of various approaches to physician behavior change, which are observations that have potential ramifications beyond the specific issue of reducing elective deliveries at <39 weeks of gestation.

Under these circumstances, we were encouraged by a 55% reduction in elective early term delivery rate that was achieved in 2 years (9.6-4.3%,) in facilities of the nation's largest healthcare delivery system in which individual medical staffs were free to choose their approach to quality improvement. Given the myriad of indications for admission of a term infant to a special care unit, the fact that a modest change in this single practice resulted in a 16% decline in overall term newborn intensive care unit admissions is testament to the magnitude of the morbidity that is incurred by the practice of elective early term delivery in the United States today.

Concern has been raised regarding the potential effects on stillbirths of delaying elective delivery until 39 weeks of gestation.⁸ In light of such concerns, our finding of no statistical increase in the rate of stillbirth that is associated with implementation of this policy is important and merits further discussion. Delivery at any gestational age for any reason whatsoever absolutely eliminates the possibility of subsequent stillbirth; the earlier the delivery, the greater will be the observed effect. Thus, it is certain that, with a sufficiently large denominator, reduction of elective deliveries at <39 weeks of gestation would be associated with an increased rate of stillbirth compared, for example, with a cohort of infants who were delivered at 38 weeks of gestation.

Uniform delivery at 28 weeks of gestation would yield an even more impressive reduction in stillbirths. In such an analysis, 3 considerations appear germane. First, our inability to demonstrate any statistically significant increase in stillbirths in a population of almost onequarter million births suggests that the number of actual stillbirths that potentially are associated with this policy is very small. Second, any objection to the implementation of such a policy based on concern for stillbirths is only logically consistent if accompanied by advocacy of uniform delivery at <39 weeks of gestation. Otherwise, the benefit of such objections would accrue only to those women whose physicians violate current practice guidelines.⁴ Finally, an appropriately conducted randomized clinical trial in a very large population potentially could define the cost, in terms of both dollars and morbidity of each stillbirth avoided by uniform delivery at <39 weeks of gestation. However, such a trial is not only logistically unrealistic, but also the data would be of no value in the absence of universal agreement on the relative value of large amounts of iatrogenic morbidity vs the prevention of a small number of deaths. Under these circumstances, we believe it appropriate to invoke primum non nocere and advocate avoidance of a practice associated with well-documented iatrogenic morbidity in the complete absence of contrary data.1-7,15-20

A comparison of the 3 approaches to practice change that is outlined in Table 1 and Figures 1 and 2 is instructive. All facilities began with similar rates of elective delivery at <39 weeks of gestation. Groups 1 (formal policy enforced by hospital staff) and 2 (formal policy not enforced by hospital staff, but with automatic peer review of exceptions) both demonstrated significant decreases in this practice, with the greatest improvement seen in group 1. On the other hand, medical staffs eschewing any form of formal practice oversight (group 3: education only) achieved a much smaller, nonsignificant decrease in elective early term deliveries, despite the longstanding recommendations of the American College of Obstetricians and Gynecologists against this practice. These data suggest a correlation between quality of care and physician willingness to accept practice standardization and oversight, in accordance with observations from the Institute of Medicine.^{19,20}

Unfortunately, our data document the relative ineffectiveness of education alone in changing the practice of many obstetricians and demonstrate how far the specialty has to go in embracing the concept of evidence-based (as opposed to anecdotal experience-based) practice. It is also disheartening that self-oversight (peer review) appears to be of limited value in this regard, compared with outside oversight (hospital enforcement.) (Tables 1 and 2; Figures 1 and 2). The relative ineffectiveness of physician peer review is a phenomenon previously noted by us and others.^{9,21}

Approximately 5% of babies in the United States are born in a facility of the Hospital Corporation of America. An extrapolation of our data to the entire US population reveals the staggering medical and economic impact of the practice of elective early term delivery. We have shown previously that those infants who were delivered electively between 37 and 39 weeks of gestation who are admitted to newborn intensive care units have an average length of stay in such units of 4.5 days.1 A calculation that involved the number of admissions that were avoided in our system with a reduction in the rate of elective early term delivery to 4.3% and the observation that a rate of 1.7% is achievable with a "hard stop" approach suggests that one-half million newborn intensive care unit days could be avoided in the US population were a national rate of 1.7% to be achieved; the cost savings would approach \$1 billion annually.

Nonrandomization of facilities might be viewed as a limitation of this study. However, the achievement of voluntary randomization (and actual practice compliance) of independent medical staffs with an issue as emotional as the elimination of elective early term deliveries would not be possible. Further, because this study deals with decisionmaking and the clinical consequences of these decisions, artificial randomization would impact negatively the degree to which our results would be generalizable to real-life medical staff situations. In addition one cannot discount a potential Hawthorne effect on the absolute rates of compliance with departmental policies. However, the relative changes that were seen in the 3 groups would not be effected markedly, because comparison was made with the same facilities that were undergoing the same scrutiny with respect to compliance with a decades-old standard of care during the 2007 control period. Moreover, given the recent addition of this metric as a quality indicator by the National Quality Forum, Joint Commission, and Leapfrog, an ongoing Hawthorne effect is now an integral part of this issue for all facilities in the United States, which makes such an effect on our data a strength rather than a weakness.

Elective early term delivery may be reduced to a level of $\leq 2\%$ by the use of a "hard stop" policy described earlier. Correcting patient misconceptions regarding the safety of early term births will also play an important role in practice change.²² Current definitions of "elective" used by organizations such as the National Quality Forum and Joint Commission rely on the absence of indications that are defined by a diagnosisrelated group code. Because some valid indications for such practice exist but do not have a specific diagnosis-related group code (for example, a history of a precipitous delivery in a woman with a dilated cervix at 38 weeks of gestation who lives remote from the hospital), no facility would be expected to reduce the rate of such "elective" deliveries to zero. However, a review of the variability seen in Figure 2 would suggest that achievement of a rate of such deliveries at <5%would be realistic for use as a national quality benchmark. Our data also suggest that, as a general rule, a hard stop approach to elective early term delivery with hospital oversight will be needed to achieve the type of change that is mandated by the practice of evidence-based medicine.

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Aligning Our Efforts to Transform America's Healthcare

National Priorities Goals

November 2008

National Priorities Partnership

Convened by the National Quality Forum

1-1

NATIONAL PRIORITY: OVERUSE *Eliminate overuse while ensuring the delivery of appropriate care*

OUR VISION: We envision healthcare that promotes better health and more affordable care by continually and safely reducing the burden of unscientific, inappropriate, and excessive care, including tests, drugs, procedures, visits, and hospital stays.

Why is Overuse a National Priority?

A significant amount of attention on healthcare focuses on the care that Americans do *not* receive, but there is growing evidence that a significant portion of the care we receive is actually redundant and unwarranted—and beyond that, in some cases, even harmful.

Since the problem of overuse was defined more than 10 years ago—as when "the potential for harm exceeds the possible benefits of care"—a growing body of evidence has emerged documenting its pervasiveness and consequences.¹³⁴ Perhaps the

most compelling evidence of this problem lies in the work of researchers at Dartmouth Medical School, who for many years have studied variation in healthcare service delivery and its relation to quality and costs. Their studies have shown that there is significant variation

Areas with more specialists have more consultations and consequently provide more surgeries and procedures and have higher expenditures, regardless of whether such care is warranted.

in healthcare spending between regions of the United States, only 40 percent of which can be attributed to different rates of illness and price. The remaining variation can be explained in part by practice variations that have little or nothing to do with evidence-based medicine, but rather with the capacity to provide healthcare, such as the number of hospitals, physicians, and physician specialists. Areas with more specialists have more consultations and consequently provide more surgeries and procedures and have higher expenditures, regardless of whether such care is warranted. $^{\scriptscriptstyle 135}$

The Partners identified targeted areas of potential waste, building on a broad evidence base, including recent work by the New England Health Institute,¹³⁶ which compiled a comprehensive compendium of evidence of overuse, underuse, and misuse from 1998 to 2006 that emphasizes high-value opportunities for tackling this problem. The Partners solicited and received important feedback from a broad array of stakeholder groups, including specialty societies, nursing organizations, hospital associations, and health plans.¹³⁷

The resulting list of nine targeted areas encompasses multiple Priorities, care settings, and target populations and builds on the momentum of growing public and media attention to the issue.

The idea that "more does not necessarily mean

better" is starting to resonate outside of the quality community and is entering into broader public consciousness. In the past year, a best-selling book on the topic was read by millions,¹³⁸ and reputable news outlets and national consumer organizations, including the *New York Times*, *U.S. News & World Report*, the *Wall Street Journal*, AARP, and Consumers Union, all ran articles that have increased public awareness of this issue.¹³⁹ The time is right to tackle this area, particularly given the potential for savings amidst the dire financial situation of our healthcare system and the number of under- and uninsured. It is important to emphasize, however, that for all of the identified target areas,

The idea that "more does not necessarily mean better" is starting to resonate outside of the quality community and is entering into broader public consciousness. Americans.¹⁴⁰ Inappropriate use of antibiotics contributes to the emergence of antibiotic-resistant bacteria, making all of us more susceptible to infections and leaving us with fewer options to combat them.¹⁴¹ Such antibiotic use also puts

there are patients for whom these tests and procedures are absolutely appropriate and necessary. This goal is therefore not limited just to reducing overuse, but one that equally stresses the provision of appropriate care for each and every patient. Importantly, the other five Priorities explicitly focus on underuse and ensuring that safe, effective, and culturally sensitive care is delivered.

Making Overuse a National Priority Will:

REDUCE HARM. The inappropriate use, misuse, or overuse of medical interventions poses many serious threats to our population. Beyond the negative impact of wasted resources that we can ill afford, the areas of inappropriate use identified may cause unnecessary harm to millions of

patients at unnecessary risk for adverse drug reactions, yet many patients, particularly children, are still inappropriately prescribed antibiotics for the common cold (see Chart 7).142 Unwarranted surgeries and procedures present opportunities for medical errors and serious adverse events, including surgical errors and infections, yet many women still receive unwarranted cesarean sections (c-sections)¹⁴³ and hysterectomies,¹⁴⁴ and patients with stable coronary disease receive coronary revascularization procedures when pharmacologic therapy may suffice.145 Unnecessary testing exposes patients to additional risks as well-inappropriate imaging exposes patients unnecessarily to radiation, unwarranted endoscopies increase a patient's risk of internal injuries, and unnecessary

Chart 7

Rate that Antibiotics Were Prescribed at Outpatient Visits with Diagnosis of Common Cold (per 10,000 Population), by Age Group, 2001-2002



Data: National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey (Agency for Healthcare Research and Quality, 2006).

Source: McCarthy and Leatherman, Performance Snapshots, 2006. www.cmwf.org/snapshots.

EFFICIENCY

Chart 8

Went to Emergency Room for Condition That Could Have Been Treated by Regular Doctor, Among Sicker Adults

Percent of adults who went to emergency room in past two years for condition that could have been treated by regular doctor if available



AUS = Australia; CAN = Canada; GER = Germany; NETH = Netherlands; NZ = New Zealand; UK = United Kingdom. Data: 2005 and 2007 Commonwealth Fund International Health Policy Survey.

Source: Commonwealth Fund National Scorecard on U.S. Health System Performance, 2008.

laboratory tests may induce more testing or exploratory procedures exposing patients to further potential harms.

REDUCE DISPARITIES. Effectively addressing the burden of unnecessary care is one way to remedy the problem of disparities in how care is and is not provided. The discussion of healthcare disparities typically focuses around the lack of access to healthcare services and the lack of appropriate care; however, assuring access to appropriate healthcare services early on can also help to reduce more costly utilization downstream. Studies indicate that the overutilization of emergency departments and unnecessary hospitalizations, which have been associated with poor access to primary care, are more common in minority populations.146 A study of neonates seen in an urban emergency room found that 60 percent of all emergency department visits were nonurgent and that patients of younger maternal age, patients with Medicaid, and patients of nonwhite race all had more frequent nonurgent emergency department use.147 Separate research indicates, however, that 50 percent of hospitalizations for children who are admitted for any one of six

diagnoses, including asthma, dehydration, and skin infections, may be avoidable through better parent education and follow-up clinical care.¹⁴⁸ Minority populations may also suffer more from certain unnecessary procedures than nonminority patients. In a phone survey of women in seven different U.S. cities, the highest rates of hysterectomy were found in disadvantaged African American and Hispanic subgroups, which could not be explained by known risk factors.¹⁴⁹

REDUCE DISEASE BURDEN. The rising number of cesarean sections can have long-term unintended consequences for women and their offspring. For example, women who have c-sections are at increased risk for chronic pelvic pain or even bowel obstruction as a result of abdominal adhesions. Subsequent pregnancies following a c-section introduce dual risks for mother and child, including placenta previa, uterine rupture, low birth weight, preterm birth, stillbirth, and admissions to neonatal intensive care units. Babies that do not experience vaginal delivery may be at increased risk of respiratory problems such as allergies and asthma.¹⁵⁰

EFFICIENCY

Chart 9

30 2005 2007 20 20 18 16 15 10 9 10 8 4 0 NETH CAN UK NZ AUS GER United States International Comparison AUS = Australia; CAN = Canada; GER = Germany; NETH = Netherlands; NZ = New Zealand; UK = United Kingdom. Data: 2005 and 2007 Commonwealth Fund International Health Policy Survey.

Duplicate Medical Tests, Among Sicker Adults

Percent reporting that doctor ordered test that had already been done in past two years

Source: Commonwealth Fund National Scorecard on U.S. Health System Performance, 2008.

On the other end of the spectrum, approximately 20 percent of patients are given chemotherapy in the last 14 days of life,¹⁵¹ at which point the disease has progressed to such an extent that the chemotherapy has essentially no chance of helping. Receiving chemotherapy at this point can be detrimental to incurable patients, who may still suffer the negative side effects of the medication and who may forego limited opportunities for spiritual growth, quality family time, and an easier transition to death.¹⁵²

REDUCE WASTE. Drawing on the Dartmouth research, individuals who live in "high-spending" areas receive approximately 60 percent more in services than those who live in "low-spending" areas, which is at least in part attributed to differences in the supply of healthcare providers in the area as well as practice variation. Furthermore,

and contrary to intuition, the low-spending regions perform as well or better on a range of quality indicators.¹⁵³ This "over spending" is substantial. In fact, one report indicates that Medicare spending would decrease by 29 percent if spending in medium- and high-spending regions reached the level of that in low-spending regions.¹⁵⁴ Evidence shows that Americans are more likely to be seen in an emergency department for a condition that is treatable by a primary care professional than in six other developed countries (see Chart 8).¹⁵⁵ Reducing preventable hospitalizations by 5 percent for ambulatory care-sensitive conditions could result in savings of more than \$1.3 billion.¹⁵⁶ The waste of healthcare resources also can be attributed to such things as duplicate testing that could be remedied by systems that allow better tracking of ordered tests and results (see Chart 9).157

In collaboration with medical groups, HealthPartners, a Minnesota insurer, has developed a "decision support" tool that medical groups can embed in their electronic medical records. The tool allows physicians to enter a planned diagnostic procedure, such as a CT scan, into the computer while a patient is in the exam room and receive immediate feedback regarding whether that particular procedure makes sense; if not, alternatives are suggested. HealthPartners emphasizes that it will pay for the diagnostic procedure even if the physician does not follow its recommendation. Still, the company says its efforts have helped it avoid some 7,000 inappropriate scans.¹⁵⁸

UnitedHealth's "advanced notification," program requires many of its physicians to notify United before proceeding with a nonurgent scan. The company then reviews the case in advance to make sure the test makes sense. Although it sounds like prior authorization, the company says the distinction is that doctors risk not being paid only if they do not provide the notification. Once they have done that, it does not matter for payment purposes whether the doctor follows the company's advice. United says that doctors have changed what test they have ordered 3 percent of the time, and 9 percent of the time they have canceled the order altogether.¹⁵⁹

The home health community has been targeting preventable hospitalizations and emergency department visits through the Centers for Medicare & Medicaid Services' QIO Program. Many home health agencies have implemented interventions such as telemonitoring to better keep an eye on a high- or moderate-risk patient's medical condition, especially when the patient is first discharged home from the hospital. Others are emphasizing better education for patients that historically have higher rehospitalization rates or emergency department visits to help them understand when a condition is a true emergency as opposed to when it is more appropriate to call the home care agency for assistance.¹⁶⁰

AARP has been informing its membership about the issue of overuse and about the potential dangers of inappropriate medical care. An article in the Health section of its magazine, "Why Does Health Care Cost So Much?," provided an overview of the problem as well as some of the potential causes. AARP went one step further to speak to this issue by including five tips for consumers of things to do now to lessen the risk of receiving care they do not need.¹⁶¹

OVERUSE:

HOW WILL WE GET THERE?

The Partners will work together to ensure that:

Goal: All healthcare organizations will continually strive to improve the delivery of appropriate patient care and substantially and measurably reduce extraneous service(s) and/or treatment(s).

The recommended areas of concentration are as follows:

✓ Inappropriate medication use, targeting:

- Antibiotic use
- Polypharmacy (for multiple chronic conditions; of antipsychotics)

✓ Unnecessary laboratory tests, targeting:

- Panels (e.g., thyroid, SMA 20)
- Special testing (e.g., Lyme Disease with regional considerations)
- ✓ Unwarranted maternity care interventions, targeting:
 - Cesarean section

✓ Unwarranted diagnostic procedures, targeting:

- Cardiac computed tomography (noninvasive coronary angiography and coronary calcium scoring)
- Lumbar spine magnetic resonance imaging prior to conservative therapy, without red flags
- Uncomplicated chest/thorax computed tomography screening
- Bone or joint x-ray prior to conservative therapy, without red flags
- Chest x-ray, preoperative, on admission, or routine monitoring
- Endoscopy

✓ Inappropriate nonpalliative services at end of life, targeting:

- Chemotherapy in the last 14 days of life
- Aggressive interventional procedures
- More than one emergency department visit in the last 30 days of life

✓ Unwarranted procedures, targeting:

- Spine surgery
- Percutaneous transluminal coronary angioplasty (PTCA)/Stent
- Knee/hip replacement
- Coronary artery bypass graft (CABG)
- Hysterectomy
- Prostatectomy

Unnecessary consultations

✓ Preventable emergency department visits and hospitalizations, targeting:

- Potentially preventable emergency department visits
- Hospital admissions lasting less than 24 hours
- Ambulatory care-sensitive conditions

Potentially harmful preventive services with no benefit, targeting:

- BRCA mutation testing for breast and ovarian cancer – female, low risk
- Coronary heart disease screening using electrocardiography (ECG), exercise treadmill test (ETT), electronbeam computed tomography (EBCT) – adults, low risk
- *Carotid artery stenosis screening general adult population*
- Cervical cancer screening female over 65, average risk and female, posthysterectomy
- Prostate cancer screening male over 75

(See U.S. Preventive Services Task Force D Recommendations List at www.ahrq.gov/clinic/prevenix.htm)

To get there, we will continue to pursue a collaborative, multidisciplinary approach with the healthcare organizations and healthcare professionals who played a major role in the development of the targeted areas. We will work with the practicing and academic professional communities and the medical specialty societies to identify strategies to achieve this goal (e.g., embedding performance measurement in the maintenance of certification requirements). We will engage all key stakeholders, including patients, payers, employers, suppliers, and the media to promote an understanding of the nine targeted areas. We will support patient shared decisionmaking to ensure that the patient's needs are met, ensure that there are evidence-based resources for the targeted areas, and assist in the development of payment and consumer information processes to discourage inappropriate and unnecessary care. We will provide tools for successful implementation where possible and appropriate. We will develop metrics to measure successful implementation and outcomes and publicly report this data on a timely basis.



Value Based Benefit Design: Large Employers (50+)

Level One Benefits

These benefits would be provided at no charge and not subject to any deductible. They would provide coverage for chronic conditions and at the plan discretion, wellness benefits.

<u>Chronic Care Management Benefits</u> would cover generic prescriptions, lab, and imaging and other ancillary services as specified for the following chronic conditions. All members who select this product would receive the benefits. There would be no need for a health risk assessment to identify those eligible for this benefit.

Condition	Rx	Lab-	Imaging/Ancillary
Depression	Generic: SSRI's, SNRI's and Tricyclic	None	None
CHF	Generic: Beta Blocker, ACE inhibitor, Diuretics	LDL-C (one per yr.)	Ejection fraction echocardiogram
CAD	Generic: Beta Blocker, ACE inhibitor, Diuretics, Statins, Alpha Methyl Dopa	LDL-C (one per yr.)	None
Diabetes Mellitus	Generic: Sulfonylureaus, Heneric metformin, NPH, regular insulins and supplies	HbA1C, LDL-C, Urine Microalbum (one each per yr.)	None
COPD/Asthma	At least 1 inhaled corticosteroid controller (e.g. fluticasone, betamethasone, memetasone, etc.) AND at least 1 long acting beta agonist (e.g. salemtrerol, formoterol, etc.)	None	2 Spirometry tests per year

<u>Including Office Visits In Level 1; Use of a Health Risk Assessment:</u> The initial design reviewed by the group included waiving 4 office visits for each of the six conditions as part of the Level I benefit. It was determined to be administratively challenging, but still a desirable feature of the benefit plan. We discussed the concept of an employer using a health risk assessment to identify employees with any of the chronic conditions, in advance, in order to receive the office

visits at no/minimal co-pays. If feasible, plans should consider solutions that can waive these office visit co-pays.

<u>Wellness Benefits</u> could be provided under Level 1 or Level 2 benefit structures. Wellness benefits could include proven age/gender sensitive preventive care including screening and immunizations following national guidelines. A preventative dental benefit may be considered. The group recommends the benefit provide 2 cleanings per calendar year for employees under treatment for these chronic conditions. Coverage of these benefits have not been included in the pricing of the value based benefit design. Each plan would need to make this determination and price accordingly.

Level 2 Benefits

Except for those benefits covered in Level 1 and Level 3, these benefits would be subject to a standard deductible and co-pay/coinsurance level as specified by the plan.

Level 3 Benefits

These benefits are applied under a separate deductible, different co-insurance and aggregated against a separate out of pocket maximum. The amounts would be double the standard deductible, co-insurance and OOP outlined in Benefit Level 2.

All treatments listed below would be subject to this separate deductible/coinsurance benefit. Both professional and facility charges would be applied, except as noted. Elective and emergent treatment would be subject to coverage under Level 3. Recommend adhering to the list—no additional items added and Plans may need to be flexible to consider a shorter list, however price reduction will not be achieved. Existing appeal processes would apply.

- Outpatient Upper Endoscopy
- Outpatient MRI, CT, and PET screening
- Spine surgery for pain
- Orthopedic joint procedures
 - Knee replacement
 - Hip replacement
 - Arthroscopies
 - Shoulder surgery for osteoarthrosis
- PTCA
- Stents
- CABG surgery
- Nuclear cardiology diagnostics--Electron beam computerized tomography (EBCT/SPECT)
- Hysterectomy
- Emergency Room Visits. (ED visit waived if admitted. If admitted for one of the Level 3 treatments, the Level 3 benefit would apply).


Patient-Centered Outcomes Research Institute

Draft National Priorities for Research and Research Agenda Version 1

Presented for Public Comment

January 23, 2012

Draft National Priorities for Research and Research Agenda

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Introduction and Invitation for Public Comment

The **Patient-Centered Outcomes Research Institute (PCORI)** is an independent, non-profit health research organization. Its mission is to fund research that offers patients and caregivers the information they need to make important healthcare decisions.

PCORI focuses on "comparative clinical effectiveness" research. These are studies that compare options for preventing disease and providing treatment and care. PCORI does so by:

- 1. Identifying national priorities for research.
- 2. Creating a research agenda based on identified priorities.
- 3. Funding research consistent with these priorities and agenda.
- 4. Providing patients and their caregivers with useful research information.



PCORI invites you to help. PCORI is looking for comments about its first set of research priorities and agenda from patients, caregivers, professionals, and the general public. This document includes information about PCORI and ways you can help.

PCORI's Proposed National Priorities for Research

PCORI has prioritized five research areas. These focus on information that patients and caregivers need in order to make important healthcare decisions. PCORI strives to meet the needs of all patients.

PCORI's proposed national priorities for patient-centered comparative clinical effectiveness research are:

- Assessment of Prevention, Diagnosis, and Treatment Options. The research goal is to determine which option(s) work best for distinct populations with specific health problems.
- Improving Healthcare Systems. Focuses on ways to improve healthcare services, such as the coordination of care for patients with multiple chronic conditions.
- **Communication and Dissemination.** Looks at ways to provide information to patients so that they, in turn, can make informed healthcare decisions with clinicians.
- Addressing Disparities. Assures that research addresses the healthcare needs of all patient populations. This is needed as treatments may not work equally well for everyone.
- Accelerating Patient-Centered and Methodological Research. Includes patients and caregivers in the design of research that is quick, safe, and efficient.

PCORI's Proposed Research Agenda

This is the first version of PCORI's Research Agenda. PCORI expects to learn and update this as we move forward. We are not specifying or prioritizing any particular condition or disease for research, although we may do so in the future. Consistent with the criteria outlined in the Patient Protection and Affordable Care Act (also known as "health care reform"), PCORI's first research agenda looks at:

- Assessment of Prevention, Diagnosis, and Treatment Options. Research should focus on 1) clinical options with emphasis on patient preferences and decision-making, 2) biological, clinical, social, economic, and geographic factors that may affect patient outcomes.
- Improving Healthcare Systems. Research should focus on 1) ways to improve access to care, receipt of care, coordination of care, self-care, and decision-making, 2) use of non-physician healthcare providers, such as nurses and physician assistants, and the impact on patient outcomes, 3) system-level changes affecting all populations, diseases, and health conditions.
- Communication and Dissemination. Research should focus on 1) strategies to improve patient and clinician knowledge about prevention, diagnosis and treatment options, 2) methods to increase patient participation in care and decision-making and the impact on health outcomes, 3) communication tools that enhance decision-making and achieve desired outcomes, 4) ways to use electronic data ("e-health records") to support decision-making, 5) best practices for sharing research results.
- Addressing Disparities. Research should focus on 1) ways to reduce disparities in health outcomes, 2) benefits and risks of healthcare options across populations, 3) strategies to address healthcare barriers that can affect patient preferences and outcomes.

Accelerating Patient-Centered and Methodological Research. Research should focus on 1) ways to improve the quality and usefulness of clinical data in follow-up studies, 2) methods to combine and analyze clinical data that follow patients over time, 3) use of registries and clinical data networks to support research about patient-centered outcomes, including rare diseases, 4) strategies to train researchers and enable patients and caregivers to participate in patient-centered outcomes research.

Public Comment: How You Can Help

PCORI encourages bold thinking about research projects. This means that PCORI is looking to you—patients, caregivers, professionals, and the general public—for help in shaping its national priorities and research agenda. Here are ways you can help:

- Provide comment through the online survey. You can do so from January 23-March 15, 2012, at the PCORI website, http://www.pcori.org/provide-input
- Attend the National Patient and Stakeholder Dialogue. This will be held February 27, in Washington, D.C. A webcast and teleconference will be provided, if you cannot attend in person. Learn more and register at the PCORI website, <u>http://www.pcori.org/meetingsevents/event/pcori-national-patient-and-stakeholder-dialogue/</u>
- Learn more. You can find more information at the PCORI website, <u>www.pcori.org</u>

Thank you for your interest in PCORI. Together, we offer patients and caregivers the information they need to make important healthcare decisions. Questions about the Proposed National Priorities for Research and Research Agenda may be directed to PCORI by email at info@pcori.org.

Draft National Priorities for Research and Research Agenda

I. Statutory Requirements and Draft Development Process Overview

As described in the Patient Protection and Affordable Care Act (the Act), one of the Patient-Centered Outcomes Research Institute's (PCORI's) first responsibilities is to establish and publish for comment National Priorities for Research and a Research Agenda. The priorities and agenda are intended to lay the foundation for a portfolio of comparative clinical effectiveness research that addresses PCORI's statutory purpose:

"to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations."

The Act does not specify either the content or form of the Priorities or Agenda. Previous priority-setting and research agenda-setting efforts have varied greatly in form and degree of specificity in their final recommendations, depending on their intended uses. The Act does, however, point out a set of criteria (the "PCORI Criteria") to be considered in formulating the Priorities and Agenda:

"...identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act that are consistent with this section."

Over the past five months, workgroups of PCORI's board formed to address both the National Priorities for Research and the Research Agenda. Along with PCORI staff and members of the Methodology Committee, these workgroups:

- examined the processes and products of other, recent priority- and agenda-setting efforts;
- reviewed the PCORI criteria specified above; worked to ensure that the working definition of "patient-centered outcomes research" (PCOR) and its core premise of keeping the patient's voice central are implemented in PCORI-funded research;
- presented the status of deliberations and requested feedback at PCORI's public board meetings; and
- engaged, updated and received input from stakeholder groups through a number of public presentations and other modes of communication.

II. PCORI's Draft National Priorities for Research

The development of PCORI's first set of National Priorities for Research was led by the National Priorities Workgroup, a subgroup of the PCORI Board of Governors' Program Development Committee. The workgroup received input from the committee, the PCORI Board of Governors, PCORI's Methodology Committee, and stakeholders.

A Strong Foundation of Research Prioritization

To develop the initial National Priorities for Research, PCORI reviewed nine previous national efforts to prioritize comparative effectiveness research and related healthcare activities. Five of the efforts were by non-governmental organizations: the Institute of Medicine (twice); National Pharmaceutical Council; National Priorities Partnership; and the National Quality Forum. Four were by federal agencies or councils: Agency for Healthcare Research and Quality; Federal Coordinating Council for Comparative Effectiveness Research; National Prevention, Health Promotion and Public Health Council; and U.S. Department of Health and Human Services. PCORI examined the degree to which each of these efforts had involved significant stakeholder engagement and public input. Table 1 lists these efforts and their method of receiving public input.

Table 1: Comparative Effectiveness Research Prioritiz	ation Efforts
Priority Setting Organization	Method of Receiving Public Input
Institute of Medicine: Priority Areas for National Action: Transforming Health Care Quality (2003)	No formal public comment period
Agency for Healthcare Research and Quality (AHRQ): What is the Effective Health Care Program? and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003	 In-person and webinar town hall meetings Docket for comment submission Patient/Consumer/Clinician Involvement
National Quality Forum: National Priorities for Healthcare Quality Measurement and Reporting (2004)	Patient/Consumer Involvement
National Priorities Partnership: National Priorities and Goals: Aligning Our Efforts to Transform America's Healthcare (2008)	Input from 50 stakeholder organizations
Institute of Medicine: Initial National Priorities for Comparative Effectiveness Research (2009)	 In-person Stakeholder Meeting Web-based questionnaire
Federal Coordinating Council for Comparative Effectiveness Research: Report to the President and the Congress on Comparative Effectiveness Research (2009)	 3 Listening Sessions 92 Panelists Testified >300 entities commented
U.S. Department of Health and Human Services (HHS): National Strategy for Quality Improvement in Health Care (2011)	>300 entities commented
National Prevention, Health Promotion and Public Health Council: National Prevention and Health Promotion Strategy (2011)	 Engagement Sessions National Webinars Sector Outreach Email/Web Letters from organizations
National Pharmaceutical Council: Lessons from Prior Efforts and Opportunities for Prioritization of Comparative Effectiveness Research (2011)	▶ No formal public comment period

In reviewing these nine priority setting processes, PCORI noted that seven of the nine included significant public input. These seven processes were reviewed further to determine their key priorities and criteria for prioritizing health research. Ten priorities were identified (See Table 2). The first five priority areas (prevention, acute care, care coordination, chronic disease care, and palliative care) encompass the complete health cycle from staying healthy to treating conditions to reducing pain and suffering. The second five (patient engagement, safety, overuse, information technology (IT) infrastructure, and the impact of new technology) include issues that are systemic in nature to healthcare. All but one of the 10 priorities (impact of new technology) appear in at least three of the seven processes. Prevention appears in all seven and patient engagement in six.



PCORI's Proposed National Priorities for Research

PCORI analyzed the 10 priority areas from previous prioritization processes in light of PCORI's working definition of "patient-centered outcomes research" (PCOR) which approaches research questions as information needs, without regard to where a patient is in the disease continuum, from healthy, to symptomatic, to facing a chronic condition. (The working definition of PCOR is provided on the PCORI website: www.pcori.org/patient-centered-outcomes-research/.) This prioritization process identified five cross-cutting areas where additional health research is needed to give patients and those who care for them more information to support decision making.

PCORI's national priorities can be applied to and used to advance the quality of information for any health condition or disease where evidence is lacking or current decision-making is suboptimal. PCORI, at this early stage of its work and of patient-centered outcomes research as a discipline, does not want to focus on a narrower set of questions or healthcare conditions, nor does it want to exclude any diseases or conditions.

These five comparative clinical effectiveness research priorities were developed in in light of PCORI's statutory requirements, PCORI's working definition of "patient-centered outcomes research," and the previous research prioritization efforts. They are:

- 1. Assessment of Prevention, Diagnosis, and Treatment Options Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.
- Improving Healthcare Systems Comparing health system-level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.
- Communication and Dissemination Research Comparing approaches to providing comparative effectiveness research information and supporting shared decision-making between patients and their providers.
- 4. Addressing Disparities Identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.
- 5. Accelerating Patient-Centered Outcomes Research and Methodological Research Improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients and other stakeholders to participate in this research.

These five broad areas comprise PCORI's first proposed national priorities for research and encompass the patient-centered comparative clinical effectiveness research PCORI will support. As PCORI's work progresses, and particularly as PCORI continues to engage, in a transparent manner, with the broad range of stakeholders in healthcare, and particularly with patients, it is possible that PCORI may develop additional national priorities for research as needs evolve.

III. PCORI's Draft Research Agenda

This draft Research Agenda, version 1, was developed by a second working group of the Program Development Committee, in collaboration with the Methodology Committee and PCORI staff. The process began by considering the five areas proposed as National Priorities for Research in the first part of this document. To these priorities, PCORI applied the criteria provided in the Act. The resulting Research Agenda contains a set of more specific research areas within each priority. Each area represents a line of research inquiry that addresses currently unmet needs of patients, their caregivers, clinicians and other healthcare system stakeholders in making personalized healthcare decisions across a wide range of conditions and treatments.

Establishing the Scope of the Research Agenda

This document is intended to address the statutory requirement that PCORI publish an agenda to describe and guide the research it will fund. By design, it does not cover all the activities that PCORI sees as part of its mission. For instance, it does not describe how PCORI intends to invest in efforts to maintain active engagement with patients and all other stakeholder groups over time. It does not describe how PCORI, in partnership with the Agency for Healthcare Research and Quality (AHRQ) and the U.S. Department of Health and Human Services (HHS), will invest in efforts to disseminate research findings or build capacity for patient-centered outcomes research through training programs or infrastructure development. This document is the foundation upon which the first set of PCORI funding announcements will be developed. Taken together, the series of funding announcements that PCORI will produce, beginning in mid-2012, will create a portfolio of research that builds from this agenda and is consistent with Congress' intended purpose.

PCORI intends to be a learning organization; it will continue to evolve as it gains experience. This initial Research Agenda, when finalized after public comment, presents a broad sweep of current research possibilities, encouraging the community to think boldly about specific opportunities and to describe how a proposed project or initiative aligns with PCORI's criteria. With time, PCORI expects its Research Agenda to be updated and refined based upon more specific analyses of where current gaps exist and where patient-centered outcomes research can have the most impact. Each update will be achieved through a "due diligence" process that includes dialogue with a broad range of stakeholders, input through a formal public comment process and additional forums, including focus groups, PCORI presentations to various audiences, outreach through PCORI's website and other vehicles, advisory panels and stakeholder meetings. Additionally, PCORI is examining its initial round of funded grants (the PCORI Pilot Projects Grants Program) to gauge community interests and needs and to determine and apply lessons learned from those funding opportunities.

Level of Specificity of the Research Agenda

By intent, this draft Research Agenda does not specify a restricted set of conditions or treatments that PCORI will study. Although some previous prioritization efforts have focused on specific high-prevalence or high-cost conditions, PCORI's priorities and agenda do not place such limits on the scope of research that will be supported. The criteria specified in the legislation, when considered together, do not point strongly to such conditions, but suggest that a more diverse research portfolio that considers a range of conditions, interventions, and research methods, may be more appropriate.

Rather than focusing on specific conditions or treatments, PCORI's initial approach specifies a set of questions and topics that we believe are most in need of attention – across a range of conditions and treatments. Within any topical area, studies may focus on specific diseases, conditions and interventions, or they may be cross-cutting, including broader study populations or examining interventions or other questions that apply across multiple diseases and conditions. This approach recognizes the likelihood that as PCORI begins its funding program, researchers partnered with stakeholders are well-positioned to present a range of compelling questions. Ultimately, decisions about funding will depend on the quality of applications – with special attention to the likelihood that the research may lead to improvement in patient outcomes, as determined by alignment with PCORI criteria.

Over time, we anticipate that PCORI will develop a research portfolio that includes both broad calls for proposals as well as contracts or grants targeted to high-priority conditions or treatments identified from public input, dialogue with stakeholders, and public needs. Targeted opportunities may focus on specific conditions or diseases, treatment modalities, outcomes or on themes that are cross-cutting. PCORI will work diligently to avoid redundancy and coordinate with other research entities that fund patient-centered outcomes research (PCOR) or comparative effectiveness research (CER), including the National Institutes of Health (NIH), AHRQ, private foundations and the pharmaceutical, life sciences and healthcare industries. PCORI will seek opportunities for collaboration with these entities. Additionally, the portfolio of research supported by PCORI will be balanced based upon the characteristics of study populations such as age, gender, race/ethnicity, socio-economic status, and disease or conditions. PCORI has a commitment to include studies of patients with rare conditions as well

as those with more common illnesses. Especially needed are studies to improve care and outcomes for patients faced with multiple conditions. All funded studies will have a strong orientation to the patient perspective and all will have patients involved in the development of the research, its governance and oversight, and its dissemination strategy.

Similarly, the Research Agenda does not specify preferred study designs or analytic approaches. Instead, it recognizes that various PCOR questions might be investigated by a variety of scientifically-valid methods and approaches. In accordance with Act (Section "(C) FUNCTIONS"), research focused on developing new methods and/or improving the science and methods of patient-centered outcomes research (PCOR) is specifically included in the Agenda. PCORI's Methodology Committee is currently developing standards for the design and conduct of different types of PCOR. These standards will be disseminated and used in the evaluation of PCORI applications. Again, the Agenda does not preclude subsequent funding announcements that would specify a preferred or required methodological design for a specific research question.

Research Agenda Process

The development of the Research Agenda was facilitated by the Research Agenda Workgroup, a subgroup of the PCORI Board of Governors' Program Development Committee. The Research Agenda Workgroup also solicited and gathered input from the committee, Board of Governors, and PCORI's Methodology Committee. Following identification of the five PCORI National Priorities, the workgroup developed a framework for the translation of these Priorities into the Research Agenda, taking fully into account the statutory language in the Act regarding both the National Priorities and the Research Agenda. (See Figure 1). The process benefited from public comment about the definition and on-going dialogue about PCORI and patient-centered outcomes research.



Each of the five National Priorities was considered in light of the set of criteria specified in the Act, shown in the above framework, to create the Research Agenda. (See Table 3) The resulting Research Agenda consists of a set of more specific statements of research interest within each of the five priority areas.

- Each Research Agenda statement maps to one or more of the Criteria.
- PCORI will develop funding announcements from these agenda statements.

The Act specified a set of criteria that must be considered in creating a research agenda. The Agenda is based on these criteria. PCORI will emphasize these criteria in funding announcements, in the review of applications, and in funding decisions. These criteria are described in the table below.

Table 3: PCORI Criteria		
PCORI Criteria	Statuatory Language	Questions
Impact on Health of Individuals and Populations	disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions)	How many people are impacted by this priority area? How severe are the consequences, in terms of mortality, symptoms, adverse effects of treatment, patient experience and loss of function?
Probability of Improvability via Research	the potential for new evidence to improve patient health, well-being, and the quality of care	How likely is additional information in this priority area to make important improvements in patients' health status, the quality of their care, or the public's health?
Inclusiveness of Different Populations	Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate.	Would new information in this priority area be particularly likely to increase understanding of differences in best treatments, prevention strategies, or a personalized assessment of an individual's unique biological characteristics and/or social circumstances?
Current Gaps in Knowledge/Variation in Care	gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care	Does medical care in this area currently show wide variations in practice or clinical outcomes, suggesting a lack of clear evidence on effectiveness or a lack of awareness about this evidence?
Impact on Health System Performance	the effect on national expenditures associated with a health care treatment, strategy, or health conditions	Will more information in this priority area help [health care systems support] improve health care treatment or get better health outcomes for the money invested?
Potential to Influence Decision-Making	the relevance to patients and clinicians in making informed health decisions	Will more information in this priority area be particularly likely to help patients and clinicians address decisions that are currently difficult to make?
Patient-Centeredness	patient needs, outcomes, and preferences	Have patients or other key stakeholders explicitly identified a need for more research or is there a lack of resources in this priority area?
Rigorous Research Methods	The Institute shall make available to the public and disclose the process and methods for the conduct of research including research protocols, including measures taken, methods of research and analysis, research results and such other information	Does proposed research or study in this priority area use or develop optimal methodologic and analytic approaches to addressing patient-centered evidence?
Efficient Use of Research Resources	taking into consideration the types of research and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research)	Will the proposed study use PCORI resources efficiently? Might it create common data or infrastructure that could support future research?

PCORI's Proposed Research Agenda

1. Assessment of Prevention, Diagnosis, and Treatment Options

Patients, caregivers and clinicians often lack the appropriate evidence on which to make the best choices regarding prevention, screening, diagnosis, monitoring, or treatment. This may be because strategies with new therapies or technologies have been approved and marketed with inadequate comparison with other approaches; because alternative longstanding approaches have not been rigorously and appropriately compared; because outcomes important to patients have not been evaluated; because existing studies have not assessed benefits and risks of treatment over an extended time period; or because previous research has not adequately attended to potential differences in effect among or within different patient groups, or research has not been relevant to the subgroups, settings and conditions (e.g. comorbidity) to which results are applied. In other situations, many studies have been conducted, but their results have not been considered and synthesized as a cohesive body of evidence or analyzed in a way that allows for comparison. Clinical effectiveness compares the effectiveness and safety of preventive, diagnostic, and treatment options to create a foundation of information for personalized decision-making. This research places emphasis on the practical utility of the comparisons, the examination of all outcomes that may be important to patients and the possible differences in outcomes across patient subgroups.

PCORI is interested in the following topics:

A. Studies that compare situations in which the effectiveness of strategies for prevention, treatment, screening, diagnosis, or surveillance have not been adequately studied against alternative options and better evidence is needed to support decision-making by patients, caregivers, and healthcare professionals. Special emphasis is placed on studies conducted in typical clinical populations considering the full range of relevant patient-centered outcomes and possibilities that results may differ among patient groups based on patient characteristics (understood broadly as possibly including clinical, psychosocial, demographic, and other domains) or preferences. PCORI recognizes that a variety of study designs and approaches may contribute valid new knowledge about the comparative clinical effectiveness of specific strategies. There is a particular interest in comparisons for which new knowledge could address individual differences in patient values and preferences and support shared-decision making. (Criteria addressed: Current Gaps in Knowledge/Variations in Care, Potential to Influence Decision-Making, Inclusiveness of Different Populations, Patient-Centeredness)

B. Studies that compare the use of prognostication/risk-stratification tools with usual clinical approaches to treatment selection, as well as studies that investigate the key determinants of treatment outcomes, with attention to various patient factors, including demographic, biological, clinical, social, economic, and geographic factors that may influence the outcomes that patients experience. The purpose of this research should be to inform and improve decisions that patients, their caregivers, and healthcare professionals face and to improve clinical outcomes. (Criteria addressed: Potential to Influence Decision-Making, Inclusiveness of Different Populations, Improved Health System Performance)

2. Improving Healthcare Systems

Healthcare systems at all levels lack evidence on the most effective strategies to support patients in obtaining the outcomes they desire. New system-level strategies are developed and implemented that have not been rigorously evaluated or tested and are not yet ready for fullscale implementation. Comparative studies of healthcare system-level interventions, including disease management, telemonitoring, telemedicine, care management, integrative health practices, care coordination, performance measurement, and quality improvement, use of incentives, protocols of treatment, clinical decision and self-management support and others are lacking.

- A. Research that compares alternative system-level approaches to supporting and improving patient access to care, receipt of appropriate care, coordination of care across healthcare services or settings for patients with complex chronic conditions, and personal decision-making and self-care. The examination of the comparative effectiveness of changes in communication and documentation with the implementation of electronic health records (EHRs) would also be appropriate. The emphasis is on comparing approaches for their effect on patients and, when relevant, their caregivers, in ways that they experience and think are important. (Criteria addressed: Improve Healthcare System Performance, Inclusiveness of Different Populations, Gaps in Knowledge/Variations in Care, Potential to Influence Decision-Making)
- B. Research that compares the effectiveness on patient outcomes of a wide range of system-level strategies to incorporate new and extended roles for allied health professionals (e.g., pharmacists, nurses, physician assistants, dentists, patient

navigators, volunteers, etc.) into the healthcare team. (Criteria addressed: Improve Healthcare System Performance)

C. Research that specifically seeks to compare patient outcomes across various populations in response to system-level interventions aimed at improving healthcare and outcomes for patient populations. (Criteria addressed: Improve Healthcare System Performance, Inclusiveness of Different Populations)

3. Communication and Dissemination Research

Knowledge about how to optimally communicate and facilitate the effective use of PCOR evidence by patients, caregivers, and healthcare professionals needs to be strengthened. There is a considerable barrier to the rapid transfer of evidence that could be useful in decisionmaking. For decisions to be informed, strategies are often needed to make existing PCOR knowledge available to patients and providers, and to make the application of this knowledge feasible in clinical settings. Research is needed that compares new and alternative approaches to facilitating uptake of information by patients, caregivers, communities, and healthcare providers in timely ways, by providing understandable language, and in a variety of settings to improve personalized and shared decision-making.

- A. Research that compares alternative communication, dissemination, and implementation strategies that aim to improve shared decision-making by increasing clinician and/or patient awareness of healthcare options and use of comparative effectiveness research results at the point of decision-making. (Criteria addressed: Potential to Influence Decision-Making, Current Gaps in Knowledge/Variation in Care)
- B. Research that compares the effectiveness, across a range of patient-centered outcomes, of alternative approaches to increase or encourage effective patient participation in care decisions and in shared-decision making. (Criteria addressed: Potential to Influence Decision-Making, Current Gaps in Knowledge/Variation in Care)
- C. Studies to develop and compare alternative methods and tools to include patientdesired outcomes in the healthcare decision-making process. (Criteria addressed: Potential to Influence Decision-Making, Patient-Centeredness, Address Current Gaps in Knowledge/Variations in Care)

D. Research that compares innovative approaches in the use of existing electronic clinical data and other electronic modalities from the healthcare system or from a network of systems to enhance clinical decision-making by patients and providers. (Criteria addressed: Improve Healthcare System Performance, Potential to Influence Decision-Making)

4. Addressing Disparities

Disparities in health status and healthcare persist in this country, based on race/ethnicity, gender, geographic location, socio-economic status, and other factors. These disparities contribute to poor quality of care and poor overall health outcomes for specific populations. Solutions that can reduce persisting disparities have been elusive and are likely to be complex. Novel, patient-centered approaches to understanding and reducing disparities in health and in healthcare quality are needed.

- A. Research that compares interventions to reduce or eliminate disparities in health outcomes, for example by accounting for possible differences in patient preferences or differences in response to therapy across socio-economic, demographic, and other patient characteristics. (Criteria addressed: Impact on Health of Individuals and Populations, Inclusiveness of Different Populations)
- B. Research that compares benefits and risks of treatment, diagnostic, prevention, or service options across different patient populations, with attention to eliminating disparities that are not a result of patient preference. (Criteria addressed: Impact on Health of Individuals and Populations, Inclusiveness of Different Populations)
- C. Research that compares strategies to overcome barriers (e.g. language, culture, transportation, homelessness, unemployment, lack of family/caregiver support, etc.) that may adversely affect patients and is relevant to their choices for preventive, diagnostic, and treatment strategies or their outcomes. (Criteria addressed: Impact on Health of Individuals and Populations, Inclusiveness of Different Populations)
- D. Research that compares and identifies best practices within various patient populations for information sharing about treatment outcomes and patient-centered research. (Criteria addressed: Inclusiveness of Different Patient Populations)

5. Accelerating PCOR and Methodological Research

The nation's capacity to conduct patient-centered CER quickly and efficiently remains extremely limited. Research that promotes a more comprehensive, complete, longitudinal data infrastructure; broader participation of patients, clinicians, health systems, and payers; and further improvements in analytic methods for both observational and experimental CER are needed. Methodological research to understand optimal approaches for identifying and addressing PCOR questions and better approaches to effectively engaging patients and other stakeholders are necessary. Future investments will not only cover the topic areas outlined below, but will also contain a component of expanding the PCOR workforce, building research networks, and accelerating infrastructure.

- A. Research that identifies optimal methods for engaging patients, those at risk, and other stakeholders in PCOR, particularly those who have been historically hard-to-reach. This also includes research that determines methods for assuring study questions, outcomes, and interventions are meaningful to patients and other stakeholders. (Criteria addressed: Rigorous Research Methods, Impact on Individuals and Populations, Inclusiveness of Different Populations, Potential to Influence Decision-Making)
- B. Research that aims to improve the validity and/or efficiency of analytic methods for comparative effectiveness research or of outcomes commonly used in PCOR. (Criteria addressed: Rigorous Research Methods, Impact on Health of Individuals and Populations, Impact on Healthcare System Performance)
- C. Research that determines the validity and efficiency of data sources commonly used in PCOR. For example, research that seeks to improve the volume, completeness, comprehensiveness, accuracy, and efficiency of use of clinical data collected across healthcare systems, clinical data networks, registries, or payer databases and the utility of this data for conducting longitudinal studies of patient outcomes; research that explores the potential of large clinical data networks to support PCOR; or research that develops and promotes the utility, performance, and efficiency of large clinical data networks or registries for supporting patient-centered outcomes research for patients with rare diseases. (Criteria addressed: Efficient Use of Research Resources, Impact on Healthcare System Performance, Impact on Health of Individuals and Populations)

- D. Research into methods to enhance the reproducibility, transparency, and replication of PCOR research. (Criteria addressed: Rigorous Research Methods, Current Gaps in Knowledge)
- E. Research that improves and possibly compares strategies for training researchers, patients and other stakeholders in the methods of patient-centered outcomes research.
 (Criteria addressed: Inclusiveness of Different Populations, Potential to Influence Decision-Making, Efficient Use of Research Resources)
- F. Research to support the routine collection of key patient-reported and patient-centered outcomes in systematic ways (Criteria addressed: Rigorous Research Methods, Potential to Influence Decision-Making)

Funding Model

PCORI will seek to fulfill the Research Agenda through a combination of grants and targeted contracts and will remain flexible and responsive to emerging challenges and community-generated questions that fall within priority areas and meet our selection criteria. PCORI's initial proposal is for funds to be allocated as identified below, recognizing that there will be overlap between categories. PCORI will reassess the distribution in response to the quality of submissions. These allocations are guideposts rather than firm funding levels and the allocations will evolve in time with the Research Agenda and with community needs.

Priority	% Funding Allocation
Assessment of Prevention, Diagnosis, and Treatment Options	► Approximately 40%
Improving Healthcare Systems	► Approximately 20%
Communication and Dissemination Research	• Approximately 10%
Addressing Disparities	• Approximately 10%
Accelerating PCOR and Methodological Research	► Approximately 20%

IV. Appendix

Features of the PCORI Research Agenda

As PCORI seeks to develop its Research Agenda, we have identified several features that will be associated with PCORI research and will be emphasized in our activities. PCORI will:

- I. Promote patients and their caregivers –and key stakeholders in implementation settings—as partners, with explicit roles in the design, governance, review, and dissemination of research.
- II. Seek to understand core questions from the expressed perspective of the patient and their caregivers.
- III. Emphasize methods and structures that produce knowledge efficiently, seeking to make best use of our resources.
- IV. Focus on outcomes that are important to patients and their caregivers and likely to be useful in making healthcare related decisions.
- V. Emphasize open and transparent science that involves participants in decisions about making data available for further study, seeking to ensure that the research produces as much new investigative activity as possible and that sharing of information and knowledge among diverse investigators is required.
- VI. Commit to a diverse research portfolio with respect to patients, geography, healthcare professionals, investigators, and organizations, seeking to catalyze activity across a broad range of patients, sites, conditions, and questions.
- VII. Emphasize knowledge that is likely to make a positive difference in the lives of patients and their caregivers and is suitable for dissemination and application; and emphasize outcomes that are important to patients and their caregivers and likely to be useful in their decision-making.
- VIII. Fund efforts that produce practical tools, aids, and skills that will assist patients, their caregivers, and their healthcare professionals.
 - IX. Emphasize ideas that emerge from the community of patients, caregivers, clinicians and researchers, seeking to listen and learn from the wisdom of those whose lives are most affected by these conditions and those who are committed to generating new knowledge that will promote better decisions and outcomes.
 - X. Measure eventual success by the impact on patient outcomes.
 - XI. Require outstanding science, compelling relevance to decisions, and meaningful results to patients, but encourage a variety of methodological approaches.
- XII. Emphasize rapid cycle, efficient, innovative research and dissemination.

TABLE 4: STAGE 2 MEANINGFUL USE OBJECTIVES AND ASSOCIATED MEASURES SORTED BY CORE AND MENU SET

Health	Stage 2 C	Dejectives	
Outcomes Policy Priority	Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures
		CORE SET	
Improving	Use computerized provider order entry	Use computerized provider order entry	More than 60 percent of medication,
quality, safety,	(CPOE) for medication, laboratory and	(CPOE) for medication, laboratory and	laboratory, and radiology orders created
efficiency, and	radiology orders directly entered by any	radiology orders directly entered by any	by the EP or authorized providers of the
reducing health	licensed healthcare professional who can enter	licensed healthcare professional who can enter	eligible hospital's or CAH's inpatient or
disparities	orders into the medical record per State, local	orders into the medical record per State, local	emergency department (POS 21 or 23)
	and professional guidelines to create the first	and professional guidelines to create the first	during the EHR reporting period are
	record of the order.	record of the order.	recorded using CPOE.
	Generate and transmit permissible		More than 65 percent of all permissible
	prescriptions electronically (eRx)		prescriptions written by the EP are
			compared to at least one drug formulary
			and transmitted electronically using
			Certified EHR Technology.
	Record the following demographics	Record the following demographics	More than 80 percent of all unique
	 Preferred language 	 Preferred language 	patients seen by the EP or admitted to the
	Gender	Gender	eligible hospital's or CAH's inpatient or
	• Race	• Race	emergency department (POS 21 or 23)
	Ethnicity	• Ethnicity	have demographics recorded as structured
	 Date of birth 	Date of birth	data
		 Date and preliminary cause of death 	
		in the event of mortality in the	
		eligible hospital or CAH	

Stage 2 Obj ssionals in vital signs: ngth essure (age 3 and	Calculate Plot and charts for pati including BN Becord emoking status for
	d display growth atients 0-20 years, MI MI
	More than 80% of all unique n

Health Outcomes Policy Priority	Stage 2 O Eligible Professionals Incorporate clinical lab-test results into	Dbjectives Elig Incorporate	tible Hospitals and CAHs clinical lab-test results into
	Incorporate clinical lab-test results into Certified EHR Technology as structured data	Incorporate clinical lab-test 1 Certified EHR Technology a	s structured data
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate lists of patients by conditions to use for quality reduction of disparities, res	y specific y improvement, earch, or outreach
	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care		
		Automatically track med administration using assi conjunction with an elec administration record (el	ications from order to stive technologies in tronic medication MAR)

																												their health care	and families in	Engage patients	Outcomes Policy Priority	Health	
each office visit	Provide clinical summaries for patients for																										information being available to the EP.	information within 4 business days of the	download, and transmit their health	Provide patients the ability to view online,	Eligible Professionals	Stage 2 (
													hospital admission	download, and transmit information about a	Provide patients the ability to view online,																Eligible Hospitals and CAHs	Objectives	
within 24 hours for more than 50 percent of office visits.	Clinical summaries provided to patients	during the reporting period	to a third party their information	or CAH view, download or transmit	(POS 21 or 23) of an eligible hospital	inpatient or emergency department	patients who are discharged from the	2. More than 10 percent of all	discharge	available online within 36 hours of	or CAH have their information	(POS 21 or 23) of an eligible hospital	inpatient or emergency department	patients who are discharged from the	1. More than 50 percent of all	their health information	download, or transmit to a third party	authorized representatives) view,	the EHR reporting period (or their	unique patients seen by the EP during	2. More than 10 percent of all	information	discretion to withhold certain	information subject to the EP's	to the EP) online access to their health	days after the information is available	provided timely (within 4 business	the EHR reporting period are	unique patients seen by the EP during	1. More than 50 percent of all	Stage 2 Measures	2	

CMS-0044-P		160	
Health	Stage 2 (Dbjectives	
Outcomes Policy Priority	Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures
	Use Certified EHR Technology to identify patient-specific education resources and	Use Certified EHR Technology to identify patient-specific education resources and	Patient-specific education resources identified by Certified EHR Technology
	provide those resources to the patient	provide those resources to the patient	are provided to patients for more than 10 percent of all office visits by the EP. More than 10 percent of all unique natients admitted to the eligible hospital's
			or CAH's inpatient or emergency
			patient- specific education resources
			Identified by Certified Erik Technology
	Use secure electronic messaging to communicate with patients on relevant health		A secure message was sent using the electronic messaging function of Certified
	information		EHR Technology by more than 10 percent
			of unique patients seen during the EHR reporting period
Improve care	The EP who receives a patient from another	The eligible hospital or CAH who receives a	The EP, eligible hospital or CAH performs
coordination	setting of care or provider of care or believes an encounter is relevant should perform	patient from another setting of care or provider of care or believes an encounter is relevant	medication reconciliation for more than 65 nercent of transitions of care in which the
	medication reconciliation.	should perform medication reconciliation	patient is transitioned into the care of the
			EP or admitted to the eligible hospital's or
			CAH's inpatient or emergency department
			(POS 21 or 23).

Health	Stage 2 O	Dbjectives	
Outcomes Policy Priority	Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures
	The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral. care or referral.	 The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.
Improve population and public health	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting nericod
		Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period as authorized.
		Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period

Health	Stage 2 O	bjectives	
Outcomes Policy Priority	Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures
Ensure adequate privacy and security protections for	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data
personal health information			at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.
		Menu Set	
Improving quality, safety, efficiency, and reducing health disparities		Record whether a patient 65 years old or older has an advance directive	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.
	Imaging results and information are accessible through Certified EHR Technology.	Imaging results and information are accessible through Certified EHR Technology.	More than 40 percent of all scans and tests whose result is an image ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology
	Record patient family health history as structured data	Record patient family health history as structured data	More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first- degree relatives

CMS-0044-P		163	
Health	Stage 2 0	Dejectives	
Outcomes Policy Priority	Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures
		Generate and transmit permissible discharge prescriptions electronically (eRx)	More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology
Improve Population and Public Health	Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice		Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period
	Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period
	Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period



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Issue Brief

Identifying, Monitoring, and Assessing Promising Innovations: Using Evaluation to Support Rapid-Cycle Change

MARSHA GOLD, DAVID HELMS, AND STUART GUTERMAN

ABSTRACT: The Center for Medicare and Medicaid Innovation (Innovation Center) was created by the Affordable Care Act to identify, develop, assess, support, and spread new approaches to health care financing and delivery that can help improve quality and lower costs. Although the Innovation Center has been given unprecedented authority to take action, it is being asked to produce definitive results in an extremely short time frame. One particularly difficult task is developing methodological approaches that adhere to a condensed time frame, while maintaining the rigor required to support the extensive policy changes needed. The involvement and collaboration of the health services research community will be a key element in this endeavor. This issue brief reviews the mission of the Innovation Center and provides perspectives from the research community on critical issues and challenges.

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OVERVIEW

The Center for Medicare and Medicaid Innovation (Innovation Center), authorized in Section 3021 of the Affordable Care Act and located in the Center for Medicare and Medicaid Services (CMS), seeks to promote innovation in health care payment and delivery.¹ It has a legislated mandate:

to test innovative payment and service delivery models to reduce program expenditures...while preserving or enhancing the quality of care furnished to individuals...(under Medicare, Medicaid, and the Children's Health Insurance Program). In selecting such models, the Secretary shall give preference to models that also improve coordination, quality, and efficiency of health care services furnished...

The Secretary shall select models to be tested...where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor

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Commonwealth Fund pub. 1512 Vol. 12 clinical outcomes or potentially avoidable expenditures.²

To support the Innovation Center's goals, the legislation provides \$10 billion in funding from 2011 to 2019 and enhanced authority to waive budget neutrality for testing new initiatives.³ The intent is to allow quicker and more effective identification and spread of desirable innovations, with the goal of ultimately modifying Medicare, Medicaid, and the Children's Health Insurance Program in ways that support program-wide change.

Though the strategic focus for the Innovation Center is still under development, there have been clear signals that its focus will be broad, with an emphasis on transformative change to address the "triple aim" of improving the quality of care, reducing cost growth, and enhancing population health.^{4,5}

Achieving this will be challenging and the time frame demanding in the face of historical experience in which years elapse between the origination of an idea and the process of designing, implementing, and evaluating.

This issue brief focuses on three critical requirements the Innovation Center must address to meet its objectives:

- 1. Focusing on change that matters;
- 2. Documenting innovation to support effective learning and spread;
- 3. Generating the evidence needed to support broad-based policy change.

Tensions between competing goals can be reduced by anticipating them and thoughtfully designing the way innovations are tested and evaluated in the Innovation Center. Different trade-offs may be appropriate for innovations at different stages or with different potential risks and rewards. Collaboration among researchers, innovators, and policymakers about how best to address different goals and potential tensions is needed to enhance the innovation center's overall prospects for success.

INTRODUCTION

The Center for Medicare and Medicaid Innovation (Innovation Center), as authorized by the Affordable Care Act and located in the Center for Medicare and Medicaid Services (CMS), seeks to promote innovation in health care payment and delivery. To support the Innovation Center's goals, the legislation provides \$10 billion in funding from 2011 to 2019 and enhanced authority to waive budget neutrality for testing new initiatives. The intent is to allow quicker and more effective identification and spread of desirable innovations, with the goal of ultimately modifying Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) in ways that support program-wide change.

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FOCUSING ON CHANGE THAT MATTERS

The Affordable Care Act provides \$10 billion in funding to support the Innovation Center's goals. This is a substantial amount, but it is less than 0.1 percent of projected federal Medicare and Medicaid spending through the end of this decade and a much smaller proportion of the projected \$32 trillion in total health spending over the same period.⁶ This small percentage stands in contrast with the much higher proportion of industry revenues devoted to research and development in the pharmaceutical industry and in other industries in which innovation is a central focus, like technology and communications.⁷ Neither this level of funding nor available staff is likely to be sufficient to invest in all the innovations that might be considered, so priorities must be set. Priority setting is a policy rather than a research decision, but research can help lead to better decision-making. Input from the research community is therefore an important element from the beginning of the innovation process.

To achieve its statutory goals, the Innovation Center must identify as priorities those innovations that have the potential to achieve demonstrably large positive impact on quality and costs, as measured by a combination of improved outcomes and reduced costs. Innovations can be successful either by generating large gains over a relatively small population or smaller gains over a large one. The relative merits of the gains that may be achieved by different strategies vary and may depend on their administrative costs and whether they are fixed or vary with the size of the population. In any case, the research community can contribute to the determination of the potential net gains from alternative pilots, as well as to the development of measures that can be used to monitor and assess the performance of those pilots.

DOCUMENTING AND LEARNING FROM INNOVATION

The Innovation Center's success depends not just on developing and implementing innovations but on the ability to monitor and evaluate innovations to provide evidence of their success and information to encourage widespread adoption. This is unlikely to occur without clear articulation of the essential logic of an innovation, how it is intended to operate, and—perhaps most important—the results it is expected to produce and how success can be recognized. It is important to document the context in which an innovation was tested and assess how important that is to its success or applicability elsewhere so that those who may be considering it have an explicit understanding of the potential gains and associated costs they may experience.

Careful Planning and Clear Definition of Success

An innovation's goals must be expressed in concrete, measureable terms that are linked to a time frame that provides a basis for monitoring performance and determining success. Essential elements of success include an explicit understanding of the activities needed to generate the anticipated outcomes; how the activities are logically connected to outcomes; the environment and context; and any potential obstacles and how they will be addressed.

Unless innovations are well defined and their connections to desired outcomes are well understood from the start, it will be difficult to achieve success. Even if positive outcomes are achieved, it will be difficult to assess the relevance of those results to other settings and to replicate them throughout the health system. Unfortunately, such clarity is often lacking or limited, with critical design elements and site-specific characteristics unstated, key details driving success or failure potentially omitted or unrecognized, and the likelihood of success low because interventions are insufficient in scope or scale to achieve their intended effects.⁸ These limitations frequently can be traced to the lack of necessary data systems and measures and the need for methods that can produce more flexible and timely, accurate analysis.

Tracking Implementation and Performance

Innovations rarely remain fixed over time. Key features are likely to be modified as experience grows or problems emerge. Time frames may depart from those anticipated. Objective short-term indicators of implementation success provide a basis to judge whether midcourse refinements may be valuable. Documenting what actually was implemented versus what was initially sought is critical for interpreting the lessons from testing and providing the basis for future spread. Case studies of implementation experience also can be invaluable to others that may seek to replicate or build upon what was learned from a given experience.

Supporting Timely Measurement

The success of rapid-cycle change depends on measurement—capturing and feeding back timely data on change after the launch of an innovation that allows fine tuning of the project, early insights on additional questions for analysis, and ongoing communication and the potential to learn from failure and success. Prior demonstrations highlight the challenges in securing timely data. For example, in the Medicare Physician Group Practice demonstration, financial results were not available for almost a year after the initial performance year; data to inform quality bonuses took even longer (Exhibit 1).⁹

Making use of data generated naturally in the course of administering an innovation on a real-time basis can lessen delays. For example, sites often will have real-time information on use of services and hospital admissions, registries that may document who was eligible for an innovation or served by it, and data on patient feedback. Sponsors of Vermont's all-payer medical home demonstration say their ability to leverage existing administrative processes to capture data was critical to reducing providers' costs of participation and enhancing the timeliness of information feedback.¹⁰ Effective use of such data is likely to require advanced planning. In a different effort, evaluators provided sites with a workbook tool for generating measures, including definitions of numerators, denominators, and the included population.¹¹ An alternate strategy that can enhance data quality and consistency is to work with payers and providers to aggregate data they receive in a centralized fashion and feed it back to providers in a consistent and timely way so that they can monitor and manage what they are learning from their efforts at innovation.

However data flow occurs, the process for data exchange and the format and content of reports should be decided up front and structured so data are useful for providers. Analyzing the data before implementation also can help with setting benchmarks and intermittent milestones.

Investing in Shared Metrics and Documentation

Developing the capacity to assess innovations also requires a concerted effort to develop metrics and documentation.¹² To facilitate this process, CMS should identify common variables that are needed across all sites testing specific kinds of innovations and standard metrics that will facilitate aggregation and comparison of performance across sites. This includes outcome metrics relevant to all innovations and critical data that identifies design elements included in particular innovations, the settings in which they are employed, and



other variables relevant to their success. Evaluations that include structured study of implementation typically address such concerns, but they have not historically included the kind of timely feedback that the Innovation Center likely will require.

Targeting Learning to Achieve Stakeholder Buy-In

If the lessons of an innovation speak to the interests of diverse users and stakeholders, widespread adoption is more likely. Successful replication of innovations will require addressing the concerns of critical participants. For example, providers will want to understand the operational demands of any innovation, how their revenue streams will be affected, and whether change will help or hinder them in achieving institutional goals. To complement the analysis of results, case studies from objective researchers can provide important insight into the key factors contributing to successes and challenges from the perspectives of multiple stakeholders.

Setting Realistic Expectations

Implementation almost always takes longer than expected, with modifications occurring along the way. The larger the scope of an innovation, the greater the complexity of the organization, and the more units or organizations involved, the more time is likely required for ramp-up. Personnel must be recruited or trained, approvals obtained, and participants defined and recruited. Delays may occur because of personnel change (e.g., loss of the champion or key source of leadership and support), competing organizational priorities that limit access to resources, or new issues that require design modifications. If Medicaid or CHIP is involved, state policymaker buy-in and approvals may be required and time may be lost reconciling different concerns that may exist in cross-state demonstrations.

Although careful planning prior to implementation is always required, pilots and demonstrations are not conducted in controlled environments and the implementation process must allow for adjustment to contingencies as they arise. This requires flexibility on the part of the entities and individuals directly involved in the innovation but also on the part of researchers responsible for evaluating initiatives and policymakers who will be acting on the results.

Emphasizing Clarity of Objectives and Timeliness of Implementation

Organizations are more likely to be able to implement innovations that are clear and simple. Successful innovation can be enhanced by avoiding unnecessarily complex elements or requirements and by limiting standardized features to those most essential to success and common analysis of cross-site activity. In any case, the objectives must be set in a way that all stakeholders understand and agree.

Timeliness in the implementation process is also important. Momentum can be critical to organizational success; once organizations are poised for action, delays can be very damaging to underlying stakeholder support. Delays can be minimized by streamlining processes between the announcement of an initiative and its implementation and by developing common procedures and approaches that work across a variety of innovations.

GENERATING THE EVIDENCE NEEDED TO SUPPORT BROAD-BASED POLICY CHANGE

The Affordable Care Act enhances the authority of the Secretary of Health and Human Services to modify payment and selected program policies for the pilots being conducted by the Innovation Center.¹³ However, the ultimate goal is to encourage better ways of financing and providing care throughout the health system, many of which are expected to require a shift away from the current fee-for-service payment methods under which providers are paid now, not only by Medicare and Medicaid, but also by other payers.¹⁴ While the Secretary has the authority to make changes in Medicare without going back to Congress, she must be convinced change is warranted by its demonstrated potential to improve quality and the CMS actuary must be willing to certify that, at a minimum, it will not add to program costs. Considering the level of concern about the federal budget, costs are likely to be a major focus and generating definitive evidence of the effects on program costs is likely to be a particular challenge.

One key question to consider is what standard of evidence is likely to be required to support such decision-making and how evaluations should be structured to generate it. This issue is critical to the design and conduct of effective evaluations, and it will be an important factor in the Innovation Center's ability to carry out its mission.

Historical Context

Historically, the effectiveness of an intervention has been assessed using relatively rigorous research methods that evaluate the actual (versus intended) effects of demonstrated program change on desired outcomes, such as the triple aims of better health, better care, and lower costs. This typically has involved independent evaluation by contracted researchers employing several basic elements, including:

- Careful definition of the target population and how it is to be assessed for purposes of judging success;
- One or more comparison populations or control groups to serve as a benchmark for indicating what might have happened in the absence of the change;
- Metrics defining the outcomes of interest and how they change over time, which often require new forms of data collection or unique data files

developed from existing claims or other program data; and

• Long time frames designed to distinguish immediate effects from more stable, longer-term effects. Five-year time frames have been common, though some initiatives have been assessed more rapidly.

The evaluation designs seek to distinguish true effects of an innovation from those that can be explained by other factors like secular trends, changes in patient mix, or other contextual change. In other words, they try to isolate the impact of the innovation compared with what would have been expected to occur in its absence.

The size of the target population and the control group is an important design factor. Large populations are helpful in developing statistically valid estimates of effectiveness and in distinguishing subpopulations most likely to benefit from the innovation. The involvement of large populations, however, typically adds to the cost of an evaluation.

Timeliness is another important factor. The design, development, implementation, and evaluation of an innovation can be a lengthy process. Exhibit 2 illustrates the time line for Medicare's Physician Group Practice demonstration, which was a model for the Medicare Shared Savings Program created in the Affordable Care Act. The more than 10-year time line is not dissimilar from the experiences of other demonstrations. The time line can be shortened by developing clear goals for new pilots and explicit criteria for participating and streamlining the decision-making process, and establishing standardized metrics for monitoring performance from data already available from claims and other sources. In addition, the methodology for identifying promising initiatives, monitoring performance, and evaluating results should be examined for its ability to meet the needs of a process intended to produce rapid change.

The Need for Timeliness and Rigor

The legislation establishing the Innovation Center seeks to accomplish rapid-cycle change in health care delivery. This will require the ability to shorten the time needed to identify, develop, and assess innovations with sufficient rigor to provide definitive evidence that they can improve the quality of care while reducing costs. Such expectations will require some modification in the process that traditionally has been used to develop demonstrations and new methodological approaches for assessing the performance of health care delivery systems and policies.

Planning and Coordination

The Innovation Center gives CMS great flexibility to test potential policy changes. Effective use of such authority will require streamlining the process for developing and implementing pilot projects. It is important not to cut corners and take shortcuts that would threaten the validity of the process and to lay out a clear and consistent approach that can be accomplished with a minimum of unnecessary delay.

Advanced planning is particularly important in this context. The establishment of clear and consistent goals for each initiative and a transparent and coordinated mechanism for approving potential pilots can not only reduce the time needed to assess effectiveness but also help ensure they will, in fact, be effective. A key factor is the ability to provide an infrastructure for supporting new initiatives, so that the data needed for CMS to monitor the performance of pilots and for the pilot participants to manage the initiatives and gauge their own performance are available on a timely basis and in a useful format.

Better coordination among the key stakeholders in the process—both within and outside government—is also important. Many parties are involved in developing the innovative strategies that the Innovation Center will test, and the approval of the Office of Management and Budget, which often has been difficult to obtain, will still be necessary to conduct the pilots. Implementation will involve CMS and the participating sites, but also—in multipayer
initiatives—may include Medicare, Medicaid, private payers, and other stakeholders in the communities and at the national level. Evaluation of pilots will involve the Innovation Center and other CMS components, as well as the Office of the Secretary, which will be responsible for attesting to the quality of Innovation Center pilots, and the Office of the Actuary, which will be responsible for certifying cost-saving potential.

Assessing Performance

With standardized evaluation procedures and better data, the time frame for evaluation could be shortened. This can be accomplished without cutting corners or sacrificing rigor, but by relying on an ongoing stream of information to monitor projects and make midcourse corrections as well as reaching definitive conclusions about effectiveness. Making assessments over a shorter time period inevitably raises questions: will the effects observed over a shorter period be borne out over the long term? The assessment of pilots implemented by the Innovation Center must take this into account and balance the desire to have results quickly with the need to have an accurate picture of how these pilots work and the results they are likely to produce over time.

Unless a change is very dramatic, its effects may not be immediate, so early assessments can result in discarding potentially promising innovations that would be proven effective if given more time. Conversely, some innovations may appear successful initially but the effects may be short-lived or offset by gaming or unintended results that are not apparent until more time has elapsed. Different outcome measures also have inherently different time frames. Policymakers must consider these risks when applying

Required Activity by Phase	Relevance to Innovation Center Context
PRE-IMPLEMENTATION	
Congressional Mandate (2000)	The Innovation Center can proceed without explicit congressional approval but will still need to define priorities.
Design (2001 to 2003)	Aim is to encourage "bottom-up" planning but the Innovation Center will still need to decide which features to focus on within each priority area and how to structure metrics and criteria for success.
Site Selection (August 2003)	The Innovation Center will need to establish standards for participation in pilots.
Waiver Approved (October 2004)	No new waiver is required, but there will be an internal process for approving flexible delivery and payment policies.
IMPLEMENTATION	
Official start to demonstration (April 2005)	
Five-year demonstration ends March 2010	Less time is required for effects that are expected sooner. Rapid feedback can give indications of whether the innovation appears to be working as planned or needs fine tuning. Even shorter term outcomes, however, are likely to require continued monitoring, particularly if short- and long-term effects differ in important ways.
EVALUATION	
Report of first-year results but no quality or expenditure data available to include (2006)	Evaluations can build in early feedback loops and timely designs that support midcourse corrections and generate lessons for refinement and spread. Doing so requires mechanisms for collecting, processing, analyzing, and distributing data that are not currently in place. Appropriate balance needed between short- and long-term evaluation of progress and performance.
Report available with data on first two years of the demonstration covering April 2005–March 2007 (2009)	
Final evaluation (expected 2011/2012)	

Exhibit 2. Illustrative Time Line: Medicare Physician Group Practice Demonstration

Note: Comments regarding how this experience would apply to the new CMMI mandate are the authors' alone.

Source: Presentation by Mark McClellan at Roundtable on Methods for Identifying, Designing, Monitoring, and Evaluating Innovations, Washington, DC, November 17, 2010.

the experiences of the Innovation Center nationally through changes in Medicare and Medicaid policy and whether the potential gains from adopting a fasttracked policy change outweigh the downside risk of adjusting the policy should subsequent longer-term evaluation warrant changes. The contributions of the health services research community will be extremely valuable in this area.

Standards of Evidence and Their Related Risks

The standard-of-evidence issue involves making judgments on the trade-offs of risks from different types of errors in interpreting pilot outcomes. There is a risk of judging change (e.g., an intervention or innovation) to be effective when it is not. This type of error has obviously adverse implications: it can lead to the propagation of a model of payment and care that has no advantages relative to the current system or is perhaps worse. Another type of error creates the opposite result: rejecting an innovation as a failure when it is actually effective. This type of error can be very harmful as well because it delays or obstructs the implementation of effective initiatives that can improve the current system.

Historically, most evaluations have been designed with the goal of limiting the risk of the first type of error. Some criticize this approach as overly conservative and insensitive to the second type of error, particularly when the objective is to find effective alternatives to the current system. There are risks from both types: moving too slow to encourage effective innovation or too fast to institutionalize innovation that may falsely believed to be effective. The appropriate way to balance the two approaches varies with the context and the potential impact of each type of error. Changes that have greater potential to harm patients or add significantly to program costs must be guarded against. Where the gain-to-risk ratio is more favorable, an approach that leans toward proceeding with new approaches may be warranted, with policy fine-tuned as additional information is generated.

Evidence and Policy Change

Since the Affordable Care Act gives the Secretary (working with the CMS actuary) authority over decisions that previously were the responsibility of Congress, it is useful to review the standards of evidence Congress historically has applied to authorize a change in program policy.

A review of Medicare history shows that Congress often has enhanced important policy changes without solid evidence to support such changes. For instance, Medicare competition demonstrations were still being evaluated when program-wide authority for the Medicare risk contracting program was enacted in 1982.¹⁵ Congress enacted the Medicare hospital prospective payment system and changed national Medicare policy on hospital payment, citing New Jersey's existing work with diagnosis-related group– based payment to support the feasibility of change. But the details of the New Jersey system tested varied substantially from the Medicare model that was put in place so the national change, in fact, was based on relatively limited testing.¹⁶

Other changes, such as the introduction of a resource-based relative value schedule for physician payment, were not tested as much as built on research to define key parameters of the payment model and expert vetting involving a range of stakeholders. Some evaluations that have shown positive results (such as competitive bidding for durable medical equipment) have never been implemented globally because of organized opposition.¹⁷ In certain cases evaluations have proven negative-as with Medicare's cost contracts that were found to increase program costs-but the programs have been retained because they serve other valued objectives.¹⁸ Important changes in Medicare, like the authority for accountable care organizations, were enacted with relatively limited empirical support.¹⁹

This history argues against applying standards of evidence that are so technically rigorous that they impede real progress in improving the performance of the health system, which requires change on many dimensions.²⁰ At the same time, clear and technically defensible standards of evidence to support major changes in program policy can serve CMS well in its mission to reform the payment and delivery systems. Standards provide a way of navigating politically contentious debates over change and provide the guidance necessary to appropriately target limited resources.

CONCLUSIONS AND IMPLICATIONS

Timely evaluation that is targeted to important concerns can help identify the kinds of innovations likely to make a big difference and support policymakers to better structure the way they test innovations to enhance the ability to learn from such testing. Evaluation also can help answer the questions anticipated to arise in applying the lessons from testing to support program-wide policy change that will institutionalize incentives to improve health care delivery and value.

It is important to keep in mind three conclusions from assessments of past experiences dealing with evaluating finance and organizational changes. First, implementation itself is important. The evidence that alternative policies can be adopted and are feasible can be a powerful lever for change. The Innovation Center appears well-suited to developing such evidence, by building systems that efficiently document the feasibility of innovation in forms that can be shared.

Second, the quality of evidence likely to be generated by testing innovations will vary. Testing and evaluation practices likely to encourage high-quality evidence include: 1) clearly articulated models developed to assess program logic, including feasibility and plausibility; 2) ongoing measurement that provides information on relevant intended and unintended outcomes associated with the innovation; 3) appropriate analysis that reinforces confidence that change can be legitimately attributed to the innovation rather than other causes; and 4) information on context and implementation experience to help others determine whether the innovation is likely to be appropriate in their setting and how to proceed.

Third, there are inherent trade-offs involving flexibility, timeliness, and the ability to generate rigorous evidence that will enhance the confidence policymakers have about the effects of policy change. There is an important distinction between rigor and rigor mortis. Methodological rigor is extremely important in distinguishing initiatives that are useful and can be propagated throughout the health system to good ends from those that "wish only to preserve the status quo."21 But decisions about methodological rigor must not stifle all attempts to improve the health system on the grounds that no data are good enough and no risk is worth taking. Risks-albeit informed risks-must be taken to improve the health system and avoid the ever-intensifying pressure, not only on federal and state governments but also on businesses and households, as a result of increasing health spending without concomitant improvements in quality and outcomes.

Tensions between competing goals can be reduced by anticipating them and thoughtfully designing the way innovations are tested and evaluated in the Innovation Center. Different trade-offs may be appropriate for innovations at different stages or with different potential risks and rewards. Collaboration among researchers, innovators, and policymakers about how best to address different goals and potential tensions is needed to enhance the Innovation Center's overall prospects for success.

Notes

- ¹ See page 306+ of the bill posted at http://docs. house.gov/energycommerce/ppacacon.pdf.
- ² The legislation provides 20 specific examples for consideration though the list is not meant to be restrictive. See Exhibit 2 in S. Guterman, K. Davis, K. Stremikis, and H. Drake "Innovation in Medicare and Medicaid Will Be Central to Health Reform's Success," *Health Affairs*, June 2010 29(6):1188–93.
- ³ Guterman, Davis, Stremikis et al., "Innovation in Medicare," 2010.
- ⁴ CMS, "The New Center for Medicare and Medicaid Innovation" Press release November 16, 2010, Available at http://innovations.cms.gov/news/pressreleases/pr110910.shtml, accessed January 5, 2010.
- ⁵ D. M. Berwick, "Introduction to the CMS Center for Medicare and Medicaid Innovation—and innovations.cms.gov," Nov. 26, 2010, available at http:// innovations.cms.gov/blog/introducing.shtml.
- ⁶ Centers for Medicare and Medicaid Services, "National Health Expenditure Projections 2009– 2019," Sept. 2010, available at http://www.cms. gov/NationalHealthExpendData/downloads/ NHEProjections2009to2019.pdf.
- ⁷ Congressional Budget Office. *Research and Development in the Pharmaceutical Industry* (Washington, D.C.: CBO, Oct. 2006).
- ⁸ See, for example, J. E. Mahoney, "Why Multifactorial Fall-Prevention Interventions May Not Work: Comment on 'Multifactorial Intervention to Reduce Falls in Older People at High Risk of Recurrent Falls," *Archives of Internal Medicine*, July 12, 2010 170(13):1117–19. Mahoney emphasizes the relevance of definition content, process, and targeting as part of evaluating interventions that aim to improve patient outcomes.
- ⁹ Presentation by Gregory Pope, RTI, at the Roundtable. The delay required six months for a claim to be 98 percent complete, an additional one to two months for data to reach the CMS data center, three months for claims acquisition and analysis, and one to two months for CMS review.
- ¹⁰ Comments by Jim Hester as part of the Roundtable.

- ¹¹ D. Esposito, E. F. Taylor, and M. Gold, "Using Qualitative and Quantitative Methods to Evaluate Small-Scale Disease Management Pilot Programs," *Population Health Management*, Feb. 2009 12(1):9–20.
- ¹² D. M. Berwick, "Developing and Testing Change in Delivery of Care," *Annals of Internal Medicine*, April 15, 1998 128(8):651–56.
- ¹³ The legislation also removed a requirement that innovations tested in the Center be assessed as budget-neutral prior to their testing. A. Cassidy, "The Fundamentals of Medicare Demonstrations," Background paper no. 63 (Washington D.C.: National Health Policy Forum, July 22, 2008); and Guterman, Davis, Stremikis et al., "Innovation in Medicare," 2010.
- ¹⁴ See S. Guterman and S. C. Schoenbaum, "Getting from Here to There in Payment Reform: Necessary Practices and Policies," *Journal of Ambulatory Care Management*, Jan./March 2010 33(1):52–57.
- ¹⁵ Communication with Randall Brown, Mathematica Policy Research, Feb. 2010.
- ¹⁶ M. Gold, K. Chu, S. Felt et al., "Effects of Selected Cost-Containment Efforts: 1971–1993," *Health Care Financing Review*, Spring 1993 14(3):183–225.
- ¹⁷ M. Likes, "The Battle Continues over Medicare Competitive Bidding Program," *HealthWatch*, July 2, 2010, available at http://thehill.com/blogs/healthwatch/medicare/107001-battle-continues-over-medicare-competitive-bidding-program.
- ¹⁸ M. Sing, R. S. Brown, and S. C. Hill, "The Consequences of Paying Medicare Managed Care Plans Their Costs," *Inquiry*, Summer 1998 35(2):210–22.
- ¹⁹ J. K. Iglehart, "Assessing an ACO Prototype: Medicare's Physician Group Practice Demonstration," *New England Journal of Medicine*, Jan. 20, 2011 364(3):198–200.
- ²⁰ See K. Davis, C. Schoen, and K. Stremikis, *Mirror*, *Mirror on the Wall: How the Performance of the* U.S. Health Care System Compares Internationally, 2010 Update (New York: The Commonwealth Fund, June 2010).

²¹ D. M. Berwick, Administrator CMS Remarks at "Workshop on Issues Related to Accountable Care Organizations" Federal Trade Commission, CMS and HHS Office of the Inspector General, Baltimore MD October 5, 2010. http://www.ftc.gov/opp/workshops/aco/index.shtml. Berwick added that "authenticity matters" and "we just do not have time for games anymore."

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Biographies and Meeting Logistics



ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

Member Biographies

Mark B. McClellan, MD, PhD (Chair) became the Director of the Engelberg Center for Healthcare Reform at the Brookings Institution in July 2007. The Center studies ways to provide practical solutions for access, quality and financing challenges facing the U.S. health care system. In addition, Dr. McClellan is the Leonard D. Schaeffer Chair in Health Policy Studies. Dr. McClellan has a highly distinguished record in public service and in academic research. He is the former administrator for the Centers for Medicare and Medicaid Services (2004-2006) and the former commissioner of the Food and Drug Administration

(2002-2004). He also served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House (2001–2002). In these positions, he developed and implemented major reforms in health policy. Dr. McClellan was also an associate professor of economics and associate professor of medicine (with tenure) at Stanford University, from which he was on leave during his government service. He directed Stanford's Program on Health Outcomes Research and was also associate editor of the *Journal of Health Economics*, and co-principal investigator of the Health and Retirement Study (HRS), a longitudinal study of the health and economic status of older Americans. His academic research has been concerned with the effectiveness of medical treatments in improving health, the economic and policy factors influencing medical treatment decisions and health outcomes, the impact of new technologies on public health and medical expenditures, and the relationship between health status and economic well being. Dr. McClellan is a Member of the Institute of Medicine of the National Academy of Sciences and a Research Associate of the National Bureau of Economic Research. A graduate of the University of Texas at Austin, Dr. McClellan earned his M.P.A. from Harvard's Kennedy School of Government in 1991, his M.D. from the Harvard-MIT Division of Health Sciences and Technology in 1992, and his Ph.D. in economics from MIT in 1993.

Bruce G. Bodaken, MPhil is chairman, president and chief executive officer of Blue Shield of California, a 3.3 million member not-for-profit health plan that serves the commercial, individual and government markets in California. Bodaken joined Blue Shield in 1994 as president and chief operating officer. Previously, he served as senior vice president and associate chief operating officer of FHP International Corporation in Southern California. Prior to embarking on a career in health care, he taught philosophy at the college level at the University of Colorado. Bodaken serves on the board of directors of the California Business Roundtable, WageWorks, and the University of California, Berkeley's Health Services Management Program. He is co-author of *The Managerial Moment of Truth*, published by Simon & Schuster in 2006. Bodaken received his bachelor's degree from Colorado State University, and earned a masters degree in philosophy and was A.B.D. in the doctoral program at the University of Colorado.

Paul Chew, MD is Senior Vice-President, Chief Science Officer, Chief Medical Officer at Sanofi-Aventis, US. Between 2007 and 2009 Dr. Chew held the position of President, U.S. Research & Development and Vice President, Therapeutic Department Head, Metabolism, Diabetes and Thrombosis in which role he was responsible for Lovenox, Lantus, and the therapeutic development portfolio. In addition, he is currently a member of the PhRMA Science & Regulatory Affairs Executive Committee and the Institute of Medicine Value & Science-Driven Healthcare Roundtable. Prior to sanofi-aventis, Dr. Chew was Vice-President, Global Head of Metabolism and Diabetes at Aventis Pharmaceuticals, 2001-2004. Prior to joining Aventis, Dr. Chew was at the Bristol-Myers Squibb Company, starting in 1992 as Medical Director of Clinical Cardiovascular Development. Dr. Chew held numerous positions of increasing R&D responsibility at BMS; Dr. Chew was Vice President, U.S. Medical Affairs from 1999-2001 where he was responsible for Plavix, Avapro, Glucophage, and Pravachol. Prior to industry, Dr. Chew was Assistant Professor of Medicine at The

Johns Hopkins Hospital, Attending Physician in Radiology, Director of the Pacemaker Clinic and a member of the Interventional Cardiology staff. Research interests included acute interventional cardiology, cardiac biomechanics, and statistical modeling of pericardial biomechanics. Dr. Chew obtained his medical education at The Johns Hopkins School of Medicine, serving his internal medicine training and cardiology fellowship at The Johns Hopkins Hospital. Dr. Chew is board-certified in Internal Medicine and Cardiovascular Diseases.

Carolyn M. Clancy, MD was appointed Director of the Agency for Healthcare Research and Quality (AHRQ) on February 5, 2003 and reappointed on October 9, 2009. Prior to her appointment, Dr. Clancy was Director of AHRQ's Center for Outcomes and Effectiveness Research. Dr. Clancy, a general internist and health services researcher, is a graduate of Boston College and the University of Massachusetts Medical School. Following clinical training in internal medicine, Dr. Clancy was a Henry J. Kaiser Family Foundation Fellow at the University of Pennsylvania. Before joining AHRQ in 1990, she was also an assistant professor in the Department of Internal Medicine at the Medical College of Virginia. Dr. Clancy holds an academic appointment at George Washington University School of Medicine (Clinical Associate Professor, Department of Medicine) and serves as Senior Associate Editor, Health Services Research. She serves on multiple editorial boards including the Annals of Internal Medicine, Annals of Family Medicine, American Journal of Medical Quality, and Medical Care Research and Review. She is a member of the Institute of Medicine and was elected a Master of the American College of Physicians in 2004. In 2009, was awarded the 2009 William B. Graham Prize for Health Services Research. Her major research interests include improving health care quality and patient safety, and reducing disparities in care associated with patients' race, ethnicity, gender, income, and education. As Director, she launched the first annual report to the Congress on health care disparities and health care quality. Dr. Clancy lives in the Maryland suburbs of Washington, D.C, with her husband, Bill. She enjoys jogging, movies, and spending time with her extended family, especially four nieces in Virginia.

Francis S. Collins, MD, PhD is the director of the National Institutes of Health (NIH). Dr. Collins, a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project, served as director of the National Human Genome Research Institute (NHGRI) at the NIH from 1993-2008. With Dr. Collins at the helm, the Human Genome Project consistently met projected milestones ahead of schedule and under budget. This remarkable international project culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. On March 10, 2010, Dr. Collins was named a co-recipient of the Albany Medical Center Prize in Medicine and Biomedical Research for his leading role in this effort. While accepting the honor, Dr. Collins declined his portion of the \$500,000 prize in order to comply with government ethics rules. In addition to his achievements as the NHGRI director, Dr. Collins' own research laboratory has discovered a number of important genes, including those responsible for cystic fibrosis, neurofibromatosis, Huntington's disease, a familial endocrine cancer syndrome, and most recently, genes for type 2 diabetes and the gene that causes Hutchinson-Gilford progeria syndrome. Dr. Collins received a B.S. in chemistry from the University of Virginia, a Ph.D. in physical chemistry from Yale University, and an M.D. with honors from the University of North Carolina at Chapel Hill. Prior to coming to the NIH in 1993, he spent nine years on the faculty of the University of Michigan, where he was a Howard Hughes Medical Institute investigator. He is an elected member of the Institute of Medicine and the National Academy of Sciences. Dr. Collins was awarded the Presidential Medal of Freedom in 2007. In a White House ceremony on October 7, 2009, Dr. Collins received the National Medal of Science, the highest honor bestowed on scientists by the United States government.

Michael J. Critelli, JD is the President and CEO of the Dossia Service Corporation, a for-profit corporation committed to the design and implementation of a portable, lifelong, secure patient-controlled health record. He retired from Pitney Bowes after a nearly 30-year career, at the end of which he served as Chairman for 12 years and CEO for 11 years. He is an innovator in employer-based health programs, having created a "culture of health" at Pitney Bowes. The Company created an environment highly conducive to prevention and wellness, to superior health care delivery, and to value-based health insurance plan design to drive optimal plan participant and provider behaviors. He is also a member of the for-profit boards of Eaton Corporation and Mollen Immunization Clinics and the non-profit boards of the Partnership for Prevention,

RAND Health Advisors, the Institute of Medicine's Roundtable on Value and Science-Driven Health Care, and the Boston University Alzheimer's Disease Center Advisory Board. He is also a board observer at Navigenics.

Helen B. Darling, MA is President of the National Business Group on Health, a national non-profit, membership organization devoted exclusively to providing practical solutions to its employer-members' most important health care problems and representing large employers' perspective on national health policy issues. Its 318 members, including 66 of the Fortune 100 in 2010, purchase health and disability benefits for over 55 million employees, retirees and dependents. Helen was the 2009 recipient of WorldatWork's Keystone Award, its highest honor in recognition of sustained contributions to the field of Human Resources and Benefits. She received the President's Award by the American College of Occupational and Environmental Medicine in 2010. She was given a lifetime appointment in 2003 as a National Associate of the National Academy of Sciences for her work for the Institute of Medicine. Helen serves on: the Committee on Performance Measurement of the National Committee for Quality Assurance (Co-chair for 10 years); the Medical Advisory Panel, Technology Evaluation Center, (Blue Cross Blue Shield Association); the Institute of Medicine's Roundtable on Value and Science-Driven Health Care, the Medicare Coverage Advisory Committee, and the National Advisory Council of AHRQ. She is on the Board of Directors of the National Quality Forum and the Congressionally-created Reagan-Udall Foundation. Previously, she directed the purchasing of health benefits and disability at Xerox Corporation for 55 thousand US employees. Darling was a Principal at William W. Mercer and Practice Leader at Watson Wyatt. Earlier in her career, Darling was an advisor to Senator David Durenberger, on the Health Subcommittee of the Senate Finance Committee. She directed three studies at the Institute of Medicine for the National Academy of Sciences. Darling received a master's degree in Demography/Sociology and a bachelor's of science degree in History/English, cum laude, from the University of Memphis.

Richard Fante, MBA serves as President of AstraZeneca US as well as CEO North America. Rich Fante is responsible for AstraZeneca's North American businesses including: AstraZeneca US and Canada. AstraZeneca is one of the world's leading pharmaceutical companies. Rich is accountable for driving growth and maximizing contribution in North America to AstraZeneca's global business. Previously, Rich served as Vice President, Brand Strategy & Portfolio Operations, leading the development and execution of marketing strategies for all AstraZeneca brands in the United States. He has held a number of leadership roles in his 13 years at AstraZeneca, including Vice President—Primary Care for the gastrointestinal and respiratory franchises, including NEXIUM® (esomeprazole magnesium) and PULMICORT RESPULES® (budesonide inhalation suspension). Before joining Astra USA in 1995, Rich worked for Lederle Laboratories in New Jersey, where he began his career in sales. He received his bachelor's degree in biology from Princeton University, and his MBA from the University of North Carolina Kenan-Flagler Business School.

Judith R. Faulkner is CEO and founder of Epic Systems Corporation. With a BS in Mathematics from Dickinson College, an MS and an honorary doctorate in Computer Science from the University of Wisconsin, she taught computer science for several years in the UW system and then worked as a healthcare software developer, creating one of the first databases organized around a patient record. She founded Epic in 1979 and guided it from its modest beginnings as a clinical database company to its current place as a leading provider of integrated healthcare software. Epic was rated the #1 overall software vendor by KLAS and is in the Leaders Quadrant of Gartner's Magic Quadrant for U.S. Enterprise CPR Systems. Judy was honored by HIMSS as one of the "50 in 50" memorable contributors to healthcare IT throughout HIMSS's 50-year history. She currently serves on the HIT Policy Committee, the Privacy and Security sub-committee, the University of Wisconsin Computer Science Board of Visitors, and the Institute of Medicine's Roundtable.

Thomas R. Frieden, MD, MPH is the Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. Frieden has worked to control both communicable and noncommunicable diseases in the United States and around the world. From 1992-1996, he led New York City's program that rapidly controlled tuberculosis, including

reducing cases of multidrug-resistant tuberculosis by 80 percent. He then worked in India for five years where he assisted with national tuberculosis control efforts. As Commissioner of the New York City Health Department from 2002-2009, he directed one of the world's largest public health agencies, with an annual budget of \$1.7 billion and more than 6,000 staff. A physician with training in internal medicine, infectious diseases, public health, and epidemiology, Dr. Frieden is especially known for his expertise in tuberculosis control. Dr. Frieden previously worked for CDC from 1990 until 2002. He began his career at CDC as an Epidemiologic Intelligence Service (EIS) Officer at the New York City Health Department. Dr. Frieden received both his medical degree and master's of public health degree from Columbia University and completed infectious disease training at Yale University. He has received numerous awards and honors and has published more than 200 scientific articles.

Patricia A. Gabow, MD is CEO of Denver Health, one of the nation's most efficient, highly-regarded integrated healthcare systems. Dr. Gabow joined the medical staff at Denver Health in 1973 as Renal Division chief, and is known for scientific work in polycystic kidney disease, and now health services research. Author of more than 150 publications, Dr. Gabow is a Professor of Medicine, University of Colorado School of Medicine. She received her MD degree from the University of Pennsylvania School of Medicine, trained in Internal Medicine at University of Pennsylvania Hospital and Harbor General Hospital in Torrance, California, and in Nephrology at San Francisco General Hospital and University of Pennsylvania School of Medicine. She has received numerous awards including the AMA Nathan Davis Award for Outstanding Public Servant, election to the Colorado Women's Hall of Fame, and the National Healthcare Leadership Award. She received a Lifetime Achievement Award from the Denver Business Journal and from the Bonfils-Stanton Foundation; the Innovators in Health Award, New England Healthcare Institute; and the David E. Rogers Award from the Association of American Medical Colleges. Dr. Gabow was awarded honorary degrees by the University of Denver and the University of Colorado and is a Master of the American College of Physicians. She is active in numerous health care organizations including the National Association of Public Hospitals, the Commonwealth Commission for a High Performing Health System and she is a commissioner to the Medicaid and CHIP Payment and Access Commission (MACPAC).

Atul Gawande MD, MPH is a surgeon, writer, and public health researcher. He practices general and endocrine surgery at Brigham and Women's Hospital in Boston. He is also Associate Professor of Surgery at Harvard Medical School and Associate Professor in the Department of Health Policy and Management at the Harvard School of Public Health. His research work currently focuses on systems innovations to transform safety and performance in surgery, childbirth, and care of the terminally ill. He serves as lead advisor for the World Health Organization's Safe Surgery Saves Lives program. He is also founder and chairman of Lifebox, an international not-for-profit implementing systems and technologies to reduce surgical deaths globally. He has been a staff writer for the New Yorker magazine since 1998. He has written three New York Times bestselling books: COMPLICATIONS, which was a finalist for the National Book Award in 2002; BETTER, which was selected as one of the ten best books of 2007 by Amazon.com; and THE CHECKLIST MANIFESTO. He has won two National Magazine Awards, AcademyHealth's Impact Award for highest research impact on health care, a MacArthur Award, and selection by Foreign Policy Magazine and TIME magazine as one of the world's top 100 influential thinkers.

Gary L. Gottlieb, MD, MBA serves as President and CEO of Partners HealthCare, assuming the position January 2010. Dr. Gottlieb comes to this role with a deep and rich history with Partners. He served as President of Brigham and Women's/ Faulkner Hospitals since March of 2002. He is also a Professor of Psychiatry at Harvard Medical School. Dr. Gottlieb was recruited by Partners to become the first chairman of Partners Psychiatry in 1998 and he served in that capacity through 2005. In 2000, he added the role of President of the North Shore Medical Center where he served until early 2002. Prior to coming to Boston, Dr. Gottlieb spent 15 years in positions of increasing leadership in health care in Philadelphia. In 1983, he arrived at the University of Pennsylvania as a Robert Wood Johnson Foundation Clinical Scholar. Through that program, he earned an M.B.A with Distinction in Health Care Administration from Penn's Wharton Graduate School of Business Administration. Dr. Gottlieb went on to establish Penn Medical Center's first

program in geriatric psychiatry and developed it into a nationally recognized research, training and clinical program. Dr. Gottlieb rose to become Executive Vice-Chair and Interim Chair of Penn's Department of Psychiatry and the Health System's Associate Dean for Managed Care. In 1994, he became Director and Chief Executive Officer of Friends Hospital in Philadelphia. In addition to his noteworthy academic, clinical and management record, Dr. Gottlieb has published extensively in geriatric psychiatry and health care policy. He is a past President of the American Association of Geriatric Psychiatry. Dr. Gottlieb received his BS cum laude from the Rensselaer Polytechnic Institute and his M.D. from the Albany Medical College of Union University in a six-year accelerated biomedical program. He completed his internship and residency and served as Chief Resident at New York University/Bellevue Medical Center. Now, as a recognized community leader in Boston, Dr. Gottlieb also focuses his attention on workforce development and disparities in health care. He was appointed by Mayor Thomas Menino as Chairman of the Private Industry Council, the City's workforce development board, which partners with education, labor, higher education, the community and government, to provide oversight and leadership to public and private workforce development programs. In 2004-2005, he served as co-chair of the Mayor's Task Force to Eliminate Health Disparities. Dr. Gottlieb believes Partners HealthCare mission is its compass - to inspire, to nurture, to challenge the best and the brightest to step forward and care for the sickest and neediest in our community and around world.

James A. Guest, JD became President and Chief Executive Officer of Consumers Union (CU) in February 2001 after a long career in public service and the consumer interest, including 21 years as Chair of CU's Board of Directors. CU publishes Consumer Reports and ConsumerReports.org. The organization was founded in 1936 when advertising first flooded the mass media. Consumers lacked any reliable source of information they could depend on to help them distinguish hype from fact and good products from bad ones. Since then CU has filled that vacuum with a broad range of consumer information and a succession of presidents serving as passionate and outspoken consumer champions. Mr. Guest continues that tradition, fighting on Capitol Hill and in the media for the consumer's right to know about, and be protected from, unsafe and misleading products and services. Under his leadership, the organization is currently pursuing a high-profile campaign to improve the safety, quality, accessibility, and value of the health-care marketplace. This has included the successful launch of several new initiatives such as ConsumerReportsHealth.org and the Consumer Reports Health Ratings Center, which serve to educate and empower consumers to make more informed health-care decisions and to help change the market. Mr. Guest also is the President of Consumers International, a global federation of 250 organizations from 115 countries. Mr. Guest's public service career has spanned more than three decades. After graduating from Harvard law school and completing a Woodrow Wilson fellowship in economics at MIT, he worked as legislative assistant to Senator Ted Kennedy. In the early 1970s, Mr. Guest moved to Vermont where he served as Banking and Insurance Commissioner, Secretary of State, and Secretary of Development and Community Affairs. Over the last 20 years, he has headed several public policy and advocacy groups including Handgun Control Inc. and the Center to Prevent Handgun Violence, as well as Planned Parenthood of Maryland. He was also the founding Executive Director of the American Pain Foundation, a national consumer information, education, and advocacy organization for pain prevention and management. Mr. Guest credits his very first job for introducing him to one of his biggest influences in consumer advocacy. He worked as the paperboy for Dr. Colston Warne-the first Chair of CU's Board of Directors and a leader in the consumer movement.

George C. Halvorson was named chairman and chief executive officer of Kaiser Permanente, headquartered in Oakland, California in March 2002. Kaiser Permanente is the nation's largest nonprofit health plan and hospital system, serving about 8.6 million members and generating \$42 billion in annual revenue. George Halvorson has won several awards for his commitment to health technology and for his leadership and achievements in advancing health care quality. The development, implementation, and maintenance of Kaiser Permanente's information technology infrastructure represent a multi-billion dollar strategic investment that provides comprehensive care coordination and continually improving quality of care and service to members. He is the author of five comprehensive books on the U.S. health care system including the recently released *Health Care Will Not Reform Itself: A User's Guide to Refocusing and Reforming American Health Care.* Mr. Halvorson lends his time and expertise to a number of organizations, including the Institute of Medicine, the American

Hospital Association, and the Commonwealth Fund. He serves on the boards of the America's Health Insurance Plans and the board of the Alliance of Community Health Plans. Halvorson chairs the International Federation of Health Plans and co-chairs the 2010 Institute for Healthcare Improvement Annual National Forum on Quality Improvement in Health Care. In 2009, he chaired the World Economic Forum's Health Governors meetings in Davos. Prior to joining Kaiser Permanente, Mr. Halvorson was president and chief executive officer of HealthPartners, headquartered in Minneapolis. With more than 30 years of health care management experience, he has also held several senior management positions with the Health Central Hospital System, Health Accord International, and Blue Cross and Blue Shield of Minnesota.

Margaret A. Hamburg, MD is the Commissioner of the Food and Drug Administration (FDA). Dr. Hamburg graduated from Harvard Medical School, and completed her residency in internal medicine at what is now New York Presbyterian Hospital-Weill Cornell Medical Center, one of the top-ten hospitals in the nation. She conducted research on neuroscience at Rockefeller University in New York, studied neuropharmacology at the National Institute of Mental Health on the National Institutes of Health campus in Bethesda, Md., and later focused on AIDS research as Assistant Director of the National Institute of Allergy and Infectious Diseases. In 1990, Dr. Hamburg joined the New York City Department of Health and Mental Hygiene as Deputy Health Commissioner, and within a year was promoted to Commissioner, a position she held until 1997. Dr. Hamburg's accomplishments as New York's top public health official included improved services for women and children, needle-exchange programs to reduce the spread of HIV (the AIDS virus), and the initiation the first public health bio-terrorism defense program in the nation. Her most celebrated achievement, however, was curbing the spread of tuberculosis. Dr. Hamburg's innovative approach has become a model for health departments world-wide. In 1994, Dr. Hamburg was elected to the membership in the Institute of Medicine, one of the youngest persons to be so honored. Three years later, at the request of President Clinton, she accepted the position of Assistant Secretary for Policy and Evaluation in the U.S. Department of Health and Human Services (HHS). In 2001, Dr. Hamburg became Vice President for Biological Programs at the Nuclear Threat Initiative, a foundation dedicated to reducing the threat to public safety from nuclear, chemical, and biological weapons. Since 2005, and until her confirmation as Commissioner of the FDA, Dr. Hamburg served as the Initiative's Senior Scientist.

James Allen Heywood, is the Co-Founder and Chairman of PatientsLikeMe and the d'Arbeloff Founding Director of the ALS Therapy Development Institute. An MIT engineer, Jamie entered the field of translational research and medicine when his brother Stephen was diagnosed with ALS at age 29. His innovations are transforming biotechnology and pharmaceutical development, personalized medicine, and patient care. As co-founder and chairman of PatientsLikeMe, Jamie provides the scientific vision and architecture for its patient-centered medical platform, allowing patients to share in-depth information on treatments, symptoms and outcomes. In 1999, he founded the ALS Therapy Development Institute, the world's first non-profit biotechnology company and largest ALS research program. Jamie's work has been profiled by the *New Yorker, New York Times*, 60 Minutes, NPR, *Science*, and *Nature*. He and Stephen were the subjects of Pulitzer Prize winner Jonathan Wiener's biography, *His Brothers Keeper* and the Sundance award-winning documentary, "So Much So Fast."

Carmen Hooker Odom, MRP is currently President of the Milbank Memorial Fund, a New York-based foundation that conducts nonpartisan analysis, study, and research on significant issues in health policy. Prior to joining the Fund in 2007, she was appointed the Secretary of the North Carolina Department of Health and Human Services by Governor Mike Easley in January 2001. Ms. Hooker Odom, a former Massachusetts lawmaker and healthcare lobbyist, has spent her professional life working in health and human services. Before her appointment, she served as Vice President of Government Relations for Quintiles Transnational Corporation in Research Triangle Park and as the Group Vice President for Carolinas HealthCare System (CHS). She is also an Adjunct Professor at the UNC School of Public Health. From1995 to 1996, Hooker Odom worked as a Project Officer for the Milbank Memorial Fund. Prior to moving to North Carolina in 1995, Hooker Odom served as a member of the Massachusetts House of Representatives for nearly eleven years. As House Chairman of the Joint Committee on Health Care, she was the primary legislative author of

both the 1991 Massachusetts comprehensive health reform legislation and the Children's Medical Security Plan, which targeted young children not covered by medical insurance. Hooker Odom co-chaired the North Carolina Health Care Reform Commission and is a member of the North Carolina Institute of Medicine. She received a bachelor's degree in sociology and political science from Springfield College and a master's degree in regional planning from the University of Massachusetts at Amherst.

Ralph I. Horwitz, MD, MACP is Senior Vice President for Clinical Evaluation Sciences and Senior Advisor to the Chairman of Research and Development at GlaxoSmithKline, and Harold H. Hines, Jr. Professor Emeritus of Medicine and Epidemiology at Yale University. Dr. Horwitz trained in internal medicine at institutions (Royal Victoria Hospital of McGill University and the Massachusetts General Hospital) where science and clinical medicine were connected effortlessly. These experiences as a resident unleashed a deep interest in clinical research training which he pursued as a fellow in the Robert Wood Johnson Clinical Scholars Program at Yale under the direction of Alvan R.Feinstein. He joined the Yale faculty in 1978 and remained there for 25 years as Co-Director of the Clinical Scholars Program and later as Chair of the Department of Medicine. Before joining GSK, Dr. Horwitz was Chair of Medicine at Stanford and Dean of Case Western Reserve Medical School. He is an elected member of the Institute of Medicine of the National Academy of Sciences; the American Society for Clinical Investigation; the American Epidemiological Society; and the Association of American Physicians (he was President in 2010). He was a member of the Advisory Committee to the NIH Director (under both Elias Zerhouni and Francis Collins). Dr. Horwitz served on the American Board of Internal Medicine and was Chairman in 2003. He is a Master of the American College of Physicians.

Ardis D. Hoven, MD an internal medicine and infectious disease specialist in Lexington, Ky., has been a member of the American Medical Association (AMA) Board of Trustees (BOT) since 2005. She served as its secretary for 2008–2009, and in June 2010 she began serving as chair for 2010–2011. Prior to her election to the AMA-BOT, Dr. Hoven served as a member and chair of the AMA Council on Medical Service. She was a member of the Utilization Review and Accreditation Commission for six years and served on its executive committee. Additional activities have included service on the Group Practice Advisory Council of the AMA and an appointment to the Practicing Physicians Advisory Commission. Currently Dr. Hoven serves as the AMA-BOT representative on the AMA Foundation board, the COLA board and the AMA-convened Physician Consortium for Performance Improvement®. Most recently she was appointed to the National Advisory Council for Healthcare Research and Quality. Dr. Hoven's involvement at the state level has been extensive. She was president of the Kentucky Medical Association from 1993 to 1994 and served as a delegate to the AMA from Kentucky prior to her election to the AMA-BOT. She has also been actively involved in medical staff issues at her local hospital and has held a variety of positions, including president of the medical staff, member of the board of directors and president of the hospital foundation board. Born in Cincinnati, Dr. Hoven received her undergraduate degree in microbiology and then her medical degree from the University of Kentucky, Lexington. She completed her internal medicine and infectious disease training at the University of North Carolina, Chapel Hill. Since then, she has been in active practice and currently is the medical director of the Bluegrass Care Clinic, an infectious disease and HIV/AIDS practice affiliated with the University of Kentucky College of Medicine. Board-certified in internal medicine and infectious disease, Dr. Hoven is a fellow of the American College of Physicians and the Infectious Disease Society of America. She has been the recipient of many awards, including the University of Kentucky College of Medicine Distinguished Alumnus Award and the Kentucky Medical Association Distinguished Service Award.

Brent C. James, MD, MStat is known internationally for his work in clinical quality improvement, patient safety, and the infrastructure that underlies successful improvement efforts, such as culture change, data systems, payment methods, and management roles. He is a member of the National Academy of Science's Institute of Medicine (and participated in many of that organization's seminal works on quality and patient safety). He holds faculty appointments at the University of Utah School of Medicine (Family Medicine and Biomedical Informatics), Harvard School of Public Health (Health Policy and Management), and the University of Sydney, Australia, School of Public Health. He is the Chief Quality Officer, and Executive

Director, Institute for Health Care Delivery Research at Intermountain Healthcare, based in Salt Lake City, Utah. (Intermountain is an integrated system of 23 hospitals, almost 150 clinics, a 700+ member physician group, and an HMO/PPO insurance plan jointly responsible for more than 500,000 covered lives serving patients in Utah, Idaho, and, at a tertiary level, seven surrounding States). Through the Intermountain Advanced Training Program in Clinical Practice Improvement (ATP), he has trained more than 3500 senior physician, nursing, and administrative executives, drawn from around the world, in clinical management methods, with proven improvement results (and more than 30 "daughter" training programs in 6 countries) Before coming to Intermountain, he was an Assistant Professor in the Department of Biostatistics at the Harvard School of Public Health, providing statistical support for the Eastern Cooperative Oncology Group (ECOG); and staffed the American College of Surgeons' Commission on Cancer. He holds Bachelor of Science degrees in Computer Science (Electrical Engineering) and Medical Biology; an M.D. degree (with residency training in general surgery and oncology); and a Master of Statistics degree. He serves on several non-profit boards of trustees, dedicated to clinical improvement.

Michael M.E. Johns, MD assumed the post of chancellor for Emory University in October 2007. Prior to that, beginning in 1996, he served as executive vice president for health affairs and CEO of the Robert W. Woodruff Health Sciences Center and chair of Emory Healthcare. As leader of the health sciences and Emory Healthcare for 11 years, Dr. Johns engineered the transformation of the Health Sciences Center into one of the nation's preeminent centers in education, research, and patient care. He previously served as dean of the Johns Hopkins School of Medicine and vice president for medicine at Johns Hopkins University from 1990 to 1996. In addition to leading complex administrative and academic organizations to new levels of excellence and service, Dr. Johns is widely renowned as a catalyst of new thinking in many areas of health policy and health professions education. He has been a significant contributor to many of the leading organizations and policy groups in health care, including the Institute of Medicine (IOM), the Association of American Medical Colleges (AAMC), The Commonwealth Fund Task Force on Academic Health Centers, the Association of Academic Health Centers, and many others. He frequently lectures, publishes, and works with state and federal policy makers, on topics ranging from the future of health professions education to national health system reform. Dr. Johns was elected to the Institute of Medicine in 1993 and has served on many IOM committees. Dr. Johns received his bachelor's degree from Wayne State University and his medical degree with distinction at the University of Michigan Medical School.

Craig A. Jones, MD is the Director of the Vermont Blueprint for Health, a program established by the State of Vermont, under the leadership of its Governor, Legislature and the bi-partisan Health Care Reform Commission. The Blueprint is intended to guide a statewide transformation resulting in seamless and well coordinated health services for all citizens, with an emphasis on prevention. The program is intended to improve healthcare for individuals, improve the health of the population, and result in more affordable healthcare costs. Prior to this he was an Assistant Professor in the Department of Pediatrics at the Keck School of Medicine at the University of Southern California, and Director of the Division of Allergy/Immunology and Director of the Allergy/Immunology Residency Training Program in the Department of Pediatrics at the Los Angeles County + University of Southern California (LAC+USC) Medical Center. He was Director, in charge of the design, implementation, and management, of the Breathmobile Program, a program using mobile clinics, team based care, and health information technology to deliver ongoing preventive care to inner city children with asthma at their schools and at County clinics. The program evolved from community outreach to a more fully integrated Pediatric Asthma Disease Management for the Los Angeles County Department of Health Services, and spread to several other communities across the country. He has published papers, abstracts, and textbook chapters, on topics related to health services, health outcomes, and allergy and immunology in Pediatric Research, Pediatrics, J Pediatrics, Pediatrics in Review, Journal of Clinical Immunology, Journal of Allergy and Clinical Immunology, Annals of Allergy, Asthma and Immunology, CHEST, and Disease Management. Dr. Jones was an Executive Committee and Board Member for the Southern California Chapter of the Asthma and Allergy Foundation of America, as well the chapter President. He is a past president of the Los Angeles Society of Allergy Asthma & Immunology, and a past President and a member of the Board of Directors for the

California Society of Allergy Asthma & Immunology. Dr. Jones received his undergraduate degree at the University of California at San Diego and his MD at the University of Texas Health Science Center in San Antonio, Texas. He completed his internship and residency in pediatrics at LAC/USC Medical Center, where he also completed his fellowship in allergy and clinical immunology.

Cato T. Laurencin, MD, PhD is Vice President for Health Affairs at the UCONN Health Center and the seventh dean of the UCONN School of Medicine. A nationally and internationally prominent orthopaedic surgeon, engineer, and administrator, Dr. Laurencin holds the Van Dusen Endowed Chair in Academic Medicine and is Distinguished Professor of Orthopaedic Surgery, and Chemical, Materials and Biomolecular Engineering at the University of Connecticut. As the leader of the UCONN Health Center, Dr. Laurencin guides all activities encompassing clinical, research and educational domains. Dr. Laurencin earned his undergraduate degree in chemical engineering from Princeton University and his medical degree from Harvard Medical School, where he was a *Magna Cum Laude* graduate. During medical school, he also earned his Ph.D. in biochemical engineering/biotechnology from the Massachusetts Institute of Technology.

Dr. Laurencin has been named to America's Top Doctors and America's Top Surgeons, and is a Fellow of the American Surgical Association, a Fellow of the American College of Surgeons, and a Fellow of the American Academy of Orthopaedic surgeons. Dr. Laurencin's research involves tissue engineering, biomaterials science, and nanotechnology and he is an International Fellow in Biomaterials Science and

Engineering and a Fellow of the American Institute for Medical and Biological Engineering. His work was honored by Scientific American Magazine as one of the 50 greatest achievements in science in 2007. In 2009 Dr. Laurencin was named one of the 100 engineers of the modern era by the American Institute of Chemical Engineers. Last year he received the Presidential Award for Excellence in Science, Mathematics and Engineering Mentoring from President Obama in ceremonies at the Whitehouse. He is Chairman of the Board of Directors of the National Medical Association/W. Montague Cobb Health Institute, an organization dedicated to addressing health disparities. He has been a member of the National Science Foundation's Advisory Committee for Engineering (ADCOM), and has served both on the National Science Board of the FDA, and the National Advisory Council for Arthritis, Musculoskeletal and Skin Diseases at N.I.H. He is a member of the Board of Directors of the Connecticut Children's Hospital, the University of Connecticut Health Center Finance Corporation, and served on the board of Osteotech Corporation (NASDAQ) until its recent merger with Medtronic Corporation. Dr. Laurencin is an elected member of the Institute of Medicine and the National Academy of Engineering.

Stephen P. MacMillan is Chairman, President and Chief Executive Officer of Stryker Corporation and serves on its Board of Directors. Mr. MacMillan joined Stryker in 2003 as President and Chief Operating Officer, and was appointed CEO effective January 2005. Mr. MacMillan began his career with Procter & Gamble in 1985 and later spent 11 years with Johnson & Johnson in both the U.S. and Europe, and became President of the joint venture between Johnson & Johnson and Merck. In 2000, he joined Pharmacia Corporation's Executive Committee where he oversaw five global businesses with revenues exceeding \$2 billion. Mr. MacMillan also serves on the Board of Directors of Texas Instruments, the Greater Kalamazoo United Way and AdvaMed, and is a member of the Institute of Medicine's Roundtable on Value & Science-Driven Health Care. In 2010, Mr. MacMillan was also appointed by the U.S. Commerce Secretary to a two-year term on the U.S. Manufacturing Council, a group which advises the administration on ideas to create more U.S. manufacturing jobs. He received a Bachelor of Arts degree in Economics from Davidson College and is a graduate of Harvard Business School's Advanced Management Program.

Sheri S. McCoy, MSc, MBA is Vice Chairman, Executive Committee, and member of the Office of the Chairman, Johnson & Johnson, with responsibility for the Pharmaceutical and Consumer business segments. She assumed this role in January 2011. Previously, she was worldwide chairman, Pharmaceuticals, a position she assumed in January 2009. Her appointment followed a diverse career in the Corporation's Consumer and Medical Devices businesses. Sheri began her Johnson & Johnson career in 1982 as a scientist in the research and development organization supporting the Consumer women's health business. Advancing through positions of increasing responsibility, she served as head of the consumer R&D organization and later as

global president of the Baby and Wound care consumer franchises. In 2005, she became Company Group Chairman for the Ethicon device franchise and a member of the Medical Device & Diagnostics Group Operating Committee, and assumed responsibility for the Group's businesses in Latin America. Three years later, she was named Chairman of the Surgical Care Group, and became a member of the Johnson & Johnson Executive Committee. In her most recent position as worldwide chairman of the Pharmaceuticals Group, Sheri led the organization through a period of significant product launches, acquisitions and partnerships, and pipeline advances, while managing through significant loss of patent exclusivity. She is a passionate advocate for diversity of thought, leadership development, employee engagement and customer focus. Sheri represents the Corporation on the board of PhRMA, the industry trade association, and is a member of the board of the National Quality Forum and of the Institutes of Medicine's Roundtable on Value & Science-Driven Healthcare. She serves as a board member of FIRST, a non-profit organization created to inspire young people's interest and participation in science and technology; a member of the Rutgers University President's Business Leaders Cabinet, and as a board member of Stonehill College. Sheri holds four U.S. patents. She has a B.S. degree in textile chemistry from the University of Massachusetts, Dartmouth, a master's degree in chemical engineering from Princeton University, and an MBA from Rutgers University.

Farzad Mostashari, MD, ScM, serves as National Coordinator for Health Information Technology within the Office of the National Coordinator for Health Information Technology at the U.S. Department of Health and Human Services. Farzad joined ONC in July 2009. Previously, he served at the New York City Department of Health and Mental Hygiene as Assistant Commissioner for the Primary Care Information Project, where he facilitated the adoption of prevention-oriented health information technology by over 1,500 providers in underserved communities. Dr. Mostashari also led the Centers for Disease Control and Prevention (CDC) funded NYC Center of Excellence in Public Health Informatics and an Agency for Healthcare Research and Quality funded project focused on quality measurement at the point of care. Prior to this he established the Bureau of Epidemiology Services at the NYC Department of Health, charged with providing epidemiologic and statistical expertise and data for decision making to the health department. He did his graduate training at the Harvard School of Public Health and Yale Medical School, internal medicine residency at Massachusetts General Hospital, and completed the CDC's Epidemic Intelligence Service. He was one of the lead investigators in the outbreaks of West Nile Virus and anthrax in New York City, and among the first developers of real-time electronic disease surveillance systems nationwide.

Elizabeth G. Nabel, MD is President of the Brigham and Women's Hospital (BWH) and Professor of Medicine, Harvard Medical School in Boston, Massachusetts. A teaching affiliate of Harvard Medical School, BWH has consistently been one of the nation's leaders in academic health care and one of the largest recipients of National Institutes of Health (NIH) research funding. As President, Dr. Nabel is responsible for patient care, research, education, and community missions. A native of St. Paul, Minnesota, Dr. Nabel attended Weill Cornell Medical College in New York City and conducted her internal medicine and cardiovascular training at BWH, followed by faculty positions at the University of Michigan Medical School, where she directed the Division of Cardiology and the Cardiovascular Research Center. Before assuming her position at BWH in January 2010, Dr. Nabel was Director of the NIH's National Heart, Lung, and Blood Institute (NHLBI), whose mission is to prevent, diagnose, and treat heart, lung, and blood diseases. In this capacity, Dr. Nabel oversaw an extensive national research portfolio with an annual budget of approximately \$3.0 billion. Her signature efforts included raising awareness for heart disease in women; launching a global health program to combat non-communicable diseases; creating new scientific programs to pursue the promise of genomics and stem cells, stem and progenitor cell biology, and translational research; in addition to nurturing the careers of young investigators. Dr. Nabel is a strong advocate for global health and research programs in the non-communicable diseases. She is a co-founder of the Global Alliance for the Chronic Diseases, an alliance of national health research institutions, the alliance coordinates and supports research activities that address, on a global scale, the prevention and treatment of chronic non-communicable diseases. She also established the NHLBI network of 11 Collaborating Centers of Excellence in low- and middleincome countries to build sustainable programs to combat chronic cardiovascular and lung diseases. Research and outreach activities are being conducted in 21 developing countries. As a physician scientist, Dr. Nabel has

made substantial contributions to our understanding of the molecular genetics of cardiovascular diseases. She developed gene transfer approaches for CV diseases to delineate the pathophysiology of atherosclerosis. Her work has clarified fundamental processes of cell division and growth of smooth muscle cells in blood vessels. Her recent studies have focused on the rare premature aging disorder, Hutchinson-Gilford Progeria Syndrome, where she has characterized the vascular smooth muscle cell defect that leads to premature heart attack and stroke in early adolescence. Dr. Nabel's honors include the Willem Einthoven Award; the Amgen-Scientific Achievement Award; the American Heart Association Distinguished Achievement Awards; the Eugene Braunwald Academic Mentorship Award; the Distinguished Alumni Award from Weill Cornell Medical College; the Lewis Katz Research Prize in Cardiovascular Research, and six honorary doctorates. She is a member of the American Academy of the Arts and Sciences, the Institute of Medicine (Council), the Advancement of Science. Dr. Nabel has served on the Board of Reviewing Editors for *Science* and is currently on the Editorial Board of the *New England Journal of Medicine* and *Science Translational Medicine*. She is a partner on 17 patents and the author of more than 250 scientific publications.

Mary D. Naylor, PhD, RN, FAAN is the Marian S. Ware Professor in Gerontology and Director of the NewCourtland Center for Transitions and Health at the University of Pennsylvania School of Nursing. Since 1989, Dr. Naylor has led an interdisciplinary program of research designed to improve the quality of care, decrease unnecessary hospitalizations, and reduce health care costs for vulnerable community-based elders. Dr. Naylor is also the National Program Director for the Robert Wood Johnson Foundation program, Interdisciplinary Nursing Quality Research Initiative, aimed at generating, disseminating, and translating research to understand how nurses contribute to quality patient care. She was elected to the National Academy of Sciences, Institute of Medicine in 2005. She also is a member of the RAND Health Board, the National Quality Forum Board of Directors and the immediate past-chair of the Board of the Long-Term Quality Alliance. She was appointed to the Medicare Payment Advisory Commission in 2010.

William D. Novelli, MA is a professor in the McDonough School of Business at Georgetown University. In addition to teaching in the MBA program, he is working to establish a center for social enterprise at the School. From 2001 to 2009, he was CEO of AARP, a membership organization of over 40 million people 50 and older. Prior to joining AARP, Mr. Novelli was President of the Campaign for Tobacco-Free Kids, whose mandate is to change public policies and the social environment, limit tobacco companies' marketing and sales practices to children and serve as a counterforce to the tobacco industry and its special interests. He now serves as chairman of the board. Previously, he was Executive Vice President of CARE, the world's largest private relief and development organization. He was responsible for all operations in the U.S. and abroad. CARE helps impoverished people in Africa, Asia and Latin America through programs in health, agriculture, environmental protection and small business support. CARE also provides emergency relief to people in need. Earlier, Mr. Novelli co-founded and was President of Porter Novelli, now one of the world's largest public relations agencies and part of the Omnicom Group, an international marketing communications corporation. He directed numerous corporate accounts as well as the management and development of the firm. He retired from the firm in 1990 to pursue a second career in public service. He was named one of the 100 most influential public relations professionals of the 20th century by the industry's leading publication. Mr. Novelli is a recognized leader in social marketing and social change, and has managed programs in cancer control, diet and nutrition, cardiovascular health, reproductive health, infant survival, pay increases for educators, charitable giving and other programs in the U.S. and the developing world. He began his career at Unilever, a worldwide-packaged goods marketing company, moved to a major ad agency, and then served as Director of Advertising and Creative Services for the Peace Corps. In this role, Mr. Novelli helped direct recruitment efforts for the Peace Corps, VISTA, and social involvement programs for older Americans. He holds a B.A. from the University of Pennsylvania and an M.A. from Penn's Annenberg School for Communication, and pursued doctoral studies at New York University. He taught marketing management for 10 years in the University of Maryland's M.B.A. program and also taught health communications there. He has lectured at many other institutions. He has written numerous articles and chapters on marketing management, marketing communications, and social marketing in journals, periodicals and textbooks. His

book, 50+: Give Meaning and Purpose to the Best Time of Your Life, was updated in 2008. His newest book, Managing the Older Worker: How to Prepare for the New Organizational Order (with Peter Cappelli) was published in 2010. Mr. Novelli serves on a number of boards and advisory committees. He and his wife, Fran, live in Bethesda, Maryland. They have three adult children and seven grandchildren.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI is President, Clinical and Physician 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 163 hospitals and more than 600 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 on numerous Boards and Commissions including the National Quality Forum, the Joint Commission, Meharry Medical College, and he chairs the HHS Health IT Standards Committee. Broadly published in healthcare quality and transformation, he is a Fellow of the American College of Physicians and the American College of Medical Informatics. Dr. Perlin 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). Perennially recognized 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 nine honorary members of the Special Forces Association and Green Berets. 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. He resides in Nashville, Tennessee, with his wife, Donna, an Emergency Pediatrics Physician, and children, Ben and Sarah.

Robert A. Petzel, MD was appointed Under Secretary for Health in the Department of Veterans Affairs (VA) on Feb. 18, 2010. Prior to this appointment, Dr. Petzel had served as VA's Acting Principal Deputy Under Secretary for Health since May 2009. As Under Secretary for Health, Dr. Petzel oversees the health care needs of millions of veterans enrolled in the Veterans Health Administration (VHA), the nation's largest integrated health care system. With a medical care appropriation of more than \$48 billion, VHA employs more than 262,000 staff at over 1,400 sites, including hospitals, clinics, nursing homes, domiciliaries, and Readjustment Counseling Centers. In addition, VHA is the nation's largest provider of graduate medical education and a major contributor to medical research. More than eight million veterans are enrolled in the VA's health care system, which is growing in the wake of its eligibility expansion. This year, VA expects to treat nearly six million patients during 78 million outpatient visits and 906,000 inpatient admissions. Previously, Dr. Petzel served as Network Director of the VA Midwest Health Care Network (VISN 23) based in Minneapolis, Minn. In that position, Dr. Petzel was responsible for the executive leadership, strategic planning and budget for eight medical centers and 42 community-based outpatient clinics, serving veterans in Iowa, Minnesota, Nebraska, North Dakota, South Dakota, western Illinois and western Wisconsin. Dr. Petzel was appointed Director of Network 23 (the merger of Networks 13 and 14) in October 2002. From October 1995 to September 2002, he served as the Director of Network 13. Prior to that position, he served as Chief of Staff at the Minneapolis VA Medical Center. Dr. Petzel is particularly interested in data-based performance management, organization by care lines, and empowering employees to continuously improve

the way we serve our veterans. He is involved in a collaborative partnership with the British National Health Services Strategic Health Authority. In addition, he co-chairs the National VHA Strategic Planning Committee and the VHA System Redesign Steering Committee. Dr. Petzel graduated from St. Olaf College, Northfield, Minn., in 1965 and from Northwestern University Medical School in 1969. He is Board Certified in Internal Medicine and on the faculty of the University of Minnesota Medical School.

Richard Platt, MD, MSc is a professor and chair of the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is principal investigator of the FDA's Mini-Sentinel program, of contracts with FDA's Center for Drugs Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to conduct post-marketing studies of drugs' and biologics' safety and effectiveness. He chaired the FDA's Drug Safety and Risk Management Advisory Committee, is a member of the Association of American Medical Colleges' Advisory Panel on Research and the Institute of Medicine Roundtable on Value & Science-Driven Health Care. Dr. Platt was co-chair of the Board of Scientific Counselors of the Centers for Disease Control and Prevention's (CDC) Center for Infectious Diseases. Additionally, he has chaired the National Institutes of Health study section, Epidemiology and Disease Control 2, and the CDC Office of Health Care Partnerships steering committee. Dr. Platt is also principal investigator of a CDC Center of Excellence in Public Health Informatics, the Agency for Healthcare Research and Quality (AHRQ) HMO Research Network Center for Education and Research in Therapeutics, the AHRQ HMO Research Network DEcIDE Center, the CDC Eastern Massachusetts Prevention Epicenter, and FDA contracts to conduct post-marketing studies of drugs' and biologics' safety and effectiveness.

Chesley Richards, MD, MPH is the Director, Office of Prevention Through Healthcare (OPTH) in the Office of Policy, Office of the Director, Centers for Disease Control and Prevention. OPTH, a new office at CDC, works to build and enhance strategic collaboration between public health and healthcare sector stakeholders to improve the use of preventive services, and to enhance the quality and safety of healthcare. Previously, Dr. Richards served as the Deputy Director, Division of Healthcare Quality Promotion in the National Center for Infectious Diseases at CDC. Dr. Richards is a board certified internist and geriatrician and holds an appointment as Clinical Associate Professor of Medicine in the Division of Geriatric Medicine and Gerontology at Emory University. Dr. Richards earned his MD from the Medical University of South Carolina, an MPH in Health Policy and Administration from University of North Carolina at Chapel Hill and is a graduate of the Epidemic Intelligence Service (EIS) at CDC and the Program on Clinical Effectiveness at Harvard School of Public Health. Prior to coming to CDC, Dr. Richards served as the Chief of General Internal Medicine and Associate Director for Internal Medicine Residency Training at the Medical College of Georgia. Dr. Richards's interests include patient safety, healthcare quality, preventive services, especially among older adults.

John C. Rother, JD is the Executive Vice President of Policy, Strategy and International Affairs for AARP. He is responsible for the federal and state public policies of the Association, and for formulating AARP's overall strategic direction. He also leads AARP's active program of International idea exchanges and conferences. He is a frequent speaker on Medicare, managed care, long-term care, Social Security, pensions and the challenges facing the boomer generation. Prior to coming to AARP in 1984, Mr. Rother served eight years with the U.S. Senate as Special Counsel for Labor and Health to former Senator Jacob Javits (R-NY), then as Staff Director and Chief Counsel for the Special Committee on Aging under its Chairman, Senator John Heinz (R-PA). He serves on several Boards and Commissions, including Generations United, the Leadership Council of Aging Organizations, and the National Quality Forum. He also serves on the boards of Pension Rights Center, the Alliance for Healthcare Reform, and the American Board of Internal Medicine Foundation and on advisory boards to Kaiser Permanente, Google, and several congressional fellowships. In June 2010, John received the prestigious Robert Ball Award for Outstanding Achievements in Social Insurance from the National Academy of Social Insurance, honoring his lifetime of advocacy to strengthen the Social Security and Medicare programs. John Rother is an honors graduate of Oberlin College and the University Of Pennsylvania School Of Law.

John W. Rowe, MD is a Professor in the Department of Health Policy and Management at the Columbia University Mailman School of Public Health. Previously, from 2000 until his retirement in late 2006, Dr. Rowe served as Chairman and CEO of Aetna, Inc. Before his tenure at Aetna, from 1998 to 2000, Dr. Rowe served as President and Chief Executive Officer of Mount Sinai NYU Health, one of the nation's largest academic health care organizations. From 1988 to 1998, prior to the Mount Sinai-NYU Health merger, Dr. Rowe was President of the Mount Sinai Hospital and the Mount Sinai School of Medicine in New York City. Before joining Mount Sinai, Dr. Rowe was a Professor of Medicine and the founding Director of the Division on Aging at the Harvard Medical School, as well as Chief of Gerontology at Boston's Beth Israel Hospital. He has authored over 200 scientific publications, mostly on the physiology of the aging process, including a leading textbook of geriatric medicine, in addition to more recent publications on health care policy. Dr. Rowe was Director of the MacArthur Foundation Research Network on Successful Aging and is co-author, with Robert Kahn, Ph.D., of Successful Aging (Pantheon, 1998). Currently, Dr. Rowe leads the MacArthur Foundation's Network on An Aging Society and chairs the Institute of Medicine's Committee on the Future Health Care Workforce for Older Americans. He has served as president of the Gerontological Society of America and recently chaired the Committee of the Institute of Medicine of the National Academy of Sciences on The Future Health Care Workforce Needs of An Aging Population. Dr. Rowe was elected a Fellow of the American Academy of Arts and Sciences and a member of the Institute of Medicine of the National Academy of Sciences where he is involved in the Evidence Based Roundtable. Dr. Rowe serves on the Board of Trustees of the Rockefeller Foundation and is Chairman of the Board of Trustees at the Marine Biological Laboratory in Woods Hole, Massachusetts. Dr Rowe is a former member of the Medicare Payment Advisory Commission (MedPAC).

Susan B. Shurin, MD is the Acting Director, National Heart, Lung, and Blood Institute (NHLBI). She joined NHLBI in 2006 as the Deputy Director, and has been Acting Director since December 2009. She is responsible for the scientific and administrative management of the intramural and extramural activities of the NHLBI, and oversight of the Institute's clinical research portfolio. Dr. Shurin represents the NHLBI in activities across the National Institutes of Health (NIH) and the Department of Health and Human Services. The NHLBI, third largest of the 27 Institutes and Centers at NIH, has an annual budget of over \$3.1 billion, and manages a complex portfolio of basic, clinical, translational and epidemiologic research. The bulk of the Institute's resources are allocated to support extramural research across the US and across the globe. Dr. Shurin is engaged in multiple trans-NIH research and administrative activities, and in global health research on non-communicable diseases. Before joining the NHLBI, Dr. Shurin was professor of Pediatrics and Oncology at Case Western Reserve University; director of Pediatric Hematology-Oncology at Rainbow Babies and Children's Hospital; director of Pediatric Oncology at the Case Comprehensive Cancer Center; and vice president and secretary of the Corporation at Case Western Reserve University in Cleveland, Ohio. Dr. Shurin received her education and medical training at Harvard University and the Johns Hopkins University School of Medicine. Her laboratory research focused on the physiology of phagocyte function, recognition and killing of pathogens; mechanisms of hemolysis; and iron overload. She has been active in clinical research in many aspects of pediatric hematology-oncology, including participation in the Children's Cancer Group, Children's Oncology Group, multiple studies in sickle cell disease and hemostasis.

Mark D. Smith, MD, MBA has been President and Chief Executive Officer of the California HealthCare Foundation since its formation in 1996. The Foundation is an independent philanthropy with assets of more than \$700 million, headquartered in Oakland, California and dedicated to improving the health of the people of California through its program areas: Better Chronic Disease Care, Innovations for the Underserved, Market and Policy Monitor, and Health Reform and Public Programs Initiative. A board-certified internist, Smith is a member of the clinical faculty at the University of California, San Francisco and an attending physician at the Positive Health Program (for AIDS care) at San Francisco General Hospital. He has been elected to the Institute of Medicine and serves on the board of the National Business Group on Health. Prior to joining the California HealthCare Foundation, Smith was Executive Vice President at the Henry J. Kaiser Family Foundation. He previously served as Associate Director of AIDS Services and Assistant Professor of Medicine and of Health Policy and Management at Johns Hopkins University. He has served on the

Performance Measurement Committee of the National Committee for Quality Assurance and the editorial board of the *Annals of Internal Medicine*. Smith received a Bachelor's degree in Afro-American studies from Harvard College, a Medical Doctorate from the University of North Carolina at Chapel Hill, and a Master's of Business Administration, with a concentration in Health Care Administration, from the Wharton School at the University of Pennsylvania.

Glenn D. Steele Jr, MD, PHD is President and Chief Executive Officer of Geisinger Health System. Dr. Steele previously served as the dean of the Biological Sciences Division and the Pritzker School of Medicine and as vice president for medical affairs at the University of Chicago, as well as the Richard T. Crane Professor in the Department of Surgery. Prior to that, he was the William V. McDermott Professor of Surgery at Harvard Medical School, president and chief executive officer of Deaconess Professional Practice Group, Boston, MA, and chairman of the department of surgery at New England Deaconess Hospital (Boston, MA). Widely recognized for his investigations into the treatment of primary and metastatic liver cancer and colorectal cancer surgery, Dr. Steele is past Chairman of the American Board of Surgery. He serves on the editorial board of numerous prominent medical journals. His investigations have focused on the cell biology of gastrointestinal cancer and pre-cancer and most recently on innovations in healthcare delivery and financing. A prolific writer, he is the author or co-author of more than 476 scientific and professional articles. Dr. Steele received his bachelor's degree in history and literature from Harvard University and his medical degree from New York University School of Medicine. He completed his internship and residency in surgery at the University of Colorado, where he was also a fellow of the American Cancer Society. He earned his PhD in microbiology at Lund University in Sweden. He is a member of the Institute of Medicine of the National Academy of Sciences and served on their Committee on Reviewing Evidence to Identify Highly Effective Clinical Services (HECS), the New England Surgical Society, a fellow of the American College of Surgeons, the American Surgical Association, the American Society of Clinical Oncology, and past president of the Society of Surgical Oncology. He was a member of the National Advisory Committee for Rural Health, the Pennsylvania Cancer Control Consortium and is presently a member of the Healthcare Executives Network, the Commonwealth Fund's Commission on a High Performance Health System, and served as a member of the National Committee for Quality Assurance's (NCQA) Committee on Performance Measurement. Dr. Steele serves on several boards including Bucknell University's Board of Trustees, Temple University School of Medicine's Board of Visitors, Premier, Inc (Vice Chair), Weis Markets, Inc., and Wellcare Health Plans, Inc. Dr. Steele was recently appointed to serve on The Hospital & Healthsystem Association of Pennsylvania (HAP) Board of Directors, the Harvard Medical Faculty Physicians Board at Beth Israel Deaconess Medical Center and Cepheid's Board of Directors. Dr. Steele previously served on the American Hospital Association's Board of Trustees, Executive Committee, the AHA Systems Governing Council (Chair), and the AHA Long-Range Policy Committee. He will serve as a member on the AHA Committee on Research. Dr. Steele is currently Honorary Chair of the Pennsylvania March of Dimes Prematurity Campaign, served on the Healthcare Financial Management Association's Healthcare Leadership Council, the Northeast Regional Cancer Institute, the Global Conference Institute, and previously served on the Simon School of Business Advisory Board (University of Rochester) 2002 -2007. In 2006 Dr. Steele received the CEO IT Achievement Award, given by Modern Healthcare and the Healthcare Information and Management Systems Society (HIMSS) for promoting health information technology. In 2007, Dr. Steele received AHA's Grassroots Champion Award and was named to Modern Healthcare's 50 Most Powerful Physician Executives in Healthcare. He was recognized by "Modern Healthcare's 100 Most Powerful People in Healthcare" in 2009 and 2010. Dr. Steele received the 8th Annual 2010 AHA Health Research & Education Trust Award. The HRET award honors individuals who exhibit visionary leadership in healthcare and who symbolize HRET's mission of leveraging research and education to make a dramatic impact in policy and practice. Dr. Steele was awarded the HFMA Board of Directors' Award in 2011.

Marilyn Tavenner is currently the Acting Administrator for the Centers for Medicare & Medicaid Services. Previously, Ms. Tavenner was Principal Deputy Administrator for the Centers for Medicare & Medicaid Services (CMS). As the Principal Deputy Administrator, Ms. Tavenner served as the agency's second-ranking official overseeing policy development and implementation as well as management and operations.

Ms. Tavenner, a life-long public health advocate, manages the \$820 billion federal agency, which ensures health care coverage for 100 million Americans, with 10 regional offices and more than 4,000 employees nationwide. CMS administers Medicare, and it provides funds and guidance to all states for their Medicaid and Children's Health Insurance (CHIP) programs. With the passage of the Affordable Care Act in March of 2010, Ms. Tavenner is also responsible for overseeing CMS as it implements the insurance reforms and Affordable Insurance Exchanges included in the health reform law. Prior to assuming her CMS leadership role, Ms. Tavenner served for four years as the Commonwealth of Virginia's Secretary of Health and Human Resources in the administration of former Governor Tim Kaine. In this top cabinet position, she was charged with overseeing 18,000 employees and a \$9 billion annual budget to administer Medicaid, mental health, social services, public health, aging, disabilities agencies, and children's services. Before entering government service, Ms. Tavenner spent 25 years working for the Hospital Corporation of American (HCA). She began working as a nurse at the Johnson-Willis Hospital in Richmond, Va., in 1981 and steadily rose through the company. By 1993, she began working as the hospital's Chief Executive Officer and, by 2001, had assumed responsibility for 20 hospitals as President of the company's Central Atlantic Division. She finished her service to HCA in 2005 as Group President of Outpatient Services, where she spearheaded the development of a national strategy for freestanding outpatient services, including physician recruitment and real estate development. Ms. Tavenner holds a bachelor's of science degree in nursing and a master's degree in health administration, both from the Virginia Commonwealth University. She has worked with many community and professional organizations, serving as a board member of the American Hospital Association, as president of the Virginia Hospital Association, as chairperson of the Chesterfield Business Council, and as a life-long member of the Rotary Club. Her contributions also include providing leadership in such public service organizations as the March of Dimes, the United Way and the Juvenile Diabetes Research Foundation. In addition to numerous business awards, Ms. Tavenner has been recognized for her volunteer activities, including the 2007 recipient of the March of Dimes Citizen of the Year Award.

Reed V. Tuckson, MD, FACP is a graduate of Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania's General Internal Medicine Residency and Fellowship Programs. He is currently the Executive Vice President and Chief of Medical Affairs at UnitedHealth Group, a Fortune 25 diversified health and well-being company. As the most senior clinician, Dr. Tuckson is responsible for working with all the company's diverse and comprehensive business units to improve the quality and efficiency of the health services provided to the 75 million members that UnitedHealth Group is privileged to serve worldwide. Formerly, Dr. Tuckson served as Senior Vice President, Professional Standards, for the American Medical Association (AMA); is former President of the Charles R. Drew University of Medicine and Science in Los Angeles; and he is a former Commissioner of Public Health for the District of Columbia. He is an active member of the prestigious Institute of Medicine of the National Academy of Sciences. Recently, he was appointed to the National Institute of Health's Advisory Committee to the Director and the Department of Health and Human Services' Health Information Technology (HIT) Policy Committee - Enrollment Workgroup. He is immediate past Chair of the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society. Dr. Tuckson has also held other federal appointments, including cabinet level advisory committees on health reform, infant mortality, children's health, violence, and radiation testing. Dr. Tuckson currently serves on the Board of Directors for several national organizations including the National Hispanic Medical Association; the Alliance for Health Reform; the American Telemedicine Association; the National Patient Advocate Foundation; the Macy Foundation; the Arnold P. Gold Foundation; Project Sunshine and Howard University.

Mary Wakefield, PhD, RN was named administrator of the Health Resources and Services Administration (HRSA) by President Barack Obama on February 20, 2009. Dr. Wakefield joins HRSA from the University of North Dakota (UND), where she was associate dean for rural health at the School of Medicine and Health Sciences, a tenured professor, and director of the university's Center for Rural Health. Dr. Wakefield brings experience on Capitol Hill to her post at HRSA. In the 1990s, she served as chief of staff to two North Dakota senators: Kent Conrad (D) and Quentin Burdick (D). She also has served as director of the Center for Health Policy, Research and Ethics at George Mason University in Fairfax, Va., and worked on site as a consultant to the World Health Organization's Global Programme on AIDS in Geneva, Switzerland. Dr. Wakefield is a fellow in the American Academy of Nursing and was elected to the Institute of Medicine (IOM) of the National Academies in 2004. She served on the IOM committee that produced the landmark reports To Err is Human and Crossing the Quality Chasm. She also co-chaired the IOM committee that produced the report Health Professions Education, and chaired the committee that produced the report Quality through Collaboration: Health Care in Rural America. In addition, she has served on the Medicare Payment Advisory Commission, as chair of the National Advisory Council for the Agency for Healthcare Research and Quality, as a member of President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, and as a member of the National Advisory Committee to HRSA's Office of Rural Health Policy. At UND, Dr. Wakefield also was director of the Rural Assistance Center, a HRSA-funded source of information on rural health and social services for researchers, policymakers, program managers, project officers and the general public. In addition, the Center for Rural Health administered a \$1.6 million award from HRSA under the Critical Access Hospital Health Information Technology Implementation program. Dr. Wakefield is a native of Devils Lake, N.D. She has a bachelor of science degree in nursing from the University of Mary in Bismarck and master's and doctoral degrees in nursing from the University of Texas at Austin.

Jonathan Woodson, MD is the Assistant Secretary of Defense for Health Affairs and director, TRICARE Management Activity. In this role, he administers the more than \$50 billion Military Health System (MHS) budget and serves as principal advisor to the Secretary of Defense for health issues. The MHS comprises over 133,000 military and civilian doctors, nurses, medical educators, researchers, healthcare providers, allied health professionals, and health administration personnel worldwide, providing our nation with an unequalled integrated healthcare delivery, expeditionary medical, educational, and research capability. Dr. Woodson ensures the effective execution of the Department of Defense (DoD) medical mission. He oversees the development of medical policies, analyses, and recommendations to the Secretary of Defense and the Undersecretary for Personnel and Readiness, and issues guidance to DoD components on medical matters. He also serves as the principal advisor to the Undersecretary for Personnel and Readiness on matters of chemical, biological, radiological, and nuclear (CBRN) medical defense programs and deployment matters pertaining to force health. Dr. Woodson co-chairs the Armed Services Biomedical Research Evaluation and Management Committee, which facilitates oversight of DoD biomedical research. In addition, Dr. Woodson exercises authority, direction, and control over the Uniformed Services University of the Health Sciences (USUHS); the Defense Center of Excellence for Psychological Health and Traumatic Brain Injury (DCoE); and the Armed Services Blood Program Office. As Director, TRICARE Management Activity, Dr. Woodson is responsible for managing all TRICARE health and medical resources, and supervising and administering TRICARE medical and dental programs, which serve more than 9.6 million beneficiaries. Dr. Woodson also oversees the TRICARE budget; information technology systems; contracting process; and directs TRICARE Regional Offices (TRO). In addition, he manages the Defense Health Program (DHP) and the DoD Unified Medical Program as TRICARE director. Prior to his appointment by President Obama, Dr. Woodson served as Associate Dean for Diversity and Multicultural Affairs and Professor of Surgery at the Boston University School of Medicine (BUSM), and senior attending vascular surgeon at Boston Medical Center (BMC). Dr. Woodson holds the rank of brigadier general in the U.S. Army Reserve, and served as Assistant Surgeon General for Reserve Affairs, Force Structure and Mobilization in the Office of the Surgeon General, and as Deputy Commander of the Army Reserve Medical Command. Dr. Woodson is a graduate of the City College of New York and the New York University School of Medicine. He received his postgraduate medical education at the Massachusetts General Hospital, Harvard Medical School and completed residency training in internal medicine, and general and vascular surgery. He is board certified in internal medicine, general surgery, vascular surgery and critical care surgery. He also holds a Master's Degree in Strategic Studies (concentration in strategic leadership) from the U.S. Army War College. In 1992, he was awarded a research fellowship at the Association of American Medical Colleges Health Services Research Institute. He has authored/coauthored a number of publications and book chapters on vascular trauma and outcomes in vascular limb salvage surgery. His prior military assignments include deployments to Saudi Arabia (Operation Desert Storm), Kosovo, Operation Enduring Freedom and Operation Iraqi Freedom. He has also served as a Senior Medical Officer with the National Disaster Management System, where he responded to the September 11th attack in New York City. Dr. Woodson's military awards and decorations include the Legion of Merit, the Bronze Star Medal, and the Meritorious Service Medal (with oak leaf cluster). In 2007, he was named one of the top Vascular Surgeons in Boston and in 2008 was listed as one of the Top Surgeons in the U.S. He is the recipient of the 2009 Gold Humanism in Medicine Award from the Association of American Medical Colleges.



ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

Other Participant Biographies

Rodney C. Armstead, MD, FACP is a dedicated health care professional committed to driving highest quality and cost effective health care to all Americans. He is presently on the Executive Operating Council for Optum, a UnitedHealth Group company delivering integrated, intelligent solutions that work to truly modernize the health care system and improve overall individual and population health. He is leading Optum's initiatives focused on improving care provider collaboration, patient care quality and population health in communities. Most recently, Dr. Armstead was the President of Northeast Region Plan Operations for UnitedHealthcare, Community & State a business unit of UnitedHealth Group. Dr. Armstead, a board certified general internist, was appointed the first Director, Office of Managed Care, HCFA, Department of Health & Human Services for the William J. Clinton Administration and held the position of Executive Vice President & Chief Health Officer for the WattsHealth Foundation in Los Angeles prior to joining UnitedHealthcare. He also served as the Senior Vice President of the Western Region Plan Operations prior to his current executive role. Dr. Armstead is very active in the community and volunteers his time promoting education. He is a board of trustee for the Liberty Science Center in Jersey City, New Jersey and a Clinical Associate Professor of Medicine at the University of Arizona, College of Medicine, Phoenix campus. Dr. Armstead received his undergraduate degree from the University of California, Irvine and his medical degree from Michigan State University College of Human Medicine, and is a member of the Alpha Omega Alpha Honor Medical Society and a fellow of the American College of Physicians. Dr. Armstead presently resides in Englewood, New Jersey with his wife Tana.

Kathleen A. Buto is Vice President for Health Policy, Government Affairs, at Johnson & Johnson. She has responsibility for providing policy analysis and developing positions on a wide range of issues, including the Medicare drug benefit, government reimbursement, coverage of new technologies, and regulatory requirements. In addition to reviewing how federal, state, and international government policies affect Johnson & Johnson products and customers, she is responsible for helping to identify areas of opportunity for J&J to take leadership in shaping health care policy. Prior to joining J&J, Kathy was a senior health adviser at the Congressional Budget Office, helping to develop the cost models for the Medicare drug benefit. Before that, she spent more than 18 years in senior positions at the Health Care Financing Administration, including Deputy Director, Center for Health Plans and Providers, and Associate Administrator for Policy. In these positions, she headed the policy, reimbursement, research, and coverage functions for the agency, as well as managing Medicare's fee-for-service and managed care operations. Kathy received her Bachelor of Arts from Douglass College and her Masters in Public Administration from Harvard University.

Patrick Conway, MD, MSc is Chief Medical Officer for the Centers for Medicare & Medicaid Services (CMS) and Director of the Office of Clinical Standards and Quality. This office is responsible for all quality measures for CMS, value-based purchasing programs, quality improvement programs in all 50 states, clinical standards and survey and certification of Medicare and Medicaid health care providers across the nation, and all Medicare coverage decisions for treatments and services. The office budget exceeds \$1.5 billion annually and is a major force for quality and transformation across Medicare, Medicaid, CHIP, and the U.S. health care system. Previously, he was Director of Hospital Medicine and an Associate Professor at Cincinnati Children's Hospital. He was also AVP Outcomes Performance, responsible for leading measurement, including the electronic health record measures, and facilitating improvement of health outcomes across the health care system. Previously, he was Chief Medical Officer at the Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Planning and Evaluation. In 2007-08, he was a White House Fellow assigned to the Office of Secretary in HHS and the Director of the Agency for Healthcare Research and

Quality. As Chief Medical Officer, he had a portfolio of work focused primarily on quality measurement and links to payment, health information technology, and policy, research, and evaluation across the entire Department. He also served as Executive Director of the Federal Coordinating Council on Comparative Effectiveness Research coordinating the investment of the \$1.1 billion for CER in the Recovery Act. He was a Robert Wood Johnson Clinical Scholar and completed a Master's of Science focused on health services research and clinical epidemiology at the University of Pennsylvania and Children's Hospital of Philadelphia. Previously, he was a management consultant at McKinsey & Company, serving senior management of mainly health care clients on strategy projects. He has published articles in journals such as *JAMA*, *New England Journal of Medicine, Health Affairs*, and *Pediatrics* and given national presentations on topics including health care policy, quality of care, comparative effectiveness, hospitalist systems, and nurse staffing. He is a practicing pediatric hospitalist, completed pediatrics residency at Harvard Medical School's Children's Hospital Boston, and graduated with High Honors from Baylor College of Medicine. He is married with three children.

Victor J. Dzau, MD was appointed chancellor for health affairs at Duke University and president and CEO of Duke University Health System effective July 1, 2004. He is also the James B. Duke Professor of Medicine and director of molecular and genomic vascular biology at Duke. Before coming to Duke, Dzau was the Hersey Professor of the Theory and Practice of Physic (Medicine) at Harvard Medical School, chairman of the Department of Medicine at Brigham and Women's Hospital, and physician in chief and director of research at Brigham and Women's Hospital, Boston. Prior to his work at Harvard and Brigham and Women's, he served as Arthur Bloomfield Professor and chairman of the Department of Medicine at Stanford University. Dzau's academic interests are in cardiovascular translational research and mission-based education. He is particularly interested in eliminating health disparities among underrepresented populations and the socioeconomically disadvantaged both at home and abroad. In 2001, together with Paul Farmer, MD, Dzau guided the creation of a new Division of Social Medicine and Health Inequalities at the Brigham and Women's Hospital of Harvard Medical School to reduce disparities and improve health care through training, research, education, and service. Since becoming chancellor for health affairs at Duke in July 2004, he has been actively working with university leaders to establish a campus-wide, multidisciplinary global health initiative that will draw on Duke resources to improve medical care for the underserved locally, nationally, and internationally. The recipient of many awards and honors, Dzau received the first Hatter Award from the Medical Research Council of South Africa in 2000. He was awarded the prestigious Gustav Nylin Medal by the Swedish Royal College of Medicine and the Swedish Cardiology Society, the Novartis Award for Hypertension Research by the American Heart Association (which also named him one of its Distinguished Scientists for 2004), the 2004 Max Delbruck Medal by the Max Delbruck Center for Molecular Medicine, Berlin, Germany, the 2005 Golden Door Award by the International Institute of Boston, a 2005 Ellis Island Medal of Honor by the National Ethnic Coalition of Organizations, and the 2006 Robert H. Williams, MD, Award by the Association of Professors of Medicine. Dzau has served on numerous committees and advisory boards, including, previously, the Executive Committee of The Academy at Harvard Medical School (of which he is a founding member) and the boards of Stanford Health System, Brigham and Women's Hospital, Partners Healthcare, and the Harvard Clinical Research Institute. Currently, he serves as a member of the Board of Directors for Duke University Health System and Genzyme Corporation. He has been elected to the Institute of Medicine of the National Academy of Sciences (USA) and the European Academy of Sciences and Arts. Previous chairman of the National Institutes of Health (NIH) Cardiovascular Disease Advisory Committee, he served on the Advisory Committee to the Director of the NIH. In 1999 he became editor in chief for the American Physiological Society's new journal, Physiological Genomics. A founding member of the Society of Vascular Medicine and Biology and the Council of Arteriosclerosis, Thrombosis, and Vascular Biology of the American Heart Association, Dzau was editor in chief of the Journal of Vascular Medicine and Biology. Dzau received his MD degree from McGill University Faculty of Medicine in Montreal and underwent postgraduate training at Harvard Medical School. He was born in Shanghai, China, raised in Hong Kong, and is a citizen of the United States.

A. Mark Fendrick, MD is a Professor of Internal Medicine in the School of Medicine and a Professor of Health Management and Policy in the School of Public Health at the University of Michigan. Dr. Fendrick received a bachelor's degree in economics and chemistry from University of Pennsylvania and his medical degree from Harvard Medical School. Dr. Fendrick completed his residency in internal medicine at the University of Pennsylvania where he was a fellow in the Robert Wood Johnson Foundation Clinical Scholars Program. He currently co-directs the Center for Value-Based Insurance Design at the University of Michigan [www.vbidcenter.org], the leading advocate for development, implementation and evaluation of innovative health benefit plans. Dr. Fendrick's research focuses on the clinical and economic assessment of medical interventions with special attention to how technological innovation influences clinical practice, benefit design, and health care systems. He has authored over 200 articles and book chapters and lectures frequently on the quality and cost implications of medical care to diverse audiences around the world. Dr. Fendrick remains clinically active in the practice of general internal medicine. He is the Co-editor in chief of the American Journal of Managed Care and is an editorial board member for 3 additional peer-reviewed publications. His perspective and understanding of clinical and economic issues have fostered collaborations with numerous government agencies, health plans, professional societies, and health care companies. He serves on the Medicare Coverage Advisory Committee. In 2009, he was named one of the "20 people who make healthcare better" by HealthLeaders Media for the creation and implementation of value-based insurance design.

Irene Fraser, PhD is a political scientist who has specialized in research on Medicaid, private health insurance, and health care delivery. Since 1995, she has been at the Agency for Healthcare Research and Quality, where she is Director of the Center for Delivery, Organization, and Markets. The focus of this Center and Dr. Fraser's current work is on improving the quality and value of health care by improving the organization, structure, and financing of health care organizations and markets. The Center develops and maintains measures of quality and efficiency, and leads and supports research on financial and organizational strategies to improve quality and value. In addition, the Center manages two large-scale mechanisms to facilitate implementation of evidence-based strategies: A provider-based research and implementation network (Accelerating Change and Transformation in Organizations and Networks II, or ACTION II) with 17 large partnerships across the country, and a national network of 24 multi-stakeholder community quality collaborative, the Chartered Value Exchanges. The Center also manages the Healthcare Cost and Utilization Project (HCUP), a public-private partnership with 46 state data organizations that encompasses standardized data from over 95% of all hospital inpatient stays, along with emergency department and ambulatory surgery data from over half of the states. The inpatient and emergency department data are used extensively in research and policy analyses focused on hospital quality and costs, as well as studies of potentially preventable admissions and the cost of patient safety events in hospitals. Dr. Fraser also spent eight years working on access and delivery issues at the American Hospital Association. As Senior Associate Director for Policy at the American Hospital Association, she served as the issue manager and senior policy person on indigent care, Medicaid and health care reform. As Director of Ambulatory Care at the AHA, she led a group which focused on the delivery side of health care reform-managed care and integrated delivery, preventive care, home care, primary care, and other ambulatory care issues. Earlier in her career, Dr. Fraser was Associate Professor of Political Science and director of the Public Policy Program at Barat College and adjunct faculty to the Institute for Health Law at Lovola School of Law. Dr. Fraser's work has appeared in journals including Health Affairs, Inquiry, Health Care Financing Review, Medical Care Research and Review, Journal of Healthcare Management, Journal of Ambulatory Care Management, Health Services Research, and Journal of Health Politics, Policy and Law. A monograph series on the uninsured includes volumes on state Medicaid expansions, programs to promote private health coverage for the employed uninsured, and uncompensated care pools. Dr. Fraser has a B.A. in Political Science and Spanish from Chatham College, and a Ph.D. in Political Science from the University of Illinois.

Kate Goodrich, MD joined the Center for Medicare and Medicaid Services in September of 2011 where she serves as a senior technical advisor to the Director of the Office of Clinical Standards and Quality and Chief Medical Officer of CMS. In this role, she provides leadership on quality measurement programs and oversees an HHS-wide effort to align measures across programs and with the private sector. Prior to coming to CMS, Dr. Goodrich served as a Medical Officer in the office of the Assistant Secretary for Planning and Evaluation (ASPE). She managed the portfolio of ASPE Comparative Effectiveness Research (CER) projects, including the creation of a multi-payer claims database for CER. She was also the project manager for the HHS contract with the National Quality Forum. Kate received her M.D. from Louisiana State University Medical Center in Shreveport, LA in 1995. She then moved to Washington, D.C. and completed her residency in Internal Medicine at George Washington University Medical Center whereupon she joined the faculty of GWUMC as a hospitalist in the Department of Medicine. A new Division of Hospital Medicine was created in 2005, and Dr. Goodrich was appointed Division Director. From 2005 to 2008 she expanded this division to 9 full time hospitalists and started a Physician's Assistant hospitalist program. She also served as Chair of the Institutional Review Board at GWUMC for 5 years. Dr. Goodrich is a graduate of the Robert Wood Johnson Clinical Scholars Program at Yale University where she received training in health services research and health policy. She continues to practice clinical medicine as a hospitalist and assistant professor of medicine at George Washington University Hospital.

John Haaga, PhD has served since October 2004 as Deputy Director of the Division of Behavioral and Social Research of the National Institute on Aging. He helps lead NIA's extramural program, funding research in economics, demography, epidemiology, cognitive science, behavioral and population genetics, behavioral medicine, and health services related to aging. This program includes major data collection and dissemination in the United States and cross-national comparative research on global health and aging. He also teaches courses on demography and public policy at the School of Public Policy at the University of Maryland, and has previously taught at Georgetown University and the Defense Intelligence College. Before joining NIA, he was Director of Domestic Programs and of the NIH-funded Center for Public Information on Population Research at the Population Reference Bureau, a nonprofit research and education organization. During 1994-97 he was staff director for the Committee on Population of the National Academy of Sciences, where he led projects on the demography of aging and the global demographic transition. He has served as President of the Association of Population Centers and Secretary-Treasurer of the Population Association of America. From 1991 to 1994 he directed extension research in family planning and maternal and child health at the International Centre for Diarrhoeal Disease Research, Bangladesh. During the 1980s, Dr. Haaga was a Policy Analyst in the Health and Population programs at RAND and a Research Associate for the Cornell University International Nutrition program. His PhD in Public Policy was awarded by the RAND Graduate School, and he has a BA (first-class honors) in Modern History from Oxford University and an MA in International Relations from Johns Hopkins University.

Yael Harris, PhD, MHS is Director of HRSA's Office of Health IT & Quality at the Health Resources & Services Administration. In this role, she supports HRSA in efforts to improve the quality of care for safety net providers through the use of information technology. Prior to her arrival at HRSA, Dr. Harris was Director of Evaluation for the Office of the National Coordinator for Health IT (ONC) where she led the national measurement of EHR adoption and oversaw evaluation of HITECH programs. Dr. Harris also served as staff lead for the Health IT Policy Council's Meaningful Use workgroup. Prior to joining the ONC, Dr. Harris worked for the Centers for Medicare and Medicaid Services where she led efforts on measurement and quality improvement in long term and post acute care. Before joining the federal government, Dr. Harris worked for a congressional advisory body, Georgetown University's Institute for Health Care Policy and Research, and served as an advisor to lead staff on the House Ways and Means Subcommittee on Health. She holds a doctorate in public policy from the University of Maryland and a masters degree in health sciences from Johns Hopkins University. Dr. Harris is an associate professor at the Erickson School of Aging where she teaches courses on technology and aging services.

Peter Hussey, PhD is a policy researcher at the RAND Corporation. His research focuses on innovations in health care payment and delivery. Dr. Hussey is currently engaged in studies of bundled payment, episodebased performance measurement, patient-centered medical homes, clinical decision support, care coordination, and health care efficiency measurement. Prior to joining RAND, Dr. Hussey worked at the Organization for Economic Cooperation and Development in Paris, France. Dr. Hussey received his doctorate in Health Policy and Management from the Johns Hopkins Bloomberg School of Public Health.

Emily Jones, MPP, PhD [candidate] is a Public Health Analyst in the Office of Quality and Data in the Health Resources and Services Administration's Bureau of Primary Health Care. The Bureau of Primary Health Care administers the Health Center Program that supports the health care safety net for many underserved people across the country. The Health Center Program includes over 8,000 community health centers and clinics, migrant health centers, health care for the homeless centers, and public housing primary care centers. Located in communities nationwide, these sites provide comprehensive, culturally competent, quality primary health care to more than 19 million people. Prior to joining HRSA, Emily was the Associate Director of the Geiger Gibson/RCHN Research Collaborative at George Washington University and the Assistant Director of the Outstanding Scholar Program in the Bureau of Competition at the Federal Trade Commission. She has also served as a researcher at the Urban Institute and the Georgetown Health Policy Institute. Emily earned her Bachelor of Arts degree in Organizational Behavior and Management, with Honors, from Brown University and her Masters in Public Policy from Georgetown University. She is currently working on her Doctorate in Public Policy and Public Administration at George Washington University.

Page Kranbuhl is the Vice President of U.S. Government Affairs for Stryker Corporation, a global medical technology company that offers a diverse array of innovative medical technologies, including reconstructive, medical and surgical, and neurotechnology and spine products to help people lead more active and more satisfying lives. Page joined Stryker from the Office of U.S. Senator Lamar Alexander where she served as the Senator's Senior Health Policy Advisor and worked on his Health, Education, Labor and Pensions (HELP) Subcommittee. Prior to that, Page was Legislative Director and Health Policy Advisor for former U.S. Congressman Ed Bryant. Page also worked for VHA Inc. as a Government Relations Representative where she served as a liaison with Congress, the White House, the Department of Health and Human Services, and the Food and Drug Administration.

Peter M. Loupos has been responsible for providing the vision, strategy, and leadership for innovative largescale technology initiatives in the pharmaceutical and healthcare industries. Peter began his career in the field of Health Information Technology where he led the development of clinical, financial, and physician services in the US, Europe, and Japan. He joined Rorer Pharmaceutical to lead the R&D Information Technology organization, growing in responsibility through successive mergers until the creation of Sanofi-Aventis. During this time he was recognized for his achievements in the design and delivery of industry leading solutions to support the life sciences. He then joined the Strategic Initiatives group focusing on the assessment and response to trends impacting the Pharmaceutical industry. He was a co-author of a PhRMA white paper documenting the potential impact of eHealth for the industry and has contributed to numerous initiatives such as the Observational Medical Outcomes Partnership, IMI Electronic Healthcare Records for Clinical Research, and Coalition Against Major Diseases. Peter is currently a member of the Advocacy team where his focus is to develop strategies and relations with patient groups to accelerate science and innovation in support of key platforms such as patient centered research, translational and personalized medicine, new approaches in clinical development, and open innovation collaboration models. He also is a member of the corporate Digital Steering Committee chartered to develop the social media strategy and policies for the company and leads the eHealth subgroup of this committee.

Roger C. Merrill, MD is the Chief Medical Officer at Perdue Farms, the Nation's 3rd largest integrated poultry processing company with 18 major processing facilities in 12 states employing 20,000 associates. Dr. Merrill's achievements include the development of an integrated health care delivery system in rural areas serving 35,000 lives. The system has a strong emphasis on primary care with on-site Patient-Centered Medical Home clinics. Dr. Merrill also created and implemented a proprietary Health Improvement Program (HIP), which includes a health risk appraisal with associated biometrics driving a "Personal Plan for Health." That Plan is characterized by identification of the most dangerous modifiable risks personalized to each individual. This national award-winning program has resulted in a 2-3 fold improvement (vs. national statistics) in control of diabetes, hypertension, and other measurable health endpoints in the population. Additionally, Dr. Merrill created and implemented a ground-breaking evidence-based plan design that uses drivers to move members to care with proven value and away from interventions with proven population negative value. Proven results are that members have responded appropriately to those drivers and are following evidence-based interventions at a much higher rate than non-participants. The measured health status is higher and has improved more in this plan than in the other plans. As a result of these interventions, Perdue has experienced a medical inflation rate and a per capita cost well below national averages, and measurably improved health status for Perdue associates. Dr. Merrill is a widely sought-after speaker and has presented at such venues as the Patient -Centered Primary Care Collaborative, the World Health Congress, Keynote speaker at the American Academy of Family Physicians annual Scientific Meeting, the Louisiana Health Care Quality Foundation, the Patient-Centered Primary Care Collaborative, the Ohio Employer Coalition, the National Governors' Association, and the National Business Group on Health.

Nancy E. Miller, PhD serves as Senior Science Policy Analyst in the Office of Science Policy, Office of the Director, NIH, where she serves as principal staff advisor to the Director, NIH, on health care reform policy issues, and programmatic activities related to the agency's Comparative Effectiveness Research (CER) portfolio. She coordinates NIH Institute and Center (IC) efforts for the purpose of organizing meetings to address major programmatic and science policy research issues, conceptualizes the needs of ICs in crosscutting health care reform activities; prepares reports on ARRA-supported CER advances, and coordinates and provides senior level expert policy advice on development of complex collaborative CER activities with multiple organizations, senior NIH staff, and sister federal agencies. Dr. Miller serves as principal staff advisor to the Director, NIH on activities related to the Patient-Centered Outcomes Research Institute, (PCORI) a private, non-profit corporation, established by the Patient Protection and Affordable Care Act, to develop and fund CER. She supports the Director, NIH, in his role as a member on the Board of Governors (BOG) and on the Program Development Committee (PDC), and tracks PCORI Methodology Committee Subcommittee activities. She provides advice regarding research policy issues affecting both NIH and the national biomedical research community, coordinates with OD offices, and makes recommendations for establishing precedents and/or resolving technical and procedural problems. Dr. Miller directs activities of the Trans-NIH Comparative Effectiveness Coordinating Committee (CER CC) where she serves as the Committee's Executive Secretary. A high-level committee established by the Director, NIH, and co-chaired by the Director, National Institute on Aging, and NHLBI, the CER CC is tasked with reviewing and prioritizing CER spending decisions for the NIH Director, shaping and supporting the next generation of CER studies, integrating the promise of personalized medicine with CER, and advancing research methods and science to benefit health care reform. In addition to coordinating trans-NIH initiatives, Dr. Miller advises OD offices regarding the development of agency and DHHS-wide collaborative policy related to CER and health-care reform related research; provides monthly IC briefings; oversees policy development pertaining to ethical, legal, societal and health implications raised by CER, and facilitates collaboration on CER and health reform research activities with DHHS, and among sister federal agencies. She oversees requests for information on CER from Congress, DHHS, OMB, GAO, PCORI, federal contractors and from IC Directors. Dr. Miller has served as Executive Secretary of the Common Fund initiative on the "Science of Behavior Change," helped initiate the NIH Common Fund program on the "Patient-Reported Outcome Measurement Information System (PROMIS)", and contributes to the Common Fund "Health Economics Initiative to Advance Healthcare Reform."

Michael Painter, MD, PhD is a distinguished physician, attorney, health care policy advocate, 2003-2004 Robert Wood Johnson Health Policy Fellow, and a senior member of the RWJF Quality/Equality Team. In 2003-2004, Painter was a Robert Wood Johnson Foundation Health Policy Fellow with the office of Senator William Frist, former majority leader. Prior to that, he was the chief of medical staff at the Seattle Indian Health Board, a community health center serving urban American Indians and Alaska Natives. He is a member of the Cherokee Nation of Oklahoma, American Academy of Family Physicians, Association of American Indian Physicians, and California Bar Association. Painter earned a J.D. from Stanford Law School and an M.D. from the University of Washington. He earned a B.A. in economics and mathematics from Vanderbilt University.

Eric Racine, PharmD, MBA currently serves as the Vice President, Advocacy, North America Corporate Affairs for Sanofi. His department is accountable for strategic partnerships with the advocacy community. In his role, Eric addresses critical health issues by working at the intersection of customers and the healthcare ecosystem to improve patient health. He and his team are devoted to finding collaborative solutions and partnerships to achieving this goal. Since 2002, Dr. Racine has held multiple leadership positions within Sanofi spanning Pharmaceutical Operations, Market Access, Healthcare Policy, and Corporate Affairs. He has been instrumental in readying the company for changes stemming from the dynamic healthcare environment. Prior to joining the pharmaceutical industry, Dr. Racine held various positions in clinical pharmacy including academic, clinical, and management roles. In these roles, he improved patient outcomes and financial performance by developing and implementing new clinical programs that delivered enhanced quality of care while reducing overall healthcare costs. Dr. Racine has published abstracts, posters, peer-reviewed publications and book chapters. He also spoke on topics such as quality improvement and patient access. He is a member of boards and committees including the American Heart Association (AHA) New York Board of Directors, the American Foundation for Pharmacy Education (AFPE), and the National Dean Advisory Board for the University of Arizona, College of Pharmacy. In addition, Eric is the Treasurer for the National Health Council (NHC) Board of Directors. Eric holds a Doctor of Pharmacy (Pharm.D) and an Executive MBA degree. He and his wife are the parents of two children and reside in New Jersey.

Anthony D. Rodgers, MSPH has over 30 years of healthcare executive management experience in public and private health plans, hospital systems, and State and Federal Government. In March 2010, he was appointed by the Secretary for Health and Human Services to the position of CMS Deputy Administrator, Center for Strategic Planning. In addition to directing the Center for Strategic Planning he is responsible for the State Innovation Initiative Program funded by Center for Medicare and Medicaid Innovation. Previously Mr. Rodgers was a Principal with the national consulting firm Health Management Associates. Mr. Rodgers also held the position of Agency Director of the Arizona Health Care Cost Containment System (AHCCCS). In this role he reported to the Governor and was responsible for the Arizona Medicaid and Children Health Insurance Program. Mr. Rodgers has held positions as General Manager, WellPoint Health Networks, CEO LA Care Health Plan, Chief Executive Maricopa Integrated Healthcare System, Associate Hospital Administrator Olive View Medical Center, and Administrator, H. Claude Hudson Comprehensive Health Center. He also has been a member of numerous public commissions and Boards of Directors. Mr. Rodgers has a Master of Science Public Health degree and BA degree in Economics and Political Science from UCLA. He has held visiting professor appointments at Arizona State University, the W.P Carey School of Business and at UCLA School of Public Health.

Murray N. Ross, Ph.D. is Vice President, Kaiser Foundation Health Plan, Inc. and leads the Kaiser Permanente Institute for Health Policy in Oakland, California. Kaiser Permanente is the nation's largest private integrated health care delivery system, serving nine million people in nine states and the District of Columbia. The Institute seeks to leverage evidence and experience from Kaiser Permanente's operations to shape public policy and private practice. The Institute supports research, expert roundtables, and conferences all intended to increase understanding of policy issues and help identify solutions. Dr. Ross brings the valuable ability to absorb and synthesize complex health care issues, and to explain the practical implications of market developments and public policies to government leaders and health care industry decision makers.

He speaks frequently to domestic and international audiences on a wide range of health care topics. His current work focuses on how American health care can make better use of new medical technology and how public policy can encourage greater integration of care delivery to improve quality. Dr. Ross holds a number of external advisory positions. Before joining Kaiser Permanente in 2002, Dr. Ross was a policy advisor to the United States Congress. He served five years as the executive director of the Medicare Payment Advisory Commission, an influential nonpartisan agency that makes recommendations on Medicare policy to the Congress. Before that, he spent nine years at the Congressional Budget Office, ultimately leading the group charged with assessing the budgetary impact of legislative proposals affecting Medicare and Medicaid. Dr. Ross earned his doctorate in economics from the University of Maryland, College Park, and completed his undergraduate work in economics at Arizona State University. He enjoys distance running, writing, and traveling.

Joshua J. Seidman, PhD directs the Meaningful Use Division at ONC, overseeing three areas: helping to evolve meaningful use practice and policy; supporting providers through ONC's regional extension program to become meaningful users of health IT; and oversight of ONC's e-Quality Measurement agenda.

Previously, Seidman was the founding President of the Center for Information Therapy, which advanced the practice and science of delivering tailored information to consumers to help them make better health decisions and lead healthier lives. At the IxCenter, Seidman focused on stimulating innovation, diffusing best practices, and evangelizing for a patient-centered orientation to implementation of HIT applications. Before launching the IxCenter, Dr. Seidman served as Senior Editor and Director of Quality Initiatives for the Advisory Board Company's Consumer Health Initiative. In that capacity, he played a leading role in strategic planning and product development and provided leadership in the development of quality-of-care information for consumers. Dr. Seidman has worked for the National Committee for Quality Assurance (NCQA) as the Director of Measure Development, overseeing development of HEDIS. He has also worked at the Advisory Board Company as a Consultant and at the American College of Cardiology as Assistant Director of Private Sector Relations, conducting extensive research and analysis in managed care and qualityof-care issues. Dr. Seidman holds a PhD in health services research and a master of health science degree in health policy and management, both from the Johns Hopkins School of Public Health. His doctoral research involved the development of a tool to evaluate the quality of health information on the Internet and an assessment of what Web site characteristics influenced health information quality. He earned a bachelor of arts in political science from Brown University. For five years, Dr. Seidman volunteered as President of the board of directors for Micah House, a transitional house in Washington, D.C., for homeless women recovering from substance abuse. When he's not chasing after his three children, Seidman uses distance running as his own therapy of sorts, and has completed 34 marathons.

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 more than 35 years of experience in patient care, research and administration. He will identify strategic issues and opportunities for PCORI and implement and administer programs authorized by the PCORI Board of Governors. Building on the work of the Board and interim staff, Selby will lead the organizational development of PCORI. In addition to creating an organizational structure to carry out a national research agenda, Selby will lead PCORI's external communications, including work to establish effective two-way communication channels with the public and stakeholders about PCORI's work. Selby joined PCORI from Kaiser Permanente, Northern California, where he was Director of the Division of Research for 13 years and oversaw a department of more than 50 investigators and 500 research staff working on more than 250 ongoing studies. He was with Kaiser Permanente for 27 years. Selby has authored more than 200 peerreviewed articles and continues to conduct research, primarily in the areas of diabetes outcomes and quality improvement. His publications cover a spectrum of topics, including effectiveness studies of colorectal cancer screening strategies; treatment effectiveness, population management and disparities in diabetes mellitus; primary care delivery and quality measurement. Selby was elected to membership in the Institute of Medicine in 2009 and was a member of the Agency for Healthcare Research and Quality study section for Health Care Quality and Effectiveness from 1999-2003. A native of Fulton, Missouri, Selby received his medical degree

from Northwestern University and his master's in public health from the University of California, Berkeley. He was a commissioned officer in the Public Health Service from 1976-1983 and received the Commissioned Officer's Award in 1981. He serves as Lecturer in the Department of Epidemiology and Biostatistics, University of California, San Francisco School of Medicine, and as a Consulting Professor, Health Research and Policy, Stanford University School of Medicine. Selby was appointed PCORI executive director on May 16, 2011, and formally begins his duties on July 1, 2011.

Edward H. Shortliffe, MD, PhD is President and Chief Executive Officer of AMIA, the informatics professional association based in Bethesda, MD. His academic appointments are as Adjunct Professor of Biomedical Informatics at Columbia University's College of Physicians and Surgeons and at Arizona State University. Previously he was Professor of Biomedical Informatics at the University of Texas Health Science Center in Houston and, before that, at Arizona State University. He also served as the founding dean of the Phoenix campus of the University of Arizona's College of Medicine. From March 2007 to May 2008, he served as the founding dean of the Phoenix campus of the University of Arizona's College of Medicine. Before that he was the Rolf A. Scholdager Professor and Chair of the Department of Biomedical Informatics at Columbia College of Physicians and Surgeons in New York City (2000-2007) and Professor of Medicine and of Computer Science at Stanford University (1979-2000). After receiving an A.B. in Applied Mathematics from Harvard College in 1970, he moved to Stanford where he was awarded a Ph.D. in Medical Information Sciences in 1975 and an MD in 1976. During the early 1970s, he was principal developer of the medical expert system known as MYCIN. After internal medicine house-staff training at Massachusetts General Hospital and Stanford Hospital between 1976 and 1979, he joined the Stanford internal medicine faculty where he served as Chief of General Internal Medicine, Associate Chair of Medicine for Primary Care, and was director of an active research program in clinical information systems and decision support. He spearheaded the formation of a Stanford graduate degree program in biomedical informatics and divided his time between clinical medicine and biomedical informatics research. In January 2000 he assumed a new post at Columbia University, where he was also Deputy Vice President of Columbia University Medical Center and Senior Associate Dean of the College of Physicians and Surgeons for Strategic Information Resources, Professor of Medicine, Professor of Computer Science, and Director of Medical Informatics Services for the NewYork-Presbyterian Hospital. He continues to be closely involved with medical education and biomedical informatics graduate training. His research interests include the broad range of issues related to integrated decision-support systems, their effective implementation, and the role of the Internet in health care. Dr. Shortliffe is an elected member of the Institute of Medicine of the National Academy of Sciences, the American Society for clinical Investigation, and the American Clinical and Climatological Association. He is also been elected to fellowship in the American College of Medical Informatics and the American Association for Artificial Intelligence. He is Master of the American College of Physicians (ACP). He is Editor-in-Chief of the Journal of Biomedical Informatics, and serves on the editorial boards for several other biomedical informatics publications. In addition, he received the Grace Murray Hopper Award of the Association for computing and Machinery in 1976, the Morris F. Collen Award of the American College of Medical Informatics in 2006, and has been a Henry J. Kaiser Family Foundation Faculty Scholar in General Internal Medicine. Dr. Shortliffe has authored over 300 articles and books in the field of biomedical computing and artificial intelligence.

William Shrank, MD, MSHS, is the Director of the Rapid-Cycle Evaluation Group at the Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services. In this capacity, Dr. Shrank leads the evaluation efforts of programs supported by the Innovation Center to reduce the cost and improve the quality of care in the U.S. He also leads the intramural research enterprise at CMS. Prior to joining CMS, Dr. Shrank served as an Assistant Professor of Medicine at Harvard Medical School and an Associate Physician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital where he practiced Internal Medicine. His research is focused on improving the safe, appropriate and cost-effective use of prescription medications. His research interests also include evaluating quality in pharmacologic care, enhancing adherence to chronic medications, and improving prescription drug labels. Dr. Shrank serves or has served on national advisory committees for the FDA, AHRQ, CMS, USP,

and the American College of Physicians Foundation. He attended Brown University, received his M.D. from Cornell University, and trained in Internal Medicine at Georgetown University. He finished a health services research fellowship at UCLA, Rand, and the West Los Angeles VA Hospital where he earned an M.S. in Health Services.

Tom Valerio has worked in several industries where he has been responsible for designing and implementing major organizational transformation programs, strategic planning, and business performance management. He currently works for AstraZeneca and is responsible for Strategic Planning in the Americas Region comprising Canada, the US, and the countries of Latin America. Some of his responsibilities include business planning, development of the regional strategic objectives, and the processes to manage and deliver business performance. His prior responsibilities at AstraZeneca were as Director of Sales Strategy and Execution and Director of Brand and Portfolio planning where he had responsibility for managing the brand strategic planning and portfolio prioritization processes. He has held similar positions at other financial service firms, most notably CIGNA Property and Casualty and Guy Carpenter.

Matthew Wynia, MD, MPH, FACP is an internist and specialist in infectious diseases. He directs both the Institute for Ethics and the Center for Patient Safety for the American Medical Association. In these roles he oversees a wide range of research, education and outreach projects, on topics including: learning from medical errors, physician professionalism, ethics and epidemics, medicine and the holocaust, inequities in health and health care; and how demographics and technology are changing medical practice. Dr. Wynia is the author of more than 125 published articles, book chapters and reports and a book on fairness in health care benefit design. His work has been published in the *New England Journal of Medicine, JAMA, Health Affairs* and other leading medical and ethics journals. He is contributing editor for bioethics and public health at the *American Journal of Bioethics*. He has been a guest on *ABC News Nightline*, the *BBC World Service*, *NPR*, and other programs. In addition to his work at the AMA, Dr. Wynia is a past president of the American Society for Bioethics and Humanities (ASBH), and has chaired the Ethics Forum of the American Public Health Association (APHA) and the Ethics Committee of the Society for General Internal Medicine (SGIM). He cares for patients at the University of Chicago Hospital, where he is a Clinical Assistant Professor of Medicine in the Division of Infectious Diseases.

John Yee, MD, MPH serves as Vice President, and U.S. Head Medical Officer at AstraZeneca Pharmaceuticals. In this role, he is responsible for leading all medical affairs and strategic development activities in the U.S. Prior to joining AstraZeneca, John served as Vice President and Global Head, Evidence-Based Medicine at Genzyme as well as the head of Global, US, and European medical affairs for Genzyme's rare genetic disease business. John has also served in leadership roles at a major academic medical center, at health care technology start-up companies, and as a clinical research consultant to pharmaceutical, biotechnology, and medical device companies. Prior to joining industry, John was a member of the faculty at Harvard Medical School and Children's Hospital Boston. He is a graduate of Harvard College, and earned his medical degree from Harvard Medical School in addition to a master's degree in public health from the Harvard School of Public Health. He completed a residency in pediatrics and fellowships in immunology/rheumatology and health services research at Children's Hospital Boston.


Meeting Logistics

IOM Roundtable on Value & Science-Driven Health Care: Meeting 13

The Roundtable on Value & Science-Driven Health Care is looking forward to your participation on March 14, 2012. If you have any questions regarding meeting logistics, please contact our office at jcsanders@nas.edu or 202-334-3889.

LOCATION:

The meeting will be held from 8:30AM – 4:00PM on March 14, 2012 at the Keck Center of the National Academies in Washington, DC. The building is located at 500 5th Street, NW. While the agenda for this meeting has not been finalized, these times provide an accurate estimation for travel planning purposes. Breakfast will be served starting at 8:30am, with the meeting's official agenda commencing at 9:00am.

DIRECTIONS:

The meeting site is approximately 5 miles from Washington National Airport and approximately 30 miles from Dulles International Airport. Taxis are most easily hailed on E or F Streets.

The Gallery Place/Chinatown Metro station (YELLOW and GREEN lines) is two blocks away, and only a 15-minute ride from Washington National Airport.

1. Exit the station by following signs to Seventh and F Streets/Arena.

2. Turn LEFT and walk EAST on F Street NW, two blocks past the Verizon Center.

3. Turn RIGHT on to Fifth Street NW

4. Walk past the fire station parking lot. The next building on your right will be 500 Fifth St. NW

The **Judiciary Square Metro station (RED line)** is located one block away from the meeting site. Exit the station by following signs to the Building Museum (F Street) exit, between Fourth and Fifth Streets NW

1. Turn LEFT and walk WEST on F Street NW

2. Cross Fifth Street NW and turn LEFT.

3. Walk past the fire station parking lot. The next building on your right will be 500 Fifth St. NW