

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Roundtable on Value & Science-Driven Health Care



September 22, 2011
Keck Center, The National Academies
500 Fifth Street, NW
Washington, DC 20001

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- *Calling the Question—Health system leaders implementing what is known to work*.
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Clinical Effectiveness Research Innovation Collaborative

- *Health Disparities and the Learning Health System—A Proposed Project of the IOM Clinical Effectiveness Research Innovation Collaborative*.
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- Classen, David C and Bates, David W. *Finding the Meaning in Meaningful Use.* New England Journal of Medicine. 2011.
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- *Digital Infrastructure for the Learning Healthcare System: The Foundation for Continuous Improvement in Health and Health Care-Workshop Series Summary.* Appendix A. 2011.

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Agenda



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

MEMBERS MEETING

SEPTEMBER 22ND 2011
KECK CENTER
500 FIFTH ST., NW | WASHINGTON, DC

Meeting Goals

1. Identify Roundtable Member views on issues and opportunities of particular priority in improving patient and public understanding and action on behalf of value and science-driven health care.
2. Propose ways in which Member initiatives, within and across organizations, can foster cooperative progress in engaging people as full participants and advocates 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.

Agenda

8:30 am Coffee and light breakfast available

9:00 am	Welcome and introductions
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Opening remarks

Mark McClellan, The Brookings Institution and Roundtable Chair
Harvey Fineberg, Institute of Medicine

9:15 am	Roundtable update and observations
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Overview update on Roundtable activities

Michael McGinnis, Institute of Medicine

Member reflections on activities and interests

Mark McClellan, The Brookings Institution and Roundtable Chair

10:00 am	Public outreach and engagement on value & science-driven health care
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Introduction of issues, opportunities and approaches to public engagement

Peggy Conlon, The Advertising Council

Roundtable public engagement activities & opportunities

Richard Fante, AstraZeneca

Jim Guest, Consumers Union

Roundtable project on public and patient engagement on value (VILC)

Sheri McCoy, Johnson & Johnson

Leah Binder, The Leapfrog Group

Roundtable project on messaging about evidence (ECIC)

George Halvorson, Kaiser Permanente

Bill Novelli, Georgetown University

Open discussion

12:30

Lunch and view from the policy arena

Joe Selby, Patient-Centered Outcomes Research Institute

Open Discussion

1:30 pm

Discussion of Collaborative projects

Clinical Effectiveness Research Innovation Collaborative

- 5 minute update: *Cato Laurencin, Rich Platt*

Best Practices Innovation Collaborative

- 5 minute update: *Michael Johns, Mary Naylor*
- Reflections on priorities: *Darrell Kirch, AAMC*

Digital Learning Collaborative

- 5 minute update: *Jonathan Perlin*
- Reflections on priorities: *Doug Fridsma, ONC*

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

4:00 pm **Adjourn**

Background Materials

General Articles

Public outreach and engagement on value & science-driven health care

- Clancy, Carolyn M. *Patient Engagement in Health Care*. Health Services Research. 2011.
“As efforts to reform the quality and efficiency of care in the United States accelerate, it is clear that a focus on the interactions between new models of care and patients’ engagement will be an indispensable component of research illuminating which models are most effective.”
- Leape, Lucian et al. *Transforming healthcare: a safety imperative*. BMJ Quality & Safety. 2009.
The Lucian Leape Institute...has identified five concepts as fundamental to the endeavor of achieving meaningful improvement in healthcare system safety: transparency, care integration, patient/consumer engagement, restoration of joy and meaning in work, and medical education reform.
- Frieden, Thomas R. *A Framework for Public Health Action: The Health Impact Pyramid*. American Journal of Public Health. 2010.
“Interventions that address social determinants of health have the greatest potential public health benefit.”

Editorial

Patient Engagement in Health Care

People's interactions with health care are now widely acknowledged to be a central focus of health services research. In the past several decades the research community has made great strides in developing and testing frameworks and influences on numerous aspects of individuals' engagement at multiple points in the increasingly complicated matter of seeking and using health care services. Individuals are expected to decide whether and when to seek care, which plans and providers meet their needs, how to manage their health, and how to cope with sometimes conflicting advice from providers and friends and family, all amplified by advances in communications and information technology. To evaluate these increased responsibilities and expectations, researchers have used an array of methods and designs, drawing on economics, psychology, sociology, and other fields to enhance our understanding of how individuals participate at these and other decision points. Moreover, publication of the Institute of Medicine's landmark report *Crossing the Quality Chasm* in 2001 formally articulated patient-centered care as an essential dimension of high-quality care, a clear focus of new models of delivering care such as primary care patient-centered medical homes (PCMH) and accountable care organizations (ACO) (Committee on Quality of Health Care in America, Institute of Medicine 2001).

At the same time, while the use of researcher-developed tools to assess patient experiences of care (e.g., CAHPS) is now considered routine, and numerous provisions of the Patient Protection and Affordable Care Act reinforce patient-centered care as pivotal to achieving high-quality, affordable care, it is also clear that individuals' tasks are increasingly complex. A recent report on patient engagement in health care describes an Engagement Behavior Framework and multiple behaviors that individuals must master to benefit optimally from their care (Center for Advancing Health 2010). Drawing on previous research, this report represents a precursor to estimating the scale and complexity of challenges confronting individual patients and caregivers, from navigation to managing increasingly sophisticated medical technology at home, often magnified by limited health literacy or past experiences.

In short, effective engagement requires considerable skill and motivation, and well-intended initiatives often appear to fall short of collective aspirations to build a system responsive to the needs of patients and families.

In this issue of the journal, four papers address distinct tasks of patient engagement in health care, and one presents a patient-centered approach to assessing health care expenditures. Papers by Boonen, Donkers and colleagues, and Sinaiko examine the impact of financial incentives and limited quality information on consumers' decisions (Boonen et al. 2011; Sinaiko 2011). The first paper is a discrete choice experiment conducted among Dutch consumers eliciting their willingness to switch general practitioners (GP) or pharmacies in response to different levels and presentations of copayments and very succinct information on quality. Results suggest that negative incentives (e.g., higher copayments) are far more effective than positive, and that respondents were far more likely to switch pharmacies than GPs, a finding attributed to status quo bias. In addition, respondents were aware of and more willing to pay for GP's with higher quality ratings, a dichotomous summary rating, than for pharmacies. Individuals register with a GP in the Dutch system, who serves as a "gatekeeper" to all hospital and specialized services and longstanding relationships are the norm. It is plausible that this context underlies the finding that status quo bias was more predominant for choice of GP than pharmacy. The authors note that insurers may be more successful in channeling all patients to selected pharmacies including those with previous experience, while efforts regarding the choice of GP would be better focused on educating patients who have not yet selected one. Of note, such cost sharing strategies are currently nonexistent in the Netherlands, so the context is quite different than the United States.

In contrast, Sinaiko's experimental study was designed to assess how quality information from multiple sources and financial incentives affect consumer choice of physician in Massachusetts. State employees enrolled in Group Insurance Commission (GIC) tiered plans were randomly assigned to one of six sites of hypothetical-tiered networks of specialist physicians, with different scenarios involving choice of either a cardiologist or a dermatologist, with varying levels of copayments. Participants were also asked about choices of a tier 1 or tier 2 specialist according to GIC quality rating, either with no additional information or with positive information about lower-rated (tier 2) physicians derived from personal experiences or information from family or friends. Starting with a base case of 84 percent of respondents choosing a tier 1 specialist, the results found that almost one half of respondents would switch to a tier 2 specialist if recommended by a friend or family member, and

two-thirds would switch to a tier 2 specialist if recommended by their own physician. Copayments between U.S.\$10.00 and U.S.\$35.00 increased the probability of selecting a tier 1 specialist from 3.5 percent to 11.7 percent. Simulations suggested that copayments would need to exceed U.S.\$300.00 to counteract positive recommendations of tier 2 specialists from trusted sources, with some differences by specialty. The authors note that previous analyses suggested that one-third of enrollees do not have full confidence in GIC quality ratings. Whether the results would have been different if respondents had more confidence in the quality ratings in this study, or if more detail regarding quality had been provided, presents fertile ground for future study.

Once decisions regarding when and where to seek care have been made, individuals can seek information and make decisions about involvement in their health care. Skolasky assessed the psychometric properties of Hibbard's Patient Activation Measure (PAM), central to emerging models of chronic illness care, in older adults with multiple comorbid conditions (Hibbard et al. 2004). The findings support the construct validity of the PAM in this population, with significant associations between some health-related behaviors and functional status. Patient activation was not related to the number of comorbid conditions. Patients with higher PAM stages reported better quality of care, suggesting that activated patients may go to extra efforts to seek and obtain better care, raising intriguing questions regarding the extent to which interventions to effect health behavior changes are mediated by patient activation, itself a multidimensional construct (Skolasky et al. 2011). The quality assessments used in this study are both patient-reported surveys. The authors acknowledge that their design cannot demonstrate causality, leaving open the possibility that perceived quality is confounded by the fact that older patients tend to be far less skeptical about medical care than younger patients (Fiscella, Franks, and Clancy 1998). Future studies should address the relationship between patient activation and clinical quality assessments, and whether the results observed here are generalizable to younger people.

Patients' reported experience of care has become an important component of quality assessment of health plans, hospitals, and other care delivery settings since the late 1990s. Most recently, a tool to assess patient experience with clinicians and groups, Clinician-Group CAHPS (CG-CAHPS), has been endorsed and used by some medical groups. Several studies have demonstrated that individuals from different racial and ethnic minority groups frequently report very different summary ratings than Caucasians. Weinick's

innovative study was designed to assess the extent to which racial/ethnic differences in ratings of patient experience represent true differences or perceptions (Weinick et al. 2011). Taking advantage of a nationally representative online panel, the investigators developed a video that simulated CG-CAHPS items with varying degrees of physician responsiveness for a patient with a headache. African Americans and whites had similar perceptions of the quality of the physician–patient interaction when presented with the same behaviors, underscoring that reported differences by race are not merely due to differences in how they judge effective interaction. Based on these findings, the authors make specific policy recommendations regarding the use of CAHPS report items rather than summary ratings to stratify findings by race and ethnicity.

Conway's paper presents a patient-centered approach to assessing national health expenditures (Conway et al. 2011). The investigators used the Medical Expenditure Panel Survey (MEPS) to categorize expenditures into seven patient-centered categories: chronic illness (47 percent), acute illness (25 percent), trauma and poisoning (8 percent), dental (7 percent), routine preventive care (6 percent), pregnancy (4 percent), and other (3 percent). The authors appropriately note that the MEPS does not include people who are institutionalized or receive care from the military of Veterans Health Administration. However, as public and private policy makers struggle to identify and communicate approaches that support high quality, affordable care, the potential for presenting information in ways that patients and families experience care is quite intriguing. In particular, this approach may be particularly useful to the newly created Patient Centered Outcomes Research Institute, a private organization supported by a combination of public and private sector revenues, with the unique feature of a 21 member multistakeholder board.

Together, these papers push well beyond the boundaries of earlier work examining how individuals use information on quality or benefit design and illustrate multidimensional challenges ahead. For example, the paper by Sinaiko suggests that the perceived credibility and trustworthiness of quality information and the ability to evaluate information from multiple sources are essential components of effective engagement, albeit far from straightforward. As efforts to reform the quality and efficiency of care in the United States accelerate, it is clear that a focus on the interactions between new models of care and patients' engagement will be an indispensable component of research illuminating which models are most effective.

Carolyn M. Clancy

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EDITOR'S
CHOICE

Transforming healthcare: a safety imperative

L Leape,¹ D Berwick,^{1,2} C Clancy,³ J Conway,² P Gluck,⁴ J Guest,⁵ D Lawrence,⁶ J Morath,⁷ D O'Leary,⁸ P O'Neill,⁹ D Pinakiewicz,⁴ T Isaac,¹⁰ for the Lucian Leape Institute at the National Patient Safety Foundation

ABSTRACT

Ten years ago, the Institute of Medicine reported alarming data on the scope and impact of medical errors in the US and called for national efforts to address this problem. While efforts to improve patient safety have proliferated during the past decade, progress toward improvement has been frustratingly slow. Some of this lack of progress may be attributable to the persistence of a medical ethos, institutionalized in the hierarchical structure of academic medicine and healthcare organizations, that discourages teamwork and transparency and undermines the establishment of clear systems of accountability for safe care. The Lucian Leape Institute, established by the US National Patient Safety Foundation to provide vision and strategic direction for the patient safety work, has identified five concepts as fundamental to the endeavor of achieving meaningful improvement in healthcare system safety. These five concepts are transparency, care integration, patient/consumer engagement, restoration of joy and meaning in work, and medical education reform. This paper introduces the five concepts and illustrates the meaning and implications of each as a component of a vision for healthcare safety improvement. In future roundtable sessions, the Institute will further elaborate on the meaning of each concept, identify the challenges to implementation, and issue recommendations for policy makers, organizations, and healthcare professionals.

Healthcare is unsafe. In its groundbreaking report, *To Err Is Human*, the Institute of Medicine (IOM) estimated that, in the USA, as many as a million people were injured and 98 000 died annually as a result of medical errors.¹ Subsequent studies in multiple countries suggest these may be underestimates.^{2–5} The IOM called in 2000 for a major national effort to reduce medical errors by 50% within 5 years,¹ but progress since has fallen far short.^{6–8} Many patients continue to fear, justifiably, that they may be harmed when they enter a hospital.

The slow progress is not for want of trying. Both public and private organisations have initiated major programmes to develop and implement new safe practices and to train healthcare workers in patient safety.^{9–16} In the USA, since 1997, the National Patient Safety Foundation has worked with stakeholder groups to advance learning and bring forward new solutions. The Agency for Healthcare Research and Quality has invested in defining measures to assess and improve safety and to build capacity through its Patient Safety Improvement Corps.¹⁷ The National Quality Forum has certified safe practices ready for use.¹⁸ The Joint Commission has required hospital compliance with new patient safety goals.¹⁹ The

Institute for Healthcare Improvement has launched two massive national and international campaigns¹¹ to inspire thousands of hospitals to adopt evidence-based safe practices.

Similar advances have occurred in many other countries. Voluntary nongovernmental patient safety organisations have been established in Denmark, Canada, Spain, Sweden, and Switzerland. Many have conducted studies to determine the extent of medical injury, and several have developed reporting systems.^{20–21} In Australia, the work of the Australian Council on Safety and Quality continued when the Australian Commission of Safety and Quality in Health Care was established by the government to develop a national strategic framework and associated patient safety work programme.

The UK has led the way in government commitment to safety, with the establishment of the National Patient Safety Agency under the Department of Health, and has developed a reporting system and a clinical assessment service. The department has also established and enforced performance measures. In addition, voluntary efforts, such as the Patient Safety First campaign, have been extensive. Liam Donaldson from the National Health Service also led the formation of the World Alliance for Patient Safety, which has launched seven major programmes, including successful worldwide hand hygiene and surgical checklist campaigns.^{22–23}

However, these efforts have been insufficient. As other industries have learned, safety does not depend just on measurement, practices and rules, nor does it depend on any specific improvement methods; it depends on achieving a culture of trust, reporting, transparency and discipline. For healthcare organisations in every country, this requires major culture change.

Too many healthcare organisations fit James Reason's definition of the "sick system syndrome." They are hierarchical and deficient in mutual respect, teamwork and transparency. Blame is still a mainstay solution. Mechanisms for ensuring accountability are weak and ambiguous. Few have the capacity to learn and change that is characteristic of the so-called high reliability industries.²⁴ Most do not recognise that safety should be a precondition, not a priority. Or that fulfilling the interests of their patients in safe care and of their staffs in a safe workplace will enhance productivity and profitability.

Many physicians do not know how to be team players and regard other health workers as assistants. Outmoded hierarchical structures inhibit

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collaboration and learning. Nurses are trapped in rigid organisational structures in which they often spend more time tending to their records than to their patients. Often, their work environment does not permit them to realise their full potential and is unsafe because of system vulnerabilities and leadership inattention. Too many practitioners—doctors, nurses, pharmacists, therapists, technicians—function in “silos,” focusing on their own performance and communicating with others in fragmented and inefficient ways that inhibit teamwork. Patients are seldom included in organisational planning or in the analysis of adverse events that have harmed them.^{25 26}

WHAT NEEDS TO BE DONE?

The Lucian Leape Institute was established by the National Patient Safety Foundation to provide strategic guidance for achieving safe healthcare. Like the vast majority of safety experts, we believe that healthcare entities must become “high-reliability organisations” that hold themselves accountable to consistently offer safe, effective, patient-centred care.²⁴ This will require all parties—hospitals and their boards, doctors, nurses, pharmacists, administrators, regulators, government officials, payers, professional societies, and patients—to move beyond the IOM recommendations for changes in systems and to radically change the ways in which they think about care and how it is provided. Healthcare needs not just to be improved but to be transformed.

A VISION FOR TRANSFORMATION

We envision a culture that is open, transparent, supportive and committed to learning; where doctors, nurses and all health workers treat each other and their patients competently and with respect; where the patient’s interest is always paramount; and where patients and families are fully engaged in their care. We envision a culture centred on teamwork, grounded in mission and purpose, in which organisational managers and boards hold themselves accountable for safety and learning to improve. In a learning organisation, every voice is heard and every worker is empowered to prevent system breakdowns and correct them when they occur. The culture we envision aspires to, strives for, and achieves unprecedented levels of safety, effectiveness, and satisfaction in healthcare.

How do we get there? We believe that to become safe, effective, high reliability organisations, healthcare organisations must implement five major transforming concepts. Although many other ideas and actions are needed to bring about the changes needed in our complex system, we believe these are the essential core: if an organisation achieves them all, it will be well on the way to becoming a high reliability organisation. If not, it is unlikely to succeed.

The five transforming concepts are as follows: (1) transparency must be a practiced value in everything we do; (2) care must be delivered by multidisciplinary teams working in integrated care platforms; (3) patients must become full partners in all aspects of healthcare; (4) healthcare workers

need to find joy and meaning in their work; and (5) medical education must be redesigned to prepare new physicians to function in this new environment.

Each of these concepts calls for moving thinking beyond current boundaries and each implies profound behavioural changes. We will develop these ideas further in stakeholder roundtables for each concept that will define the challenges in detail and make specific recommendations to policy makers, organisations and healthcare professionals.

TRANSPARENCY

Transparency—the free, uninhibited sharing of information—is probably the most important single attribute of a culture of safety. In complex, tightly coupled systems like healthcare, transparency is a precondition to safety. Its absence inhibits learning from mistakes, distorts collegiality and erodes patient trust.

Healthcare leaders have been far too timid about becoming truly transparent. We urge giant steps—now. Healthcare organisations must become transparent in all dimensions: among caregivers, between caregivers and patients, between organisations, and with the public.

First, caregivers need to share information openly about hazards, errors and adverse events. People cannot improve systems if they cannot talk about what they are experiencing. Individuals must be able to report errors without fear of punishment or embarrassment. They must be convinced that the response will be, not, “Who failed?” but, rather, “What happened?”

Second, caregivers need to be open with patients when things go wrong. Unfortunately, many risk managers still coach clinicians to limit what they reveal, blaming the malpractice dragon, despite examples, such as the University of Michigan Hospital, that have adopted “extreme honesty” and seen substantial decreases in the number of suits and costs.²⁷ We should emulate their bold example: promptly acknowledge when things go wrong, explain the causes as they are understood and apologise when patient harm comes from failures in care. Hospital leaders must fully support caregivers as they strive to be more transparent.

This form of transparency is not just a technical imperative, it is a moral imperative. We have neither a legal nor a moral right to withhold from patients information on harm done to them, even if that harm is accidental.

Third, just as individual clinicians should exchange information on injuries and hazards, so should organisations. In the aviation industry, if a hydraulic device proves faulty in Dallas, the sun will not set before mechanics know about it in Denver and Dubai. However, in healthcare, organisations hesitate to exchange lessons openly for many of the same reasons that individual staff do. To make this sharing worthwhile, healthcare organisations also need to invest heavily in the analysis of those reports by experienced professionals.

A vision for healthcare

We envision a culture that is open, transparent, supportive and committed to learning; where doctors, nurses and all health workers treat each other and their patients competently and with respect; where the patient’s interest is always paramount; and where patients and families are fully engaged in their care.

Five transforming concepts

- ▶ Transparency
- ▶ Integrated care platform
- ▶ Consumer engagement
- ▶ Joy and meaning in work
- ▶ Medical education reform

Original viewpoint

The fourth meaning of “transparency” is the one that most laypeople, purchasers and regulators use: public reporting about harmful incidents. Many organisations have championed public reporting on harm, and some states are now requiring it for so-called never events.

So far, healthcare has addressed transparency mainly in the form of incident-reporting systems—our fourth definition. A more robust approach will serve us better: extreme transparency of all four types: among staff, between caregivers and patients, among institutions, and in open and clear reports to the public at large.

INTEGRATED CARE PLATFORMS

The integrated care platform is an organisational structure within a healthcare system that enhances quality and patient safety by bringing together across all venues—inpatient, outpatient and residential—the care and the support systems required to provide evidence-based, appropriate and responsive care to patients according to their needs (such as various chronic diseases).²⁸

The purpose of the platform is to maximise efficiency, safety, quality and reliability to produce consistently superior outcomes at the lowest cost. It fosters the multidisciplinary solutions that are essential for safe management of complex clinical conditions. Distinct platforms are designed for conditions that share common work and support requirements, such as chronic disease care, complex acute care, palliative and end-of-life care.

Every care platform must have the following characteristics:

- ▶ Patient centredness: personnel, facilities and services are organised to meet all patients’ needs efficiently and responsively; to be available when and where needed, 24/7; and to include the patient and family as partners in care.
- ▶ Work assignment: work is assigned to the individuals who are responsible for its completion. Assignments strive to maximise the performance capability of each individual while ensuring that work is done by the least expensive qualified caregiver or multidisciplinary team at the location most accessible to the patient. The physician participates when his/her special expertise is required and when patient expectations permit no alternative.
- ▶ Support: The support framework—people, systems and tools (eg, technologies, IT, telecommunications)—is defined by the work and patient participation design.
- ▶ Community linkage: Linkages to community advocacy, support, and education groups (especially health literacy) are incorporated into the design as appropriate (eg, for patients with chronic conditions).
- ▶ Variation management: Ensuring quality and efficiency requires determining whether variations in process are appropriate (ie, evidence-based). Exception analysis assesses whether variations result from (1) adaptations to a specific patient requirement, (2) evolution of new evidence (good), (3) lack of training in appropriate care or (4) poorly defined care pathways (bad).
- ▶ Transparency: Because care is designed and expected variation is defined, both the output and delivery process within a platform can be observed, measured and shared with all concerned, including patients.

Dividing healthcare needs into disease or condition groupings and designing an integrated care platform for each achieves the impact lacking in other integration approaches. It also places accountability at the appropriate level—the integrated system—rather than solely on the individual clinician.

CONSUMER ENGAGEMENT—“NOTHING ABOUT ME WITHOUT ME”

The engagement of consumers in care partnerships is essential to achieve quality and safety in healthcare.²⁵ Whether pursuing healthy living, as patients receiving care, or as purchasers (future patients), individuals and their families must play a central role. The guiding principle is “If health is on the table, then the patient and family must be at the table, every table, now.”

In 2001, the IOM report “Crossing the Quality Chasm” included patient centredness as one of the six core aims for healthcare.²⁹ Earlier, in 1997, the Salzburg Seminar suggested that efforts to improve care might take strikingly different shape if patients worked as full partners with caregivers to design and implement change. The patient experience should be “nothing about me, without me.”³⁰

The power of the involvement of patients and families is seen in their contributions to the safety system, in recognising and responding to literacy problems, in the improved management of acute and chronic diseases and in sharing experiences so that others can learn.^{31 32}

Despite the evidence of the effectiveness of consumer engagement,^{33 34} implementation to date has been modest. Actions are more often *for* than *with* the consumer. Many clinicians are reluctant to share knowledge and care plans with patients. Analysis of safety systems and adverse events has not usually involved patients, even in areas where they have a great deal to add, such as medication management and transitions in care. Consumer advocacy groups have not always been welcomed as participants in organisational and community policy-setting efforts.

We envisage patients as essential and respected partners in their own care and in the design and execution of all aspects of healthcare. In this new world of healthcare:

- ▶ Organisations publicly and consistently affirm the centrality of patient- and family-centred care. They seek out patients, listen to them, hear their stories, are open and honest with them, and take action with them.
- ▶ The family is respected as part of the care team—never visitors—in every area of the hospital, including the emergency department and the intensive care unit.
- ▶ Patients share fully in decision-making and are guided on how to self-manage, partner with their clinicians and develop their own care plans. They are spoken to in a way they can understand and are empowered to be in control of their care.

JOY AND MEANING IN WORK

Caregivers cannot meet the challenge of making healthcare safe unless they feel valued and find joy and meaning in their work. The evidence abounds that in the USA, many do not. In a recent survey, 60% of physicians indicated they were considering leaving medical practice because they are discouraged³⁵; a study of newly licensed registered nurses showed that 33% might seek another job within the year.³⁶

Among physicians, reasons include loss of control, the malpractice liability threat and declining revenues.³⁷ Among nurses, lack of respect from both administrators and physicians ranks high, along with the increasing burden of regulation and record-keeping that separates them from patient care. For many, the transformation of healthcare from a public service to a business in the last quarter of the 20th century reduced complex, highly intimate care processes to transactional industrial production schemata, divorcing work from meaning.

Another cause of poor morale is tolerance of disrespectful and disruptive behaviour. Sixty-two per cent of nurses reported verbal abuse as the most frequently encountered injury at work.³⁸ A permissive environment exacerbates the risk-prone conditions in which people work, demoralises workers and leads to conflict.^{39 40} Failure of leadership to address interpersonal communication issues depletes the energy of an organisation and raises doubt about the organisation's commitment to fairness.

Although addressing some of these issues requires major national policy changes, it is also a fact that some healthcare organisations have created environments where morale is high and workers do find joy and meaning in their work. This strongly suggests that the causes—and the remedies—are local. Creating an environment where every worker finds joy and meaning in work is a foundational leadership challenge for a healthcare organisation.

What needs to be done? Capturing the soul of an organisation, where joy and meaning resides, requires a true partnership to align values among organisation leaders, professionals and the workforce. Leaders must create the environment where it is possible for improvements to take place. However, the richest source of ideas for improvement is the frontline workers. It is they who live in the complexities of the current systems, have direct insights into failures and see daily opportunities for improvement.⁴¹

These lessons can only be harvested if all members of the workforce feel valued and work together in meaningful teams. This requires that everyone is (a) treated with dignity and respect; (b) given the education, training, tools and encouragement they need to make a contribution that gives meaning to their life; and (c) recognised and appreciated for what they do.⁴²

Leaders have a choice: they can view organisations as industrial models and focus on restructuring, production and regulation, or they can, as we urge, view them as being composed of people with the skills and energy to perform meaningful work, and focus on the shared vision and values that provide meaning and joy in work.

REFORM OF MEDICAL EDUCATION

Medical education needs to be restructured to reduce its almost exclusive focus on the acquisition of scientific and clinical facts and to emphasise the development of skills, behaviours and attitudes needed by practicing physicians. These include the ability to manage information; understanding of the basic concepts of human interaction, patient safety, healthcare quality and systems theory; and possession of management, communication and teamwork skills. Although a similar need exists across all health professions, it is most compelling in medicine because the decisions of physicians influence the care that all other professionals provide.

The principal conclusion of the *To Err Is Human* report is that the major cause of adverse events is poorly designed systems, not negligent individual performance.¹ The implication is that physicians, managers, nurses and others should work together in teams to redesign flawed processes to prevent harm. One reason this has not happened faster is that physicians have not been educated to carry out this critically important work.

In the typical medical school curriculum, little or no instruction is provided in engineering concepts applicable to systems thinking, safety science, improvement science, human factors, leadership or teamwork. Students obtain little experience in examining the patient care processes, which constitute

the everyday practice in the real world of healthcare or experience working with students in nursing, pharmacy or other health fields. Nor do they receive instruction in skills needed to communicate effectively with coworkers and patients, or how to deal with their own feelings of doubt, fear and uncertainty. Yet, these are the knowledge and skills that most people consider essential for a physician.

Over the past 5 years, the IOM,⁴³ the Accreditation Council for Graduate Medical Education⁴⁴ and the American Board of Medical Specialties⁴⁵ have formulated concise sets of desired practitioner behavioural competencies. These suggest that medical schools should pay greater attention to teaching concepts that underlie the behaviours for which future physicians will be held accountable. That teaching should be undertaken in an interdisciplinary fashion and capitalise on the rapidly expanding applications of simulation as a teaching tool.

Today's medical schools are producing square pegs for our care system's round holes. This disconnect requires immediate attention, as does the need for retraining practicing physicians, who are the students' mentors and role models.

CONCLUSION

These transformations comprise a major culture change for healthcare. Achieving them will require enlightened leadership, commitment and support from all stakeholders. However, without them, we believe progress in making healthcare safe will continue to sputter.

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APPENDIX

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A Framework for Public Health Action: The Health Impact Pyramid

A 5-tier pyramid best describes the impact of different types of public health interventions and provides a framework to improve health. At the base of this pyramid, indicating interventions with the greatest potential impact, are efforts to address socioeconomic determinants of health. In ascending order are interventions that change the context to make individuals' default decisions healthy, clinical interventions that require limited contact but confer long-term protection, ongoing direct clinical care, and health education and counseling.

Interventions focusing on lower levels of the pyramid tend to be more effective because they reach broader segments of society and require less individual effort. Implementing interventions at each of the levels can achieve the maximum possible sustained public health benefit. (*Am J Public Health*. 2010;100:590–595. doi:10.2105/AJPH.2009.185652)

Thomas R. Frieden, MD, MPH

LIFE EXPECTANCY IN DEVELOPED COUNTRIES has increased from less than 50 years in 1900 to nearly 80 years today.¹ The greatest improvement occurred in the first half of the 20th century, when life expectancy in the United States and many parts of Europe increased by an average of 20 years,² largely because of universal availability of clean water and rapid declines in infectious disease,³ as well as broad economic growth, rising living standards, and improved nutritional status.⁴ Smaller gains in the latter half of the 20th century resulted primarily from advances in treatment of cardiovascular disease and control of its risk factors (i.e., smoking, high blood pressure, and high cholesterol).⁵

The traditional depiction of the potential impact of health care interventions is a four-tier pyramid, with the bottom level representing population-wide interventions that have the greatest impact

and ascending levels with decreasing impact that represent primary, secondary, and tertiary care.⁶ Other frameworks more specific to public health have been proposed. Grizzell's 6-tier intervention pyramid emphasizes policy change, environmental enhancement, and community and neighborhood collaboration.⁷ Hamilton and Bhatti's 3-dimensional population health and health promotion cube incorporates 9 health determinants (e.g., healthy child development, biology and genetics, physical environments, working conditions, and social support networks) and evidence-based actions to address them (e.g., reorienting health services, creating supportive environments, enacting healthy public policy, and strengthening community action).⁸ The maternal and child health pyramid of health services, developed by the US Health Resources and Services Administration, consists of 4 levels

of services used by states to allocate resources for mothers and children.⁶ Infrastructure building (e.g., monitoring, training, systems of care, and information systems) is at the bottom of the pyramid, followed by population-based services (e.g., newborn screening, immunization, and lead screening) and enabling services (e.g., transportation, translation, case management, and coordination with Medicaid), with direct health care services at the top.

All of these models, however, focus most of their attention on various aspects of clinical health services and their delivery and, to a lesser extent, health system infrastructure. Although these are of critical importance, public health involves far more than health care. The fundamental composition, organization, and operation of society form the underpinnings of the determinants of health, yet they are often overlooked in the development frameworks to

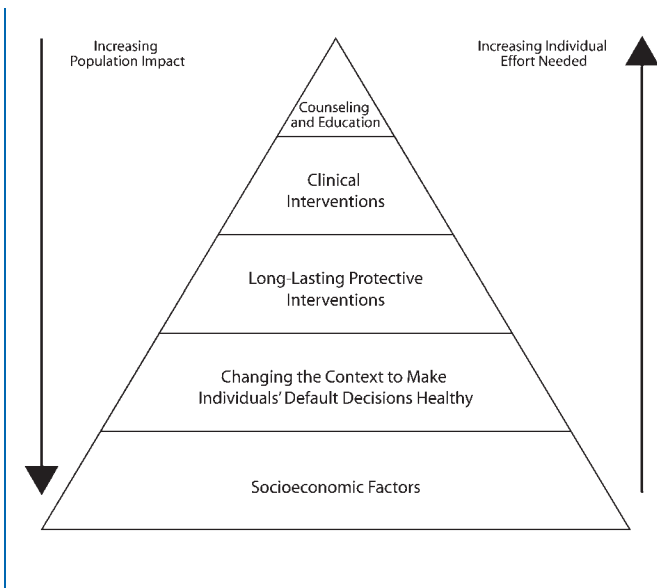


FIGURE 1—The health impact pyramid.

describe health system structures. As a result, existing frameworks accurately describe neither the constituent elements nor the role of public health.

A FIVE-TIER PYRAMID

An alternative conceptual framework for public health action is a 5-tier health impact pyramid (Figure 1). In this pyramid, efforts to address socioeconomic determinants are at the base, followed by public health interventions that change the context for health (e.g., clean water, safe roads), protective interventions with long-term benefits (e.g., immunizations), direct clinical care, and, at the top, counseling and education. In general, public action and interventions represented by the base of the pyramid require less individual effort and have the greatest population impact. However, because these actions may address social and economic structures of society, they can be more controversial, particularly if the public

does not see such interventions as falling within the government's appropriate sphere of action.

Interventions at the top tiers are designed to help individuals rather than entire populations, but they could theoretically have a large population impact if universally and effectively applied. In practice, however, even the best programs at the pyramid's higher levels achieve limited public health impact, largely because of their dependence on long-term individual behavior change.⁹ As Rose writes,

Personal life-style is socially conditioned. . . . Individuals are unlikely to eat very differently from the rest of their families and social circle. . . . It makes little sense to expect individuals to behave differently than their peers; it is more appropriate to seek a general change in behavioural norms and in the circumstances which facilitate their adoption.^{10(p135)}

Socioeconomic Factors

The bottom tier of the health impact pyramid represents changes in socioeconomic factors

(e.g., poverty reduction, improved education), often referred to as social determinants of health, that help form the basic foundation of a society.^{11,12} Socioeconomic status is a strong determinant of health, both within and across countries.¹³ Although the exact mechanisms by which socioeconomic status exerts its effects are not always apparent, poverty, low educational attainment, relative deprivation, and lack of access to sanitation increase exposure to environmental hazards.¹⁴ Educational status is also tightly correlated with cardiovascular risk factors, including smoking.^{15,16}

Although poverty increases ill health within a society, economic development can also increase illness and death from noncommunicable disease. As living standards and life expectancy improve, risk for cardiovascular disease and some cancers increases.¹⁷ Much of this increase results from modifiable risk factors related to overconsumption of tobacco, unhealthy food, and alcohol, with a concurrent decrease in physical activity. Greater wealth can also lead to more roads and an increase in motor vehicle use, which can result in increased outdoor air pollution and more injury and death from traffic crashes.

A third of the world's urban population lives in slums.¹⁸ Substantial health improvements in high-poverty areas will require improved economic opportunities and infrastructure, including reliable electric power, sanitation, transport, and other basic services.¹⁹ Clean water and improved sanitation introduced in the United States in the late 19th and early 20th centuries may have been primarily responsible for reducing mortality rates by about half and child mortality rates by nearly two thirds in major cities.²⁰

Still, more than 900 million people worldwide have no access to clean drinking water and about 2.5 billion have no access to adequate sanitation.²¹ As the World Health Organization's Commission on Social Determinants of Health reported, "Social injustice is killing people on a grand scale."^{11(p26)}

Changing the Context to Encourage Healthy Decisions

The second tier of the pyramid represents interventions that change the environmental context to make healthy options the default choice, regardless of education, income, service provision, or other societal factors. The defining characteristic of this tier of intervention is that individuals would have to expend significant effort not to benefit from them. For example, fluoridated water—which is difficult to avoid when it is the public supply—not only improves individual health by reducing tooth decay,²² but also provides economic benefits by reducing health spending and productivity losses. In countries without either adequate natural or added fluoridation, health authorities are limited to counseling interventions, such as encouraging toothbrushing.

Other contextual changes that create healthier defaults include clean water, air, and food; improvements in road and vehicle design; elimination of lead and asbestos exposures; and iodization of salt.²² The potential societal impact of decreasing cardiovascular risk factors by changing from saturated to unsaturated cooking oils was demonstrated in Mauritius²³; eliminating artificial *trans* fat in food is another way to prevent cardiovascular disease.²⁴ Strategies to create healthier environmental contexts also include

designing communities to promote increased physical activity; enacting policies that encourage public transit, bicycling, and walking instead of driving; designing buildings to promote stair use; passing smoke-free laws; and taxing tobacco, alcohol, and unhealthy foods such as soda and other sugar-sweetened beverages.

Cardiovascular disease risk factors (e.g., hypertension) are currently addressed at the individual level through screening and medication. But even assuming perfect treatment, this approach fails to prevent almost half of the disease burden caused by elevated blood pressure; cardiovascular risk increases with systolic blood pressure above 115 mm Hg, a level at which medical treatment is not recommended currently.^{25,26} Changing the environmental context so that individuals can easily take heart-healthy actions in the normal course of their lives can have a greater population impact than clinical interventions that treat individuals.

For example, modern diets contain many times the minimum daily requirement of sodium—mostly from packaged foods and restaurant meals—making it difficult for individuals to control their intake.²⁷ Reducing dietary sodium can reduce hypertension at the population level.^{28,29} A healthier food environment can be created by decreasing salt in packaged foods. This is happening in the United Kingdom, which introduced four-year sodium reduction targets,³⁰ and in Finland, where dietary sodium intake decreased approximately 25% in the past 30 years.³¹

Long-Lasting Protective Interventions

The third level of the pyramid represents 1-time or infrequent

protective interventions that do not require ongoing clinical care; these generally have less impact than interventions represented by the bottom 2 tiers because they necessitate reaching people as individuals rather than collectively. Historic examples include immunization, which prevents 2.5 million deaths per year among children globally.³² Another example is colonoscopy, which can significantly reduce colon cancer and is only needed every 5 to 10 years for most people. Smoking cessation programs increase quit rates; life expectancy among men who quit at age 35 is almost 7 years longer than for those who continue to smoke.³³

Male circumcision, a minor outpatient surgical procedure, can decrease female-to-male HIV transmission by as much as 60%.³⁴ Scale-up could potentially prevent millions of HIV infections in sub-Saharan Africa.^{35,36} A single dose of azithromycin or ivermectin can reduce the prevalence of onchocerciasis, a major cause of blindness.³⁷

Clinical Interventions

The fourth level of the pyramid represents ongoing clinical interventions, of which interventions to prevent cardiovascular disease have the greatest potential health impact. Although evidence-based clinical care can reduce disability and prolong life, the aggregate impact of these interventions is limited by lack of access, erratic and unpredictable adherence, and imperfect effectiveness. Access can be limited even in systems that guarantee health coverage for all³⁸ and is a much greater problem in the United States and other countries without universal health care coverage.^{39,40} Nonadherence is especially problematic for chronic conditions that are

usually asymptomatic, such as hypertension, hyperlipidemia, and diabetes. At least a third of patients do not take medications as advised, and nonadherence cannot be predicted from socioeconomic or demographic characteristics.^{41,42}

Rigorous accountability, incentives for meaningful outcomes (e.g., blood pressure and cholesterol control), and systems to enable improved performance are all essential to improve health care system performance. Electronic health records have the potential—if and only if they are implemented with prevention and accountability as guiding principles—to facilitate greatly improved preventive and chronic care.⁴³ This goal is more likely to be attained if electronic record keeping is implemented along with changes in both financial incentives and physician practices to proactively support preventive care and control of chronic diseases.⁴⁴

Counseling and Educational Interventions

The pyramid's fifth tier represents health education (education provided during clinical encounters as well as education in other settings), which is perceived by some as the essence of public health action but is generally the least effective type of intervention.⁹ The need to urge behavioral change is symptomatic of failure to establish contexts in which healthy choices are default actions. For example, counterbalances to our obesogenic environment include exhortations to increase physical activity and improve diet, which have little or no effect. More than one third of US adults, or 72 million people, were obese in 2006, a dramatic increase over

1980.⁴⁵ Two thirds of these individuals were counseled by a health care provider to lose weight,⁴⁶ yet daily calorie and fat intake continues to rise.

Counseling, either within or outside the clinical context, is generally less effective than other interventions; successfully inducing individual behavioral change is the exception rather than the rule. For example, although clear, strong, and personalized smoking cessation advice, even in the absence of pharmacological treatment, doubles quit rates among smokers who want to stop and should be the norm in medical care, it still fails to help 90% of those who are motivated to quit.^{47,48}

Nevertheless, educational interventions are often the only ones available, and when applied consistently and repeatedly may have considerable impact. An example of a successful evidence-based educational intervention is trained peer counselors advising men who have sex with men about reducing HIV risk.⁴⁹

PROGRAM IMPLEMENTATION

Comprehensive tobacco control programs, which contain elements that work at all levels of the pyramid, illustrate the potential application of this paradigm and the synergies among different levels of intervention. People with low incomes and low educational attainment have higher rates of smoking than do people with higher incomes and education.⁵⁰ Interventions that address social determinants of health, such as increasing a population's educational and economic status, should therefore reduce smoking rates. However, because these changes often require fundamental social

TABLE 1—Structural Approaches to Health Promotion for Communicable Disease, Noncommunicable Disease, and Injury Prevention

Approaches to Prevention	Communicable Disease	Noncommunicable Disease	Injuries
Counseling and educational interventions	Behavioral counseling to reduce sexually transmitted infections	Dietary counseling Counseling to increase levels of physical activity Public education about avoiding lifestyle-mediated disease	Counseling and public education to avoid drinking and driving and encourage compliance with traffic laws School-based programs to prevent or reduce violent behavior
Clinical interventions	HIV treatment to decrease viral load and reduce transmission Treatment of tuberculosis, resulting in decreased spread of infection	Treatment of hypertension and hyperlipidemia Aspirin therapy for people with coronary heart disease	Methadone and buprenorphine treatment to decrease opiate overdose Screening and treatment of women older than 65 years for osteoporosis to reduce fractures
Long-lasting protective interventions	Immunizations Male circumcision in countries with high HIV prevalence and significant female-to-male transmission Mass antibiotics to prevent or treat tropical diseases (e.g., onchocerciasis)	Colonoscopy Treatment of tobacco addiction Surgical sterilization, intrauterine device insertion, or other long-acting contraception to reduce maternal mortality Dental sealants	Brief behavioral counseling to reduce alcohol consumption Home modification, such as installation of grab bars and handrails, to prevent falls among the elderly
Changing the context	Clean water Reduced indoor smoke pollution from biomass cooking Ubiquitous condom availability	<i>Trans</i> fat elimination in processed food to reduce cardiovascular disease Sodium reduction in packaged foods and food served in restaurants to reduce cardiovascular disease Fluoridation of water to prevent dental cavities Elimination of lead paint and asbestos exposures Increased unit price for tobacco, alcohol, and sugar-sweetened beverages Smoke-free workplaces Community and transit design to promote greater physical activity	Road and vehicle design requirements to reduce crashes and protect pedestrians and bicyclists Laws prohibiting the sale of alcohol to minors and increased alcohol price Laws prohibiting driving at even low blood alcohol levels Effectively implementing laws to mandate helmet use by motorcyclists and motorcycle passengers Occupational safety requirements
Socioeconomic factors	Reduced poverty to improve immunity, decreased crowding and environmental exposure to communicable microbes, and improved nutrition, sanitation, and housing	Reduced poverty, increased education levels, and more nutritional options to reduce cardiovascular disease, some cancers, and diabetes	Reduced poverty levels to reduce drug use and violence, improved housing options, and lowered vulnerability to extreme weather conditions

change, they are generally not within the traditional purview of tobacco control or public health programs.

Context-changing interventions, such as increasing tobacco taxes, establishing smoke-free workplaces, and changing the social norms regarding smoking through hard-hitting antitobacco campaigns and elimination of advertising and promotional cues to smoke, are highly effective in reducing tobacco use.⁵¹ Hard-hitting

ad campaigns, particularly as part of a comprehensive tobacco control program, not only reduce tobacco use by changing the social context of smoking⁵² but also provide in effect a social immunization against smoking that persists over time. Clinical care that includes cessation medications can triple quit rates in individual smokers, but even the best systems treat only a small proportion of smokers, and only one third of those who are

motivated to quit and are treated will succeed.⁴⁸ Education about the harms of smoking provides people with information to help them change their behavior. Other examples of this 5-tiered framework applied to communicable disease, chronic disease, and injury prevention are given in Table 1. Inevitably, some programs blur the distinctions between tiers. For example, mass media campaigns for tobacco control could be viewed as an educational

intervention (tier 5), but if done effectively, such actions can change the context by altering the social norms related to tobacco use (tier 2).

PRACTICAL APPLICATION OF THE HEALTH IMPACT PYRAMID

The health impact pyramid, a framework for public health action, postulates that addressing socioeconomic factors (tier 1, or

the base of the pyramid) has the greatest potential to improve health. Interventions that change the context for individual behavior (tier 2) are generally the most effective public health actions; 1-time clinical interventions (tier 3), such as immunizations, can be more effectively applied than those requiring ongoing care; and clinical interventions (tier 4) are generally, although not inevitably, more effective than counseling and education (tier 5).

Although the effectiveness of interventions tends to decrease at higher levels of the pyramid, those at the top often require the least political commitment. Achieving social and economic change might require fundamental societal transformation. Contextual change is often controversial, as evidenced by disputes over smoke-free laws, restrictions on artificial trans fat, and water fluoridation.^{53,54} One-time interventions tend to be less controversial, although immunization programs that attempt to reach all members of a society often meet resistance arising from suspicion and disbelief.⁵⁵

Although the structure and financing of health care systems can be controversial, clinical care itself rarely is. While exceptions exist, health education usually requires minimal political backing. Hence the greater popularity of school-based antismoking programs (despite consistent evidence they provide little to no benefit⁵⁶) than of proven tobacco control interventions such as taxation, smoke-free environments, and comprehensive marketing bans. Similarly, exhorting people to exercise more and eat less is politically popular, but taxation of soda and other sugar-sweetened beverages,⁵⁷ bans on marketing junk food to

children, and community redesign to encourage walking and bicycling, although far more effective, are also politically more difficult.

Interventions that address social determinants of health have the greatest potential public health benefit. Action on these issues needs the support of government and civil society if it is to be successful.⁵⁸ The biggest obstacle to making fundamental societal changes is often not shortage of funds but lack of political will; the health sector is well positioned to build the support and develop the partnerships required for change.⁵⁹

To say that social and contextual changes are more effective at improving public health is not to imply that other interventions should be ignored. For different public health problems, different interventions may be the most effective or feasible in any given context. Education to encourage condom use, although of only limited effectiveness, can reduce HIV transmission and save lives. Changing the context to make condoms ubiquitously available and acceptable makes education about their use more effective. Comprehensive public health programs should generally attempt to implement measures at each level of intervention to maximize synergy and the likelihood of long-term success. ■

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Value Incentives Learning Collaborative

Roundtable project on public and patient engagement on value

- *Engaging Patient Support & Leadership in Value Initiatives—A project of the IOM Value Incentives Learning Collaborative.*
- *Accelerating Innovations in Care Delivery—A proposed workshop of the IOM Value Incentives Learning Collaborative.*
- *Calling the Question—Health system leaders implementing what is known to work.*
- Volpp, Kevin G et al. *Redesigning Employee Health Incentives — Lessons from Behavioral Economics.* New England Journal of Medicine. 2011.
“In general, the effectiveness of outcome-based wellness incentives is uncertain, and their use raises concerns about distributional equity; nevertheless, these approaches are gaining momentum because of rising health care costs and payers’ belief that incentives should work in health care as they do in other spheres.”
- Robert Wood Johnson Foundation. *Talking about Health Care Payment Reform with U.S. Consumers: Key Communications Findings from Focus Groups.* 2011.
“A series of intensive focus groups with consumers has shown that Americans are uncomfortable talking about the role money plays in delivering their health care to them, and insist that dollars should not be a part of the quality-care equation.”



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

ENGAGING PATIENT SUPPORT & LEADERSHIP IN VALUE INITIATIVES

A project of the IOM Value Incentives Learning Collaborative

Activity: Marshaling collaborative initiative to improve public and patient recognition, demand, and action related to the prospects and benefits of achieving better health outcomes at lower costs.

Compelling aim: *Improving value in health care by bridging the current disconnect between patient care decisions and awareness and patient incentives for wasteful, even harmful, healthcare expenditures and practices.* This project aims to achieve better patient engagement and leadership for improving healthcare value by identifying the factors that reflect and shape patient perspectives on value, exploring approaches to improving understanding, and marshaling initiative of stakeholders with the capacity to influence patient attitudes and behavior.

Issue: As noted in the IOM's *Quality Chasm* report, the healthcare system should center its efforts on the patient. This means that all features of the organization, structure, financing, and delivery of health care should be oriented around what is best for patient outcomes, satisfaction, and well-being. The culture of health care has historically been one of dictation by clinician to patients, with little opportunity for discussion or exchange of perspectives. In the face of increasing insight about individual variation in response to diagnostic and treatment tools and approaches—personalized medicine—as well as growing awareness of the impact of patient engagement on outcomes, efforts are underway to build a culture of care with stronger patient awareness and involvement. Despite the fact that patients are expressing greater and greater concern about the level and growth of out-of-pocket health costs, some of society's most difficult challenges relate to engagement of patients around costs and value. Since health costs and waste are prominent threats to both personal welfare and the nation's fiscal integrity, public perspectives are essential in transforming our healthcare system from one that rewards volume to one that rewards value.

Approach: Operating under the auspices of the IOM Value Incentives Learning Collaborative, a stakeholder working group will explore perspectives, issues and approaches in detail. Research efforts will be undertaken to gather available information about patient experience, understanding, and attitudes with respect to health expenditures, and explore the factors shaping those views. Strategies will be fashioned to improve and empower awareness and action, and joint stakeholder action mobilized on the approaches. The two areas of primary attention are: 1) characterizing how patients interact with reported cost and quality information; and 2) engaging patients in their own health care through value initiatives, financial incentives, and benefit design.

Deliverables: A discussion paper summarizing the current status of patient and public attitudes and behaviors related to value; development of a learning network of those working on the issues; and collaborations fashioned with related ongoing improvement activities, e.g. Partnership for Patients.

Related IOM work: *Patients Charting the Course: Citizen Engagement and the Learning Health System* (2011, in press); *The Healthcare Imperative: Lowering Costs and Improving Outcomes* (2010); *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation* (2010); *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001)

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ACCELERATING INNOVATIONS IN CARE DELIVERY: MAKING ACO'S WORK*A Proposed Workshop of the IOM Value Incentives Learning Collaborative*

Activity: The development of Accountable Care Organizations (ACOs) is a conceptual and programmatic centerpiece for implementation of the intent of the Affordable Care Act of 2010 (ACA) to foster effective and efficient health care and health outcomes for individuals and populations. The Institute of Medicine will hold a public workshop to consider early progress in implementation of ACOs; observed successes; challenges encountered; and issues, opportunities, and strategies to accelerate successful implementation of ACOs.

Compelling aim: *Accountable Care Organizations can have a transformative impact on the effectiveness and efficiency of health care delivery, and contribute directly to better health outcomes for both individuals and their communities.* Progress is anticipated by virtue of workshop content (spotlighting key opportunities), process (cooperative engagement of those important to progress), and products (IOM publication to provide touchstone reference points) that will help guide successful ACO implementation nationally.

Issue: It is well recognized that the fragmented nature of health care in the United States, in concert with the misplaced incentives of its payment structure, has driven health expenditures that are by far the highest in the world (nearing \$3 trillion), results that are mediocre for many (health system performance ranking 41st globally), and waste that is crippling (an estimated 30 percent of expenditures). Provisions in the ACA envision the nationwide establishment of ACOs responsible for channeling and assessing health investments in a manner that will yield better outcomes for lower costs at population and individual levels. Current CMS ACO efforts include: pilots, the Medicare Shared Savings Program for ACOs, the Pioneer ACO Model (for health care organizations and providers experienced in coordinating care), and a proposed Advance Payment Initiative (up-front access to capital for investing in infrastructure for care coordination). But these initiatives face significant organizational, economic, legal, political, cultural, and conceptual challenges.

Approach: An IOM planning committee will be formed to develop the program for a meeting or series of meetings to discuss these issues in detail. Building on the work underway through activities at CMS, ACO pilots, private payers, and others, the discussions will engage the most knowledgeable stakeholders in describing current efforts, the major barriers, approaches to addressing those barriers, and the potential design of cooperative activities to implement approaches, nationally and locally. Potential participants include: federal agencies (CMS, CDC, HRSA, ONC), state leaders, leaders in ACO pilots, private payers, healthcare delivery organizations, and public health officials.

Deliverable: A summary of the key ACO opportunities, needs, challenges, strategies, and stakeholder responsibilities; published and disseminated as an IOM workshop report, an individually-authored IOM discussion paper, or both.

Related IOM work: The Healthcare Imperative: Lowering Costs and Improving Outcomes (2010); Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation (2010); Rewarding Provider Performance: Aligning Incentives in Medicare (2007)

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CALLING THE QUESTION

Health system leaders implementing what is known to work

Issue: The unprecedented economic and financial challenges facing the United States today call for transformational changes to the U.S. healthcare system. Insurance premiums for families and individuals have more than doubled over the past decade, with the costs of public health programs, such as Medicare and Medicaid, experiencing a 115 percent increase over the same time frame. Healthcare costs now account for over 17 percent of the U.S. economy, but this substantial investment does not yield superior results. Assessments of waste and inefficiency in health care, including those sponsored under the auspices of the Institute of Medicine, not only suggest that perhaps a third of all health expenditures make no contribution to better outcomes, and sometimes contribute to added illness, injury and expense. Moreover, related assessments and studies have identified practice improvements that can clearly improve the efficiency and effectiveness of care. Despite a growing inventory and awareness of such measures they often go unimplemented by healthcare organizations.

Activity: Building on the Learning Health System work of the IOM Roundtable on Value & Science-Driven Health Care, the IOM proposes to convene key health system chief executives or their equivalents in a one-day invitational meeting—provisionally titled “calling the question”—to identify, explore, and discuss strategies to address chronic system underperformance of healthcare practices widely known to improve efficiency and outcomes.

Participants: CEOs and CFOs of hospitals, healthcare systems, payers, and physician practices

Agenda Topics: New opportunities for addressing waste and experimenting with new incentives are provided by the Affordable Care Act and other recent federal legislation. These policies create new opportunities for Medicare and Medicaid payment incentives, delivery system reforms, and reimbursement structures. The workshop would build on these opportunities and explore areas where the healthcare system could:

- improve the consistency of care, especially using system approaches and design;
- reduce duplicative or redundant diagnostics and therapeutics through improved communications and health IT;
- coordinate care between multiple settings and providers through new care models;
- prevent disease, enhance the health of communities, and improve overall population health;
- disseminate promising care delivery strategies, high-value diagnostics and therapeutics, and evidence-based clinical care processes; and
- strengthen organizational culture and leadership to encourage continuous improvement in safe, effective, seamless, patient-centered care.

The workshop will consider both individual institutional practices that might make an immediate impact on costs and outcomes of care, as well as policy initiatives CMS could undertake to meet these objectives, including redesigning payment systems and financial incentives, regulations and legal structures, data sharing and access, and quality and population health metrics. To use these levers successfully, innovative payment practices should be inventoried, including those that proved unsuccessful; the critical elements for measuring provider and hospital performance for financial incentives must be identified, with an understanding of how to adjust these measures for different healthcare settings and different patient populations; and an ongoing public discussion is needed on health financing and delivery system reform.

es could affect safety or efficacy. Tracking adverse events associated with the use of reference and biosimilar products will be difficult if the specific product or manufacturer cannot be readily identified, and appropriate strategies must be developed to ensure the implementation of robust, modern pharmacovigilance programs for biologics.

Under the BPCI Act, biosimilars will also have the opportunity to meet a higher standard of similarity to a reference product — “interchangeability,” reflecting an FDA assessment that pharmacists can make substitutions between biologics without the prescriber’s intervention. A biologic will be considered interchangeable with a reference product if the developer demonstrates that it can be expected to pro-

duce the same clinical result in any given patient and that the risk associated with alternating or switching between the two products is not greater than that involved in continuing to use the reference product.

The FDA will carefully consider what data will be necessary for this purpose and translate that assessment into effective regulatory standards. The agency will also develop standards to ensure that products not deemed interchangeable are not inadvertently substituted for a reference product without the prescriber’s consent. But even without interchangeability, recognition that two products are biosimilar will give clinicians far more information than the mere knowledge that they were developed for the same indication.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD.

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Redesigning Employee Health Incentives — Lessons from Behavioral Economics

Kevin G. Volpp, M.D., Ph.D., David A. Asch, M.D., M.B.A., Robert Galvin, M.D., M.B.A., and George Loewenstein, Ph.D.

Buried as Section 2705 of the Patient Protection and Affordable Care Act (ACA) is a provision of potentially momentous importance. Beginning in 2014, employers may use up to 30% of the total amount of employees’ health insurance premiums (50% at the discretion of the secretary of health and human services) to provide outcome-based wellness incentives. Such rewards can “be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or co-

insurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.”

This provision represents an attempt to rein in health care costs, to which health conditions associated with unhealthy behaviors, such as smoking, overeating, and not exercising, are major contributors. Projections that the provision would reduce costs arose, in part, from claims that Safeway Supermarkets had achieved flat health care costs from 2005 to 2009 by tying employees’ health insurance premiums to outcome-

based wellness incentives.¹ It later became clear, however, that Safeway’s program began in 2008 — too late to deserve credit for flat costs starting in 2005.²

Although it may seem obvious that charging higher premiums for smoking (or high body-mass index, cholesterol, or blood pressure) would encourage people to modify their habits to lower their premiums, evidence that differential premiums change health-related behavior is scant. Indeed, we’re unaware of any health insurance data that have convincingly demonstrated such effects.

Enabling employers to vary premiums on the basis of employees' health-related behaviors or health outcomes could undermine some of the ACA's intended benefits. The law aims at universal coverage, partly to spread the costs of addressing health risks across the population and partly

haviors and outcomes that may not be completely under their control.

The hope behind this ACA provision is that it will improve health-related behavior and reduce the prevalence of chronic disease caused by unhealthy lifestyles. Our research and that of other

interventions involve immediate costs (the inconvenience of taking a drug or undergoing a preventive medical procedure) with delayed and often uncertain benefits of better health years later. From this perspective, attempts to motivate behavior change through annual premium adjustments are unlikely to be maximally effective because the consequences are delayed. Ideally, incentives should provide small but tangible and frequent positive feedback or rewards. A program that promotes exercise with a year-end rebate for gym attendance or a small year-end reduction in one's health insurance premium is far less likely to succeed than one providing incentives, and symbolic encouragement, at every visit. Similar concepts apply to most health-related behaviors, such as smoking or medication adherence, for which incentives might bring immediate and frequent attention to otherwise delayed benefits.

Another relevant behavioral economics concept is mental accounting, which reflects how people tend to categorize monetary receipts and payments. For instance, the effect of rewards (or punishments) diminishes when they're bundled into larger sums of money: a \$100 discount on premiums may go unnoticed, whereas a \$100 check in the mail may register as an unexpected windfall. Increases or decreases in insurance premiums that are deducted from periodic paychecks will probably be less salient and effective than similar financial incentives provided separately.

Finally, although there's generally wider support for programs that reward people for healthy behavior than those that penal-

Findings of behavioral economics suggest that the same decision errors that contribute to poor health-related behaviors can be used to “supercharge” incentive programs.

to discourage insurers from trying to enroll only the healthiest (and lowest-cost) individuals. Although the health benefits achievable through wellness incentives may be greater in lower-income than in higher-income populations — both because lower-income people would place greater value on the same level of incentive and because their rates of poor outcomes tied to behaviors such as smoking tend to be higher — a system linking premiums to health outcomes would probably lead to higher premiums for lower-income individuals and families. If some employers or insurers started reducing rates for healthier people and raising them for the less healthy, healthier people would gravitate toward firms with such policies, and other employers and insurers would feel pressure to follow suit. Although employers and payers increasingly see personal accountability as fair and as an important aspect of effective health care reform, many people would end up paying higher premiums for be-

behavioral economists shows that this premise cannot be assumed. The effectiveness of incentive programs depends critically on how the incentives are timed, distributed, and framed,³ and several factors might make insurance-premium adjustments, the most common implementation mechanism, less effective dollar for dollar than other approaches.

Findings of behavioral economics suggest that the same decision errors that contribute to poor health-related behaviors can be used to “supercharge” incentive programs so that they motivate behavior change more effectively than simple premium adjustments do.⁴ For example, in making decisions, people place more weight on the present than the future — they're more attracted by immediate than delayed benefits and more deterred by immediate than delayed costs. Many behavioral patterns that undermine health involve immediate benefits and delayed costs (eating provides immediate gratification but may cause later obesity) and many

ize them for unhealthy behavior, issues of perceived efficiency and fairness often cause the former to be transformed into the latter. Efficiency favors penalty programs because they effectively target people who could benefit from changing their behavior, whereas reward programs may expend resources on people who are already performing targeted behaviors (e.g., not smoking) or, if they target behavior change, could motivate people to adopt the undesired behavior so as to reap rewards through cessation. Many people may favor penalty programs because they find it distasteful to reward people for behaviors that are in their own self-interest. However, reward programs are more likely than penalty programs to convey a sense of cooperation between employer and employee in seeking a mutually beneficial goal — employees' health. Data are scarce on whether reward or penalty programs are more effective — a critical question that may override philosophical preferences.

Our experience with implementation of a program following the completion of a randomized, controlled trial in which \$750 incentives resulted in a tripling of smoking-cessation rates, from 5.0% to 14.7%, after 9 to 12 months in a large-employer setting highlights some of the limitations of a straightforward application of concepts from be-

havioral economics.⁵ Once the company decided to implement an incentive program based on the study findings, feedback from nonsmoking employees led to the replacement of the \$750 reward with a \$625 penalty for smokers. Nonsmokers believed that their colleagues shouldn't be rewarded for "something I did myself without any reward." In addition, for practical reasons, the penalty was tied into health insurance premiums: incorporating it into payroll deductions was far simpler administratively than setting up a separate system for financially penalizing smokers. The anticipated difficulty of collecting money from smokers who didn't quit suggests that whereas reward systems can be made more effective by being separated from paychecks, that approach probably isn't feasible for penalties. Providing rewards outside the premium framework would make them taxable, and it's unclear whether a taxed but more salient reward is more effective than a premium adjustment.

In general, the effectiveness of outcome-based wellness incentives is uncertain, and their use raises concerns about distributional equity; nevertheless, these approaches are gaining momentum because of rising health care costs and payers' belief that incentives should work in health care as they do in other spheres. Lessons from behavioral eco-

nomics could improve incentive-program design, but real-world implementation challenges may lead to substantial deviation from theoretically optimal design. Developing and testing a variety of programs between now and 2014 will generate the data needed to determine how best to use this new approach to improve health.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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Robert Wood Johnson Foundation

Talking about Health Care Payment Reform with U.S. Consumers: **Key Communications Findings from Focus Groups**

Communications research conducted on behalf of the Robert Wood Johnson Foundation

April 2011

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Talking About Health Care Payment Reform with U.S. Consumers:

Key Communications Findings from Focus Groups

Finding effective language to talk to consumers about changing the way health care is paid for in the United States is extremely challenging. A series of intensive focus groups with consumers has shown that Americans are uncomfortable talking about the role money plays in delivering their health care to them, and insist that dollars should not be a part of the quality-care equation. When forced to have discussions about system reforms or controlling health care costs, emotions quickly escalate and fears that access to care may be limited dominate the conversation. But as difficult as conversations about new models for paying for health care may be, the nation still needs to have them, and soon.

The Robert Wood Johnson Foundation (RWJF) is the largest foundation focused exclusively on health and health care in the United States. As a core part of its mission, RWJF is helping to lead a transformation in the quality of care provided to people in communities nationwide. *Aligning Forces for Quality* (AF4Q) is RWJF's signature effort to lift the overall quality of health care in targeted communities, as well as reduce racial and ethnic disparities and provide real models of local reform to national leaders. In the regions where Aligning Forces operates, people who get care, give care and pay for care are working to rebuild health care systems, so they work better for everyone involved. The program intends to drive change in local health care markets that will result in measureable improvements by 2015.

Since AF4Q kicked off in 2006, it has helped define the field of regional quality improvement. When the program began, the idea of diverse local stakeholders linking approaches to enhance quality and increase the value of health care was novel. Since then, Aligning Forces' emphasis on 1) engaging consumers, 2) measuring the performance of providers and reporting it publicly, and 3) improving the quality and equality of care being delivered has taken hold.

RWJF has long been committed to changing the current health care payment system to one that rewards value instead of volume. The foundation believes public and private payers should use common measures to assess provider performance, and that providers who deliver high-quality, cost-effective care or who improve significantly should be rewarded. RWJF also believes providers should be fairly compensated for preventive care, time spent coaching patients and coordinating care for those with chronic conditions.

As part of their commitment and beliefs, RWJF leadership has invested in considerable research and demonstration projects to explore different models for delivering care and for paying doctors and hospitals to deliver high-quality health care. The insights gained from this work are foundational to the work undertaken as part of the third phase of the Aligning Forces initiative, begun in 2011.

From 2011 to 2013, communities involved in AF4Q will engage in their own exploratory efforts to improve the way providers are reimbursed. Each will implement – or set the stage to implement – a workable model for reforming a segment of the health care payment system in their community. They will develop and test small-scale models that incentivize providers to deliver high-quality, cost-effective care.

As organizers in Aligning Forces communities begin their payment reform efforts, it is important that they have tested language and messages that best explain the need for payment reform in ways that consumers will understand and not fear their work.

The AF4Q program has traditionally provided this type of message assistance. In the summer of 2007, RWJF began a process to develop messages for use by the Aligning Forces communities to begin conversations with consumers and patients about “quality” health care. The foundation recognized that educating the public about the importance of quality health care and making informed choices about one’s health is an instrumental part of health care transformation. Thus, RWJF sponsored research on how best to begin explaining the problems with health care quality, highlighting the types of solutions AF4Q is pursuing and calling people to action. Later, messages to use in beginning conversations with physicians about performance measurement and public reporting were developed and tested.

The goal of this communications research project was to develop and test simple messages that explain the concepts of payment and delivery reform to consumers in ways they understand and support.

IMPORTANT: The focus group results explained in this report were conducted for the sole purpose of identifying and testing messages for communications purposes. The groups were not conducted to determine – and the results do not explain – how to design different payment or reimbursement systems, or which types of systems consumers will support.

The Message Research Process

RWJF staff and communications consultants from GYMR Public Relations and MSLGROUP worked with Lake Research Partners, a nationally respected message research and polling firm, to craft basic messages that explain the issues around health care payment, cost and value. These included concepts about delivery and payment reforms that coupled would improve the doctor-patient relationship and provide direct benefits to the patient. Dozens of words, phrases and message concepts were discussed in focus groups with people who are informed and engaged health care consumers and caregivers in their communities. Based on their reactions, initial messages were edited and some were refined for further exploration in a second round of focus groups, again with informed and engaged consumers. Based on the results, the team developed a final set of core messages. The four-step process for developing and testing messages included:

1. Brief analysis of existing research

Despite its importance, surprisingly little research had already been conducted into how consumers view the role money plays in delivering health care. A sampling of existing research on consumer views on health care costs, and payment and delivery reform were reviewed. Using the insight gained from this review, sample messages and a focus group guide were developed.

2. Initial round of six focus groups

Six focus groups were conducted in December 2010 in Detroit, Kansas City, Mo. and Boston, all AF4Q communities. Groups were segmented by gender and included a mix of age, race, ethnicity, education and income. All participants were insured and half were managing at least one chronic condition. The initial groups tested concepts around payment reform and responses to negative reactions. The challenges encountered were used to refine message concepts.

3. Second round of four focus groups

A second round of four focus groups took place in March of 2011 in Charlotte, N.C. and Philadelphia, neither of which are AF4Q communities. The participants were of the same profile as in the first round. The aim was to further test concepts and determine what language resonated most favorably with consumers.

4. Finalize messages

Based on the results of the focus groups, final messages were selected and reviewed by RWJF staff and prepared for the AF4Q communities and related audiences.

Three Key Takeaways

1. **This is not a conversation most consumers want to engage in.** Beginning an aggressive public discussion about payment reform with consumers right now could raise more questions than answers, creating more problems than clearing paths toward solutions. The focus groups made it abundantly clear that consumers do not want to think or talk about how, when or why their health care providers are paid. They have little to no knowledge about how the current reimbursement process works, and linking money or payment to their health and health care makes them uncomfortable at best, very angry at worst. Especially in this economy, the notion that physicians should be paid differently to do high-quality work or go the extra mile to give their patients the care they need is a non-starter. The messages in this report therefore, are best used reactively rather than proactively.
2. **There is a gender gap with this issue.** In every focus group, men and women responded very differently to the topics of health care payment, earning more for higher performance and using adherence of established guidelines to measure quality of care. While both men and women expressed deep commitment to their doctor-patient relationship, men were far more ready to consider quantifying the relationship in terms of care-provided-for-dollars-earned. Women, in contrast, almost always spoke of the relationship in much more personal terms, and repeatedly expressed concerns that data alone do not provide information on the patient's *personal experience* with the doctor. This is interesting, because while *men* seemed more ready to think about reforming the payment system, communications research has shown that *women* are typically a family's gatekeeper to the health care system and choose doctors for family members. Closing this gender gap will be key to any broad changes to the system for paying doctors.
3. **While consumers don't want to discuss payment and reform, they do want changes in care delivery – and these changes open the door to the conversation.** Patients want to spend more time with their physicians, and they want the care they receive from different doctors to be better coordinated among them. While they are not keen to think about the role of money in their own personal health care, they are open to hearing about new methods of structuring the system if it would result in more of what they want without more cost to them.

Lessons Learned from Exploring Message Concepts

✓ **“Reform” is not a popular word.**

Regardless of political ideology, there seemed to be fatigue, at best, and fear, at worst, about any concepts of further “reform” of American health care. Even when reform was seen as positive, there was little support from participants for it to be tested in their backyard. To reduce instant negative reactions by consumers, “payment and delivery reform” is best described as “improvements/changes to the payment and reimbursement system” rather than reform.

✓ **Focus on improving the doctor-patient relationship as the primary reason to change the payment/reimbursement system.**

Consumers value the personal nature of the doctor-patient relationship, want to be involved in the decision-making process and want physicians to communicate with them more effectively. They support changes that would enable providers to spend enough time with them during appointments to address all of their questions, stay open late so they can see the doctor after the work day, or to at least answer their questions through a phone call, email or quick visit - even if they aren’t scheduled for an appointment, and can help them avoid a trip to the emergency room.

✓ **Focus messages on PATIENTS not physicians.**

Consumers were ambivalent towards messages about changing the way health care is reimbursed to help physicians overcome barriers to practicing medicine the way they want to. The team tested initial messages focused on the plight of today’s primary care physicians under the current fee-for-service system, and consumers did not respond well. While they like their own doctors, they have little sympathy for the complaints of physicians. They see them as being among the best paid professionals. When told that physicians often do not get paid for doing the types of things necessary to effectively manage their patients’ care, many cite examples of “going above and beyond” what they are paid to do in their own jobs, having to stay late to do it and not getting a bonus for it. Most believe physicians did not go into health care for financial reasons and it unnerved them that doctors could be motivated by money. These feelings were especially strong when discussing incentivizing doctors for doing things they don’t currently get paid for, or “rewarding” them for providing high-quality care. They were shocked that physicians would need to be paid more to “provide good care.” Further discussion made them angrier, and many questioned whether physicians were “being greedy.”

I didn’t like this “easier” for your doctor. I am the patient and it may sound selfish but I am not worried about making it “easier” for the doctor.

Female - Detroit, MI

✓ **Position the benefits to consumers as “improving care coordination” and “increasing preventive care.”**

Phrases like “improving care by having doctors and nurses and other medical professionals work together more” elicited positive reactions. People do not initially believe that doctors should be paid more to coordinate care, but certainly want coordination between their different doctors’ offices to be improved. By adding that better care coordination is a key to ensuring patients receive all the necessary preventive services and avoiding unnecessary hospital visits, participants’ positive reactions intensified.

I hate when the left hand doesn’t know what the right hand is doing. It’s so frustrating.
Male – Philadelphia, PA

I like the idea of everyone communicating because I know that when I go to a new doctor or someone like a specialist that I don’t want to have to explain myself all over again. It is like retelling my story all over again and they say have you done this -- yes I have done that, my primary doctor has done that.

Female – Charlotte, NC

✓ **Explain the need to improve the reimbursement system around benefits of action, not risks of inaction.**

Consumers reacted poorly to messages that positioned this work as curtailing incidents of physicians performing the “wrong tests” or prescribing the “wrong medications.” They do not like the idea that they may receive the wrong care and this line of messaging caused them to shut down. They responded much more positively when the issue is framed as, “[making] sure you get the right medications and tests.”

✓ **Do not discuss “efficiency” and “value.”**

In initial focus groups, conversations about “eliminating waste,” “increasing efficiency” or even “saving money” sparked consumers to think this work could lead to rationing care that they want – and feel they need – but that may be expensive. The same holds true for the concept of increasing “value” in health care. They think of value as something they “go to a big box store for” – certainly not their doctor’s office. Anything that makes them feel that their care will be cheapened, time with their physician will be lessened, or – worst of all – that the care that they want will be curtailed, is a massive threat and not supported.

✓ **People want to hear about actions taken, not ideas discussed.**

After failing with passive messages like, “our community is talking about how to improve care” that focus group participants said sounded unsubstantial and inconsequential, success was found with active phrases like, “our doctors and

hospitals are working with insurers, employers and everyday people to find better ways to make sure people get the best care possible.” Focus group participants reacted positively to this line of messaging and noted that it sounded like real change was in the works, something they are eager to see (if described just right).

✓ **Frame conversation about costs as “spending dollars more wisely” – not cutting costs from the system.**

Consumers think health care is expensive, and messages about “spending health care dollars more wisely” resonate with them. They know a lot of money flows through the health system and think some of it could be repurposed – not necessarily eliminated – with better results. They liked the concept of finding better ways to deliver health care without paying more for it and without taking dollars away from it (which sparks fears of rationing). Consumers are aware that the U.S. spends more money than other countries on health care – but don’t know if that is a good or bad thing. They also know that examples of health care systems that provide quality, individually-tailored health care and use consumer dollars wisely already exist in the U.S., at places like the Mayo Clinic, and they want that kind of care. (Mentioning that a payment and delivery model - or type of care - was tried at the Mayo Clinic increased interest.)

✓ **Consumers want to see their doctor, not his/her nurse and not necessarily a “team.”**

Talk about the concept of well-coordinated “teams” managing a patient’s care sparks concerns among consumers. They feel that it means they will see less of their primary provider, be cared for by others who are not necessarily physicians (e.g., nurses and other assistants) or that too many people will be involved in their care with no one in charge. Some worried about privacy if too many people were involved. Many focus group participants felt the “team” concept undermined the patient-doctor relationship by involving too many people and could limit the time a patient has with his/her provider. Others felt that a “team” setting would create confusion around who would be in charge of a person’s care. With further discussion and clearly explaining that a patient’s doctor would be in charge, or the “quarterback” of the health care team, and that it would not limit their time with their doctor, the participants had a more positive view of the health care “team.”

If you have ever been a part of the whole team concept at your job, all of this money they spent on this and all of this training ... and it ended up not working. They hand off everything to each team member and something gets dropped, then it becomes a big bother and they spent thousands of dollars on the whole thing.

Female – Detroit, MI

✓ **It's tough to explain “measures,” “quality” and “guidelines.”**

Previous research has shown that consumers do not understand the concept of performance measures in health care, and references to measures and guidelines feel constraining to them. These terms speak to their fear that they will not be able to get whatever care they want whenever they want it in the future. They want to know who determines the guidelines and are concerned that using them will limit the care that they passionately feel they need to receive. Emphasizing that national medical experts/organizations created the guidelines, and that they are based on scientific evidence and are not binding on anyone helped defuse concerns.

Tested Messages for Use with Consumers

Tested Statement that Effectively Describe the Overall Effort to Consumers

- a. Right here in our community, XXXXX, a nonprofit group, is looking at ways to improve the health care that we all receive. We're bringing together patients, doctors, business owners, insurers and others to find ways to get better outcomes and spend dollars more wisely. That includes making sure that doctors understand that we want to pay for the *right* care, not tests or procedures that we do not need.

Tested Statements that Effectively Explain Payment and Delivery Reform to Consumers

- b. We want to make sure the way insurance pays for health care is consistent with the way you want to receive it. That means high-quality care that is tailored just for you, based on the best medical evidence, well-coordinated and communicated across your health care providers.
- c. We have all heard about mistakes in health care – stories of people who did not get the care they should have gotten, or got care they never needed. Across America and right here at home, experts are looking at different ways of paying doctors – without any of us having to spend any more money – that would ensure patients are more likely to get high-quality care.
- d. We want to test different ways insurance companies pay doctors to see what methods lead to physicians providing the highest-quality patient care most often.

Tested Statements that Effectively Link Payment to Quality/Guidelines

- e. We are looking to see if paying physicians for providing care that is proven to work – like regularly checking the feet of people with diabetes in order to prevent complications like amputation later down the road – results in more physicians giving these check-ups.
- f. There is an effort underway locally to look at ways to pay physicians based on whether they deliver care that is recommended by guidelines developed by national medical experts. Guidelines are just recommendations and do not need to be followed with every patient, but they indicate the type of care that generally works best for most patients, based on the evidence.

Tested Explanatory Narrative to Use with Consumers:

Our community is looking for ways to improve health care. Working with XXXXX, a nonprofit organization, our doctors and hospitals are working with insurers, employers and everyday people to find better ways to make sure people get the best care possible. Everyone who provides care (like doctors), pays for care (like employers) and gets care (like all of us) has a role to play, but it all starts with making sure patients have a strong relationship with their doctor. We want your doctor to have enough time to talk to you and address all of your concerns. We want you to be able to see or talk to your doctor or someone else in his office when you need to, even if it is after office hours, so you do not have to go to the emergency room if you do not need to.

Some communities are improving care by having doctors and nurses work together more. This gives them more time to talk with you and more opportunities to involve you in decisions about your care. It allows doctors and their staff to help coordinate your care, especially if you see more than one doctor or are getting out of the hospital. This could improve communication with you and your other doctors – and improve communication between them about you.

Your doctor is the best person to help you manage your different health care needs, so we want your doctor to be more in the loop on the health care you receive. Coordination between your different doctors is important for making sure you get all the preventive care you need, as well as the right medications and tests, and that you do not have to take tests twice or repeat yourself over and over as you explain your health needs.

Research has shown that when doctors and nurses work closely together, they do a better job of coordinating your care and making sure you understand all of your health care needs, especially what you are supposed to do at home. They can even call you to make sure you understand your follow-up care.

We are also working to find better ways to pay for health care. Right now, insurance companies pay most doctors based on the number of patients they see in a day, or how many different procedures they do. We want to make sure that the way insurance pays for health care is consistent with the way you want to receive it, which is high-quality care tailored just for you, based on the best medical evidence and your doctor's recommendations, and well-coordinated. Health care is expensive, so it is important that we spend every dollar wisely. The goal is not to spend more money – it is to spend money in ways that best serve you, the patient. We are learning how to do this from some of the best health care systems in the country, like the Mayo Clinic, who have already found ways to improve care while using dollars more wisely.

#

Tested Answers to Five Common Questions

1. How can you measure quality?

- There are also certain things that medical experts agree that doctors should do for people with certain health conditions. When you get these things it indicates you're getting high-quality care. These standards are measurable, like whether or not a doctor gives a diabetes patient a foot exam, eye exam and blood test when they're supposed to.

2. Who determines quality/standards?

- Medical organizations establish certain standards for care, based on scientific evidence, to improve health and prevent illness. Every patient is different and there are always exceptions to the standards. But these standards of quality are widely accepted by doctors across the country. Whether or not doctors follow these standards can indicate the quality of care he or she provides.

3. How would payment changes affect my doctor and my care?

- Your doctor's pay could depend in part on providing consistently high-quality care, based on standards. He or she would not get less payment under any circumstances. You would not pay any differently than you currently do.

4. I'm skeptical of changing the way doctors are paid. Won't they just follow the money?

- We hope so. Instead of just getting paid for seeing as many patients as possible, doctors would be paid, in part, to provide high-quality care, based on standards. That's the care that medical experts agree should usually be provided and that you should expect.

5. Wouldn't this make health care more expensive?

- This would not cost you more. Right now doctors are paid for a lot of things that are not related to making sure your care is the absolute best care or making sure your condition is well-managed. For example, a lot of the costs that come from serious complications from diabetes – like losing a foot – could be avoided if we paid doctors specifically for giving you the care that we know results in fewer complications. We are trying to use existing health care dollars more wisely.

###

Evidence Communication Innovation Collaborative

Roundtable project on messaging about evidence

- *Communicating Evidence in Health Care—Advancing patient and consumer engagement with healthcare evidence.*
- Gawande, Atul. *Cowboys and Pit Crews*. The New Yorker. 2011.
“The problems of making health care work are large. The complexities are overwhelming governments, economies, and societies around the world. We have every indication, however, that where people in medicine combine their talents and efforts to design organized service to patients and local communities, extraordinary change can result.”



COMMUNICATING EVIDENCE IN HEALTH CARE

Advancing patient and consumer engagement with health care evidence

Activity: Identify factors most influential to patient and consumer understanding of evidence in health care and develop principles and strategies to guide evidence communication and decisions by patients and their clinicians that yield the most effective health care.

Compelling aim: *Increase the routine use of the best available evidence in medical decision-making by raising awareness and increasing demand among patients, clinicians, healthcare organizations, and policy-makers for medical evidence.* In three steps that engage patients, clinicians, and managers/policy-makers, this project will uncover successful strategies for communication of medical evidence in the context of the clinical encounter.

Issue: Involving patients in their own health decisions yields better adherence to treatment and screening recommendations, higher satisfaction, lower costs, and better health outcomes. Achieving high quality medical decisions requires established scientific evidence, sound clinician judgment, revealed patient goals and preferences, and communication strategies to facilitate the effective exchange of reliable information. Challenges and complications to the use of evidence arise from many sources: the ever-changing nature of the evidence base, limitations in generalizability of research findings, inconsistent or competing interpretations, distorted or erroneous reporting by the media, commercial advertising, perceptions that evidence might restrict options (e.g. force lower cost, lower quality care, limit clinician). An effort is needed to improve patient and public understanding of the nature of evidence, including identification of effective, consistent approaches to communication that are harmonized across sources.

Approach: A working group of participants in the Evidence Communication Innovation Collaborative (ECIC) of the IOM Roundtable on Value & Science-Driven Health Care will undertake an effort to identify and explore the issues, propose touchstone principles and strategies, and test approaches. The project has 3 stages: 1) identify influential factors shaping perspectives and understanding of evidence among patients; 2) develop principles and strategies to guide evidence communication between patients and clinicians; 3) explore and test messages within health care environments to support shared decision-making which incorporates evidence. Activities will include framing and testing messages that enhance understanding of the nature of evidence, as well as quantification of message uptake. There will be a particular focus on leveraging the existing dissemination networks within ECIC- and BPIC-participating public, private, governmental, professional, payer, and commercial organizations. Findings will be used to develop a plan for further dissemination and implementation by other interested parties (e.g.: general public, government, consumer groups, health leaders, commercial marketers, policy makers).

Deliverables: Tested messages about evidence communication for use by clinicians, healthcare and consumer organizations, and policy-makers.

Related IOM work: *Patient-Clinician Communication: Principles & Expectations* (2011); *Learning What Works: Infrastructure Required for Comparative Effectiveness Research—Workshop Summary* (2011); *Clinical Data as the Basic Staple for Health Learning—Workshop Summary* (2011); *Health Literacy, eHealth, and Communication: Putting the Consumer First. Workshop Summary* (2009); *Speaking of Health: Assessing Health Communication Strategies for Diverse Populations* (2002); *Science and Risk Communication: A Mini-Symposium Sponsored by the Roundtable on Environmental Health Sciences, Research, and Medicine* (2001)

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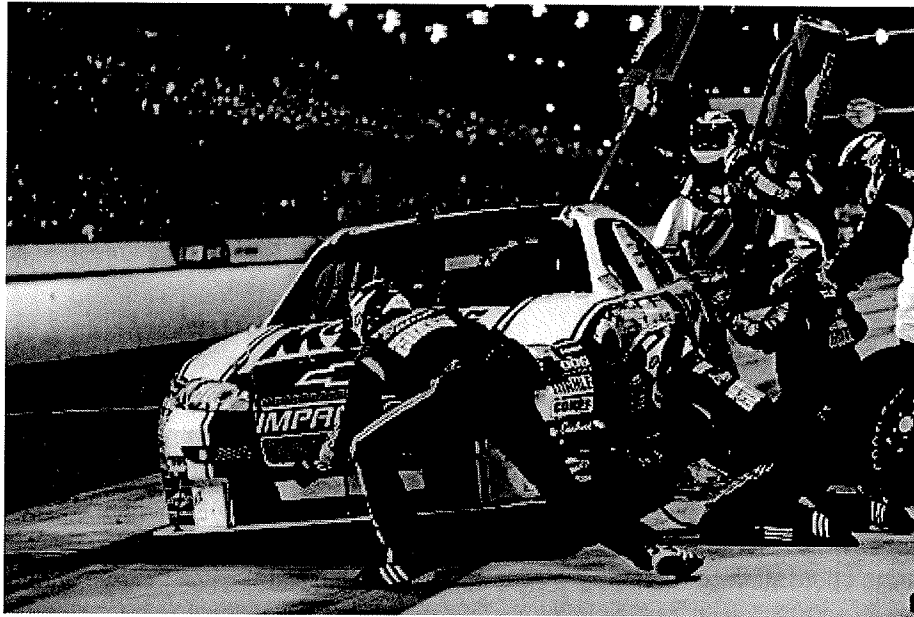
THE NEW YORKER

- « Video: The Reprogrammer
- Main
- Ratko Mladic's Downfall »

May 26, 2011

Cowboys and Pit Crews

Posted by *Atul Gawande*



This afternoon, Atul Gawande delivered this year's commencement address at Harvard Medical School.

In his book “The Youngest Science,” the great physician-writer Lewis Thomas described his internship at Boston City Hospital in pre-penicillin 1937. Hospital work, he observed, was mainly custodial. “If being in a hospital bed made a difference,” he said, “it was mostly the difference produced by warmth, shelter, and food, and attentive, friendly care, and the matchless skill of the nurses in providing these things. Whether you survived or not depended on the natural history of the disease itself. Medicine made little or no difference.”

That didn't stop the interns from being, as he put it, “frantically busy.” He learned to focus on diagnosis—insuring nothing was missed, especially an illness with an actual, effective treatment. There were only a few. Lobar pneumonia could be treated with antiserum, an injection of rabbit antibodies against the pneumococcus, if the intern identified the subtype correctly. Patients in diabetic coma responded dramatically to animal-extracted insulin and intravenous fluid. Acute heart failure patients could be saved by bleeding away a pint of blood from an arm vein, administering a leaf-preparation of digitalis, and delivering oxygen by tent. Early syphilitic paresis sometimes responded to a mix of mercury, bismuth, and arsenic. Surgery could treat certain tumors and infections. Beyond that, medical capabilities didn't extend much further.

The distance medicine has travelled in the couple of generations since is almost unfathomable for us today. We now have treatments for nearly all of the tens of thousand of diagnoses and conditions that afflict human beings. We have more than six thousand drugs and four thousand medical and surgical procedures, and you, the clinicians graduating

today, will be legally permitted to provide them. Such capabilities cannot guarantee everyone a long and healthy life, but they can make it possible for most.

People worldwide want and deserve the benefits of your capabilities. Many fear they will be denied them, however, whether because of cost, availability, or incompetence of caregivers. We are now witnessing a global societal struggle to assure universal delivery of our know-how. We in medicine, however, have been slow to grasp why this is such a struggle, or how the volume of discovery has changed our work and responsibilities.

The rapid growth in medicine's capacities is not just a difference in degree but a difference in kind. We have experienced the sort of vast, quantum alteration that my father describes experiencing during a life that brought him from childhood in rural India to retirement from a surgical practice in Ohio. The greatest leap for him, he tells me, wasn't in taking that first step off the plane in New York City, extraordinary as that was. It was in going from his rural farming village of five thousand people to Nagpur, a city of millions where he was admitted to medical school, three hundred kilometers away. Both communities were impoverished. But the structure of life, the values, and the ideas were so different as to be unrecognizable. Visiting back home, he found that one generation couldn't even grasp the other's challenges. Here is where we seem to find ourselves, as well.

We are at a cusp point in medical generations. The doctors of former generations lament what medicine has become. If they could start over, the surveys tell us, they wouldn't choose the profession today. They recall a simpler past without insurance-company hassles, government regulations, malpractice litigation, not to mention nurses and doctors bearing tattoos and talking of wanting "balance" in their lives. These are not the cause of their unease, however. They are symptoms of a deeper condition—which is the reality that medicine's complexity has exceeded our individual capabilities as doctors.

The core structure of medicine—how health care is organized and practiced—emerged in an era when doctors could hold all the key information patients needed in their heads and manage everything required themselves. One needed only an ethic of hard work, a prescription pad, a secretary, and a hospital willing to serve as one's workshop, loaning a bed and nurses for a patient's convalescence, maybe an operating room with a few basic tools. We were craftsmen. We could set the fracture, spin the blood, plate the cultures, administer the antiserum. The nature of the knowledge lent itself to prizing autonomy, independence, and self-sufficiency among our highest values, and to designing medicine accordingly. But you can't hold all the information in your head any longer, and you can't master all the skills. No one person can work up a patient's back pain, run the immunoassay, do the physical therapy, protocol the MRI, and direct the treatment of the unexpected cancer found growing in the spine. I don't even know what it means to "protocol" the MRI.

Before Elias Zerhouni became director of the National Institutes of Health, he was a senior hospital leader at Johns Hopkins, and he calculated how many clinical staff were involved in the care of their typical hospital patient—how many doctors, nurses, and so on. In 1970, he found, it was 2.5 full-time equivalents. By the end of the nineteen-nineties, it was more than fifteen. The number must be even larger today. Everyone has just a piece of patient care. We're all specialists now—even primary-care doctors. A structure that prioritizes the independence of all those specialists will have enormous difficulty achieving great care.

We don't have to look far for evidence. Two million patients pick up infections in American hospitals, most because someone didn't follow basic antiseptic precautions. Forty per cent of coronary-disease patients and sixty per cent of asthma patients receive incomplete or inappropriate care. And half of major surgical complications are avoidable with existing knowledge. It's like no one's in charge—because no one is. The public's experience is that we have amazing clinicians and technologies but little consistent sense that they come together to provide an actual system of care, from start to finish, for people. We train, hire, and pay doctors to be cowboys. But it's pit crews people need.

Another sign this is the case is the unsustainable growth in the cost of health care. Medical performance tends to follow a bell curve, with a wide gap between the best and the worst results for a given condition, depending on where people go for care. The costs follow a bell curve, as well, varying for similar patients by thirty to fifty per cent. But the

interesting thing is: the curves do not match. The places that get the best results are not the most expensive places. Indeed, many are among the least expensive. This means there is hope—for if the best results required the highest costs, then rationing care would be the only choice. Instead, however, we can look to the top performers—the positive deviants—to understand how to provide what society most needs: better care at lower cost. And the pattern seems to be that the places that function most like a system are most successful.

By a system I mean that the diverse people actually work together to direct their specialized capabilities toward common goals for patients. They are coordinated by design. They are pit crews. To function this way, however, you must cultivate certain skills which are uncommon in practice and not often taught.

For one, you must acquire an ability to recognize when you've succeeded and when you've failed for patients. People in effective systems become interested in data. They put effort and resources into collecting them, refining them, understanding what they say about their performance.

Second, you must grow an ability to devise solutions for the system problems that data and experience uncover. When I was in medical school, for instance, one of the last ways I'd have imagined spending time in my future surgical career would have been working on things like checklists. Robots and surgical techniques, sure. Information technology, maybe. But checklists?

They turn out, however, to be among the basic tools of the quality and productivity revolution in aviation, engineering, construction—in virtually every field combining high risk and complexity. Checklists seem lowly and simplistic, but they help fill in for the gaps in our brains and between our brains. They emphasize group precision in execution. And making them in medicine has forced us to define our key aims for our patients and to say exactly what we will do to achieve them. Making teams successful is more difficult than we knew. Even the simplest checklist forces us to grapple with vulnerabilities like handoffs and checklist overload. But designed well, the results can be extraordinary, allowing us to nearly eliminate many hospital infections, to cut deaths in surgery by as much as half globally, and to slash costs, as well.

Which brings us to the third skill that you must have but haven't been taught—the ability to implement at scale, the ability to get colleagues along the entire chain of care functioning like pit crews for patients. There is resistance, sometimes vehement resistance, to the efforts that make it possible. Partly, it is because the work is rooted in different values than the ones we've had. They include humility, an understanding that no matter who you are, how experienced or smart, you will fail. They include discipline, the belief that standardization, doing certain things the same way every time, can reduce your failures. And they include teamwork, the recognition that others can save you from failure, no matter who they are in the hierarchy.

These values are the opposite of autonomy, independency, self-sufficiency. Many doctors fear the future will end daring, creativity, and the joys of thinking that medicine has had. But nothing says teams cannot be daring or creative or that your work with others will not require hard thinking and wise judgment. Success under conditions of complexity still demands these qualities. Resistance also surfaces because medicine is not structured for group work. Even just asking clinicians to make time to sit together and agree on plans for complex patients feels like an imposition. "I'm not paid for this!" people object, and it's true right up to the highest levels.

I spoke to a hospital executive the day after he'd presented to his board a plan to reorient his system around teams that focus on improving care outcomes, improving the health of the community, and lowering its costs of care. The meeting was contentious. The aims made sense, but hospital finances are not based on achieving them, and the board wasn't sure about asking payers to change that. The meeting ended unresolved. These aims are not yet our aims in medicine, though we need them to be.

Not long ago, I had an experience at our local school that brought home the stakes. I'd gone for a meeting with my children's teachers, and I ran into the superintendent of schools. I told him how worried I was to see my kids' art classes cut and their class sizes rise to almost thirty children in some cases. What was he working on to improve matters? I asked.

“You know what I spend my time working on?” he said. “Health-care costs.” Teachers’ health-benefit expenses were up nine per cent, city tax revenues were flat, and school enrollment was up. A small percentage of teachers with serious illnesses accounted for the majority of the costs, and the only option he’d found was to cut their benefits.

“Oh,” I said.

I went to the teacher meetings. On the way, I ran into a teacher I had operated on. She’d had a lymphoma. She was one of that small percentage who accounted for most of the costs. That’s when it struck me. I was part of the reason my children didn’t have enough teachers. We all are in medicine. Reports show that every dollar added to school budgets over the past decade for smaller class sizes and better teacher pay was diverted to covering rising health-care costs.

This is not inevitable. I do not believe society should be forced to choose between whether our children get a great education or their teachers get great medical care. But only we can create the local medical systems that make both possible. You who graduate today will join these systems as they are born, propel them, work on the policies that accelerate them, and create the innovations they need. Making systems work in health care—shifting from corralling cowboys to producing pit crews—is the great task of your and my generation of clinicians and scientists.

You are the generation on the precipice of a transformation medicine has no choice but to undergo, the riders in the front car of the roller coaster clack-clack-clacking its way up to the drop. The revolution that remade how other fields handle complexity is coming to health care, and I think you sense it. I see this in the burst of students obtaining extra degrees in fields like public health, business administration, public policy, information technology, education, economics, engineering. Of some two hundred students graduating today, more than thirty-five are getting such degrees, intuiting that ordinary medical training wouldn’t prepare you for the world to come. Two years ago, the Institute for Healthcare Improvement started its Open School, offering free online courses in systems skills such as outcome measurement, quality improvement, implementation, and leadership. They hoped a few hundred medical students would enroll. Forty-five thousand did. You’ve recognized faster than any of us that the way we train, practice, and innovate has to change. Even the laboratory science must change—toward generating treatments and diagnostics that do not stand in isolation but fit in as reliable components of an integrated, economical, and effective package of care for the needs patients have.

The problems of making health care work are large. The complexities are overwhelming governments, economies, and societies around the world. We have every indication, however, that where people in medicine combine their talents and efforts to design organized service to patients and local communities, extraordinary change can result.

Recently, you might be interested to know, I met an actual cowboy. He described to me how cowboys do their job today, herding thousands of cattle. They have tightly organized teams, with everyone assigned specific positions and communicating with each other constantly. They have protocols and checklists for bad weather, emergencies, the inoculations they must dispense. Even the cowboys, it turns out, function like pit crews now. It may be time for us to join them.

Photograph: Dale Earnhardt, Jr.,’s pit crew, at Darlington Raceway, 2008. United States National Guard.

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By Kristin L. Carman, Maureen Maurer, Jill Mathews Yegian, Pamela Dardess, Jeanne McGee, Mark Evers, and Karen O. Marlo

Evidence That Consumers Are Skeptical About Evidence-Based Health Care

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ABSTRACT We undertook focus groups, interviews, and an online survey with health care consumers as part of a recent project to assist purchasers in communicating more effectively about health care evidence and quality. Most of the consumers were ages 18–64; had health insurance through a current employer; and had taken part in making decisions about health insurance coverage for themselves, their spouse, or someone else. We found many of these consumers' beliefs, values, and knowledge to be at odds with what policy makers prescribe as evidence-based health care. Few consumers understood terms such as "medical evidence" or "quality guidelines." Most believed that more care meant higher-quality, better care. The gaps in knowledge and misconceptions point to serious challenges in engaging consumers in evidence-based decision making.

Many studies have shown that some health care provided in the United States is inappropriate, inefficient, and unsafe.^{1–5} Moreover, as the rise in health care costs continues to outstrip wages and growth in other sectors of the economy,⁶ it is critically important to increase the quality and value of health care.^{7,8} Passage of the Patient Protection and Affordable Care Act of 2010 has now laid the groundwork for major reforms, including greater use of evidence-based medicine, shared decision making, comparative effectiveness research, evidence-based benefit design, and transparency of cost and quality information. We refer to these diverse efforts as evidence-based health care.

Although much attention has been focused on the roles of governments, employers, insurers, and providers in evidence-based health care, less attention has been paid to the critical role of consumers. Their attitudes and beliefs about evidence-based health care, and their understanding and acceptance of it, will help determine its success or failure. If consumers don't under-

stand it or reject it, or if they see it as an invalid basis for making decisions about providers and treatments, the most ambitious goals of this movement may fail.

Increasingly, consumers are being asked to use evidence to manage chronic conditions, choose between treatment regimens, and select providers and health plans. In some respects, consumers are rising to the challenge. Research shows that decision aids, which provide information about options and outcomes, can help increase consumers' confidence with decision making and improve their understanding and knowledge of treatment options.⁹ If consumers are more involved in decision making generally and self-management of health conditions, the results can be improved adherence to treatment,¹⁰ increased use of screening,¹¹ increased patient satisfaction,¹² better health outcomes,^{12–14} and lower health care costs.¹⁴

At the same time, many consumers' values, beliefs, and behaviors remain rooted in traditional expectations about the doctor-patient relationship and the medical care system.¹⁵ The dominant role of physicians in determining

patient care has been a fact of medical care delivery for many decades.¹⁶⁻¹⁸ Therefore, many consumers may find it difficult to move into a more active and accountable role in which they are expected to understand and weigh multiple pieces of complex and potentially conflicting evidence.

The purpose of this study was to determine how the concept of making health care decisions based on evidence of effectiveness could be translated into language that consumers would understand and embrace. We conducted this research as part of the development of a “communication toolkit” to help employers communicate more effectively about evidence-based health care. In conducting this research, we identified a number of specific values, beliefs, and misconceptions among consumers that present major challenges to efforts to engage them in evidence-based health care decision making.

Study Data And Methods

We used qualitative research methods including focus groups, in-depth interviews with stakeholders, and cognitive interviews with employees. Cognitive interviews are individual interviews that explore how well consumers understood the materials and what aspects of the materials needed improvement. The project also used quantitative, online survey research methods to assess consumers’ values, beliefs, and experiences with evidence-based health care. Details are available in an online Appendix.¹⁹

How consumers understand and react to evidence-based health care is not well known. Thus, a review of the literature and qualitative methods were most appropriate at the beginning of our research. We used quantitative methods to assess specific topics that our qualitative research showed would be helpful to employers.

LITERATURE REVIEW AND QUALITATIVE METHODS Our research included reviewing published literature and other material such as technical reports and white papers; collecting and reviewing materials from organizations that communicate with consumers about health care; and interviewing forty employer intermediaries such as human resources staff, stakeholders, and experts. In addition, we conducted four focus groups with a total of thirty-four consumers in August and September 2006 to explore their understanding of the components of evidence-based health care and health care decision making, and to obtain their reactions to different ways of conveying information about evidence-based health care.

Between March and December 2007, we conducted one-on-one, two-hour, in-person cogni-

tive interviews with fifty-seven employees to explore how well consumers understood the concepts of evidence-based health care, the consumers’ reactions to the use of evidence of effectiveness in decision making, and their preferred sources of health care information.

The focus-group and interview participants were people ages 18–64 who had health insurance through a current employer and who had taken part in making decisions about coverage for themselves, their spouse, or someone else. We audiotaped all focus groups and interviews. We transcribed the focus-group tapes and generated extensive notes for the interviews, analyzing these to identify key themes.

We employed a variety of well-established techniques to draw conclusions from the data, such as identifying patterns, assessing the plausibility of findings, and noting relationships between patterns. We tested and confirmed our findings by looking for exceptions and alternative explanations.^{20,21}

ONLINE SURVEY AND ANALYSIS In a related effort, the National Business Group on Health commissioned an online survey in September 2007 of 1,558 employees. This survey used the Greenfield Online panel, a convenience sample recruited primarily from the Internet. Findings from our project’s qualitative research were used to ask additional questions about attitudes and behaviors regarding health care, health information needs, preferred sources of information, and health care decisions.²²

Respondents were ages 22–69, employed at least part time by a firm with at least 2,000 employees, insured through an employer- or union-sponsored health plan, and functioned as a key health care decision maker for their household. All panel members who met the selection criteria were eligible to respond to the survey. The survey was discontinued after we reached a sample size of approximately 1,500.

Unless otherwise noted, the findings presented here are consistent within the qualitative methods and between the qualitative and quantitative methods. The findings express recurring issues and themes stated by consumers across the range of methods used (Exhibit 1).

STUDY LIMITATIONS Overall, because of recruitment methods and selection criteria, the project findings overrepresent people who were employed, particularly by large firms; who were insured; and who identified themselves as responsible for health care decision making. As a result, we would expect that our study population is consistently biased toward a “best case” scenario: that individuals understand and value evidence-based health care. Thus, our findings may reflect a more optimistic assessment of

EXHIBIT 1

Consumers' Knowledge, Beliefs, And Attitudes Toward Evidence-Based Health Care Principles

Features of evidence-based health care	Themes from focus groups and interviews
Using medical evidence and quality standards to make decisions	Unfamiliar with and sometimes confused by the terms "medical evidence," "quality guidelines," and "quality standards" Believe that all medical care meets minimum quality standards Think that medical guidelines represent an inflexible, bargain-basement approach to treating unique individuals
Reducing the underuse, misuse, and overuse of treatments and health care resources	Believe that more care is better (higher-quality) care, newer care is better Believe that more costly care is better care
Encouraging consumers to be actively involved in their health care	Workers have limited experience with engagement behaviors

SOURCE Authors' analysis of focus groups, interviews, and online survey.

consumer engagement than would be found in the broader U.S. population.

Study Findings

The key finding from focus groups, interviews, and the online survey is that there is a fundamental disconnect between the central tenets of evidence-based health care and the knowledge, values, and beliefs held by many consumers. For health care experts, variation—in quality among health care providers, the evidence base regarding therapies, and the effectiveness and cost-effectiveness of treatment options—is a well-established fact of the health care delivery system, documented extensively in the published literature and well understood after years of careful study.¹⁻⁵ Yet such concepts are unfamiliar to many Americans and may even seem threatening, to the extent that they raise unwelcome questions about the quality of medical care that people receive.

This study identified gaps in knowledge, specific values and beliefs, and behaviors that will challenge ongoing efforts to ensure patients' acceptance of decision making in evidence-based health care (Exhibit 1).

MISCONCEPTIONS Participants had crucial misconceptions about the underlying concepts of evidence-based health care. They found terms such as "medical evidence," "quality guidelines," and "quality standards" unfamiliar and confusing. This lack of familiarity with key concepts was consistent with a finding from our national online survey that only half of the respondents had read or heard about "medical research studies [that] help doctors know what works best for patient care."

Additionally, only 34 percent of participants ever recalled having a physician discuss what scientific research had shown about the best way to manage their care. Many participants as-

sumed that their health care providers always based decisions on medical evidence, which to them consists just of "things like my test results and medical history."

BELIEFS AND VALUES Study participants consistently voiced a number of values and beliefs that were at odds with evidence-based approaches.

► **ALL CARE MEETS MINIMUM QUALITY STANDARDS:** Although focus-group participants could envision a health care provider's making an occasional mistake, they found it hard to believe that providers could deliver truly substandard care—and certainly not their own providers. When focus-group participants were told that providing beta-blockers for heart attack patients represents the accepted standard of care, but 25 percent of patients do not receive them,²³ participants immediately offered justifications for the lack of treatment: the patient was "allergic," the hospital was "too poor" to provide the drugs, or the doctor knew that the patient needed a different medication.

► **MEDICAL GUIDELINES ARE INFLEXIBLE:** Although policy experts define guidelines as best clinical practices based on a large body of medical evidence, focus-group participants perceived them as rigid rules that interfere with providers' ability to draw upon their medical training and experience to tailor their care to the characteristics of individual patients. As one participant said, "Using medical guidelines sounds like... your doctor can't give you other treatment without approval. It's taking your choice away and putting the decision in somebody else's hands."

Participants were more inclined to trust their own and their physicians' judgments of quality, instead of relying on guidelines that might "discriminate against doctors who give you better care" and "cripple medical advantage. It's thinking outside the box that helps you find a

treatment that works. It's not always rule of thumb."

Some also worried that doctors could use guidelines to protect themselves from potential lawsuits by invoking them to deny care, especially new or innovative care that patients consider necessary. One participant said, "This is just a way for doctors to say, 'I'm following the national guidelines, so you can't sue me if something goes wrong.'"

► **MORE CARE, AND NEWER CARE, IS BETTER:** The idea that getting high-quality care or the "right" care could mean getting less care was counterintuitive. As one interview participant said, "I don't see how extra care can be harmful to your health. Care would only benefit you."

Participants also believed that any new treatment is improved treatment. This attitude may help explain the survey finding that only 47 percent of respondents agreed that it is reasonable to pay less out of pocket for the most effective treatments and drugs. Linking cost sharing to clinical effectiveness may be perceived as restricting treatment options, particularly for unproven therapies (Exhibit 2).

► **MORE COSTLY CARE IS BETTER:** A substantial portion of focus-group and interview participants expressed the view that "you get what you pay for." A third (33 percent) of our survey respondents agreed or strongly agreed with the statement that "medical treatments that work the best usually cost more than treatments that don't work as well." Although 27 percent disagreed or strongly disagreed, 40 percent reported that they were not sure about this (Exhibit 2).

Given the widespread view that lower-cost care is clinically inferior, it is perhaps not surprising that focus-group participants found it inappropriate to discuss with their physician the costs of different treatments, believing that decisions about medical treatments should be based on individual needs alone. A number of participants reacted negatively to the term "good value for the money," equating it with bargain-basement pricing and low quality.

BEHAVIORS IN THE MEDICAL ENCOUNTER Our survey results indicate that many consumers do not engage in behaviors that could be beneficial to them during medical encounters. More than half of the respondents had never taken notes during a medical appointment (55 percent) or brought online information to discuss with their doctor (60 percent). Almost half had never brought someone to provide support or advocacy (44 percent). In addition, 28 percent of the respondents had never brought questions to ask their doctor (Exhibit 3).

Patients often rely heavily on their doctors for information, interpretation, and guidance on treatment options. Thus, they may be reluctant to question or challenge what the doctor advises. In our survey, 41 percent of respondents reported that they had not asked questions or told their doctor about medical problems, because the doctor seemed rushed or they were unsure about how to talk to him or her (Exhibit 3).

Interview participants said that they were reluctant or too timid to raise concerns about unnecessary care. They believed that determining what constituted necessary care was mainly their provider's job: "You are not an expert. The

EXHIBIT 2

Consumers' Views On The Quality, Effectiveness, And Cost Of Health Care, As Related To Consumer Behavior

Variable	Scale (%)		
	Strongly disagree/ disagree	Neither agree nor disagree	Strongly agree/ agree
Medical treatments that work the best usually cost more than treatments that don't work as well	27	40	33
If employees use doctors who have scored high on quality ratings, it is appropriate to have those employees pay less for their health insurance benefits and medical care	16	43	41
If employees use the particular treatments and drugs that research has shown work best for their condition, it is appropriate to have those employees pay less for their health insurance benefits and medical care	15	38	47
If employees have healthy lifestyles or participate in programs sponsored by employers that could help them improve their health (such as programs to quit smoking or lose weight), it is appropriate to have those employees pay less for their health insurance benefits and medical care	10	24	66

SOURCE National Business Group on Health Online Survey, September 2007. **NOTES** Respondents were asked to rate how strongly they agreed or disagreed with each statement. N = 1,558.

EXHIBIT 3

Consumers' Engagement With Their Care, And Communication With Physicians

	Never	Yes, once	Yes, more than once
ENGAGEMENT BEHAVIORS			
These questions ask about things you might have done before or during a medical visit. Have you ever...			
Brought information you found on an Internet Web site to a medical visit and talked about it with your doctor?	60%	20%	20%
Taken notes during a medical visit to help you remember what the doctor or nurse said?	55	16	29
Brought along a friend or family member to your medical visit as your advocate or to give you support?	44	21	35
Brought a list of questions to ask during a medical visit?	28	23	49
PHYSICIAN COMMUNICATION			
During a medical visit, have you ever held back on asking questions or telling the doctor about your medical problems because...			
You were unsure how to talk about your medical problems or how to ask your questions?	59	19	22
The doctor seemed rushed?	59	16	25

SOURCE National Business Group on Health Online Survey, September 2007. **NOTE** N = 1,558.

doctor is supposed to be the expert—you [the system] need to hold the doctor accountable.” Similarly, participants expressed concern about assuming the burden of avoiding medical errors instead of relying on doctors and other providers. Finally, some participants explicitly asked whether their providers knew they (consumers) were being told to raise these issues and wanted reassurances that their providers knew and would welcome their expressions of concern.

Implications

For consumers to truly engage in using evidence for decision making, they have to be informed about the relevant choices for their own situation; value the use of evidence in making those decisions, even if it contradicts conventional wisdom; and accept their role in this process and feel capable and ready to assume it. This is no small challenge, given the continued dominance of paternalistic models of physician decision making, relatively low levels of health and scientific literacy in the general public,²⁴ and the increasing complexity of the choices that patients are asked to make.

Our findings indicate some cause for optimism: A minority—small, but nontrivial—of the public accepts the underlying concepts of evidence-based health care and wants to assume a more informed and active role in their health care and decision making. These individuals are in all likelihood “early adopters,” who, as potential opinion leaders, can help influence later adopters. They represent a foundation on which to build greater acceptance of evidence-based

health care, and they may be a useful resource in stimulating change.

At the same time, our findings illuminate real and significant challenges to the pursuit of broader acceptance of evidence-based health care among consumers. The beliefs underlying the themes that surfaced in both the qualitative research and the survey—more is better, newer is better, you get what you pay for, guidelines limit my doctor’s ability to provide me with the care I need and deserve—are deeply rooted and widespread. Our findings, although preliminary, have implications for several public and private efforts. These efforts intend to foster—and to some degree depend on—consumer engagement, or at least on the absence of overt consumer resistance.

COMPARATIVE EFFECTIVENESS RESEARCH The Institute of Medicine defines *comparative effectiveness research* as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care.”²⁵

To the extent that consumers perceive that the application of comparative effectiveness research to decision making could limit their choice of providers, inappropriately interfere with physicians’ recommendations for treatment, or appear to “ration” care based on cost, these efforts will encounter consumer resistance and could lead to a broad consumer backlash. In fact, news articles and commentaries by critics of the \$1.1 billion for comparative effectiveness research included in the American Recovery and Reinvestment Act of 2009 (ARRA) cited these

Consumers will revolt if evidence-based efforts are perceived as a way to deny them needed treatment.

arguments to discourage government funding of this work.^{26–29}

Now, under the Patient Protection and Affordable Care Act, comparative effectiveness research will be carried forward under the aegis of the planned Patient Outcomes Research Institute. But the act explicitly prohibits the research from being used as the basis of coverage or reimbursement decisions for either public or private payers—which illustrates how much the public worries about rationing health care.

EVIDENCE-BASED BENEFIT DESIGN Whether the effort is called “quality-based benefit design” or “value-based health insurance,” the objective is to use insurance benefit design such as copayments, prior authorization, formularies, and provider network design to encourage effective, high-value care and to discourage ineffective, low-value care. Our findings suggest that this approach, although perfectly logical from the perspective of health policy experts, might not resonate with consumers.

For those who believe that all medical care meets minimum standards and that more care is better, differentiating among physicians, hospitals, or other providers based on quality and efficiency profiles is likely to meet with resistance. Findings from our national online survey are consistent with this notion. Only 41 percent of survey respondents agreed that it is appropriate for employees to pay less for their health insurance or medical care if they use doctors who score high on quality ratings, and 47 percent agreed that employees should pay less for treatments that research has shown to work best (Exhibit 2).

TRANSPARENCY OF COST AND QUALITY INFORMATION Efforts during the past decade to make information available about the quality of care have assumed that if patients are given information about cost and quality, they will be able to make informed and appropriate decisions about plans, providers, and treatment options. How-

ever, consumers’ views that high-quality care might cost more and that clinical guidelines represent a minimum standard of care undercut this assumption. The consistent finding that consumers prefer subjective information from friends and family about selecting doctors and hospitals to objective information about performance and outcomes shows how difficult it is to shift toward an evidence-based approach to making health care choices.³⁰

Next Steps

Our findings show that consumers’ current knowledge, beliefs, attitudes, and experiences related to health care are often incompatible with evidence-based approaches. In addition, consumers have deep concerns about how physicians and other providers will respond to questions about the appropriateness of treatments, the basis for referrals to specialists and hospitals, or the cost of treatment.

Effective communication with and support of consumers is essential to improving the quality of health care and containing health care costs. Clearly, consumers will revolt if evidence-based efforts are perceived as rationing or as a way to deny them needed treatment. Policy makers, employers, health plans, providers, and researchers will thus need to translate evidence-based health care into accessible concepts and concrete activities that support and motivate consumers. A necessary condition for effective communication, after all, is to start where your audience is—even if that is not where you hoped or expected it to be.

On the basis of the research we have described, we developed a “communication toolkit.”³¹ It is designed to enable employers and unions to communicate with consumers about evidence-based health care and help them become active participants in their care through customizable materials that translate these concepts into clear, simple, and relevant language. The response from employers and other health care purchasers, health plans, and provider organizations has been enthusiastic, judging by the number of downloads and Web-site hits to the toolkit Web site housed at the National Business Group on Health, feedback at meetings and presentations of the toolkit, and active use of the materials by organizations. We are currently conducting implementation case studies as employers and unions begin to use the toolkit, and we hope that these may provide further guidance on bridging the gap between the need for evidence-based health care and the consumers’ current perceptions of it. ■

Portions of the findings from the research conducted to develop the communication toolkit were presented in different venues, including research,

advocacy, and substantive conferences focused on evidence-based health care. The toolkit and this article were created with funding from the California

HealthCare Foundation. The survey was funded with support from the National Business Group on Health. [Published online 3 June 2010.]

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Clinical Effectiveness Research Innovation Collaborative

- *Health Disparities and the Learning Health System—A Proposed Project of the IOM Clinical Effectiveness Research Innovation Collaborative.*
- *Health System Leadership & Effectiveness Research—A project of the IOM Clinical Effectiveness Research Innovation Collaborative*
- Hoffman, Ari et al. *How Best To Engage Patients, Doctors, And Other Stakeholders In Designing Comparative Effectiveness Studies*. Health Affairs. 2010.
“Research does not begin with the careful design of a study or the enrollment of patients in a trial, but with the selection of a topic that researchers believe is important and interesting. Stakeholder engagement should also begin before study design and patient enrollment, if comparative effectiveness research is to succeed in bridging the gaps in evidence between research results and clinical decision making.”



HEALTH DISPARITIES AND THE LEARNING HEALTH SYSTEM

A Proposed Project of the IOM Clinical Effectiveness Research Innovation Collaborative

Proposed activity: A public IOM workshop will consider how features of a continuously learning health system can best address and close the gaps for our most salient health and health care disparities, with particular focus on opportunities from innovation in clinical effectiveness research.

Compelling aim: *Accelerate practical progress in eliminating disparities in the health and healthcare experiences and outcomes among population groups.* Progress is anticipated by virtue of the potential follow-up to the workshop content (spotlighting key opportunities), process (cooperative engagement of those important to progress), products (IOM publication as touchstone reference point for collaborative work and responsibilities).

Issue: Disparities in health and healthcare processes and outcomes are pervasive within our health system. These include across racial, ethnic, socioeconomic, and geographic demographics as well as in access and quality of care. Such disparities are often symptomatic of the inefficiencies in a fragmented care delivery system, one with misaligned incentives, but their nature and causes are poorly understood. Since 2006, the Roundtable on Value & Science-Driven Health Care has been working to facilitate progress towards the development of a learning health system, in which science, informatics, and culture are aligned for continuous innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the care experience. For example, the continuous monitoring of health care outcomes, providing greater and more meaningful data, could lead to a more complete understanding of the problem, just as the generation of knowledge about the nature of disparities can allow for better, more targeted intervention, and improved health outcomes. Such a system is technically feasible, and would provide great potential both for better understanding of health issues among minority and other underserved population groups, and greater opportunity for their engagement across the board. It could contribute greatly to achieving society's goal of eliminating health disparities.

Approach: A planning committee will be formed to consider the issues and opportunities and develop an agenda for a one or two-day meeting to discuss the issues in detail. Building on the work underway, through activities such as the DHHS report on health disparities, the announcement of the Comparative Effectiveness Research for Eliminating Disparities awards by the National Institute for Minority Health of the NIH, as well as the establishment of the Patient Centered Outcomes Research Institute, the agenda planning committee will identify key issues and areas of possible collaborative progress. Potential participants include national leaders in health care delivery, clinical research, academic medicine, health data, information technology, health care financing, public health, economics, including those from relevant HHS agencies focused on disparities—e.g. the HHS Office of Minority Health, HRSA, AHRQ, IHS, FDA, CDC and its program on Determinants of Health and Equity, the NIH and its National Center on Minority Health and Health Disparities—as well as from the Patient-Centered Outcomes Research Institute.

Deliverable: A summary of the key opportunities and stakeholder responsibilities discussed, either through an IOM workshop report or an individually-authored IOM Discussion paper.

Related IOM work: *Health Literacy Implications for Health Reform (2011), Demographic Changes, A View From California (2010), Race, Ethnicity, and Language Data (2009), Toward Health Equity and Patient-Centeredness (2009)*

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HEALTH SYSTEM LEADERSHIP & EFFECTIVENESS RESEARCH*A project of the IOM Clinical Effectiveness Research Innovation Collaborative*

Activity: Engaging and investing executive leaders of large health centers and systems on the approaches and potential to use clinical data for real-time effectiveness research and continuous improvement in the effectiveness and efficiency of health care.

Compelling aim: *Achievement of one of the foundational concepts of a learning health system—real-time knowledge generation through the seamless integration of research and practice—through the visible and committed investment by the heads of the nation's largest, most innovative health centers and systems.* Demonstrating to system leaders the feasibility, potential, and tools available to analyze and learn from clinical data for improved clinical research and care improvement, will prompt the necessary initiatives and investments, which can in turn serve as examples to accelerate broader progress.

Issue: Real-time evidence development on clinical effectiveness (“what works in practice”) is a central requirement of the continuously learning health system. Health care systems, hospitals, medical practices, and other health delivery organizations seek to continuously innovate to improve the quality, effectiveness, and efficiency of care, yet the clinical enterprises of most institutions are not “research ready”, or capable of providing ongoing monitoring of the circumstances and outcomes of care processes. In fact, some larger systems operate as federated departments and functional groups, with limited cross-links and fragmented systems and strategies that serve as barriers to integrated system-wide approaches to continuous feedback and learning.

Approach: The engagement of senior leadership, through the exchange of lessons and strategies among senior operations staff will accelerate progress towards greater systematic and integrated evidence development. This project will engage stakeholders in: articulating the needs and benefits of routine evidence development as part of practice; creating a constituency for more and better evidence among the public, patients, providers, and payers; identifying institutional, operational, and regulatory barriers and solutions; creating a forum to identify and describe cases of best practices for incorporation of evidence development into routine practice; facilitating collaboration among organizations in identifying specific topics of mutual interest and in adopting joint approaches to their solution. The first phase of the effort will focus on Academic Medical Centers, through a meeting of AMC leadership, operations staff, innovation leaders and researchers, organized by the IOM in collaboration with AAMC. Leadership, innovators and researchers from other (non-AMC) health systems, also participants in the initial meeting, will be engaged in the design, implementation, and dissemination of broader follow-on efforts. Initial working group participants include: Joshua Metlay/Penn, Richard Platt/Harvard, Alyce Adams/Kaiser, Chris Dezii/Bristol-Myers, Rosemarie Filart/NIH, Kathy Gans-Brangs/AstraZeneca, Don Goldmann/IHI, Anthony Hayward/NIH, Gregg Meyer/MGH, William Mezzanotte/AstraZeneca, Veronique Roger/Mayo, Lucy Savitz/Intermountain, Harry Selker/Tufts, Mildred Solomon/AAMC, Harold Sox/Dartmouth.

Deliverable(s): The initial series of position papers, case studies, and meeting proceedings will be published as a theme issue of *Academic Medicine* (or other publication). Other products to be determined.

Related IOM work: *Clinical Data as a Basic Staple for Health Learning (2011); Redesigning the Clinical Effectiveness Research Paradigm (2010); Leadership Commitments to Improve Value in Healthcare (2009); Initial National Priorities for Comparative Effectiveness Research (2009).*

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How Best To Engage Patients, Doctors, And Other Stakeholders In Designing Comparative Effectiveness Studies

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ABSTRACT Having patients, doctors, health plan managers, hospital executives, and other stakeholders participate in the design of comparative effectiveness studies can ensure that this vital research focuses on the evidence gaps most relevant to health care decision makers. Through a qualitative assessment of case studies, we identify five key principles for the effective engagement of a broad coalition of participants in research intended to improve health care and control costs. Those principles are to ensure balance among the participating stakeholders; get participants to “buy in” to the process and understand their roles; provide neutral and expert facilitators for research discussions; establish connections among the participants; and keep the participants engaged throughout the research process.

Patients and health care providers can find it difficult to make decisions about clinical care because many clinical studies are not very relevant, good, or accessible. A recent report, for instance, estimated that 48 percent of the joint clinical guidelines from the American College of Cardiology and the American Heart Association are based solely on expert opinion, case studies, or standards of care, rather than on high-quality clinical research.¹

Similar evidence gaps exist throughout the clinical specialties in medicine. These compromise decision making on a range of issues by stakeholders including payers, purchasers of insurance, and policy makers as well as patients and providers. Although responsible for individual health care choices, professional policies, and reimbursement decisions, these stakeholders have historically been the passive recipients of evidence produced by researchers and have had little influence on research priorities or what specific questions studies should ask.

When no data exist to compare health care options or the available data are not applicable to real-world scenarios, decision makers have

done little but express their frustration at these critical gaps in knowledge. This divide between research and decision making has recently received increasing scrutiny and public attention, and it has become clear that we need a research program that can provide the missing information.^{2,3}

Comparative effectiveness research is one possible solution to the lack of good evidence in health care decision making. The methods of this research include both the synthesis of existing evidence and the production of new data. By definition, the research compares the relative benefits and harms of medical tests, treatments, or modes of health care delivery. The purpose of comparative effectiveness research, according to the Institute of Medicine (IOM), is “to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”^{4(p41)} In other words, the research aims to fill the evidence gaps that matter to stakeholders in health care, leading to better decisions.

It follows that the success of comparative effectiveness research depends on the involvement

of stakeholders in all aspects of the research process, including setting priorities, designing studies, conducting research, and disseminating the findings. However, the broad range of stakeholder perspectives complicates the task of producing new information that is relevant and credible to many audiences.

Stakeholder engagement has rapidly gained acceptance as central to the purpose of comparative effectiveness research, and recent federal grant announcements for comparative effectiveness research projects have encouraged or required the involvement of advisory groups representing multiple stakeholders.^{5,6} In its report on the research, the IOM emphasized the importance of engaging stakeholders⁴ in setting priorities, and of designing and implementing studies to meet the needs of various decision makers. However, even the term *stakeholder engagement* remains vague, and very little published work describes experience with it or methods of using it.

The Patient Protection and Affordable Care Act of 2010, in section 6301, mandates the creation of a Patient-Centered Outcomes Research Institute to set priorities for comparative effectiveness research based on a multistakeholder approach. In addition, the American Recovery and Reinvestment Act of 2009 allocated funds for a citizens' forum to "expand and systematize broad citizen and stakeholder engagement" in federally funded comparative effectiveness research.⁷

The US government has clearly endorsed involving stakeholders at the highest levels of oversight and funding for comparative effectiveness research. As the outcomes institute and citizens' forum are organized and begin to speed the development of research projects in the next few years, it will be important for researchers to understand how to engage health care stakeholders in comparative studies. This will help ensure that the most pressing gaps in clinical evidence are investigated and that the research results will be used to inform clinical and health policy decision making.

This paper discusses five general principles for successful stakeholder engagement in comparative effectiveness research. They are based on best practices and lessons learned from five comparative effectiveness research projects that involved the substantial engagement of multidisciplinary groups of experts and stakeholders. These projects are currently under way at the Center for Medical Technology Policy, in Baltimore, Maryland.^{8,9} This paper's main purpose is to describe and assess our experiences with engaging stakeholders in comparative effectiveness research, to provide useful insights for

others doing similar work. We also hope that the paper will encourage more-systematic documentation and sharing of information about these activities.

Study Data And Methods

We conducted a qualitative assessment of experience generated through five comparative effectiveness projects with substantial engagement of multidisciplinary groups of experts and stakeholders, conducted at the Center for Medical Technology Policy. The center's mission is to provide a neutral forum for experts, decision makers, and other stakeholders to collaborate on a range of comparative effectiveness research issues. Those issues include setting priorities for research topics and guiding research methods.

The center also facilitates the design and implementation of comparative effectiveness studies. In these projects, multistakeholder groups play an advisory role in guiding research topics and study designs toward meaningful conclusions.

We collected information through documents and semistructured interviews with one or more of the center's staff members as well as with stakeholder participants in each of the five studies. The studies focused on the following: setting comparative effectiveness research priorities for emerging technologies in cardiology; setting research priorities and refining research questions in the care of breast cancer patients; providing methodological guidance for pharmaceutical studies of real-world populations, competitive treatments, and patient outcomes; designing comparative effectiveness studies of a genetic test to determine the correct dose of warfarin, to prevent blood clots; and designing and implementing a national registry of patients who have undergone hip and knee replacement surgery, to enable comparative effectiveness studies of artificial joints.

Each project has provided a number of important insights into the process of engaging stakeholders in comparative effectiveness research. Collectively, they have produced a greater understanding of the challenges associated with this work, as well as helpful strategies to facilitate the process.

Five Principles For Engaging Stakeholders

From the interviews, our personal experience, and a review of documents from the Center for Medical Technology Policy, we identified five general principles that contribute to the successful engagement of stakeholders in comparative

effectiveness research.

The principles are as follows: ensure a balanced representation of all stakeholder groups; get stakeholders to “buy in” to the process and make sure that they clearly understand their roles; provide neutral, expert facilitation of the stakeholder discussions; establish connections among the stakeholders; and keep the stakeholders engaged throughout the research process.

Balanced Representation Among All Groups

Sponsors and investigators must carefully select appropriate members of advisory or working groups to ensure that each relevant perspective is adequately represented. The IOM report on comparative effectiveness research priorities specifically lists “patients, caregivers, providers, payers, and policy makers” as the categories of people who should be engaged in this research.^{4(p33)}

DIFFERENT POINTS OF VIEW Patients are a particularly important group to engage. Once they have agreed to participate, it is vital not to limit their input by presenting material in too technical a form. An experience at the Center for Medical Technology Policy in May 2009 underscores this lesson.

The center convened a working group of four clinicians, one health plan representative, and one patient. The group was charged with setting priorities for the development of methods to compare the effectiveness of emerging technologies in cardiology. A meeting facilitator asked the participants to rank technologies based on a defined set of criteria, including potential clinical benefit; quality of current clinical evidence; cost-effectiveness; potential for widespread acceptance based on demand for the technology from the health care community; and feasibility of completing studies.

After receiving a packet of briefing materials on each technology, the patient expressed concern about his ability to understand the complex clinical material, which would limit his contributions to the discussion. His response underscored the fact that the technical and multidisciplinary nature of clinical research makes it challenging to engage stakeholders from a wide range of educational backgrounds and personal experiences. Even clinicians and researchers who have a great deal of experience with a technology might not have a background in assessing cost-effectiveness, quality-of-life metrics, or other important elements of comparative effectiveness research.

During the actual meeting, the clinicians in academic medicine or community practice were

It is vital not to limit patients' input by presenting material in too technical a form.

most interested in the clinical usefulness of the technologies in question and the types of studies needed to evaluate their use in patients. The health plan representative wondered if the studies would be rigorous enough to demonstrate improved health outcomes and therefore to meet criteria for coverage by health insurance. The patient representative was most concerned about the possible improvement in quality of life offered by each intervention and the probability of success.

All of the participants agreed that costs were important, but not as much as clinical effectiveness. Disagreements mainly focused on the levels of evidence needed for adoption or coverage, as participants recognized that evidence thresholds might be different for individual decisions compared to population-based decisions. Based on the patient's comments mentioned above, the center had prepared briefing materials that explained the clinical evidence for each technology in a standardized format, without using technical jargon. Since then, the center has prepared similar briefing materials for all patient and consumer representatives participating in comparative effectiveness projects.

Another method is to hold separate preparatory sessions with patient and consumer representatives before the full meeting of the multistakeholder group. This gives the non-specialist participants an opportunity to ask questions and increase their level of understanding of the interventions being compared. Participants who have been prepared in this way are considerably more engaged in the full group's discussions than are those who have not been briefed in advance.

SENSITIVITY TO BACKGROUNDS Despite efforts to make briefing materials accessible to nonexperts, the project to set priorities in cardiology research highlighted the importance of not overwhelming any one group with too many representatives from different groups. The clinicians decisively outnumbered the patient and the health plan representative, and the center realized that it couldn't rely on a single patient and his personal experience with cardiovascular dis-

ease to guide considerations such as quality of life when designing a comparative effectiveness study.

In this regard, it is unfortunate that the charter of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) states that there shall be only one voting patient advocate on the committee.¹⁰ The Center for Medical Technology Policy now ensures that at least two patients participate in any stakeholder engagement process, based on a recommendation from its Patient and Consumer Advisory Committee, a standing group of six patients and consumers that advises it on patient and consumer engagement. This decision has provided a richer and more comprehensive representation of patient concerns and has made discussions in its projects more interactive.

Stakeholders' Understanding And Acceptance Of Roles

Comparative effectiveness research is a relatively new concept that is still evolving. Stakeholders not normally involved in the design of clinical research studies—such as patients and representatives of health plans—might not understand why they are being invited to join a comparative effectiveness research project, or what they stand to gain from participation. Some researchers might also be unclear about their role. It is crucial that all the participants understand the fundamental purpose of the research and the rationale for involving stakeholders.

'HELP US HELP YOU' Experience suggests that researchers should approach stakeholder groups with a “help us help you” mentality, acknowledging that the stakeholders are decision makers in health care and that well-designed research can help them do their jobs. Lead investigators may need to remind stakeholders in the group that the goal of their participation is to link the priorities, methods, and implementation of comparative effectiveness research to their information needs.

In 2010 the Center for Medical Technology Policy assisted the investigators of the Athena Breast Health Network, a new collaboration among University of California breast cancer centers, in incorporating stakeholders into a project. Athena investigators from across the university system are preparing to launch comparative effectiveness studies in genomics and personalized medicine. The studies are intended to improve breast cancer care, from screening through diagnosis to post-treatment survival. A stakeholder advisory group was formed to help set priorities and refine research questions; it also made recommendations on how to imple-

ment the studies quickly and efficiently.

INCREASED BUY-IN Some health plan and hospital representatives in the group did not initially see the relevance of their participation. The Center for Medical Technology Policy explained that their input would help ensure that the studies produced more-relevant clinical evidence for health plan coverage determinations and other decisions, such as which diagnostic tests a hospital should offer for the management of breast cancer and how to promote the appropriate use of the tests.

When these representatives understood their roles in comparative effectiveness research and in this project specifically, they became enthusiastic contributors. Based on their suggestions, the center will continue working with health plans on comparative effectiveness studies of waiving preauthorization requirements for insurance coverage and of innovative reimbursement strategies that increase coverage for breast cancer prevention.

The Athena case demonstrates the importance of clear guidance for stakeholders. With it, they are more likely to buy in to the project and make meaningful contributions to the comparative effectiveness research.

Neutral, Expert Facilitation Of Discussions

Engaging stakeholders requires that individual participants feel comfortable expressing their views and concerns in a productive manner. Participants may appear to be in conflict with each other and may perceive risks—such as embarrassment or even financial loss—in speaking openly. Participants with different priorities and preferences are likely to want to move the discussion in directions more relevant to their backgrounds and expertise.

An expert facilitator with no stake in the meeting's outcome and without broader responsibility for the project can create a neutral environment in which people can share their perspectives and find common ground. The facilitator should be well versed in group management, the issues being discussed, and the benefits of stakeholder engagement.

SAFE ENVIRONMENT Our third case example further illustrates this point. It pertains to a meeting to identify principles that could guide the design of pharmaceutical clinical trials focused on real-world research questions. There was much disagreement among regulatory officials and other stakeholders on the need for these more pragmatic study designs in the clinical trials.

Many stakeholders expressed the concern that

regulators have required trial designs to be so narrow that the results are not broadly useful or applicable. For example, providers often worry that their patients with multiple diseases are different from the otherwise healthy participants in trials with strict inclusion and exclusion criteria. In contrast, the regulatory official in the stakeholder group contended that trials should be designed to assess a drug's efficacy—performance in a controlled environment—as opposed to effectiveness—performance in practice. This determination of efficacy is best made by controlling variables through narrow inclusion criteria; if the results are based on enrolling a broad patient population in the trial, it may be more difficult to show efficacy, even if the results are more generalizable.

MOVING TOWARD AGREEMENT By addressing the concerns of both parties, an experienced facilitator helped the group move beyond their conflicting perspectives and agree that the clinical trials could move incrementally toward enrolling a broader patient population without compromising the researchers' ability to make valid comparisons of alternative treatments. This move may be an important step toward making trial results more useful. The group first agreed that the goal of making trials more closely reflect the real world was worth achieving. This led to their agreement that trials should include a broader group of patients, such as those who receive care in a range of community settings. That consensus led the group to define a seamless transition from early to advanced clinical research.¹¹

Connections Among Stakeholders

Stakeholders in the health care arena often work in relative isolation and do not regularly communicate. The Institute of Medicine identified as a hallmark of comparative effectiveness research the vetting by researchers of their projects' questions with representatives of health plans and payers. Yet it is rare for clinical researchers to consult regularly with those other stakeholders, and even rarer to involve patients and consumers in research design.¹²

As a result, the Center for Medical Technology Policy has been developing a model for conducting coverage with evidence development in the private sector. As with the similar program in Medicare, an intervention would be provisionally covered for patients who enrolled in clinical trials to establish better evidence for that intervention. The goal is to bring stakeholders with different and sometimes competing interests together to find common goals and mutually beneficial arrangements. For example, the

private-sector coverage-with-evidence-development project, funded by the California Health-Care Foundation, has required recruiting an advisory group that included health plan representatives, physicians, consumers, researchers, and other experts. Specifically, the comparative effectiveness research in question will evaluate the effectiveness of genetic testing to customize doses of warfarin, a blood-thinning medication.

By way of background, it is useful to explain that Medicare has already agreed to cover provisionally genetic testing to determine the appropriate starting dose of warfarin.^{13,14} The testing is paid for by Medicare under its coverage-with-evidence-development policy, which allows payment for some promising interventions on the condition that patients receiving them are enrolled in an approved clinical trial or registry. The trial or registry provides data, which CMS uses to reevaluate its coverage decision based on outcomes in populations relevant to Medicare.

In 2009, CMS outlined appropriate methodology for the design of clinical trials to evaluate the genetic testing and tailored warfarin dosing. One of the approved and currently active trials is the five-year Genetics Informatics Trial of Warfarin to Prevent Deep Venous Thrombosis, sponsored by the Washington University School of Medicine.

In a separate but parallel process, the private-sector advisory group recruited by the Center for Medical Technology Policy also decided to assess genetic testing and tailored dosing for warfarin, after an extensive priority-setting process. It was clear to the private-plan representatives that a trial for the population under age sixty-five, separate from the Medicare-approved trials, was not only necessary but also appropriate, as many patients being considered for genetic testing of this type are too young to be covered by Medicare.

The private-sector group was also concerned about the original trial design measuring results in a single "composite endpoint" that included several outcomes, such as hemorrhage or death. The health plans found this composite endpoint too difficult to interpret and not meaningful enough for clinicians. Consumers felt that the design should include more quality-of-life measures, such as the number of visits required to check blood levels.

Staff at the center contacted researchers working on the deep venous thrombosis trial to provide them with the opinions and concerns of the private-sector stakeholder group focused on the same research topic. They reached a tentative agreement to expand the criteria for human subjects to include a cohort of younger patients not

Stakeholder engagement is not something that can be achieved through a single event.

yet eligible for Medicare. In addition, the composite endpoint will be replaced with separate endpoints for death, major bleeding, and blood clot formation, so that clinicians can better understand the specific effects of the testing and tailored warfarin dosing. Secondary endpoints address time elements that may affect the number of blood draws that patients need.

Through connections among stakeholders with different perspectives on the issue, the private-sector group managed to find common ground on broader inclusion criteria for studying the effectiveness of genetic testing. This channel of communication was also crucial to aligning the study design with the needs of health plans, providers, and patients. Inspired by this progress, two national health plans involved in the advisory group have indicated a strong interest in sponsoring coverage with evidence development for their beneficiaries once the model is fully developed and research funding is secured.

Sustained Stakeholder Engagement

Engaging stakeholders in comparative effectiveness research is a process that should continue alongside the research, requiring regular meetings that provide ample opportunities for discussion. An example is a plan for a national joint replacement registry to track patients with joint replacements and their outcomes. In many ways, it serves as a testament to the success of such sustained stakeholder engagement.

In 2001 the American Academy of Orthopaedic Surgeons and the Agency for Healthcare Research and Quality (AHRQ) held a workshop to discuss the potential for launching such a registry. The academy then took steps to launch a national registry but encountered obstacles. Part of the problem is that establishing a national registry in the United States is more difficult than in countries with single-payer systems,¹⁵ since in the US system, medical claims and other data are distributed across multiple payers,

many of them private. The academy determined that stakeholder engagement was thus one key to establishing the registry.

In September 2008 the Center for Medical Technology Policy facilitated a multistakeholder meeting to identify barriers to implementing a national joint registry, find solutions to these barriers, and create a plan to establish the registry. Participants in the meeting included representatives of the Food and Drug Administration, CMS, AHRQ, the National Institutes of Health, the Advanced Medical Technology Association, the American Hospital Association, CIGNA, and Aetna.

The group produced a detailed and comprehensive list of barriers from the combined perspectives of the stakeholders. Possible solutions included a multistakeholder governance structure for the registry, funding models to pay for it, methods for reducing the burden on hospitals of submitting data to the registry, and ways to achieve provider compliance.

The American Academy of Orthopaedic Surgeons is now making important progress toward launching a national registry. Called the American Joint Replacement Registry, it was established as a 501(c)(3) nonprofit organization in May 2009.

In subsequent meetings, the stakeholder group expanded to include several patient representatives. Feedback from the group has led to modifications in certain features of the registry. Industry groups have agreed to help fund the registry, hospitals and nursing groups are helping the academy find ways to make the submission of data more efficient, and the academy has hired full-time staff members for the registry. Unique among registries launched by professional organizations of clinicians, the joint replacement registry's governing board, which recently held its first meeting, has patient members.

Discussion

In this paper we have provided descriptions of and an organized approach to stakeholder engagement in comparative effectiveness research. We have offered suggestions for meaningful stakeholder engagement, developed through a qualitative assessment of ongoing projects at the Center for Medical Technology Policy. Our intent is to provide a framework to describe and organize this type of engagement. As we analyze and document similar projects, we will refine this framework to guide future efforts in the field.

LONGITUDINAL PROCESS It is important to emphasize that stakeholder engagement is a longi-

tudinal process, not something that can be achieved through a single event. Instead, it should proceed in parallel with the research process.

Research does not begin with the careful design of a study or the enrollment of patients in a trial, but with the selection of a topic that researchers believe is important and interesting. Stakeholder engagement should also begin before study design and patient enrollment, if comparative effectiveness research is to succeed in bridging the gaps in evidence between research results and clinical decision making. When groups of stakeholders are meaningfully engaged in the entire process, they can advise comparative effectiveness investigators on setting priorities for study, designing and executing trials, deciding what meaningful results would be, and setting strategies for how to disseminate results for maximum impact.

Stakeholder engagement in comparative effectiveness research is still relatively uncharted territory, and many questions remain to be answered. Researchers may experience more suc-

cess with groups of stakeholders if they begin with balanced representation, get the participants to buy in to the process and clearly understand their part in it, provide neutral and expert facilitation, connect the stakeholders with each other, and sustain their engagement over time. These five principles are interdependent.

POLICY IMPLICATIONS This work has important policy implications as the federal government endorses comparative effectiveness research, not only with new funding but with new institutes. The formal involvement of the public in research, through initiatives like the citizens' forum, may help assuage some of the fear that comparative effectiveness research could lead to rationing, or skepticism about its potential impact in improving the quality of care.¹⁶ The success of this new wave of research will depend on effective stakeholder participation. It is our hope that researchers will derive useful insights from our preliminary work as they strive for the results that matter most to the decision makers in clinical medicine. ■

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Ari Hoffman is a medical resident at the University of California, San Francisco (UCSF).

In this issue, Ari Hoffman and coauthors take on the topic of how best to engage patients, doctors, and other stakeholders in designing comparative effectiveness studies. Hoffman, a resident in internal medicine at the University of California, San Francisco (UCSF), was inspired by a recent fellowship at the National Institutes of Health, where he worked in the Bioethics Department at the Clinical Center developing conceptual frameworks for evaluating wasteful spending in medicine and health care. He received his medical degree from UCSF.



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Russ Montgomery is a first-year doctoral student in health policy at

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Montgomery spent much of last year working with the Athena Breast Health Network, a collaborative research project across the University of California system. Athena is a "rapid learning" health care system that combines research and practice to [please describe].



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Best Practices Innovation Collaborative

- *Team-Based Care: Principles and Practices—A project of the IOM Best Practices Innovation Collaborative.*
- *Multiple Chronic Conditions & Clinical Practice Guidelines—A project of the IOM Best Practices Innovation Collaborative*
- *Harmonizing the COI Disclosure Process—Exploring common elements for conflict of interest disclosure in health care and the life sciences*
- Bechtel, Christine and Ness, Debra L. *If You Build It, Will They Come? Designing Truly Patient-Centered Health Care.* Health Affairs. 2010.
“Our years of working with consumers lead us to conclude that there is a core message that policy makers must understand if reforms are to succeed: New models of care must be designed to fully address the challenges that patients themselves say most affect their health outcomes.”
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“Call it patient-centeredness, but, I suggest, this is the core: it is that property of care that welcomes me to assert my humanity and my individuality. If we be healers, then I suggest that that is not a route to the point; it is the point.”



TEAM-BASED CARE: PRINCIPLES & EXPECTATIONS

Project of the IOM Best Practices Innovation Collaborative

Activity: Identify basic principles and expectations for contributions of participants in the care process, to serve as common reference points guiding cooperation across health professionals, patients, and families.

Compelling aim: *Transformation of the culture of health care from one of serial patient-clinician encounters—often disassociated, uncoordinated, and tailored to the needs of the provider—to one of shared vision and seamless interplay and continuity among all participants in the care process, including patients and family.*

Issue: Currently, many of the week-to-week, day-to-day, even hour-to-hour processes in health care are poorly coordinated and poorly related to the needs of patients. One-quarter of adults say their medical history and test results were not available to other clinicians who needed it, and nearly one of five said that results or records were not at their doctor's office in time for appointments. Seven of 10 have difficulty either getting doctors' appointments when needed, getting phone advice, or receiving after-hours care without having to visit the emergency room. The problem is compounded by the fact that patients with multiple chronic medical conditions routinely visit 16 different physicians per year. To address the issues, innovative team-based care models are being developed and demonstrated in various settings, with positive benefits on patient outcomes—e.g. coordinated team processes demonstrated to shorten treatment time for heart attacks to less than 90 minutes, patient length of stay by up to 50%, and unnecessary hospital readmission by 30% or more, as well as to reduce mortality. Over 85% of patients feel that it is important for physicians to work within a team. Nonetheless, barriers exist in bringing team demonstrations to scale, including deep-seated traditions in the culture and education of different health professions, differing expectations among provider groups, nomenclature incompatibilities, payment incentives, and institutional organizational structures.

Approach: A working group comprised of diverse health professionals from the IOM Best Practices Innovation Collaborative will consider issues, common principles, approaches, and expectations, and will draft a paper presenting their vision of team-based care: principles to guide its conduct; expectations for participants; policy, program and stakeholder priorities; and approaches to assessing results and measuring its achievements. In addition to input from individual professional societies, the work will build upon, and include participants from, the Interprofessional Education Collaborative. Although not a consensus document, comments will be sought from all BPIC institutional participants, including on dissemination and implementation. Progress is anticipated through the approaches identified, an inclusive development process, and the fostering of common inter-professional views, relationships and expectations.

Deliverable: An IOM Discussion Paper on the principles and expectations for team-based care, prepared for wide dissemination and adoption, as appropriate, by individual societies and institutions.

Related IOM work: *Patients Charting the Course* (2011), *Engineering the Learning Healthcare System* (2010), *The Learning Healthcare System* (2007), *Rewarding Provider Performance* (2006), *Crossing the Quality Chasm* (2001), *To Err is Human* (1999)

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MULTIPLE CHRONIC CONDITIONS & CLINICAL PRACTICE GUIDELINES*A project of the IOM Best Practices Innovation Collaborative*

Activity: An IOM-hosted meeting to discuss how condition-specific clinical practice guidelines (CPGs) developed by various authorities can better address the practical reality of multiple chronic conditions, including a focus on the roles and opportunities for health profession societies and organizations.

Compelling aim: *Effective and efficient prevention, management, and treatment of multiple co-morbidities, leading to better health outcomes and reduced costs in health care.* Progress can be broadly facilitated by virtue of the meeting content (discussion of common goals and processes, identification of gaps in current knowledge and practice), process (cooperative engagement of those engaged in guideline development), and products (clarification of important steps by key stakeholders).

Background: In December 2010 the US Department of Health and Human Services released Multiple Chronic Conditions: A Strategic Framework to “catalyze change within the context of how chronic illnesses are addressed in the United States—from an approach focused on individual chronic diseases to one that uses a multiple chronic conditions approach.” The third goal of this Strategic Framework is to enhance tools and information for those who deliver care to individuals with multiple chronic conditions. One strategy for accomplishing this goal is to include in clinical practice guidelines information about management of index conditions in the face of common co-morbidities (Strategy 3.C.1). In March 2011, an AHRQ-funded IOM report—*Clinical Practice Guidelines We Can Trust*—also highlighted the importance and challenge of including co-morbidities in CPGs. Efforts are currently being undertaken by interested agencies and societies, thus, an opportunity exists for collaborative “crosswalks” between efforts. Engagement of professional and specialty societies who develop CPGs is key to identifying opportunities and strategies for systematic incorporation of co-morbidities into harmonized guidelines.

Approach: The IOM Roundtable on Value & Science-Driven Health Care will convene, under the auspices of its Best Practices Innovation Collaborative, a one-day meeting to explore the current state of inclusion in CPGs of items related to management of patients with multiple co-morbidities, the key opportunities and obligations for improvement, the strategies for engaging field leadership, and potential for meeting participants to contribute. Consideration will also be given to identifying gaps in the existing evidence that could be addressed through research and would improve health care and health outcomes for those with multiple chronic conditions.

Potential participants: National leaders from professional and specialty societies involved in the development of CPGs; researchers in the area of multiple chronic conditions, geriatrics, guidelines; agency leadership from the Secretary of HHS, AHRQ, CDC; other interested parties.

Deliverable(s): An individually authored IOM Discussion Paper that reviews the issues and opportunities, and reflects on key next steps and stakeholder responsibilities.

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HARMONIZING THE COI DISCLOSURE PROCESS

Exploring Common Elements for Conflict of Interest Disclosure in Health Care and the Life Sciences

Activity. Engage key stakeholders who require and provide disclosure of conflicts of interest (COI) to identify issues relevant to harmonization of the conflicts of interest disclosure process and develop principles and strategies to streamline and synchronize reporting.

Compelling aim. *Harmonize COI disclosure to reduce burden and streamline provision of necessary information between those requesting and providing COI data.* Achievement of this aim will be accomplished by virtue of careful exploration of the current and evolving regulations and requirements for COI disclosure, identification of the needs and preferences of multiple stakeholders, facilitation of discussions regarding common elements and shared priorities, and generation of practical principles and strategies to guide system design and implementation.

Issue. In 2009, the IOM Committee on Conflict of Interest in Medical Research, Education, and Practice recommended approaches to managing conflicts of interest without stifling fruitful collaborations. One concern identified by the Committee was the substantial and possibly unnecessary burden placed on health care professionals and biomedical researchers by frequent, repetitive, inconsistently configured, and time-consuming COI disclosure processes required by academic institutions, research organizations, funding organizations, journals, CME providers, professional societies, federal agencies, advisory committees, and more. The Committee recommended simplifying the process, urging “national organizations that represent academic medical centers, other health care providers, and physicians and researchers should convene a broad-based consensus development process to establish a standard content, a standard format, and standard procedures for the disclosure of financial relationships with industry.” Viewing this recommendation as a priority issue for follow up, IOM President Harvey Fineberg hosted a meeting in August of 2010, bringing together representatives from national organizations representing key stakeholders to share perspectives on harmonization of COI disclosure. Strong interest was expressed in moving forward on the possibility.

Approach. This activity will convene a COI multi-stakeholder working group in a cooperative effort to identify common elements and standardized approaches to satisfy conflict of interest disclosure requirements in health care and the biomedical sciences. The project will 1) identify stakeholder organizations—representing both those organizations requiring disclosures, and those filing them; 2) review a representative sample of information required in existing practices; 3) identify and consider the issues, barriers, and challenges to streamlining and harmonizing the COI disclosure process; 4) propose elements of a common approach as the recommended product of the stakeholder organizations; and 5) present to representatives of key requiring organizations options for consideration and follow up. The discussions will be hosted by the IOM, under the auspices of its affinity group of professional societies, the Best Practices Innovation Collaborative.

Participants. National organizations and academic institutions representing health care providers and researchers, as well as organizations requiring COI disclosure such as academic journals, federal agencies, and public and private grant-making institutions. Participants will also include those from industry organizations and authorities specializing in issues of ethics and conflicts on interest.

Deliverables. An individually-authored IOM Discussion Paper reviewing issues and opportunities, key next steps, and stakeholder responsibilities.

Related IOM work: *Conflict of Interest in Medical Research, Education, and Practice (2009)*

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If You Build It, Will They Come? Designing Truly Patient-Centered Health Care

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ABSTRACT As the United States debates how to reorganize its health care system, policy makers must ask what patients really want and need from their primary care providers. There is often a disconnect between what patients say they want and what other providers or payers think patients want. Our research at the National Partnership for Women and Families suggests that a truly patient-centered health care system must be designed to incorporate features that matter to patients—including “whole person” care, comprehensive communication and coordination, patient support and empowerment, and ready access. Without these features, and without consumer input into the design, ongoing practice, and evaluation of new models, patients may reject new approaches such as medical homes and accountable care organizations.

Redesigning the U.S. health care system to improve quality and use resources more effectively has taken on increasing urgency. Costs continue to rise, and patients struggle in a nonsystem that they say often fails to address their most pressing needs. As a result, there is widespread agreement that health care should be anchored in a stronger primary care system and that primary care itself should be more patient centered. Models such as the patient-centered medical home and accountable care organizations are being developed and tested at the local, state, and national levels as promising approaches to use in advancing and achieving these goals.

Historically, consumers have not been engaged in the design of new health care delivery and payment models. When they have been engaged, it has been mostly after physicians, employers, or health plans have constructed a new model. Then consumer engagement has typically been conducted under the guise of “education” and designed primarily to convince or compel consumers to participate in it. This is an oft-repeated pattern in health care, reflecting the

pervasive notion that if we simply build a system the “right way,” patients will embrace it.

The problem with this approach is that non-consumer stakeholders often don’t know what matters to patients in terms of what has the most impact on their ability to get and stay well. For example, in research regarding medical decision making, Karen Sepucha and colleagues found significant differences between physicians’ understanding of patients’ values and what patients said is actually important to them.¹ In explaining treatment options, providers tended to focus more on the benefits of a particular course of treatment, while patients most wanted to know about potential harms and effects on their daily activities. With information about all of their options, patients may make different treatment choices than physicians surmise.²

Patients’ desire for information on all of their options should not be interpreted to suggest that providers should simply give patients whatever treatment they want. There can be no doubt that patients and families rely on clinicians for guidance. At the same time, they also want a full understanding of options, benefits, and risks so that they can decide with clinicians what is

best for them. If even the providers who are arguably closest to the patients they treat do not fully understand what those patients want, neither can policy makers, health plans, or others assume that building a new system without consumer input will work.

When patients cite system characteristics that matter to them—such as shared decision making, partnership, and communication—these qualities are sometimes classified by other stakeholders as valuable but less important than system attributes such as high clinical quality. We argue that these characteristics are not at all mutually exclusive. Yet efforts to measure quality have focused predominantly on the clinical aspects of care, rather than on systematically measuring and improving patients' experiences with care. This lapse seems indicative of a broader failure to recognize that these experiential attributes can translate directly into improved clinical outcomes for patients, often at a lower cost.³⁻⁶

Given these dynamics, models designed without consumer input run the risk that patients not only will not embrace them, but also will perceive them as contrary to their best interests. There is perhaps no better example of this than consumer backlash to managed care, where the “if you build it, they will come” assumption backfired in a profound way because of perceptions regarding limiting access to care. There are a number of attributes of new models of primary care such as medical homes and accountable care organizations that could conjure up similar consumer concerns, thus generating the potential for the kind of consumer backlash that would threaten the long-term scalability and sustainability of these approaches.

Most important, we believe based on our work that putting patients at the center of redesign is more likely to yield better outcomes, as well as a system that consumers will embrace, than could be achieved if patients are left on the edges.

Our Work

To inform our policy work, in 2008 and 2009 the National Partnership for Women and Families launched a variety of initiatives. These were designed to gather information about what consumers see as the key attributes of patient-centered care and to gauge their views on some of today's most prominent models of delivery system reform.

First, we convened a series of meetings with consumer advocates at the local, state, and national levels who work daily with patients and their families, many in underserved areas. Most of these advocates had worked with the National Partnership previously on various health care

quality initiatives and thus had at least a basic understanding of delivery systems. We explored with these advocates the core elements of patient-centered care and collaboratively drafted a set of consensus-based consumer principles that describe how key attributes of patient-centered care should be incorporated into the medical home model from the consumer perspective.⁷

We subsequently commissioned focus groups with patients and caregivers to explore their reactions to proposed new models of delivery and payment reform. Focus groups were conducted by Lake Research Partners 10–14 August 2009. Participants were adults over age forty who either had at least one chronic condition or cared for someone with a chronic illness. They came from a variety of racial, ethnic, and socioeconomic backgrounds. Groups convened in four cities: Philadelphia, Memphis, Albuquerque, and Minneapolis. The conversation in the Albuquerque focus group was conducted in Spanish.

The focus-group findings were followed by a nationally representative survey of adults age forty and older.⁸ This communication-oriented survey was not designed to measure support or opposition to a given reform solution in a systematic way. Rather, the goal was to find ways to speak persuasively to consumers about these reforms.

As such, we asked questions designed to ascertain whether or not respondents thought that key elements of these reforms—including elements such as team-based care and electronic health records—would improve the way care is delivered. When combined with our focus-group findings, this research offered important insights into consumers' views about the benefits and drawbacks of various approaches.

In this paper we first identify the attributes of patient-centered care that matter most to patients based on our work and a sample of the available literature. We then review in broad terms how people in our focus-group and survey research reacted to some of today's most-talked-about delivery system and payment reforms.

What We Believe Patients Want From Primary Care

Our work with consumer organizations and our focus-group and survey findings identify a number of key attributes that patients want in primary care. These are generally consistent with the body of research that has previously explored patient-centered care on an empirical basis.^{4-6,9-13} They are reflected to varying degrees in today's health care system, but on the whole, patients do not consistently experience them.¹⁴

In our view, that is in large part because payment systems such as fee-for-service do not reward the kinds of services, structures, or supports that are required to achieve them. It is also in part because clinicians don't have the kinds of tools to comprehensively or systematically redesign their practices in ways that would be responsive to the attributes of care that patients seek.

The attributes can be organized into four key areas: "whole person" care, comprehensive communication and coordination, patient support and empowerment, and ready access.

"WHOLE PERSON" CARE For the consumers we worked with, one of the most important attributes of patient-centered care is that clinicians take the time to really know the patients they are treating. This means understanding each patient as a whole person rather than a collection of body parts. This is not a trivial wish; other research indicates that it has an important impact on clinical outcomes.^{5,12}

Consumers we talked to described a "disease-centered" approach in which they believe the focus on treating one body part in isolation from others results in misdiagnoses and harmful drug interactions. They also said that when clinicians understand the full range of factors affecting a patient's ability to get and stay well—including life situation, home environment, personal preferences, and caregiver status—they can make treatment recommendations that patients are more likely to follow, because the recommendations will align with patients' values and are realistic given their life circumstances.

COORDINATION AND COMMUNICATION Our work demonstrated that patients wanted their clinicians to take active responsibility for coordinating care across settings and services, in collaboration with the patient and family. Simply put, they wanted their doctors and other providers to talk to each other. This desire for comprehensive coordination and communication is consistent with research demonstrating the importance of these two factors in improving health outcomes and addressing costs, particularly for Medicare beneficiaries.¹⁵

A key ingredient of effective coordination is organizing providers into teams. Patients and caregivers are highly receptive to this concept, as both our research and other quantitative research has shown.¹⁶ In our research, people expressed great enthusiasm for a "point" or "go-to" person who can answer questions, help them navigate the system, and help them understand their condition and what they need to do. They also defined the care team in very broad terms to include not only their primary care clinicians, but also specialists and other clinical and non-clinical professionals in the community—such as

pharmacists, physical therapists, dentists, transportation providers, and support-group leaders.

For patients and caregivers, meaningful coordination and communication would include the following: (1) Assistance in choosing specialists and getting appointments with them in a timely manner. (2) Steps to ensure that other providers who care for the patient have that patient's medical information ahead of time. As a result, the patient would not have to repeat the information or come back and repeat the visit when the information was at hand. The provider would also have essential information about the "whole person" and could accommodate physical or cognitive limitations or limited English proficiency in a way that was conducive to effective treatment.

(3) Help in understanding test results or treatment recommendations, and in making sure that patients receive appropriate and timely follow-up care. (4) Ensuring smooth transitions between settings, free from the errors caused when multiple clinicians do not communicate effectively. Safe transitions also include giving patients and caregivers information so they know what to expect and how to care for themselves, as well as linking them to community resources and other appropriate supports.

PATIENT SUPPORT AND EMPOWERMENT Consumers also cited as a key priority expanding patients' and caregivers' capacity to manage health conditions more effectively. Several dimensions in this area are important to patients.

► **PARTNERSHIP:** To make effective health decisions, whether regarding treatment options, care plans, or self-management practices, patients need and want to be partners with clinicians. This desire reflects patients' awareness that one size doesn't necessarily fit all when it comes to health care.

This awareness is potentially good news for practitioners as they help patients navigate a medical world in which there are increasingly no right or wrong answers. It is also a potential platform for building patients' or consumers' understanding that because options and preferences vary, "more care" might not always be better. Patients want guidance from clinicians, but they also want complete, unbiased information that enables them to assess all of their treatment options; to discuss with clinicians side effects and costs; and to review the risks and benefits of various options, including alternative therapies.

► **SUPPORTS FOR SELF-MANAGEMENT:** Our work also reinforced the importance of providing tools and services that help patients and caregivers better manage their conditions. In quantitative research, having these tools and

services has been identified by patients as one of the three most important aspects of good care (along with communication and partnership).⁴

Patients and caregivers want clinicians to work with them to develop and set health goals, and to support them in meeting those goals over time. They see this kind of self-management support as including linkages to culturally appropriate community-based services such as transportation, exercise programs, assistance with daily living activities, and condition-oriented support groups.

► **TRUST AND RESPECT:** An environment of trust and respect is the essential foundation for all of the above attributes—a meaningful relationship with the care team, effective communication, and genuine partnership and empowerment. Patients want respect for their preferences, their physical and emotional comfort, and their privacy.

READY ACCESS Consistent with other research,¹⁷ having ready access to care was a top concern. Consumers defined *access* in many ways, including as getting appointments promptly; keeping office wait times brief; and having care team members available when needed, whether by phone, by e-mail, online, or in person, including nights and weekends. Access also meant accommodating needs that arise from limited physical mobility, cognitive impairment, language barriers, or cultural differences that impede effective treatment or successful patient self-management.

It was particularly important to these patients and consumer advocates that their primary care teams serve as trusted gateways to other professionals and to the services they need, rather than as gatekeepers who monitor or limit their access to care. Fears of care being rationed or denied, which drove the backlash against managed care, persist and are frequently reinforced by sub-optimal experiences in our current health care system.

Our focus-group participants made clear that problems with accessing needed care are experienced most by vulnerable and low-income populations. These concerns are powerful and will be particularly important to address as new care systems are designed.

How Consumers View Delivery System Reforms

In addition to identifying the core attributes of patient-centered care, we sought to explore how consumers react to some of the most prominent tools and strategies that are being proposed and tested in today's health care debate—including health information technology, the concept of a

medical home, patient engagement, performance measurement, and payment reform. The focus-group and survey findings were sobering. They make a compelling case for engaging consumers as new models are developed, to ensure that these models address the problems that patients experience in today's system.

The solutions that fared best in our research were the ones that patients perceived as addressing their most pressing challenges around coordination and communication—and especially their desire for providers to talk to each other.

HEALTH INFORMATION TECHNOLOGY Health information technology (IT) was received positively because consumers understood its potential to minimize the breakdowns in communication and coordination of care that they say afflict the health care system today. They viewed health IT as a key tool for supporting more efficient and whole-person care, with the potential to reduce the burden that caregivers and patients face in ferrying records from one doctor to another and across settings of care.

Consumers thought that health IT could help reduce medical errors caused by a fragmented focus on individual body parts. A few focus-group participants raised concerns about privacy and security, although they characterized these concerns as minor when compared to the potential benefits of electronic records.

MEDICAL HOME The concept of a medical home was well received, although the terminology was a problem. Knowing this, in our focus groups we tested the term *medical home base*, but this did not increase the model's appeal. In our survey, we described it as “a team approach” to providing care. The primary factors that made this solution so appealing were vastly improved coordination and communication; having a “point” or “go-to” person who can answer questions and help navigate the system; and a focus on knowing and treating the whole person. Focus-group participants and survey respondents easily saw the benefit of having providers work together as a team and share information. However, some focus-group members raised concerns about how this model would be paid for, whether care would be limited by “gatekeepers,” and whether new fees would accompany this approach.

PATIENT ENGAGEMENT Patient engagement, when defined as partnership and shared decision making with providers, resonated with consumers. They saw engagement as a mechanism to strengthen patients' voices in deciding what is best for them, and also as a way for patients to better understand their conditions. Consumers felt strongly about wanting a voice in decisions about their care and the care of loved ones. But they were more likely to see this as a right, rather

than as a strategy for improving care.

PERFORMANCE MEASUREMENT AND PAYMENT REFORM Although viewed by many experts as critical strategies for improving quality, these were not generally perceived in the same way by consumers. This reality may be related to the fact that most consumers did not label the breakdowns they encounter in coordination and communication as “quality” problems. Many were resigned to the idea that this is just the way the system is, and they had little expectation that it would change. In that context, performance measurement and public reporting did not immediately resonate as a strategy for improving care.

However, when focus-group participants were asked to think about variations in care and the potential for “good” and “bad” care, they were more able to recognize a role for quality standards and accountability. Through that lens, they were able to consider the merits of performance measurement as a strategy for improving care. Nonetheless, they raised concerns about who would set standards, how they would be applied, whether they would be fair to providers, and whether they could be misused to deny care or remove control from the doctor-patient relationship.

In addition, consumers did not intuitively see payment reform as a strategy for improving care. They were loath to think that physicians need financial motivations to provide good care, and they reacted negatively to the idea of payment incentives or rewards. However, once focus-group participants understood that many of the aspects of care coordination they desire are not now reimbursed, they were generally supportive of changing payment to ensure that the things they want most, such as better coordination and communication, receive adequate compensation.

Our View Of The Path Forward

If we want a truly patient-centered health care system, we have to design it around what patients say is important to them. Unless patients' needs and preferences are at the center of these changes, we believe, reforms will be able to drive better care outcomes only in limited ways.

Incorporating this realization into system redesign would amount to a major paradigm shift. It would mean recognizing that other stakeholders, including clinicians, don't always understand the attributes of care that patients are seeking—and that play a role in achieving the improved health outcomes we all seek. Achieving this paradigm shift means undertaking the following actions.

ENGAGING CONSUMERS We must begin to engage consumers meaningfully as full partners—not just in their care but in the design of their care. First, we must recognize their seat at the tables where policy decisions are made. Policy making needs to include not just budget analysts and Medicare experts, but also consumer organizations and actual patients and caregivers.

Advisory bodies need consumer representatives who help shape how models are built, monitored, and evaluated. Decisions about what makes pilot projects successful and worthy of expansion must also be informed by the perspectives and experiences of consumer groups.

We also need to help consumers and caregivers develop new skills and pathways for becoming informed and activated patients. Doing so will require delivering better information to patients and their families; improving health literacy; and finding effective means to facilitate shared decision making, goal setting, coaching, and problem solving between providers and patients. Developing an “ecosystem” of electronic tools and community resources should be explored as a promising support for helping consumers engage as partners in their care and reach their health goals.

LINKING PAYMENT TO PATIENT-CENTERED METRICS In moving toward a health care system that bases payment on performance, metrics by which clinicians are held accountable must be patient centered. Payment models should be assessed against whether they measurably improve patients' outcomes and functional status, patients' experiences, care coordination, and resource use.

PUTTING A HIGHER PRIORITY ON PATIENT EXPERIENCE Many of the attributes that patients say are important to them are best expressed through surveys of patient experience. We cannot get to a truly patient-centered system unless we routinely and comprehensively integrate the use of such surveys into the standard practice of care delivery. Survey results should be used by providers to continuously improve their care, and public reporting of results can inform patients' decision making. Payment should reward these surveys and foster their use.

INVESTING IN INFRASTRUCTURE The redesign of care will require that we make investments in the critical infrastructure upon which patient-centered care depends. The effective use of private and secure health IT is essential to better communication and coordination through sharing information electronically across care teams and with patients. Data from electronic health records should also be used to support outcomes-based payment.

We should also continue to invest in advancing

the science of quality measurement, reporting, and improvement to create the next generation of measures that comprehensively assess patient outcomes and functional status, care coordination and transitions, patient-centeredness and equity, and efficiency and resource use.

We should also build a stronger primary care workforce through robust medical education focused on patient-centered care, as well as adequate compensation and working conditions for direct care workers.

Finally, investments in comparative effectiveness research should help give clinicians and patients better information about the most effective treatments and services and should provide the foundation for shared decision making.

If You Build It, Will They Come?

Our years of working with consumers lead us to conclude that there is a core message that policy makers must understand if reforms are to succeed: New models of care must be designed to

fully address the challenges that patients themselves say most affect their health outcomes. If we do not make these patient-centered attributes the focal point for reform, and if changes in payment and delivery are instead perceived as primarily benefiting health plans and providers, there is a high probability that patients will see them as ineffective at best, and contrary to their interests at worst.

As has been the case in the past, the next round of payment and delivery models will surely be implemented with keen attention to providers' needs and interests, driven by an understandable desire to recruit providers to participate. But patients' influence and needs should be considered as being just as important as those of providers and payers, if not more so. The attributes of patient-centered care, as articulated by patients and consumers themselves, provide a clear path forward. If we build a truly patient-centered system in collaboration with consumers, they will embrace it, benefit from it, and help ensure its success. ■

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Deborah L. Ness

Debra L. Ness is president, and Christine Bechtel vice president, of the National Partnership for Women and Families. The National Partnership, founded in 1971 as the Women's Legal Defense Fund, is a nonprofit, nonpartisan organization based in Washington, D.C.

Its goals include promoting fairness in the workplace, increasing access to high-quality and affordable health care, and promoting policies that help women and men meet the dual demands of work and family. In the health sector, the National Partnership's goal is to "improve care for the most vulnerable patients, and to ensure access to high-quality, affordable health care, which is essential if women and families are to have real economic security," says Ness.

The National Partnership also works on engaging consumer on health information technology (IT) to help fulfill its "promise of improving communication and coordination, reducing duplicative tests and medical errors, and helping support a more

patient-centered health care system," says Bechtel.

Ness, 54, has worked on health and public policy for her entire career. She joined the National Partnership in 1991. She graduated from Drew University and received her master of science degree from the Columbia University School of Social Work. She was deputy director of the National Abortion Rights Action League, and she serves on several boards, including the National Committee for Quality Assurance and the National Quality Forum.



Christine Bechtel

Bechtel, 36, has a bachelor's degree in politics from Goucher College and a master's in political management from George Washington University. She served as a legislative aide to Sen. Barbara Mikulski (D-MD), director of community development for Louisiana's Medicare Quality Improvement Organization, a senior research adviser at AARP, and vice president of the eHealth Initiative.

Under the current health care system, a huge obstacle to patients'

receiving the type of health care they say they want is that payment and delivery systems focus on providers, and not patients. "Our system is oriented toward treating acute needs rather than managing chronic conditions, rewards quantity of service over quality of care, and promotes fragmentation over coordination," Ness says.

Advocating for women is key to the National Partnership's mission. "Women are generally the primary caregivers for their families and are disproportionately burdened by the poor communication and lack of coordination in our system," Ness says.

Both Ness and Bechtel draw on their personal experiences to illustrate the need for more patient-centered care. Ness says that she, like others, has repeatedly run into problems that stem from clinicians' not talking to each other, having to repeat visits or tests because of poor communication, and other unnecessary challenges.

Bechtel says that her current primary care doctor uses an electronic health record yet never uses it to remind her about preventive care or to communicate information to her other doctors. "The great irony is that now this practice is applying to be a 'medical home.' Hopefully, they will make the changes needed to be worthy of a true medical home," she says.

What ‘Patient-Centered’ Should Mean: Confessions Of An Extremist

A seasoned clinician and expert fears the loss of his humanity if he should become a patient.

by **Donald M. Berwick**

ABSTRACT: “Patient-centeredness” is a dimension of health care quality in its own right, not just because of its connection with other desired aims, like safety and effectiveness. Its proper incorporation into new health care designs will involve some radical, unfamiliar, and disruptive shifts in control and power, out of the hands of those who give care and into the hands of those who receive it. Such a consumerist view of the quality of care, itself, has important differences from the more classical, professionally dominated definitions of “quality.” New designs, like the so-called medical home, should incorporate that change. [*Health Affairs* 28, no. 4 (2009): w555–w565 (published online 19 May 2009; 10.1377/hlthaff.28.4.w555)]

THE CONCEPT OF THE MEDICAL HOME (a practice team that coordinates a person’s care across episodes and specialties) is now reaching center stage in proposals for redesign of the U.S. health care system.¹ The major primary care societies—the American College of Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Osteopathic Association—are united in their advocacy for it. This is welcome, of course, for those who hope for a shift of investment into primary care, integrated care, and prevention.² The question remains open, however, about the degree to which medical homes will shift power and control into the hands of patients, families, and communities. In this paper I argue for a radical transfer of power and a bolder meaning of “patient-centered care,” whether in a medical home or in the current cathedral of care: the hospital.

Three years ago, a close friend began having chest pains. She headed for a cardiac catheterization, and, frightened, she asked me to go with her. As I stood next to her gurney in the pre-procedure room, she said, “I would feel so much better if you were with me in the cath lab.” I agreed immediately to go with her.

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The nurse didn't agree. "Do you want to be there as a friend or as a doctor?" she asked.

"I guess both," I replied. "I am both."

"It's not possible. We have a policy against that," she said.

The young procedural cardiologist appeared shortly afterward. "I understand you want to have your friend in the procedure room," she said. "Why?"

"Because I'd feel so much more comfortable, and, later on, he can explain things to me if I have questions," said my friend.

"I'm sorry," said the cardiologist, "I am just not comfortable with that. We don't do that here. It doesn't work."

"Have you ever tried it?" I asked.

"No," she said.

"Then how do you know it doesn't work?" I asked.

"It's just not possible," she answered. "I am sorry if that upsets you."

Moments later, my friend was wheeled away, shaking in fear and sobbing.

What's wrong with that picture?

Most doctors and nurses, I fear, would answer that what is wrong with that picture is the unreasonableness of my friend's demand and mine, our expecting special treatment, our failure to understand standard procedures and wise restrictions, and our unwillingness to defer to the judgment of skilled professionals.

I disagree. I find a lot wrong with that picture, but none of it is related to unreasonable expectations, special pleading, or disrespect of professionals. What is wrong is that the system exerted its power over reason, respect, and even logic in order to serve its own needs, not the patient's. What is wrong was the exercise of a form of violence and tolerance for untruth, and—worse for a profession dedicated to healing—needless harm.

The violence lies in the forced separation of an adult from a loved companion. The untruth lies in the appeal to nonexistent rules, the statement of opinion as fact, and the false claim of professional helplessness: "impossibility." The harm lies in increasing fear when fear could have been assuaged with a single word: "Yes."

The IOM Committee

In 1998 the Institute of Medicine (IOM) established a major program on Quality of Health Care in America. I served on the first major IOM committee on that topic, the Committee on Quality of Health Care in America, and I chaired one of its two subcommittees: the one called informally the "chassis subcommittee," because our job was to suggest new designs for care—a better "chassis." That term dated to several years earlier, to the predecessor IOM activity, the National Roundtable on Health Care Quality. One of its members, David Lawrence, famously said, "The problem is that the chassis is broken." He called into question the fundamental design of U.S. health care as standing between the quality of care we have and the quality we could have.

In 1998 the roundtable published a landmark article in the *Journal of the American Medical Association* laying out the basic framework that would guide the subsequent committee.³ It labeled quality problems as a trio—“overuse, underuse, and misuse”—and it embraced this definition of *quality*: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

With that as background, the IOM Committee on Quality of Health Care in America set out to reconsider aims for improvement. The group considered “overuse, underuse, and misuse” to be a good start, but somehow incomplete—too technical. In the summer of 2000 we developed a new draft of aims: “safety, effectiveness, patient control, timeliness, efficiency, and equity.”

The sticking point in the committee’s deliberations was the third item on the list: “patient control.” Members sorted themselves into camps along a line that ran, more or less, from radical consumerism (as in, “The customer is always right”) to a classic professionalism (as in, “Patients make decisions that are not in their best interests,” and “Does that mean that anyone who asks for a CT scan gets one?”). Compromise words surfaced: “partnership,” “sharing,” “respect for patients,” and more. We settled on the term “patient-centeredness” as the aim.

The disagreement surfaced again in the committee’s struggle to write what became the “ten simple rules” for redesign—the guiding principles of how the health care system should operate to achieve the six aims for improvement. Rule 3, drafted by the radicals, started out as, “Patients have all the control.” Some argued that patients’ demands would be unreasonable. Others imagined patients who would not want such control. Rule 3 ended up as, “The patient is the source of control.” The third of the six aims, “patient-centeredness,” and the third of the ten rules for redesign, “The patient is the source of control,” found themselves in those forms in the committee’s chartering document, *Crossing the Quality Chasm*.⁴

I find an important, and usually underestimated, difference between the 1997 roundtable’s focus on “overuse, underuse, and misuse” as bounding the problem of health care quality and the six aims and ten rules of the *Quality Chasm* report. The difference centers on the third aim and the third rule, which, taken as strongly as I would have them taken, are potentially revolutionary. They can and, in my opinion, should redefine professionalism itself.

■ **“Professionalism” versus “consumerism.”** The sociologist Eliot Freidson, in his classic study of health care, *Profession of Medicine*, defines a profession as a work group that reserves to itself the authority to judge the quality of its own work.⁵ Freidson posits that society cedes this authority to a profession because of three beliefs: (1) altruism—that professionals will work in the best interests of those they serve, rather than their own interests; (2) expertise—that professionals are in command of a special body of technical knowledge not readily accessible to nonprofessionals, and (3) self-regulation—that professionals will police each other.

Freidson’s definition of a profession contradicts the usual assumption of con-

“The words ‘patient-centeredness’ are verbal analgesics, but they mask real pain.”

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sumer-oriented production, in which the customer, not the producer, has the “authority,” exercised by marketplace choices, to judge quality. In Freidson’s world of professions, excellence is in the eye of the professional. In the more normal world of products and services, excellence is in the eye of the customer.

The latter is not a moral position; it is a pragmatic one. The business theory underlying modern quality strategies is that producers that meet consumers’ needs, as judged by consumers, will thrive, and those that do not will wither.

The IOM committee found itself uncomfortably torn between Freidson’s form of professionalism—“Trust us; we know best what will help you”—and the consumerist view of quality—“Let us know what you need and want, and that is what we will offer.” The words “patient-centeredness” and “the patient is the source of control” are verbal analgesics, but they mask real pain.

If the roundtable’s technocratic definition of *quality* holds, then only two of the six IOM aims are primary, and “patient-centeredness” is not one of them. The only two that stand on their own are “safety” (“avoiding misuse”—that is, not doing harm from care) and “effectiveness” (“avoiding overuse and underuse”—that is, grounding care in evidence). The importance of the other four aims—patient-centeredness, timeliness, efficiency, and equity—depends only on the extent to which they help determine safety and effectiveness. Of course, we can define *health* to include emotional well-being, which may give more traction to the four lesser aims, but, in the end, “timeliness” and “patient-centeredness” are on the defensive as aims unless evidence shows that they affect health.

A consumerist view of quality differs; it takes each of the six aims on its own merits, just as in judging the “quality” of an automobile, we can independently assess safety, comfort, reliability, gas mileage, beauty, and driving fun as separate characteristics. Although they might be unequal in importance, the merit of each does not depend on its influence on another.

Notice that in the consumerist view, the current IOM definition of *quality* is defective. It is a professionally dominated view of excellence—one that Freidson would immediately recognize. It subordinates by implication the four lesser IOM aims to the technical triad of “overuse, underuse, and misuse.”

■ **Defining the ideal practice.** Ten years ago, to help with the Institute for Healthcare Improvement’s (IHI’s) project on the Idealized Design of the Clinical Office Practice, I suggested as an overarching aim for an ideal practice that its patients would say of it, “They give me exactly the help I need and want exactly when I need and want it.” Dartmouth’s John Wasson incorporated that question in an improved form in his “How’s Your Health” questionnaire: “They give me exactly the help I need and want exactly when and how I need and want it,” to emphasize the increasingly

wide range of ways to extend care to patients.

Note that the IHI question explicitly and uncomfortably stresses the view of care through the patient's eyes, especially with the words "need and want," rather than "need" only. The word "want" remains the focal point of ongoing debate and controversy, for the same reasons that the IOM committee argued about Rule 3.

In the territory between the professionally dominant view of quality of health care and the consumerist view, my views are far from Freidson's definition. I think it wrong for the profession of medicine—or any other health care profession, for that matter—to "reserve to itself the authority to judge the quality of its work." I eschew compromise words like "partnership." For better or worse, I have come to believe that we—patients, families, clinicians, and the health care system as a whole—would all be far better off if we professionals recalibrated our work such that we behaved with patients and families not as hosts in the care system, but as guests in their lives. I suggest that we should without equivocation make patient-centeredness a primary quality dimension all its own, even when it does not contribute to the technical safety and effectiveness of care.

Pedigree Of Patient-Centeredness

The idea of "patient-centeredness" did not, of course, spring to life first with the IOM committee; it has a long intellectual pedigree. A complete review is impossible here, but a few pioneers include the following. (1) Barbara Korsch of the University of California, Los Angeles (UCLA), for decades explored skills, attitudes, and knowledge to underpin the listening skills of physicians in training.⁶ (2) John Ware and colleagues in the RAND Health Insurance Experiment uncovered and clarified components and drivers of "patient satisfaction."⁷ (3) Debra Roter and Judith Hall explored the properties of doctor-patient communication, revealing its dysfunctions and ways to improve it.⁸ (4) Howard Waitzkin and John Stoeckle articulated the nature and value of patients' own attributions of their symptoms to causal factors and showed how tapping their views and knowledge could lead to more satisfactory interviews and relationships.⁹ (5) Michael Barry, Jack Fowler, Al Mulley, Joseph Henderson, and Jack Wennberg developed theory and technology for shared decision making and showed improvements in outcomes and efficiency as patients become more active participants in the decisions that affect them.¹⁰ (6) Judith Hibbard has investigated the "receiver" end of transparency, deepening our understanding of what patients want to know and how to help them know it.¹¹

Although I believe that "patient-centeredness" ought to have stature as a dimension of quality in its own right, it is also true that most researchers who have studied it systematically have found that it does often have a positive relationship to classical health status outcomes.¹² This is in part because patients and families can bring useful knowledge to care if they are invited to do so. Beatrice Golomb and colleagues, for example, found that patients on statin drugs were far more

likely than doctors to initiate discussions of symptoms possibly related to the drugs ($p < 10^8$).¹³ Annette O'Connor and colleagues' masterful systematic review of the effects of shared decision-making technologies found a 23 percent reduction in surgical interventions among patients using them, with better functional status and satisfaction.¹⁴ Patient education can help make technical health care interventions more effective, largely through better compliance.

■ **Three maxims.** Others have struggled to find a proper definition of *patient-centeredness*. Three useful maxims that I have encountered are these: (1) "The needs of the patient come first." (2) "Nothing about me without me." (3) "Every patient is the only patient."

"The needs of the patient come first" is a pervasive slogan at Mayo Clinic. In his detailed study of Mayo Clinic, Leonard Berry, a leading scholar of service industries, emphasizes Mayo's teamwork and brand clarity as advantages, but he traces these strengths to the continual and conscious reinforcement of the rule of William J. Mayo: "The best interest of the patient is the only interest to be considered."¹⁵ This perspective is still formally technocratic; Dr. Mayo did not choose to say, "The needs and wants of the patient....," and one wonders how he would have greeted the consumerist assertion that patients know their "best interest" better than physicians do. Nonetheless, the idea that designs of habit or convenience are subordinate to designs that serve the patient is fully modern.

I heard "Nothing about me without me" from Diane Plamping, a U.K. health care organizational sociologist.¹⁶ It calls for levels of transparency and participation uncharacteristic of most health care systems.

I first saw "Every patient is the only patient" at the entryway to the Harvard Community Health Plan Hospital at Parker Hill in Boston, placed there by its chief executive officer, Arthur Berarducci.¹⁷ It connotes to me the attitude of "guest" in the patient's life, and it also expresses confidence in the feasibility and desirability of customization of care to the level of the individual.

As I stood in the pre-catheterization room, watching my friend be rolled away, crying, on her gurney, none of these three design ideas was in evidence. The needs of the patient did not come first—the habits and rules of the doctors and nurses did. Many things were going on about her without her; the alleged rules were neither negotiated in advance nor open for discussion. And she was not "the only patient"; she was anonymous, a member of a class, and her unique needs, wants, and reasons had no voice at all in the face of blunt, deaf standard practices.

■ **A new definition.** My proposed definition of "patient-centered care" is this:

The experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care.

In most circumstances, people would, and should be able to, amend the subject—"patient-centered care"—to include the experience of family and loved ones of

their choosing: “patient- and family-centered care.” In this view, a patient- and family-centered health care system would be radically and uncomfortably different from most today. Let me suggest a few examples.

(1) Hospitals would have no restrictions on visiting—no restrictions of place or time or person, except restrictions chosen by and under the control of each individual patient. (2) Patients would determine what food they eat and what clothes they wear in hospitals (to the extent that health status allows). (3) Patients and family members would participate in rounds. (4) Patients and families would participate in the design of health care processes and services.¹⁸ (5) Medical records would belong to patients. Clinicians, rather than patients, would need to have permission to gain access to them. (6) Shared decision-making technologies would be used universally. (7) Operating room schedules would conform to ideal queuing theory designs aimed at minimizing waiting time, rather than to the convenience of clinicians.¹⁹ (8) Patients physically capable of self-care would, in all situations, have the option to do it.

Professionals’ Objections

In this form of truly patient-centered design, many, if not most, classically trained health care professionals will find cause for alarm. Let me anticipate three objections.

■ **Evidence-based medicine sometimes must take a back seat.** First, leaving choice ultimately up to the patient and family means that evidence-based medicine may sometimes take a back seat. One e-mail correspondent asked me, “Should patient ‘wants’ override professional judgment about whether an MRI is needed?” My answer is, basically, “Yes.” On the whole, I prefer that we take the risk of overuse along with the burden of giving real meaning to the phrase “a fully informed patient.” I contemplate in this a mature dialogue, in which an informed professional engages in a full conversation about why he or she—the professional—disagrees with a patient’s choice. If, over time, a pattern emerges of scientifically unwise or unsubstantiated choices—like lots and lots of patients’ choosing scientifically needless MRIs—then we should seek to improve our messages, instructions, educational processes, and dialogue to understand and seek to remedy the mismatch. For the same reason, I wish we would abandon the word “noncompliance.” In failing to abide by our advice or the technical evidence, the patient is telling us something that we need to hear and learn from. Honestly, how many of us have ever faithfully taken a full ten-day course of a prescribed antibiotic or never consciously skipped a statin dose? Are we fools who did that? Or did we choose that because of some sensible, local considerations of balance, convenience, or even symptom information that the doctor never had?

I can imagine just as easily as my critics can a crazy patient request—one so clearly unreasonable that it is time to say, “No.” A purely foolish, crazy, or venal patient “want” should be declined. But my wife, a lawyer, told me long ago the apho-

“I believe that the moats we dig between patients and clinicians can drain spirit from both.”

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rism in her field: “Hard cases make bad law.” So it is in medicine: “Exceptional cases make bad rules.” You do not successfully rebut my plea for extreme patient-centeredness by telling me that, on rare occasions, we ought to say, “No.” I say, “Your ‘rare occasions’ make for very bad rules for the usual occasions.”

■ **Physician as steward of social resources.** A second objection emphasizes the duty of the professional as steward of social resources. Is patient-centeredness of the type I envision socially responsible? No one can yet know the answer to that question. Pandora’s box may be empty. O’Connor and colleagues’ summary of shared decision making for surgery cuts the other way: more sharing, less invasive care; and the work of Wennberg and Elliott Fisher suggests that supply drives demand, not the other way around.²⁰ At a minimum, I suggest that becoming responsive to individual needs and wants can give us the information we need for informed social choices to be made where they mostly belong: at the level of public policy.

■ **Clinicians’ needs and wants.** A third objection concerns the needs and wants not just of the patient, but of the clinician, too. Does patient-centeredness require of the doctor self-denial and martyrdom? Will it exhaust us? I think not. I believe, rather, that the moats we dig between patients and clinicians can drain spirit from both. When in a caring relationship we deny to the other what we could with free hearts give, we both suffer from the denial; one loses the help, the other loses the joy of helping. Among the most destructive forms of denial is the message: “You should not want that.” Even more destructive, in my opinion, is the training and institutional habit of phrasing our choices as lies, in the form, “We cannot do that,” when we darn well could.

In a remarkable essay, “A New Professional: The Aims of Education Revisited,” Parker Palmer argues against definitions of *professionalism* that separate human beings from their own feelings and hearts. He writes, in part:

The education of the new professional will reverse the academic notion that we must suppress our emotions in order to become technicians.... We will not teach future professionals emotional distancing as a strategy for personal survival. We will teach them instead how to stay close to emotions that can generate energy for institutional change, which might help everyone survive.²¹

Ask patients today what they dislike about health care, and they will mention distance, helplessness, discontinuity, a feeling of anonymity—too frequently properties of the fragmented institutions in which modern professionals work and train. Palmer is arguing for a reconnection of the feelings of health care professionals with their work, and he believes that violence is done when that connection is sundered by institutional norms and training. I claim that threats to the health of the professions come far more from denying our basic instincts to help

than from embracing them. What undergirds authentic patient-centeredness are the very same words we use when we first came to the patient's side: "How can I help you?" Helping, not the enforcing of restriction, is tonic for our souls.

Issues Related To Health System Design

Let me suggest a few design constraints on the health care system that we need and want, and let me urge the leadership of the professions, those to whom has been reserved the right to judge the quality of their own work, to abdicate that monopoly and instead to bring a never-ending inquiry to those we serve: "What do you want and need?" "What is your way?" "How am I doing at meeting your needs?" "How could I do that better?" "How can I help you?"

The pursuit of truly patient-centered care of this sort can be designed into the medical home, if we wish to do so, just as well as into the design and conduct of a hospital. Here is how.

■ **Patient-centered care as a quality dimension.** First, affirm patient- and family-centered care as a dimension of quality in its own right, and not just through its effect on health status and outcomes, technically defined. A simple way to begin in a proper medical home is to ask the following question at the end of most interactions: "Is there anything at all that could have gone better today from your point of view in the care you experienced?" And then, listen and learn. For quantitative ratings, ask patients to rate on a 1–5 scale disagreement to agreement with the assertion: "They gave me all the care I needed and wanted exactly when and how I needed and wanted it." Seek 5s and study the low raters.

■ **Locus of control.** Second, firmly vest in patients and families control over decisions about care in all its aspects. Take over control only rarely and with permission freely granted.

■ **Transparency.** Third, extend transparency to all aspects of care, including science, costs, outcomes, processes, and errors. Apologize when things go wrong.

■ **Individualization and customization.** Fourth, learn and use individualization and customization as design targets. This means creating flexible systems that can adapt, on the spot, to the needs and circumstances of individual patients.

■ **Training.** Fifth, train all young professionals in these as norms of professionalism. Equip students with confidence in their own emotional intelligence, as well as skills in mindfulness, inquiry, and dialogue.

■ **Toll on clinicians.** Clinicians may fear that extreme patient-centeredness will demand their time and energy with little or no reimbursement. This threat may lessen if and when health care evolves more toward episode-based or population-based payment and as information systems modernize. Visit rates declined at Kaiser Permanente when e-mail care—a major step toward patient-centered design—was widely adopted.²² I suspect that clinicians expend enormous energy when they enforce restrictive rules and otherwise lose touch with patients' underlying needs, and they will experience patient-centered designs not as burdens, but as reliefs.

An Extreme View

I freely admit to extremism in my opinion of what patient-centered care ought to mean. I find the extremism in a specific location: my own heart. I fear to become a patient. Partly, that fear comes from what I know about technical hazards and lack of reliability in care. But errors and unreliability are not the main reasons that I fear that inevitable day on which I will become a patient. For, in fighting them, I am aligned with the good hearts and fine skills of my technical caregivers, and I can use my own wit to stand guard against them.

What chills my bones is indignity. It is the loss of influence on what happens to me. It is the image of myself in a hospital gown, homogenized, anonymous, powerless, no longer myself. It is the sound of a young nurse calling me, “Donald,” which is a name I never use—it’s “Don,” or, for him or her, “Dr. Berwick.” It is the voice of the doctor saying, “We think...,” instead of, “I think...,” and thereby placing that small verbal wedge between himself as a person and myself as a person. It is the clerk who tells my wife to leave my room, or me to leave hers, without asking if we want to be apart. Last month, a close friend called a clinic for her mammogram report and was told, “You have to come here; we don’t give that information out on the telephone.” She said, “It’s OK, you can tell me.” They said, “No, we can’t do that.” Of course, they “can” do that. They choose not to, and their choice trumps hers: period. That’s what scares me: to be made helpless before my time, to be made ignorant when I want to know, to be made to sit when I wish to stand, to be alone when I need to hold my wife’s hand, to eat what I do not wish to eat, to be named what I do not wish to be named, to be told when I wish to be asked, to be awoken when I wish to sleep.

Call it patient-centeredness, but, I suggest, this is the core: it is that property of care that welcomes me to assert my humanity and my individuality. If we be healers, then I suggest that that is not a route to the point; it is the point.

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Digital Learning Collaborative

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- *Aligning Core EHR Data through Healthcare Reform—A proposed meeting of the IOM Digital Learning Collaborative.*
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“Thus, with HITECH, providers have an unparalleled opportunity to accelerate their adoption of health information technology and realize benefits for their practices, institutions, patients, and the broader system.”
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INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

ACCELERATING CONTINUOUS LEARNING FROM THE DIGITAL DATA UTILITY

A project of the IOM Digital Learning Collaborative

Activity: An Institute of Medicine public workshop on issues and strategies in accelerating the development of the digital data utility—integrated capacities from electronic health records, registries, and related digital information—as reliable tools continuous health learning and improvement.

Compelling aim: *Continuous improvement in personal and population health through the use of electronic health records, registries, and related digitalized clinical data as a practical, reliable, and regular source of real-time knowledge and guidance.* Achievement of this aim will be accomplished by virtue of careful exploration of the current and evolving content and capacities in electronic medical records and the major registries, the nature of their interfaces, their applicability for different needs, and the quality improvement requirements to attain their potential for real-time knowledge generation and continuous program improvement.

Issue: The constant innovation around the collection and use of digital health data, in addition to the existence of many legacy systems, raises the question of the potential, the constraints, and the strategies for data sources to be collectively drawn upon to support a continuously learning and improving health system. The quality of the clinical record data contained in these systems inevitably reflects the *ad hoc* evolution of their development, in particular prior to the implementation of the HITECH Act, and continues to characterize the state of patient registries. Using EHR and related registry data to support learning health system processes, including population health and management, is lightly considered territory—little is known about the match between data quality status and the requirements imposed by these uses. Organizations such as the Veteran’s Health Administration, Kaiser Permanente, Geisinger Health System and the HMO Research Network are leading the way in supporting learning process from their digital health information and will be important resources for their lessons learned and the establishment of best practices. The need exists for a systematic assessment of current and evolving capacity from the EHR and registry components of an integrated digital data utility, and consideration of strategies for its continuous improvement and application.

Approach: An IOM-appointed Planning Committee will develop an agenda for a meeting to engage leading experts in considering the current status, the challenges, the key questions, and exploring a strategic framework for progress on using EHRs and patient registries for learning and system operational and improvement purposes—e.g. those related data quality requirements to support population health and management; knowledge on the current state of digital health data quality; available analytic methods to assess data quality; essential components of a strategy for integrated stewardship of the EHR and patient registry components of the digital data utility.

Deliverable(s): An IOM workshop summary, or an individually-authored IOM Discussion Paper, or both, reviewing issues and opportunities, key next steps, and stakeholder responsibilities.

Related IOM work: *Digital Infrastructure for the Learning Health System (2011); Clinical Data as a Basic Staple for Health Learning (2011); A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care (2010); Enhancing Data Systems to Improve the Quality of Cancer Care (2000)*

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ALIGNING CORE EHR DATA THROUGH HEALTHCARE REFORM

A proposed meeting of the IOM Digital Learning Collaborative

Proposed activity: Involve key stakeholders in an initial meeting to explore the feasibility of, and approach to, identifying the smallest set of key data that, if integrated as a core feature of all electronic health records, would both simplify data reporting efforts and streamline the planning and execution of population health improvement efforts.

Compelling aim: *Automated, routine collection of a core evaluation-ready set of clinical encounter data which could be seamlessly reported to meet the basic requirements for reporting related to population health improvement, healthcare performance, and use of federal grant funds.* Achievement of this aim will require a highly informed cooperative mutual exploration by key stakeholders—those developing and reporting data, those requiring the data submission, and those using data for population health and program improvement.

Issue: Passage of the Affordable Care Act (ACA) in 2010 has implications for system reform beyond filling gaps in health insurance coverage. One of the key elements in that respect—a window of opportunity—is the fact that several implementation steps have a bearing on the prospect of developing, harmonizing and aligning certain core data elements important to tracking progress a new national environment in which health services are seamless, well-coordinated, oriented towards prevention, and cost effective. Federal policy guiding this complex transformation involve a large array of initiatives and programs funded through various agencies, e.g. ONC, AHRQ, CMS, CDC, ASPE. This includes novel clinical and health services models, overarching financial reforms, innovative payment strategies, and processes that can support ongoing evaluation and quality improvement, based on carefully designed, integrated data systems and information technology. In this work, it is important that the reporting requirements and approaches of the various independent activities be strategically aligned and coordinated before that window of opportunity closes. Without such strategic alignment there is a very real risk that this substantial national investment will result in an array of high quality but fragmented elements, disruptive to a well-coordinated learning health system.

Approach: Convene at the Institute of Medicine a one-day meeting of federal, state, and local stakeholder leaders to consider major data reporting requirements under the Affordable Care Act (ACA), activities of Federally Qualified Health Centers, multiple quality improvement efforts, federal grants for state and local public health, and Meaningful Use requirements for HIT, along with consideration of the most acute needs of those working to improve population health and health care at the sub-state level. Topics for consideration could include: identifying core data elements for collection during care for inclusion in EHR systems, coordination of metrics needed for payment reform models (eg. ACOs) with CMS health IT incentive payment requirements. Explore informatics and data needs and priorities for each initiative, and drawing from lessons based on comprehensive reform models at the state level (eg. VT) identify areas for potential coordination and alignment.

Deliverable: A summary of the key opportunities and stakeholder responsibilities discussed, either through an IOM workshop report or an individually-authored IOM Discussion paper—or both.

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20-June-2011

SOUNDING BOARD

Finding the Meaning in Meaningful Use

David C. Classen, M.D., and David W. Bates, M.D.

Health care has long lagged behind all other major industries in the adoption of information technology, but it is beginning to catch up. Because of the belief that electronic health records (EHRs) will be a key foundational tool for improving safety and quality of care and for reducing costs, the federal government has implemented substantial incentives for providers to adopt EHRs through the Health Information Technology for Economic and Clinical Health (HITECH) Act.¹ Some recent surveys suggest that physicians are now using EHRs in nearly half of outpatient practices² and in 44% of U.S. hospitals.³ The challenge will be to ensure that adoption of these systems will actually result in the desired improvements. Data from several studies have suggested that simple adoption of EHRs does not necessarily improve the quality of care⁴ and that quality does not appear to improve even over a number of years among EHR users.⁵

This challenge was recognized in the HITECH Act, which included the new concept of “meaningful use” of EHRs. The intent of meaningful use was to provide incentives to providers not only to adopt EHRs but also to use them in ways that would improve quality, safety, and efficiency.⁶ However, even though the concept of meaningful use is extremely attractive, it remains to be shown that the standards that are being established will result in improvement in care. Some recent studies have suggested that achieving these goals through meaningful use of EHRs may be much harder than originally anticipated.^{7,8} It is important to note that the adoption of the HITECH Act and meaningful use is intended to be only a starting point. These programs will be interacting with the delivery-system reforms encouraged under the Affordable Care Act,⁹ including the Accountable Care Organization program, bundled payments, and the National Quality Strategy.

WHAT IT TAKES TO ACHIEVE BENEFITS WITH EHRs

Success in improving care with EHRs may be related to the types of EHRs that are used, their settings of use, and the incentives in place. Most studies of the successful effect of EHRs on quality and safety of care have come from four organizations that use internally developed EHRs that have been in place for more than 25 years: Brigham and Women’s Hospital in Boston, LDS Hospital in Salt Lake City, Vanderbilt University Medical Center in Nashville, and the Regenstrief Institute in Indianapolis.¹⁰ All four institutions have spent decades expanding, iterating on, and improving their EHRs and have shown improvements in safety, quality, and efficiency.¹¹⁻¹⁴ Because these systems are under local control, the EHRs have been highly customized with the use of relatively rapid improvement cycles. They also have built informatics cultures of continuous quality improvement that allow for ongoing evaluation and iterative improvement. However, such cultures have not been widely replicated in other organizations, and vendor applications do not facilitate customization to nearly the same extent.

All these organizations, however, have struggled to maintain these systems, since doing so requires substantial development, and certification has further raised the bar. Several organizations with homegrown systems have discontinued them and purchased commercial systems,¹⁵ and nearly all future EHR implementations will probably involve vendor applications. However, the commercial EHR systems currently marketed are much younger than their homegrown counterparts and thus have been through far fewer improvement cycles. The vendors typically update only once or twice annually, and any customizations that are made may be lost with the next upgrade. Studies regarding whether commercial

systems improve quality or safety are far less extensive than those regarding homegrown systems, but many studies have not shown any benefits for commercial systems.^{16,17}

Nonetheless, large networks such as Kaiser and Geisinger, which have wholeheartedly adopted commercial EHRs and are using them heavily, have realized substantial improvements in care.^{18,19} Thus, at least within large health care system networks that have aligned incentives, large changes are possible with vendor systems, though it is important to underscore that both Kaiser and Geisinger made substantial investments and changes in the design of their care delivery that went far beyond the use of health information technology. Furthermore, a recent study by Buntin et al. showed that 92% of articles on health information technology were positive and that benefits were beginning to be defined in smaller practices and organizations.²⁰

MEANINGFUL USE AND COMMERCIAL EHRs

The HITECH Act and meaningful-use requirements for EHRs have been well described elsewhere.¹ To maximize the likelihood that improvement will occur, detailed criteria have been developed to certify EHRs, and certification is required under the HITECH Act.²¹ The presumption is that this process will help ensure that EHR vendor products will include key functionality to enable hospitals and providers to improve their safety and quality and eventually patient outcomes. These regulations have clearly affected both vendors and health care organizations as they scramble to meet tight timelines and to ensure that their EHRs have long lists of capabilities. Vendors are adding new features and functionality, and health care organizations are changing their implementations to focus on achieving meaningful use. Nearly half of all institutions (49%) ranked meaningful use as their leading information-technology priority for 2011.^{22,23} Ironically, the usual vendor-improvement cycles have been interrupted by the rush to achieve meaningful use as vendors focus the majority of their efforts on it. This explosion of organizations' interest in speeding up their implementations of EHRs to achieve meaningful-use incentives has further increased the vendor

workload, which may have unintended consequences, such as unplanned system shutdowns or system-induced errors in patient care.²⁴ Substantial discontent with vendor EHRs among providers has emerged at some sites, often over usability problems.

GETTING TO "MEANINGFUL" MEANINGFUL USE

The stage 1 criteria for meaningful use include an array of requirements, ranging from systems for computerized physician order entry (CPOE) to decision support. A major concern is whether the criteria will be sufficient to result in the adoption of EHRs that have what it takes to enable substantial improvement. One study of commercial EHRs involved going beyond the current criteria and determining whether in safety simulations the systems identified serious medication problems in CPOE systems that had already been implemented in hospitals and pharmacies.^{25,26} Only 53% of fatal medication orders were picked up by implemented commercial CPOE systems in hospitals, and only 28% of commercial information systems in ambulatory pharmacies picked up critical problems with drug-drug interactions. The study in hospitals evaluated EHR systems that had been approved by the Certification Commission for Health Information Technology in a fashion that is more rigorous than current meaningful-use certification, suggesting that certification alone does not determine performance after implementation. Other studies have catalogued new safety issues introduced with EHRs²⁷ and have underscored the need to address human-factor issues relating to them.²⁸

The meaningful-use criteria require the collection of specific quality measures: in particular, 15 inpatient and 6 outpatient quality measures that will have to be collected and reported to meet these criteria. The stage 2 criteria for quality measures will raise the bar further, although they are still in a draft stage. Broadly, the hope is that stage 2 will encourage providers to begin improving process, whereas stage 3 will result in improved outcomes. However, vendors and hospitals have already identified major challenges in collecting, calculating, and reporting even the first 15 measures of inpatient quality.²² Overall, it will be a challenge for organizations both to

tick all the boxes they need to cover and to make sure that they put in place the change management, processes, and clinical-decision support that will improve care.

NEED FOR EVALUATION TOOLS AFTER IMPLEMENTATION

The above-mentioned studies are consistent with several reports that commercial EHR products have not had a measurable effect on the very goals to which meaningful use aspires.^{4,7,17} This finding is perhaps not surprising, given the limitations of many current EHR products in showing such effects on quality and safety, their relative immaturity, the length of vendor-improvement cycles, and the challenges in local customization of commercial vendor products. We cannot assume that increased rates of CPOE implementation for certified vendor products will result in improved patient safety — especially medication safety — in the near term. It will be necessary to go further in evaluating these systems after implementation to show their beneficial effect. Many studies have suggested that implementation of these systems is highly variable, which may be the central factor in whether patient safety and quality goals are achieved.²⁹ In other industries, complex information technology systems are extensively tested in an ongoing fashion after implementation to ensure proper performance. Although airplane flight-management systems are continuously retested during routine operation, EHRs in intensive care units are rarely retested, even after they crash or shut down. Indeed, the ability to send fatal medication orders through these systems after major updates that have unknowingly disabled critical safety checks is a particularly serious concern.³⁰

Our health care system needs tools for evaluating these systems when they are operational, not just before implementation. Such tools will be needed to ensure meaningful benefit from EHRs, and they should be used to retest high-risk applications after unexpected EHR shutdowns or even regularly scheduled updates to EHR programs. They also should be used to assist hospitals and clinics in ongoing self-assessment and improvement of their systems. This self-assessment guide for users should include, at a minimum, questions about the top 25 most

common actions that a user should be capable of performing (e.g., look up a patient according to name or medical-record number or review the three most recent laboratory test results), the organization's downtime and reactivation procedures, and any patient safety events or potential hazards that have had a direct effect on EHR users or patients. Such self-assessment tools could be developed and implemented with the use of simulation approaches similar to the way the Leapfrog Group's assessment tool for EHRs and clinical-decision support has been used.²⁴ In addition, each organization should carry out an extensive review of its clinical information systems on a yearly basis. This review could address each of the eight facets of the EHR safe-use model, which include hardware and software, clinical content, user interfaces, user training and authorization procedures, clinical workflow and communication, organizational policies and procedures, compliance with state and federal rules and regulations, and periodic measurements of system activity.²⁴ To help vendors understand how to improve the design of their products, postmarketing surveillance could be used as it currently is with respect to drugs.³¹

CONCLUSIONS

As the broad adoption of EHRs accelerates, the challenge of ensuring that meaningful use actually leads to meaningful benefits, such as improvements in safety and quality of care, remains a serious concern. Another major issue is who will produce the needed innovation for these new tools, since the vendors are far too busy meeting deadlines to innovate, and even the organizations that have historically filled this role are considering switching to vendor applications. Providers that qualify for the meaningful-use incentives will not necessarily achieve meaningful benefits, so that the links with other parts of health care reform, which will directly provide incentive for those benefits, are critical.

Getting the full benefits of EHRs will be especially hard for organizations that do not have the experiences of the pioneers, and this will be a particular challenge in primary care settings and smaller hospitals, which do not yet have cultures focused on health information technology and improvement and are using less-devel-

oped vendor systems. We have three recommendations: First, providers must go beyond making sure they qualify for the incentives and track whether they have the key tools for improving efficiency, quality, and safety. Second, testing after implementation will be essential to ensure the safety and effectiveness of clinical information systems in actual use. This will be permitted in the next phase of certification. Finally, federal research support is critically needed to ensure that continued innovation, improvement, and safe implementation of these complex EHR systems actually happen and do so in a way that promotes safety and quality of care.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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The Benefits Of Health Information Technology: A Review Of The Recent Literature Shows Predominantly Positive Results

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ABSTRACT An unprecedented federal effort is under way to boost the adoption of electronic health records and spur innovation in health care delivery. We reviewed the recent literature on health information technology to determine its effect on outcomes, including quality, efficiency, and provider satisfaction. We found that 92 percent of the recent articles on health information technology reached conclusions that were positive overall. We also found that the benefits of the technology are beginning to emerge in smaller practices and organizations, as well as in large organizations that were early adopters. However, dissatisfaction with electronic health records among some providers remains a problem and a barrier to achieving the potential of health information technology. These realities highlight the need for studies that document the challenging aspects of implementing health information technology more specifically and how these challenges might be addressed.

Health information technology (IT) has the potential to improve the health of individuals and the performance of providers, yielding improved quality, cost savings, and greater engagement by patients in their own health care.¹ Despite evidence of these benefits,² physicians' and hospitals' use of health IT and electronic health records is still low.^{3,4}

To accelerate the use of health IT, in 2009 Congress passed and President Barack Obama signed into law the Health Information Technology for Economic and Clinical Health (HITECH) Act, as part of the American Recovery and Reinvestment Act. HITECH makes an estimated \$14–27 billion in incentive payments available to hospitals and health professionals to adopt certified electronic health records and use them effectively in the course of care.¹ The legislation also established programs within the Office of the National Coordinator for Health Information Technology to guide physicians, hospitals, and

other key entities as they adopt electronic health records and achieve so-called meaningful use, as spelled out in federal regulations.⁵

The legislation and subsequent regulations were designed to spur adoption and yield benefits from health information technology on a much broader scale than has been achieved to date. Building on that effort, the Affordable Care Act of 2010 underscored the importance of health IT in achieving goals related to health care quality and efficiency.

Specifically, establishing the Center for Medicare and Medicaid Innovation emphasized the importance of identifying and testing innovative payment and care delivery models. Many of the payment and care delivery model opportunities in the legislation, and in the initial projects specified by the Innovation Center, require an information technology infrastructure to coordinate care. For example, the medical home demonstrations project in federally qualified health centers that is an initial focus of the Innovation

Center requires electronic record keeping, communication with patients, and e-prescribing.

Earlier reviews of the effects of health IT have found some evidence of the benefits of the technology. The reviews also revealed that benefits accrued more often to large organizations that were early adopters of health information technology. As a result, an important question is whether or not new evidence suggests that benefits might be more widely attainable than previously thought. This review will update policy makers, innovators, health IT users, and those contemplating adoption on the newer literature about the technology's effects on care delivery and on provider and patient satisfaction.

Study Data And Methods

Two previous articles presented results from systematic reviews of the peer-reviewed literature from 1994 to June 2007. Basit Chaudhry and colleagues⁶ covered articles from 1995 to January 2004, and Caroline Goldzweig and colleagues² examined articles from June 2004 to June 2007. We used the methods and selection criteria of these two studies to update their findings on the effects of health IT for the period July 2007 up to February 2010.

Other reviews evaluating effects of health information technology exist; our study turned up thirty-four during this period. But these reviews do not address the same set of health IT functionalities as the articles by Chaudhry and Goldzweig and their colleagues. Similar to those two earlier reviews, we tried to be as comprehensive as possible and included peer-reviewed publications assessing effects of electronic health records; computerized provider order entry; clinical decision-support systems; health information exchange; e-prescribing for outpatients; patients' personal health records; patient registries; telemedicine or remote monitoring; information retrieval; and administrative functions.

Using the same criteria as in the reviews by Chaudhry and Goldzweig and their colleagues, we searched the online journal database MEDLINE for the period July 2007 up to February 2010. The search resulted in a baseline of 4,193 articles. Exact search terms and an "evidence table" depicting study purpose, clinical setting, areas of health IT addressed, outcomes measured, and findings are provided in the online Appendix.⁷

Following Chaudhry and Goldzweig and their colleagues, we decided that to be included in this review, an article had to address a relevant aspect of health IT, as listed in the Appendix;⁷ examine the use of health information technology in clinical practice; and measure qualitative or quanti-

tative outcomes. Analyses that forecast the effects of a health IT component were included only if they were based on effects experienced during actual use. Evaluations of health IT components not used in clinical practice were dropped. For example, a retrospective analysis of strategies to identify hospitalized patients at risk for heart failure was excluded because the methods were not implemented in a hospital.⁸

Using this framework, the review team removed 2,692 articles based on their titles. An additional 1,270 articles were determined to be outside the study's scope after the team examined the article abstracts. For example, 269 abstracts focused solely on health IT adoption. By the third review stage, the review team had 231 articles. An additional forty-three were excluded after further review because they did not meet the criteria, and thirty-four review articles were dropped from the analyses because they did not present new work. This left 154 studies that met our inclusion criteria, 100 of which were conducted in the United States. This is comparable to the 182 studies found over a slightly longer time period that were evaluated by Goldzweig and colleagues.²

CLASSIFYING STUDIES Studies were classified by study design, care setting, health IT components, functions included in the meaningful-use criteria, and outcomes addressed.⁵ In terms of study design, there were sixty-five that tested hypotheses quantitatively; fifty descriptive studies with quantitative results; thirty-two descriptive qualitative studies; three case studies; and four predictive studies. Two different members of the review team classified each article. Differences between first and second abstractions were discussed. Final decisions involving 16 of the 154 articles were made by the study leader, Melinda Beeuwkes Buntin.

Discussions of the health IT systems in the literature usually were not specific enough to determine precisely which meaningful-use criteria were met. As a result, we tracked the components that were included in the criteria to the best of our abilities and coded only those functions that were explicitly mentioned in the articles. Articles were also categorized by overall conclusion as either: positive, mixed-positive, neutral, or negative. In addition, each outcome measure within each article was classified into one of the four categories.

Positive articles and outcomes were ones in which health information technology was associated with improvement in one or more aspects of care, with no aspects worse off. In articles that tested for significant differences, the improvements were statistically significant; in other articles, findings were classified as positive if they

were portrayed as improvements by the authors.

For a neutral rating, health information technology was not associated with any demonstrable change in care or care setting according to the criteria above.

To earn our mixed-positive rating, either the authors had to draw a positive conclusion overall in the abstract or conclusion, or, in the absence of a summary judgment, our best assessment of the evidence presented in the article had to be that the positive effects of health IT outweighed the negative effects. However, the article or outcome, or both, had to include at least one negative aspect. Articles in this category had roughly three positive outcomes for every negative outcome (data not shown).

We created a mixed-negative rating for articles or outcomes with overall negative conclusions but positive aspects. However, we found so few mixed-negative and negative outcomes that we categorized them together as negative. In negative articles, therefore, health information technology was associated with at least one outcome's being worse off.

For articles that evaluated multiple outcomes, we also assigned multiple outcome categories. For example, a study that assessed the effect of a health IT system on both quality (effectiveness) and cost (efficiency) of care was assigned individual effectiveness and efficiency conclusions and an overall conclusion.

Under this system, it is still possible to have a mixed result with respect to the effect of information technology on the individual measure in question. For example, a study that assessed the efficiency effects of a health IT implementation could find that it both decreases transcription costs yet increases the time physicians spend performing administrative functions related to the electronic health record.

We acknowledge the shortcomings of categorizing often nuanced findings. It is also rarely possible to capture every effect of implementing IT in a peer-reviewed publication. We felt, however, that this rating system allowed us to aggregate the studies' findings in a useful way.

Our criteria differed in two respects from the earlier reviews. First, we included descriptive qualitative studies in order to capture focus-group reports, studies using qualitative interviews, and firsthand assessments of health IT implementations, which we considered important evidence when aggregated as in this study. Second, we excluded systematic reviews, because we reasoned that such reviews would cover articles already included in our review or in prior reviews. The opposite choice was made in a recent review of review articles published by Ashley Black and colleagues.⁹

Had we followed the exact methodology prescribed by Goldzweig and colleagues,² thirty-two descriptive qualitative studies would have been dropped, and thirty-four systematic reviews would have been included. However, applying their methodology would not have altered qualitatively any of the overall findings described below.

LIMITATIONS Our findings must be qualified by two important limitations: the question of publication bias, and the fact that we implicitly gave equal weight to all studies regardless of study design or sample size. We elaborate on both below.

► **PUBLICATION BIAS:** First, publication bias is always a concern when conducting a review. This bias exists in two forms: Negative findings are not published as often; and potential negative effects are not always sought or uncovered. A recent study found that for clinical trials, studies with positive results are roughly four times more likely to be published than those without positive findings.¹⁰

Because the articles were limited to health IT adopters, we anticipated that authors more often approached studies looking for benefits rather than adverse effects. Similarly, we relied on the standards of the journals in which the studies were published to weed out situations in which financial relationships existed between the authors and the systems evaluated, but it is possible that ongoing vendor relationships would affect decisions to publish.

It is important to note that although publication bias may lead to an underestimation of the trade-offs associated with health IT, the benefits found in the published articles are real.

► **EQUAL WEIGHT:** Second, as noted above, we implicitly gave equal weight to all studies, regardless of study design or sample size. We did this, however, with the realization that any method of weighting the evidence would be subjective, given the wide variation in settings and outcomes covered by this review. Hence, when discussing the evidence, we took into account—but did not attempt to formally weight—factors that can increase the generalizability of the evidence, such as sample size, inclusion of multiple measures, and use of statistical methods.

Results

Of the 154 included studies, 96 (62 percent) were positive, which means that health information technology was associated with improvement in one or more aspects of care, with no aspects worse off; and 142 (92 percent) were either positive or mixed-positive. As described in more detail above, mixed-positive articles or outcomes

were those in which the authors drew a positive conclusion overall but the article demonstrated at least one negative aspect of health information technology. These 154 studies tracked 278 individual outcome measures. Of these measures, 240 (86 percent) had at least mixed-positive outcomes (Exhibit 1).

POSITIVE FINDINGS In the 92 percent of articles with positive overall conclusions, most either used statistical methods to test hypotheses (sixty-two studies) or were descriptive studies that included quantitative findings (forty-five studies). Indeed, studies using statistical methods to test hypotheses, assessing two or more outcomes of health IT use, or including efficiency or effectiveness were more likely to have positive conclusions than those that did not (Exhibit 2).

For example, studies that used statistical hypothesis testing were more than twice as likely (2.1 times greater) to produce an overall positive conclusion compared to those that did not use statistical hypothesis tests. Studies that assessed provider or staff satisfaction were less likely to reach positive conclusions than those that did not, as were descriptive studies, as indicated by an odds ratio less than 1. In these studies, providers often cite unsatisfactory technology or technology support as barriers to adopting and realizing the benefits of health IT.^{3,4,11,12}

Of the eighteen qualitative articles that did not address provider or staff satisfaction, sixteen had at least mixed-positive conclusions overall. Most negative findings within these articles relate to the work-flow implications of implementing health IT, such as order entry, staff interaction, and provider-to-patient communication.

We also found that articles addressing more health IT functionalities included in the meaningful-use regulation⁵ had slightly higher numbers of positive findings on individual measures (0.2 more positive findings on average, $p < 0.05$) compared to articles that did not address such functionalities. This was not because of the statistical artifact of articles' including more meaningful-use criteria that incorporated more measures (and thus more positive ones), so this is limited evidence that addressing meaningful-use criteria yields positive benefits.

We included fourteen studies assessing both quality and efficiency outcomes, none of which was categorized as negative overall. Eleven of the fourteen used statistical methods to test hypotheses.

Among these fourteen articles, one study found that patient mortality and nurse staffing levels decreased by as much as 48 percent and 25 percent, respectively, in a three-year period after three New York City dialysis centers implemented an electronic health record.¹³ Another

study found that clinical decision support decreased the amount of time dialysis center staff spent with patients for anemia management by nearly 50 percent, but clinical outcomes were maintained.¹⁴

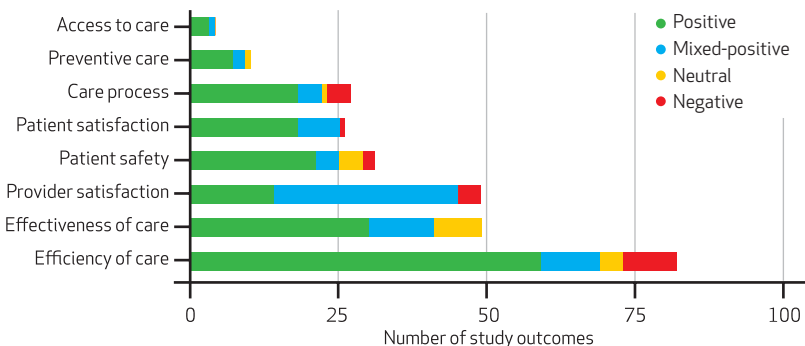
On the inpatient side, a clinical decision-support tool designed to decrease unnecessary red blood cell transfusions reduced both transfusions and costs but did not increase patients' length-of-stay or mortality.¹⁵ A study addressing health IT in forty-one Texas hospitals found that hospitals with more-advanced health IT had fewer complications, lower mortality, and lower costs than hospitals with less-advanced health IT.¹⁶ On the negative side, one of these articles reported that "most wired" hospitals had higher costs than those less wired during the study period, although mortality was lower for heart attack patients in these hospitals.¹⁷

We included sixty-nine studies that assessed electronic health records, forty-four that addressed computerized provider order entry, and forty-four that assessed clinical decision-support systems (categories are not mutually exclusive, which accounts for the fact that the total exceeds the number of articles included in our study). These represent increases in the number of articles with these functionalities over those found by Goldzweig and colleagues.²

There was also suggestive, but not significant ($p < 0.10$), evidence that studies assessing more complete electronic health records, compared to specific health IT tools, were more likely to reach more positive findings (data not shown). Of the included studies, fifty-four evaluated health information technology outside the United States. International studies were no more positive or negative than those from the United States (data not shown).

EXHIBIT 1

Evaluations Of Outcome Measures Of Health Information Technology, By Type And Rating



SOURCE Authors' analysis of published peer-reviewed studies. **NOTE** A total of 278 outcome measures were evaluated across all studies included in our final sample.

EXHIBIT 2

Health Information Technology: Study Design And Scope Factors Associated With Positive Overall Conclusions

	Number of applicable articles	Odds ratios for overall positive effect	p value
STUDY DESIGN			
Statistical methods used to test hypotheses	65	2.13	0.03
Descriptive, qualitative	32	0.38	0.02
MEASUREMENT			
Included two or more outcome measures	67	2.39	0.001
Included efficiency effects as a measure	73	2.34	0.01
Included effectiveness/quality effects as a measure	45	2.75	0.01
Included provider/staff satisfaction as a measure	44	0.16	0.001

SOURCE Authors' analysis of published peer-reviewed studies. **NOTES** Odds ratios compare the odds of a positive overall finding for the category shown against the relevant reference group. The reference groups are as follows. For hypothesis tests: descriptive studies (qualitative or quantitative), case studies, or predictive analyses; for descriptive qualitative studies: hypothesis tests, descriptive studies with quantitative results, case studies, or predictive analyses; for measurement variables: included less than two outcome measures, did not include efficiency effects, did not include effectiveness/quality effects, did not include provider/staff satisfaction.

NEGATIVE FINDINGS We categorized ten studies as containing negative overall findings. These represent potential problems associated with the implementation and use of health information technology. Two of these studies used statistical methods to test hypotheses; four of them were qualitative in nature. In addition, negative articles addressed fewer meaningful-use criteria than did articles with neutral, mixed-positive, or positive overall conclusions (data not shown).

Of the two negative articles testing hypotheses, one evaluated e-prescribing at three ambulatory care sites. After the site was adjusted for, e-prescribing took marginally longer than handwritten prescriptions. However, the article did not evaluate the accuracy of prescription orders from the electronic application versus a paper-based method.¹⁸ The second article evaluated associations between patient factors and using health information exchange to access patient data. The study concluded that providers' use of health information exchanged with other providers was positively correlated with patients' prior utilization, chronic conditions, and age. In other words, providers were more likely to access information via exchanges for higher-risk patients than for those who received less-frequent care. As a result, the authors concluded that expectations of use reductions from health information exchanges may have to be re-examined.¹⁹

Among the descriptive studies with negative conclusions, one evaluated the implementation of health IT in a small rural hospital. According to the authors' assessments, the hospital faced a lack of clinical leadership, staff skepticism, lead-

ership turnover, an unrealistic schedule, and a vendor whose products were not ready on time. The implementation was associated with an increase in patient care errors, including medication errors, procedure errors, and patient falls. Had the IT system been better planned and implemented, the authors believe that these pitfalls could have been avoided.²⁰

Another article found that use of an electronic health record inhibited interaction during ward rounds compared to use of paper charts.²¹ Two negative studies addressed electronic orders. One qualitative study found that work-flow problems emerged at an Australian pathology lab after the lab began receiving orders electronically.²² In a second qualitative study at an Australian emergency department, providers believed that the computerized provider order entry system was not usable, did not meet their expectations, and improperly altered their responsibilities.²³

The remaining negative articles addressed other issues. A US study addressing a clinical decision-support system for depression found, in pilot testing, that variability in computer literacy and information systems led to unsuccessful implementations.²⁴ After adopting electronic health records, some Norwegian physicians found that the overall availability of patient records improved but that the comprehensiveness of information within each record, especially for chronically ill patients, was worse.²⁵

A study in the Netherlands focused on the outcomes of implementing computerized provider order entry in six internal medicine wards of an academic medical center. The article found that

nurse-physician medication collaboration was impaired by the implementation of computerized provider order entry.²⁶ A study in New Jersey after the state implemented electronic reporting for suspected Lyme disease cases found that the number of reports increased, yet the percentage of positive cases after investigation decreased, which suggested that the e-reporting system facilitated overreporting.²⁷

In addition to ten articles with negative overall conclusions, five individual negative findings were included in the group of mixed-positive articles. These additional findings related to patient safety, efficiency of care, patient satisfaction, and provider satisfaction.

The negative outcomes on patient safety and provider satisfaction occurred during implementation of an inpatient computerized provider order entry system at the aforementioned Dutch academic medical center.²⁸ Although computerized provider order entry improved prescription legibility and completeness, it introduced work-flow problems that clinicians were dissatisfied with and thought might compromise safety.

In addition to the negative finding regarding costs in the “most wired” hospitals mentioned above, a negative efficiency finding was discerned in a third study by the same authors at a Dutch academic medical center that implemented a computerized provider order entry system.²⁹ Qualitative interviews found that although the implementation improved the transfer of medication-related information from physicians to nurses or pharmacists, the system did not allow transactions in both directions, and it could not account for different medication-related tasks of different disciplines, such as having a physician review a current medication list or having nurses or pharmacists verify a new prescription and dosage. To overcome these barriers, professionals reverted to traditional methods of communication.

The negative finding on patient satisfaction was observed in a US study. It reported that par-

ticipants in focus groups did not view as an advantage the ability to have secure e-mail communication with providers through the patient portal.³⁰

SINGLE-INSTITUTION STUDIES AND HEALTH IT LEADERS Goldzweig and colleagues also examined studies of leaders in health information technology.² We added the Department of Defense to their health IT leaders list, which included institutions such as Intermountain Healthcare in Salt Lake City, Utah; Partners Healthcare in Boston, Massachusetts; Regenstrief Institute in Indianapolis, Indiana; and Vanderbilt in Nashville, Tennessee. The list also included leaders at care systems including the Veterans Affairs system, the Kaiser Permanente health system, and the National Health Service in the United Kingdom, all of which have been recognized for their pioneering efforts in health information technology.

Twenty-eight articles (18 percent) included in our study came from health IT leaders, compared with thirty-six (20 percent) in the study by Goldzweig and colleagues² and sixty-four (25 percent) in the study by Chaudhry and colleagues.⁶ These studies did not differ systematically from the others in terms of overall conclusions, use of statistical methods, number of outcome measures, or number of meaningful-use criteria explicitly addressed (Exhibit 3).

More than half (98, or 64 percent) of our 154 studies addressed health IT in a single institution or tightly integrated network. Of these, twenty-eight came out of the health IT leaders discussed above: twelve from Partners Healthcare, five from Veterans Affairs, four from Kaiser Permanente, three from the UK National Health Service, two from Intermountain, and one each from Regenstrief and Vanderbilt.

Discussion

A large majority of the recent studies show measurable benefits emerging from the adoption of health information technology. However, with

EXHIBIT 3

Outcomes And Study Methods: Health Information Technology Leaders Compared To All Others

	From health IT leader	All others	p value (two-tail)
Number of studies	28	126	
Reached positive overall conclusion	19 (68%)	83 (61%)	0.25
Used statistical methods to test a hypothesis	13 (46%)	52 (41%)	0.31
Mean number of outcomes	1.64	1.52	0.20
Mean number of meaningful-use criteria	1.89	1.63	0.18

SOURCE Authors' analysis of published peer-reviewed studies.

so few negative articles and findings, there is only suggestive evidence that more advanced systems or specific health IT components facilitate greater benefits.

In fact, the stronger finding may be that the “human element” is critical to health IT implementation. The association between the assessment of provider satisfaction and negative findings is a strong one. This highlights the importance of strong leadership and staff “buy-in” if systems are to successfully manage and see benefit from health information technology.

The negative findings also highlight the need for studies that document the challenging aspects of implementing health IT more specifically and how these challenges might be addressed. Taking a cue from the literature on continuous quality improvement, every negative finding can be a treasure if it yields information on how to improve implementation strategies and design better health information technologies. Specific data on the aspects of electronic health records and other tools that physicians find most difficult to use, the training and support needed before implementation begins, and the unintended consequences of technology adoption could be fed into product development and technical assistance programs for providers.

In terms of assessing how the evidence has changed, perhaps the most important point of contrast with earlier reviews is that the newer studies are no more robust and the findings are no more positive for health IT leaders than for organizations outside that group. In other words, providers other than the large integrated care models that have led health IT adoption seem to be experiencing effects similar to those of early health IT leaders.

When considering new federal efforts designed to bring forth benefits from health IT on a broad scale, this is perhaps the most important finding. Federal funding was traditionally used to spur basic research in science, technology, and medicine. More recently, policy makers and clinicians have recognized the importance of translational research and behavioral factors in the diffusion of medical innovation. Health information technology is an arena in which new federal efforts to align payment

The “human element” is critical to health IT implementation.

with delivery system reforms can reinforce the translation of research into broad practice.

President Obama and Congress envisioned that the HITECH Act would provide benefits in the form of lower costs, better quality of care, and improved patient outcomes. This review of the recent literature on the effects of health information technology is reassuring: It indicates that the expansion of health IT in the health care system is worthwhile. Articles addressing both efficiency and effectiveness—the outcomes most in line with national goals—are more positive, and have more sophisticated study designs, than those that do not—most notably, articles addressing single outcomes or focusing on provider satisfaction. Thus, with HITECH, providers have an unparalleled opportunity to accelerate their adoption of health information technology and realize benefits for their practices, institutions, patients, and the broader system.

In addition, studies of innovative uses of health IT continue to emerge. The challenge for federal policy makers will be to monitor these developments, spur the development of new information tools, and disseminate the most promising findings more widely.

In this way, the broad base of electronic health record use fostered by the HITECH Act will be only the beginning. The Innovation Center created under the Affordable Care Act, together with the actions of private-sector health plans and providers, will be able to build on this foundation to test innovative care delivery and payment strategies. What’s more, through the broad use of health information technology, they will be able to test innovations in care delivery and payment in diverse practice settings, capture data on the effects of those strategies, and feed data back into the cycle of innovation. ■

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Research Meeting, Boston, Massachusetts, June 27–29, 2010; the National Conference on Health Statistics, Washington, D.C., August 16–18, 2010; and the Workshop on Health IT and Economics, University of

Maryland, College Park, October 8–9, 2010. The authors thank Gwen Cody and Matthew Swain, who categorized articles and provided data entry support, and Fred Blavin, who provided helpful comments and feedback.

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Appendix A

The Learning Health System and the Digital Health Utility

FOUNDATIONAL ELEMENTS	LEARNING HEALTH SYSTEM CHARACTERISTICS				
	Data utility: data stewarded and used for the common good	Digital technology: the engine for continuous improvement	Trust fabric: strong, protected, and actively nurtured	Leadership: multi-focal, networked, and dynamic	
	Care: starting with the best practice, every time	Health information: a reliable, secure, and reusable resource	Outcomes and costs: transparent and constantly assessed	Knowledge: ongoing, seamless product of services and research	
	Culture: participatory, team-based, transparent, improving	Design and processes: patient-anchored and tested	Patients and public: fully and actively engaged	Decisions: informed, facilitated, shared, and coordinated	
NEXT GENERATION DIGITAL INFRASTRUCTURE	MEANINGFUL USE REQUIREMENTS*				
	Core structured personal data (age, sex, ethnicity)	Core list of active problems	Core structured clinical data (VS, meds, [labs])	Clinical decision support	Care coordination support/ interoperability
	Outpatient medicines electronically prescribed	Automated medication safeguard/ reconciliation	Visit-specific information to patients	Automated patient reminders	e-Record patient access (copy or patient portal)
	Embedded clinical quality measures	Security safeguards	[Condition-specific data retrieval capacity]	[Public health reporting (reportable conditions)]	[Advance directives for ages >65]
NEXT GENERATION DIGITAL INFRASTRUCTURE	LHS DIGITAL HEALTH UTILITY Next generation requirements		STRATEGY ELEMENTS Activities that advance:		STAKEHOLDER RESPONSIBILITIES**
	TECHNICAL PROGRESS	<ul style="list-style-type: none">• Ultra-large scale system perspective• Distributed, local data maintenance• Virtual interoperability• Reliable use and system security protocols• Standards vehicles for setting/revising:<ul style="list-style-type: none">◦ metadata, vocabulary, data transport◦ common core data sets◦ sentinel indicators◦ access authorization/authentication◦ data quality review protocols	<ul style="list-style-type: none">• Ultra-large-scale system perspective• Functionality focus• System specifications/interoperability• Workflow and usability• Security and privacy safeguards• System innovation		<ul style="list-style-type: none">• ONC works with NIST, other agencies and IT community to advance interoperability and security protocols• NSF works with ONC/NIH on test beds for digital infrastructure component technologies including ULSS approach• Interoperability agreements among delivery systems utilizing EHRs• CMS develops test beds for digital infrastructure application in care coordination/delivery model innovation
	KNOWLEDGE GENERATION/USE	<ul style="list-style-type: none">• Core clinical data elements available for quality improvement and research• Channels and protocols for integrating clinical and public health data• Capacity and protocols for query-driven data use in quality and research and monitoring of sentinel indicators• Novel statistical and database tools for reliable new insights	<ul style="list-style-type: none">• Shared learning environment• Point of decision support and guidance• Research-ready records for data reuse• Patient-generated data• Integration/use of data across sources• Distributed data repositories• Sentinel indicators• Query capacity• Analytic tools and methods innovation		<ul style="list-style-type: none">• NIH, NSF, AHRQ and FDA work on innovative approaches to research insights from clinical data• CDC develops templates/protocols for integrating population and clinical data• Healthcare organizations form research collaboratives
	PATIENT/POPULATION ENGAGEMENT	<ul style="list-style-type: none">• “New norm” for patient involvement• Facilitated personal record interface• Clinician-patient electronic partnership• Patient information access/control• Updated best practices delivered at point of decision• Active patient support for data use in care improvement• Clinician-public health e-partnership	<ul style="list-style-type: none">• Value proposition and patient confidence• Shared learning culture• Patient-clinician outcome partnerships• Person-centric, lay-oriented health information• Closing the disparity gap• Continuous evaluation		<ul style="list-style-type: none">• AHRQ, FDA, NIH and ONC use established links with patient community to foster active embracing of the digital health utility• Patient and clinician groups mediate public engagement and facilitate dialogue among stakeholders to develop shared learning culture/trust
	GOVERNANCE	<ul style="list-style-type: none">• Progressively evolving requirements, specifications, process protocols for exchange, interoperability and research• Cross-national harmonization to foster the global e-Health utility• Broad on-going evaluation capacity		<ul style="list-style-type: none">• The vision• Guiding principles• Participant roles and responsibilities• Process and protocol stewardship• Implementation phasing• Continuous evaluation	
<p>* Optional elements denoted with [] – see Appendix B for details **Sample list, neither definitive nor complete. See page xvii for list of acronyms</p>					

* Optional elements denoted with [] – see Appendix B for details

**Sample list, neither definitive nor complete. See page xvii for list of acronyms

Biographies and Meeting Logistics

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.

Donald M. Berwick, MD, MPP is the Administrator for the Centers for Medicare and Medicaid Services (CMS). As Administrator, Dr. Berwick oversees the Medicare, Medicaid, and Children's Health Insurance Program (CHIP). Together, these programs provide care to nearly one in three Americans. Before assuming leadership of CMS, Dr. Berwick was President and Chief Executive Officer of the Institute for Healthcare Improvement, Clinical Professor of Pediatrics and Health Care Policy at the Harvard Medical School, and Professor of Health Policy and Management at the Harvard School of Public Health. He also is a pediatrician, adjunct staff in the Department of Medicine at Boston's Children's Hospital and a consultant in pediatrics at Massachusetts General Hospital. Dr. Berwick has served as Chair of the National Advisory Council of the Agency for Healthcare Research and Quality, and as an elected member of the Institute of Medicine (IOM). He also served on the IOM's governing Council from 2002 to 2007. In 1997 and 1998, he was appointed by President Clinton to serve on the Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. Dr. Berwick is the recipient of numerous awards and honors for his work, including the 1999 Ernest A. Codman Award, the 2001 Alfred I. DuPont Award for excellence in children's health care from Nemours, the 2002 American Hospital Association's Award of Honor, the 2006 John M. Eisenberg Patient Safety and Quality Award for Individual Achievement from the National Quality Forum and the Joint Commission on Accreditation of Healthcare Organizations, the 2007 William B. Graham Prize for Health Services Research, and the 2007 Heinz Award for Public Policy from the Heinz Family Foundation. A *summa cum laude* graduate of Harvard College, Dr. Berwick holds a Master in Public Policy degree from the John F. Kennedy School of Government. He received his medical degree from Harvard Medical School, where he graduated *cum laude*.

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.

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, MBA 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 of 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. From 1995 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.

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 middle-income 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 Association of American Physicians (Council), and a fellow of the American Association for 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 chairs the Board of the Long Term Quality Alliance. She was recently appointed to the Medicare Payment Advisory Commission. Dr. Naylor received her MSN and PhD from the University of Pennsylvania and her B.S. in Nursing from Villanova University.

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.

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.

Other Participant Biographies

Leah Binder is CEO of The Leapfrog Group, a national organization based in Washington, DC, representing employer purchasers of health care demanding improvements in the safety of the nation's hospitals. In 2009 and 2010, she was named on Modern Healthcare's list of the 100 Most Powerful People in Healthcare. Additionally Ms. Binder was also named on HealthLeaders Media's list of the 20 People Who Make Healthcare Better in 2010. Ms. Binder plays a leading role in healthcare policy. She currently sits on the National Quality Forum's Serious Reportable Events Steering Committee, the National Priorities Partnership Board, the Critical Care Roundtable, and the Advisory Board of the Institute for Interactive Patient Care. Before joining Leapfrog in the spring of 2008, Ms. Binder spent 8 years as vice president at an award-winning rural hospital network in Farmington, Maine, Franklin Community Health Network, and before that she was a senior policy advisor for the Office of Mayor Rudolph Giuliani in New York City. She started her career at the National League for Nursing, where she handled policy and communications for over 6 years. Ms. Binder has a BA from Brandeis, and two masters from the University of Pennsylvania, one from the Annenberg School of Communication and the other from the Fels Institute of Government.

Peggy Conlon is President & Chief Executive Officer of The Advertising Council. She joined The Advertising Council in June 1999. As President, Ms. Conlon serves as Chief Executive Officer of an organization that mobilizes yearly more than \$1.5 billion of advertising time and space, the creative services of over 50 major advertising agencies and related financial support from hundreds of corporations. Since Ms. Conlon joined the Ad Council, the organization has tripled the work done on behalf of premier government and non-profit organizations such as the American Red Cross, Big Brothers Big Sisters, United Way of America, the American Heart Association, the U.S. Department of Homeland Security, and many more. She has worked closely with President Obama on critical issues such as high school dropout prevention, civic engagement and fatherhood involvement, as well as the First Lady's "Let's Move" campaign to end childhood obesity. Ms. Conlon organized the entire U.S. advertising industry to address the critical issues resulting from the events of September 11th and to help Americans respond to the crisis. She also led the organization's production and distribution of the PSAs featuring former Presidents Bush and Clinton in support of the Tsunami Relief Effort, Hurricane Katrina and the Earthquake in Haiti. Ms. Conlon serves on the Board of Trustees of the United Way Worldwide and served for six years on the United Way of America board. Ms. Conlon has been appointed by former President George Bush and First Lady Barbara Bush to lead the national media initiative for C-Change, formerly the National Dialogue on Cancer and served on its Board of Directors for six years. Ms. Conlon is also a member of the World Economic Forum's Media, Entertainment and Information Global Agenda Council. Ms. Conlon comes to The Advertising Council from Cahners Business Information where she served as Vice President, Group Publisher of the Broadcasting & Cable Group. Her experience has also included work at advertising agencies and as an advertising director for corporations. Ms. Conlon earned her B.A. in communications from the California State University at Fullerton and her M.A. from the Annenberg School of Communications at the University of Southern California. She also served as a public affairs officer in the U.S. Naval Reserve for seven years. She was awarded the New York Women in Communications Matrix Award for Advertising in 2002, and she was named "2005 Advertising Woman of the Year" by Advertising Women of New York (AWNY).

Michael Dinneen, MD, PhD currently serves as Director, Office of Strategy Management for the Military Health System, a position he assumed after retiring from the USN in January 2005. Following his medical training he served as a staff psychiatrist and then transferred to the National Naval Medical Center where he was first a residency training director, then Chairman of the Department of Psychiatry and finally Director of Medical Services. In the context of a Congressional threat to outsource all military mental health care in the

National Capital Area he developed and implemented a strategic plan to reduce psychiatric hospital beds from 200 to 60 while actually increasing the military's share of the mental health market. Changes resulted in an integrated training and service delivery program with expanded child and adolescent services. Overall operating expenses were reduced by over 30%. While at Bethesda he served as special psychiatric consultant to the Secret Service, the State Department, the Attending Physician to Congress, the National Organization for Victim Assistance, and the Office of the White House Physician. He developed special expertise in psychological trauma and military psychiatry while leading Navy Special Psychiatric Rapid Intervention Teams for over ten years, directing Mental Health Services aboard the Hospital Ship USNS Comfort during Desert Shield/Desert Storm, and treating service members and their families. He has lectured internationally on traumatic stress, developed curricula in trauma psychiatry, and trained personnel for specialized wartime assignments. His publications on psychological trauma include original research on the effects of exposure to deployment stress during Desert Shield and Desert Storm. In 2002, Dr. Dinneen became Director of Healthcare Planning and Tricare Operations at the Navy Bureau of Medicine. He implemented a standard business planning process for the Navy's 38 Medical Treatment Facilities and was responsible for the orderly transition to the new generation of Tricare Contracts. A diplomat of the American Board of Psychiatry and Neurology, Dr. Dinneen graduated from Harvard University (cum laude) and then received both an MD and PhD Neurochemistry) from the Medical College of Virginia.

Doug Fridsma, MD, PhD is the director of the Office of Interoperability and Standards in the Office of the National Coordinator for Health Information Technology. Prior to arriving at ONC, Dr. Fridsma was on the teaching staff in the Department of Biomedical Informatics at Arizona State University and had a clinical practice at Mayo Clinic Scottsdale. Dr. Fridsma completed his medical training at the University of Michigan in 1990, and his PhD in Biomedical Informatics from Stanford University in 2003. His research interests include the development of computational tools to study patient safety, clinical work processes, and methods to improve model-driven standards development processes. He has served on the Clinical Data Interchange Standards Consortium (CDISC) Board of Directors from 2005-2008, and was appointed to the HIT Standards Committee in 2009. He recently resigned from the Health IT Standards Committee when he joined ONC. He has recently become a board member of HL7.

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

Darrell G. Kirch, MD is president and CEO of the Association of American Medical Colleges (AAMC), which represents the nation's medical schools, teaching hospitals, and academic societies. A distinguished physician, educator, and medical scientist, Dr. Kirch speaks and publishes widely on the need for transformation in the nation's health care system and how academic medicine can lead that change across medical education, biomedical research, and patient care. Prior to becoming AAMC president in 2006, Dr. Kirch served as dean of the college of medicine and CEO of the Milton S. Hershey Medical Center at The Pennsylvania State University and as dean and senior vice president for clinical activities at the Medical College of Georgia. He has co-chaired the Liaison Committee on Medical Education, the accrediting body for U.S. medical schools, and now serves as a member-at-large of the National Board of Medical Examiners and as chair of the Department of Veterans Affairs' Special Medical Advisory Group. Dr. Kirch also is a member of the Institute of Medicine of the National Academies. A psychiatrist and clinical neuroscientist by training, Dr. Kirch began his career at the National Institute of Mental Health, becoming the acting scientific director in 1993 and receiving the Outstanding Service Medal of the United States Public Health Service. A native of Denver, he earned his B.A. and M.D. degrees from the University of Colorado.

Page Kranbuhl is the Director 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.

Joel Kupersmith, MD is the Chief Research and Development Officer of the Veterans Health Administration where he oversees the VA's medical research program. He is a graduate of New York Medical College where he also completed internal medicine training. Subsequently, he completed a cardiology fellowship at Beth Israel /Harvard Medical School. After research training in the Dept of Pharmacology, Columbia College of P. & S, he rose to the rank of Professor and Director of Clinical Pharmacology at the Mt. Sinai School of Medicine. After this he became Chief of Cardiology at the Univ. of Louisville, Chair, Dept of Medicine, Michigan State University and then Dean, School of Medicine and Graduate School, VP for Clinical Affairs & CEO of Faculty Practice at Texas Tech University. Under his leadership as Dean, there were many advances in research, education and clinical care as well as the initiation of a process for a new medical school in El Paso, TX. Dr. Kupersmith was then a Scholar-in-Residence at both the IOM and the AAMC before assuming duties as Chief Research and Development Officer at VHA. At the IOM he completed projects and published papers on a number of health and research policy projects including accountability of Academic Medical Centers and Comparative Effectiveness Research. During his tenure at VA, advances have included the creation of a major Genomics program, establishment of a Central Institutional Review Board, improved communications to increase public and stakeholder awareness of VA research, increased collaboration with Veterans representative groups, academics and other partners, and increases and advances in Comparative Effectiveness Research. Additionally, substantial improvements in the conduct of research and central office process—including the receipt of a Baldrige quality award—and significant increase the number of research projects to improve Veterans' lives have been achieved. Dr. Kupersmith has over 160 publications and 2 books. His earlier research interests were in the area of electrophysiology, heart rhythm abnormalities and implantable cardioverter defibrillators. Most recently he has published on health policy issues and Comparative Effectiveness Research. He is a member of numerous professional organizations including the American Society for Clinical Investigation. Dr. Kupersmith is a winner of an Affirmative Action Award from the University of Louisville and an Alumni Association distinguished achievement award from New York Medical College. Dr. Kupersmith has also been a Visiting Scholar at the Hastings Center for ethics. He is also a member of the National Advisory Research Resources Council of NIH and was on the Federal Coordinating Council on Comparative effectiveness Research.

Eric Racine, PharmD, MBA is Vice President Advocacy for Sanofi. His department is responsible for interacting with the advocacy community representing patients, providers, and payers. Eric and his team are devoted to finding collaborative solutions to improve patient health. Prior to this current position, Eric held different leadership positions within sanofi in Commercial Operations and Corporate Affairs. Prior to joining the pharmaceutical industry, Eric held various positions in clinical pharmacy including academic, clinical, and management roles. Eric's past presentations, publications and research focused on quality improvement and patient access. Eric holds a Doctor in Pharmacy degree and an Executive MBA degree.

Lisa Rovin, JD is the Senior Advisor for Strategic Initiatives in the Office of the Chief of Staff at the Food and Drug Administration. Ms. Rovin's responsibilities include coordinating a variety of cross-agency initiatives, helping initiate FDA's Critical Path Initiative, and coordinating FDA involvement with the Reagan-Udall Foundation. She currently serves as FDA's liaison to the HHS health reform implementation effort, and handles an array of additional strategic priorities for the Chief of Staff and Commissioner. Prior to joining FDA in 2003, Ms. Rovin served as the Director of the Division of Health Care Delivery Systems in the Office of the Assistant Secretary for Planning and Evaluation. In that capacity, she was responsible for overseeing policy development on issues ranging from private health insurance markets to medical information privacy. Ms. Rovin received her BA in Human Biology from Stanford University, and her JD from Boalt Hall School of Law at University of California, Berkeley.

John Santa, MD, MPH is the Director of the Consumer Reports Health Ratings Center. He has been interested in explicit approaches evaluating health services, products and practitioners throughout his career and been involved in many successful efforts to do so. The Health Ratings Center focuses on comparisons of drugs, devices, treatments, hospitals, physicians and other health topics by identifying and analyzing current, robust, independent sources of information. Prior to coming to Consumer Reports, Dr. Santa worked in multiple sectors in the health care industry, most recently as an associate professor in public administration at Portland State University and in Family Medicine at Oregon Health & Science University. His research interests focused on comparative effectiveness, the integration of medical care and public health, preventive medicine and benefit design. Dr. Santa was the administrator of the Office of Oregon Health Policy and Research from 2000 to 2003 during the administration of Governor John Kitzhaber MD. During that time Oregon implemented an evidence-based approach to prescription drug purchasing that eventually came to be known as the Drug Effectiveness Review Project. Dr. Santa provided administrative and medical direction to the Project. Dr. Santa served on the board of the Public Employees Benefit Board, Oregon's largest private health benefits purchaser, while in state government, serving as the chair of the Benefit Design Committee and chair of the Board. He has served on multiple boards including the Oregon Medical Insurance Pool, Oregon's high risk insurance pool, and the Cascade AIDS Project, Oregon's largest non-profit AIDS services provider. Dr. Santa has taught in multiple environments including medical school, internal medicine residencies and preventive medicine residencies. His recent teaching responsibilities focused on Masters of Public Health students. Dr. Santa received his bachelor's degree from Stanford University in 1972, his MD from Tufts University in 1976 and MPH from Portland State University in 2005. He has practiced primary care internal medicine in solo, group and institutional settings, most recently at the VA.

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 peer-

reviewed 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.

Nancy J. Wilson, MD, MPH is Senior Advisor to the Director of the Agency for Healthcare Research and Quality (AHRQ) and leads the Agency's work to support and coordinate the ongoing development and implementation of the National Quality Strategy called for by the Affordable Care Act. This includes implementing the Strategy across Health and Human Services Agencies and facilitating implementation among public and private sector stakeholders. Dr. Wilson also leads the Agency's efforts to establish a federal-wide Working Group on Health Care Quality. Dr. Wilson also provides strategic leadership and technical assistance on improvement implementation and data sharing among the AHRQ sponsored Medicaid Medical Director's Learning Network. In 2010, the Network successfully completed its first data sharing project on the use of antipsychotic medications for children and adolescents. The subsequent report and resource guide prompted adoption of promising program and policy interventions across states throughout the Network. Dr. Wilson also leads an AHRQ/CMS collaboration to identify, by January 2012, a core set of quality measures to monitor the health and health care of adults eligible for Medicaid. Dr. Wilson represents AHRQ on a number of national public/private alliances such as the National Quality Forum (NQF) Board of Directors, the Hospital Quality Alliance, the National Priorities Partnership, and Measures Application Partnership Coordinating Council. Dr. Wilson previously served as the Agency's lead on the Department's Value Driven Health Care Initiative. Her work to establish multi-stakeholder regional healthcare improvement collaboratives resulted in Dr. Wilson and her teammates receiving the HHS Hubert H. Humphrey Service to America Award in 2009. Prior to joining the Department of Health and Human Services, Dr. Wilson was Vice President and Medical Director for VHA, Inc., a nationwide network of 2,200 leading community-owned health care organizations and their affiliated physicians. Dr. Wilson designed and led nationwide improvement collaboratives that translated evidence-based practices into improved patient outcomes. For her work raising awareness and orchestrating company-wide efforts in patient safety, Dr. Wilson was awarded VHA's first President's Council Leadership Award. Before joining VHA, Dr. Wilson was Director of the Office of Performance and Quality for the Veterans Health Administration. Among her accomplishments Dr. Wilson designed and implemented a new comprehensive performance management system that 1) aligned VA's vision, mission, and goals with quantifiable strategic objectives; 2) defined measures to track progress in meeting those goals and objectives; and 3) held management accountable for results achieved. During her tenure, performance on process and outcome measures dramatically improved including patient experience of care. For her work she received one of former Vice-President Gore's Hammer Awards for Reinventing Government. Dr. Wilson is a 1976 BSN honors graduate of the University of Pittsburgh. She received her MD from Johns Hopkins School of Medicine in 1986 where she also completed her medical internship and residency in 1989. In 1994 she completed a General Medicine/Health Services Research Fellowship at Harvard Medical School while obtaining her MPH in Health Care Management at the Harvard School of Public Health. Dr. Wilson is an advisor to the National Association for Healthcare Quality, and a founding designer and ongoing judge for the AHA Quest for Quality Award. She is a member of several professional societies including the Society of General Internal Medicine, the American College of Physicians, American College of Physician Executives, and the American Public Health Association.

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 12

The Roundtable on Value & Science-Driven Health Care is looking forward to your participation on September 22, 2011. 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 **September 22, 2011** 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.

HOTEL ACCOMODATIONS

While we do not have a block of rooms available for this meeting, we are happy to reimburse our guests up to **\$211** for the hotel of their choice. Please email jcsanders@nas.edu with any questions regarding lodging.

TRAVEL: AIR OR TRAIN RESERVATIONS

For those requiring reimbursement, we ask that you book your own air or train reservations through Executive Travel Associates (ETA) at 1-800-660-0031. Please refer to Event Code **IOM110312**. The cost of your flight will be billed directly to our office. Please note that if you choose to use your own travel agency, the Academies reimburse for coach airfare only (U.S. federal regulations prohibit the Academies from reimbursing upgrades to business class for any air travel not exceeding 14 hours). Moreover, if you book travel with an outside agent and anticipate that your travel plans will require a deviation from a direct itinerary—departure from and return to your home base—please contact your travel coordinator for approval in advance of booking your trip; IOM has strict guidelines that may affect the amount of your reimbursement.

We request that you forward your travel itinerary to jcsanders@nas.edu once completed. If you need assistance in making reservations, please contact our staff.

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