Patients Charting the Course: Citizen Engagement in the Learning Health System

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THE LEARNING HEALTH SYSTEM SERIES

ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

PATIENTS CHARTING THE COURSE

Citizen Engagement and the Learning Health System

Workshop Summary

LeighAnne Olsen, Robert S. Saunders, and J. Michael McGinnis,
Editors and Rapporteurs

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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

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

Adam M. Clark, FasterCures
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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **Joseph E. Scherger,** University of California, San Diego. Appointed by the National Research Council and the Institute of Medicine, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the editors and the institution.

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

The Institute of Medicine's Roundtable on Value & Science-Driven Health Care has been convened to help transform the way evidence on clinical effectiveness is generated and used to improve health and health care. Participants have set a goal that, by the year 2020, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence. Roundtable members will work with their colleagues to identify the issues not being adequately addressed, the nature of the barriers and possible solutions, and the priorities for action, and will marshal the resources of the sectors represented on the Roundtable to work for sustained public–private cooperation for change.

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The Institute of Medicine's Roundtable on Value & Science-Driven Health Care has been convened to help transform the way evidence on clinical effectiveness is generated and used to improve health and health care. We seek the development of a ***learning health system*** that is designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care.

Vision: Our vision is for a healthcare system that draws on the best evidence to provide the care most appropriate to each patient, emphasizes prevention and health promotion, delivers the most value, adds to learning throughout the delivery of care, and leads to improvements in the nation's health.

Goal: By the year 2020, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence. We feel that this presents a tangible focus for progress toward our vision, that Americans ought to expect at least this level of performance, that it should be feasible with existing resources and emerging tools, and that measures can be developed to track and stimulate progress.

Context: As unprecedented developments in the diagnosis, treatment, and long-term management of disease bring Americans closer than ever to the promise of personalized health care, we are faced with similarly unprecedented challenges to identify and deliver the care most appropriate for individual needs and conditions. Care that is important is often not delivered. Care that is delivered is often not important. In part, this is due to our failure to apply the evidence we have about the medical care that is most effective—a failure related to shortfalls in provider knowledge and accountability, inadequate care coordination and support, lack of insurance, poorly aligned payment incen-

tives, and misplaced patient expectations. Increasingly, it is also a result of our limited capacity for timely generation of evidence on the relative effectiveness, efficiency, and safety of available and emerging interventions. Improving the value of the return on our healthcare investment is a vital imperative that will require much greater capacity to evaluate high-priority clinical interventions, stronger links between clinical research and practice, and reorientation of the incentives to apply new insights. We must quicken our efforts to position evidence development and application as natural outgrowths of clinical care—to foster health care that learns.

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

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

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

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

Foreword

Over the past decade, much attention has focused on rising costs and inadequate access in the U.S. healthcare system. However, another vital shortcoming of the current system has been its inability to truly maximize the health of individuals. As stated in the Charter of the Roundtable on Value & Science-Driven Health Care, too much care that is important is often not delivered, and too much care that is delivered is often not important.

In 2006, the Institute of Medicine chartered the Roundtable (originally, the Roundtable on Evidence-Based Medicine) to engage key stakeholders in a discussion of ways to transform healthcare delivery in this country to ensure that all Americans are receiving the best care. The Roundtable brings together patients and consumers, providers, researchers, health product manufacturers, payers, employees, and policy makers to discuss health reform priorities in a neutral venue and identify key impediments to progress toward a patient-centered learning health system. This vision of the learning health system, developed by the Roundtable, describes a health infrastructure characterized by evidence-based care that ensures proper decision making for each patient and provider, and consequently generates scientific evidence as a natural course of care. To accelerate progress toward this vision, the Roundtable convened leaders, researchers, and policy makers from the healthcare sector for a public workshop, *Patients Charting the Course: Citizen Engagement and the Learning Health System*.

This compilation summarizes the presentations and discussions from the workshop, which provide an overview of the nature and promise of the learning healthcare system for achieving a culture of patient-centeredness,

science, and value. The contributions and insights in this volume are imperative in formulating strategies to reform the U.S. healthcare system and improve patient-care outcomes.

I would like to offer my personal thanks to the members of the Roundtable who advocate for better health for Americans, to the Roundtable staff for their contributions to this publication and for organizing the activities, and to the sponsors who made this discussion possible: the Agency for Healthcare Research and Quality, AstraZeneca, Blue Shield of California Foundation, California Health Care Foundation, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Charina Endowment Fund, Department of Veterans Affairs, Food and Drug Administration, Johnson & Johnson, Kaiser Permanente, National Institutes of Health, Office of the National Coordinator for Health IT, The Peter G. Peterson Foundation, sanofi-aventis, Stryker, and the UnitedHealth Foundation.

Harvey V. Fineberg, M.D., Ph.D.
President, Institute of Medicine

Preface

Patients Charting the Course: Citizen Engagement and the Learning Health System summarizes the 2-day workshop convened in April 2010 to identify and reflect upon current strategies and programs advancing public understanding of a transformative, patient-centered learning health system. Stakeholders and leaders within the health sector identified patients and providers as the groups who must be fully engaged to reform the current health system infrastructure, and discussed ways to involve these key constituents. The meeting provided a forum for participants to further discuss issues in communication strategies around science-driven care, patient engagement, and health information technology. This volume of presentations and discussions provides insights and reflections from government leaders, patient advocacy groups, health providers, manufacturers, and other key stakeholders about the issues that must be addressed to reform the way evidence is generated and used to improve health and health care. Participants discussed issues such as the structural details of a system of real-time and continuous learning that anticipates research needs and produces evidence that is timely and applicable; the importance of clinical data, health management, and health information technology as drivers during the information age; patient engagement to improve science and value; and the formation of a patient-centered culture focused on applying evidence and embracing team-based healthcare approaches.

The vision of the IOM Roundtable on Value & Science-Driven Health Care is for a learning health system in which evidence is both applied to ensure best care practices and generated in a timely manner. Since its inception in 2006, the Roundtable has set out to help realize this vision through

the involvement and support of senior leadership from key healthcare stakeholders. In engaging the nation's leaders in workshops and other activities, Roundtable members and colleagues provide guidance on topics important to a patient-centered, integrated system. The objective of this workshop was to assess the current situation and the progress that has been made toward a learning health system, with a specific focus on effective strategies to improve public and patient understanding of the system's transformative nature and methods to involve both in the change. The workshop provided a venue for leaders to share their perspectives on methods to enhance stakeholder engagement in building a new health infrastructure, as well as how to develop effective communication strategies around evidence-based care, patient self-management, and health information technology. In the discussions, fundamental ideas emerged on the roles and strategies for patients, providers, and systems as elements in the learning health system.

Participants articulated the numerous opportunities that have been made possible by the passage of the Patient Protection and Affordable Care Act of 2010 and the subsequent challenge of realizing the potential of this new, transformative platform. Despite this challenge, presenters focused on the use of health information technology to drive evidence-based care and the importance of improving the effectiveness of communication between patients and providers. Workshop discussions also highlighted continuous evaluation and collaboration across healthcare sectors as necessary elements that must be in place for the learning health system to be actualized. The Roundtable will follow this workshop with deeper consideration of a number of the highlighted issues through future workshops, commissioned papers, collaborative activities, and public communication efforts. Although the challenges are formidable—as they always are with culture change—Roundtable members, colleagues, and stakeholders are committed and well-equipped to accelerate the progress of a learning health system.

Multiple individuals and organizations donated their valuable time toward the development of this publication. We would like to acknowledge and offer strong appreciation for the contributors to this volume, for the care and thought that went into their analyses and presentations, for the ideas and observations they shared at the workshops, and for their contributions to this summary publication. In this respect, we should underscore that this volume contains a collection of individually authored papers and intends to convey only the views and beliefs of those participating in the workshops, not the express opinions of the Roundtable on Value & Science-Driven Health Care, its members, its sponsors, or the Institute of Medicine.

We are especially indebted to the members of the Planning Committee, which crafted this unusually productive and path-breaking discussion series. The members of this stellar group were: Jay Bernhardt (Centers for Disease Control and Prevention), Michael Fordis (John Baylor College),

Michael Lauer (National Heart, Lung, and Blood Institute), Joel Kupersmith (Veterans Health Administration), Murray Ross (Kaiser Foundation Health Plan), Karen Smith (formerly of AstraZeneca, now with Allergan), and Myrl Weinberg (National Health Council).

A number of Roundtable staff played instrumental roles in coordinating the workshops and translating the workshop proceedings into this summary, including Neha Agarwal, Christie Bell, Malcolm Biles, Claudia Grossmann, LeighAnne Olsen, Brian Powers, Robert Saunders, Kate Vasconi, and Catherine Zweig. We would also like to thank Greta Gorman, Christine Stencel, Vilija Teel, and Jordan Wyndelts for helping to coordinate the various aspects of review, production, and publication.

We have the potential for a transformative learning health system that could revolutionize the way care is delivered and understood. While great strides have already been made with new policy, sturdy dedication and engagement will continue to be instrumental as healthcare delivery in the United States is restructured. We look forward to building upon the ideas that have emerged in this workshop and realizing a *learning health system*.

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Abbreviations and Acronyms

ACA	Patient Protection and Affordable Care Act (2010)
ACGME	Accreditation Council for Graduate Medical Education
AF4Q	Aligning Forces for Quality
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
AMIA	American Medical Informatics Association
ARRA	American Reinvestment and Recovery Act (2009)
CCCP	Connected Cardiac Care Program
CER	comparative effectiveness research
CMS	Centers for Medicare & Medicaid Services
CNVs	copy number variants
CRM	crew resource management
CRS	Care Records Service (UK)
DHMC	Dartmouth Hitchcock Medical Center
EGAPP	Evaluation of Genomic Applications in Practice and Prevention
EHR	electronic health record
eMERGE	electronic MEdical Records and GEnomics
EMR	electronic medical record
FCC	Federal Coordinating Council
FDA	Food and Drug Administration

GDP	gross domestic product
GEDDI	Genetics for Early Disease Detection and Intervention to Improve Health Outcomes
GHP	Geisinger Health Plan
GHS	Geisinger Health System
GWAS	genome-wide association study
HCC	Hierarchical Condition Categories
HEDIS	Healthcare Effectiveness Data and Information Set
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIT	health information technology
HITECH	Health Information Technology for Economic and Clinical Health Act (2009)
HPV	human papillomavirus
IHI	Institute for Healthcare Improvement
INR	International Normalized Ratio
IOM	Institute of Medicine
IPADS	International Patient Decision Aids Standards
IRB	institutional review board
IT	information technology
JAMA	*Journal of the American Medical Association*
MA	Medicare Advantage
NBCC	National Breast Cancer Coalition
NCI	National Cancer Institute
NHS (UK)	National Health Service
NIH	National Institutes of Health
NWHIN	Nationwide Health Information Network
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
PAMF	Palo Alto Medical Foundation
PCMH	patient-centered medical home
PCORI	Patient-Centered Outcomes Research Institute
PheWAS	phenome-wide scanning
PHR	personal health record

PSA	prostate-specific antigen
PXE	pseudoxanthoma elasticum
RCT	randomized controlled trial
REP	Rochester Epidemiology Project
RPIWs	Rapid process improvement workshops
RWJF	Robert Wood Johnson Foundation
SCP	shared care plan
SHARP	Strategic Health IT Advanced Research Projects
SNP	single nucleotide polymorphism
SORT	Strength of Recommendation Taxonomy
SR	systematic review
SSRI	selective serotonin reuptake inhibitor
STEPPS	Strategies and Tools to Enhance Performance and Patient Safety
USPSTF	U.S. Preventive Services Task Force
VAP	ventilator-associated pneumonia
VMMC	Virginia Mason Medical Center

Synopsis and Overview

INTRODUCTION AND OVERVIEW

The prosperity of a nation is tied fundamentally to the health and well-being of its citizens. It follows, then, that citizens—each one a past, current, or future patient—should represent both the healthcare system's unwavering focus, and its fully engaged agents for change. This precept has several major implications. It means that the quality of health care should not be judged solely by whether clinical decisions are informed by the best available scientific evidence, but also by whether care accounts for a patient's personal circumstances and preferences. It implies that careful listening should be the starting point for every patient encounter. And it suggests that the success of and innovations in healthcare delivery should depend on direct consumer engagement in the design of healthcare models and their aims.

One of the central lessons of the Institute of Medicine (IOM) report *Crossing the Quality Chasm: A New Health System for the 21st Century* is that much of health care in the United States has lost its focus on the patient (IOM, 2001). Instead, the healthcare system has been designed and motivated primarily by the perspectives of its component facilities, companies, payers, and providers. *Crossing the Quality Chasm* urges that care be refocused around six aims: care should be *safe, effective, patient-centered, timely, efficient, and equitable*. In the decade since the report was published, it has become even clearer that citizen and patient engagement is central to taking advantage of advances in the personalization of care based on genetics, preferences, and circumstances. Building off the *Chasm*

report, a learning health system requires that patients help chart the course and operation of the learning process.

In this context, the IOM, under the auspices of the Roundtable on Value & Science-Driven Health Care, focused the tenth workshop in its *Learning Health System* series on public and patient engagement and leadership. This volume, *Patients Charting the Course: Citizen Engagement and the Learning Health System,* presents a summary of the issues and perspectives addressed at that meeting.

As discussed by many participants in the meeting, most health systems today are not centered on patients. Instead, volume drives service; supply influences demand; and clinician—not patient—preferences shape practice (Wennberg et al., 2007). The notion of patient-centeredness often still feels unfamiliar, even disruptive, for many of those unexposed to the advantages of such a culture (Berwick, 2009).

Patients have shown an interest in becoming more involved and learning more about their conditions. A Pew Research Center Survey found that 61 percent of adults go online to seek information on specific diseases, medical treatments, and other health subjects. Although the increased availability of health information is important, new communication approaches are needed to provide information that is reliable, relevant, and understandable so patients can make informed healthcare decisions.

Data and information are a first step toward improving communications between providers and patients. Providers will increasingly need to discuss with patients the risks and benefits of competing treatment options and engage patients in shared decision making about their treatment choices. This represents a shift away from the historical model of medicine toward one in which physicians and patients work together to manage complex conditions, and make decisions on the basis not only of the best medical knowledge, but also the patient's life circumstances, preferences, and personal biology.

Recent legislative efforts and national interest around these issues have provided an important impetus for progress and prompted a reassessment of priorities and the articulation of practical next steps for developing a learning health system. The American Recovery and Reinvestment Act of 2009 (ARRA) included more than $1.1 billion to enhance the nation's capacity for comparative effectiveness research and nearly $20 billion for the adoption and use of health information technology through the Health Information Technology for Economic and Clinical Health (HITECH) Act. Through incentives for the meaningful use of electronic medical records, the HITECH Act will encourage the adoption of electronic medical records by clinician practices and hospitals, which will enable improved access to clinical information, coordination of care across multiple healthcare settings, and a comprehensive record of a patient's medical history. This will provide

the foundation for many aspects of the learning health system, including expanded clinical data for research, patient access to their own health information, and new models of care outside the traditional clinical encounter.

Signed into law one week before the workshop, the Patient Protection and Affordable Care Act of 2010 (ACA) underscored the importance of patient choice and engagement, including provisions to promote choice, accountability, consideration of patient preferences, and shared healthcare decision making. As this law is implemented, new opportunities will become available for establishing innovative models to deliver care, creating incentives to coordinate and improve care quality and value, and expanding the clinical workforce.

THE ROUNDTABLE AND THE *LEARNING HEALTH SYSTEM* SERIES

The IOM Roundtable on Value & Science-Driven Health Care has since 2006,- provided a venue for health leaders from various stakeholder sectors—health professionals, patients, health system leaders, insurers, employers, manufacturers, information technology, research—to work cooperatively to address their common interest in improving the effectiveness and efficiency of health care. The Roundtable members have set the goal that, by 2020, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date information and will reflect the best available evidence. Over the past five years, the Roundtable's *Learning Health System* series of workshops has identified and considered the key elements whose transformation can be central to achieving this goal: clinical research, clinical data, information technology, evidence standards, healthcare tools, caregiver culture, patient engagement, and financial incentives. For each of these elements, the workshops have explored priorities and approaches integral to harnessing interests and expertise across healthcare sectors to drive improvements in the value of medical care delivered in the United States. The following publications summarizing these workshops offer perspectives on the issues involved, and identify priorities and projects in need of cooperative stakeholder engagement:

- *The Learning Healthcare System (2007)*
- *Evidence-Based Medicine and the Changing Nature of Health Care (2008)*
- *Leadership Commitments to Improve Value in Health Care: Finding Common Ground (2009)*
- *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation (2010)*

- *Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Evidence-Based Approaches (2010)*
- *Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good (2011)*
- *The Healthcare Imperative: Lowering Costs and Improving Outcomes (2011)*
- *Engineering a Learning Healthcare System: A Look at the Future (2011)*
- *Learning What Works: Infrastructure Required for Comparative Effectiveness Research (2011)*
- *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care (2011)*

In addition to the meeting series focused on exploring concepts and strategies for the learning health system, the Roundtable operates a series of Innovation Collaboratives, aimed at stewarding joint projects among organizations key to field advancement.

Across the range of issues engaged in the *Learning Health System* workshops and the Innovation Collaboratives, greater public interest and patient engagement have emerged as essential and potentially transformative elements for driving health system change. Empowering and supporting the public in these new roles requires the creation of a healthcare culture that supports continuous improvement and learning; elicits and considers public perspectives on key healthcare issues; and better characterizes needed partnerships, resources, tools, and communication approaches. Listed in the front of this publication are members of the IOM planning committee[1] charged with guiding the development of a workshop to consider these issues in detail. The committee worked with IOM staff to develop the workshop objectives and emphases and to plan the agenda. Box S-1 summarizes the motivating issues and objectives for the workshop.

The planning committee designed day 1 of the workshop to focus on key elements of progress in science-driven health care—care culture, clinical research and the evidence process, clinical data, health information technology systems—with specific attention to the role of patient engagement in the success of each. Day 2 was devoted to understanding opportunities to develop the communications, culture, and incentives that will help in reorienting the focus and performance of a value- and science-driven health system. The workshop agenda is provided in Appendix A, speaker

[1] Institute of Medicine planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published workshop summary rests with the workshop rapporteurs and the institution.

BOX S-1
Motivating Issues and Objectives

Motivating Issues

- *Implications of knowledge advances*. Progress in medical science, basic research, information technology, and operations research offers the potential for immediate, continuous, and transformative improvement in health care. In the context of increasing understanding of the importance of individual factors to patient outcomes, reaching health care's full potential requires a reorientation to the patient.
- *Performance shortfalls*. In terms of both effectiveness and efficiency, the nation's healthcare system is underperforming. The United States has the highest per capita health expenditures—twice the average for other developed countries—yet consistently rates no better than the middle tier of developed nations on such key indicators as infant mortality, life expectancy, and overall health system performance.
- *Disconnects in core aims.* The core aim of health care is improved outcomes: to maintain or enhance patient status with respect to disease, injury, functional status, and sense of well-being. Yet often the system's dominant characteristics are oriented more to clinician preferences or interests and economic rewards for volume over value.
- *Anchor misalignment.* The primary focus of care should be on outcomes rather than service volume and on the interdependent aims of patient-centeredness, better science, better value, and continuous improvement.
- *Imperative to make patients a central element.* Efforts of the IOM and others have underscored the necessity of making patient perspectives, preferences, and needs a strong, central focus of a learning health system, for several reasons, including: the basic fact that patients are the health system's key focus and its agents for change, the fact that care has been shown to be more effective and efficient with more patient involvement, and the growth of preference-sensitive care as new interventions are developed.
- *Importance of communication.* Central to progress are the communication strategies necessary to inform and engage the public and patient communities as understanding advocates, partners, and change agents.

Objectives

- Identify the state of play with respect to the foundational elements of a learning health system, the role of patients and the public in achieving progress on each element, and the most important priorities and policy levers for accelerating progress.
- Explore and clarify the integral links among three key desired characteristics of care: science-driven, patient-centered, and value-enhancing.
- Discuss communication and public engagement strategies important to improving the awareness and patient-focused action necessary for the transition to a learning health system.

biographical sketches in Appendix B, a listing of workshop participants in Appendix C, and an overview of common themes from each workshop in the *Learning Health System* series in Appendix D. This publication summarizes the workshop presentations and discussions and the issues addressed. Summaries of common themes and of the workshop presentations and discussions are provided below; further detail is provided in the main text.

COMMON THEMES

Representatives from the multiple healthcare sectors represented on the Roundtable participated in the workshop discussions. Although the perspectives brought to bear were diverse, the presentations and discussions shared a focus on the issues and challenges involved in moving to care centered on patients and their families, as envisioned by the *Quality Chasm* report. As noted by one workshop participant, such a focus means that "it is not about my condition—it's about me." During the workshop, a number of common themes emerged as participants discussed the importance of a patient-focused culture in addition to the content, structure, and functioning of a patient-centered, learning health system. These themes are listed in Box S-2 and discussed in detail below.

Listening. *Each patient-clinician interaction starts with uninterrupted attention to the patient's voice on issues, perspectives, goals, and preferences.* These patient views should then be used to guide clinical decisions, which often involve choices among multiple treatments that have both benefits and risks. Workshop participants reported that care often improved when staff and providers listened carefully to the concerns of patients and their families. Yet, it has been noted that physicians tend to interrupt patients within about 15 seconds of beginning to speak at the outset of the visit. On the other hand, an uninterrupted patient tends to conclude their remarks in under a minute (Beckman and Frankel, 1984). Listening fully to the patient, then, does not cause any significant delays in the physician's schedule, and adds substantially to creating an environment where patients feel comfortable sharing their health information. Achieving this goal will require a new focus on patient communication starting early in provider education to ensure that providers have the tools they need to share complex health information with patients and help them with these decisions.

Participatory. *Health outcomes improve when patients are engaged in their own care.* In addition to improving health outcomes and patient adherence, participants noted that engagement can increase employee satisfaction and financial performance. People are eager to play a strong role in their own health care when given the right tools, as evidenced by the rapid uptake of

BOX S-2
Patient-Anchored Care: Common Themes

- **Listening.** Each patient-clinician interaction starts with uninterrupted attention to the patient's voice on issues, perspectives, goals, and preferences.
- **Participatory.** Health outcomes improve when patients are engaged in their own care.
- **Reliable.** All patients should expect proven best practice as the starting point in their care.
- **Personalized**. With proven best practice as the starting point, science-based tailoring is informed by personal biological traits, circumstances, and preferences.
- **Seamless.** Care delivered by multiple providers in multiple settings should be fully integrated and seamless.
- **Efficient.** Patients, their families, and clinicians should expect care to be appropriate to the need, available resources, and time required.
- **Accountable.** All relevant aspects of the clinical experience, including patient perspectives, should be captured and routinely assessed against expectations.
- **Transparent.** Information on the outcomes of care—both effectiveness and efficiency—should be readily accessible and understandable to patients and their families.
- **Trustworthy.** Patients should expect a strong and secure foundation of trust on all dimensions—safety, quality, security, efficiency, accountability, and equity.
- **Learning.** In a learning health system, the patient is an active contributor to and supporter of the learning process.

Web 2.0 health information applications. Yet as one speaker mentioned, surveys indicate that only half of patients receive clear information on the benefits and trade-offs of the treatments under consideration for their condition. Patients' involvement may be increased by providing them with additional information tools for learning about their health, helping them see the impact of their efforts, and acquainting them with new technologies with which to monitor their health and assist with lifestyle changes. Public participation is not limited to the clinic; the workshop highlighted new initiatives to provide access to health data and allow individuals to create new applications to improve their health.

Reliable. *Each patient should expect proven best practice as the starting point in their care.* The current variability in medical practice impacts patient care and results in uneven quality and safety for patients. Participants described tools that minimize this variation, such as dashboard displays that highlight the interventions that are due, done, or overdue and improve the consistency of the delivery of interventions to patients; other tech-

nologies that show promise include clinical decision support systems that present best practices to clinicians. Several participants also noted that, although technologies provide new opportunities, incentives, such as bundled payments and pay for performance, are needed to promote reliability and effectiveness in healthcare organizations and ensure accountability.

Personalized. *With proven best practices as the starting point, science-based tailoring is shaped by personal biological traits, genetics, circumstances, and preferences.* Since the sequencing of the human genome was accomplished, medical science has sought to personalize treatments to specific biological traits and genetics, in addition to personalizing care based on individual patient circumstances and preferences. This effort challenges the traditional approach of giving the highest priority to evidence gathered by means of large randomized controlled clinical trials, in which treatments are measured in a large population with a diverse genetic profile. Using multiple types of complementary evidence could better guide medical decisions and account for these personal factors. This new approach focuses on the applicability of results to the clinic, rather than automatically giving priority to the results of randomized controlled trials.

Seamless. *Care delivered by multiple providers in multiple settings should be nonetheless expected to be fully integrated and seamless.* As patients move among providers and settings, they often encounter communication problems, which may result in treatment errors and duplicative services. Participants described how team-based care offers the potential to rectify this disconnected care and limit human error. Effective teams are aided by an appropriate information technology infrastructure, which facilitates efficient and effective communication of health information. Encouraging the use of such teams will likely require the use of financial incentives, including bundled payments and payments that focus on outcomes; applying disincentives for poor outcomes, such as for preventable hospital readmissions; and creating incentives for delivery system reforms, including medical homes and accountable care organizations.

Efficient. *Patients, their families, and clinicians should expect care to be appropriate to need, resources, and time required.* Participants underscored the fact that currently, much of the care that is delivered is neither necessary nor efficient, with patients facing increasing out-of-pocket costs and lost time in the care process. This finding is not surprising given that the current incentive structure, focused on volume over value, encourages overuse and waste. As multiple participants noted, the United States spent roughly 17 percent of its gross domestic product on health care last year, yet this investment did not yield the health outcomes commensurate with

the costs. To gain greater value, many participants stressed that the costs and outcomes of care should be more transparent to patients, and new payment models—ranging from bundling payments for an entire episode of care, to pay-for-performance systems, to global payment—need to be implemented.

Accountable. *All relevant aspects of the clinical experience, including patient perspectives, should be captured and routinely assessed against expectations*. This information is vital not only to achieving effective patient management, but also to judging whether experiments with new delivery system models, payment incentives, or standards of care are having their intended effect on improving patient health and promoting efficiency. Measuring performance and disseminating innovations that work (and eliminating those that do not) constitute a systematic way of improving healthcare delivery. One presentation highlighted how this systematic approach to improvement allowed the speaker's organization to enhance care by conducting comprehensive reviews of interventions for different conditions, adopting the best practices identified by that review, and measuring the performance of the revised standard of care.

Transparent. *Information on the outcomes of care—both effectiveness and efficiency—should be readily accessible and understandable to patients and their families*. Several speakers mentioned the frustration felt by patients regarding the lack of understandable information on the costs, quality, and outcomes of care, especially in light of reports about medical errors and the increasing personal burden of costs and inefficiencies of care. It was noted that, when offered a choice, patients do not routinely choose more costly or more intensive interventions. However, patients rarely have choice or information about alternatives. It is clear that information needed to improve value—better outcomes at lower cost—requires transparent information on the costs and outcomes of care.

Trustworthy. *Patients should expect a strong and secure trust fabric on all dimensions—safety, quality, security, efficiency, accountability, and equity.* In few areas of human endeavor is trust on each of these dimensions more important. Yet one presenter noted that, even though 50,000 to 90,000 deaths per year are caused by medical errors, health care lacks the basic trust elements of transparency and accountability needed to drive improvements in quality and safety. In a learning system that draws lessons from each care experience, public trust must be bolstered in all aspects of the healthcare enterprise: equitable access to reliable clinician knowledge and skills, safeguards on clinical processes, the privacy and security of medical records, and the validity and safety of clinical trials.

Learning. *In a learning health system, the patient is an active contributor to, and supporter of, the learning process.* Each patient experience offers the potential to deepen the knowledge base that drives care quality and outcomes—at the individual, practice, and societal levels. A focus of the workshop was the stake of the patient in fostering a digital health utility that provides needed information to patients and their clinicians, ensures synchronization among providers, and generates knowledge for progress—for example, for comparative effectiveness insights, public health activities, or postmarket monitoring of approved technologies and drugs. Reference was made, for example, to the need for a common core data set for electronic health record–based data that would allow reliable, platform-independent research across large patient populations. These are issues in which patients have a strong stake, and they must have confidence in the system's functionality for the generation of timely and reliable new insights.

Many participants stressed that meeting these important expectations will require new tools, a new culture, and new organizational structures. This transformation must start with patients' involvement in their own medical care and their inclusion in decision making about the treatment that is best for them. Beyond individual patient decisions, workshop participants discussed the importance of including consumers in healthcare policy making at all levels—from hospital advisory committees to clinical trials—to ensure that all levels of the healthcare system consider patients at all times.

PRESENTATION SUMMARIES

The workshop presentations and discussions reviewed progress toward a learning health system; explored the links among the three key aims of care—science-driven, patient-centered, and value-enhancing; and identified priorities, policy levers, and public engagement strategies necessary to move forward. To provide context, the workshop began with keynote remarks by Harvey Fineberg, president of the IOM. He provided an overview of the current U.S. healthcare system and offered observations on the important framework and impetus for progress provided by the foundational elements of a learning health system in the context of the ACA.

The Learning Health System in 2010 and to Come

Dr. Fineberg addressed key challenges facing the U.S. healthcare system, drawing attention to the nation's high expenditures on health care. The United States spends $7,500 per person on health care, yet life expec-

tancy, infant mortality, and system performance lag behind those of many developed countries that spend far less (OECD, 2009). In 2009 the United States spent $2.5 trillion on health care, which, as noted, represents nearly 17 percent of gross domestic product. In the coming years, expenditures are expected to continue to climb and life expectancy is expected to worsen if the healthcare system continues to function as it does today.

A learning health system, as defined in the charter of the Roundtable on Value & Science-Driven Health Care, is a system designed to generate and apply the best evidence for care; provide evidence discovery as a natural outgrowth of patient care; and strive for innovation, quality, safety, and value in health care. In redesigning the health system to transition to this ideal, patients and the public must be engaged as active partners. Their perspectives are invaluable on topics ranging from how to personalize care and treatments to how to judge the value of care delivered. Despite the potential, evidence suggests that the system currently engages the public and patients in a limited fashion at the level of either the health system or individual healthcare decisions (Berwick, 2009; Sepucha and Barry, 2009; Zikmund-Fisher et al., 2010). Increased involvement of the public and patients is essential for progress toward a learning health system and greater value in health care.

Passage of the ACA just 7 days before this workshop added momentum and urgency to transforming the health system. However, passage of this legislation alone will not accomplish this transformation; careful implementation will be necessary to better orient health care toward science and value. In short, reform will be an ongoing process and evolve over time in response to changing national conditions. Sustaining these reform efforts will require the creation of a learning culture that nurtures systems and enables continuous learning, improvement, and innovation.

Clinical Research, Patient Care, and Learning That Is Real-Time and Continuous

A learning health system seeks to develop and continuously refine the evidence base needed for timely care, tailored to individual patient needs. However, the rapid pace of development of new therapies and ongoing evolution of existing treatment strategies create substantial, unmet demands on the research enterprise as current clinical research approaches require significant investments of time and resources but offer only static determinations of the average treatment effects on narrow and homogeneous populations (Greenfield et al., 2007). As a result, only a fraction of the many pressing clinical questions can be investigated, and research findings are limited in their timeliness and generalizability to real-world patient populations (IOM, 2009, 2011b).

Presenters of the papers included in Chapter 2 considered key strategies for expanding capacity and improving the volume, level, and applicability of clinical research. These strategies include developing the infrastructure and methods necessary for comparative effectiveness research, harnessing integrated healthcare delivery systems as platforms for research in real-world care settings, and engaging patients as full partners in the research enterprise.

Comparative Effectiveness Research: Patient, Clinician, and Policy Needs

By focusing on health outcomes and the information needs of patients, clinicians, and policy makers, comparative effectiveness research may improve the utility of all clinical research for guiding care decisions (FCC, 2009; IOM, 2009). Departing from the traditional, investigator-driven research paradigm, the priorities and study designs of comparative effectiveness research must reflect routine practice settings and the heterogeneity of real-world patient populations. As noted by Patrick Conway, formerly of the Office of the Secretary of Health and Human Services, this type of research provides an opportunity to take better advantage of health information technology and innovative research methods. Ensuring the success of comparative effectiveness research efforts will depend on improving the translation of its evidence into health outcomes through improved adoption and dissemination interventions as well as enhanced efforts to evaluate and publicly report the impacts of research investments.

The ARRA and ACA provided funding and expanded capacity for the entire comparative effectiveness research enterprise. To guide the investment of a portion of these new research funds, the Federal Coordinating Council for Comparative Effectiveness Research developed prioritization criteria for scientifically meritorious research, as well as a strategic framework outlining core research components (research, human and scientific capital, data infrastructure, dissemination, and translation) and priority themes (populations, conditions, and intervention types).[2] Key initial investments include the development of data infrastructure, encompassing, for example, claims data, clinical data networks, and patient registries, as well as efforts to enhance information dissemination and use. In addition to discussing the work of the Coordinating Council, Conway suggested several next steps as important to ensure maximal impact and sustainability of the Patient-Centered Outcomes Research Institute (PCORI) created under the ACA: (1) develop an overall funding strategy, informed by clinicians,

[2] The Coordinating Council recommended priorities for the comparative effectiveness research funds provided to the Office of the Secretary of Health and Human Services ($400 million). The ARRA also allocated comparative effectiveness funds to the National Institutes of Health ($400 million) and the Agency for Healthcare Research and Quality ($300 million).

patients, and a stakeholder advisory board; (2) establish priority topics, and evaluate the current state of knowledge about each; (3) select research methods that will best address existing knowledge gaps; (4) strive for a balanced portfolio of high-impact research topics; and (5) evaluate progress, and report back to the public (VanLare et al., 2010).

Health Systems as Research Platforms: Enhancing Science, Value, and Innovation

Electronic health records and other health information technology (IT) tools have become commonplace in many large healthcare delivery organizations. The resulting increase in clinical and health data presents an opportunity to conduct research that better reflects clinical practice and is relevant to real-world patients and settings. The research enabled by health IT includes research on comparative effectiveness, health services, patient preferences, surveillance of pharmaceuticals and other therapeutics, and population health.

To illustrate the potential of better integrating health systems into the national research enterprise, John Noseworthy and Sherine Gabriel of Mayo Clinic offered several examples of Mayo's use of clinical data to improve the safety and effectiveness of medical care. One such example, the Rochester Epidemiology Project, creates a common data resource for the study of health and illness that is large enough to facilitate routine and passive population-based research. Taking a similar approach, the Total Joint Registry supports comparative analysis of surgical techniques and implant types—including consideration of patient demographics and comorbid conditions—with respect to long-term outcomes. A third example is the Warfarin Project, which implements a standardized, rule-based algorithm for administration of this anticlotting agent and improves the algorithm through surveillance, performance data, and user feedback.

Taking a more disruptive approach, the proposed High Value Healthcare Initiative would focus on improving the value of care by benchmarking the quality and costs of best practices over time, implementing models for evidence-based best practice and shared decision-making, and studying new reimbursement approaches that would better align payments with patient care outcomes. As a final example, the Enterprise Data Trust is a centralized repository for the management, integration, and sharing of information collected during care delivery—including biospecimen-related and phenotypic data—with the data being used to inform and improve future care.

Collectively, these examples suggest several key characteristics for a knowledge-driven healthcare delivery system of the future: patient-centeredness with a strong focus on quality and coordination of care;

information-enabled practice with real-time data and feedback available to providers at the point of care; a culture of collaboration, innovation, and translation of scientific knowledge into improved health for patients and communities; health information technology systems that are integrated, standardized, and interoperable; and a focus on high-value care.

Enhancing the Culture of Patient Contributions to Learning in Health Care

A learning health system is characterized by real-time and continuous knowledge generation, with patients actively engaged in the research enterprise. The patient-centered focus of comparative effectiveness research and the increased capability of health systems to use course-of-care data for learning foreshadow expanded opportunities for patients and the public to contribute to advancing knowledge. Diane Simmons and Kenneth Getz of the Center for Information and Study on Clinical Research Participation reviewed key opportunities to foster a culture supportive of greater public and patient engagement in learning in health care.

One measure of public engagement in healthcare learning is public confidence and trust in the clinical research enterprise, which has eroded over the past decade as has public awareness of and appreciation for study volunteers (Woolley and Propst, 2005). These trends are reflected in research participation rates, with enrollment dropping from 75 percent in 2000 to 59 percent in 2006 despite a concurrent 12 to 14 percent spending increase recruiting clinical trial volunteers. It may be possible to reverse this trend by examining the common motivations for research participation. According to a survey of study volunteers, key drivers for sustained participation include the need to take control of one's medical condition and well-being, the desire to develop personal relationships with study staff, a feeling of being treated appropriately throughout the study, and the knowledge that participation will make a difference.

Based on the work of the Center for Information and Study on Clinical Research Participation, bolstering public confidence and trust could be accomplished through programs that (1) increase appreciation for study volunteers and illustrate the value of clinical research to the public health; (2) repair the credibility of research sponsors, study staff, and professionals responsible for regulating the research enterprise and protecting human subjects; and (3) engage the public as partners in the development of new medical and health advances.

Clinical Data as a Public Good for Discovery

Essential to a dynamic research enterprise is the broad availability of quality clinical and health data. Currently, data are scattered across the

healthcare system in siloed repositories, representing substantial but latent resources for advancing a variety of research streams, including drug discovery, comparative effectiveness, quality improvement, and public health surveillance (IOM, 2011a; NRC, 2009). Efforts now under way to create infrastructure for data capture, linkage, and information sharing will help make clinical data a public good. Presenters of the papers included in Chapter 3 reviewed the wide array of needs and potential uses for data in a learning health system, opportunities to better utilize data generated through public investment, and strategies to improve data integrity and develop a culture supportive of the application of the broad range of available data resources for progress in health care.

Information Needs for the Learning Health System

The Office of the National Coordinator for Health Information Technology (ONC) aims to improve health and health care through the appropriate use of information technology. Initial work has focused on encouraging broad adoption and use of electronic health records through Centers for Medicare & Medicaid Services (CMS) payment incentives so as to achieve measurable improvements in the quality, safety, and efficiency of health care. Farzad Mostashari of ONC reported on what is needed to attain a secondary goal of electronic health records: contributing to a learning health system and serving as a means for understanding and influencing other key functions such as public health, care quality, drug discovery, and clinical effectiveness research.

Current efforts to develop independent systems for these purposes are using different architectures and approaches, which poses two significant challenges to the creation of a unified, multipurpose digital infrastructure: sharing data and designing the system. Accelerating data sharing will require the creation of a limited care data set, developed from collaboration among key data users that can meet the key needs for each community. Although such an approach will not immediately satisfy all data needs of all users, it is a necessary starting point for the development of a national infrastructure that is not saddled with burdensome and excessive data demands. To meet the broader needs of each research community, the core data set should be accompanied by deeper data collection when appropriate and relevant to the circumstances. Discussing system design, Mostashari highlighted the potential benefits of creating a distributed rather than a centralized infrastructure. In the context of the fragmented and heterogeneous U.S. healthcare system, a distributed approach is likely to produce a more resilient, feasible, cost-effective, and privacy-protective infrastructure.

Opening Access to High-Value Data Sets

The vast stores of data captured by the agencies of the Department of Health and Human Services (HHS) are an important national resource for enhancing value, the science base, and the patient experience. Todd Park, HHS's chief technology officer, provided an overview of efforts to open access to these data as part of the White House's Open Government Initiative. Existing data from HHS agencies such as the Agency for Healthcare Research and Quality (AHRQ), CMS, the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) are a tremendous public good, yet the data cannot produce transformative change without additional efforts to stimulate their use and improvement. HHS therefore is seeking to develop a data ecosystem in which an array of users can access the data supplied by HHS and others, providing opportunities for users to develop new methods for the data's display or application in ways that improve the health of U.S. communities.

The data ecosystem concept has been tested through the Community Health Data Initiative, which seeks to help Americans better understand and take action to improve local healthcare performance. The promise of this approach has been demonstrated in the Initiative's initial meetings and has led to the development of several applications that use data to improve understanding of national and community health issues, as well as areas for their improvement. Park encouraged additional input from the public, noting that although HHS data are useful now, their quality and utility will improve dramatically as new uses and needs for the data are developed.

Ensuring Data Integrity: Addressing Privacy Protection and Proprietary Concerns

Although Americans strongly favor legitimate biomedical, public health, and health services research, current policy does not promote access to patient data for such research. Don Detmer of the University of Virginia noted the need for new policies that expand data availability and reduce data collection costs while ensuring the privacy and security of personal health information.

Current policy places the burden of collecting clinical data on researchers, creating significant disincentives for clinicians and investigators to pursue promising lines of enquiry. To address this misalignment, Detmer proposed several policies for promoting research while protecting data security, including (1) creating a unique personal health identifier, with the ability for patients to opt out; (2) providing the availability of genetic information for research, with the ability for patients to opt out; (3) sharing clinical data for research, with the ability for patients to opt

out; and (4) developing a public–private collaboration for engaging citizens who wish to participate in clinical research studies. These policies would give the public the option of becoming full and open participants in a learning health system while ensuring that patients retain the ability to choose whether they want their health data shared for research purposes.

Engaging Patients to Improve Science and Value in a Learning Health System

Patients bring unique and important perspectives as well as personal agency to health care—elements essential to closing important gaps in health system performance and health management, and ensuring the effectiveness of care received. Unfortunately, patients too often are not engaged as meaningful decision makers in their own care or as partners in health research. As illustrated by the papers included in Chapter 4, the vision for a learning health system takes a broader view by making informed patients a central system goal. Achieving this goal requires medical evidence to be presented to patients in a form that is understandable and actionable, based on patient preferences, expectations, health concerns, and health literacy. Building on the foundation of an informed patient, patient engagement strategies also seek to improve collaboration, respect, and participation. As emphasized in these presentations, once engaged, patients serve as a powerful driver for enhancing value in health care by improving research, health system effectiveness, safety, outcomes, and the quality of care decisions.

Investing Patients in the Research and Continuous Improvement Enterprise

Patients can be engaged as full partners in research if learning transforms health care to better serve the needs and interests of individuals, families, and communities. Sharon Terry of the Genetic Alliance offered a vision for the range of contributions patients and the public can make to improve research through better use of clinical data and health information. These patient-initiated data collection efforts have established biological repositories and clinical registries that provide important resources for research and discovery. Other efforts include social networks and sites that enable the aggregation and sharing of health information, such as PatientsLikeMe®, Love/Avon Army of Women, and Facebook health groups, as well as genetics-based initiatives such as the Genetics for Early Disease Detection and Intervention to Improve Health Outcomes program at the Centers for Disease Control and Prevention. This ongoing work indicates increased public interest in participating in one's own care, and that expanded participation will accelerate learning in the health system.

Public and Patient Strategies to Improve Health System Performance

Numerous policy statements from the public and private sectors speak to the importance of engaging patients, their families, and their communities in improving health and the experience of health care. However, no widely embraced framework exists for defining patient engagement. James B. Conway of the Institute for Healthcare Improvement proposed a two-dimensional taxonomy for such initiatives based on the chain of effect for quality (environment, organization, microsystem, and experience of care), grouped according to the elements of the Institute for Family Centered Care's definition of patient- and family-centered care (respect, information, participation, and collaboration). Although only an initial attempt, the framework provides support for the design, measurement, assessment, and improvement of various interventions seeking to enhance different aspects of engagement.

This overarching framework underscores the importance of involving patients in their health. Decades of work illustrate the powerful potential of greater patient and public engagement to improve health system performance, including improved adherence, reduced malpractice risk, decreased adverse events, and increased employee retention. This research supports the notion that health systems can be dramatically better if staff and leaders listen to and engage with patients and families. A second, related theme from Conway's presentation was that engaging patients and their families promotes improvements not just for one patient but also for all patients. Both themes highlight the benefits of transforming the health system by organizing it around the patient and the public.

Communicating with Patients About Their Concerns, Expectations, and Preferences

Although the necessary course of action is clear for some situations in medicine, a surprising number of clinical decisions require choice among multiple diagnostic or treatment options. According to Karen Sepucha of Massachusetts General Hospital, a high-quality choice among competing care approaches requires effective communication between patients and providers about the potential benefits and risks of each option, as well as consideration of a patient's expectations, health concerns, goals, and personal preferences. However, the patient experience often falls short of this ideal. In general, patients are not meaningfully involved in the decision-making process, and providers do not explore patient health goals or preferences that might influence a decision (Zikmund-Fisher et al., 2010). In addition, patients receive poor information. According to one

study, just half of patients were aware of the advantages and disadvantages of the treatment or intervention under consideration, and fewer than half were able to answer correctly more than one of four to five questions about those treatments (Fagerlin et al., 2010).

These quality gaps in decision making have implications for health outcomes, patient satisfaction, and the overall value of care received. In the case of elective surgery, for example, informed patients were 25 percent less likely to choose surgery, a finding that suggests that one in four patients may be receiving unwanted care. Sepucha also reviewed existing efforts to promote shared decision making through provider training to improve communication and decision coaching skills in addition to patient coaching to facilitate discussions with providers about patient preferences and concerns. Also discussed were patient decision aids, which have been demonstrated to increase patients' knowledge and perceptions of risk as well as improve a patient's desire to participate in decisions (Sepucha and Barry, 2009). Improved use of these tools requires new incentives, as well as changes in the organizational structure to include patients in care decisions.

Health Information Technology as the Engine for Learning

Presenters of the papers included in Chapter 5 reviewed trends and strategies for health information technology adoption and how the necessary infrastructure can be developed as a knowledge engine, a tool for care improvement, and a portal for practical patient engagement.

Meaningful Use of Health Information Technology

David Blumenthal, formerly of ONC (now Harvard University), stressed that health information technologies, particularly electronic health records, need to be adopted more broadly if they are to contribute to learning and science-driven care. "Meaningful use" denotes an early incentive to drive adoption, with additional incentives needed for further dissemination. Dr. Blumenthal provided an update on federal efforts to create a health information technology environment based on routine, continuous learning (Blumenthal and Tavenner, 2010). Building on ONC's statutory responsibilities under the Health Information Technology for Economic and Clinical Health Act, ONC is focusing on the nationwide exchange of health data and establishing a digital data infrastructure (Blumenthal, 2010). As the data infrastructure is built, privacy issues will need to be addressed in order to ensure access to data for research and assuring the public that their personal health information is protected.

New Classes of Data, New Opportunities to Learn

Emerging classes of healthcare data are providing new ways to measure various aspects of health care and to improve healthcare delivery, as well as translational and clinical research. Daniel R. Masys, Jack M. Starmer, and Jill M. Pulley of the Vanderbilt University School of Medicine described three examples of these data sources. The first example presents data in a novel way through dashboard displays, or real-time presentation of data, to indicate which care measures are due, done, or overdue. These displays have proved more effective than computerized alerts for individual care measures. As a second example, the Electronic Medical Records and Genomics Network uses electronic medical records to verify previous genetic studies and to discover new genetic effects with phenome-wide scanning. A final example is Vanderbilt University's patient portal MyHealthAtVanderbilt, which supports patient and clinician communication, appointment scheduling, and access to lab results. It also acquires data on health outcomes that are seldom recorded, such as the unexpected beneficial effects of newly prescribed medications. Each of these three examples illustrates how different sources of data can be used to create a learning health organization and inform both research and care.

Web 2.0 and Patient Engagement

Health information technology is helping to bridge the gap between patients and providers by enabling communication and interaction beyond the typical clinical encounter. Kemal Jethwani and Joseph Kvedar from the Center for Connected Health at Partners HealthCare discussed the use of technology to deliver patient care outside the hospital or doctor's office, help patients monitor their health status, and obtain relevant feedback and coaching to achieve the best possible outcomes. As an example, the Connected Cardiac Care Program enrolls heart failure patients for intensive monitoring using a weight scale, blood pressure cuff, and pulse oximeter; the patient's data are reviewed by a nursing team that recommends follow-up care by a cardiologist if they notice concerning changes. Since the start of this program, readmission rates have been halved, and patients have reported higher awareness of how to better manage and control their conditions. Lessons learned from this and similar disease management programs include the benefits of patient engagement tools, such as consistent and meaningful feedback, coaching, and increased communication with providers, in changing patient behavior to meet clinical goals.

Patients, Clinical Decisions, and Health Management in the Information Age

The availability of health information has grown tremendously with websites, blogs, discussion groups, and forums providing ready access to information for those curious about their own or their family's health problems. Although in general the increased abundance of information is positive, it brings several challenges. Most notably, patients now must sort through a plethora of information and judge what is reliable and what is not. Patients can easily be misdirected on the Internet, where numerous sites of uncertain benefit and possible harm abound (Tang and Ng, 2006). Likewise, when test results are provided electronically with no context, patients may be puzzled or disturbed by results that deviate from the normal range and assume the worst possible diagnosis (Hartzband and Groopman, 2010). Presenters of the papers included in Chapter 6 provided an overview of the current digital health infrastructure, ranging from health information posted online to health monitoring technologies for improving care.

Public and Patient Information Access and Use as a Core Care Component

The Internet has dramatically transformed the quantity and convenience of health information available to the public, offering users a wide range of resources from which to choose. As noted by George L. Lundberg, editor-in-chief of Cancer Commons, most patients now receive the majority of their new medical and health information from the Internet, with many accessing the information after visiting their physician to learn more about diagnoses and findings. This represents an important opportunity for physicians to deliver information to patients who are motivated and primed to learn by helping them find relevant, reliable information. In addition to making existing information more broadly available, the Internet is promoting faster translation of research through open-source science. Lundberg presented one example, the Cancer Commons, a rapid learning community focused on real-time translational cancer research and personalized oncology. These types of applications seek to build on the genomics and molecular medicine revolution while reducing the time from initial observation to successful implementation.

Health Information Technology–Based Approaches to Health Management

Through the provision of real-time information and feedback, health information technology has contributed to changing physician behavior and improving overall health system performance. However, as observed by Paul Tang of the Palo Alto Medical Foundation, if the technology

fails to engage patients and support their active participation in managing their own health, the nation will still fall short of its health goals. Tang illustrated how health information technology has been helpful in transforming the patient experience of a chronic disease such as diabetes. The Foundation provides patients with wireless glucometers that transmit glucose readings to its electronic health records system; the readings are then displayed on a diabetes dashboard and can be viewed and annotated by patients and providers. These data provide an important opportunity for patients and providers to actively monitor blood glucose and examine how it varies with daily diet, exercise, and medication regimens. Thus, patients have been able to learn how their behavior and decisions impact their health outcomes and improve their health conditions.

Health and Disease Management Outside the Clinic Doors: There's an App for That!

Healthcare delivery continues to change to adapt to an aging population, increased prevalence of chronic conditions, genomic medicine, and information technology advances. Dorianne C. Miller, formerly of the University of Chicago Medical School discussed three examples of innovative approaches to improve healthcare delivery by extending care outside of the clinical practice setting. The first example is a patient electronic health records portal that facilitates communication between chronically ill patients and their providers and allows patients to store all of their health-related information together in a shared care plan. This system has increased patients' satisfaction with their clinical care and lowered costs by $3,000 per year for enrolled patients. Second is a web-based support group that allows patients to form a community that can support each member as well as provide information to the members' clinical partners that may affect their care. Although results are not yet available, the program has drawn interest and highlighted the importance of addressing privacy and security for the participants. A final example is electronic provider visits, which extend the availability of primary care providers to care for nonurgent conditions and enhance patient–provider communications. An initial assessment of this program found that it reduced work absences, decreased costs, and lowered the number of times patients had to visit a physician's office to solve their clinical problems. Barriers to broader adoption of these electronic applications include the social acceptability of visiting doctors via the Internet, limited access to the Internet among certain groups, a lack of electronic health records in many physician practices, and unknown reimbursement for delivering care electronically.

Applying Evidence for Patient-Centered Care: Standards and Expectations

Improving how evidence is communicated to patients is a critical challenge that must be addressed in transforming the health system to one that is centered on patients' individual values and preferences. Presenters of the papers included in Chapter 7 explored the added value of shared decision-making tools in helping patients decide among clinical options, ways to develop evidence that better meshes with individual patient needs, and methods for communicating evidence when the evidence base is uncertain.

The Role of Evidence in Patient-Centered Care

Regardless of whether the evidence available on treatment options is clear or uncertain, patient-centered care should ensure that "patient values guide all clinical decisions" (IOM, 2001). The current method for patient feedback—the informed consent process—falls short of the goal of helping patients understand risks and benefits to make informed decisions, according to Dale Collins Vidal of the Dartmouth Institute for Health Policy and Clinical Practice. Particularly when a patient faces treatment decisions not supported by adequate evidence or when treatment can impact a patient's quality of life, both patient and provider would benefit from a more structured decision-making process that supported informed patient choice, incorporating a discussion of treatment alternatives, the best evidence available, and the patient's personal values. An alternative to the current decision model is shared decision making, a process that requires both patients and providers to contribute information and participate. Dartmouth has implemented shared decision making by deploying decision aids, conducting surveys of patient preferences and reported health information, providing feedback to patients about their health behaviors and conditions, and feeding forward information helpful to clinicians at the point of care. Results from experiments with shared decision making have shown its impact on treatment choices: 30 percent of patients changed their initial treatment preference, and the overall rate of surgery was 22 percent lower (Deyo et al., 2000). Further adoption of this patient decision model will require comprehensive training of healthcare providers, increased consumer health literacy, and the successful identification of implementation models.

Evidence Standards and Application: Right Care, Right Patient, Right Time

Evidence standards and their application to treatment decision making must account for specific clinical circumstances, individual variation, and the range of intervention types. As described by Clifford Goodman of The Lewin Group, evidence hierarchies and their application to patient

care have remained relatively constant despite incremental modifications. Although randomized controlled trials provide strong internal validity, overreliance on this experimental design is a critical limitation to getting the right care to the right patient at the right time. Goodman suggested the need to develop a diversity of evidence methodologies that are better tailored to specific research questions and account for real-world variations in individual circumstances, patients, and settings. An alternative evidence rating approach has been introduced by the Evaluation of Genomic Applications in Practice and Prevention initiative, which advocates a systematic process for evaluating genomic tests based on analytical validity, clinical validity, and clinical utility. Other promising approaches use multiple and complementary methods to triangulate findings. Advances in evidence standards will require engaging the public on the nature of evidence, as well as fostering greater interaction among innovators, regulators, payers, and health technology assessment organizations with respect to evidence expectations.

Translation and Communication Needs for Care in the Face of Uncertain Evidence

Ensuring that patients are informed and active partners in health care requires effective approaches to translating and communicating evidence. Unfortunately, many health messages are delivered to the public in an overly brief and simplistic manner. Fran Visco of the National Breast Cancer Coalition reviewed the effects of this communication strategy in cases where evidence is uncertain. One illuminating case study is the controversy over the U.S. Preventive Services Task Force's updated recommendations on breast cancer screening. One reason these recommendations generated such controversy is that they conflicted with previous communication campaigns that ignored the limitations of mammographic screening, and failed to address the uncertainty surrounding the evidence behind screening. Lessons learned from this case study include the need to be honest with patients about uncertainty; the role professional societies play in influencing clinical recommendations; and the need to better educate policy makers, the media, and the public about the importance of evidence.

Team-Based Care and the Learning Culture

A system in which health professionals work as individuals limits the coordination of care, prevents the flow of information, and discourages quality improvement. Therefore, a team-based culture is key to a learning health system and improved patient care. Presenters of the papers included in Chapter 8 addressed fundamental elements of team culture, ways to create and sustain an environment that fosters the pursuit of clinical excel-

lence and continuous improvement, and the use of teams to structure care transitions that are efficient and ensure that the right person is transferred in the optimal way.

Practical Experience with Collaborative Models in the Health Professions

Team-based care involves more than the coordination of individuals responsible for a patient's care. According to Allan Frankel and Michael Leonard of Pascal Metrics, successful continuous learning environments link teamwork with improvement. Currently, few in health care methodically combine these elements, probably because of differences in the origins and backgrounds in teamwork training and improvement science. Teamwork training is based on a combination of psychology, sociology, and engineering while being heavily influenced by the science of human factors. In contrast, improvement science focuses on using statistics to manage variation in stable industrial processes and derives from the teachings of skilled statisticians and managers. Weaving these disciplines together is the responsibility, and a core function, of hospital leaders and healthcare managers.

Frankel described several key barriers to the implementation of a collaborative improvement model. First, the culture of medicine often has a hierarchical structure, whether based on academic stature, hospital–physician relationships, or other factors. Second, managers currently have limited appreciation of the components of a continuous learning environment or how such an environment can be achieved. Finally, senior leaders must devise strategies and allocate resources to ensure that continuous learning systems thrive.

Measures and Strategies for Clinical Excellence and Continuous Improvement

Developing new models of collaborative care requires engaging all team members, including patients, in the development of evidence and its use to ensure that healthcare decisions are grounded in effectiveness, safety, and value. As noted by Joyce Lammert of the Virginia Mason Medical Center, this paradigm shift in the practice of medicine will require a fundamental change in the approach to learning and its application in providing health care—one that involves leveraging teams to support systems of clinical excellence and continuous improvement. Rapid advances in science and technology, as well as the complexity of twenty-first century care, have made old paradigms of learning and caring for patients obsolete. The necessary culture change must start in medical school, with a focus on examining patient care processes. As much of the content of medical education will be out of date by graduation, more emphasis is needed on skills for lifelong learning,

such as how to ask the right questions and use information systems to obtain just-in-time answers that are evidence-based and reflect best practices. Similar changes may be needed on the organizational level and throughout residency training as well to encourage interdisciplinary and team-based practices. Finally, moving toward a learning health system will require other changes in such areas as recruiting, the practice environment, continuing education, and the payment structure.

Care Cooperation and Continuity Across Clinicians, Facilities, and Systems

Adverse events often occur during care transitions and too often result in hospitalizations, lower quality of care, and reduced patient satisfaction. Alice Bonner, formerly of the Massachusetts Department of Public Health (now Centers for Medicare & Medicaid Services) summarized work ongoing in Massachusetts to identify and quantify issues associated with care transitions and develop and implement a statewide strategic plan for addressing those issues. The goals of this strategic plan are to disseminate current knowledge about effective care transitions, summarize the state's current projects on care transitions, and build consensus among stakeholders on the most important principles of care transition. Key lessons learned from this process include the importance of including the patient's voice in the process, the need to engage stakeholders early to improve cooperation across institutions, and the importance of using evaluation measures to track progress. The plan is now being implemented, with workgroups refining and deploying a statewide form and process for interfacility transfer, and education efforts on effective care transitions being initiated.

Incentives Aligned with Value and Learning

Transformative change of the health system will require incentives that are aligned with a learning health system. Incentives should focus on promoting value over volume, revamped payment schemes supporting science and value, and changes in insurance design. Presenters of the papers included in Chapter 9 provided examples of strategies that show promise for helping to realign the health system. Taken together, these papers offer key strategies that can contribute to a reengineering of the system.

Paying for Value and Science-Driven Care

If the current trajectory of healthcare spending continues, by 2020 the U.S. debt will reach 90 percent of the gross domestic product ratio (CBO, 2010). Michael Chernew of Harvard University argued that addressing this fiscal situation will require a focus on value and reduced growth in spend-

ing. Chernew discussed several incentive structures designed to promote value, from pay for performance, to episode-based bundled payments, to global payment. Although all of these approaches are promising, each has technical challenges that must be addressed before its widespread application can reduce the cost trajectory. In particular, each new payment model will require performance measurement that can account for new clinical evidence and healthcare innovation. Crucial determinants of success for these and future payment systems will be their capacity to contain costs, the way they incorporate quality and performance measures, their ability to incentivize patients appropriately, the availability of cost and quality information, and the way they encourage organizational reform.

Generating Evidence to Guide Care

Innovation in the American health system is driven by financial incentives that reward volume and provider revenue. According to Richard Gilfillan, formerly of Geisinger Health Plan, there are ample opportunities for improving the value for patients in the healthcare system. However, whether the system produces more or less value for patients depends on the industry's business model. Gilfillan illustrated the impact of the current healthcare business model on innovation. Businesses proactively select innovation and learning initiatives that promise to provide a positive return on investment. Businesses further avoid innovations that might threaten their future success; an example is hospitals traditionally avoiding programs designed to decrease readmissions. Therefore, changing healthcare practice will require changing the healthcare business model toward one that rewards value. Gilfillan noted further that improvement will require multiple incentives, not just financial ones, as well as dissemination of best practices and leadership by clinicians and payers.

Creating a Learning Culture

Although financial incentives are clearly instrumental in transforming the health system, powerful nonfinancial incentives can be used to influence behavior and create a learning culture. Anne Weiss of The Robert Wood Johnson Foundation highlighted several of these nonfinancial incentives, from performance measurement, to technical assistance, to patient engagement. These incentives are central to the Aligning Forces for Quality strategy, which is currently being implemented in 17 regions across the country. Although still under development, the strategy has produced several insights into how to move toward a learning health system. First, health care is delivered locally, and different localities will have different needs. Second, strategic communication is critical to engage the general public, physicians,

patients, and employers in healthcare improvement. Third, progress will require participation by multiple stakeholders, from health system leaders to patients, each of whom has a role to play in measuring and improving quality. While the Aligning Forces for Quality project focused on non-financial means of creating a learning culture, such efforts are impeded by traditional payment systems that often punish learning and improvement, a fact that underscores the importance of reforming the payment system to reward quality and value.

NEXT STEPS

The workshop participants expressed optimism about building a learning health system that focuses on patients and consumers. Although many barriers may hinder this transition, transformational change is within reach. Comments offered throughout the workshop highlighted the following key questions, many of which may be addressed through the convening capacity of the Roundtable, whose exploration offers opportunities for advancement in different healthcare sectors.

Clinical Effectiveness Research

- How do various research methodologies produce results that contribute to personalized treatments, real-time learning, and clinical relevance? Should the Roundtable and its Clinical Effectiveness Research Innovation Collaborative develop a new taxonomy of research approaches that advance these goals?
- What steps can encourage greater patient involvement in the evidence process, from fostering participation in clinical trials, to initiating data collection for disease research, and developing applications from existing data?

Evidence Communication

- How can the Roundtable and its Evidence Communications Innovation Collaborative encourage the development of best practices in health communications, whereby complex information is delivered in simple and easy-to-understand formats? What steps can be taken to compile information on successful concepts, such as patient coaching, question checklists, and patient decision aids?
- What steps can be taken to encourage the education system to teach students how to analyze health information as well as related concepts, such as how to gauge risks and benefits, in order to promote broader health literacy?

- How can the Roundtable connect leaders from enterprises with expertise in consumer communications, such as media outlets and advertising, with health system leaders to transfer the lessons they have learned?
- Given that the media are a key supplier of health information, what steps can be taken to enhance the health literacy of journalists so as to improve the information delivered to the public?
- With more Americans obtaining health information from the Internet, how can the Roundtable encourage the development of websites with authoritative medical information for consumers?

Best Practices

- Given the benefits of engaging patients and families in their medical care, how might patient-centered care be encouraged throughout the medical system?
- What steps can the Roundtable and its Best Practices Innovation Collaborative take to encourage the use of technologies, such as dashboard displays or procedure checklists, that reduce variability in care management and improve the reliability of the use of best practices?
- What impediments prevent patient preferences and goals from being considered in all care decisions?
- Given the advantages of team-based care in promoting coordinated care and quality improvement, how can a team approach to care delivery be encouraged?

Electronic Health Records

- Developing a learning health system will require the use of clinical data as a reliable source for clinical research. How might the Roundtable and its Electronic Health Record Innovation Collaborative encourage the development of standards and approaches to assure the quality of these data?
- Since an effective health information utility was identified as a prerequisite for care coordination, continuous learning, and measurement of outcomes, what steps could the Roundtable and its Electronic Health Record Innovation Collaborative take to accelerate the adoption and use of such a utility?
- Given the accelerated development of medical evidence, what might the Roundtable do to explore expanded decision support at the point of care?

Value

- With the creation of new reimbursement incentives to promote value, how might the Roundtable and its Value Incentives Learning Collaborative develop a framework for ongoing assessment of the efficacy of these reimbursement experiments with respect to increasing value?
- What specific actions could be taken to reduce healthcare costs and increase value? What incentives are needed to encourage those actions?
- What incentives, financial or otherwise, are needed to encourage providers to place greater emphasis on engaging patients in their care?

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1

The Learning Health System

INTRODUCTION AND CONTEXT

The prosperity of a nation is tied fundamentally to the health and well-being of its citizens. It follows, then, that citizens—each one a past, current, or future patient—should represent both the healthcare system's unwavering focus, and its fully engaged agents for change. This precept has several major implications. It means that the quality of health care should not be judged solely by whether clinical decisions are informed by the best available scientific evidence, but also by whether care accounts for a patient's personal circumstances and preferences. It implies that careful listening should be the starting point for every patient encounter. And it suggests that the success of and innovations in healthcare delivery should depend on direct consumer engagement in the design of healthcare models and their aims.

One of the central lessons of the Institute of Medicine (IOM) report *Crossing the Quality Chasm: A New Health System for the 21st Century* is that much of health care in the United States has lost its focus on the patient (IOM, 2001). Instead, the healthcare system has been designed and motivated primarily by the perspectives of its component facilities, companies, payers, and providers. *Crossing the Quality Chasm* urges that care be refocused around six aims: care should be *safe, effective, patient-centered, timely, efficient, and equitable*. In the decade since the report was published, it has become even clearer that citizen and patient engagement is central to taking advantage of advances in the personalization of care based on genetics, preferences, and circumstances. Meeting this challenge is the core goal of what the Institute of Medicine's (IOM's) Roundtable on

Value & Science-Driven Health Care has termed a *learning health system*. Central to such a system is the notion that advances in biological research, clinical medicine, and information technology provide powerful tools for health improvement if applied within a system that promotes the mutually dependent aims of science, value, and patient-centered care (IOM, 2007, 2010b, 2010c, 2011a, 2011b).

Currently, health care in the United States falls substantially short of what should be possible given the nation's substantial healthcare investment. At $2.5 trillion, $7,500 a person, and 17 percent of gross domestic product in 2009, that investment totaled twice the expenditure levels of other industrial countries, yet the United States consistently rates poorly (currently 37th) on overall health system performance and on key component measures such as infant mortality (39th) and life expectancy (36th) (IOM, 2010a; Murray and Frenk, 2010). Although the overall quality of care in the United States compared with other developed nations varies by condition—for example, the United States is a leader in cancer care but lags behind other nations in asthma and hip fracture mortality—perhaps the most compelling illustration of system shortfalls is found in the wide variation in the quality of care from state to state and practice to practice. It is not unusual to see several-fold differences in care intensity and costs, with no effect on outcomes (Docteur and Berenson, 2009; Fisher et al., 2003; OECD, 2009). This geographic variation in quality of care has been shown to extend to cities in the same state and hospitals in the same city.

The systematic barriers to effective and efficient healthcare decisions have contributed to the development of a system that, by some estimates, delivers recommended care less than half of the time and often lacks definitive research evidence to guide clinical practice (IOM, 2008, 2009). Across the United States, however, many organizations deliver high-value care, and collectively, these organizations illustrate the many missed opportunities for healthcare improvement, such as system fragmentation, a lack of infrastructure and healthcare culture to support learning and continuous improvement, and incentives that reward care volume over value.

Perhaps the greatest missed opportunity for creating a health system that delivers the right care to the right patient at the right time is the failure to fully engage patients and the public as active partners in advancing the delivery of care that works best for the circumstances and ensuring that the care delivered is of value. Despite the potential to achieve this engagement, evidence suggests that such efforts are limited at both the health systems level, where provider preferences and supply often shape the care delivered, as well as at the level of individual healthcare decisions (Berwick, 2009; Sepucha and Barry, 2009; Zikmund-Fisher et al., 2010).

In part, this shortfall is a communication problem with respect to public awareness as well as encouragement and support by the healthcare

system. Patients may express frustration with their care because they do not feel they have adequate input into the clinical decision-making process or that the decisions made reflect their preferences. Currently, however, more than two-thirds of U.S. consumers believe their personal care is "evidence-based"—derived from the best available science and appropriately targeted to individual patient needs—and consistently of high quality (Campaign for Effective Patient Care, 2009). Increased public awareness of and appreciation for current shortfalls in health care and the role patients and the public can play in effecting needed improvements are essential for progress (Carman et al., 2010).

THE ROUNDTABLE AND THE *LEARNING HEALTH SYSTEM* SERIES

Since 2006, the Roundtable has provided a venue for health leaders from various stakeholder sectors—health professionals, patients, health system leaders, insurers, employers, manufacturers, information technology, research—to work cooperatively to address their common interest in improving the effectiveness and efficiency of health care. Roundtable members have set the goal that, by 2020, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date information and will reflect the best available evidence. Over the past 5 years, the Roundtable's *Learning Health System* series of workshops has identified and considered the key elements whose transformation can be central to achieving this goal: clinical research, clinical data, information technology, evidence standards, healthcare tools, caregiver culture, patient engagement, and financial incentives. For each of these elements, the workshops have explored priorities and approaches integral to harnessing interests and expertise across healthcare sectors to drive improvements in the value of medical care delivered in the United States. The following publications summarizing these workshops offer perspectives on the issues involved, and identify priorities and projects in need of cooperative stakeholder engagement:

- *The Learning Healthcare System (2007)*
- *Evidence-Based Medicine and the Changing Nature of Health Care (2008)*
- *Leadership Commitments to Improve Value in Health Care: Finding Common Ground (2009)*
- *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation (2010)*
- *Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Evidence-Based Approaches (2010)*

- *Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good (2011)*
- *The Healthcare Imperative: Lowering Costs and Improving Outcomes (2011)*
- *Engineering a Learning Healthcare System: A Look at the Future (2011)*
- *Learning What Works: Infrastructure Required for Comparative Effectiveness Research (2011)*
- *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care (2011)*

In addition to the meeting series focused on exploring concepts and strategies for the learning health system, the Roundtable operates a series of Innovation Collaboratives, aimed at stewarding joint projects among organizations key to field advancement.

Across the range of issues engaged in the *Learning Health System* workshops and the Innovation Collaboratives, greater public interest and patient engagement have emerged as essential and potentially transformative elements for driving health system change. Empowering and supporting the public in these new roles requires the creation of a healthcare culture that supports continuous improvement and learning; elicits and considers public perspectives on key healthcare issues; and better characterizes needed partnerships, resources, tools, and communication approaches. Listed in the front of this publication are members of the IOM planning committee[1] charged with guiding the development of a workshop to consider these issues in detail. The committee worked with IOM staff to develop the workshop objectives and emphases and to plan the agenda. Box 1-1 summarizes the motivating issues and objectives for the workshop.

The planning committee designed day 1 of the workshop to focus on key elements of progress in science-driven health care—care culture, clinical research and the evidence process, clinical data, health information technology systems—with specific attention to the role of patient engagement in the success of each. Day 2 was devoted to understanding opportunities to develop the communications, culture, and incentives that will help in reorienting the focus and performance of a value- and science-driven health system. The workshop agenda is provided in Appendix A, speaker biographical sketches in Appendix B, a listing of workshop participants in Appendix C, and an overview of common themes from each workshop in the *Learning Health System* series in Appendix D. This publication summa-

[1] Institute of Medicine planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published workshop summary rests with the workshop rapporteurs and the institution.

BOX 1-1
Motivating Issues and Objectives

Motivating Issues

- *Implications of knowledge advances*. Progress in medical science, basic research, information technology, and operations research offers the potential for immediate, continuous, and transformative improvement in health care. In the context of increasing understanding of the importance of individual factors to patient outcomes, reaching health care's full potential requires a reorientation to the patient.
- *Performance shortfalls*. In terms of both effectiveness and efficiency, the nation's healthcare system is underperforming. The United States has the highest per capita health expenditures—twice the average for other developed countries—yet consistently rates no better than the middle tier of developed nations on such key indicators as infant mortality, life expectancy, and overall health system performance.
- *Disconnects in core aims.* The core aim of health care is improved outcomes: to maintain or enhance patient status with respect to disease, injury, functional status, and sense of well-being. Yet often the system's dominant characteristics are oriented more to clinician preferences or interests and economic rewards for volume over value.
- *Anchor misalignment.* The primary focus of care should be on outcomes rather than service volume and on the interdependent aims of patient-centeredness, better science, better value, and continuous improvement.
- *Imperative to make patients a central element.* Efforts of the IOM and others have underscored the necessity of making patient perspectives, preferences, and needs a strong, central focus of a learning health system, for several reasons, including: the basic fact that patients are the health system's key focus and its agents for change; the fact that care has been shown to be more effective and efficient with more patient involvement; and the growth of preference-sensitive care as new interventions are developed.
- *Importance of communication.* Central to progress are the communication strategies necessary to inform and engage the public and patient communities as understanding advocates, partners, and change agents.

Objectives

- Identify the state of play with respect to the foundational elements of a learning health system, the role of patients and the public in achieving progress on each element, and the most important priorities and policy levers for accelerating progress.
- Explore and clarify the integral links among three key desired characteristics of care: science-driven, patient-centered, and value-enhancing.
- Discuss communication and public engagement strategies important to improving the awareness and patient-focused action necessary for the transition to a learning health system.

rizes the workshop presentations and discussions and the issues addressed. Summaries of common themes and of the workshop presentations and discussions are provided below; further detail is provided in the main text.

This chapter provides contextual information for that discussion, including an overview of opportunities presented by the recent healthcare reform legislation and a summary of the keynote remarks of Harvey V. Fineberg, president of the Institute of Medicine, to help set the stage for the workshop. The remainder of this volume contains speaker-authored papers presented at the workshop in the areas of clinical research, patient care, and learning that is real-time and continuous (Chapter 2); clinical data as a public good for discovery (Chapter 3); engaging patients to improve science and value in a learning health system (Chapter 4); health information technology as the engine for learning (Chapter 5); patients, clinical decisions, and health management in the information age (Chapter 6); applying evidence for patient-centered care: standards and expectations (Chapter 7); team-based care and the learning culture (Chapter 8); and incentives aligned with value and learning (Chapter 9).

HEALTHCARE REFORM AND A LEARNING HEALTH SYSTEM

Many of the basic aims of the American Recovery and Reinvestment Act of 2009 (ARRA) and the Patient Protection and Affordable Care Act of 2010 (ACA) reflect key features of the Roundtable's vision for health care. These features are focused on better harnessing technology and innovation—by advancing information networks and research methodologies—as well as the expertise and resources of all healthcare stakeholders to promote greater coordination, communication, transparency, and accountability in health care.

A learning health system is one that maintains a constant focus on improving the value of the return on the nation's healthcare investment. Emerging from the Roundtable's work on reducing healthcare costs and improving outcomes and on advancing the infrastructure required for comparative effectiveness research (CER) are many immediate opportunities to improve the overall value of health care delivered (IOM, 2010c, 2011b). Echoing this work are efforts targeting the reduction of unnecessary services, waste, and other system inefficiencies; the alignment of incentives to reward care value rather than volume; and establishment of a means for continuous measurement, tracking, and improvement of the effectiveness and efficiency of the healthcare system. Reflecting the interdependence between controlling costs and providing coverage that ensures timely and appropriate care to all, the ACA also significantly expands health insurance coverage.

A focus on the development and application of evidence on what works best for whom is fundamental to understanding and ensuring the

value of health care delivered. Funds provided as part of the ARRA represent an important initial investment in several components of a learning health system, including $19 billion allocated for improved deployment and application of electronic health records (EHRs) and $1.1 billion for expanded capacity for CER, which encompasses funding for the conduct of such research and the development of key infrastructure elements such as databases and other clinical data resources. Efficient use of these new resources for quality improvement and evidence development is contingent upon recognition of their qualities as a public good and assessment of issues related to ownership, availability, and use of clinical data as a public utility for real-time clinical insights.

Underscoring the importance of developing the point of care as a knowledge engine, provisions in the ACA also target healthcare delivery systems as a vehicle for driving improvements in system performance and efficiency. Building the capacity to learn as a natural outgrowth of clinical care will foster a health system that continually improves the quality of health care delivered. Furthermore, developing capacity to measure and track quality and efficiency will not only improve transparency and accountability in health care, but also lay the foundation for building innovative clinical effectiveness research into practice to improve the speed and relevance of evidence development.

The fragmented nature of the U.S. health system compounds the challenge of healthcare delivery but at the same time creates system-wide opportunities for innovation and improvement. Healthcare reform provisions such as the Innovation Center at the Centers for Medicare & Medicaid Services (CMS) aim at accelerating sharing and dissemination of this learning across the system and supporting greater efficiency and effectiveness in the delivery of high-quality health care by fostering greater synchrony, consistency, and coordination in the development, interpretation, and application of clinical evidence.

In addition to these healthcare reform provisions, a trusted scientific intermediary could help both broker the perspectives of different parties and ensure that leadership stems from every sector. Strong, visible, and multifaceted leadership from all involved sectors will be essential to marshal the vision, nurture the strategy, and motivate the actions necessary to create a learning health system.

CREATING A LEARNING CULTURE

The passage of the ARRA and ACA does not guarantee dramatic gains in the efficiency or effectiveness of medical care. Careful implementation of the legislation will be necessary to better orient health care toward science and value, and reform will be ongoing and constantly evolving. Sustain-

ing these efforts will require the creation of a learning culture that fosters continuous learning, improvement, and innovation.

Fundamental to a learning culture is the full engagement of patients and the public. The Roundtable envisions learning in health care as a partnership in which the patient is central to ensuring improved health and the delivery of appropriate care, and the public is engaged in the evidence process. Supporting patients and the public in these roles will require improved communications between patients and health professionals about the nature of the evidence base and its use and strengthening of the patient–provider relationship.

Many workshop participants stressed that such a culture will require not only outreach to patients and the public, but also adoption in full of patient-centered care across health sectors and stakeholders. Although identified nearly 10 years ago by the IOM as a key dimension of quality, patient-centered care still feels unfamiliar, even disruptive, to many stakeholders (Berwick, 2009; IOM, 2001). Ultimately, value and science-driven health care comes from a sustained, system-wide focus on fostering a health-care culture and activities that reflect the interests, values, and priorities of patients and the public. Attention is needed to the identification and development of opportunities, across health system activities, to better elicit and act on patient and public perspectives and input.

THE LEARNING HEALTH SYSTEM IN 2010 AND TO COME

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The U.S. healthcare system is vast, complicated, and multifaceted. Unlike many other countries, the United States has several alternative healthcare models across the nation, each with its own niche. While some systems differ in their financial infrastructure, designed as either integrated, prepaid, or privately insured, others specialize in innovation, incentive schemes, or primary care and other specialties. For example, the Veterans Health Administration, an integrated, prepaid, wholly central system, differs largely from privatized health coverage programs such as health maintenance or preferred provider organizations, yet both are successful in their own light. Thus, the U.S. healthcare system currently is characterized by pockets of innovation and demonstrated success. These successes, however, are swimming in a sea of chaos and lack of achievement. Aspects of our current healthcare system are not working well and must be addressed.

Flaws of the Current Healthcare System

Healthcare spending in the United States surpasses that in most other countries, yet the nation's patient care outcomes fall well below those of most other Organisation for Economic Co-operation and Development (OECD) countries. A comparison of life expectancy and health spending per capita across different countries illustrates that the United States is an outlier along these two dimensions, spending by far the most and yet achieving less than many other countries (see Figure 1-1). Despite monetary investments amounting to 17 percent of the nation's gross domestic product, the United States ranks among the lowest in life expectancy and highest in infant mortality rate, and has poor system performance. Moreover, it has been estimated that about one-third of healthcare expenditures do not improve patient outcomes (McGlynn et al., 2003; OECD, 2009; Truffer et

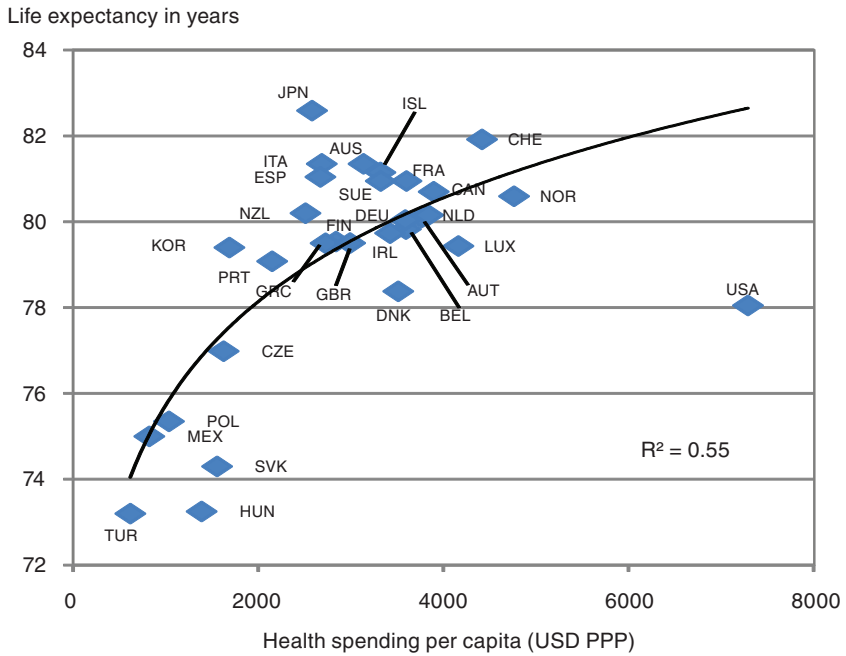

FIGURE 1-1 Healthcare outcomes in the United States compared with other countries. The graph shows life expectancy at birth in different countries versus per capita expenditures on health care in dollar terms, adjusted for purchasing power. The United States is a clear outlier on the curve, spending far more than any other country yet achieving less.
SOURCE: OECD, 2009.

al., 2010). With $2.5 trillion spent in 2009 on health care, the United States sees a low return on a high investment.

Still, addressing healthcare expenditures is only one facet of the larger issue of healthcare reform. Classic problems of overuse, underuse, and misuse of interventions still exist as critical challenges for U.S. health care—challenges that will not disappear with the adoption of universal healthcare coverage. Similarly, universal healthcare coverage will not be possible unless these critical issues of health spending and intervention variabilities are addressed. U.S. health care must address both of these concerns in conjunction to ensure that people are receiving care and the system is getting the right care to the people who need it. The systems perspective of a learning health system is therefore the first step toward achieving this high level of care.

A Comprehensive, Systematic Focus

Learning in health care does not apply solely to the practicing physician or professional. Although formal training and education are vital components of learning in health care, a systems perspective encompasses a number of different foci and catalyzes learning among all healthcare stakeholders. The system involves individual interventions and constituents, thus placing focus on what providers can do for their patients. However, it also encompasses the performance of individuals and organizations, the role of patients in everything from health literacy to participation in decision making, and the engagement of technologies such that equipment and information systems deliver better services. We must consider these individual components holistically to comprehend what it means for the healthcare system to be operating at a higher level; a level characterized by better outcomes, better value, and better ability to address patient needs. Five key tools will be instrumental in achieving this level of performance:

- **Health information technology, electronic medical records, and integrated systems** that involve both patient management and the ability to learn can engage patients and help make them active participants in their own care.
- **New research and innovation in diagnosis and treatment** can increase the scope of what healthcare providers can do for their patients and the ways in which they can provide those services.
- **Insights in genetics** are enabling the move into an era of personalized medicine, wherein patients have access to information that is relevant to them as individuals. This knowledge can be a powerful tool, encouraging patients to fundamentally alter their lifestyles and take charge of their own health.

- **Innovative care delivery approaches** go beyond individual technologies and place the emphasis on systems of care delivery and a holistic perspective.
- **Public engagement** is a root source of progress and a critical tool in achieving a learning system.

A Vision of a Learning Health System

The charter of the Roundtable on Value & Science-Driven Health Care describes a learning health system as a system designed to generate and apply the best evidence for collaborative healthcare choices for each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care. In working toward this vision, discussions in previous efforts of the Roundtable and, more generally, the IOM have identified key features of a learning health system (Box 1-2).

Together, these characteristics allude to a virtuous cycle in which all healthcare stakeholders deliver established best practices and learn how to improve from the care delivered. This cycle ensures that learning can be perpetuated and that effective, quality care is delivered. The clinician is both the steward of information and the agent acting on behalf of the patient, but decision making and action are centered on the patient's needs. Furthermore, it is not enough to be *able* to provide best practices; a learning health system must ensure that best practices *are* provided every time, all the time. These elements should all be embedded in a system that feeds back information and action in a seamless way, a system that regards knowledge and data as a public trust, respecting privacy yet acting in the public interest. Information technology is a clear foundation for the engine of a knowledge-driven system. Health care must depend on individuals who can be trusted without conflict to provide science-based advice and act for the well-being of the people they serve. Finally, all these parts must be brought together in a network that requires not only good leadership but also good followership, as individuals recognize and quickly adopt proven methods that work elsewhere. In realizing a learning health system, each of these elements must be embedded in an integrated model that provides relevant, real-time results to enable more effective care, encourage participatory and science-based decision making, and foster continuous learning for all healthcare stakeholders.

Moving Forward

In actuating this vision of a learning health system, value, science, and policy will be the fundamental driving forces. Value, or performance at

BOX 1-2
Learning Health System Characteristics

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

Care: starting with best practice, every time

Outcomes and costs: transparent and constantly assessed

Knowledge: ongoing, seamless product of services and research

Health information: a reliable, secure, and reusable resource

The 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

SOURCE: Adapted from The Learning Healthcare System (IOM, 2007).

cost, denotes what is gained per dollar spent. Science generates evidence that informs and shapes care delivery, and policy encompasses the choices individuals make that define the rules of the game. Together, these three drivers make a holistic, systematic perspective on health care possible.

Current policy efforts are aimed at helping to bring a learning health system into practice. Just seven days before this workshop was held, President Barack Obama signed the ACA. The legislation not only created a new independent payment advisory board, but also established the Innovation Center at CMS and the Patient-Centered Outcomes Research Institute (PCORI). As a center dedicated to testing innovative payment and program service delivery methods, the Innovation Center has the potential to reduce Medicare and Medicaid costs substantially while enhancing health care quality. With a health system populated by countless alternative care delivery models, the United States can benefit immensely from the Center's

testing of the feasibility, cost-effectiveness, and quality outcomes of different models. PCORI, another key provision of the ACA, has as its goal to advance the quality and relevance of evidence concerning medical conditions and ailments; this goal parallels a learning health system's pursuit of evidence-based care and focus on value and quality. In establishing both of these centers, the healthcare reform legislation helps align provider incentives with patient-centered value and spurs the development of an integrated learning health system.

Furthermore, the ARRA will accelerate the adoption of health information technology and expand comparative CER through increased investment. The official establishment of the Office of the National Coordinator for Health Information Technology and the Federal Coordinating Council for Comparative Effectiveness Research has proven instrumental in fostering the adoption of electronic health records and the assessment of research on health care treatments and strategies, respectively.

Setting the Agenda

Moving forward with a learning health system will require identifying, understanding, and assessing both challenges and opportunities. These workshop sessions illustrate how to move forward on key elements such as science, patients, and value, as well as the communication and patient engagement that are so critical to success. In highlighting programs currently under way and discussing information technology as the engine for an integrated system, these sessions explore the next steps that will lead to the development of a learning health system.

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2

Clinical Research, Patient Care, and Learning That Is Real-Time and Continuous

INTRODUCTION

The United States is home to vital and dynamic biomedical research enterprises. Science-driven care, however, requires a focus beyond advancing understanding of disease mechanisms. The same level of passion, creativity, and rigor must be applied to the translation of these discoveries into effective patient care and improved health outcomes. Several recent reports call for improvements in the level, quality, and effectiveness of clinical research through a sharper focus on generating timely information that is relevant to care decisions faced by patients and providers and on the science of care delivery (Conway and Clancy, 2009; Dougherty and Conway, 2008; IOM, 2010, 2011).

Current clinical research capacity is underdeveloped, substantially fragmented, and limited in its ability to support such work, particularly learning in real-world settings (Califf, 2009; IOM, 2010, 2011). A more dynamic clinical research infrastructure that draws research closer to practice is needed to facilitate ongoing study and monitoring of the relative effectiveness of clinical interventions and care processes. Innovative research approaches (e.g., novel study designs, analytical tools, use of course-of-care data from electronic medical and personal health records) will also accelerate learning (IOM, 2011; Lauer and Collins, 2010).

The papers that follow explore leading opportunities to improve the efficiency, effectiveness, and volume of clinical research. They also describe strategies for fostering the development of the capacity and culture needed for real-time and continuous learning that anticipates research needs and

produces evidence that is timely, relevant, and applicable to real-world care. Patrick Conway, formerly of the Office of the Secretary of the Department of Health and Human Services (HHS), reviews the unique nature of comparative effectiveness research (CER) and its core aim of helping to inform decisions of patients, clinicians, and policy makers. Recent federal investments have expanded national capacity for CER, and ensuring the long-term success of this emerging enterprise will require a near-term focus on devising a sustainable funding strategy, developing a research agenda for a balanced portfolio of high-impact topics, selecting methods appropriate to information needs, and evaluating and reporting progress to the public. Elements essential to ensuring the availability and use of comparative information at the point of decision making are discussed as well. John Noseworthy and Sherine Gabriel of Mayo Clinic offer insights into what might be possible if health systems were better engaged in the research enterprise. To illustrate the potential, they review several examples of the use of clinical data captured as part of healthcare delivery to improve care quality and health outcomes. They describe key characteristics of knowledge-driven healthcare delivery systems of the future, including patient-centered care; real-time data and feedback; a culture of collaboration, innovation, and translation; health information technology (HIT); and delivery of high-value health care.

Without the willing participation of the public and patients as contributors to learning, however, capacity for research will remain limited. Diane Simmons and Kenneth Getz of the Center for Information and Study on Clinical Research Participation review current public and patient attitudes toward participation in clinical research and offer some suggestions for fostering a culture that better supports and encourages public appreciation of and participation in such research. Educational and outreach efforts by the clinical research community and other stakeholders are needed to enhance public awareness, enable participation, and sustain interest over time.

COMPARATIVE EFFECTIVENESS RESEARCH: PATIENT, CLINICIAN, AND POLICY NEEDS

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National Investments in a Comparative Effectiveness Research Enterprise

The American Recovery and Reinvestment Act (ARRA) of 2009 dedicated $1.1 billion to CER and established the Federal Coordinating Council

(FCC) for CER. The FCC established a common federal government definition for CER, prioritization criteria for scientifically meritorious research (Box 2-1), and a strategic framework to guide investment decision making and priorities, and offered recommendations for initial priorities (Figure 2-1). The FCC definition of CER is as follows:

> Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. (FCC, 2009)

ARRA allocated $400 million to the National Institutes of Health (NIH), $300 million to the Agency for Healthcare Research and Quality (AHRQ), and $400 million to the Office of the Secretary for CER. The Office of the Secretary funding supported an array of data infrastructure projects, whose focus ranged from claims data to clinical data networks to patient registries. These investments also focused on selected priority populations, such as children and persons with multiple chronic conditions (Conway and Clancy, 2009). Another major priority for the Office of the Secretary

BOX 2-1
Federal Coordinating Council for Comparative Effectiveness Research

- Prioritization criteria for scientifically meritorious research
- Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, costs, potential for increased patient benefit or decreased harm)
- Potential to evaluate comparative effectiveness in diverse populations and patient sub-groups and engage communities in research
- Uncertainty within the clinical and public health communities regarding management decisions and variability in practice
- Addresses need or gap unlikely to be addressed through other organizations
- Potential for multiplicative effect (e.g., lays foundation for future CER such as data infrastructure and methods development and training, or generates additional investment outside government)

SOURCE: FCC, 2009.

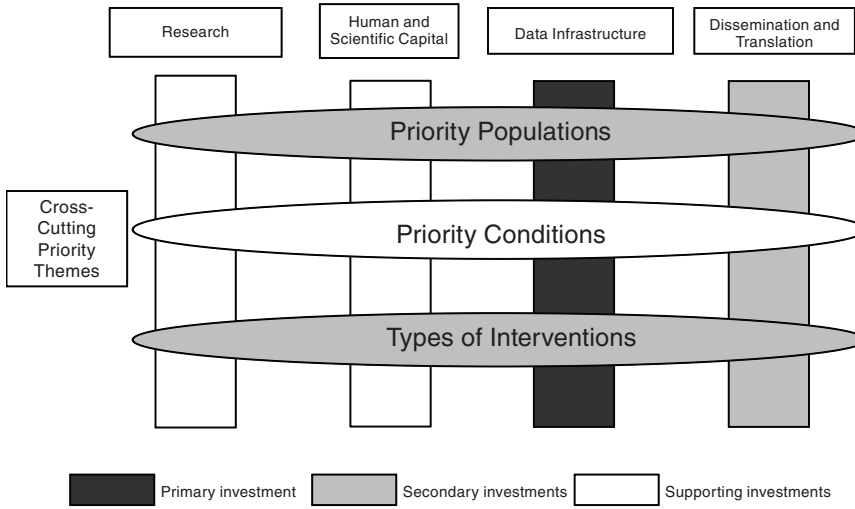

FIGURE 2-1 Federal Coordinating Council (FCC) strategic framework and recommended Office of the Secretary investment priorities for CER. This framework, including core activities (research, human and scientific capital, data infrastructure, and dissemination and translation) and cross-cutting priority themes (populations, conditions, and intervention types), was developed by the FCC to guide investment decisions and priorities.
SOURCE: FCC, 2009.

investment was dissemination of CER findings and their incorporation into practice. This effort will encompass both clinicians and patients, and will utilize networks and the delivery system. Finally, the Office of the Secretary investments targeted selected research topics—such as delivery systems; prevention; behavioral change; and priority populations, including racial and ethnic minorities and persons with disabilities—to complement the funding from AHRQ and NIH. Finally, the ARRA CER investment included funding for an ongoing inventory of CER and evaluation of the CER portfolio.

The Affordable Care Act (ACA) of 2010 included additional focus and funding for CER. Specifically, it established the Patient-Centered Outcomes Research Institute (PCORI). The duties of PCORI include identifying research priorities and establishing a research agenda. The Institute will have a 17-member Board of Governors and several expert advisory panels. Its budget will increase over time and likely exceed $600 million annually.

For the national CER program to have maximum impact on health and the value of healthcare delivery, the following five next steps have been proposed (VanLare et al., 2010):

1. Develop an overall funding strategy, influenced by clinicians and patients and the program's stakeholder advisory board.
2. Establish an initial list of priority topics, and evaluate the current state of knowledge about each.
3. With input from the advisory board and decision makers, select the research methods appropriate to fill the gaps in knowledge on a particular topic/question.
4. Strive for a balanced portfolio of high-impact research topics.
5 Evaluate progress, and report to the public.

CER Enterprise Implementation

Multiple additional considerations are involved in implementing a successful CER enterprise. First, the research methods must address the level of evidence necessary to influence decision makers. The level of evidence will vary based on the question and decision involved, but certain decisions may not require randomized controlled trials. Decision makers, including patients and clinicians, should be actively engaged in the planning and funding of research so CER meets their needs. The level of evidence needed to influence decisions should be considered an integral part of funding decisions and research designs. In addition, funding is needed to develop research methods and build understanding of how the methods used and the communication of findings will best meet decision makers' needs (Chalkidou et al., 2009).

The FCC (2009) and IOM (2009) reports on CER were strongly influenced by public input, and ARRA includes funding for actively seeking input to guide CER (e.g., horizon scanning). Building on this work to involve stakeholders, PCORI should focus its efforts on maintaining and increasing clinician, patient, and other stakeholder input. This input is important because one of the unique aspects of CER is that it must be guided by the needs of routine practice and consumers, which involves a different paradigm from that which informs traditional, investigator-driven research. To garner input efficiently and effectively, technology and other means of obtaining "real-time" input from a broad sample of patients, clinicians, and other stakeholders are needed. Finally, a feedback loop from users and implementers of research back to the research enterprise is essential. Examples of such feedback loops exist in certain delivery systems and networks, but they need to become the rule as opposed to the exception.

The FCC report and subsequent ARRA funding (especially that for the Office of the Secretary) focused on dissemination and adoption. Without any investment in adoption, the CER enterprise will fail to translate comparative evidence into improved health outcomes (Dougherty and Conway, 2008). To better understand the factors underlying successful adoption

interventions will require research, supported by HIT as a tool for both driving and measuring adoption. Although challenging, successful adoption will provide significant rewards by allowing the healthcare system to deliver higher-quality care, better value, and better population health, fundamentally transforming U.S. health care.

Although research funders often do not systematically evaluate the impact of their research investments. Evaluation is critical not only for measuring impact but also for understanding how to improve future research investments. In contrast, the Office of the Secretary CER investment included evaluation of ARRA CER funding to focus on impact and guide future CER investments. Going forward, the CER research enterprise should be accountable to the public by evaluating investments and publicly reporting the evaluation results.

Concluding Observations

Overall, CER represents an opportunity to focus research on the needs of clinicians, patients, policy makers, and other decision makers. Unfortunately, all of these groups often are faced with health-related decisions for which insufficient evidence exists to guide decisions or the evidence is not adequately available at the point of decision making. Therefore, the evidence must be generated to meet decision makers' needs and disseminated effectively to the point of decision making, in order to inform care and drive better outcomes and value.

HEALTH SYSTEMS AS RESEARCH PLATFORMS: ENHANCING SCIENCE, VALUE, AND INNOVATION

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Mayo Clinic

The IOM's Learning Health System series of workshops has defined foundational elements for a healthcare system that enables both the implementation of best care practices and the real-time generation and application of new evidence. This paper focuses on one of these elements—health systems as research platforms. It considers how healthcare organizations can be structured to support a system that advances clinical research and produces and applies evidence that is timely, relevant, and applicable to real-world care. One example of such a system is Mayo Clinic, a health system with a long tradition of creating and sustaining research platforms built upon its rich clinical practice.

Traditionally, leading healthcare organizations have fostered the incorporation of discovery and clinical research into clinical practice. For more

than a hundred years, Mayo Clinic has applied a singular focus on excellent patient care through its primary value—"The needs of the patient come first"—and its mission statement—"Mayo Clinic will provide the best care to every patient every day through integrated clinical practice, education, and research." Figure 2-2 shows a page from a patient ledger that contains the oldest medical records at Mayo Clinic. Written by Dr. William Worrall Mayo in 1866, it indicates that the patient record is "left open for further thought and research," exemplifying the philosophy of continuous learning during the course of clinical care.

Mayo Clinic has applied its culture of patient-centeredness to incorporate advances from clinical research into practice as expeditiously as possible. Research has always been a fundamental component of Mayo's core activities. The "conventional" approach of identifying key basic science and clinical research questions, publishing the results of these hypothesis-driven studies, and incorporating them into practice has helped Mayo Clinic grow its reputation as a knowledge-driven, patient-centered healthcare system. Three examples of this conventional approach are the Rochester Epidemiol-

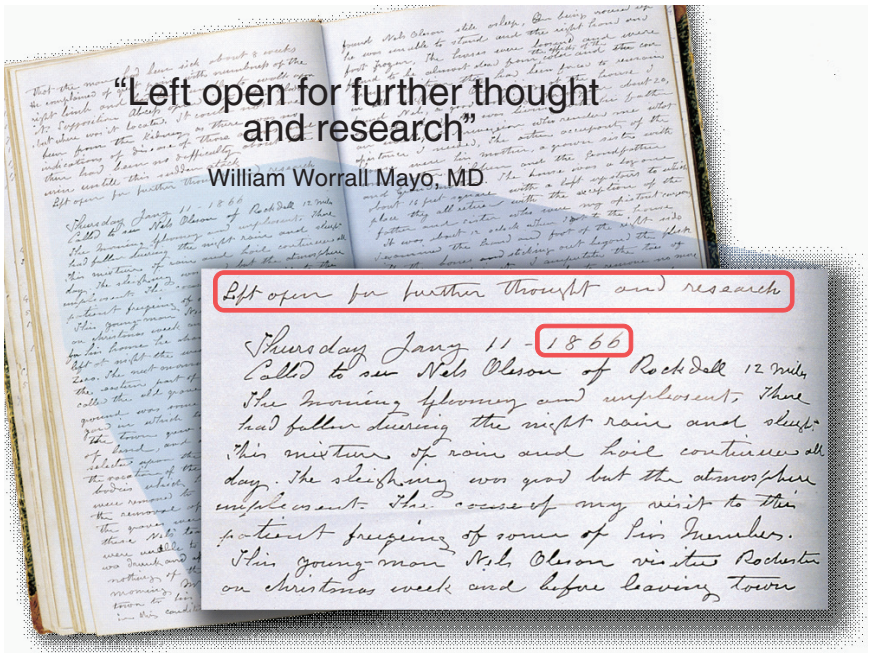

FIGURE 2-2 Mayo Clinic patient ledger, 1866.
SOURCE: Reprinted courtesy of the Mayo Clinic.

ogy Project, the Total Joint Registry, and the recently completed Warfarin Project. A description of each of these efforts is followed by a discussion of two new transformational initiatives currently under way, designed to meet the healthcare needs of the future.

Rochester Epidemiology Project

The Rochester Epidemiology Project (REP) is a long-standing collaboration among healthcare providers in Olmsted County, Minnesota (Kurland and Molgaard, 1981; Kurland et al., 1970; Melton, 1996, 1997). Many decades ago, these providers formally agreed to share medical records collected during the course of care of Olmsted county residents in order to study the health and illnesses of people in this community. Inferences drawn from this unique population-based resource could then be used to inform and improve health and health care in the entire country. The REP is one of a few venues where population-based research can be conducted passively and on a routine basis. REP studies typically address disease incidence and prevalence, time trends, risk and protective factors, effectiveness of treatments, natural history and outcomes, genetic factors, quality of care, and cost of care through careful identification of cases and controls and of exposed and nonexposed individuals. The infrastructure for the REP has been NIH-funded since 1966, supports many individual NIH-funded research grants (approximately 40 during the past 5 years), and has yielded approximately 2,042 peer-reviewed research papers to date. From these publications have come such observations as the following: the occurrence of Guillain-Barré Syndrome is increased only slightly by swine flu vaccination (Beghi et al., 1985); silicone breast implantation carries a high risk of surgical complications, but is not associated with previously claimed significant autoimmune adverse sequellae (Beghi et al., 1985; Gabriel et al., 1994, 1997); routine immunizations do not increase the risk of autism (Barbaresi et al., 2005); and prophylactic bilateral oophorectomy is associated with both increased mortality and an increased risk of neurological disorders (Rocca et al., 2006, 2007, 2008).

Total Joint Registry

The Mayo Clinic Total Joint Registry[1] is the most comprehensive joint replacement registry in the world. The database was established in 1969, has been carefully maintained since that time, and now contains data on 97,500 arthroplasties. Structured standardized information is gathered from

[1] See http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648098c1d0 (accessed October 11, 2010).

patients before, during, and at scheduled intervals after their surgeries for the lifetime of the patient and the orthopedic implant. This registry has allowed for comparison of surgical techniques, implant types, patient demographics, comorbid conditions, and long-term outcomes. It has allowed physicians to determine which surgical practices and implant models are most effective over time and has informed decision making on these issues. The registry has been a valuable clinical and research tool, allowing orthopedic surgeons, for example, to compare planned hip replacement surgery with 35,000 such operations performed since 1966. Work based on this registry has enabled continuous improvement in the processes of care, favorably influencing lengths of stay, resource use, and the results of care (i.e., delivery of high-value care). The registry has served as a data source for more than 800 academic publications. It has enabled CER and has led to improvements in information systems that facilitate and enhance the continuity of care delivery after surgery.

Mayo Clinic Warfarin Project

The Mayo Clinic Warfarin Project is a third example of conventional, focused clinical research designed to improve the quality of care. This intervention was launched with the goal of reducing warfarin-related overanticoagulation, which is acknowledged to be a leading iatrogenic illness. In 2005, 18,700 inpatients were treated with warfarin at Mayo Clinic. It was determined that 3.5 percent experienced iatrogenic overanticoagulation, with a score greater than 5.0 on the blood coagulation International Normalized Ratio (INR) laboratory test, resulting from in-hospital warfarin administration, and no definitive, published, evidence-based guidelines for administering warfarin in the hospital existed. We recognized that there was considerable variability in risk for iatrogenic overanticoagulation across the five states where Mayo Clinic practices. Therefore, a prospective study was designed to develop a standardized warfarin protocol that would improve outcomes. The goal was to reduce the number of inpatients who had a single recording of an unsafe inpatient INR (greater than 5.0) from 3.5 percent to less than 1.5 percent. This project involved standardized rule-based algorithms supported by the prescriber using computerized provider order entry, with the hospital pharmacist determining the final dose from these algorithms. This work takes advantage of the principle of reflexivity; the prescribing system algorithm was improved dozens of times through the "plan, do, study, act cycle" based on surveillance, performance data, and user feedback. Since implementation of the standardized, rule-based algorithms, consistently fewer than 1.5 percent of Mayo Clinic warfarin inpatients have had an INR above 5.0, and there has been no increase in the proportion of patients with an INR below 1.7 after the third dose. Thus not only was the risk of potential hemorrhage reduced, but also the risk

of clotting was not commensurately increased. This change in practice has significantly reduced the risk of inpatient warfarin-related adverse events.

Transformational Initiatives

The High Value Healthcare Initiative

A learning healthcare system has as its central focus improving the value of care. For many years, Mayo Clinic has maintained an institution-wide emphasis on quality (best clinical outcomes, safety, and service), which has been applied both to the care of individual patients and through population-based strategies to manage chronic disease across communities of patients. Recently, Mayo Clinic has gone beyond its focus on the numerator (quality in terms of best outcomes, safety, and service) of the value equation (e.g., value = quality/cost) to address the denominator (i.e., the cost of care over time). Together with the Dartmouth Institute, Intermountain Healthcare, and the Geisinger Health System, Mayo is proposing a pilot project for the Innovation Center at Centers for Medicare & Medicaid Services (CMS) called the High Value Healthcare Project. This represents the first step in a broad-based initiative that will benchmark the costs of best practices over time, implement evidence-based best practice and patient shared decision-making models, and study new reimbursement models that better align payments with the outcomes of patient care. Together with similar initiatives under way around the country, the High Value Healthcare Initiative is motivating a fundamental transformation of health systems from their traditional focus on compliance with process to a more meaningful focus on results, outcomes, and value.

As famously reported by Balas and Boren (Balas and Boren, 2000), the lag time between the discovery of more efficacious forms of treatment and their incorporation into practice is unacceptably long—about 15–20 years. Moreover, a majority of patients at any given time receive care that is not supported by evidence-based research (Advisory Commission on Consumer Protection and Quality in the Health Care Industry, 1998). Stakeholders across the healthcare system—from patients to practitioners to payers—recognize the need for disruptive change to bring about fundamental improvements in health care. It is becoming increasingly apparent that such change requires new information systems to accelerate discovery, drive clinical research, identify best practices, and diffuse these practices rapidly across the profession.

The Mayo Clinic Enterprise Data Trust

The Mayo Clinic Enterprise Data Trust is an example of a centralized repository system created to manage, integrate, and share collective information resources with appropriate regulatory protections (Figure 2-3). This consolidated infrastructure can, for example, integrate biospecimen-related data generated by research core laboratories with phenotypic data extracted from clinical records through natural language processing techniques, analyze those data to develop improved biomarkers to guide therapy, and provide that information to physicians for use in caring for patients. Data and biospecimens collected during the course of care are fed back into the system to inform and improve the care of future patients. Systems such as this are needed to enable the evolution to a knowledge-driven healthcare delivery system.

Conclusions

The examples discussed above demonstrate how a patient-centered, knowledge-driven healthcare delivery system can serve as a research plat-

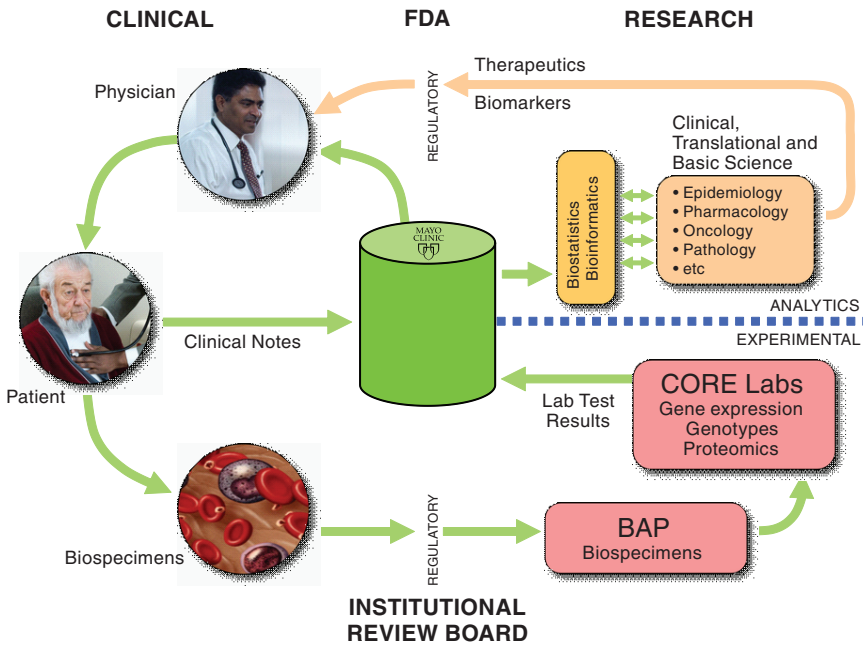

FIGURE 2-3 Schematic of Mayo Clinic Enterprise Data Trust.
SOURCE: Reprinted courtesy of the Mayo Clinic.

form both to improve outcomes for future patients and to identify the most compelling questions for future research. More important than these specific examples, however, are the underlying conceptual model and the set of fundamental principles upon which these (and other) examples are built. Although the specific examples may not be replicable elsewhere, the underlying model and key characteristics are widely translatable and transportable around the country and, indeed, around the world.

Figure 2-4 illustrates a model for a knowledge-driven healthcare delivery system of the future. As shown, knowledge generated from routine clinical settings is integrated with biological information garnered from biospecimen banks and other sources; aggregated and analyzed using sophisticated data warehousing and computational tools; and then used to improve patient outcomes through enhanced clinical practice, business processes, education, and research. The system rests on a foundation of data security and governance, metadata, and terminology standards.

The key characteristics of a knowledge-driven healthcare delivery system are summarized in Box 2-2. Patient-centeredness must be at the core of

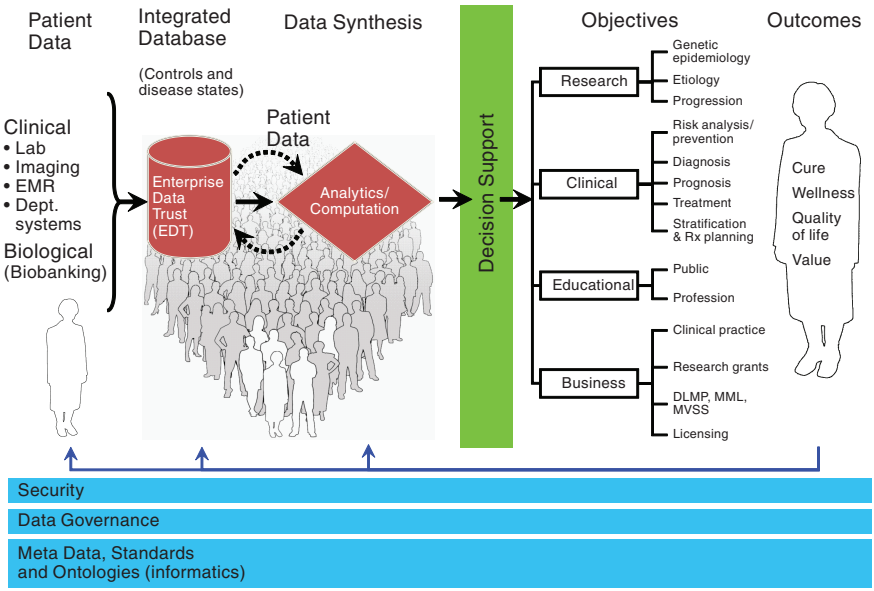

FIGURE 2-4 Model for a knowledge-driven healthcare delivery system. The model focuses on generating and synthesizing knowledge in daily clinical settings to advance research, education, clinical practice, and business operations to improve patient outcomes.
SOURCE: Reprinted courtesy of the Mayo Clinic.

BOX 2-2
Characteristics of the Knowledge-Driven Healthcare Delivery System of the Future

- Patient-centered care—a focus on quality (best results) and coordination of care
- Real-time data and feedback for providers at the point of care (horizon scanning)
- A culture of collaboration, innovation, and translation of scientific knowledge into improved health for patients and communities
- Health information technology systems—integration, standardization, interoperability
- Delivery of high-value health care in an information-enabled single practice

health care. Although patient-centered care is often assumed, it is but by no means universally applied. Providers must design and implement systems to be focused on quality and team-based, integrated, coordinated care centered on the patient. To enable the evolution to a knowledge-driven, learning healthcare delivery system, future HIT systems must have the capability to provide real-time data and real-time feedback to providers at the point of care/point of need. This capability will require scanning disparate internal and external data resources to rapidly find answers to scientific, clinical, and operational questions. HIT systems must also be integrated, standardized, and highly interoperable. Finally, the delivery of high-value care in the information-enabled practice of medicine requires a culture of collaboration, innovation, and translation of scientific knowledge into improved health for patients and communities. Although perfect and complete actualization of the conceptual model for each of the above characteristics may be a long way off, an intense focus on the development of integrated, patient-centered, and knowledge-driven healthcare delivery systems will lead to better health care and better health.

ENHANCING THE CULTURE OF PATIENT CONTRIBUTIONS TO LEARNING IN HEALTH CARE

Diane Simmons and Kenneth Getz, M.B.A.
Center for Information and Study on Clinical Research Participation

How can a durable relationship be built with the millions of past, present, and potential future clinical research study volunteers? A portfolio of strategic initiatives is needed to regain public trust in the clinical research enterprise and establish a culture that welcomes input from patients. Since its founding in 2004, the nonprofit Center for Information and Study on

Clinical Research Participation has developed an effective, multifaceted strategy of outreach and education to improve public understanding of the clinical research process and the important role of participation in advancing medical science. After a discussion of the current culture, this paper presents a number of examples of strategic initiatives for recruiting, retaining, and sustaining a community of study participants who will ultimately become the ambassadors for learning in health care.

Current Culture

During the past decade, public confidence and trust in the clinical research enterprise has eroded steadily (Center for Information and Study on Clinical Research Participation, 2006; HarrisInteractive, 2007; Kaiser Family Foundation, 2008). Distrust of clinical research professionals and of those organizations responsible for ensuring patient safety has increased dramatically. Public polls reveal startling statistics. For example, a 2007 poll among 1,726 U.S. adults found that 27 percent of respondents distrusted the Food and Drug Administration (FDA) "somewhat" or "very strongly." That same poll found that only 31 percent of respondents believed that the FDA is effective at ensuring safety, down from 56 percent who held this belief in 2004 (HarrisInteractive, 2007). Equally alarming, nearly half (46 percent) of the 1,726 Americans polled said they distrusted Capitol Hill officials who govern regulatory oversight and drug development processes (HarrisInteractive, 2007).

Four of ten respondents (42 percent) distrusted pharmaceutical and biotechnology companies. The poll showed that a significantly higher percentage (39 percent) gave poor ratings to pharmaceutical and biotechnology companies for failing to serve consumers as compared with 1997, when 19 percent of Americans surveyed rated pharmaceutical and biotechnology companies on this item poorly (HarrisInteractive, 2007).

Nearly half (44 percent) of the 1,695 American adults polled in a January 2008 survey likewise reported having an unfavorable view of pharmaceutical and biotechnology companies. In that same survey, 27 percent of Americans said they did not trust these companies to offer reliable information about drug side effects and safety. And 45 percent said they did not trust research sponsors to inform the public quickly when safety concerns with a drug are uncovered (Kaiser Family Foundation, 2008).

The public displays similar levels of distrust in principal investigators and their study staff. A self-administered survey conducted among 717 U.S. adults in 2007 found high levels of public distrust in clinical research staff. This level of distrust was significantly higher among minority adults (HarrisInteractive, 2004). Nearly half (49 percent) of white respondents and 73 percent of minority respondents reported that it was "very likely"

or "somewhat likely" that they might be used as guinea pigs without their consent. One of four (25 percent) minority respondents and 22 percent of white respondents believed that their doctors would expose them to unnecessary risk in clinical trials (Braunstein et al., 2008).

The majority of respondents (72 percent) in a 2002 poll said they believed that physicians get involved in clinical research to help patients find new and better treatments (HarrisInteractive, 2002). Still, one of four said they believed that doctors and study staff are motivated to recruit volunteers primarily by money and selfish interests. In a 2005 survey, 25 percent of respondents said they believed physicians participate in clinical research to receive money from pharmaceutical and biotechnology companies, and another 20 percent said that physicians participate primarily for fame, glory, and publication rights (HarrisInteractive, 2005).

By extension, public distrust in clinical research professionals has tainted the public's view of clinical research volunteers. In a 2002 poll, 8 of 10 Americans said they believed that study volunteers are taking a gamble with their health (HarrisInteractive, 2002). A 2006 survey conducted among 900 U.S. adults found that one of four believed people choose to participate in clinical research because they are "very sick without any other options" or they are "looking to make money." A smaller percentage—19 percent—believed that people choose to participate in clinical trials to benefit the public's health. In that same survey, 34 percent of respondents said they "do not admire" people who volunteer for clinical trials (Center for Information and Study on Clinical Research Participation, 2006).

As public appreciation for study volunteers has waned, public willingness to participate in clinical trials has also dropped. Research!America, for example, reported that in 2004, 55 percent of those polled said they would be willing to participate in a clinical trial, down from 63 percent in 2001 (Woolley and Propst, 2005). A later public poll, conducted in 2007, found that only 41 percent of white adults and 28 percent of minority adults would be "very likely" or "likely" to participate in clinical trials (Braunstein et al., 2008).

Investigative sites report that growing levels of public distrust have contributed to delays in bringing new treatments to market and to increased drug development costs. Since 2000, spending on patient recruitment promotional programs by investigative sites and research sponsors has grown by 12 to 14 percent annually, reaching more than $500 million in 2003 (Korieth, 2004). Enrollment rates dropped from 75 percent in 2000 to 59 percent in 2006, and retention rates fell from 69 percent to 48 percent during that same period (Kaitin, 2008).

In an attempt to understand how to improve patient recruitment and retention rates, the Center for Information and Study on Clinical Research Participation conducted focus groups among study volunteers to probe for

factors that most inform and educate clinical research participants. This research was conducted in 2009 at Piedmont Medical Group in North Carolina. In these focus groups, participants emphasized the essential role of study staff and healthcare professionals in volunteer recruitment and retention. They consistently described relationships with study staff as tough but fair, disciplined but supportive. At a time when recruitment and retention strategies and tactics tend to marginalize the role of study staff and trusted healthcare professionals, the results of these focus groups strongly suggest the need to engage these professionals more effectively as real assets in the clinical trial process.

The focus group participants revealed core motivations of all study volunteers regardless of age and socioeconomic status. These motivations can serve as a blueprint for patient and public education and outreach. Study volunteers

- want to feel that they are taking control of their medical condition and well-being,
- want to develop personal relationships with study staff,
- want to be treated as human beings, and
- want to know that their participation will make a difference.

Participating in medical research as a way to steer personal and public health reinforces the drive toward patient-centered health care. Yet the focus groups clarified that "patient-centered" does not mean that they want medical autonomy. Despite common expressions such as "take control," study participants from the focus groups explained that they do not seek total independence in their efforts to improve their well-being. The prospect of being accountable to the research coordinator spurred and sustained volunteers' interest in trials. In fact, the volunteer–study staff relationship forms and solidifies at several critical junctures. When research sites reach out to potential volunteers with the right messages and modes of communication at decisive moments and invite them to begin conversations, the relationship grows into a lasting commitment to the center and its staff.

The focus group participants' comments show that money-focused recruitment campaigns and comparisons of research volunteers to "guinea pigs" or "lab rats" depersonalize the trial experience and keep the volunteers from feeling as though they are truly part of an extended research team. Typical perceptions of clinical research participation must shift before people can take part proudly and comfortably in a research community. The emphasis on monetary compensation in media and recruitment rhetoric impedes public and participant recognition that volunteers are part of a vital exchange in which they are compensated for sacrificing their time, effort, and even physical welfare.

To be effective, the education provided before and after trials must reflect what volunteers expect, need, and want to know about clinical research. The public's primary source for education about the clinical research enterprise is the media, which tend to focus on sensationalistic accounts of human error, concealment, fraud, and corruption. More than two-thirds (69 percent) of Americans are exposed to information on clinical research studies through television, radio, print media, and Internet advertising. Only one of seven adult Americans is exposed to information about clinical research studies from a primary or specialty care physician (HarrisInteractive, 2004). Although the public has the greatest trust in information from healthcare providers, the medical and health professional communities are largely absent from efforts to educate the public and prospective volunteer communities. In a recent survey conducted among board-certified physicians in active community practices throughout the United States, fewer than half reported referring their patients to clinical trials, with an average referral rate for each physician of less than one patient per year (Getz and Faden, 2008).

Without broad understanding and context, recruitment advertising and promotional messages are met with, at best, passing curiosity from the public and prospective volunteers. Only 20 percent of those diagnosed with severe and life-threatening illnesses report considering clinical trials as a healthcare option (HarrisInteractive, 2004). Despite a wealth of online information available, less than 5 percent of the general public knows where to find information about relevant clinical trials (Getz, 2004). And the public is largely unaware of where clinical research is taking place. A 2005 public poll found that 62 percent of respondents were unable to name a single institution, company, or organization where medical and health research is conducted (Woolley and Propst, 2005). Research sponsors rarely, if ever, respond to media coverage, as government and corporate employees are usually instructed not to interact with journalists for fear of bringing more attention to a story or of appearing defensive and self-serving. As a result, the public is receiving a largely one-sided education in the clinical trials industry from the media.

Outreach Initiatives and Their Impact

If the public is to be engaged, the stage must be set with a national public education media campaign. The Center for Information and Study on Clinical Research Participation developed a public service campaign, with pro bono support from the international advertising agency Ogilvy HealthWorld, to educate and win over the public regarding the importance of participation in clinical research. During the campaign's yearlong development process and extensive focus group testing, strong support was expressed for the easy-to-remember messaging and acknowledgment of or-

dinary people's contributions to public health. During screenings before test audiences, the ads were lauded for their "humanity and emotional appeal." Viewers declared, "These people are heroes in their own way," "They've done something great for all of us," and "I see the benefit of clinical research to society."

This "Medical Heroes" public service campaign was market tested in 30 sites across 18 U.S. markets by Eli Lilly and Company. In the first wave of the market test, the control group was established as 12 markets that ran their typical recruitment ads; in 6 comparable markets, concurrent "Medical Heroes" ads were run, as well as recruitment ads, and these markets showed a 38 percent increase in patient recruitment rates relative to the control group. The test was repeated, and the results of the second wave showed that rates of response to recruitment ads more than doubled in the markets where the "Medical Heroes" campaign was run. The campaign met its ultimate goal of providing the public with increased awareness of research participation and an improved perception of clinical research volunteers.

Another Center for Information and Study on Clinical Research Participation initiative is a grassroots education and outreach process known as "AWARE for All-Clinical Research Education." AWARE programs, held in major cities across the United States, bring together disease advocacy groups, hospitals and healthcare organizations, educational institutions, and community organizations to provide AWARE's message directly to their constituents. In addition, distinguished local politicians and opinion leaders, physicians, healthcare providers, and clinical research professionals serve as keynote speakers and workshop leaders—all volunteering their time to help educate the public.

To date, more than 300,000 people have been impacted by the program. AWARE has put a human face on the people who volunteer for clinical trials while building public understanding of the risks and benefits of participating. The initiative is creating a movement at the local level, and there is a need to bring this form of outreach to many more communities. When asked whether they were more or less likely to participate in a clinical trial after attending AWARE, 75 percent of attendees responded "more likely."

An additional example of an outreach initiative is post-trial communication with research volunteers. The Center for Information and Study on Clinical Research Participation and Pfizer collaborated to test a new process for routinely communicating clinical trial results to study volunteers after their participation has ended. Between June and December 2009, trial results for Celebrex®/Celecoxib and Sutent®/Sunitinib were translated into lay language by a team of consumer, science, and medical writers and published in print, web, and audio formats. These summaries were then tested

in focus groups among volunteers who had participated in the studies. The pilot study results demonstrate that a process for preparing and disseminating summaries of trial results to patients following their participation in clinical trials is feasible. Moreover, patients reacted very positively to the variety of formats and showed marked improvement in their comprehension of their clinical trial findings. Study personnel are also very receptive to disseminating summaries of trial results to their volunteers.

A final example of a public education and outreach initiative is the development of a traveling exhibit for science museums. Still in the preliminary planning stages, such an exhibit would provide inquiry-based, multimedia learning experiences focused on the how-to and importance of health research as presented by practicing scientists. It would use an innovative mix of video storytelling and digital support technologies to show people how real-world scientists conduct their research and create a continuum from basic to translational science to clinical trials that produce new treatments and solutions. This type of exhibit would highlight what it means to participate in a clinical trial and the impact of participation on science and drug discovery.

Conclusions

Despite low levels of trust and confidence today, there is no evidence to suggest that the public will abandon the clinical research enterprise outright. A foundation of general public support exists on which to rebuild public confidence and trust through education and outreach initiatives. Such initiatives need to focus on improving public awareness and appreciation of the study volunteer and the value of clinical research to the public health; repairing the credibility of research sponsors, study staff, and regulatory and human subject protection professionals; and engaging the public as partners in the development of new medical and health advances. Given how far public support has fallen, however, there is no time to waste in repairing and rebuilding trust and confidence.

To enhance the culture of patient contributions to learning in health care, a portfolio of strategic initiatives is needed, as shown in Figure 2-5. If general education about and awareness of the clinical research process are enhanced and if patients are enabled to participate because of the support network and tools provided to help them become active participants in clinical trials, recruitment and retention in trials will improve. With this solid foundation, volunteers will become a community of participants and ultimately the ambassadors of a process that advances medical science and improves the public health.

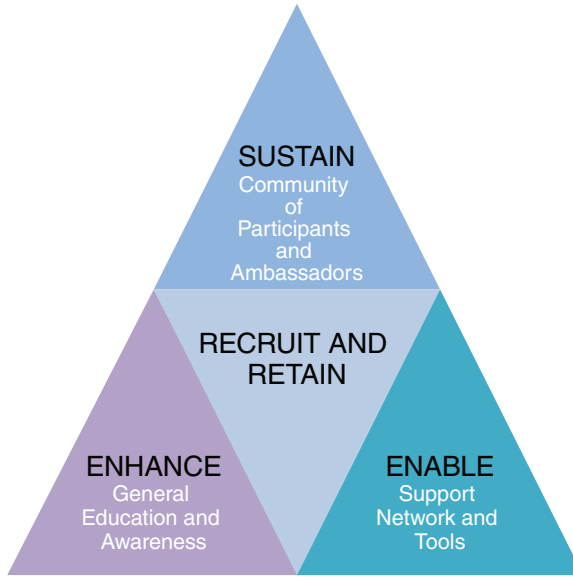

FIGURE 2-5 Model for enhancing the culture of patient contributions to learning in health care. A portfolio of strategic initiatives is needed that enhances the public's general education about and awareness of the clinical research process and enables patients to become active participants in clinical trials. This foundation will lead to improvements in patient recruitment and retention and ultimately to the formation of a community of research volunteers.
SOURCE: Center for Information and Study on Clinical Research Participation model—permission for use in this publication authorized by Diane Simmons, President and CEO.

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3

Clinical Data as a Public Good for Discovery

INTRODUCTION

Clinical data have immense potential to drive progress in health care by providing the means to measure and track care processes and outcomes, to develop and refine best practices, and to enable rapid discovery and innovation. Over the past decade, the amount of data captured in electronic form has increased exponentially. Given the federal government's encouragement of the adoption of electronic health records (EHRs), these data will increasingly be augmented by clinically rich course-of-care data. With the potential to be easily stored, aggregated, and shared, these data can enable rapid learning and continuous improvement in the efficiency and effectiveness of care practices (Blumenthal, 2010; IOM, 2007). Harnessing the power of these data, however, will require efforts to address barriers to their access and use.

The papers in this chapter explore the potential of clinical data to improve research and health care, strategies to enhance access to health data and information, and key challenges to ensure data integrity (e.g., privacy, security, and proprietary concerns). Additionally, this chapter discusses opportunities to better inform and engage patients and the public as advocates.

The first paper, by Farzad Mostashari of the Office of the National Coordinator for Health Information Technology (ONC), argues that as the nation works to develop a unified health information technology (HIT) infrastructure, efforts will be needed to identify a limited set of core data that can meet the basic needs of multiple functions. As ONC continues its efforts to encourage and support data capture and use, it is considering how

to create data requirements that are relevant and not burdensome, how to reward patients and providers for the creation and documentation of structured data, and the merits of distributed versus centralized approaches to information exchange.

Todd Park of the Department of Health and Human Services (HHS) highlights the significant amount of data currently held by the various agencies of HHS and how these data could improve the value, science base, and patient experience of health care. He describes HHS's efforts to open access to high-value data sets and to encourage public participation in the use of these data for socially beneficial purposes.

The quality and accuracy of research results depend on the availability and integrity of data. Don Detmer of the University of Virginia discusses opportunities to increase the quantity and quality of data for health care and research. To achieve this end, he proposes several options for national policy that address security and privacy concerns while empowering citizens to allow their health data to be used for learning and discovery.

INFORMATION NEEDS FOR A LEARNING HEALTH SYSTEM

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Office of the National Coordinator for Health Information Technology

The mission and goal of the Office of the National Coordinator for Health Information Technology is to improve health and health care for all Americans through the appropriate use of HIT. ONC is therefore focused on characterizing key system needs and outcomes in addition to determining how technology can be a means to that end.

Meaningful Use and a Learning Healthcare System

"Meaningful use" is the term coined by Congress to connect technology to desired outcomes, and ONC's proposed regulations represent our best guess as to how technology should be used to achieve these outcomes. If providers—eligible professionals or hospitals—use HIT systems in a meaningful way, they will be able to qualify for payments from CMS.

It is our goal, however, that meaningful use be applied for more than just qualifying for payments. Rather, it should be used to ensure that measurable improvements are made in health and in the quality, safety, and efficiency of health care. A secondary goal is to move beyond improving care for an individual patient at the point of care to creating a learning healthcare system. This is an outcome to which ONC aspires and a worthy endpoint toward which to build.

The next decade will witness a fundamental transformation of the

healthcare delivery system, including changes that in many ways will be more profound than those that transpired during the previous decades of American medicine. HIT will certainly help providers take better care of patients, but there is also the prospect that, in the aggregate, electronic health systems will contribute to a learning healthcare system and enable providers to understand and influence healthcare improvement—whether in public health, quality improvement, drug discovery, or clinical effectiveness research. The HIT infrastructure of the future should not just be the eyes and ears but also be the action arm of population health.

Key Considerations for Developing a National Unified HIT Infrastructure

A number of projects now under way focus on developing HIT infrastructure for many different functions, including clinical effectiveness research, drug discovery, quality measurement, and public health surveillance. Because these projects are taking different approaches and building different architectures, it is temping to call for a halt to work on these siloed activities. Indeed, if investment in HIT continues to create and support a multitude of data islands, the nation will not achieve a unified HIT infrastructure.

This is the critical challenge faced by ONC in its work to implement a national system, to define meaningful use, and to develop grant programs: How can we work to develop a common, national HIT infrastructure while not creating additional network and system silos? Because projects now under way will not be put on hold, this is a critical time to bring key stakeholders and HHS together to begin a discussion on laying the groundwork for a unified HIT infrastructure.

Clinical Data Needs and the 80/20 Rule

One approach to clarifying key data needs for a learning health system is to agree on a core data set—sufficient, if not perfect, for a number of information needs. Known as the 80/20 rule, this approach advocates starting with something simple that can be achieved now and developing clever approaches over time. The American Recovery and Reinvestment Act (ARRA) presented a significant opportunity for HIT in this respect, as it gave patients a right to their records in electronic format. Even if only a small fraction of the patients in any given system choose to exercise this right, every healthcare provider and EHR vendor must produce a patient summary document in a common format. This could be a key opportunity to use the clinical care summary—which includes the medications list, the problem list, the allergies, the lab values, and the patient encounters—as

the foundational 80 percent, the common data core on which to build a unified HIT infrastructure.

As data users have a wide variety of needs and will require additional information based on these needs, some users are likely to believe that starting with the clinical care summary is inadequate. For quality reporting, for example, detailed information with which to calculate exclusions may be needed; for public health case reporting, information on whether a certain infection was central line associated may be required; for drug safety, the first date of prescribing of the medication may be needed. Although this may be true in each instance, the nation will never achieve a unified HIT infrastructure if the starting point is to identify a data set that is perfect for each user. An alternative approach is to leverage the 80/20 rule and supplement it with targeted additional data collection where needed.

Creating Infrastructure for Targeted Data Collection

The example of clinical trials recruitment at a storefront doctor's office illustrates this approach. One cannot expect a provider to use an EHR in the routine delivery of care while also collecting all the information needed to determine patient eligibility for a multitude of clinical trials. As one example, an individual's occupation may be a data element necessary to determine eligibility for a clinical trial. Although those with an interest in this information may think that requiring it as a data element should be elementary, a provider's front-office staff is not going to determine and select each patient's occupation from among the hundreds of potential Census Bureau categories as a routine part of delivering care.

A more feasible approach would be to collect a limited amount of information in the routine delivery of care, which could also serve as an opportunity to screen for the need for additional data collection. Instead of asking each provider to record each patient's occupation and expecting these data to be collected in a structured form, a system could be developed to trigger deeper data collection when appropriate (i.e., manual rather than routine data collection on a small subset of patients). If a patient is diagnosed with hepatitis A, for example, it is entirely appropriate to prompt the clinician to inquire about the patient's occupation—specifically, whether the patient is a healthcare worker, daycare worker, or food worker. This type of approach makes sense to providers, as the information requested is relevant to the person's care and is limited in scope. For clinical trials, minimal information can also serve as an initial screen, with follow-up questions about trial participation asked only as appropriate.

This example clearly illustrates that despite the broad data needs of a learning health system, the nation should start with something simple—perhaps the humble clinical care summary. Additional work could expand

on this data core to create infrastructure that supports additional and targeted data collection only as needed.

Adding Value for Providers and Patients

To ensure data quality, it is also important to consider the value proposition for data capture and use. The provider is doing work that involves both the care of the patient and the creation and documentation of the structured data needed for other purposes. A business case needs to be made to ensure that the latter work is done well. For recruitment of clinical trial participants, for example, it would be beneficial for all if recruiting appropriate patients for trials was not just the right thing to do, but also a source of income for the primary care provider. As the owner of the data, this notion extends to the patient as well. Perhaps patients should also benefit financially from the use of their health information.

Choosing the Best Approach for Critical Infrastructure

ONC continues to identify the key principles that should underlie the creation of a national HIT infrastructure and develop supporting policies and incentives. A particularly important principle to consider as we work toward achieving our goals is to use a distributed rather than centralized infrastructure. Although a centralized infrastructure works well for some purposes, it is not particularly effective for supporting the participation of individual physicians in advancing a wide range of population health missions.

A centralized infrastructure requires separation of the data producer from the data, centralization of the data, and central analysis. In today's fragmented and heterogeneous system, this approach typically does not yield the answers people expect in a timely way. The costs are always higher, the points of failure are always greater, the system is more fragile, and the quality and cost of cleaning the data (once separated from the source) become prohibitive. My view is that a decentralized system whereby the questions go out to the data and the answers come back is a much more resilient, feasible, cost-effective, and privacy-protective approach.

Part of ONC's mission is to think about how such distributed queries can be expressed in a standardized way. Again, the 80/20 rule can be applied to these issues—whether to develop a standardized data model across spheres of activity or a standardized way of expressing the question or receiving responses. Formulating a strategy across fields, whether public health surveillance, quality measurement, or effectiveness research, will require simple case definitions tailored to the needs of the field—perhaps

one case definition for public health, two (numerator and denominator and maybe exclusions) for quality reporting, and four (i.e., a 2 × 2 table) for much of clinical effectiveness research and drug discovery.

Next Steps

Throughout its work, ONC needs to consider opportunities to streamline data needs and create limited but multifunctional shared elements of a unified HIT infrastructure. These actions can include identification of overriding policies and principles, such as those discussed above ("architecture"); establishment of basic, shared infrastructure (standards, services, directories, terminologies, value sets); development and deployment of common tools (e.g., CONNECT, National Health Information Network [NHIN] Direct, popHealth); demonstrations (e.g., Beacon Community Program); research (e.g., the Safety and Health Achievement Recognition Program [SHARP]); and coordination across federal agencies. ONC looks forward to receiving the input of all stakeholders and to making progress on these critical issues. How much progress the nation will make depends on our collective ability to start simple and work together.

OPENING ACCESS TO HIGH-VALUE DATA SETS

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Across many industries, opening access to and encouraging the use of quality data has driven dramatic innovation and performance improvement. Recognition of data's transformative potential is reflected in the Open Government initiative launched by the Obama Administration in 2009, which seeks to enhance the efficiency and effectiveness of the public sector through improved transparency, public participation, and collaboration. The vast stores of data captured by HHS agencies, for example, are an important national resource for enhancing the value, science base, and patient experience of health care. The creation within HHS of the position of Chief Technology Officer—whose mission is to leverage the power of data, technology, and innovation to improve health—and the development of an HHS Open Government Plan signal HHS's commitment to the principles of open government and to playing a catalytic role in the development of a learning health system.

Open Government

Fostering the development of open government is an important means of improving government efficiency and effectiveness and ensuring public trust, and is an ongoing priority of the Obama Administration. Almost immediately following his inauguration, the President issued a memorandum to heads of Executive departments and agencies outlining key principles of open government—transparency, public participation, and collaboration.[1]

- *Transparency* means publishing data with the intent of improving government accountability and enabling citizens to access and use data in ways that are socially beneficial.
- *Public participation* means welcoming and accessing widely dispersed national interests and expertise to help the government better accomplish its mission of improving the well-being of the American people.
- *Collaboration* means the federal government will work effectively across agencies; with state and local governments; and with others outside of government, such as nonprofits, advocacy organizations, business, and academia.

Collectively these principles reflect the reality that the challenges and opportunities facing the United States are so complex that no one organization, regardless of how capable, ingenious, or well funded, can possibly address them alone. Instead, efforts are needed to improve the availability of data; to engage a broad spectrum of talent and expertise in the use of these data; and to support the work, across all sectors, needed for meaningful progress.

A Presidential memorandum led to an Open Government Directive issued by the Office of Management and Budget (OMB),[2] which required all federal departments and agencies to take steps to better support and implement these principles. Key opportunities outlined by the directive include publishing government information online, improving the quality of government information, creating and institutionalizing a culture of open government, and establishing an enabling policy framework for open government.

In response to the OMB directive, HHS developed an Open Government Plan, which outlines immediate opportunities to improve access to data and to provide a means for their use in accomplishing HHS's mission

[1] See http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment/ (accessed October 11, 2010).

[2] See http://www.whitehouse.gov/sites/default/files/microsites/ogi-directive.pdf (accessed October 11, 2010).

more effectively. The plan represents a sharp break from past approaches to HHS data and is an initial step toward better leveraging these data to accomplish the following objectives: "to help citizens understand what (HHS) does and hold (HHS) accountable; help the public hold the private sector accountable; increase awareness of health and human services issues; generate insights into how to improve health and well-being; spark public and private sector innovation and action; and provide the basis for new products and services that can benefit the American people" (HHS, 2010).

Key elements of the plan are summarized in Box 3-1. Of particular note are 14 new data sets and three tools that will be released by the end of 2010.[3] These new resources are considered "high value" because they can be used to "increase agency accountability and responsiveness, improve public knowledge of the agency and its operations, further the core mission of the agency, create economic opportunity, or respond to need and demand as identified through public consultation" (HHS, 2010). The plan also includes five Flagship Initiatives: the Centers for Medicare & Medicaid Services (CMS) Dashboard; the Food and Drug Administration (FDA) Transparency Initiative; FDA Transparency, Results, Accountability, Credibility, and Knowledge-Sharing; Freedom of Information Act Excellence; and the Community Health Data Initiative.

From Open Government to a Learning Healthcare System

Open government is a paradigm for how HHS can help catalyze a learning health system. HHS has a fiscal year 2010 budget of $840 billion and comprises 27 agencies and offices—including Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention, CMS, FDA, and National Institutes of Health (NIH). It has assembled vast stores of data that have the power to yield insights into how to improve health. These data stores would be a tremendous public good even if HHS were to invent nothing new and simply make these data more accessible. Yet more is needed to catalyze and foster the development of a national learning healthcare system. In essence, publishing data is necessary, but insufficient, to drive the transformative change needed without support for data use and improvement.

Developing a Data Ecosystem

Developing a system that encourages access to and use of healthcare data will make available important information and guidance for patients, clinicians, and many other health system stakeholders. Perhaps most impor-

[3] As of April 2010, HHS has 117 data sets and tools posted on Data.gov.

BOX 3-1
HHS Open Government Plan

Key elements (**Flagship Initiatives indicated in bold**):

- A multi-faceted new transparency push by the Centers for Medicare & Medicaid Services (CMS) in 2010:
  - — A new interactive "**CMS Dashboard**," debuting in beta mode with the launch of this Open Government Plan, which allows the public to visualize and analyze Medicare spending with unprecedented ease and clarity—starting with inpatient hospital spending. You can visit the Dashboard at http://www.cms.gov/Dashboard/
  - — Creation of 9 Medicare claim "basic files," one for each major category of healthcare service, to be released from September to December 2010 for free public download on Data.gov. These files will contain a limited number of variables and be de-identified and configured through a rigorous process, in close consultation with privacy experts, re-identification experts, researchers, and key stakeholders, to ensure the protection of beneficiary privacy and confidentiality
  - — A significantly improved user interface and analytical tool for viewing existing CMS COMPARE data on quality performance of hospitals, nursing homes, home health agencies, and dialysis centers. This interface and tool is debuting at http://data.medicare.gov with the launch of the Open Government Plan
  - — Online publication of detailed Medicaid State Plan documents and amendments on the CMS website by 2011
  - — The release of new national, state, regional, and potentially county-level data on Medicare prevalence of disease, quality, costs, and service utilization, never previously published, as part of HHS's Community Health Data Initiative by the end of 2010
- A **Food and Drug Administration (FDA) Transparency Initiative** is being formulated with extensive public input, and focused on (1) providing the public with information regarding how FDA works, (2) proactive disclosure of useful, nonproprietary information in the possession of the agency, and (3) ways in which FDA can become more transparent to regulated industry. FDA is also launching **FDA-TRACK** (**T**ransparency, **R**esults, **A**ccountability, **C**redibility, and **K**nowledge-Sharing), a new agency-wide performance management system, which debuts in beta mode with the launch of the Open Government Plan. FDA-TRACK, when fully implemented, will allow the public to monitor more than 300 performance measures and 80 key projects across 90+ FDA program offices on an ongoing basis
- Other new data sets and tools to be published from across HHS
- Implementation of a new process for the proactive identification, prioritization, publication, and monitoring of data releases—to be coordinated overall by HHS's Data Council. This process will include an "HHS Apps Challenge"—a public competition for the best applications built utilizing our data

continued

BOX 3-1 Continued

- A major push to assess current HHS operations in support of the Freedom of Information Act (FOIA), identify and prioritize improvement opportunities, and define a roadmap to implement the improvements **[FOIA Excellence]**
- Expanded opportunities for public participation in HHS activities and for collaboration across HHS and with the world outside HHS—especially via the use of new information and communications technologies. Through a new HHS "Community of Practice" for Participation and Collaboration, Open Government innovators at HHS will be able to network with each other, share learnings and best practices, compile these best practices into an HHS "workplace menu" of participation and collaboration tools, compare the efficacy of different approaches, and work together on common issues. The Community of Practice will focus in particular on the advancement of innovative mechanisms for participation and collaboration at HHS—mechanisms that apply blogging, "crowdsourcing," group collaboration, idea generation, mobile, and on-line challenge capabilities to key HHS activities:
  - — Medical research collaborations—e.g., via the application of "crowdsourcing" and innovative patient engagement approaches to research on diabetes and women's health issues
  - — Collaboration among HHS employees—e.g., via work by the Office of the Assistant Secretary for Planning and Evaluation to research and pilot advanced collaboration tools
  - — Better health care through better information—e.g., via the community-driven, highly collaborative
  - — "Nationwide Health Information Network–Direct" initiative being pursued by the Office of the National Coordinator for Health Information Technology

tant, ongoing data use will drive improvements in data quality and applicability. HHS therefore seeks to catalyze the development of an ecosystem of data by stimulating both data supply and use.

Building on the foundation provided by increased availability of data, HHS will encourage public participation and collaboration by engaging in an ongoing dialogue with potential users of the data. Through such communication, HHS seeks to catalyze learning by advancing understanding of what types of data could be useful, the limitations of currently available data, and means of better supporting data use. This approach is best illustrated by the Community Health Data Initiative, which seeks to help Americans better understand and take action to improve healthcare performance in their communities. The initiative's initial short-term goal is to build a network of data suppliers and users. In the longer term, this network will

— Innovation in the workplace—e.g., via the piloting of an online employee idea-generation tool and challenge program by the CMS

- **Community Health Data Initiative.** A major new public–private effort whose goal is help Americans understand health and healthcare performance in their communities relative to others—and to help spark and facilitate action to improve performance. As a core enabler of this initiative, HHS will be providing to the public, free of charge and any intellectual property constraint, a large-scale Community Health Data Set harvested from across HHS—a wealth of easily accessible, downloadable data on public health and health care performance across communities, including a major contribution of Medicare-related data from CMS (i.e., prevalence of disease, quality, cost, and service utilization data at the national, state, regional, and potentially county levels). The initiative is simultaneously working with a growing array of technology companies, researchers, health advocates, consumer advocates, employers, providers, media, etc. to identify and deploy uses of the data that would be most effective at

  1. Raising awareness of community health performance,
  2. Increasing pressure on decision makers to improve performance, and
  3. Helping to facilitate and inform improvement efforts.

  Such applications and programs could include interactive health maps, competitions, social networking games that educate people about community health, enhanced web search results for health searches, etc. By leveraging the power of transparency, participation, and collaboration, the Community Health Data Initiative seeks to significantly improve the health of our communities.

develop into a community health data ecosystem in which a broad array of users take data supplied by HHS and others and develop means for their display or application in ways that drive continuous improvement in the health of communities across the United States (Figure 3-1).

HHS tested the potential of such a data ecosystem at a workshop, convened with the help of the Institute of Medicine (IOM) on March 11, 2010, featuring leaders from two largely separate worlds—healthcare and information technology applications. About 40 individuals with deep expertise in either healthcare data or how to use data to change people's lives came together at this meeting, and an amazing thing happened. The information technologists became excited about data already captured by HHS and began a conversation with healthcare experts in a burst of creativity. By the end of the day, ideas had been developed for 19 new applications

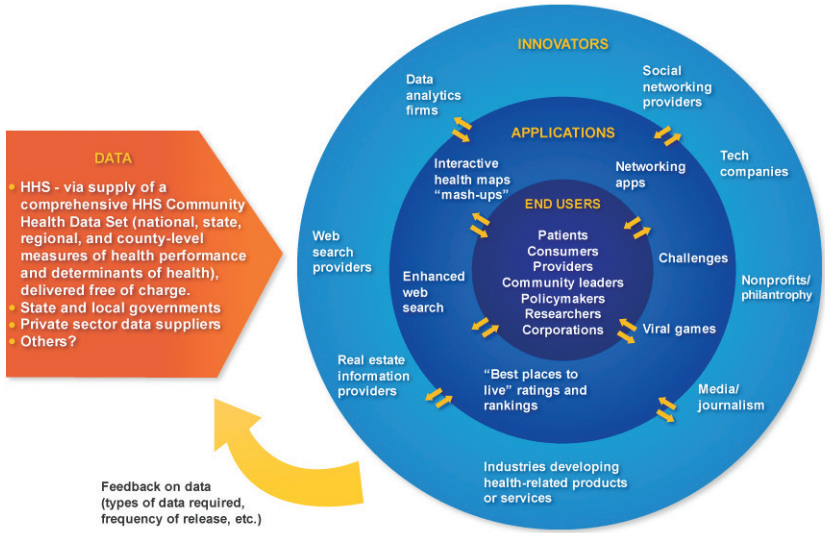

FIGURE 3-1 Design framework for HHS's Community Health Data Initiative. This initiative is a public–private effort to catalyze the development of a network of community health data suppliers (beginning with HHS) and data "appliers" who will use these data to create a variety of applications aimed at raising awareness of and improving performance on community health issues.
SOURCE: HHS, 2010.

that could help monitor and drive improvements in community health—all of which were plausible and doable in 2010. Participants formed volunteer teams to develop 11 of these applications.

New Data Applications for a Learning Healthcare System

A sample of the proposed applications is presented in Box 3-2. They range from interactive health maps, to means of improving public understanding of national health issues, to community health dashboards that can aid city or county officials in identifying key regional health issues and communicating about these issues with the public.

One application, for example, based on a real estate website that displays school system performance metrics as part of a property's description, would also include health performance data in home listings. This application alone would probably educate more people about health performance than would be possible with any health-focused interactive map, because the number of people who would seek out such a map is dwarfed by the

BOX 3-2
Selected Examples of Community Health Data Initiative (CHDI) Applications

Palantir—Palantir has integrated several of the CHDI data sets with other publicly and privately available data sets to allow program administrators and other analysts to make data-driven resource allocation decisions. Nontechnical users can identify where at-risk populations are distributed geospatially, determine their demand for services, and evaluate the current supply of services versus this demand. Current providers and government programs in the region can be analyzed to aid the analyst in taking action.

Microsoft Bing—Bing, the decision engine from Microsoft, represents a new generation of search. Finding health information is a mainstream online activity and 60% of people start with a search engine. Unfortunately, 41% of people state that health information found online had no impact on their decisions. Using community health data, Bing has created new features that allow easier selection of hospitals based on patient quality of care ratings and new ways to assess potential areas to live based on a combination of community health measures and access to goods and services.

The Network of Care for Healthy Communities (*Trilogy and Health Communities Institute*)—Trilogy Integrated Resources and Healthy Communities Institute's system highlights how existing applications will be able to enable community change. The existing application is a local web portal that brings national, state, and local information to families and policy makers, relative to decisions about health. The site integrates multiple data sources into a Community Dashboard with health and quality of life indicators. The constantly updated dashboard visually presents CHDI and other quality of life data (roughly 150 indicators for a community) and then compares it to other counties via the County Rankings project data as well as allows mapping through a live GIS system from Health Landscape. It also tracks progress toward Healthy People 2010 Goals and automatically ties in "best practice" information from around the nation showing how other communities have tackled similar problems and made positive change in their community.

Asthmapolis: Remote Asthma Monitoring and Collaborative Community Surveillance—Every day, millions of people with asthma use rescue inhalers, inadvertently indicating how well their disease is managed. Knowing when and where these symptoms occur can reveal valuable clues about environmental exposures that trigger asthma. But until now, there has been no way to accurately collect this information. We created a device called the Spiroscout, which uses the global positioning system (GPS) to track inhaler use, automatically capturing the time and geographic location of symptoms. We've also developed web and mobile phone applications so that patients and physicians can monitor asthma in daily life, take steps to control the disease, and prevent costly exacerbations. By aggregating this anonymous, crowdsourced data about asthma, we can improve

continued

BOX 3-2 Continued

management and understanding of the disease. Asthmapolis provides people with the latest information about asthma in their communities, and helps scientists and public health agencies target interventions designed to reduce the burden of asthma.

Reach for the Top: Improving Health, Healthcare Delivery, and Cost of Care in Your Community—Reach for the Top is a collaborative, community-based initiative in initial planning stages with support from the Institute for Healthcare Improvement (IHI) and Ingenix. Reach for the Top uses data to provoke communities to improve across three dimensions of care: the health of the population, the individual experience of care, and the cost of care. First, communities will be able to access information from a variety of sources, including both commercial and government data, to gain an understanding of their current status in each of these three dimensions. They will then be able to monitor their improvement as they work to move to the top tenth percentile of each metric. By seeing how their metrics compare to those of other communities, participating communities will be able to seek out top performers and learn from each other. Reach for the Top metrics will expand as more data become available.

Google—To highlight the value of HHS's Hospital Compare database, public data were imported into Google Fusion Tables so that they can be easily explored and visualized by anyone who wants to ask questions or tell a story about them. Hospitals can be ordered in a given geography by 30-day heart attack mortality, how well they do with pain control, or a combination of these and other measures. The data can be viewed in a table, a graph, or on a map. Most importantly, we can collaborate with others, combine this data with other data, and easily share a given visualization as a link or embed it in a blog or other publication. We expect that more data transparency and tools to explore data will result in a virtuous cycle of better healthcare decisions, new hypotheses, and innovations that will transform health in ways we can't yet imagine.

Community Clash: Healthiest city wins. You play the cards. (*MeYou Health—a Healthways company*)—Community Clash is an online card game that engages you in a discovery of your community's health and well-being status and how it compares to other communities in a head-to-head clash. A mash-up of community health indicators, the Gallup-Healthways Well-Being Index and the Healthways Well-Being Assessment, Community Clash lets you pick community indicators you believe give you an edge in the head-to-head game play. Play endless hands, exploring different metrics and locations each time, and share key victories with your social network. After a hand is played, the experience is brought alive with Twitter conversations, filtered by the metric being explored. Finally, Community Clash gets personal, prompting each player to compute his or her own Well-Being Score and encouraging social comparison with friends through Facebook integration. The Community Clash user experience can be enriched in the future by expanding the deck of playing cards to incorporate additional community indicators.

SCVNGR—SCVNGR is an interactive mobile game all about going places, doing challenges, and earning points. This location-based mobile gaming platform helps individuals and communities better understand the relationship between environment, lifestyle choices, and health. The game begins when players check in to rediscover their city and find places where health happens. The "Presidential Trek" will engage players in behavioral health challenges where they can compete with others, create new challenges, earn points and badges, and share their achievements with friends. SCVNGR uses mobile gaming to bridge the gap between information and real-world action. To play in DC after June 2, download the SCVNGR app from the App Store or Android Market. Once in the app, select the Treks Tab and search for PRESIDENTIAL.

Community Health Map—HHS keeps track of a variety of healthcare indicators across the country, resulting in a large geospatially multivariate data set. Community Health Map is a web application that enables users to visualize and analyze healthcare data in multivariate space as well as geospatially. It is designed to aid exploration of this huge data repository and deliver deep insights for policy makers, journalists, and researchers. Users can visualize the geospatial distribution of a given variable on an interactive map, and compare variables using charts and tables. By employing dynamic query filters, visualizations can be narrowed down to specific ranges and regions. The Community Health Map provides a comprehensible and powerful interface for policy makers to visualize healthcare quality, public health outcomes, and access to care in order to help them make informed decisions about health policy.

iTriage—i Triage is a mobile and web-based healthcare platform helping consumers make better healthcare decisions. As a free app for iPhone, Android, Blackberry, and all other Web-enabled devices, iTriage helps consumers process symptoms, explore possible causes, identify the proper level of care and locate the most appropriate treatment facility. iTriage has now integrated more than 7,000 federally-qualified community health centers (FQHC) from the government dataset into its provider database. This helps individuals find the Health Resources and Services Administration (HRSA) centers appropriate for their condition, using GPS. Giving consumers a tool like iTriage empowers Americans to better understand the healthcare system in their communities. By doing this, iTriage changes consumer behavior to reduce unnecessary emergency room (ER) visits, and helps people to find the appropriate level of care, while facilitating a more efficient healthcare delivery system.

GE Healthymagination—GE's Healthymagination is committed to creating better health for more people by improving the quality of, increasing the access to, and reducing the cost of health care. The world has access to increasing amounts of valuable health data, but the data are frequently complicated or better understood in context. Using advanced data visualization techniques, GE is simplifying

continued

BOX 3-2 Continued

complexity and revealing new insights about important healthcare issues. For example, The County Health Map, created by Ben Fry, allows users to explore County Health Rankings data using key indicators. The resulting maps unveil hot spots and highlight the factors that influence the health of a community. The maps are designed to allow users to see both broad U.S. patterns as well as individual county metrics.

Pillbox—Pillbox, from the National Library of Medicine (NLM) and FDA, has transformed FDA's drug label data into a platform for innovation. Working with patient, clinical, and HIT communities, the Pillbox team broke through barriers to the creation of applications based on FDA's drug label data. Opening Pillbox's data, images, and search function enabled the building of innovative applications that improve the health of citizens. Applications currently in development include voice-activated and instant-messaging pill identification systems, as well as iPhone medication identification and information applications. A group of programmers at the Great American Hackathon used Pillbox's data to begin development of a Facebook game, writing hundreds of lines of open source code in the process. This fall, as part of the Community Health Data Initiative, the Pillbox team will repeat this process with other government health data sets.

County Health Rankings—The *County Health Rankings*—a collaboration between the University of Wisconsin and Robert Wood Johnson Foundation (RWJF)—uses a model to describe the overall health of a community, as well as the factors that affect health. This annual "check-up" for each county in the United States allows everyone to compare the health of where they live to that of their neighbors or other counties in their state. Following the February 2010 release of the interactive website (www.countyhealthrankings.org), the *Rankings* have garnered significant attention throughout the nation. The use of summary measures of health and ranking within states engages the news media and policy makers, leading to community-wide collaborations to "dig deeper" and better understand the problems, as well as to seek solutions.

Quick Health Data Online (*HHS Office on Women's Health*)—Quick Health Data Online is an interactive database that provides state- and county-level data for all 50 states, the District of Columbia, and U.S. territories and possessions. Data are available by gender, race, and ethnicity and come from a variety of national and state sources. The system is organized into eleven main categories, including demographics, mortality, natality, reproductive health, violence, prevention, disease, and mental health. Within each main category, there are numerous

subcategories. Users have the flexibility of presenting results in tables, bar graphs, and maps, or exporting results into other processing or display tools.

The MedWatcher Application: Mobile Phones and Crowdsourcing for Drug Safety Surveillance (*Children's Hospital Boston*)—The application is designed to engage users (general public and healthcare practitioners) in issues of drug safety. The system has two functions: alerting and reporting. First, the application alerts users about new drug warnings through both official FDA channels (such as MedWatch Alerts) and through informal channels (such as news media). Second, using forms tailored separately to the public and clinicians, we provide a user-friendly tool for reporting information about drug side effects. Serious adverse events from clinicians are automatically submitted to FDA, while public discourse between patients creates a sense of community, as well as a source of information for hypothesis generation for researchers. We believe these early efforts represent an important step in engaging the public as participants in the public health process and empowering individuals to make informed health decisions.

HealthLandscape (*Health Foundation of Greater Cincinnati*)—HealthLandscape is a web-based data mapping platform developed in collaboration by the Robert Graham Center and the Health Foundation of Greater Cincinnati that helps Americans understand health and healthcare system performance in their communities—and to help spark and facilitate action to improve performance and value. It allows users to create and display maps of community health and health resource data. It also allows secure access to data for limited sharing and for secure uploading for display in combination with the other public data. The goal is to help users add a spatial context to data in order to promote understanding and improvement of health and health care. Tools include

- *Community HealthView*: A home for data relevant to health in communities.
- *Primary Care Atlas*: A place to explore physician workforce data and federally designated shortage area data.
- *Health Center Mapping Tool*: A Health Insurance Portability and Accountability Act-compliant, secure home for uploading, geocoding, and mapping patient data to understand service areas, neighborhood penetration, and relationships to local and regional populations.
- *My HealthLandscape*: A secure environment for users to upload and geocode their own health-relevant data.

SOURCE: IOM Workshop, Community Health Data Initiative, June 3, 2010.

number who will buy homes in the next 5 years. Such an application also has the potential to create a new business case for investing in health at the community level, as it transforms health improvement from something that is a good thing to do into something that also affects property values, a principal revenue source for communities.

This innovation—just one of the many possibilities with increased availability of data—underscores the need for public participation and collaboration to develop creative applications that serve local needs. Because creating applications requires users to gain familiarity with the data, such work also helps HHS identify opportunities to improve the quality and utility of the data to support learning and health system and health improvement. The ecosystem approach therefore solves two problems. First, data that were previously collected but not used are being applied in a timely way to generate a discernable social return and a means to improve data quality. Second, because of these returns, a business case is developed for HHS to produce and deliver more data as a vehicle to engender social change.

At a follow-up meeting hosted by the IOM on June 3, 2010, the 11 volunteer teams showcased their results to an audience that included individuals interested in joining the work under way or starting new projects, organizations that could supply data beyond those captured by HHS, and community leaders who could use the applications to improve health.

As a result of these initial discussions, the potential impact of these data has dramatically expanded. For example, Clay Johnson of the Sunlight Foundation has proposed launching a great American hack-a-thon for health, in which advocacy organizations and nonprofits would compete to develop innovative ideas for applications that leverage community health data to advance their mission. The best ideas would then be handed over to hundreds of hackers in 30 different cities who would volunteer for a weekend out of the year to build these applications. Other participants, such as Ingenix, are considering contributing data to help make some of the proposed applications more robust.

Concluding Thoughts

The spirit of commonwealth and of "all hands on deck" emerging from efforts to foster open government is essential to a data ecosystem and to a learning health system. Initial results of HHS's Open Government Plan also illustrate the important catalytic role government can play in health system and health improvement. Instead of developing a centralized system to control data access and use, HHS can supply data to all and help consolidate and catalog ecosystem information so that data use can be driven by and serve the needs of the community.

Opening access to health-related data from the public and private sectors could be transformative for improving the health of Americans and the effectiveness of the healthcare system. However, people of all talents, capabilities, and resources must come together to realize this potential. HHS needs guidance from the public about what data it should capture and release and how the data can be used to advance social missions. As good as the HHS data are now, they will become much better over time with public input. The dialogue should be about how HHS and the public, in the spirit of open government, can collaborate on an ongoing basis to achieve the promise of a learning health system.

ENSURING DATA INTEGRITY: ADDRESSING PRIVACY PROTECTION AND PROPRIETARY CONCERNS

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In the American context, a worthy society is exemplified by a healthy citizenry pursuing happiness through the beneficence of sound governance and positive expressions of personal freedom. Key to those positive expressions of personal freedoms is the exploration of "the illimitable expressions of the human mind."[4] The nation's origins were suffused with the optimism and courage characteristic of the Enlightenment. Discovery and support of progress across all dimensions of human activity were central themes, as characterized by efforts as diverse as the pursuit of copyright law and the rapid spread of smallpox vaccination (Sheldon, 2010). As Ralph Waldo Emerson noted, however, "The first wealth is health."[5]

These early emphases on discovery and improvements in health and health care were underscored 150 years later when, in the midst of a great world war, Franklin Delano Roosevelt dedicated the NIH for the discovery of cures for the maladies plaguing humanity. Over the years, this national investment has benefited the care of Americans and people everywhere, while also leading to major improvements in the health of domesticated and even wild animals.

The Blue Ridge Academic Health Group has advocated for some years for a value-driven healthcare system (Blue Ridge Academic Health Group, 1998, 2004) that continually improves the quality of care and practices evidence-based management of illnesses. To secure such a system requires

[4] See http://wiki.monticello.org/mediawiki/index.php/Illimitable_freedom_of_the_human_mind_(Quotation) (accessed October 11, 2010).

[5] See http://www.notable-quotes.com/e/emerson_ralph_waldo.html (accessed October 11, 2010).

that the entire enterprise focus on learning and become a learning health system (IOM, 2007). Requirements for a learning health system include (1) widespread access to patient information to better understand the comparative effectiveness of treatments and foster ongoing research into less understood conditions; (2) policies and procedures that do not waste scarce resources, including money and the valuable time of health professionals; (3) active engagement of patients in their care to improve their understanding of and commitment to treatments of known effectiveness; and (4) ongoing, credible systems that preserve privacy and manage patient information securely to achieve data integrity for both healthcare operations and research of all types (e.g., biomedical, public health, and health services research).

Recently, Secretary of Health and Human Services Kathleen Sebelius noted: "The key to benefiting from change will be in ensuring that healthcare decision makers are guided by science and research" (Sebelius, 2010). With the passage of the ACA, access to basic healthcare services was affirmed as worthy of the investment in terms of national health status and social productivity. The absence of prior legislation providing all citizens with access to basic healthcare services gave rise to fears that unauthorized distribution of personal health data would lead to healthcare uninsurability. With the passage of ARRA, the Genetic Information Nondiscrimination Act of 2008, and the ACA, we have now entered a new era where this concern is moot.

Secretary Sebelius wants decisions to be based on evidence and research. To this end, public policy must support a learning health system. Further, citizens should be actively engaged in the support of legitimate healthcare research and institutional review boards (IRBs). The nation now has stringent policies and regulations, including both civil and criminal policies, relating to the use and protection of person-specific health information. Indeed, in 2009, ARRA added so many new protections that many experts consider this law to have created a second incarnation of the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1997. Even before ARRA was passed, multiple expert groups involved in the nation's research enterprise had examined the impact of HIPAA on a range of biomedical, public health, and health services research. An IOM report reviewed all such studies and offered the conclusion that improvements to HIPAA were needed to facilitate better privacy protections (some of which are included in ARRA), as well as better access to data for research (IOM, 2009).

Another component of ARRA is a mandate that the government assess the comparative effectiveness of treatments to develop greater understanding of which treatments are most effective. This mandate specifically calls for health services research that will require access to person-specific health-

care data. The time has come to put before the American people the opportunity to support the discovery of new treatments and help ensure that only those resources needed to support research and protect data integrity and security are expended. At the same time, the research enterprise should be constructed so as to offer the greatest levels of patient safety and highest quality of care for standard practices.

To address these needs, Congress should introduce and pass a law that will facilitate the achievement of a number of important objectives with respect to biomedical, public health, and health services research. This law should include a number of features (Box 3-3). First, it should enable Americans to have a unique personal health identifier, which will facilitate the integrity of research data. The identifier should also be allowed to be used for authentication of routine care unless the individual wishes to formally opt out of such usage. Second, the law should mandate that all research studies meeting HIPAA requirements and having been approved by an IRB have access to nonanonymized health record data for legitimate research purposes. Further, citizens should explicitly be given the opportunity to opt out of the accessibility of any personal genetic information for research that meets HIPAA requirements and has been approved by an IRB to use nonanonymized health record data for legitimate research purposes. Any breaches of data security relating to research use would fall within

BOX 3-3
Components for a "Health Research and Safe Care Act of 2011"

Citizens have the opportunity to

- opt out of selection of a unique personal health identifier for use in research databases (including an option for the identifier to be used for routine personal health care);
- opt out of consent to share their personal health data for IRB-approved research that complies fully with HIPAA security regulations and requirements without any data anonymization; and
- opt out of consent to share their personal genetic data, if available, for IRB-approved research that complies fully with HIPAA security regulations and requirements without any data anonymization.

In addition:

- use of anonymized data would continue to be allowed without explicit personal consent; and
- public–private partnerships would be able to allow researchers to identify potential research participants, who might then be approached to take part in clinical studies for which consent is needed.

the current boundaries of HIPAA and ARRA as defined above. Finally, a public–private collaboration should be established to develop a process by which citizens interested in becoming involved in a research protocol that may apply to them as a result of preliminary data screening could be located and offered information on potential inclusion in the study.

Some further explanations are appropriate to better understand the logic behind the above policy proposal. The above proposal flows from the 2008 policy conference of the American Medical Informatics Association (AMIA). AMIA held a conference on "Informatics, Evidence-based Care, and Research: Implications for National Policy" (Bloomrosen and Detmer, 2010). A diverse group including federal regulators, citizens, researchers, and informaticians, concluded that national policy must be revised to secure a learning health system, improve and ensure data integrity, attend to data security and privacy, and facilitate research. The group concluded that only through a refocusing of public policy with respect to data access could these objectives be met. It concluded that a learning health system requires broad access to personal health data. Further, citizen support for legitimate biomedical and health research should be facilitated because today the entire burden of engaging citizens in research falls not on society but on researchers and IRBs, thereby creating significant disincentives for caregivers and researchers to pursue many promising lines of inquiry. In short, at this time, federal policy adversely impacts legitimate biomedical and health research by restricting data access, and there is no evidence that this is the will of most Americans.

The perspective of clinicians is important to data integrity as well. With the drive to make EHRs the norm for clinical practice settings, it is important to motivate the clinical community to be highly committed to data integrity. Payment for "meaningful use" holds promise to at least encourage recording data to enhance payment rather than spending the time to capture the exact clinical situation. There is a real possibility that data quality will benefit from clinicians learning that their data will be reviewed for both research purposes and for assessing their clinical practice behavior for quality assurance and maintenance of licensure. EHRs have the potential to reduce the quality of clinical notes as well as improve care through better data access, and it is wise not to overlook the role that support for professionalism can play in a contractual regulatory world.

At the broader policy level, instead of supporting research, current policy focuses overwhelmingly on privacy protection of personal health information, and such federally enforced protections continue to mount with neither the ability nor support by citizens to alter this policy course. Further, with Americans strongly in favor of legitimate biomedical, public health, and health services research, no policy exists to encourage the system to

favor access to patient data for such research (Allcott and Mullainathan, 2010; Thaler and Sunstein, 2008).

Equally disturbing in the context of a learning healthcare system, current policies and regulations limit data integrity through a variety of mechanisms. The most prominent of these is the absence of unique personal health identifiers, which is a threat to privacy and safety in day-to-day care and a major threat to data integrity because data (especially those relating to people with common names) can be misfiled quite easily. Another issue with major implications in terms of cost and wasted time relates to the gap between the use of health data for quality management and for clinical and health services research. There is a substantial risk that ARRA will further limit data access through the "minimum necessary" requirement reviewed in summer 2010.

Other nations are ahead of the United States in addressing this problem. For example, the Research Capability Program of the Department of Health of England and Wales,[6] passed in 2007, is explicitly establishing mechanisms to allow researchers full access to 21 formal data sets created by the Department. The goal is to facilitate access to such data by researchers, including the pharmaceutical industry. England is convinced that this can be good law while remaining consistent with patient privacy protections. The National Health Service (NHS) data sets include NHS Care Records Service (CRS) Personal Demographics Service, Death Registration, Birth Notification Dataset, Commissioning Data Set/Hospital Episode Statistics, Cancer Register, NHS CRS Electronic Prescribing Service and National Prescribing Service, General Practice Research Database, Health Improvement Network, EMIS Primary Care (QResearch), IMS-Mediplus, General Practice Extraction Service, Cardiac Register; National Diabetes Audit, National Congenital Anomaly System, UK Renal Registry, Townsend Material Deprivation Score, Jarman Underprivileged Area Score, Office for National Statistics Demographic indexes, National Statistics Postcode Directory, NHS HealthSpace, and Mental Health Minimum Data Set.

Specific recommendations of the United Kingdom Research Capability Program include "safe havens" for population-based research in which the protection of confidentiality is paramount; systems for approving and accrediting researchers allowed to work in such environments; involvement of academic and other partners in safe havens; and development of systems to allow researchers to identify potential participants, who may then be approached to take part in clinical studies for which consent is needed.

The recommendation for an opt-out option relates to recent multiyear experiences in Massachusetts, Minnesota, and Utah (Okwumabua, 2010).

[6] See www.connectingforhealth.nhs.uk/systemsandservices/research (accessed October 11, 2010).

Recently, Massachusetts has used an opt-in option for gaining informed consent to share personal data among regional caregivers using a unique health identifier. Upward of 90 percent of patients opt in to data sharing, but the monetary costs to maintain this approach are significant, and substantial time is required by clinicians as well. Meanwhile, in Minnesota, a data sharing system has been in play for some years. It too uses an opt-in option, and experience with this system mirrors that in Massachusetts (e.g., monetary costs and clinician and other administrative costs are substantial). Finally, Utah has had an opt-out program for children's health data whose original focus was on minimizing under- and overimmunization. Roughly 3 percent of parents opt their children out, and the system is much less expensive than those of Massachusetts and Minnesota. Public acceptance is thus shown by these real-world experiences to approach or exceed 90 percent for sharing of data for care purposes.

With respect to such options and biomedical research, Daniel Masys of Vanderbilt University offered to the author the following personal communication relating to deidentified data:

> Vanderbilt has an opt-out model for building a biobank of DNA samples from blood left over from clinical testing linked to de-identified electronic medical record (EMR) data that currently has more than 63,000 samples in it, growing at about 800 per week. The predicted opt-out rate before the project started, based on focus groups and a 5000 person patient survey was five percent. The observed opt-out rate over the past two years, across about one million consent-for-treatment signing events, is about 3.8 percent. Surveys of those who did opt out suggest an "anti-science" phenotype that is suspicious of all organizations, a belief that commercial profit motives are behind any veneer of science altruism. Most are personally convinced to a degree that no additional information would change their minds. These data seem to be a useful validation of the estimated size of an often vocal minority who figure so prominently in all of the public debates about research, uses of clinical data and electronic data systems. . . . This is not to say that such views are not valid and they clearly must be accommodated in discussions of architecture and policy, but they often seem to occupy a disproportionate amount of public dialog and pedagogy. (Masys, 2009)

If the recommended opt-out option were signed into law, one might predict that, based on available data and with sensible administration, well over 75 percent of the American public would "sign up." This would benefit research immensely and save billions of dollars and thousands of hours as well.

In conclusion, two quotations from James Madison relate directly to this public policy issue and the challenge facing those seeking to help

Americans find more cures sooner through the passage of legislation such as that suggested here. Madison noted: "A people who mean to be their own Government, must arm themselves with the power to which knowledge gives."[7] Progress comes only when information flows. Madison observed in a letter to Benjamin Rush that he was no stranger to the clash of deeply felt values and how the intensity of belief can warp perception. He stated: "Nothing is so contagious as opinion, especially on questions which, being susceptible of very different glosses, beget in the mind a distrust of itself."[8] One cannot but reflect on this quotation in the context of the continuing health data privacy wars of the past two decades. Within the Beltway, it is commonly taken as fact that patients are more concerned about the privacy of their data than anything else and that trust in health care and EHRs is based overwhelmingly on assurance of this privacy. What facts exist reveal that this is so much finely glossed opinion. According to Mechanic and Meyer (Mechanic and Meyer, 2000), trust in health care is based on three main pillars and a fourth that sometimes is not even mentioned. First and foremost is the ability of the clinician to communicate and connect with the patient. Second is the perceived competence of the clinician. Third is whether the clinician is willing to advocate for the patient's benefit if necessary. If it is mentioned at all, maintaining privacy and confidentiality of data is fourth.

Americans should be given the option to become full and open participants in a learning health system. To do otherwise is to prevent them from being either Americans in the finest sense of that word or adults with respect to their care and concern for their fellow beings. The right of Americans to be left alone must not be allowed to become a right to be unknown.

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[7] See http://presspubs.uchicago.edu/founders/documents/v1ch18s35.html (accessed October 11, 2010).

[8] See http://www.revolutionary-war-and-beyond.com/james-madison-quotes-6.html (accessed October 11, 2010).

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4

Engaging Patients to Improve Science and Value in a Learning Health System

INTRODUCTION

An informed patient, invested in healthcare improvement and engaged in shared decision making, is central to a learning health system. Inherent to this vision is the notion that patients bring unique and important perspectives to health care, as well as the ability to spark improvement; both of which are essential to closing important gaps in health system performance and ensuring that care is effective. Unfortunately, patients, families, and caregivers too often are not engaged as meaningful decision makers in their own care or as partners in health research. This shortcoming has been associated with improvements in the effectiveness, safety, and patient experience of care (Coulter and Ellins, 2007). Given these initial promising results, a key challenge will be to foster the development of a learning culture in health care, in which patients' contributions to health improvement, clinical research, and their own health decisions are expected and embraced by the health system.

The papers in this chapter explore what is meant—theoretically and practically—by patient engagement in health care, and how health systems might better learn from patient participation to advance clinical science and healthcare delivery as well as better support patients in care and care management decision making. Strategies for improving public awareness of key opportunities for such engagement and for providing tools to enable greater participation also are discussed.

The first paper, by Sharon F. Terry of the Genetic Alliance, offers a vision for the range of contributions patients and the public can make

to improve research. Patient-initiated data collection initiatives, including social networking and information sharing services, have provided important resources for discovery and played a role in better informing patients and investing them in the research enterprise. James Conway of the Institute for Healthcare Improvement explores the potential for greater patient and public engagement to improve health system performance, noting the growing evidence base of how patient engagement could improve a wide array of health and system outcomes, from patient adherence, to clinical outcomes, to financial performance. He proposes a framework to better connect and align the interventions currently under way and encourage and support the development of effective public engagement initiatives. A third paper, by Karen Sepucha of Massachusetts General Hospital, addresses opportunities to better engage patients in treatment decisions through more effective patient–provider communication about patient concerns, expectations, and preferences in order to make shared decision making a routine part of the clinical care encounter.

INVESTING PATIENTS IN THE RESEARCH AND CONTINUOUS IMPROVEMENT ENTERPRISE

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At the center of a learning health system are individuals, families, and communities. As all citizens are eventually members of this stakeholder group, an effective healthcare system must keep this group's interests paramount. The learning touted as part of the exemplary system must fuel action to transform health care to better serve the needs and interests of individuals, families, and communities, and in essence be accountable and self-correcting. A key component of such a system is a culture that promotes and supports public interest and investment in helping to advance the research enterprise. Although public engagement in health care is often viewed from the narrow perspective of participation in clinical trials, many initiatives currently under way create a very different vision for the range of contributions individuals, families, and communities can make to improve research efforts on the value, science base, and patient experience of health care delivered—from information for basic research to efforts to drive improvements to best practices.

This paper reviews trends in public awareness of and interest in opportunities to contribute to learning about what works in health care, such as improving access to and expanding the use of clinical data, and provides examples of initiatives aimed at supporting patients in these roles. Key lessons learned from current efforts to improve public understanding of the issues

involved and encourage patient contributions to learning in health care are identified, as well as communication strategies that move beyond disease-centric approaches to increase receptivity and insistence by the public with respect to their engagement and investment in the research enterprise.

A Learning Health System

Individuals, families, and communities, while serving as the primary focus of a learning health system, interact with the system in different ways. Collectively, however, these stakeholders value a system that focuses on prevention and wellness, proper diagnosis, and individualized care. An ideal system therefore requires an intelligent blend of savvy stewards and systems that advance the public's health on the one hand, and on the other, consumer-initiated and/or consumer-driven tools and resources that aggregate and analyze clinical and other health information over time to help enhance understanding of health and disease.

Progress toward this ideal system requires expanding the current concept of a healthcare system to include promoting health, not simply addressing disease. A robust healthcare system must not only include prevention (Frieden, 2010); it must focus on prevention and wellness if the greatest improvements in both health and the system that serves it are to be realized.

Further, the current healthcare system expends a great deal of resources on treatment and not enough on diagnosis, the highest priority for health care according to innovator Clayton Christensen (Christensen et al., 2008; Frieden, 2010). Diagnosis lends a critical granularity to the treatment process, allowing the individualized medicine in which the public is so interested. Although a great deal of attention is given to genetics and genomics as the backbone of personalized or individualized medicine, it is probably more accurate to assume that all of medicine, properly executed, should be individualized, with genetic and genomic information integrated into the individualized plan. The impact will be felt by the diagnosed; the not yet diagnosed, which might be termed the general public; and the public's health.

Finally, although not an issue at the forefront of public attention, the system needs to be oriented around learning and continuous improvement, or progress toward more efficient and effective health services will continue to be dismally slow.

Beyond Trial Participation: Enabling Consumer Contributions to Learning and Research

While recognizing the importance of the perspectives of the other system stakeholders, this paper focuses only on the consumer perspective.

The paper highlights efforts of some of the 1,200 disease-specific organizations that make up the Genetic Alliance,[1] as well as others, to empower consumers to drive learning in health care. A common perspective of these organizations is that keeping the essence and ultimate mission of their work on the patient will necessarily shorten the distance between discovery and services. When faced with a loved one's devastating illness, it becomes easier to measure every action and develop a plan to help achieve the ultimate objective of improving the prognosis for a disease.

Clinical trials are an important part of the healthcare system, albeit in the translational rather than the services realm. Best estimates for enrollment in clinical trials for cancer indicate that fewer than 5 percent of adults diagnosed with cancer each year participate in such trials (NCI, 2001). From the National Institutes of Health to the largest pharmaceutical companies, difficulty in enrolling individuals in these trials is of major concern.

At the same time, clinical trials are just one opportunity for consumers to contribute to research and health advancement, and many notable initiatives are beginning to provide a means for consumers to help catalyze the creation of a learning health system through better use of the clinical data and information now being amassed. With these contributions, the system itself will generate hypotheses, not just collect and redisplay data and test hypotheses. The data can talk, and with appropriately balanced privacy and confidentiality protections, individuals and families can communicate to the health information exchange systems in their lives what it is that they value. In this ideal system, the system architecture, the privacy scheme, and the manner in which they assist consumers to cut through a mass of decisions to establish highly granular privacy settings without becoming overwhelmed will be simple (see the section below on consumer health information systems).

Initiatives that provide consumers with control over their data and the opportunity to open access to their data for research have tremendous potential for advancing a consumer-driven culture of research and continuous improvement. However, much more needs to be learned about how to encourage consumers to see the value of such engagement. Several key lessons learned to date are illustrated by the examples provided below.

Biologic Repositories and Clinical Registries

The Genetic Alliance BioBank[2] is a biologic repository and clinical registry established in 2003. It was built on the infrastructure of a disease-specific bank established in 1995 for a rare genetic condition called pseudoxanthoma

[1] See http://geneticalliance.org (accessed October 11, 2010).
[2] See http://biobank.org (accessed October 11, 2010).

elasticum (PXE). PXE International advised a large number of other disease-specific organizations and determined that the community would be better served with a cost-effective, shared common infrastructure. The community using the BioBank—a number of large and small common and rare disease–specific organizations—brings donors closer to the research enterprise they wish to impact. Researchers using the BioBank can solicit clinical information over time and as needs emerge by making requests to disease-specific organizations (for example, the National Psoriasis Foundation, the Inflammatory Breast Cancer Research Foundation, the Chronic Fatigue and Immune Dysfunction Syndrome Association of America). Thus the gap between research and those waiting for treatment is narrowed. Members of the disease community drive the research through understanding of the day-to-day issues of living with the condition.

Consumer Health Information Systems

Private Access enables individuals to establish granular privacy settings for clinical information that, when properly catalogued, allows researchers to find individuals for specific cohorts. This technology allows individuals to grant "private access" to all or selected portions of their information and thereby determine the information flow with which they are comfortable, mitigating privacy concerns (Lo and Parham, 2010). The controls can be granular down to the data element if desired, enabling individuals to decide whether their genetic, mental health, or any other information they deem sensitive should be shared and if so, with whom. Moreover, the controls are dynamic—anticipating that users will wish to change their settings as their circumstances change and as different needs arise or levels of trust are established. From simple scenarios such as releasing one's child's immunization record to a summer camp to making one's clinical information searchable by selected researchers, this online system provides an important service. It includes a comprehensive audit log and tracking, all consistent with emerging health information technology standards for the coming years. Trusted guides in this system help users establish privacy preferences, which can be difficult to navigate depending on the user's literacy level.

The healthcare system in the United States (and often abroad as well) can be paternalistic. A highly hierarchical system, with "expert" gatekeepers in the form of physicians, limits the learning that can be accomplished by the system. A system in which all stakeholders play a role and in which consumers are offered the opportunity to help drive learning is much more nimble. The current healthcare system does not allow the kind of consumer engagement needed for a learning health system. Therefore, it is critical to understand how to better guide people to become empowered and informed consumers.

Social Networks and Information Sharing

Consumers are helping to advance learning about health care at a rapid rate through multiple means. An excellent example of the power of consumer participation is PatientsLikeMe®. The founders, Massachusetts Institute of Technology (MIT) engineers, describe their endeavor this way: "Our goal is to enable people to share information that can improve the lives of patients diagnosed with life-changing diseases. To make this happen, we've created a platform for collecting and sharing real world, outcome-based patient data and are establishing data-sharing partnerships with doctors, pharmaceutical and medical device companies, research organizations, and non-profits."[3] The site allows individuals to aggregate and share their information with one another, and also to choose to share clinical information with pharmaceutical companies. Some may argue that this does not constitute real learning for the biomedical enterprise because some data are self-reported, because individuals' quality of life is weighted heavily, or because individuals are too involved to maintain the objectivity traditionally sought in clinical research. Moreover, participants and the medical team managing the site are beginning to see trends in the participants' progression relative to their treatment plans in a far more dynamic and timely manner than is possible with traditional natural history or other clinical trials.

Another example of the power of consumer engagement is Facebook. As of this writing, 520 million members of Facebook from around the world have created 1.2 million health groups on the site. This phenomenon demonstrates an intense interest among people in engaging in some activity around health, and it challenges traditional bricks-and-mortar organizations, in networks such as the Genetic Alliance and the National Health Council, to consider new ways of meeting the needs of consumers. Individuals who once had to make a substantial effort to connect with others around a health issue now find it easy to do so. If 10 years ago one imagined creating a business to sell books from attics and basements throughout the world, this model would have appeared to be unsustainable. Now Amazon and other "long-tail" technologies enable just that. These advances have not yet been incorporated into medicine and health.

Another good example, the Love/Avon Army of Women,[4] has attracted more than 300,000 women who do not necessarily have breast cancer, but are simply interested in improving the health of women. Founder Dr. Susan Love started this initiative to provide researchers with a large cohort of healthy women available to take part in research into the causes of breast cancer.

[3] See http://patientslikeme.com (accessed October 11, 2010).
[4] See http://www.armyofwomen.org/ (accessed October 11, 2010).

Genetics and Genomics: Advancing Individualized Medicine and Public Health

The explosion of information in genetics and genomics creates a tension between the amount of information available and its interpretation. Consumer-oriented learning in this domain will be essential to the integration of genetics into medicine, and consumer genomics companies are advancing this concept at a rapid rate. There are several such companies, the most commonly referred to being 23andMe, Navigenics, and deCODEme. For example, 23andMe aggregates the data of individuals who pay to have hundreds of thousands of single nucleolide polymorphisms (SNPs) genotyped by the service. These are not primarily individuals with a diagnosis, such as those involved in PatientsLikeMe. The individuals who participate in 23andMe are not seeking a disease community perspective, but instead are interested in genotyping embedded in social networking technologies. 23andMe reports genotypes to individuals, aggregates the scientific literature on those SNPs, and presents representations of an individual's SNPs compared with interpretations in the current scientific literature and genealogic databases. Individuals can then examine categories called Disease Risk, Carrier Status, Drug Response, and Traits. The company offers genetic counseling and the opportunity to compare one's genotype with everyone else's in the database and find potential relatives.

As another example, the company Illumina has created an iPhone application for use with its genome sequencing service. Users can compare their genome with someone else's and receive updates in the interpretation of that genome on the fly.

Ethicists and regulators have concerns about services provided by these consumer-oriented companies, offering what is often called direct-to-consumer marketing. There is no question that all genetic testing, regardless of the service delivery method, should have appropriate oversight leading to safe and efficacious testing and interpretation. This has been and will continue to be an iterative process for the various systems engaged. Letters sent to several of these companies by the Food and Drug Adminstration[5] declare the agency's determination that the companies must get approval for the testing services they offer. This is a time of dynamic tension between two systems. The more staid, and perhaps antiquated, regulatory system is characterized by great caution and dependence on traditional models of evidence that derive from reliance on traditional experts, and do not allow for the involvement of consumers and the accelerated learning that comes from systems that are able to capture their wisdom. Direct-access testing

[5] See http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm (accessed October 11, 2010).

could be an important catalyst for increasing the learning of the health system in a more dynamic way. In addition, direct-access testing accelerates the examination of social issues and policies around genetic testing and technologies and their delivery.

In considering a learning health system, it is important to include public health. The newborn screening system, probably the nation's most successful public health program, is an excellent program in which the sharing of information could serve to engage the public in the healthcare system. Most parents do not even know that their child has been screened or that their state has stored the child's dried residual blood spot. The results have ranged from distrust to lawsuits and destruction of these blood spots. If parents participated in the decision to store blood spots and further, using a dynamic electronic consenting system, consented to levels of use for them, this currently invisible system would enjoy greater support. Integration of the newborns' screening results with the dried blood spots, dynamic consent for use, and electronic and personal health records can constitute an important learning system for health in the United States. Almost 5 million babies are screened each year, representing 99 percent of the nation's newborns, so this accomplishment would serve as the basis for a national clinical registry and biological repository system. Efforts such as those of the Genetic Services Branch of the Health Resources and Services Administration and Genetic Alliance's Newborn Screening Clearinghouse give parents and providers ways of interacting with the system so it can learn from the engagement.

Another federally funded effort, the Genetics for Early Disease Detection and Intervention to Improve Health Outcomes (GEDDI) program of the Centers for Disease Control and Prevention, is also capturing learning in the system to accelerate the usefulness of genomic applications. Understanding that there is far too much information for any clinician to digest in making decisions about the use of genetic and genomic tests, GEDDI is building a knowledge base and using the public participation tool Google Knol to create a body of expert-moderated knowledge that will allow correlations to be drawn and affirmed more quickly than is typical in more traditional models. Ultimately the program is asking when and where genetics can be used for early detection, and answering this question will require consumer participation in the process of understanding what brings value not only for the individual, but also for communities and ultimately the public's health on a large scale.

Concluding Observations

The activities described in this paper reveal that there is a long way to go in developing the policies necessary to encourage and support patients

becoming invested in the research and continuous improvement enterprise of a learning health system. However, they also indicate an increasing interest among the general public in participating in health care—rather than just being spectators, and given the acceleration of consumer-driven advances in other fields—such as the computer industry, health care will accelerate its learning with increased consumer participation. Indeed, data from the Genetics and Public Policy Center indicate that individuals would like to participate in large data collection efforts in the United States and would like to receive individual results (Kaufman et al., 2008). When individuals in these surveys and town halls were asked whether they would participate if they did not receive individual results, 75 percent said they would be less likely to participate. Regardless of one's opinion on sharing results, such data indicate that the public would like to participate and learn.

A learning health system is not just a laudable goal but is essential for the health of the nation. At present, we are dependent on antiquated systems that rely on hierarchical gatekeeping. Phenomenal advances have been made in many areas of technology that can support social services. Health care lags behind other domains in its ability to capitalize on the learning available to it. Ultimately, the problem may lie in "knowledge turns," a term to describe "how well we transform raw ideas into finished products and services" (Savage, 2010). Knowledge turn rates describe many kinds of transactions in this information age. Disruptive insertion of consumers into the equation will ultimately generate faster knowledge turns and accelerate the learning of the health system.

PUBLIC AND PATIENT STRATEGIES TO IMPROVE HEALTH SYSTEM PERFORMANCE

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The charter of the IOM Roundtable on Value & Science-Driven Health Care underscores the centrality of the patient. The summary of the *Learning Healthcare System* workshop refers to both the need for a culture of shared responsibility that includes patients, providers, and researchers and the need for improved communication around the nature of public engagement (IOM, 2007). Widespread federal, state, public, and private position and policy statements, as well as those from healthcare industry leaders, speak to the importance of engagement of the patient, family, public, and community (Berwick, 2009). Excitement about public engagement grows daily, driven as much by financial constraints as by the synergy of engagement and improvements in population health and the healthcare experience. This excitement is being fueled by early successes in communities, organizations,

and microsystems and in the direct experience of care, as well as by the increasingly widespread view that members of the public must "do their part to improve outcomes and reduce cost" (AHA, 2004; Frampton et al., 2008; IHI, 2009; Johnson et al., 2007).

Yet there exists no widely embraced framework defining patient (consumer, public, family) engagement. Conversations about its meaning elicit differing views, typically focused on one discrete aspect of the issue. Opinions of health professionals about what the public "wants" or "needs to do" are often at odds with research findings on these issues. The need for and potential power of an overarching framework for public engagement is apparent. With such a framework, the various interventions (threads) of experimentation, research, and innovation could be connected for design, measurement, assessment, and improvement purposes.

This paper briefly examines the current state of public engagement, including shortfalls, definitions, opportunities, and evidence; presents a framework for public engagement; and provides a focused charge for moving forward.

Shortfalls in Public Engagement

In the midst of exceptional care, caring, hope, and discovery, there is extraordinary suffering, harm, tragedy, waste, and inefficiency in the healthcare system (IOM, 1999, 2001). Prevention and wellness are losing out to failures in the patient experience and population health—failures such as harm, obesity, and poorly managed chronic care. Care coordination fails both at the system level and for the individual. If it is organized for anyone, the care system is built around those who deliver care, not those who receive it. Enormous national resources produce comparatively poor health outcomes.

There is a growing realization that until the healthcare system is organized around the patient and the public, it will not be transformed as it needs to be. The Lucian Leape Institute of the National Patient Safety Foundation presents five transforming concepts for health care, one of which is that the public must become full partners in all aspects of health care. The Institute believes, "if health or health care is on the table, the patient/consumer must be at the table, every table. Now" (Leape et al., 2009). Likewise, the National Priorities Partnership of the National Quality Forum includes patient and family engagement as one of the six overarching priorities of a transformed U.S. healthcare system (NPP, 2010).

Definitions of Patient Engagement

There are many descriptions and definitions of the attributes of patient engagement and participation. Three are presented here.

The IOM defines patient-centered care as care based on continuous healing relationships; care that is customized according to patient needs and values; care where the patient is the source of control; care where knowledge is shared and information flows freely; and care where transparency is necessary and where the patient's needs are anticipated (IOM, 2001).

The Institute for Family Centered Care (Institute for Family-Centered Care, 2008) offers four key concepts for patient- and family-centered care, all with a focus on collaboration:

- *Dignity and respect*—Providers listen and honor patient and family perspectives and choices.
- *Information sharing*—Providers share complete and unbiased information in ways that are affirming and useful.
- *Participation*—Patients and families participate in care and decision making.
- *Collaboration*—Patients and families collaborate in policy and program development, implementation, and evaluation, as well as the delivery of care.

Finally, according to the National Quality Forum's National Priorities, patient- and family-centered care is health care that honors each individual patient and family, offering voice, control, choice, skills in self-care, and total transparency, and that can and does adapt readily to individual and family circumstances, and to differing cultures, languages, and social backgrounds (NPP, 2010).

Striking in all of these definitions is the importance of control and shared ownership—a clear sense of "we." The aim is collaboration all the time, not just when it is convenient. In the words of the Saltzberg Seminar, "Nothing about me, without me" (Delbanco et al., 2001).

Opportunities: One View of What Is Possible

Decades of work demonstrate the powerful opportunities created by public engagement. At Children's Hospital in Boston in the 1970s, mothers began to tell leaders and staff, "I don't care who you are, I'm staying with my child overnight." Leaders learned that "there is no force in the world stronger than a mother in their face advocating for her child." In a dispute between the hospital's record and the mother's record, one should believe the mother's—the only person taking care of the whole child. In 1996, leaders at Dana-Farber Cancer Institute invited patients and family members to populate all decision-making structures and processes in the organization (Ponte et al., 2003). In both organizations, after parents, patients, and family members were invited into groups working on hospital design,

care system design and delivery, visiting hours, resource centers, and much more, the enormous power of engagement began to appear. Patients and families were the only ones in the room who actually experienced care. Leaders also learned that while they often ask people what they want, they often fail to listen long enough to hear the answer. When leaders listen, the public, the patient, and the family can teach and tell them things they never knew. Healthcare systems, delivery, care, and outcomes are better as a result (Popper et al., 1987).

During the period 2005–2006, the IOM Committee on Identifying and Preventing Medication Errors examined organizing the medication system around the patient and those who care for the patient (IOM, 2006). For the committee members, when the lens was through the patient, the enormous power and complexity of such an effort was clear.

In two communities in Massachusetts, a grassroots effort has been under way for almost 2 years to encourage the public to participate more actively in their own care. The Partnership for Healthcare Excellence[6] is seeing and measuring important improvements in understanding of key healthcare themes in this study. Learning has focused on the ability to engage communities (public, healthcare, civic agencies) around common themes and the strength of simple and positive messages, such as "smart patients ask questions," "wash your hands," and "carry a medication list."

Finally, two Institute for Healthcare Improvement (IHI) initiatives provide further insight and illustration. A collaborative project among IHI, The Robert Wood Johnson Foundation, and the Institute for Family Centered Care, called New Health Partnerships,[7] produced a program on self-management. New practices and improved outcomes associated with shared care planning were apparent. In the IHI Get Boards on Board initiative, part of the 5 Million Lives Campaign, key content has focused on encouraging governance and executive leadership to seek out opportunities to meet patients and families in several contexts: at the sharp end of error, through rounding, in ad hoc invitations to participate in improvement, in the community, or through patient and family advisory councils. Across the nation, energized boards and executive leadership speak to the power of the experience: "It's the first time I saw our organization through the eyes of the patient." It is also sobering to routinely hear the question, "How do I talk with patients?" (Conway, 2008).

These are just a few of the many thousands of engagement initiatives under way across the country. From these and other experiences many themes emerge. Two are of particular note. The first is most sobering: "If only we had listened." If staff and leaders had stopped, listened, and en-

[6] See http://www.partnershipforhealthcare.org (accessed October 11, 2010).
[7] See http://www.newhealthpartnership.org (accessed October 11, 2010).

gaged with patients and families, healthcare systems could be dramatically better; for many family members, their loved one might not have suffered harm or death. The second theme is that engaging patients, families, and the public leads to better outcomes for everyone.

Evidence of the Impact of Public Engagement

For many, public engagement is seen as "nice but not necessary," "the soft stuff"—"if only they did what they were told." Yet growing research reveals the impact patient engagement can have on health outcomes, patient adherence, process-of-care measures, clinical outcomes, business outcomes, patient loyalty, reduced malpractice risk, employee satisfaction, and financial performance—including reduced lengths of stay, lower cost per case, decreased adverse events, higher employee retention rates, reduced operating costs, decreased malpractice claims, and increased market share (Charmel and Frampton, 2008; Edgman-Levitan and Shaller, 2003; Stewart et al., 2000). A literature review conducted by IHI in 2009 identified extensive findings on public engagement, with a particular focus on care of the hospitalized patient (IHI, 2009). A recent review by the Picker Institute, *Invest in Engagement*, presents much more evidence and further exemplars across the breadth of engagement.[8]

A Framework for Public Engagement

As noted, no comprehensive framework currently exists for engaging patients and families and the public. There are many interventions, but connections among them are loose or nonexistent. In 2002, Donald Berwick introduced the notion of the "chain of effect for quality," proposing that it will take integrated change at four levels to achieve the goals of the IOM's *Crossing the Quality Chasm* (IOM, 2001): environment, organization/system, microsystem, and the care experience (Berwick, 2001). Applying that thinking in the context of current examples, a rudimentary organizing approach for all of the activities in public engagement emerges (Table 4-1).

Yet something remains missing. Although each of these activities in its own right adds to understanding and improvement, collectively they could be far more powerful if built across levels on common threads or principles. For example, advanced care planning, access to the hospital chart, access to help and care around the clock, honoring patient wishes, and experience surveys achieve their real potential only if the activities at one level (environment, organization, microsystem, experience of care) are reinforced at the other three levels.

[8] See http://www.investinengagement.info/ (accessed February 9, 2011).

TABLE 4-1 An Organizing Approach for Public Engagement

	Location	Examples
Environment	Community, Region, State	Community groups Care Coordination, ACOs, Medical Homes Advanced care planning, POLST, MOLST School & church programs Public health & other consumer campaigns
Organization	Health System, Trust, Hospital, Nursing Home	Experience Surveys P&F councils, Advisors, Faculty Resource centers, patient portals Access to help and care 24/7 Medication lists
Micro-system	Clinic, Ward, Unit, ED, Delivery	Parent, advisors, & advisory councils Open access, optimized flow Family participation in rounding
Experience of care	Bedside, Exam Room, Home	Access to the chart Shared care planning "Smart Patients Ask Questions"

NOTE: ACOs = Accountable Care Organizations; MOLST = Medical Order for Life-Sustaining Treatment; POLST = Physician Orders for Life-Sustaining Treatment.

Figure 4-1 plots these four levels against the elements of the Institute for Family Centered Care's definition of patient- and family-centered care. Further threads of these elements are detailed under each that cut across all levels. Each of the examples in Table 4-1 could then be layered on at the appropriate intersections of Figure 4-1 to produce Figure 4-2. Although these graphics are only a beginning, the possibilities emerge for aligning, building, connecting, and evaluating. Informing this work will be advanced models of thinking in other countries where population health, care transitions, and community already have a much stronger role in health and health care than they do in the United States today.

Moving Forward

In a study of patient/public engagement in Europe, Groen and colleagues (2009) note, "The widespread implementation of policies to ensure patients' rights, privacy, and confidentiality is noteworthy. Patient involvement in quality improvement activities, on the other hand, so far appears to be more a rhetorical exercise than a practice." The same is the case for the United States. What is needed to advance that agenda rapidly is clarity of expectation: if health care is on the table, the public is at the table,

DIMENSION / SYSTEM LEVEL	RESPECT Dignity and respect of values, privacy, and perspectives				INFORMATION Complete and unbiased sharing of Information				PARTICIPATION Participation in care and decision making				COLLABORATION Collaboration in policy and program development			
	CULTURALLY COMPETENT CARE	PERSONAL CHOICE/CUSTOMIZATION	HEALTH LITERACY	SAFE QUALITY CARE	PERSONAL HEALTH RECORD	HEALTH EDUCATION RESOURCES	TRANSPARENCY OF INFO AND OUTCOMES	EXPERIENCE OF CARE IN AND ACROSS	PARTNERSHIP WITH SHARED DECISIONS	FAMLY PARTICPATION	SUPPORT RESOURCES	ACCESS AND NAVIGATION	SYSTEM DESIGN, MEASURE, ASSESS, IMPROVE	TEACHER	COMPARATIVE EFFECTIVENSSS	
Environment Community, Region, State																
System Health System, Trust, Hospital, Nursing Home																
Microsystem Clinic, Ward, Unit, ED, Delivery																
Experience Bedside, Exam Room, Home, Ambulance																

FIGURE 4-1 Public engagement level and dimensions: A rudimentary framework.

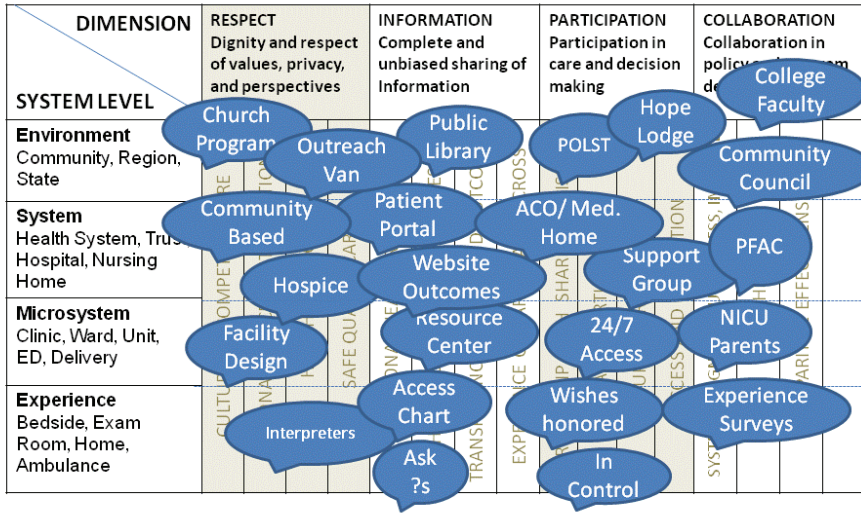

FIGURE 4-2 Figure 4-1 with examples at each level.

every table; visionary leadership, experimentation, and innovation are rewarded and incentivized; model frameworks for public engagement are introduced; and the evidence base is disseminated and enhanced.

Finally, making patient engagement personal is essential to connect the heart as well as the mind. The effort is about the care for everyone, for family and friends as well as for the communities the system is privileged to serve.

COMMUNICATING WITH PATIENTS ABOUT THEIR CONCERNS, EXPECTATIONS, AND PREFERENCES

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Should I take this medication? Should I skip that screening test? Should I tell my doctor about these new symptoms? Patients and providers need to communicate in order to determine appropriate courses of action across a range of health issues. A high-quality decision on testing or treatment requires communication about the options and the potential good and bad outcomes, as well as consideration of patients' concerns, goals, expectations, and preferences for those outcomes. This paper highlights gaps in the quality of medical decisions made in the United States, describes interventions that have been shown to improve the quality of decisions, and reviews some promising approaches to putting these interventions into practice.

The Quality of Medical Decisions in the United States

Some situations in medicine are fairly straightforward; there is a clear diagnosis and a single best treatment or approach. This is the case when there is considerable evidence of benefit with little evidence of harm. These situations have been referred to as "effective care," and communication with patients has focused on convincing them to implement the proven approach (Wennberg et al., 2007). Yet a surprising number of clinical situations are not examples of effective care. Instead of one approach, there are multiple options. Instead of clear evidence of benefit, there are limited or low-quality data on efficacy. Instead of benefits clearly outweighing harms, there are difficult trade-offs to be made. These kinds of situations are referred to as "preference-sensitive" situations (Wennberg et al., 2007). In such cases, the "best" option is determined not only by the medical evidence but also by patients' individual views. Many common medical decisions, such as the treatment of lower back pain, osteoarthritis, breast and prostate cancers, and benign prostate and benign uterine conditions, are considered preference-sensitive situations.

Preference-sensitive situations are not easy for patients or providers. The burden of decision making is now added to the burden of illness. The

decision making is complicated because neither patient nor provider can do it well alone. The patient needs the medical expertise of the provider, which includes evidence about the options and the potential good and bad outcomes. The physician needs the patient's self-knowledge, which includes the meaning of the illness and the potential treatments in the patient's life, as well as the patient's motivation and confidence to implement the different options. This information needs to be shared and then used to select the option that will best meet the patient's goals and needs (Charles et al., 1999; Mulley, 1989). This interactive process has been termed "shared decision making" and is necessary to ensure that patients get the treatment they need and no less, and the treatment they want and no more (Science Panel on Interactive Communication and Health, 1999).

How close is clinical practice to achieving a shared decision-making process? The DECISIONS study provides some evidence for the quality of common decisions across the United States. A nationally representative telephone survey interviewed 3,010 adults about nine common medical decisions on elective surgery (for back pain, knee/hip osteoarthritis, and cataracts), cancer screening (for breast, colon, and prostate cancers), and medication (for high blood pressure, high cholesterol, and depression). Respondents reported on their involvement in the decision, their knowledge of four to five key facts related to the decision, and their goals and concerns (Zikmund-Fisher et al., 2010).

The key findings of the study raise questions about the quality of medical decisions and the amount of shared decision making in the United States today. For the most part, respondents had very little knowledge about the options available to them and the likely consequences of those options. For seven of nine conditions, fewer than half of the respondents could answer more than one knowledge question correctly (Fagerlin et al., 2010). For example, only 17 percent of respondents who reported making a decision about taking cholesterol medication could correctly identify its most common side effect. Most men who had made a decision about screening for prostate cancer vastly overestimated the likelihood of dying of the disease, believing the risk was 20 percent as opposed to the actual likelihood of approximately 3 percent (Fagerlin et al., 2010). In other words, there is substantial evidence that patients are not making informed decisions.

Shared decision making requires meaningful discussion among providers and patients about treatment options, including both pros and cons. Respondents in the DECISIONS study were much more likely to report that their providers discussed the reasons for undergoing a treatment or test compared with the reasons for not doing so. In fact, respondents reported discussing both the pros and cons less than half the time (Zikmund-Fisher et al., 2010). Shared decision making also requires discussion of what is most important to patients. Respondents reported that providers asked them what they wanted only about half the time. This result varied by

situation and ranged from 33 to 50 percent for cancer testing decisions to 64 to 80 percent for surgery decisions (Zikmund-Fisher et al., 2010). The data suggest that communication about patients' concerns and preferences is variable, and often lacking.

Implications and Opportunities for Improvement

Not sharing accurate, complete information about options and likely outcomes can lead to patients receiving the wrong treatment. Not asking patients what is most important to them and using that information to guide treatments also leads to patients receiving the wrong treatment. How often does this happen? In a subset analysis of the Cochrane Collaborative systematic review of decision aids focusing on decisions aids for elective surgery, informed patients were 25 percent less likely to choose surgery compared with controls (O'Connor et al., 2007a). That finding suggests that one in four patients going to the operating room may be receiving the wrong treatment—surgery they would not have chosen if they had been informed and if providers had listened to them. The patient safety and resource implications of these findings are significant.

How can these gaps in the quality of decisions be filled? Three main approaches have been used to promote shared decision making—provider training, patient coaching and question checklists, and patient decision aids.

Provider Training

Provider training focuses on teaching communication skills and decision coaching skills (for example, risk communication) using a variety of teaching methods. Coulter and Ellins (2006) summarize results from several systematic reviews of provider training in communication skills and conclude that most training programs have a positive impact on both provider communication behaviors and patients' knowledge and satisfaction. However, there was mixed evidence of an impact on patient health outcomes and utilization of services (e.g., a positive impact on medication adherence but no impact on diabetes outcomes) (Coulter and Ellins, 2006).

Patient Coaching and Question Checklists

Patient coaching and question checklists, typically administered in advance of the visit, are designed to help patients communicate with providers and may promote shared decision making. A Cochrane systematic review of 33 randomized controlled trials of these interventions found that they produced a modest impact on patient outcomes (Kinnersley et al., 2007). In the Cochrane meta-analysis, the interventions were shown to increase

the number of questions patients asked, as well as patient satisfaction. The meta-analysis did not find a statistically significant change in patient anxiety or knowledge or in length of consultation.

Patient Decision Aids

Decision aids are tools that provide balanced information on options and outcomes and help patients think through their values and what is most important to them before making a decision. The International Patient Decision Aids Standards (IPDAS) Collaboration is an international group of researchers, clinicians, consumers, and policy makers created to set standards for the development, organization, and content of decision aids (Elwyn et al., 2006). The tools are available in a variety of media, and researchers at the University of Ottawa maintain a library of decision aids that is available online (OHRI, 2010).

There have been more than 55 randomized controlled trials of patient decision aids. A Cochrane systematic review of these studies found that these tools increase patients' knowledge, the accuracy of their risk perceptions, and their desire to participate in decisions (O'Connor et al., 2007a). The tools also help those who are undecided to make a choice, and to do so without increasing anxiety. As mentioned earlier, subgroup analysis of trials comparing elective surgery with nonsurgical options found a 25 percent decrease in use of surgery for those exposed to a decision aid. Of course, the goal of decision aids is not to increase or decrease utilization, but to increase the proportion of patients who are matched to the right treatment for them.

Many decision aids are widely available, although their use is not common. A few organizations and researchers have made significant, sustained investments in developing and disseminating patient decision aids. Three companies that have developed many of these tools are Healthwise, Inc., Health Dialog, Inc., and the Foundation for Informed Medical Decision Making. Researchers at Ottawa Health Research Institute, McMaster University, and the University of Wisconsin have also developed patient decision aids. Commercial entities disseminate decision support via a health coaching model implemented through a call center at the health plan level (e.g., Health Dialog) and Internet-based models that deliver decision aids directly to consumers (e.g., Healthwise via WebMD) (O'Connor et al., 2007b).

Experience with the implementation of decision aids at the provider level in the United States is coming largely from demonstration projects and learning collaboratives, several of which are funded by the Foundation for Informed Medical Decision Making. The Breast Cancer Initiative has found significant interest in and sustained use of breast cancer deci-

sions aids among both community and academic cancer centers (Silvia et al., 2008). Massachusetts General Hospital has launched an "ePrescribe" project that gives primary care physicians the capability to prescribe decision aids electronically. Dartmouth Hitchcock Medical Center (DHMC) has integrated decision aids into primary and specialty care and seen significant success in their ability to reach patients. The use of decision aids at DHMC has resulted in improved patient knowledge and increased ability to tailor treatments to patients' goals (Collins et al., 2009).

Shared Decision Making and Clinical Practice

What is needed to support patients and providers in making the changes required to integrate shared decision making into routine clinical care? Repeatedly it has been shown that organizational change seldom occurs unless the desired performance is routinely measured. This suggests that if there were a way to document the gaps between routine care and the knowledge-based and patient-centered ideal, it might stimulate changes in provider and patient behavior.

Systematically documenting the large gaps in decision quality could generate significant demand for tools and approaches such as decision aids (Sepucha et al., 2004). This documentation would require rigorous and practical survey instruments that could capture the gaps in patients' understanding and highlight the numerous instances in which patients received care they did not want or need (Sepucha et al., 2004). Fostering competition among hospitals and practices in how well they inform their patients and how attentive they are to their patients' preferences could lead to substantial improvements in the quality of health care. In fact, the recent healthcare reform legislation calls for the development of quality measures, including those focused on decision quality, as well as for the development of certification for decision aids and other tools designed to promote shared decision making.

Conclusion

In summary, the data show much variability in the quality of medical decisions. Too often patients are not meaningfully involved or well informed, and their goals and concerns are not taken into account. Decision aids are effective tools that promote shared decision making and have been integrated successfully into routine clinical care. Shared decision making, which requires productive communication between healthcare providers and patients about the evidence and their concerns and preferences, is a critical foundation for a learning health system.

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5

Health Information Technology as the Engine for Learning

INTRODUCTION

Health information technology (HIT) is changing every aspect of health care, from the patient experience, to the way physicians make notes, to the dispensing of medications. Using HIT wisely is central to building a real-time knowledge engine, tools for care improvement, and a portal for practical patient involvement. For primary care physicians and patients, electronic data permit tracking of health status, outcomes, self-management, and more. At the health insurer or health system level, trends in care and outcomes can point the way to continuous quality improvement and learning. The availability of new data sources provides a broader view that can further expand quality improvement. Finally, as patients use new technology, such as cell phones, to communicate with providers, additional opportunities emerge for enhanced patient self-management, patient activation, public health messaging, and coaching.

Yet HIT has not gained a foothold with most physicians. Many have resisted purchasing electronic health record (EHR) systems because of high up-front costs and an uncertainty that EHRs will improve patient care and justify the expenditure. As the culture changes to promote "meaningful use" of patient data, new incentives are expected to drive broader adoption. Meanwhile, many physicians and patients must wrestle with the limitations of paper. It is nearly impossible to track test results, outcomes, or side effects by shuffling through a paper chart. Another challenge is that health information generated by government reports lags years behind in production. Transforming these databases into tools for learning will require new approaches.

The papers in this chapter explore the major trends toward and strategies for accelerating a nationwide HIT culture. The first paper, by David Blumenthal, formerly of Office of the National Coordinator (ONC) for Health Information Technology (now Harvard University) addresses the "meaningful use" of HIT—collecting data and disseminating them in such a way as to make science-driven care and value routine. As the concept gains traction, its meaning can broaden to include data sharing and more robust exchange.

Better types of data are also critical for success. Daniel R. Masys, Jack M. Starmer, and Jill M. Pulley of the Vanderbilt University School of Medicine describe three cases in which new classes of data support a learning health system and improved outcomes. Dashboard displays can improve the reliability of complex healthcare processes. Some electronic networks can link and use data that are scattered around the country, while others can track the experience with a particular drug after it has been approved.

Kemal Jethwani and Joseph Kvedar of Partners HealthCare report on how patients are reaping benefits as they use the Internet to connect with health systems. Notably, patients with congestive heart failure, diabetes, and high blood pressure are able to better manage their condition through electronic connectivity via cell phones, computers, and dialog with their patient team. Patients like this kind of connectedness. Also, as wireless technology grows, it offers promise for the development of many more new applications for learning.

THE MEANINGFUL USE OF HEALTH INFORMATION TECHNOLOGY

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As the entity charged with coordinating efforts to implement and use advanced HIT and develop capacity for nationwide health information exchange, ONC plays a critical role in laying the groundwork for a learning health system. In its work to meet these critical short-term requirements, ONC also seeks to provide a pathway for achieving the potential of HIT to serve as an engine for continuous learning and care improvement. This paper reviews ONC's efforts to date and some of the key technical, human, and political challenges to making available the kind of information that could be used to provide real-time and retrospective feedback to the healthcare system. Meeting all of these challenges is critical for improving health and the quality of care delivered in the United States.

HITECH Provisions and the Learning Healthcare System

Through the Health Information Technology for Economic and Clinical Health (HITECH) Act—part of the American Recovery and Reinvestment Act of 2009—Congress and the Obama Administration made investments in HIT aimed at improving health system performance and health outcomes. This act creates both the need and the requirement for ONC to lay a foundation for moving data from individual health records into some other form, as well as the need to enable solo physicians to exchange data in a way that is clinically meaningful to their patients and their practice. In so doing, the act also provides an opportunity to create capacity to support the collection and analysis of health information for addressing a variety of questions, including those involved in the study of technologies and medications or trends in public and population health. With Medicare and Medicaid funding becoming available in 2011 to reward the meaningful use of EHRs by qualified users, ONC must move quickly to meet these initial requirements.

Developing a learning health system requires that data be stored in electronic form in a way that can be translated and communicated to other sites and for other uses, and that most U.S. physicians—particularly those who work in practices of five or fewer physicians—be engaged in the capture and use of these data. But it also requires that these efforts be part of a larger national enterprise to achieve a nationwide, interoperable, private, and secure electronic health information system. ONC has several activities under way to advance progress on these near- and longer-term requirements.

State of Play: Ensuring Adoption and Effective Use of EHRs

The HITECH concept of meaningful use establishes an important link between the adoption of EHRs and their use to achieve specific health and health system performance goals. ONC's rulemaking authority is therefore an important tool for guiding several stages of HIT infrastructure development. As part of the first stage, ONC is working to identify data elements that will meet fundamental needs for learning in the future and to enable data collection, information sharing, and reporting. As the work evolves, stages 2 and 3 will emphasize the use of EHRs to improve care processes and outcomes, respectively (Blumenthal, 2010).

Rulemaking for stage 1—defining meaningful use and certification criteria for EHRs that must be satisfied to qualify for payment—is under way. The key question driving this process is whether data specified will have almost universal value now and in the future.

ONC is also engaged in work to create robust capabilities and incentives—an ecosystem—that will permit and encourage the exchange of

health information. This capacity is essential for the extraction and analysis of data widely dispersed across the health system in individual records. ONC is working to develop the Nationwide Health Information Network, which has many of the technical features required to support such robust information exchange and the kind of inquiries necessary for metadata analysis. Cognizant of the importance of reaching clinicians where they are, ONC also seeks to provide simple, alternative methods of information exchange that may not have all the properties needed to achieve long-term aims, but will contribute to improved care for patients and providers in the short term. This simpler form of exchange will provide a pathway toward the kind of information transfer capacity needed for an ideal system.

These initial efforts to get physicians and other health professionals in small hospitals to store data electronically and to create an infrastructure that makes it possible to find and transfer data are pivotal to establishing a foundational capacity for a learning health system and are achievable within the current policy and funding provided under HITECH. ONC's work has been substantially aided by the discussions and guidance of its committees on HIT policy and HIT standards with respect to approaches to health information exchange and requirements and data elements to include in the initial meaningful use framework. Stakeholder input on opportunities to encourage adoption and make information exchange more feasible is welcome.

Development of a National Infrastructure for Learning

If the meaningful use concept proves its value and gains durability, it may continue to be a focus of policy making. It is possible to imagine ever more demanding requirements for meaningful use, including data sharing and participation in more robust information exchange. However, ensuring the realization of the overarching vision for a national interoperable health information system that drives improvements in system performance and health depends upon leadership in Congress and the next administration, as well as public support.

Public Trust and Health Information Privacy and Security

Careful and constant attention to privacy and security issues will be essential to securing public trust and support. While people do take risks with their private information every time they go online to bank or make a purchase, there is clearly something more personal about the kinds of information stored in medical records. ONC will not be successful in creating an infrastructure for information exchange unless the public is confident—and conveys that confidence to the Congress—that those who collect and use

health data are doing so in a responsible way. The public must believe that the government is protecting its right to privacy and that the infrastructure is well protected against security breaches. To garner and maintain public trust, ONC will constantly reconsider and adapt its privacy and security frameworks, technologies, and legislative framework.

A working group of the ONC policy committee has reexamined the privacy and security needs associated with this new infrastructure and made recommendations in this area in summer 2010. Furthermore, ONC is also interested in investigating further the subject of data segmentation—the process by which sensitive data are potentially made more secure than routine health data. Technical issues exist in this area as well.

Concluding Thoughts

ONC's goal is to enable realization of the vision of a learning health system. The problem is a technical, a human, and a political one that requires the careful balancing of, and constant attention to, a broad array of issues. Much work is required to make the needed technical infrastructure available and useful to researchers, policy makers, and the custodians of the public health. However, the potential benefits for the health and care of Americans make the success of this endeavor an imperative.

NEW CLASSES OF DATA, NEW OPPORTUNITIES TO LEARN

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The concept of a learning health system intersects in a compelling way with the wisdom that one cannot manage what one cannot measure, or the more useful correlate that one can manage what one can measure. The society-transforming power of information technologies has been amply demonstrated by the spontaneous cultural shifts that have accompanied the global adoption of cell phones, electronic messaging of various types, and the web. The Internet is a ubiquitous set of distribution channels for digital data, and provides vivid examples of how the emergence of a new class of data results in what might be called the "leveraged creativity" of applications that dynamically use and add value to a basic infrastructure. Web "mashups"—real-time syntheses of data from multiple sources on the Internet—are typified by the many current applications that use geographic data (e.g., Google maps) and overlay hyperlinks on a seemingly endless variety of associated information, ranging from weather and traffic to shopping, as well as people joined by social networking applications. These phe-

nomena predict and are mirrored by changes in healthcare delivery—such as translational and clinical research that emerges as a result of either new classes of data with relevance for process control and/or scientific discovery or the new presentation of data that existed previously but were not available at the time and location of decision making. Three real-world examples serve to illustrate this premise.

The first is an instance of the effect of real-time presentation of data already captured in an inpatient environment, but not previously available to support quality control of a complex, team-based healthcare operation. Effective outcomes for many diseases require a multistep process, and the completion of any single step is necessary but not sufficient to achieve the desired outcome. For example, it is recommended that patients on ventilator support in intensive care units undergo a set of preventive measures to reduce risk of ventilator-associated pneumonia (VAP) (Coffin et al., 2008). These measures include prophylaxis against deep venous thrombosis, measures to reduce stress ulcers, sedation "vacations" to assess readiness to extubate, elevation of the head of the bed, mouth care, and hypopharyngeal suctioning. At Vanderbilt University Medical Center, electronic clinical decision support systems in use since 1994 provide alerts and reminders to clinicians about recommended best practices (Starmer et al., 2000). Each alert is triggered by an event monitor, a computer program that continuously reviews available data on an individual patient. The program generates a system message if a specific set of findings, such as a new laboratory value (e.g., falling serum potassium in the setting of digoxin administration) appears in the clinical data system.

Computerized alerts were developed for the care measures needed to prevent VAP, and although compliance was high for most individual measures, the end-to-end consistency of all measures being administered for all patients was below 30 percent. A new set of displays of existing data, called "dashboards," was created, showing all members of the care team which measures were due, done, and overdue (using simple green-yellow-red color coding, as shown in Figure 5-1). Also instituted was a set of web-based, real-time management reports of consistency of care showing "improvement opportunities" across all patients by time and location (see Figure 5-2). These changes were associated with a dramatic and sustained improvement in compliance with all measures and a reduction in the annual incidence of VAP per 1,000 patient days from 15.2 to 9.3 (Zaydfudim et al., 2009). Information technology alone was not responsible for this sustained improvement—which also required people and process—but it was a key enabling element.

A second example of new data sources catalyzing change is in the realm of personalized medicine—care tailored to known individual variability (particularly genetic variability) rather than being based on statistical

Bed	Patient name	Age	LOS	Orders			Vent	SBT Scrn	SBT Trial	DVT	SUP	RASS Ord.	RASS Pt.	HoB	swab	teeth	hySx
3002B	T, V W	72y	6 d		flowsheet	MAR	v	F		v	v	-4	-4	30			
3003X	N, D	60y	17 d		flowsheet	MAR	v	F		v	v	0	-2	45			
3004B	T, P L	64y	34 d		flowsheet	MAR	v			v	v	-1	-1	30			
3005A	C, D E	61y	7 d		flowsheet	MAR				v	v	0	-1	30	v	v	
3005B	B, J	66y	7 d		flowsheet	MAR	v	F		v	v	-1	-3	30			
3006X	W, A A	20y	66 d		flowsheet	MAR	v			v	v	-1	-2	30			
3007X	W, L E	49y	9:14		flowsheet	MAR				v		0	-1	30			
3008X	P, J L	69y	50 d		flowsheet	MAR	v	F		v	v	0	0	30			
3009X	R, C	72y	15 d		flowsheet	MAR	v	F		v	v	-1	-2	30			
3011A	P, J E	88y	9 d		flowsheet	MAR				v	v	0	0	45	v	v	
3011C	J, W D	69y	2 d		flowsheet	MAR				v	v	0	-1	30			
3011D	P, P J	55y	10 d		flowsheet	MAR	v	P	P	v	v	0	-3	30			
3011E	R, R E	74y	9 d		flowsheet	MAR				v	v	0	0		v	v	
3011F	N, E Y	55y	3 d		flowsheet	MAR				v	v	-1	0	30	v	v	
3012A	S, J D	56y	14 d		flowsheet	MAR	v	F		v	v	0	0	30			
3012B	R, M	63y	10 d		flowsheet	MAR	v	F		v	v	-2	-2	30			
3013A	N, B D	60y	8 d		flowsheet	MAR	v	F		v	v	-3	-2	30			
3013B	H, S M	66y	16 d		flowsheet	MAR				v	v	0	-1	30	v	v	

FIGURE 5-1 Ventilator-associated pneumonia prevention "dashboard."

		Improvement Opportunity									
Percent Range	Percent of Time Compliance	Rasso	RassT	HOB	Swab	Teeth	Hysx	SBT Scr	SBT	DVT	SUP
	41.115 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
	7.488 %	13 %	0 %	0 %	27 %	0 %	60 %	0 %	0 %	0 %	0 %
	30.273 %	21 %	6 %	6 %	18 %	0 %	18 %	27 %	0 %	0 %	0 %
	18.483 %	21 %	18 %	0 %	21 %	0 %	21 %	15 %	0 %	6 %	0 %
	1.843 %	27 %	18 %	0 %	33 %	0 %	12 %	0 %	0 %	0 %	0 %
	0.198 %	14 %	14 %	14 %	14 %	14 %	29 %	0 %	0 %	0 %	0 %
	0.000%	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
	0.000%	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
	0.000%	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
	0.000%	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
	0.000%	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %

FIGURE 5-2 "Improvement opportunity" web display of summary compliance for each ventilator-associated pneumonia preventive measure.
SOURCE: Vanderbilt University Medical Center.

averages from large studies. In this realm, a large and growing number of studies employ genome-wide association studies (GWAS) to correlate physiologic states, such as the presence of a disease or a favorable or unfavorable response to a therapy, with individual genetic variation as represented by single nucleotide polymorphisms (SNPs), copy number variations (CNVs), and other manifestations of the genetic similarities and differences among individuals (Altshuler et al., 2008). These research efforts are made possible by high-throughput laboratory methods capable of assessing hundreds of thousands to millions of DNA molecular patterns (still representing measurement of less than 1 percent of the complete human genome) in a cost- and time-efficient manner. More than 650 such studies have been published (Hindorff et al.), based generally on an experimental model that involves finding individuals who have a condition of interest, constituting a research cohort, and performing a consistent set of research assessments to establish the phenotype. These findings are then correlated with genome-wide scans of genotype to look for statistically significant associations with SNPs, CNVs, and other types of individual genetic variation.

A National Institutes of Health-sponsored consortium named eMERGE (electronic MEdical Records and GEnomics)[1] has demonstrated that phenotypes extracted from EHRs as a byproduct of health care delivered and documented for healthcare service rather than research purposes can replicate the observations drawn from carefully constituted research cohorts and also yield new observations (Ritchie et al., 2007). In addition, medical records may be regarded as reflecting the real-world experience of large collections of "experiments of nature," thus enabling a new form of discovery that has been termed PheWAS (phenome-wide scanning) (Denny et al., 2010). In contrast to GWAS, which begin with an observable phenotype and perform a genome-wide scan, PheWAS begins with a genotype and scans all clinically documented health conditions to validate existing genetic effects, as well as to discover new, previously unanticipated relationships that can be based on specific gene effects and common molecular pathways or co-occurrences of disease states. A particularly fertile area of genomics is the evolving science of pharmacogenomics, wherein the focus is on the identification of genetic variation that affects drug absorption, metabolism, and distribution, and on the identification of biomarkers that predict unusually good or bad response to drug therapy (Ginsburg et al., 2005). As the adoption of interoperable EHRs makes clinical events available for research on a larger scale, the discovery of molecular predictors and correlates of important health states and outcomes becomes an increasingly powerful source of new classes of data for a learning health system.

A third example, with particular relevance to the themes of patient

[1] See http://www.gwas.net.

empowerment and patients' ability to contribute to improved outcomes, is embodied in a prototype research application developed within Vanderbilt's web-based patient portal, called MyHealthAtVanderbilt.[2] Like patient portals at many academic and a growing number of community provider organizations, the MyHealthAtVanderbilt website provides registered users with a secure communication channel with their doctors and other providers, the ability to make appointments and renew medications, and online access to results of laboratory and imaging tests, as well as administrative functions related to billing and payment (Duncavage et al., 2007). More than 100,000 users of this portal have been enrolled, and each day more than 3,500 unique users log on to the site. This venue provides an opportunity to acquire data on types of health outcomes that are seldom if ever recorded by healthcare professionals, specifically the unanticipated positive effects of newly prescribed medications. Much attention and infrastructure are focused on identifying adverse drug effects, and surveillance for expected and unexpected adverse effects is a long-standing component of healthcare operations. Biological variability predicts that all unexpected effects are unlikely to be negative, but beyond the initial drug development process, there exists no systematic means of harvesting such serendipitous outcomes, and providers have no incentive to seek this information from patients or record it.

An institutional review board–approved pilot project undertaken within the MyHealthAtVanderbilt portal offered recipients of newly prescribed medications the opportunity to participate in an online survey of expected and unexpected drug effects. As shown in Figure 5-3, the individualized home page of a system user would display the invitation to participate if the associated pharmacy records showed that a new medication had been prescribed. Subsequently, the patient would confirm that he/she was currently taking the medication. Likert scale–like data entry would enable users to quickly describe both positive and negative reactions to medications, and unstructured text entry would enable them to describe unexpected effects (see Figure 5-4). More than 200 patients participated in the pilot feasibility study, which confirmed the expected distribution of therapeutic responses and known adverse effects and generated several "serendipity candidate" events (Pulley et al., 2010). Statistical validation of rare drug-associated events requires large populations that were not available for this pilot, but the prototype demonstrates that patient portals can be used to harness patients' observations about their health as part of the clinical and translational research enterprise.

Each of the above examples is a data source that can be used to create a learning healthcare organization. Although quite different in the types

[2] See http://www.myhealthatvanderbilt.com.

FIGURE 5-3 Patient portal home page inviting participation in a research study regarding medication effects. The invitation is keyed on pharmacy records showing a recent new drug prescription.

of data they handle—real-time process measures in an intensive care unit, DNA variation associated with conditions recorded in EHRs, and patient-observed serendipitous drug effects—each conveys the power of new types of data to inform both research and care.

WEB 2.0 AND PATIENT ENGAGEMENT

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"Connected health" is a term used to describe a model for healthcare delivery that uses technology to provide health care remotely. Technology is used to deliver patient care outside the hospital or doctor's office, thus em-

FIGURE 5-4 Sample online survey screen soliciting expected and unexpected medication effects. Patients responding "much better" or "much worse" were provided a text box for entry of their experiences.

powering patients to monitor their condition and obtain relevant feedback and coaching to achieve the best possible clinical outcomes.

The Center for Connected Health,[3] a division of Partners HealthCare

[3] See http://www.connected-health.org (accessed October 12, 2010).

in Boston, follows these principles to deliver care for a range of high-risk patients with chronic conditions. Participants in its programs are patients and providers in Partners' integrated delivery network throughout eastern Massachusetts. The Center has reported high rates of acceptance of its programs by patients and significant clinical improvement with a variety of patient groups, such as heart failure patients, hypertensive patients, and diabetics (Center for Connected Health).

Some forward-thinking employers in the area are also looking at such programs to help employees better manage their health. A recent example is EMC, a large data storage company that used SmartBeat, a hypertension self-management program developed by the Center for Connected Health. Such employee-based programs use characteristics that are unique to the work environment, such as competition, teamwork, and reward schemes, to motivate employees to adopt healthier behaviors.

Center for Connected Health: Overview

The Center currently offers three active programs for patients across the Partners network of hospitals: the Connected Cardiac Care Program (CCCP) for patients with chronic heart failure, Diabetes Connect for patients with type 2 diabetes mellitus, and Hypertension Connect for patients with hypertension (Table 5-1). The programs are designed to maximize opportunities for patient self-management of chronic diseases. The traditional model of care at the doctor's office is overly episodic and minimizes the opportunity for patients to be active participants in their own care. Connected health programs change this model, bringing care directly to patients while their care provider coaches them through the process of care. The programs follow a similar structure, based on the following four cornerstones.

Accurate Physiologic and Behavioral Data

The connected health programs harness physiologic and behavioral data using technologies that obtain these data objectively, such as wireless scales and blood pressure cuffs, smart glucometers, and pulse oximeters. These objectively derived data are often more accurate and reliable than hand-entered data and are important in gaining both patient and provider engagement.

Data-Specific Feedback

Using the data transmitted to the Center's servers, various levels of feedback are provided to users. This feedback ranges from a graphical

TABLE 5-1 Connected Health Programs Designed to Support Patient Self-Management of Chronic Disease

	Connected Cardiac Care Program (CCCP)	Diabetes Connect	Hypertension Connect
Physiologic data collected	Heart rate, blood pressure, blood oximetry, weight	Blood glucose	Blood pressure
Feedback	Live feedback by tele-monitoring nurses, graphical display, and context-specific messages	Graphical display, messages from a nurse when readings out of range	Graphical display, messages from a nurse when readings out of range
Coaching model	Centralized tele-monitoring nurse driven	Practice driven	Practice driven
Patients enrolled as of April 1, 2010	>1,000	>150	>40

display of users' data points over time, to assessment of their progress, to automatic alerts when their readings are out of a predetermined range.

Coaching

Data generated by users serve as the basis for context-specific feedback in the form of coaching. Coaching can be of two types: automatic and provider driven. Most connected health programs currently rely on coaching delivered by nurses who are working at the primary care level. These educators contact patients on a regular basis, provide feedback on their progress, and guide them to help improve control of their condition. The Center also has successfully demonstrated the use of automatic coaching by a "virtual coach."

Interface with Physicians

The connected health approach places special emphasis on the presentation of data to clinicians. The main design principle is finding meaningful trends and exceptions and presenting them to clinicians in a concise and actionable format.

Connected Health Patients

Connected health programs use primarily the Internet to collect data, engage patients, and provide feedback on their success. Despite recent survey data from the Pew Internet Project indicating that only 62 percent of adults living with at least one chronic illness have access to the Internet, compared with 81 percent of adults with no chronic diseases (Pew Internet and American Life Project, 2010), most programs at the Center have seen almost 100 percent acceptance by users. The current challenge for connected health is to create programs that employ advanced technology in a way that is simple to use and even simpler to understand and access—hence the Center's use of technology that connects to the Internet through simple telephone lines or Internet modems. Evidence also indicates that almost 70 percent of people with two or more chronic illnesses use mobile phones (as opposed to the 52 percent that use the Internet), underscoring the importance of mobile phones in reaching this population.

Mobile phones have proven to be an inexpensive, effective, and culturally acceptable means of keeping patients engaged with connected health programs. Mobile text messaging has been used in various programs as a tool to improve engagement. One such example is a sunscreen adherence study conducted by the Center, which demonstrated that participants who received daily text message reminders had significantly higher adherence rates (56.1 percent versus 30.0 percent, $p < 0.001$) (Armstrong et al., 2009).

User Engagement

One commonly raised concern with connected health programs is whether patients will really use them. All programs of the Center for Connected Health are currently practice based; hence the decision regarding how active patients should be is made by the practice based on how sick the patients are, what their perceived comfort with technology is, and how far away from their goals they are.

An important observation in the Center's ongoing program evaluation has been that patients who are not active in a program within the first 30 days of starting on the program almost never become active again. Patients who are active in the first month but not in the second likewise never become active again. Conversely, patients who remain active for the first 2 months have a 90 percent likelihood of remaining above the activity threshold throughout the program.

Another important determinant of success has been practice engagement, defined according to the number of times practitioners from a practice log on to the web portal to check their patients' activity. Preliminary

data show that practices whose providers log on more frequently have more patients who are active and have greater clinical success.

Connected Cardiac Care Program

The CCCP is currently in its third year of operation, making it possible to study the program's value in managing heart failure patients. Of about 3,000 eligible discharges from Partners each year, about 1,000 are enrolled in intensive monitoring using the CCCP. The program employs a weight scale, blood pressure cuff, and pulse oximeter as sensors, which upload data through a hub device given to the patient on enrollment. Three to four nurses oversee readings for 250 patients on any given day and reach out to the patients for software-flagged exceptions. Thus care can be focused on the patient, with data being uploaded every day and continuous telemonitoring being performed by the nurses. The involvement of the cardiologist is thus tailored to provide specialized care for those who need it, exactly when it is needed. Finally, the doctor is able to collaborate with patients on how their data relate to their clinical condition and affect their clinical outcomes and quality of life. As a result of this program, readmission rates have been reduced by almost half (from 0.92 annualized readmissions per person per year to 0.48) among program enrollees. Patients have reported higher awareness of how better to manage and control their clinical parameters and a greater sense of control over their disease condition.

Diabetes Connect: An Illustration of Lessons Learned

Diabetes Connect was started in February 2009 with two practices in the primary care network at Partners HealthCare that vary significantly in administration, activity, and success in the program. At the time of this analysis, the program had enrolled 75 patients divided almost equally between the two practices who were similar in age, gender, and pre-enrollment blood glucose level.

Practice 1 has a diabetes management center with dedicated staff (two registered nurses, certified diabetes educators, and a nutritionist) that supported the team of physicians. Practice 2 receives diabetes patient referrals from an endocrinologist and primary care providers in the community and is managed by one registered nurse. In the first 10 months of the program, practice 1 providers consistently logged on more often to the website (59 times/month versus 8 times/month by practice 2, $p < 0.001$).

The overall drop in HbA1c, the main clinical outcome measure, varied by practice (–1.8 points for practice 1 and –0.9 points for practice 2, $p < 0.05$). One explanation for this difference is how engaged the providers in charge of the application were as measured by the number of times they

logged on. Anecdotally, patients reported that they were more likely to participate in the program if they knew a provider was looking at their glucose upload data. Indeed, 78 percent of patients in practice 1 were found to be active, compared with 33 percent of patients in practice 2.

Active patients (defined as those who uploaded blood glucose readings) experienced a larger drop in HbA1c than patients who had no activity (practice 1: –1.85 vs. +0.1, $p < 0.001$; practice 2: –1.38 vs. –0.6, $p < 0.05$). These numbers point to a potential dose-effect relationship between patient activity and clinical success. Although the sample size is not large enough to permit definitive conclusions, the trend is convincing: those patients who uploaded their data more had better outcomes.

As already mentioned, getting patients to be engaged in the first 30 days appears to be extremely important. In this analysis, 50 patients had some activity in the first month. This number dropped to 40 in the second month. At the end of 10 months, 35 of those 40 patients were still active in the program. The 10 patients who ceased being active in the second month never became active again.

Conclusion

The recent healthcare reform legislation has opened up possibilities for changing reimbursement patterns and definitions of what is considered acceptable care. The connected health programs described in this paper show promise for helping physicians achieve clinical goals with their patients not only to meet reimbursement targets, but also to raise the standard of care provided to each patient. Early results suggest it is important to ensure and maintain both patient and provider engagement in the program.

Constant and meaningful feedback, coaching, and increased communication with providers could be useful tools to ensure patient engagement. Similarly, reimbursement patterns and improved clinical outcomes could influence provider engagement. Experience with the connected health programs shows that factors not only are individually important, but also enhance each other's effects.

The evolving understanding of these programs will help improve the patient selection process to ensure that patients who are able to fully utilize and benefit from the programs will be enrolled. New technology, such as mobile phone applications and text messaging, provide an opportunity to simplify care provision even more and increase the range of patients that can be helped. Finally, strong organizational commitment to aligning reimbursement strategies to reflect clinical outcomes and superior patient care is essential to the successful implementation of any innovative care process, including connected health.

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6

Patients, Clinical Decisions, and Health Information Management in the Information Age

INTRODUCTION

Until recently, health care was characterized by an information asymmetry in which physicians served as the dominant source of medical information for patients. The Internet has rapidly transformed the health information landscape—initially opening up myriad resources, targeted to the general public, for health-related guidance and information, and then, with the emergence of Web 2.0, enabling the public to easily create and share health-related content online. Patients have responded to this shift by increasingly seeking health-related information outside of the care environment (Fox and Jones, 2009) and creating and contributing to a wide variety of social networks and health websites (Sarasohn-Kahn, 2008). Perhaps the most important opportunity that comes with greater information availability is the emergence of a culture that recognizes and supports the unique contributions of both patients and providers to care decisions and health management.

Such a shift moves patient-centered care beyond a focus on "information, communication, and education of patients" (IOM, 2001) to a system in which patients are engaged as full partners in their care and disease management. Greater engagement of patients is imperative, with more than 90 million Americans now being afflicted with one or more chronic conditions. Chronic disease management, for example, requires continuous monitoring and evaluation of disease progression and treatment effects, coordination of care across specialists and organizations, and patient adherence to long-term treatment regimens. Another tool for achieving patient

engagement is through electronic health records (EHRs) and patient portals, which are beginning to be adopted nationwide as novel ways for providers to partner with patients by providing information and support for care management.

The papers in this chapter review lessons learned from efforts to support the active engagement of patients in their healthcare decisions and health management and identify priorities and strategies for progress. In the first paper, George D. Lundberg of Cancer Commons provides an overview of the Internet revolution, which has democratized information. He reviews opportunities to improve the information available to or accessed by patients, as well as to use the Internet as a platform to engage patients in real-time, rapid learning communities.

In the second paper, Paul C. Tang of the Palo Alto Medical Foundation demonstrates the critical importance of engaging patients in their own care to close gaps in health outcomes and system performance. He reviews how information technology applications such as patient dashboards has helped make patients part of the health team, fostered patient and provider collaboration in tracking progress toward health goals, and provided tools to transform data into information from which patients can learn.

Dorianne C. Miller, formerly of the University of Chicago Medical Center, draws attention to initiatives that are helping to extend health care to settings outside of the clinical encounter. Shifts in patient population demographics and in the focus and capacity of health systems are driving the creation of applications to ensure that patients receive care (e.g., patient health records and portals, e-visits) and support beyond the traditional care environment. In addition to highlighting opportunities, she discusses barriers to expanded use of such technologies, such as social acceptability, lack of Internet access, and clinician reimbursement.

PUBLIC AND PATIENT INFORMATION ACCESS AND USE AS A CORE CARE COMPONENT

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Cancer Commons

Change is everywhere and affects everyone. People handle change in three different ways:

- Fear it; fight it; not recognize that change is inevitable; lose.
- Fail to recognize the need for and reality of change and be swept away by it.
- Seek it; recognize it; harness it; guide it; and eventually win with it.

The future is very difficult to predict; in fact, the only certain way to predict the future is to create it. Change for the sake of change may not be necessary or desirable. Too often, however, the need for change is not evident until it is too late.

The Democratization of Information

Three individuals merit mention when one is discussing information as a core component of care: the late Archie Cochrane, for his demand that evidence underpin clinical decisions; the late Dr. Tom Ferguson, the original e-patient, who was in many ways the father of participatory medicine and use of the Internet to empower patients; and Don Berwick, who has been a major leader in patient-centered care.

Most health care is self-care. In some ways, basic self-screening for health concerns is a routine part of everyday life; however, people should be better supported in taking charge of their health. Moreover, all medical care is personal. The credo of the Lundberg Institute states: "one patient; one physician; one moment; one decision."[1] Health decisions should be shared by the patient and physician, be informed by the best available evidence, and include consideration of cost (regardless of who—the patient, the insurance company, the government, the provider [charity care]—pays the bill) and of whether there is a lower-cost alternative with equivalent safety and effectiveness. That is economic informed consent. In a nonemergency, noncritical care situation in which the patient has control of his/her mental faculties, the patient and physician should know the cost before making an informed decision.

The Internet changed everything, much as electricity did. Health information began appearing on the Internet in the mid-1990s. Physicians On-Line began in 1994, Medscape in May 1995, and the American Medical Association (AMA) website with the *Journal of the American Medical Association* (JAMA) and the *Archives Journals* in August 1995. In 1995, e-Medicine began. About that time, GlaxoWellcome provided a $250,000 grant to AMA to start an HIV/AIDS online information base with JAMA. Initially, this resource was aimed at sophisticated HIV researchers and physicians, but the actual audience was HIV patients and their families, loved ones, and caregivers. This illustrates the principle that more than any other medium, the Internet democratizes information. The reader really does choose.

[1] See http://www.lundberginstitute.org (accessed October 14, 2010).

Caveat Lector

Consumer choice, however, raises concerns about misinformation. In 1997, an editorial in JAMA addressed this issue (Silberg et al., 1997). Titled "Assessing, Controlling, and Assuring the Quality of Medical Information on the Internet. Caveat Lector et Viewor—Let the Reader and the Viewer Beware," the article outlines key questions that readers should ask about any serious information on health and medicine posted on the web:

- Who wrote this?
- Where does that person work?
- If the information comes from elsewhere, what is its attribution; when was it published?
- If it was updated, when?
- Who owns the site where the article is published, and what is the funding source?

This editorial is frequently cited, and these criteria have had some influence as a result of being widely quoted and applied in practice by many publishers, editors, and authors. However, these caveats are routinely ignored by readers who consume whatever information search engines lead them to. Readers seek out trusted brands and return to sites they perceive to have helped them; thus, it is an information provider's responsibility not to mislead the reader.

Although many dismiss the Internet because so much of the information is suspect or worthless, the same is true of most media. The web is simply another medium, albeit a very powerful one.

Ensuring Open Access to Quality Information

Patients and consumers, like physicians, now receive most of their new medical and health information from the Internet (Fox and Jones, 2009). In many cases, patients receive more health information from the Internet than from their own physicians (Gualtieri, 2009). Typically, instead of bringing their printouts to their physician's office, patients log on *after* seeing their physician to check on findings, diagnoses, and diagnostic tests performed and drugs prescribed (Diaz et al., 2002). These searches likely start with the few details the patient remembers from the provider visit. Usually, the patient starts with a general search engine, most likely Google, Yahoo, or Bing. Given this common practice, the information age presents an enormous opportunity for savvy physicians to deliver an "information prescription" to patients who are motivated to learn and have access to the world's greatest library at their fingertips.

An informal survey of which medical/health websites provide the most consumer-friendly and useful information on cancer identified the following as key resources for patients:

- www.cancer.gov (National Cancer Institute website)
- www.pubmed.gov (Medline Plus)
- www.cancer.org (American Cancer Society website)
- A tie between www.webmd.com, www.mayoclinic.com, and www.wikipedia.com
- www.nccn.org (National Comprehensive Cancer Network website)
- www.intelihealth.com (Harvard Medical School and Aetna website)
- www.ACOR.org (Association of Cancer Online Resources website)
- www.cancer.net (American Society of Clinical Oncology website)

Additional suggestions for new websites that are interesting and useful for consumers include www.keas.com and www.medhelp.com; additionally, although intended for medical professionals, www.medscape.com, www.medpagetoday.com, and www.emedicine.com are all very useful for patients. All of these sources are open access—available to anyone with access to the Internet, free of charge, and usually without user registration requirements.

The deliberate practice of limiting the flow of medical information on the part of most of the medical publishing industry compromises the public interest. Although most new medical information in the United States emanates from tax-supported research, such as that funded by the National Institutes of Health, the authors of papers reporting the results of such studies still overwhelmingly choose to submit the papers to journals owned by those that are, or function as, for-profit publishers. The taxpayers, who own the information by virtue of having paid for it, are therefore impeded by these publishers from using the data to treat (if a physician) or be treated (if a patient). As much as 90 percent of the medical research literature is still provided by such "closed" sources.

The case for the unfairness of this situation has been made since about 1999 and has led to great progress in creating more open-access sources. Leaders in this field include www.pubmedcentral.gov, www.biomedcentral.com, the Public Library of Science/Medicine, the *Medscape Journal of Medicine* (1999–2009), Medscape's Publishers Circle, Lund University Library's *Directory of Open Access Journals*, the Cochrane Collaboration (easily available through MedPage Today), and the Effective Care Program of the Agency for Healthcare Research and Quality.

Many believe that the single greatest barrier to successful public access to and use of medical information as a core care component is the general lack of reliable information sources in the traditional public media

(e.g., newspapers, magazines, radio, and television—all major information sources for patients) (Schwitzer et al., 2005). Gary Schwitzer, a professor of journalism at the University of Minnesota, publishes www.healthnews-review.org, which weekly rates the handling of major health-related news stories. He uses ten criteria to assess the quality of these reports. Did the news report:

- establish the availability of the treatment, test, product or procedure;
- address costs;
- avoid disease-related fear mongering;
- evaluate the quality of evidence;
- quantify potential harm;
- establish the true novelty of the treatment, test, product, or procedure;
- quantify potential benefits;
- rely solely or largely on a press release;
- use independent sources and report conflicts of interest; and
- compare the new approach with existing alternatives?

Major medical and health reports emerge every day, but few receive passing grades in the Schwitzer reviews. Network television reports are consistently the worst, and the situation is not improving. Many major newspapers and local television stations no longer even have health reporters on their staffs, relying on general beat reporters to cover health.

The Next Phase: Open-Access, Real-Time Information for Personalized Health

The poet Alexander Pope wrote, "The proper study of mankind is man." In health, one might say, "The proper study of me is me." While 99.9 percent of all DNA is shared, the remaining 0.1 percent make all the difference. With some diseases, "the proper study of my disease is my disease." This statement is particularly important when one is considering the molecular genomics of cancer because one person's cancer may actually be unique. This fact constitutes the basis for personalized molecular oncology and pharmacogenomics. Increased recognition of the uniqueness of individuals and individual diseases has led to a conflict between two perspectives on information needs and approaches to evidence development.

On the one hand is Archie Cochrane's basic tenet: the gold standard for evidence development is a large randomized controlled trial (RCT) that has sufficient statistical power to be meaningful. If there are conflicts among clinical trial results, those conflicts are settled through meta-analysis

(Juni et al., 1999). RCTs work well when the populations to be studied are molecularly and genomically homogeneous, allowing standardized interventions to be tested.

On the other hand, an important movement to a more personalized approach to medicine is taking place. This approach seeks to address the needs of patients who fall outside the traditional groups that participate in RCTs—the outliers and those whose diseases are molecularly and genomically heterogeneous (West et al., 2006).

For many decades, case studies have been out of vogue in medical journals, but they may now be returning to favor. Some time ago, *JAMA* published the hierarchy of evidence based on quality: RCTs are at the top, while Level II-3 includes "dramatic results in uncontrolled experiments," such as the results of the introduction of penicillin therapy. During the *JAMA* centennial, 68 of the best articles over 100 years of the journal were selected and published as "landmark articles." Notably, 5 were case reports: in 1933, Graham's first removal of an entire lung for bronchial carcinoma; in 1939, Gross's report of the successful ligation of a patient with ductus arteriosus; also in 1939, Levine's discovery of the Rh factor; in 1956, Merrill and Murray's homotransplantation of a human kidney between two homozygous twins; and in 1956, DeBakey's first aorto-coronary bypass with a saphenous vein graft. These were all crucial events in medicine, and all were case reports.

Cancer as a Case Study

Each year, 3.5 million Americans are diagnosed with some form of cancer. Skin cancer is diagnosed in 2 million and other forms of the disease, including melanoma, in 1.5 million. During 1969–1971, President Nixon declared a war on cancer, initiating a massive outlay of research funding and effort that continues today. The result has been tremendous advances in cancer science and some therapeutic progress, primarily against childhood cancers, leukemia, lymphoma, and germ cell tumors. Extensive antitobacco efforts have prevented many cancers. And the movement toward palliative and hospice care continues to grow. However, between 500,000 and 600,000 Americans still die of cancer each year, and progress on significantly reducing that number has been distressingly slow.

The slow progress of the translation of research into positive outcomes in the treatment of cancer is disappointing. The multiyear delays from observation to successful implementation are in part a product of a system of excessive bureaucracy; old-fashioned communication methods; and an academic and publishing establishment that sometimes appears to care more about preserving its ancient institutions, procedures, and self-interest than about defeating cancer.

Two concurrent revolutions in medicine and technology are currently under way:

- *The genomics and molecular medicine revolution*—Advances in understanding of cancer biology are leading to the rapid development of molecular diagnostics and targeted therapies that can work together with traditional pathology to lower costs and improve patient care and outcomes.
  - — Next-generation sequencing, proteomics, and other such technologies are rapidly becoming available at dramatically lower costs.
  - — Personalized, molecular medicine (oncology) is now being added to traditional large-scale clinical trials as an approach to creating evidence that can inform clinical decision making.
  - — Patient-centric research focusing in depth on individuals or small groups is delivering results that can apply to patients with similar disease profiles whose cancer has not responded to "standard-of-care" treatments. This research has proven that so many cancers are so unique that large trials are problematic in addressing the disease.
- *The Internet revolution*—The Internet has democratized access to information for patients, physicians, and researchers so they can rapidly learn more about diseases and treatment options. The result is demand for new services, tools, and approaches for cancer care, including
  - — the organization, indexing, and personalization of credible information to make it actionable and computable for individual cases;
  - — the development of decision tools and resources specific to cancer care;
  - — open science that allows physicians and researchers to collaborate in real time to defeat cancer, one patient at a time;
  - — new approaches to funding research, including patient-funded research and individualized fund raising, now possible at a rapidly decreasing cost; and
  - — active participation of patients in their own treatment decisions, as well as in rapid-learning communities that share what they learn and experience with each other—what works, side effects and quality of life—a development that raises the possibility of every patient taking charge of his/her destiny and leaving no stone unturned in the quest for a cure.

CollabRx is a company that seeks to harness both of the above revolutions to improve individual patient care. Its initial approach was to develop

an Internet platform called Cancer Commons for real-time translational cancer research and personalized oncology. Key goals are:

- to bring together patients, primary care physicians, oncologists, and researchers in academia and industry interested in applying the latest developments in personalized, molecular oncology;
- to provide them with the latest information, tools, and resources they need to enable each patient to achieve the best possible outcome and to defeat cancer, one patient at a time;
- to capture and aggregate the results over all studied patients to improve cancer treatment generally;
- to share what is learned from each patient with the clinical community in real time so the next patient can benefit through a reduction in the time from observation, to trial, to presentation, to publication, to treatment guidelines; and
- as the overarching goal, to run this translational loop in real time so that what is learned from one patient can be applied to the next, rather than waiting many years for the traditional process to play out.

Cancer Commons is likely the only rapid-learning community that links researchers, clinicians, and patients to defeat cancer, one patient at a time. It is intended to disrupt traditional thinking by promoting real-time, open-source science that includes patient input, especially from those highly motivated individuals known as "super patients" or "disease warriors." The medical writing and publishing industry will also be disrupted, as it will rely on house vetting, rapid sharing, and postpublication peer review that promote the open exchange of creative information. The bias that inevitably results from a principal reliance on prepublication peer review will decrease, including the potential bias against the publication of unpopular or surprising results.

HEALTH INFORMATION TECHNOLOGY–BASED APPROACHES TO HEALTH MANAGEMENT

Paul C. Tang, M.D., M.S.
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Effective use of health information technology (HIT) can drive significant improvements in physician and health system performance. Without engaging patients and supporting their active participation in managing their own health, however, the nation will still fall short of its health goals—for both individuals and the population. A learning health system

for patients places priority on meaningful applications of HIT to help patients gain access to their health data, relevant knowledge, and tools to guide self-care and health management. Shared information can help to create an effective partnership between the professional health team and patients in order to improve patients' health.

The Palo Alto Medical Foundation (PAMF) has developed several promising approaches to using HIT to support a learning health system for patients. These approaches involve providing information and tools at the point of care and in the home to support better decision making and to engage patients in active learning and health management.

Status Quo for Health System Improvement

Overall, national healthcare quality scores are improving by only 2 percent per year (AHRQ, 2009). In just about any other industry, this rate of improvement would be unacceptable. What can we do differently to accelerate the rate of improvement in health and health care? A key enabler is to provide data, knowledge, and tools to all decision makers—clinicians, patients, and their families.

Driving Physician Change Through Data

Providing health professionals with accurate, relevant information in real time is one of the most powerful means by which EHRs can drive care improvement. HIT-enabled clinical decision support and quality-reporting feedback have demonstrated significant and immediate impact on physician performance. Using clinical decision support tools embedded in its EHR, PAMF has been able to better support informed decision making by physicians, resulting in orders that reflect up-to-date clinical information and medical knowledge. EHR systems can also provide near real-time feedback on physician performance. PAMF provides its physicians with unblinded quarterly performance data displayed alongside data from their home medical department. Of importance, the quality metrics are derived from clinical data from the EHR, which the physicians find credible. In contrast, most public reporting measures are derived from billing data, which contain significant errors, making them less reliable to use. Credible data are key to changing behavior.

The effect of providing point-of-care decision support and frequent performance reporting has been striking. The national benchmark for control of diabetes—a hemoglobin A1c (HbA1c) level below 7—is around 50 percent. In contrast, PAMF has seen quarterly improvements in HbA1c control and is performing 40 percent better than the national average. Having a 70 percent score is still not optimal, however. For the organization

to close that 30 percent gap, patients must be included in the process of managing their health.

HIT to Transform the Patient Experience

For patients, diabetes is a ravaging disease that is lived with by making hundreds of decisions, such as what to eat and whether to exercise, remembering to take their medications, checking their blood glucose, and so on. If patients are going to make the decisions that can keep their diabetes under control, they also must have good and timely information. Not surprisingly, as with physician performance improvement, patients benefit from the provision of real-time information more than from a physician critique 3 months after making a decision. Moreover, information must be understandable to patients and relevant to their individual health goals and concerns.

Personalized Health Goals

Physicians need to understand their patients' preferences and individual health goals. Some patients want to live until 90, others may want to see their grandchildren graduate, and some want to avoid having a stroke. The way to learn about patient goals is to ask. A Stanford University project sponsored by The Robert Wood Johnson Foundation, called Living Profile,[2] illustrates the power of this approach.

In the project, children with serious chronic diseases were asked what information they would like to put in their personal health record (PHR) for their doctor to read. One teenage girl described her life activities, not referring explicitly to her chronic condition: "I don't think that my condition makes me who I am." When the same question was asked of adults with diabetes, their responses were also insightful, revealing opportunities to teach and to better understand patient needs and concerns. For example, an individual with type 2 diabetes asked, "If I do all the right things, can I reverse this diagnosis?" If the provider community does not clearly and consistently answer this question for people with diabetes—many of whom have lived with their condition for decades—it is missing an important opportunity to improve health.

Understanding patient goals also enables physicians to clarify or express guidance on aspects of the patient's situation more effectively. Sometimes patients have very specific goals. For example, one woman had a daughter in kidney failure, and her goal was to be healthy enough to give her daughter a kidney. Such strong, motivating health goals offer a physi-

[2] For more information see http://livingprofiles.net/ (accessed October 14, 2010).

cian the chance to develop, in collaboration with the patient, care management plans to reflect progress toward and attainment of patients' personal health goals.

Personal goals do not change medical advice, but they change the approach and agenda for providing the advice. Some patients may say they need help in quitting smoking. Others may say that exercise is boring. Still others may want to understand how to control their diet. In every case, patients' goals are key to helping them make decisions that can improve their health. Not many physicians engage in these sorts of discussions with their patients; thus, a focus on identifying personalized goals holds great potential for providing insight on the approaches and information that that can best help the patient.

Use of HIT to Help Patients Monitor Health Data

Once patients' goals are understood, HIT offers a means to help them achieve those goals. Take, for example, patients who want to control their diet. The physician can provide a list of appropriate foods, as well as a glucometer to help monitor blood glucose. PAMF has taken this approach a step further and distributed wireless glucometers to patients with diabetes. This changes the device from a tool that simply measures glucose into an instrument that changes behavior. Rather than requiring patients to record their glucose readings in a diary, followed by a trip to the physician's office for consultation, the electronic glucometer transmits data to the patient's cell phone, which forwards the data to PAMF's EHR system. If the graph of home glucose readings shows a little blip, patients can annotate the reading online with a short note so they can explain to the physician the circumstance causing this change.

The personal health goal therefore provides an important context for discussions with the physician about glucose data. The patient may be concerned that a relative lost a leg to diabetes or that a coworker had a heart attack or a stroke from diabetes. Using an EHR-produced diabetes dashboard, the physician can illustrate the patient's risk of experiencing the same thing. After reviewing the glucose data, the physician can review other, related tests, such as the lipid profile, the HbA1c, and blood pressure readings. Teaching the patient how certain values increase the risk for bad outcomes can help the patient select new health goals. The physician can show how certain test results relate to the goal. These data provide a learning experience for patients—connecting, in this case, the need for active monitoring of blood glucose with the effect of diet, exercise, and medications.

From Learning to Changing Behavior

The diabetes dashboard helps patients see how things change in response to their behavior and adherence to a health management plan (Figure 6-1). Its features illustrate the impact of certain behaviors and reinforce what is needed to achieve personal health goals.

PAMF is conducting a randomized controlled trial to evaluate the impact of its online disease management system, including the tools discussed above. An early focus group discussion conducted with beta trial participants reinforced the potential of the approach. Patients initially participated in measuring and tracking their glucose because PAMF clinicians were looking at the results—in a sense, because they were told to. However, focus group discussions revealed that as time went on, patients became more engaged and started using the system for themselves because the information illustrated how what they ate affected their readings, or it enabled them to actively learn and watch how *their* behavior and *their* decisions impacted *their* health outcomes. Comments from the focus group members also underscored the role of the dashboard in helping them make better decisions. For example, denial became more difficult because they now knew how a decision, say, on whether to eat a piece of pastry would affect their readings and their risk. Such a decision is just one of the hundreds that patients must make to improve their health.

The use of HIT can drive improvements in physician and health system performance, but it can also transform patients, patients' lives, and their health decisions. The use of PHRs provides patients with access to their health information; tools with which to visualize and learn from these data; and, more important, a means to engage them in their health care by making them part of the health team. Enabling learning among the entire health community, which includes patients, must be the goal of a learning health system.

HEALTH AND DISEASE MANAGEMENT OUTSIDE THE CLINIC DOORS: THERE'S AN APP FOR THAT!

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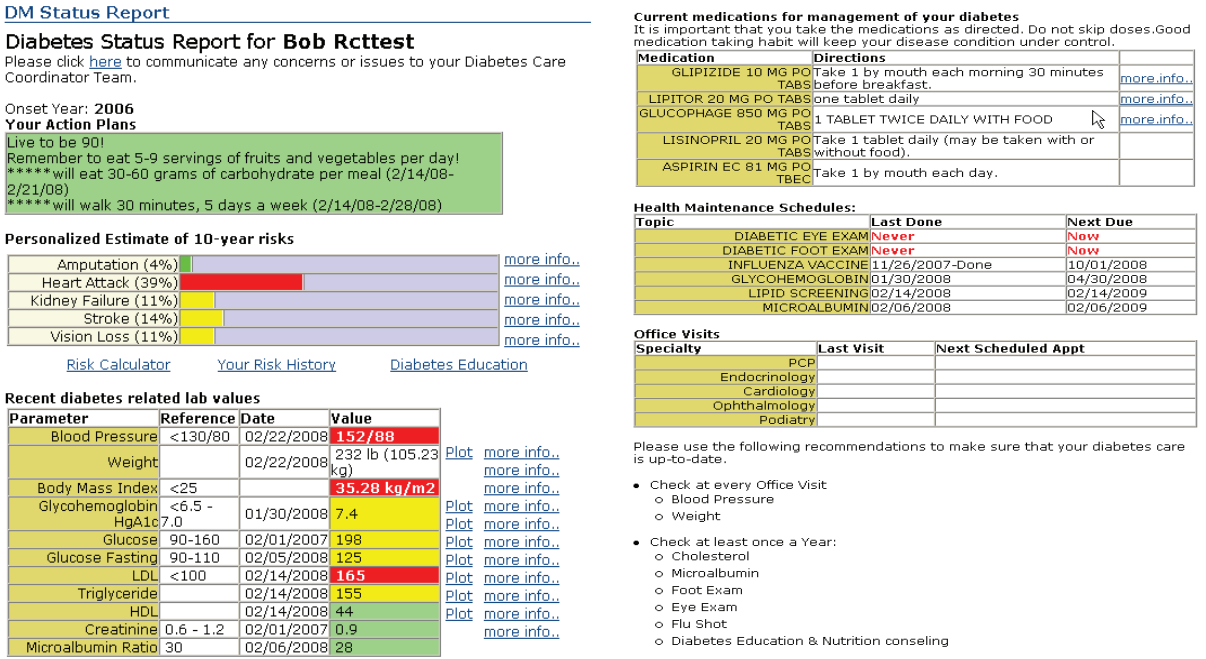
Institute for Healthcare Improvement

The availability of HIT applications, changing population demographics, and changes in capacity to deliver primary care are impacting the growth of health and disease management activities that occur outside the clinical setting. This paper reviews the context of primary care delivery for providers and patients, the challenges of providing care outside of the office visit, promising HIT approaches to help patients access information and



DM Status Report

Diabetes Status Report for **Bob Rcttest**

Please click here to communicate any concerns or issues to your Diabetes Care Coordinator Team.

Onset Year: **2006**

Your Action Plans

Live to be 90!
Remember to eat 5-9 servings of fruits and vegetables per day!
*****will eat 30-60 grams of carbohydrate per meal (2/14/08-2/21/08)
*****will walk 30 minutes, 5 days a week (2/14/08-2/28/08)

Personalized Estimate of 10-year risks

Amputation (4%)	more info..
Heart Attack (39%)	more info..
Kidney Failure (11%)	more info..
Stroke (14%)	more info..
Vision Loss (11%)	more info..

Risk Calculator Your Risk History Diabetes Education

Recent diabetes related lab values

Parameter	Reference	Date	Value		
Blood Pressure	<130/80	02/22/2008	152/88		
Weight		02/22/2008	232 lb (105.23 kg)	Plot	more info..
Body Mass Index	<25		35.28 kg/m2		more info..
Glycohemoglobin HgA1c	<6.5 - 7.0	01/30/2008	7.4	Plot	more info..
Glucose	90-160	02/01/2007	198	Plot	more info..
Glucose Fasting	90-110	02/05/2008	125	Plot	more info..
LDL	<100	02/14/2008	165	Plot	more info..
Triglyceride		02/14/2008	155	Plot	more info..
HDL		02/14/2008	44	Plot	more info..
Creatinine	0.6 - 1.2	02/01/2007	0.9		more info..
Microalbumin Ratio	30	02/06/2008	28		

Current medications for management of your diabetes

It is important that you take the medications as directed. Do not skip doses.Good medication taking habit will keep your disease condition under control.

Medication	Directions	
GLIPIZIDE 10 MG PO TABS	Take 1 by mouth each morning 30 minutes before breakfast.	more.info..
LIPITOR 20 MG PO TABS	one tablet daily	more.info..
GLUCOPHAGE 850 MG PO TABS	1 TABLET TWICE DAILY WITH FOOD	more.info..
LISINOPRIL 20 MG PO TABS	Take 1 tablet daily (may be taken with or without food).	
ASPIRIN EC 81 MG PO TBEC	Take 1 by mouth each day.	

Health Maintenance Schedules:

Topic	Last Done	Next Due
DIABETIC EYE EXAM	Never	Now
DIABETIC FOOT EXAM	Never	Now
INFLUENZA VACCINE	11/26/2007-Done	10/01/2008
GLYCOHEMOGLOBIN	01/30/2008	04/30/2008
LIPID SCREENING	02/14/2008	02/14/2009
MICROALBUMIN	02/06/2008	02/06/2009

Office Visits

Specialty	Last Visit	Next Scheduled Appt
PCP		
Endocrinology		
Cardiology		
Ophthalmology		
Podiatry		

Please use the following recommendations to make sure that your diabetes care is up-to-date.

- Check at every Office Visit
  - Blood Pressure
  - Weight
- Check at least once a Year:
  - Cholesterol
  - Microalbumin
  - Foot Exam
  - Eye Exam
  - Flu Shot
  - Diabetes Education & Nutrition conseling

FIGURE 6-1 Use of the diabetes dashboard to provide a learning system for patients. The dashboard provides a means for patients to review their health action plans, personal health risks, modifiers of their risks, and actions to reduce complications.
SOURCE: Palo Alto Medical Foundation.

care, and policy implications of these approaches and barriers to their dissemination.

The public image of the physician of the 1940s was one of being available 24 hours a day, 7 days a week; tolerating conditions of adverse weather; and neglecting personal commitments to attend to the urgent healthcare needs of patients. Indeed, a popular cigarette manufacturer promoted this image as one reason why physicians should smoke cigarettes (Gardner and Brandt, 2006).

Although scientific evidence has subsequently refuted the need for cigarettes as a "therapeutic" stimulant for physicians, the image of the availability of physicians for health information on demand has persisted. Physicians have continued to seek ways in which health care can be extended to patients outside of the clinic doors, particularly to improve health outcomes for the chronically ill.

As medical costs skyrocketed in the 1990s, payer groups concerned about the effects of healthcare costs on both the corporate bottom line and the health of the workforce made significant investments in disease management organizations that could work in conjunction with healthcare providers to improve care outside the clinical setting and encourage better outcomes (DMAA, 2006). However, the environment of healthcare delivery continues to evolve as society changes and medical advances are achieved. What are some of the environmental factors driving this change, and how is HIT helping to achieve the goal of extending care beyond the clinical setting?

Societal Changes

Personalized Medicine

In 2003, the National Human Genome Research Institute completed the mapping of the entire human genome, heralding the age of personalized medicine. Seeing the enormous potential for generating therapies specifically targeted to individuals based on their genetic profiles, environmental risk factors, and lifestyles, bench scientists, clinicians, pharmaceutical companies, information technology experts, and patients began seeking ways to link this burgeoning information to treatment of the individual. One of the recommendations generated by the Personalized Medicine Coalition through its public education arm, The Age of Personalized Medicine,[3] was to have a secure, interoperable EHR for every American, bringing together personal, clinical, and molecular information that can facilitate improve-

[3] See http://www.ageofpersonalizedmedicine.org/center/policy/hit.asp (accessed October 14, 2010).

ments in therapeutic care in a patient-centered fashion. The ability to capture electronically information submitted by both patients and clinicians, as well as genomic information, will lead to better therapeutics and better outcomes for people with chronic health conditions.

Baby Boomers and Health Care: Supply and Demand

In 2011, 78 million people, the first wave of the Baby Boom generation, will reach age 65. By 2030, it is estimated that one of five people in the United States will be over age 65. The average American over age 75 has three chronic health conditions and takes four medications. Although older Americans are living longer and healthier lives, their healthcare needs are often complex. An Institute of Medicine report titled *Retooling for an Aging America: Rebuilding the Health Care Workforce* contains the recommendations that the number of physicians trained in care of the elderly be substantially increased, that the nonphysician long-term care workforce be expanded, and that informal caregivers be better prepared to provide care to aging loved ones (IOM, 2008). Despite a 1-year trend toward increased numbers of students selecting primary care careers, however, the Association of American Medical Colleges predicts there will be a shortage of approximately 50,000 primary care physicians by 2025 (AAMC, 2010). Most aging adults are cared for by general internists or family physicians—the adult primary care physicians—but estimates suggest that there will not be enough of these physicians. Can HIT help to fill this gap?

Incentives Through Accreditation: The Patient-Centered Medical Home and HIT

In 2007, the American College of Physicians, the American Osteopathic Association, the American Academy of Family Physicians, and the American Academy of Pediatrics joined forces to delineate the principles of the patient-centered medical home (PCMH). One of the hallmark values of this document is that health care should be facilitated by the presence of registries, health information exchanges, and EHRs to ensure that patients receive care when and where they need and want it in a culturally and linguistically appropriate manner. HIT should be used to support optimal patient care, performance measurement, patient education, and enhanced communication (NCQA, 2008). The National Committee for Quality Assurance operates the voluntary accreditation PCMH demonstration through its Physician Practice Connections® program. Although not a mandatory component, advanced electronic communication—including the availability of an interactive website, electronic patient identification, and electronic care management support—was included as a 2009 update.

Approaches to Health and Disease Management Outside the Clinic Doors

With the changing demands of consumers, the aging of the population, and incentives for quality improvement, how can HIT facilitate better healthcare outcomes at lower cost? Following are three examples of approaches that might be adopted more widely with the growth of HIT.

Patient Electronic Health Record Portals

As part of the demonstration initiative Pursuing Perfection, a project of the Institute for Healthcare Improvement, participants from Whatcom County, Washington, decided to fully embrace the concept of patient-centered care by facilitating communication between chronically ill patients and their healthcare delivery system. With patients as part of the planning team, they developed the website www.patientpowered.org, which includes information on initiatives to improve patient-centeredness, as well as useful information and tools for self-management of chronic conditions. Part of the Patient Powered website is a shared care plan (SCP)—a document, either web-based or on paper, that allows patients to gather all their health-related information in one place. The document includes the patient's personal profile, healthcare team members, chronic and long-term diagnoses, self-management and lifestyle goals and action steps, treatment goals, names of prescriptions, medications and allergies, and advance directives. An SCP is designed to be much more user-friendly than a dense medical record, which typically is organized chronologically and fragments information by individual providers and locations. Patients can store the SCP information on paper or on a secure website linked to patientpowered.org and can upload information themselves or have other family members add vital information about their care. An evaluation of the implementation of the SCP through patientpowered.org in conjunction with a clinical care specialist (nurse or social worker) demonstrated increased patient satisfaction with clinical care and a cost savings of approximately $3,000 per year for enrolled patients (Safford).

The Missing Link: Web-Based Support Groups and the Patient's Medical Home

In the national demonstration effort New Health Partnerships: Improving Care by Engaging Patients, 35 teams around the United States developed demonstration projects designed to improve self-management support within and beyond the clinical setting. One of the demonstration sites, Fargo Health Center, a federally qualified health center in Fargo, North Dakota, decided to concentrate on diabetes as a target condition.

Patients at Fargo Family Health Center decided they wanted to create a blog and listserv for patients living with diabetes. Instead of joining a public blog/support group for patients with diabetes, the patient advisors in the demonstration felt it was important that their providers know about their struggles and celebrations in living with diabetes. They also wanted to learn from other patients being treated at the health center. Patients registered for the site, and individual peer-to-peer phone calls were available for additional support. In the spirit of the phrase "all politics is local," patients decided to create a geographic and condition-specific community of support for themselves that could be accessed by their clinical providers. Technical issues such as security and sharing of clinical information were challenges for this team. However, the opportunity to create a local community of patients who could offer each other support, provide information to their clinical partners, and impact the care provided at the local level helped the team decide to take on these issues and find effective ways of managing concerns about privacy and security for their participants (Miller, 2006).

eVisits: Saving Time and Money and Improving Satisfaction

Electronic provider visits hold the potential for enhancing patient–provider communication and enhancing the ability of primary care providers to offer care for nonurgent medical issues. The *webVisit Study: Impact of Online Doctor-Patient Communication on Satisfaction and Cost of Care*, conducted by researchers at Stanford and the University of California at Berkeley, evaluated whether using the eVisit platform offered by the company Relay Health was associated with satisfaction. Participating organizations included several health plans and large medical groups in California and Connecticut and 10 large self-insured employers. The intervention group included 282 physicians and 3,688 patients. Compared with controls, patients were 50 percent less likely to miss work; 45 percent were less likely to need a face-to-face visit with a physician, and 36 percent were less likely to telephone the physician's office. Physicians reported that the system was easy to use (72 percent), satisfying (53 percent), and preferable to an office visit for nonurgent care (56 percent). Analysis of health claim costs for the intervention group showed a statistically significant lower cost for office-based claims ($p < 0.01$) and total claims ($p < 0.05$) (Zimmerman et al.).

Barriers to Adoption

Social Acceptability

Are patients ready, willing, and able to "visit" their physicians via the web? In an August 2008 study from the Center for Studying Health Systems Change, investigators demonstrated a dramatic change in the way consumers are seeking health information, with a doubling of the number of survey respondents stating that they seek health information from the Internet (Figure 6-2) (Tu and Cohen, 2008). However, in a July 2008 study posing the question "Does the Internet replace health professionals?, 86 percent of all adults said they ask a health professional versus 57 percent who said they use the Internet (Lee, 2008). Blending the convenience of the Internet with a trusted source who understands one's personal medical history, the use of eVisits and personal health portals may be an acceptable way to communicate with physicians.

The Digital Divide: Race, Ethnicity, and Poverty

Given social acceptability, will patients have access to the Internet so they can communicate with their physicians? The Pew Internet and American Life Project tracks trends and issues related to age, race, ethnicity, and health. In

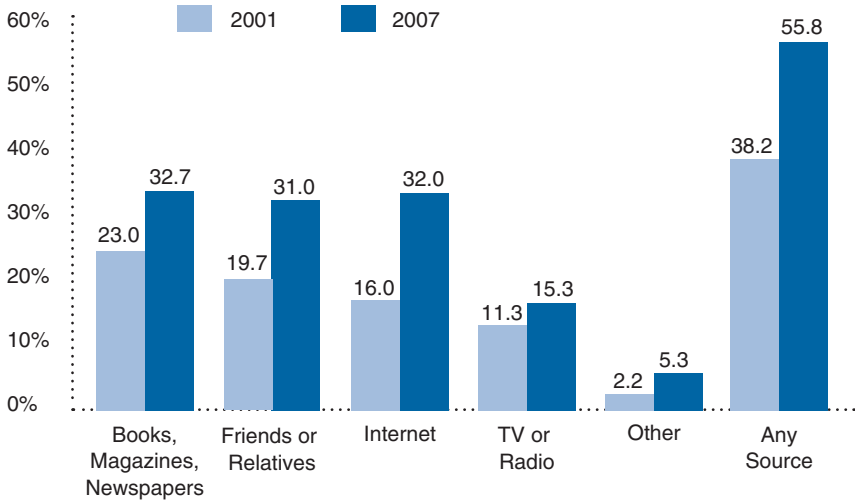


FIGURE 6-2 Consumers are increasingly seeking health information from the Internet.
SOURCE: Image appears courtesy of the Center for Studying Health System Change.

a 2009 survey, 79 percent of whites, 67 percent of blacks, and 80 percent of Latinos said they used the Internet. Use of wireless handheld devices was actually greater for blacks and Latinos than for whites (Horrigan, 2009). In addition, Latinos with annual incomes below $30,000 had increased their use of the Internet by 17 points between 2006 and 2008 (Fox, 2009). Internet use is increasing across the board, and the differential use of web-enabled handheld devices may signal just-in-time health management opportunities for some patient populations.

The Penetration of Electronic Medical Records: Supply and Demand

In a 2007–2008 national survey of 2,758 physicians, only 17 percent of practices reported having EHR systems, with 26 percent indicating that they planned to buy such a system within the next 2 years (DesRoches et al., 2008). Physicians most likely to have EHR systems belonged to large practice groups, hospitals, or medical centers. Cost has been described as a barrier to purchasing such systems. The impact of the 2010 federal health-care reform legislation supporting technical assistance for primary care providers in establishing EHR systems should be studied.

Reimbursement for Electronic Communication: Fact or Fiction

Many physicians continue to be concerned that they cannot bill third-party payers for Internet communications with patients. Although specific reimbursement policies vary from insurer to insurer, in 2008 the American Medical Association's Current and Procedural Terminology was revised to allow for billing for online patient services. Online services have a designated code that can be used once per episode of care over a 7-day period and can include any follow-up issues, including prescriptions, laboratory services, and ordering of imaging studies (Porter, 2008).

Looking to the Future

Primary care delivery capacity, evolving HIT platforms, and demographic and market forces will shape the future use of the Internet as a vehicle for extending health care beyond the clinical practice setting. Recent studies show that the delivery and support of care through web-based platforms can increase patient and provider satisfaction while decreasing cost. As these web-based platforms continue to grow, developers should keep in mind the importance of the input of patients and their caregivers in the creation of these products.

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7

Applying Evidence for Patient-Centered Care: Standards and Expectations

INTRODUCTION

Communicating evidence to patients is a critical challenge in transitioning to a health system centered on patients' individual values and preferences. The public is bombarded with inconsistent health messages and has little background or training in how to evaluate the information presented in television newscasts, daily papers, and on the Internet. Moreover, many messaging campaigns may contribute to this confusion because of oversimplification, emotional appeals, and conflicting advice.

Value and science-based care are concepts that will require rethinking how information is shared with patients. Committing to communicating evidence in all its complexity while ensuring it is understandable and pertinent to individual patient circumstances will be a challenging task. Communication strategies need to be evaluated so that shortfalls can be made clear, and effort should be given to developing new approaches to teach patients about evidence-based medicine.

The papers in this chapter address how to apply standards for evidence in the context of individual patient-centered care. They point to the importance of generating evidence applicable to individual patient outcomes, preferences, and values. This type of evidence is necessary to provide care that is more effective for the individual patient and more efficiently delivered. Additionally, the papers take up the nature of difficulties in communicating this evidence to patients and examine strategies that have proven valuable in informed decision making.

In the first paper, Dale Collins Vidal of the Dartmouth Institute for Health Policy and Clinical Practice points out that the current informed consent process fails to help patients understand the trade-offs—or specific risks and benefits—in comparing treatment options. When competing treatment options are "preference sensitive," decision making about treatment should incorporate a patient's values and preferences. To ensure that patients have the tools they need to make an informed choice, providers must adequately communicate the risks, benefits, alternatives, experience, and cost.

In the second paper, Clifford Goodman of The Lewin Group addresses the limitations of evidence hierarchies that have been used for decades. He highlights the limitations of what until now has been considered "best evidence," for example, meta-analyses and randomized controlled trials (RCTs). He suggests moving away from RCTs as best evidence for a number of reasons, including their focus on population-based care, the time lag in obtaining scientific results, high costs, and the lack of applicability to individual patients. He points to several methods that can better capture evidence applicable to personalized medicine, which is becoming increasingly important with advances in genomic data.

Fran M. Visco of the National Breast Cancer Coalition addresses translating and communicating evidence when the recommendations for care are uncertain. She reviews the barriers to understanding science-driven care, including the adoption of practices that have become standard even though evidence to back them is limited; the oversimplification of messaging that misleads the public; and the promulgation of guidelines that are self-serving. She highlights the pressing need to evaluate how to deliver complex messages about interventions so they can be made pertinent to individual patients.

THE ROLE OF EVIDENCE IN PATIENT-CENTERED CARE

Dale Collins Vidal, M.D., M.S.[1]
Dartmouth Institute for Health Policy and Clinical Practice

In *Crossing the Quality Chasm*, the Institute of Medicine (IOM) defines patient-centeredness as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, ensuring that patient values guide all clinical decisions" (IOM, 2001). However, studies reveal that the current informed consent process falls far short of this goal and frequently fails to help patients understand the specific risks and benefits of

[1] The author would like to acknowledge Allison J. Hawke, Sue Burg, and Sherry Thornburg for their contributions in preparing this manuscript.

treatment options (Holmboe et al., 2000). This is true even when the decision involves "effective care"—care that is supported by strong evidence and usually depends less on an individual's personal values and preferences (O'Connor et al., 2007). When treatments are not supported by adequate evidence or when they involve trade-offs that could impact a patient's quality of life, the traditional informed consent process is inadequate for helping patients make informed treatment decisions. In these situations, the process should more appropriately be framed as informed choice, incorporating a discussion of treatment alternatives, the evidence associated with them, and the patient's personal values.

To achieve the IOM's goals around patient-centered decision making, a framework is needed that will allow patients, families, and providers to engage in successful, mutual healthcare interactions, allowing patient and family values to guide all healthcare decisions. This paper presents elements of such a framework and describes tools used by the Dartmouth Hitchcock Medical Center to support it.

Categories of Care

Effective Care

John Wennberg is credited with defining three categories of care: effective, preference-sensitive, and supply-sensitive (Table 7-1). Effective care is that which is supported by high-quality evidence demonstrating that the benefits of a proposed treatment or intervention are large compared with the potential harms. Clinicians, and most patients, agree on the appropriate course of action for effective care. When care is deemed effective, the clinician typically makes a recommendation, and the goal is patient compliance or increased uptake by a population (Wennberg, 2002). Examples include the use of antibiotics for treatment of bacterial pneumonia, screening with pap smears, and preventive flu vaccinations for healthcare workers.

Preference-Sensitive Care

Because of conflicting, uncertain, or insufficient information as well as differing personal preferences, the quality of evidence often does not allow for a clear "right" choice. A quality decision for these "preference-sensitive" medical decisions requires that the patient be knowledgeable about the options and that his or her personal values inform the choice (Sepucha et al., 2004). Examples include elective surgeries such as LASIK eye surgery; use of screening tests, such as prostate-specific antigen for prostate cancer; and prevention of cervical cancer with human papillomavirus vaccinations. An effective care recommendation may become a preference-sensitive deci-

TABLE 7-1 Summary and Description of Categories of Care

Category of Care	Typically Characterized by:	Goal	Examples
Effective	• Proven clinical data on treatment effectiveness • Benefits large compared with harms	• Increase uptake	• Treatment—antibiotics for community-acquired pneumonia • Screening—pap smear • Prevention—flu shot
Preference-Sensitive	• Multiple treatment options • Lack of evidence-based treatment options • Benefits and risks are uncertain • Significant trade-offs for the patient	• Patient participation • High decision quality • Prevent overuse of options patients do not value	• Treatment—LASIK surgery • Screening—prostate-specific antigen (PSA) • Prevention—human papillomavirus (HPV) vaccination
Supply-Sensitive	• Lack of evidence on comparative effectiveness of treatments • Few guidelines regarding delivery of care • Assumption that more care is better	• Varies across the country based primarily on capacity • Amplified by fee-for-service model	• Care for patients with progressive chronic illness (e.g., lung disease, cancer, diabetes, heart failure)

SOURCE: Wennberg et al., 2002.

sion if a patient does not readily accept the clinician's recommendation. Preference-sensitive care avoids the overuse of options patients do not value. The essential feature common to all preference-sensitive conditions is that choice of treatment is up to the patient (Wennberg, 2002).

Supply-Sensitive Care

Wennberg and colleagues have demonstrated that capacity dictates how healthcare resources are used (Wennberg et al., 2002). Supply-sensitive care exists when the number of available hospital beds drives how often patients are hospitalized rather than cared for in the outpatient setting, or the frequency of referrals to specialists. The Dartmouth Atlas Project[2] has

[2] See http://www.dartmouthatlas.org/downloads/reports/supply_sensitive.pdf (accessed October 14, 2010).

demonstrated that supply-sensitive care varies widely across the United States. This variation may result in underuse of effective care and improper use of preference-sensitive care. The latter may occur when patients are not provided accurate information about their options and are not encouraged to incorporate their own values and preferences into care decisions.

Healthcare Variation

The Dartmouth Atlas has used Medicare data to map geographic variations in care for more than 20 years. The project reports on resource and medical care use among beneficiaries living in 3,436 hospital service areas—aggregated into 306 hospital referral regions—examining unwarranted variations in the above three categories of clinical care. It has revealed the presence of significant geographic variations in healthcare prices, practices, and providers; patient characteristics; and patient preferences. The project also has found that regions that spend more on health care and have higher rates of utilization do not experience better health outcomes compared with regions spending less on health and using healthcare services less frequently (Fisher et al., 2003).

Although higher rates of effective treatments are preferred, it is difficult to define the "right rate" for preference-sensitive treatments. The question raised by Wennberg and colleagues is, given the variation in the rates of procedures across the United States, which rate is right (Weinstein et al., 1998)? To illustrate the issue, Figure 7-1 shows the variations in spinal surgery across hospital referral regions in the United States. The number of spinal surgeries ranges from fewer than 2 to almost 11 per 1,000 Medicare enrollees. Even among high-performing academic medical centers such as Intermountain, Geisinger, Mayo Clinic, and Dartmouth-Hitchcock Medical Center, there is more than a twofold variation in the rates of spinal surgery. Why is this the case? In this area of preference-sensitive care, the indications for surgery are not universally agreed upon, and the evidence to support the decision-making process is imperfect for both the clinician and the patient. In these cases, it is impossible to know which rate is right, and ideally, well-informed patients should decide whether the intervention is right for them. Thus it is incumbent on the healthcare system to provide patients with accurate, balanced information and encourage them to participate in the decision.

Helping Patients Make Treatment Decisions

Decision Quality

When there is no clear answer as to which treatment is best, the patient should decide. High-quality decisions depend on adequate knowledge,

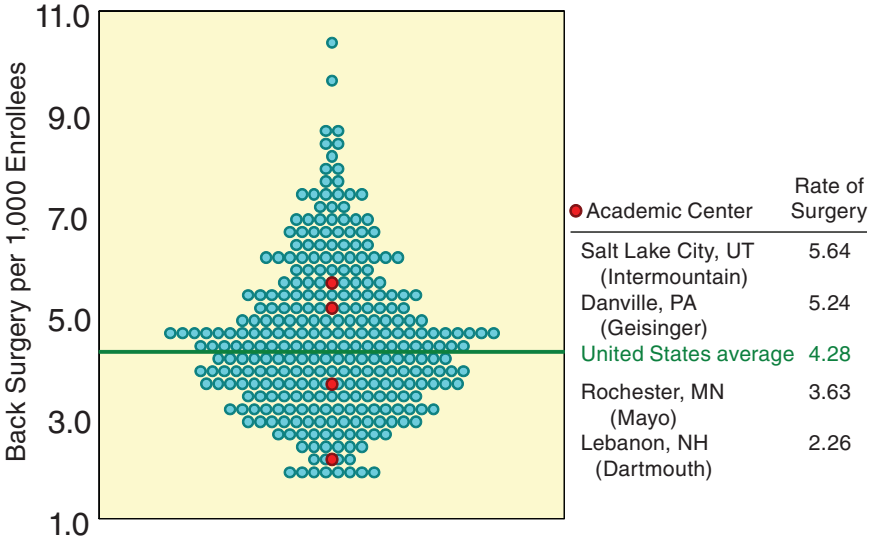

FIGURE 7-1 Turnip plot showing variation in rates of spinal surgeries.
SOURCE: The Dartmouth Atlas of Health Care. Copyright Trustees of Dartmouth College.

clarification of values, and resulting treatment choices that are consistent with the patient's values (Sepucha et al., 2004). There are, however, real challenges to providing patients with optimal support.

Creating systems and processes to inform patients about the benefits and risks of treatment alternatives, then assessing whether they have the information they need to make high-quality decisions, is an important requirement of today's healthcare system. This requirement, however, may appear to be in direct conflict with the demand for increased clinical efficiency and documentation that has resulted in ever shorter interactions with patients.

Risks of the Typical Informed Consent Process

In cases in which effective care is indicated, a recommendation from the physician may be appropriate, along with a discussion of the potential benefits and harms with the decision maker. This approach is in keeping with the traditional model of informed consent. Yet studies reveal that the typical informed consent process usually does not help patients understand the specific risks and benefits of treatment options (Holmboe et al., 2000).

Benefits of Shared Decision Making and Patient-Centered Care

Often the choice between competing treatment options is not so clear and requires preference-sensitive decisions. In these situations, the treatment choice should take into account an individual's values and preferences regarding the potential outcomes. Shared decision making is a process that incorporates evidence-based medicine and requires both patients and physicians to contribute information and participate. Providing decision support and participating in patient-centered care requires skills and core competencies. Several evidence-based practices foster communication and shared decision making at the decision point, including involvement of both the patient and the physician, information sharing by both parties, and reaching an agreement about the treatment options (Charles et al., 1997).

Recent trials of decision-support systems designed to help patients understand their treatment options reveal that informed patient choice results in different patterns of practice from those found with patients who experience usual care. However, medical opinion rather than patient preference tends to dominate the treatment choice (Wennberg, 2002).

Replacing standard informed consent practices with a patient-centered model of informed choice involves incorporating standardized communication of evidence, including risks, benefits, alternatives, experience, and cost. These changes may lead to differences in healthcare utilization and can empower patients to make informed decisions about their care (Krumholz, 2010). Providing patient-centered care depends on the comprehensive training of healthcare providers, increased consumer health literacy, and the successful identification of implementation models (Edwards and Elwyn, 2009).

Use of Information Technology to Feed Forward the Right Patient Information at the Right Time

Dartmouth-Hitchcock Medical Center uses health information technology resources, such as video decision aids and electronic surveys, to collect information from patients about their health history, behaviors, and health preferences in order to provide them with feedback and decision support and facilitate clear communication at the point of care. For example, all patients with breast cancer are electronically screened for psychosocial, financial, and emotional problems (such as anxiety and depression). Using validated surveys such as the Patient Health Questionnaire 9, the computer system can immediately score the survey and identify patients who reach preset clinical thresholds. When a patient reaches that threshold, the computer automatically e-mails Dartmouth-Hitchcock's social workers to intervene with patients identified as having a need.

In addition, our computer software systems allow us to collect information about patients' treatment preferences to share with their physician. When patients come in for their appointments, their clinicians are armed with information focused on what is meaningful to the patients. This facilitates discussion between clinician and patient and allows for the creation of a personalized and tailored treatment plan.

Impact of Decision Aids on Patients' Choices

A number of RCTs have shown the benefits of decision aids in supporting specific decisions. However, few trials have shown the impact on treatment choice. At Dartmouth-Hitchcock, the use of decision aids has resulted in approximately 30 percent of patients changing their initial treatment preference. In an RCT, Deyo and colleagues studied the impact of a video decision aid designed to inform patients about treatment options for back pain. The overall rate of surgery was 22 percent lower in the group viewing the video than in controls (26 percent vs. 33 percent). The researchers concluded that the video decision aid appeared to facilitate decision making and could help ensure informed consent (Deyo et al., 2000).

Summary

Patients and providers should each have the benefit of making decisions with the best available evidence. When treatments are not supported by adequate evidence or when they involve trade-offs that can variably impact a patient's quality of life, the decision-making process should be structured in a way that supports informed patient choice, by incorporating a discussion of treatment alternatives, the best evidence available, and the patient's personal values.

At Dartmouth-Hitchcock Medical Center, a patient's self-reported health information is collected by computer systems. This information is synthesized, and reports are created instantaneously to feed information back to the patient about his/her health behaviors and conditions. This same software can support the provision of sophisticated decision aids when patients are facing preference-sensitive treatment choices. Additionally, information on patients' treatment preferences—including their understanding of the key facts about the treatment and how they would value the different possible outcomes of care—can be collected and fed forward to their treating clinician at the point of care. This integration of technology, patient information, and evidence provides a framework for patient-centered care and informed choice.

EVIDENCE STANDARDS AND APPLICATION: RIGHT CARE, RIGHT PATIENT, RIGHT TIME

Clifford Goodman, Ph.D.
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Standards of evidence for what works in health care are generally appreciated as instrumental to the widely shared goal of getting the right care to the right patient at the right time. Such standards are used to support clinical practice guidelines and other best practices, formulary decisions, coverage policies, and more. These evidence standards are oriented largely toward the tenets of experimental methods and often presented in frameworks or hierarchies of study design. These hierarchies have not been static. They have evolved over the past few decades to better address the particular circumstances of healthcare decisions. However, persistent shortcomings in the practical utility of current approaches for appraising evidence, as well as certain mismatches between evidence hierarchies and the questions they are intended to help answer, suggest that these approaches and hierarchies need to be revisited and reconsidered in a broader context ranging from identification of research priorities bringing research to practice.

Evidence Hierarchies and Their Application

Evidence standards can inform and improve healthcare decisions and policies when they are used to appraise the quality of available evidence on the impacts of healthcare interventions. Although evidence hierarchies have evolved over the last two decades, they are oriented largely toward the relative strength of evidence regarding the causal effect of an intervention on particular health outcomes or other endpoints. In these hierarchies, internal validity is associated with study design, and the resulting evidence hierarchy of primary studies—i.e., those that collect original data—typically places RCTs at the top as the "gold standard" for primary evidence. RCTs are followed, typically, by nonrandomized controlled trials, various prospective and retrospective observational (nonexperimental) studies with concurrent or historical control groups, case series, single cases, and finally (though not a form of evidence per se) expert opinion. In some hierarchies, systematic reviews and meta-analyses of RCTs, where available, are placed above RCTs (Sackett, 1989; USPSTF, 2008).

Notable variations or adaptations of this basic framework recognize that implementation of a study design, not just the nature of the study design itself, affects the quality of the evidence yielded. Accordingly, these variations account for whether a study was "well designed" by employing an acceptable means of randomization, by eliminating or minimizing other

potential biases or threats to internal validity, and by employing adequate statistical power to detect potential treatment effects; what kind of comparison is involved (e.g., "head-to-head" trials of an intervention vs. a standard of care rather than indirect comparison of the two or comparison with placebo); whether the emphasis is on clinically relevant, rather than surrogate, outcomes; and other attributes (Atkins et al., 2005; Harbour and Miller, 2001; McAlister et al., 1999; USPSTF, 2008).

Limitations of Evidence Hierarchies

Despite improvements over the years, characteristics inherent in evidence hierarchies can limit the development and appraisal of evidence necessary for informing decisions about the right care for the right patient at the right time. That there are more than 60 published evidence hierarchies signals a lack of satisfaction or consensus in the field. Apart from inconsistencies across hierarchies in the definitions and categorization of study designs (e.g., multiple and overlapping definitions of "cohort" and "quasi-experimental" studies) and in rankings of study designs (e.g., whether RCTs or systematic reviews reside at the top), most existing hierarchies are limited by the mismatch between their original use and current application and the associated overreliance on the RCT.

Evidence hierarchies are based largely on methodological principles for assessing pharmacological models of therapy, including emphasizing experimental control; placebo control groups where possible; randomized assignment; narrowly defined patient groups; blinding of patients, clinicians, and investigators; and other attributes intended to enhance internal validity. However, this approach can jeopardize external validity—that is, the generalizability of findings to patients, settings, and other circumstances of real-world care. For example, RCTs may provide clear results when assessing the effect of a drug compared with a placebo in a narrowly defined patient population with a specific health problem. However, such RCTs may not provide information relevant for those making choices among alternative therapies used in practice or for those with multiple comorbidities along with the specific health problem. Further, while RCTs and other experimental study designs are intended to address the internal validity of the causal effect of an intervention on outcomes, they have been misapplied to other types of research questions pertaining to healthcare technologies, such as the accuracy of a screening or diagnostic test, the prognostic accuracy of a test, or rare or delayed adverse effects of a therapy.

As is recognized by some evidence hierarchies, relying on study type alone for assessing the quality of evidence can be misleading. For example, poor design or implementation of a high-ranking study type may yield findings that are less valid than those from study types lower on the hier-

archy that are well designed and rigorously implemented. Further, evidence hierarchies often cannot adequately accommodate or combine results from multiple study design types, even when no single study design can answer some evidence questions.

Limitations of Randomized Controlled Trials

RCTs are usually important, and sometimes essential, components of a rigorous evidence base for demonstrating the causal effects of healthcare interventions on outcomes. However, RCTs have important limitations, including some circumstances in which underlying assumptions about them are not valid (Rawlins, 2008; Walach et al., 2006). For example, while undertaking to randomize patients to one intervention or another assumes equipoise between the two, patients and clinicians involved in RCTs often bring preferences for one or the other. Whereas RCTs assume a lack of knowledge about the merits of the interventions in questions, there may indeed be relevant evidence from other sources (e.g., phase II drug trials) that undermines the utility of the null hypothesis in experimentation. RCTs also have a preference for specificity—i.e., that only the specific effects attributable to an intervention are therapeutically valid. Another assumption underlying RCTs that often is not valid relates to the context independence of the effect—i.e., that there is some "true" magnitude of efficacy or a stable effect size independent of the context in which an intervention is used.

Another major weakness concerns incorrectly assuming that the findings about a therapeutic effect from an RCT are externally valid—that is, readily transferable into clinical practice—if the exclusion and inclusion criteria of the trial match the characteristics of a given patient. Although this shortcoming of RCTs is generally well recognized, its extent and significance for patient care are not well understood.

Other methodological problems with RCTs can include relying on intermediate endpoints rather than health outcomes; having inadequate statistical power or duration for assessing benefits and harms, especially those that are rare or delayed; and being unsuccessfully blinded to patients, clinicians, or other investigators. Probability theories may pose problems (especially with frequentist approaches) in the form of arbitrary selection of p-values and the difficulty of applying them to everyday patient care; the multiplicity of endpoints compared, stopping rules, and analysis of subgroups; and resistance to Bayesian approaches.

Furthermore, there are various circumstances in which RCTs can be inappropriate. For example, they may raise bioethical and legal concerns; they may be difficult or impossible to conduct for rare diseases; and they may be unnecessary for very large treatment effects or to establish causa-

tion (e.g., Heimlich maneuver, cardiac defibrillation, laser removal of port wine stains). Additionally, the substantial resources needed to conduct RCTs—large, multicenter, longitudinal trials, sometimes costing hundreds of millions of dollars—limit their broad application to the myriad clinical questions important to providing patient-centered care.

Finally, the RCT's status as the "gold standard" for establishing the causal effect of an intervention on a health outcome can be extended inappropriately to other purposes. Indeed, other study designs are more suitable for answering certain evidence questions that inform many other aspects of clinical care, as summarized in Box 7-1.

Improving Evidence Hierarchies

Approaches to appraising the quality of evidence must extend beyond single hierarchies of study designs. They must consider the strengths and weaknesses of different study designs for answering specific questions, including the use of certain traditionally lower-ranked observational methods such as examination of large claims databases, patient registries, and electronic health records to supply evidence augmenting that derived from other designs.

BOX 7-1
RCTs Are Not Always the Best Method for Answering Clinical Evidence Questions

For the following situation, other experimental designs may include:

- Prognosis: patient cohort studies with follow-up at uniform points in the clinical course of a disease/disorder
- Identification of risk factors for diseases, disorders, adverse events: case control studies
- Accuracy of a diagnostic test: cohort (or cross-sectional) study of index test vs. gold standard in patients at risk of having a disease/disorder
- Effectiveness of interventions for otherwise fatal conditions: nonrandomized trials, case series
- Rates of recall or procedures precipitated by false-positive screening results: cohort studies
- Complication rates from surgery or other procedures: case series
- Incidence of rare, serious adverse events potentially due to an intervention: surveillance, registries
- Safety, effectiveness of incrementally modified technologies posing no known additional risk: registries

Different Research Questions Call for Different Study Designs

As described above, evidence requirements should address the type of intervention, application, and other attributes of evidence questions. Beyond evidence hierarchies devoted to treatments, hierarchies have been developed for assessing the quality of evidence pertaining to technologies used for screening, diagnosis, and other purposes. For example, the Strength of Recommendation Taxonomy (SORT) (Table 7-2) distinguishes different levels of evidence quality for technologies used in diagnosis, treatment/prevention/screening, and prognosis based on study design and other methodological aspects. In particular, SORT considers the availability of evidence on

TABLE 7-2 Strength of Recommendation Taxonomy (SORT), an Evidence Hierarchy That Includes Explicit Consideration of Intervention Type and Quality of Patient-Oriented Outcomes Assessed

Study Quality	Diagnosis	Treatment/	
Level 1—good-quality patient-oriented evidence	Validated clinical decision rule SR/meta-analysis of high-quality studies High-quality diagnostic cohort study	SR/meta-analysis of RCTs with consistent findings High-quality individual RCT All-or-none study	SR/meta-analysis of good-quality cohort studies Prospective cohort study with good follow-up
Level 2—limited-quality patient-oriented evidence	Unvalidated clinical decision rule SR/meta-analysis of lower-quality studies or studies with inconsistent findings Lower-quality diagnostic cohort study or diagnostic case-control study	SR/meta-analysis of lower-quality clinical trials or of studies with inconsistent findings Lower-quality clinical trial Cohort study Case-control study	SR/meta-analysis of lower-quality cohort studies or with inconsistent results Retrospective cohort study or prospective cohort study with poor follow-up Case-control study Case series
Level 3—other evidence	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series for studies of diagnosis, treatment, prevention, or screening		

SOURCE: Reprinted with permission from "Strength of Recommendation Taxonomy (SORT) Patient-Centered Approach to Grading Evidence in the Medical Literature," February 1, 2004, American Family Physician. Copyright © 2004 American Academy of Family Physicians. All Rights Reserved.

patient-oriented outcomes (morbidity, mortality, symptom improvement, cost reduction, and patient quality of life) rather than disease-oriented evidence (biomarkers and other intermediate endpoints) (Ebell et al., 2004).

Another evidence-rating approach has been developed by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) initiative to support a coordinated, systematic process for evaluating genomic tests. In this instance, EGAPP developed hierarchies suitable for appraising evidence for each of three main attributes of testing: analytic validity, clinical validity, and clinical utility (Table 7-3). For analytic validity—the ability to identify correctly a gene of interest—Level 1 evidence would consist of a collaborative study using a large panel of well-characterized test samples, or summary data from well-designed external proficiency testing schemes of interlaboratory comparison programs. For appraising evidence for clinical validity—whether the gene is associated with a given disease or other phenotype of interest—Level 1 evidence would consist of well-designed longitudinal cohort studies or a validated clinical decision rule. For clinical utility—which addresses whether a test result affects clinical decision making or patient outcomes—the evidence hierarchy resembles the more traditional ones, in which Level 1 evidence would be a meta-analysis of RCTs that followed patients from testing through clinical decisions to outcomes. Level 2 evidence would be a single RCT, and so on (Teutsch et al., 2009).

Indeed, mapping evidence requirements to clinical analytical frameworks, as is done by EGAPP, the U.S. Preventive Services Task Force (USPSTF), and the Agency for Healthcare Research and Quality's Evidence-based Practice Centers, illustrates how evidentiary needs can differ based on the decision flow. For example, Figure 7-2 illustrates the evidence framework for determining whether testing for CYP450 polymorphisms in adults entering therapy with selective serotonin reuptake inhibitors is useful in treatment decisions or leads to improved outcomes. Proponents of this test, which uses microarray technology to determine the genotype of a patient's cytochrome P450 enzymes, recommend its use for guiding the selection of effective medicines. The test's first uses have been in psychiatry (Teutsch et al., 2009). In Figure 7-2, the numbers correspond to analytical validity (2), clinical validity (3a-c), and clinical utility (4a-c), each of which could be determined using the types of evidence listed in the EGAPP hierarchy shown in Table 7-3.

The Best Scientific Evidence May Derive from a Complementary Set of Methods

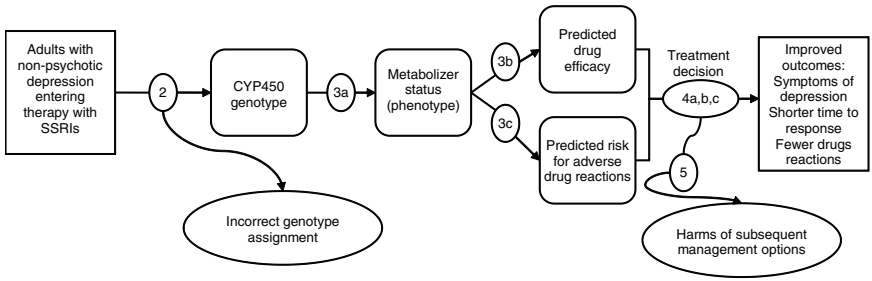
The methods in the available toolkit for assessing clinical effectiveness have their respective strengths and weaknesses. Using multiple and complementary methods (Figure 7-3) can offset vulnerabilities and triangulate

TABLE 7-3 Hierarchies of Data Sources and Study Designs for the Components of Evaluation

Level	Analytic validity	Clinical validity	Clinical utility
1	Collaborative study using a large panel of well-characterized samples Summary data from well-designed external proficiency testing schemes or interlaboratory comparison programs	Well-designed longitudinal cohort studies Validated clinical decision rule	Meta-analysis of RCTs
2	Other data from proficiency testing schemes Well-designed peer-reviewed studies (e.g., method comparisons, validation studies) Expert panel-reviewed FDA summaries	Well-designed case-control studies	A single RCT
3	Less well designed peer-reviewed studies	Lower quality case-control and cross-sectional studies Unvalidated clinical decision rule	Controlled trial without randomization Cohort or case-control study
4	Unpublished and/or non-peer reviewed research, clinical laboratory, or manufacturer data Studies on performance of the same basic methodology, but used to test for a different target	Case series Unpublished and/or non-peer reviewed research, clinical laboratory or manufacturer data Consensus guidelines Expert opinion	Case series Unpublished and/or non-peer reviewed studies Clinical laboratory or manufacturer data Consensus guidelines Expert opinion

SOURCE: Reprinted with permission from Teutsch et al., 2009.

findings—starting with results achieved with one method and replicating or augmenting them with other methods. This may constitute a powerful and comprehensive approach for developing a broader body of evidence that is helpful to guide care (Rawlins, 2008; Walach et al., 2006). For example, results of RCTs used to obtain Food and Drug Administration approval could be combined with analyses of patient registry data and longer-term follow-up of outcomes and adverse events through a cohort study to help



1. Overarching question: Does testing for cytochrome P450 *(CYP450)* polymorphisms in adults entering selective serotonin reuptake inhibitor (SSRI) treatment for non-psychotic depression lead to improvement in outcomes, or are testing results useful in medical, personal, or public health decision making?
2. What is the *analytic validity* of tests that identify key *CYP450* polymorphisms?
3. *Clinical validity*: (a) How well do particular *CYP450* genotypes predict metabolism of particular SSRIs? (b) How well does *CYP450* testing predict drug efficacy? (c) Do factors such as race/ethnicity, diet, or other medications affect these associations?
4. *Clinical utility*: (a) Does *CYP450* testing influence depression management decisions by patients and providers in ways that could improve or worsen outcomes? (b) Does the identification of *CYP450* genotypes in adults entering SSRI treatment for nonpsychotic depression lead to improved clinical outcomes compared with not testing? (c) Are the testing results useful in medical, personal, or public health decision making?
5. What are the harms associated with testing for *CYP450* polymorphisms and subsequent management options?

FIGURE 7-2 Analytic framework and key questions for evaluating one application of a genetic test in a specific clinical scenario: *Testing for Cytochrome P450 Polymorphisms in Adults With Non-Psychotic Depression Treated With Selective Serotonin Reuptake Inhibitors (SSRIs)*.
SOURCE: Reprinted with permission from Teutsch et al., 2009.

fill important gaps between what works under ideal conditions and what is needed to support real-world clinical practice.

Such efforts must not simply use multiple study designs, but must also ensure that the methods are complementary. In this respect, it is helpful to consider three types of evidence: direct, mechanistic, and parallel. Direct evidence is derived from experimentation or other studies (randomized or nonrandomized) that reveal a probabilistic association between some intervention and an outcome or result that is causal and not spurious. For a therapy, the size of the effect is not attributable to plausible confounding and exhibits appropriate temporal and/or spatial proximity, as well as dose-responsiveness and reversibility. Mechanistic evidence, playing a subsidiary

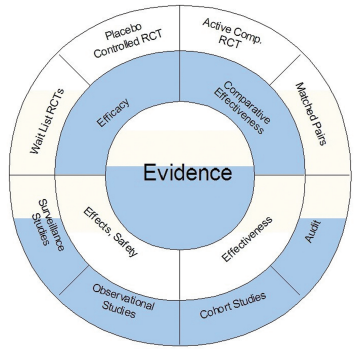


FIGURE 7-3 Circle of complementary methods and data sources. Experimental methods that test specifically for efficacy (upper half of the circle) must be complemented by observational, nonexperimental methods (lower half of the circle) that are more descriptive in nature and describe real-life effects and applicability.
SOURCE: Walach et al., 2006.

or supporting role to direct evidence, advances understanding of the likely causal process—biological, chemical, mechanical, or other—that connects the intervention to the outcomes. Parallel evidence from other studies with similar results that support the causal relationship, such as studies of similar populations and interventions in various healthcare settings over different durations, provides coherence and replicability (Howick et al., 2009).

Another framework for thinking about complementary evidence identifies experimentation, observation, and mathematics (e.g., biostatistics or modeling of therapeutic processes) as playing crucial roles in the development of the evidence base for modern therapeutics (Rawlins, 2008). Discussing this approach, Rawlins (2008) notes that "arguments about the relative importance of each are an unnecessary distraction. Hierarchies of evidence should be replaced by accepting—indeed embracing—a diversity of approaches." Indeed, strictly hierarchical thinking is increasingly giving way to such approaches as the proposed "circle of methods" illustrated in Figure 7-3 for guiding the use of complementary data and methods (Walach et al., 2006).

Promising Directions

There are many encouraging signs for the ability to ensure that evidence standards and their application are aligned with getting the right care to the right patient at the right time. Clinical decision support systems are being designed to make relevant evidence (and evidence-based decision

aids) readily accessible at the place and time of clinician–patient decisions (Pearson et al., 2009).

The field of comparative effectiveness research (CER) emphasizes the need to rely on multiple evolving methods, including more advanced data infrastructure and linkages among claims data, electronic health records, registries, and other sources. Further, consistent with the intent of Congress and national priority-setting reports for CER, the field should focus on subgroup analyses and priority populations, which will expand the base of well-founded evidence for patient decisions (FCC, 2009; IOM, 2009). Indeed, this focus on CER will help ensure that it not only generates population-based evidence but also supports progress toward personalized medicine—including patients' genomes; their health states; and the behavioral, environmental, socioeconomic, cultural, and other personal determinants of their response to healthcare interventions (Goodman, 2009).

Several other trends reflect this sharper focus on meeting the needs of decision makers. Patient input has been advanced as central to discussions of CER priority setting, study design, and identification of key outcomes, with citizen councils and forums in Europe, Canada, and the United States offering various models for engaging the public. As noted above with respect to pharmacogenomic testing, evidence appraisals are increasingly attuned to intervention types, applications, and settings. Regulators and payers are more explicit about evidence expectations, including study designs and designation of health outcomes and other study endpoints. Bayesian and adaptive clinical trial designs, the focus of increased interest, offer flexible variations on primary data collection that optimize the use of accumulated findings to derive evidence more efficiently for responsive and nonresponsive patient groups (Orloff et al., 2009).

Finally, much greater and earlier interaction among innovators, regulators, payers, and health technology assessment functions is occurring on evidence expectations or requirements well in advance of regulatory decisions or coverage decisions by payers. Of importance, these discussions are focused on anticipating evidence needs throughout the life cycle of a technology and often include clinician and patient input at the outset. Rather than retrospective reaction to fill evidence gaps or make determinations based on the available evidence, this approach allows for coordination of evidence development that takes advantage of the right methods for the right questions and builds toward a totality of evidence on what works best for individual patients.

TRANSLATION AND COMMUNICATION NEEDS FOR CARE IN THE FACE OF UNCERTAIN EVIDENCE

Fran M. Visco, J.D.
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Approaches to translation and communication needs for health care must take into account the broader context within which the public receives health information. The public receives healthcare information from a variety of sources including healthcare providers, traditional media, the Internet, family and friends, and patient and medical advocacy organizations. For many reasons, the temptation is to provide messages that are short and simple. But when evidence is uncertain, healthcare messages are not simple, and there needs to be a system that is honest about this uncertainty. Health messages must not be presented as absolute or simple when evidence is not. We need to educate the media, the public, and the medical community about evidence, and we need to institute oversight mechanisms to ensure that health communications are based on the best available evidence.

The public must trust that the healthcare system works for their benefit. The public's expectation is that care is communicated and delivered in a system in which

- patient needs are paramount,
- care is based on evidence,
- risks and benefits will be explained and understood, and
- interventions will change with new knowledge.

The Context in Which the Public Receives Information About Health Care

The public uses various sources for health information. Survey data indicate that these sources vary depending on age and education. For example, a 2009 survey conducted by the Pew Internet and American Life Project found that when asked, "Now thinking about all the sources you turn to when you need information or assistance in dealing with health or medical issues, please tell me if you use any of the following sources":

- 86 percent of all adults ask a health professional, such as a physician;
- 68 percent ask a friend or family member;
- 57 percent use the Internet;
- 54 percent use books or other printed reference material;
- 33 percent contact their insurance provider; and
- 5 percent use another source not mentioned above.

Although the Pew report found that Internet use did not replace other, traditional sources of health information, significant differences in health information sources did emerge among age groups. For example, adults aged 18–29 are significantly less likely than older adults to consult a health professional (79 percent, compared with 88 percent of those aged 30–49, 89 percent of those aged 50–64, and 89 percent of those aged 65+). Younger adults are more likely than older adults to consult a friend or family member. Seventy-eight percent of adults aged 18–29 and 72 percent of those aged 30–49 consult a friend or family member, compared with 58 percent of those aged 50–64 and 59 percent of those aged 65+ (Fox and Jones, 2009).

The Pew survey also found significant differences in health information sources by education level, with 94 percent of college graduates consulting a health professional, compared with only 83 percent of high school graduates. These findings are similar to those reported in a 2008 Center for Studying Health System Change report. According to that report, health information–seeking behavior differed by education level, with 72 percent of people with a graduate degree seeking information from any source, compared with 42 percent of those without a high school diploma (Tu and Cohen, 2008).

In a survey commissioned by the National Breast Cancer Coalition (NBCC) in 2009, a slightly different pattern of health information sources was found among women seeking information on breast cancer. Among women actively looking for information about breast cancer or its treatments, the four most common sources were the Internet, talking with a friend or relative, talking with a doctor or other medical professional, and magazine articles. Overall, the Internet was by far the most common source, consulted by 71 percent of women as compared with 53 percent who spoke with friends and relatives, 45 percent who spoke with a doctor, and 43 percent who found information in magazines. This pattern was seen in all age groups. In addition, all age groups were more likely to consult a friend or relative than a physician for breast cancer information. Women aged 25–34 were more likely to seek breast cancer information in a magazine (48 percent) than to speak with a physician (40 percent), while women aged 50+ were slightly more likely to speak with a friend or relative (49 percent) or a breast cancer survivor (47 percent) than with a physician (43 percent).

When NBCC survey respondents were asked what they had heard or read about breast cancer and where, television programs were the most likely response (57 percent). The next most common responses were the Internet and advertisements, both of which had increased in usage over the prior two years (from 29 percent to 38 percent, and 15 percent to 34 percent, respectively).

Given these findings on sources of information, no communication strategy can focus simply on physicians and patients; it is also essential to

take into account messages received through print, television, and online media. Also, historical communications about an intervention must be considered in crafting any new messages.

Several recent examples illustrate confusion in healthcare communities and among the public about recommendations for health interventions when

- the intervention became standard with limited or no evidence (e.g., breast self-examination, hormone replacement therapy, use of erythropoiesis-stimulating agents as supportive therapy, management of ductal carcinoma in situ);
- uncertainty exists among healthcare professionals; and
- self-interests of healthcare professions, advocacy groups, and the media appear to trump the evidence.

A Case History: The U.S. Preventive Services Task Force

The recent uproar over the USPSTF recommendations for breast cancer screening captures many of the difficulties of communicating health information today. In 2007, the USPSTF outlined refined methods for developing recommendations that included an outline of communication and dissemination strategies (Guirguis-Blake et al., 2007). Unfortunately, these strategies focused on dissemination to professionals via medical journals and to federal agencies, professional societies, and quality improvement organizations via public meetings. As the recent breast cancer screening example illustrates, these are not the only important audiences. Strategies for disseminating information to the media, policy makers, and the public are also crucial components of any communication plan.

On November 16, 2009, the USPSTF revised its recommendations on screening for breast cancer in the general population (USPSTF, 2009). In summary:

- The USPSTF does not recommend that women automatically begin mammography screening at the age of 40. Instead, it recommends that the decision to start regular, biennial mammography screening before age 50 should be an individual one and take into account patient context, including the patient's values regarding specific benefits and harms.
- The USPSTF recommends mammography screening every other year for women aged 50–74.
- The USPSTF concludes that evidence is insufficient to determine the harms and benefits of mammography screening in women over 74.
- The USPSTF recommends against healthcare providers teaching breast self-examination.

- Evidence was insufficient for the USPSTF to make a recommendation on clinical breast examination, digital mammography, or magnetic resonance imaging.

These recommendations were not significantly different from those issued in 2002.

The release of these updated recommendations was communicated in an article in the *Annals of Internal Medicine,* a biweekly medical journal. This typical communication strategy for releasing USPSTF recommendations had not led to mass confusion and hysteria in the previous year when the prostate cancer screening recommendations were updated. But the reaction to the revised breast cancer screening recommendations from the public, policy makers, the media, and the healthcare community was far from typical (Goldberg, 2009).

The timing of the release of the new recommendations was unfortunate, coinciding with a congressional vote on a healthcare reform bill after months of a particularly contentious debate. As a result, the revised screening recommendations were cast as one more example of "big government rationing health care," which added to the hysteria around the recommendations' release. Moreover, there have for years been simplistic messages about breast cancer screening—for example, that "early detection saves lives"—from the American Cancer Society, the National Cancer Institute, patient groups, trade associations, and the media. However, the evidence behind these statements and campaigns was not part of any discussion with the public, and the public health experts and primary care physicians with expertise in the area were on the periphery of these messaging campaigns. To further complicate the situation, Congress weighed in and demanded that the National Cancer Institute provide a clear message on screening, despite the lack of strong evidence of overall benefit. Indeed, in 1997 the Senate held hearings and passed a nonbinding resolution in support of mammograms for women under age 50 by a vote of 98-0 (Kassirer, 1997).

Years of communications about screening resulted in an ad campaign's being converted into absolute truth. In fact, any evidence of the limitations of mammography screening and questioning of the evidence on which these simplistic messages were based was ignored or vilified. For example, a research article reported data indicating that "the natural course of some screen-detected invasive breast cancers is to spontaneously regress" (Zahl et al., 2008). Rather than taking the opportunity to explain the evidence to the public, the American Cancer Society's director of cancer screening was quoted in *USA TODAY* as saying, "It's important that people not wonder if women lost their breasts for no reason. That's reprehensible conjecture" (Szabo, 2008).

Against this background, when the USPSTF issued its revised recommendations in the *Annals of Internal Medicine,* many in the media, policy makers, medical trade associations, and healthcare providers attacked the Task Force and the revised guidelines. What did the public hear?

- The American College of Radiology, a medical trade association representing radiologists and the field of medical imaging, stated: "Countless American women will die needlessly from breast cancer each year" (American College of Radiology, 2009).
- The American Cancer Society responded: "With its new recommendations, the USPSTF is essentially telling women that mammography at age 40 to 49 saves lives; just not enough of them" (American Cancer Society, 2009).
- ABC News misrepresented the guidelines with the headline "Stop Annual Mammograms, Govt. Panel Tells Women Under 50" and implied that cost savings, not evidence, motivated the change. "Anecdotally, most people in the United States can think of a woman they know who caught breast cancer through a routine mammogram long before she turned 50. Many patient advocates wonder if money fueled the decision" (Cox, 2009).
- A Fox News Sunday interview included Bernadine Healy, M.D., the former director of the National Institutes of Health, strongly urging women to ignore the USPSTF screening recommendations because they will result in more women dying of breast cancer (Fox News, 2009).
- Secretary of Health and Human Services Sebelius undermined the credibility of the Task Force and its guidelines by stating: "[The U.S. Preventive Services Task Force] has presented some new evidence for consideration, but our policies remain unchanged. My message to women is simple. Mammograms have always been an important life-saving tool in the fight against breast cancer, and they still are today. Keep doing what you have been doing for years—talk to your doctor about your individual history, ask questions, and make the decision that is right for you" (Goldberg, 2009).
- Daniel Kopans, M.D., a radiologist and director of breast imaging at Massachusetts General Hospital, is often quoted in the media along the lines of his letter to the editors of the *Annals of Internal Medicine*, which stated: "Suggesting that these guidelines are based on clear evidence is not supported by the facts. . . . I believe that some of the advisors to the USPSTF have major, undisclosed, career interests in the guidelines. They have received funding for what I believe are nihilistic approaches, constituting more insidious con-

> flicts of interest than the obvious conflicts of radiologists, such as myself. . . . Task Force members had no expertise in mammography screening or even breast cancer care. . . . In sum, the new USPSTF guidelines are unscientific, endanger women through false analyses, and should be withdrawn" (Kopans, 2010).

Unfortunately, these attacks dominated the media and the public perception of the updated guidelines, despite the fact that public health and primary care experts supported the recommendations:

- The American College of Physicians, a professional organization for physicians specializing in internal medicine, had issued clinical practice guidelines in 2007 for mammography screening among women aged 40–49 that encouraged physicians to carefully assess individual women's risks for breast cancer and discuss with them the potential benefits and harms of mammography screening so they can make informed individual decisions about screening (Qaseem et al., 2007).
- The Cochrane Collaboration published a systematic review of mammography screening in 2006 and concluded that while such screening likely reduces breast cancer mortality, the magnitude of the effect is uncertain, and the screening also results in some women receiving a cancer diagnosis even though their cancer would not have led to death or sickness (Gøtzsche and Nielsen, 2006).
- The American Academy of Family Physicians recommended that mammography screening begin in average-risk women at age 50, and that all women aged 40–49 be counseled about the risks and benefits of mammography before making a decision to undergo screening (AAFP, 2003).
- The *Annals of Internal Medicine* conducted a readers' survey and found that among clinician respondents, 67 percent reported that they will stop offering routine mammograms to women in their 40s (*Annals of Internal Medicine,* 2010).

While this is but one case study, it received a significant amount of attention. An atmosphere was created that undermined the trust between the American people and public health officials.

Lessons Learned

We need to be honest. We would all prefer that the correct message be simple and certain. However, it most often is not. We need better policies to ensure that the public, the media, healthcare providers, and policy

makers all have the tools they need to understand and explain uncertainty, understand evidence, and keep the needs of patients paramount.

Professional associations need stronger oversight because many clinical practice guidelines are issued by professional societies. Often, the developers of guidelines have a financial conflict of interest in the use of the interventions highlighted in the guidelines. For example, the American College of Radiology issues statements on breast cancer screening, although its members are not public health experts and have a financial interest in the outcome of such recommendations. The American Society for Clinical Oncology still recommends and has actively lobbied the federal government on coverage issues for the use of erythropoiesis-stimulating agents as supportive therapy for cancer patients, despite evidence that they actually stimulate tumor progression (FDA, 2010; Rizzo et al., 2008).

The public can receive particularly confusing messages when professional societies differ publicly in their assessment of the evidence, as the American College of Radiology and the American College of Physicians did on breast cancer screening for women aged 40–49. What ethical responsibilities do these trade associations have in making these pronouncements public? How do we communicate to the public who the experts are?

Campaigns to better educate the public, policy makers, and the media about the importance of evidence are crucial. We should not underestimate the public's ability to understand and accept evidence. In the 2009 NBCC consumer survey, for example, consumers identified comparative effectiveness research as more likely than other healthcare reforms to improve quality of care for breast cancer patients.

Projects such as NBCC's Project LEAD® (Leadership, Education, and Advocacy Development) training courses are important. Such courses on critically evaluating research and evidence need to be made more broadly available to the general public and journalists. Much work on this front is also being done by others, including Gary Schwitzer with his popular HealthNewsReview blog[3]; the Dartmouth Institute for Health Policy and Clinical Practice's Center for Medicine and the Media[4]; and the Foundation for Informed Medical Decision Making.[5]

[3] For more information see http://www.healthnewsreview.org/blog/ (accessed October 15, 2010).

[4] For more information see http://tdi.dartmouth.edu/centers/medicine-and-the-media/ (accessed October 15, 2010).

[5] For more information see http://www.informedmedicaldecisions.org/index.html (accessed October 15, 2010).

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8

Team-Based Care and the Learning Culture

INTRODUCTION

The value of a team-based approach to health care has been recognized for more than a decade (Grumbach and Bodenheimer, 2004; IOM, 2001; Leape et al., 2009; Wagner, 2000). It has been shown that a team-based approach adds value to the learning culture throughout health systems by preventing medical errors (IOM, 1999) and improving patient-centered outcomes and chronic disease management (Bodenheimer et al., 2002; Ponte et al., 2003; Wagner et al., 2001).

Team-based care is one of the guiding principles of a learning health system. It stresses interdependence, efficient care coordination, and a culture that encourages parity among all team members (IOM, 2001, 2007). Teamwork should be reinforced at all levels, from leadership to the unit level, and individual patients should understand that they are working with a team. Team-based care has yet to proliferate widely, yet numerous excellent team-based programs around the United States demonstrate their added value in generating superb patient-centered health outcomes and science-driven care.

The papers in this chapter delve into three aspects of team-based care as they apply to a learning health system: general concepts in team-based care; strategies for using teams to promote clinical excellence, continuous improvement, and real-time feedback; and the added value and efficiency that team care brings to streamline care transitions.

In the first paper, Allan S. Frankel and Michael Leonard of Pascal Metrics describe the essential elements that underpin team-based care and

a learning culture. Teams work by planning forward, reflecting back, communicating clearly, and resolving conflict. Data and information are continuously analyzed so that problems can be identified early on; actions can be taken; and feedback can be provided to clinicians, employees, and leaders.

Joyce Lammert of the Virginia Mason Medical Center (VMMC) explores team-based learning and care through the experiences of VMMC. She highlights changes in medicine brought about by the digital age and changes in the patient-physician compact that give more authority to the patient. Lammert offers several recommendations for accelerating team-based care and driving centers of excellence, including a shift in medical schools' teaching strategies to more of an interactive, team-based model; rapid process improvement workshops; and incorporation of routine learning collaboration in real practice settings.

Alice Bonner, formerly of the Massachusetts Department of Health (now Centers for Medicare & Medicaid Services), Craig Schneider of the Massachusetts Health Data Consortium, and Joel S. Weissman of Harvard Medical School address the importance of team-based care in the context of care transitions. They underscore the importance of interdisciplinary teams that are able to deliver safe, effective, culturally appropriate, and timely care within and across settings. Standardized procedures can improve the quality of care and reduce suboptimal outcomes and patient experiences, leading to more appropriate use of services and lower costs.

PRACTICAL EXPERIENCE WITH COLLABORATIVE MODELS IN THE HEALTH PROFESSIONS

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Across a variety of settings and industries, groups that effectively coordinate teamwork and improve science tend to achieve their goals (Mathieu et al., 2008). Since the Institute of Medicine (IOM) report *To Err Is Human* (1999) was published, the healthcare industry has learned a great deal about teamwork and improvement, but few in health care methodically combine the two in order to reap their full potential. Instead, teamwork and improvement are taught and applied separately. As a result, goals take longer to attain. Healthcare leaders have little in-depth knowledge of teamwork and improvement and therefore a limited ability to integrate the two concepts in order to improve practice. This paper explores the components of a continuous learning environment (Batalden and Splaine, 2002; Mohr and Batalden, 2002), positing that teamwork and improvement are essential—and inextricably linked—components of a successful learning environment.

Continuous Learning Environments

Figure 8-1 offers a simple description of a continuous learning environment, applicable at both a departmental and organizational level (Frankel et al., 2009). Raw data and information from a wide variety of sources—such as quality audits or an individual's concerns—are collected and made available for analysis. A management group regularly evaluates the data to identify concerns that might undermine safety or reliability. Possible solutions are discussed. Specific individuals are given responsibility for taking action to address the findings using formal improvement methods and told to report back on their efforts. The learning that occurs from this action is encapsulated and fed back to all interested individuals and groups, especially those who initially brought the raw data or information to attention. This final feedback step validates why it is worthwhile for individuals to speak up about concerns—because they see response by the organization. The end result is an engaged front line that feel their concerns are heard and acted upon and an effective management team that has a finger on the pulse of front-line activity and can respond quickly when variation in process becomes troublesome or things go wrong.

This description of a continuous learning environment might best be viewed as conceptually simple but difficult to accomplish. The difficulty exists because stellar continuous learning environments rely on outstanding leadership, teamwork, and improvement. Organizations and individuals

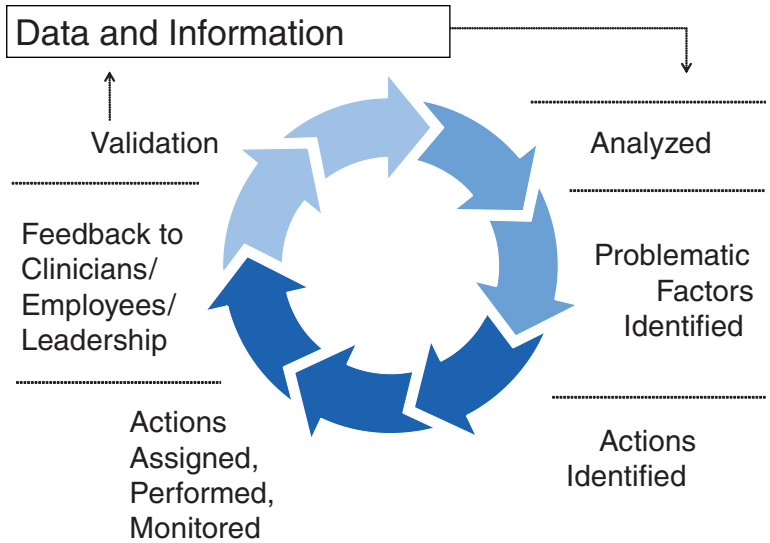

FIGURE 8-1 Components of a continuous learning environment.

must be able to manage and apply these components. Of note is that even if the three elements are excellent, that is insufficient unless they are also linked together.

A Recent History of Teamwork Practice in Health Care

Aviation in the late l980s looked to teamwork to address human error, building on a science called human factors that examined the limitations of human performance in complex environments (Porter, 1964). Scientists focused on how human beings interact cognitively and physically with their environment and cognitive frailty and physical limitations to understand the causes of error. They formed hypotheses based on concepts by psychologists such as Rasmussen (Rasmussen et al., 1991) and Reason (Dekker, 2002; Reason, 1997) that divided cognition into three discrete categories—automatic, rule-based, and knowledge-based thought—each generating specific types of errors (Table 8-1).

Initial efforts in aviation to decrease error focused on ergonomics and the physical environment, but the industry realized that most error occurred because of team dynamics (Dekker, 2002). Helmreich (1993) and others sought to understand the relationship between teamwork and error and to develop a training program to address the issues involved. The end result was a program entitled Cockpit Resource Management, so named because the goal was to have groups work effectively with the members of the team and whatever was available in the physical environment. This title quickly became Crew Resource Management (CRM), reflecting that the aviation

TABLE 8-1 Cognition: Automatic, Rule-based, and Knowledge-based Thinking

	Example	Error	Example
Automatic thinking	Driving a car	Slips and lapses	Taking the wrong route because daydreaming
Rule-based thinking	A door handle telegraphs whether to push or pull the door	Rule-based error	Walking into a door because of misreading the visual cues on the door handle
Knowledge-based thinking	The slow, laborious process of integrating new information	Knowledge-based error	Being influenced by the most recent fact because of its timing, not its importance

SOURCE: Data derived from Reason, 1997.

team included more than the cockpit members. In time, both CRM training became part of aviation's high-fidelity simulation program that combined training in skills and teamwork (Helmreich, 1997, 2000).

This new body of knowledge was initially applied to some healthcare teams (such as emergency helicopter response teams) and eventually became part of training for emergency rooms. The great leap forward occurred when Helmreich and Leonard applied CRM concepts to Kaiser Permanente's obstetric departments, whose combined hospitals deliver approximately 80,000 babies per year (Leonard et al., 2004a, 2004b). Companies such as Dynamics Research Corporation and Pascal Metrics diffused these teamwork programs. Other groups stepped forward to consult and teach on the basis of CRM concepts. From this work, the Agency for Healthcare Research and Quality (AHRQ) developed TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety),[1] a programmatic team training effort that is an extension of the training started in aviation 30 years ago.

The body of teamwork literature and teamwork videos available at AHRQ is impressive, albeit daunting. Overall, the teaching style is behaviorally based and rigid, requiring modification in order to be acceptable to physicians. It brings useful behaviors into the healthcare environment that, once sorted through and simplified, can be codified into a group of behaviors that make up good teamwork and team leadership.

Health care, however, has thus far mistakenly assumed that CRM alone, with minor modification, can be imported effectively from aviation; in fact, it cannot. One difference is that the cockpit is better suited to simulation than is the more complex healthcare environment. Furthermore, aviation altered its management structure based on CRM concepts. Delta Airlines, for example, made its chief pilot, in many ways the equivalent of a chief medical or nursing officer, responsible for simulation training. In health care, by contrast, senior leaders commonly assign "teamwork training" to subordinates or "teamwork champions," as if it is appropriately accomplished by midlevel managers. Aviation incorporated CRM concepts as a central component of its core strategy, while for the most part, health care continues to view patient-centered care and evidence-based medicine as the two mainstays for achieving excellence. Teamwork is perceived as necessary but also soft and fuzzy, peripheral to the real work at hand and assignable to the simulation center and patient safety office.

Pilots who left aviation to focus on the healthcare industry did not realize that they were leaving an industry with 30 years of sophisticated thinking about team behaviors and entering a naïve environment. Having

[1] For more information see http://teamstepps.ahrq.gov/index.htm (accessed October 15, 2010).

learned about teamwork in aviation's high-fidelity simulators, they assumed that CRM-based training would suffice. They were, and are, mistaken. This misperception has also stymied clinicians who teach teamwork in the healthcare setting. In fact, although high-fidelity operating room simulators have positively influenced and transformed anesthesiology practice in the United States over the past 25 years, they have been unable to penetrate further into the healthcare system because they did not garner interest from hospital leaders and, initially, lacked a strong evidence base showing the value of simulation training (Cooper and Gaba, 2002). Today, other disciplines are becoming engaged, but hospital leadership has been slow to do so.

Since the publication of *To Err Is Human* (IOM, 1999), teamwork trainers have also struggled to compress multiple-day aviation- and simulation-based teamwork programs into a shorter curriculum for health care. Hospitals and clinical units have balked at the idea of releasing physicians and nurses from duty, often with pay, for multiple-day sessions. Consultants and trainers, competing with each other for contracts and eager to satisfy, have shortened their sessions to accommodate demand. Even today, as an indication of just how far some organizations still have to go, some department chairs wonder whether their physicians can learn teamwork in the hour or two available for departmental meetings or grand rounds.

In health care, evidence that teamwork influences reliability is slowly appearing in the literature (Pronovost et al., 2006). However, the paucity of statistically proven links between clinical outcomes and team models is frustrating for those who believe in the value of teamwork. In aviation, by contrast, the training became an integral part of the industry as a response to the identification of human error as the major factor in accidents. Aviation did not wait for double-blind controlled trials to prove the training's efficacy. Today CRM has been a part of civil aviation for 30 years and is perceived as instrumental in producing aviation's enviable safety record. No one is suggesting that aviation CRM training be withdrawn because of a lack of evidence showing its value.

Comparing the roots of teamwork against those of improvement reveals why health care has not effectively linked the two. Teamwork training is based on a marriage of psychology, sociology, and engineering. Robert Helmreich, a psychologist, wrote the first comprehensive text on CRM. In contrast, improvement models such as LEAN and the Institute for Healthcare Improvement's (IHI) Model for Improvement are focused primarily on using statistics to manage variation in stable industrial processes, and derive from the teachings of skilled statisticians and managers such as Shewhart, Juran, and Deming (Juran, 1995). Teamwork is a social science in which measurement is difficult, and linking process to outcome is an elusive challenge. Improvement, by contrast, centers on numbers collected from definable steps that lead to clearly measurable outcomes.

Improvement Science

William Edwards Deming proposed that the science of improvement comprises four domains: psychology, appreciation of a system, understanding variation, and theory of knowledge. Although Deming described effective leadership and management behavior, he did not go into detail about team behaviors and norms of conduct. He states in *The New Economics*, "Psychology helps us to understand people, interaction between people and circumstance, interaction between customer and supplier, interaction between teacher and pupil, interaction between a manager and his people and any system of management" (Deming, 2000). By contrast, the other three domains are extraordinary in their elegance and application. They are why Japanese car manufacturers gained such an advantage over U.S. companies. In health care, Deming's work is the underpinning for IHI's Model for Improvement.

Shewhart and Deming's improvement science looks at stable industrial processes, evaluates the variation in output of the end product, and applies improvement techniques when appropriate to minimize unnecessary variation. Applied to health care, the industrial process is the care path of patients, and the output is the outcome of care for those patients. Standardization of care processes is necessary, facilitated by measurement of the processes and the outcomes. In diabetes, a standardized method of optimizing blood sugar levels culminates in good HgBA1Cs. In hip and knee surgeries, optimizing time, cost, and patient rehabilitation culminates in patients' achieving good postoperative functional outcomes. The improvement model is applicable in every aspect of health care, from ambulatory to intensive care, from billing to central sterilization.

The backgrounds of these experts differ from providers of team training. Improvement science requires the setting of measurable aims that identify how a group is going to accomplish "what by when" (Langley et al., 2009). The aims require careful and reproducible measurement, subject to the full range of statistical manipulation. Means, medians, variance, standard deviation, and the like are all part of the nomenclature, a process very different from discussing team behaviors such as briefings and debriefings and the psychology of team relationships.

The improvement advisors at IHI are a good example. IHI trains these advisors, who then support clinicians engaged in activities by helping them perform small tests of change and measure the outcome. Those who do the teaching are mainly statisticians and their primary areas of interest are variation and its management in stable environments. Some have backgrounds in sociology and psychology, and spend some time teaching about the qualities of leadership and teamwork. However, their focus is on teaching how to apply the improvement model, not how to influence groups of clinicians to function in teams.

Weaving the Two Disciplines Together

The weaving together of these two disciplines is the responsibility of hospital leaders and healthcare managers. In reality, the end result is more than a responsibility—it is the core function of management. This is an important insight for newly appointed department chairs, division chiefs, and healthcare managers and directors, yet few healthcare leaders assume these positions knowing how to do this work.

Effective managers establish a learning-to-action cycle that gathers information from across their span of authority and then shapes improvement activities. Managers know what is happening across their work area because they continuously receive information about how it is functioning. Data become information, then knowledge, then understanding, and finally wisdom about poorly functioning aspects of their units. "Poorly" in this context is likely to mean that the managers have insight into the variation that is occurring in the steps of care and can see when the variation increases. They target these areas for evaluation and assign responsibility as appropriate to members of their team for taking actions that will improve the problematic steps. Those actions must be based on improvement science, and the individuals accountable should be able to describe formally the work performed. This means being able to state what they hope to accomplish, what change they are making, and how they will learn from that change. They should make predictions about the impact of the change and be able to describe any tasks they must perform before making the change. If a series of these tests of change leads to desired improvements, the managers are responsible for making that information widely known. This process is not an addition to managers' work—it is their core function. The question then becomes, "How do managers obtain the information that becomes grist for the improvement mill?"

Debriefing: The Link Between Teamwork and Improvement

The link between teamwork and improvement is manifest in the first part of the continuous learning cycle—the collection of information. A leader responsible for running a department knows how well the department is functioning only if he or she has an open conduit for receiving data. Information technology facilitates the collection of some data, especially in the technical aspects of care. But healthcare delivery is more than clinical decision trees and quality audits; it is a social process among providers and with patients. Much is dependent on humans interacting well with each other in complex settings. Managers must get good information from their coworkers and those they manage in order to understand their clinical, technical, and social concerns. Concerns in each of these areas can under-

mine reliability and increase variation in care. The means of obtaining this information is called *debriefing*.

Debriefing, in concept, is simple enough. Team members should pause at appropriate times in their daily routine, or at the end of procedures, to ask as a group what has gone well, what has not, and what they would want to do differently the next day. Debriefing is not simply an event or behavior; it should be an ongoing process that is periodically highlighted. In other words, when team members notice something is not running as desired or when they have a concern, they should note it down, state it to someone, or in some way capture their thoughts. At the appropriate time, those insights should be collected and eventually conveyed to the manager. The manager can then use these pieces of information to form a better picture of the functioning of the unit, turning the concerns of providers into data that feed into the continuous learning-action cycle.

Caregivers, as unit team members, have a responsibility to participate in debriefings. This norm of conduct, however, is feasible only in a management system that appreciates its importance. Collecting worker insights and concerns requires that clinical leaders create an environment of mutual respect and psychological safety in which concerns emerge quickly and transparently. Mutual respect across disciplines and the creation of an environment in which all concerns are heard and addressed are the responsibility of unit leadership. Managers and clinical chairs and chiefs need to foster this kind of culture to know what is happening at the sharp end of care. There is no substitute.

Other behaviors will support the debriefing process. Briefing, also labeled a "time out," "pause," or "checklist," is when team members look ahead at the work to be performed, consider together the strengths and challenges in the group and in the work to be done, and formulate a plan of action. The goal of a briefing is to ensure that an optimal game plan is formulated, and that everyone knows that game plan as well as their roles and responsibilities. By contrast, a debriefing involves reflecting back and thinking about what has happened and how that compares against the game plan. Briefing and debriefing are the bookends of every process and support each other. Debriefing is more likely to be useful if team members have and know the game plan and whether actions taken helped achieve it. For that matter, debriefing can help improve the briefing process, ensuring that team members function more effectively when formulating the next game plan.

Conclusion

Health care has a long way to go from its current state to one comprising continuous learning environments. First, every healthcare environment

suffers from a hierarchical structure that causes some nurses and ancillary personnel to feel constrained about speaking up to physicians. In some settings, the constraint is based on academic stature, while in others it is based on hospital-physician relationships. In others, the issues may be gender and ethnically based. Second, managers currently have a limited appreciation of the components of a continuous learning environment and how to achieve such an environment. Finally, senior leaders have more work to do through strategies and resources to ensure that continuous learning systems thrive. We in health care are just beginning on this journey, although it is one that offers great promise.

MEASURES AND STRATEGIES FOR CLINICAL EXCELLENCE AND CONTINUOUS IMPROVEMENT

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In 2001, the Institute of Medicine (IOM) released the report *Crossing the Quality Chasm: A New Health System for the 21st Century*. That report identified six key clinical dimensions in need of improvement: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. To achieve progress in these dimensions will require a fundamental change in the approach to learning and the application of that learning in providing health care.

Developing new models of collaborative care requires engaging all team members, including patients, in the development of evidence and the use of evidence to make healthcare decisions grounded in effectiveness, safety, and value. However, the physician is currently regarded as the leader of the healthcare team, and in order to move successfully to new models of care it will be critical to redefine what constitutes clinical excellence for providers and develop measures to ensure excellence in all six dimensions.

Abraham Flexner's report to the American Medical Association Council on Medical Education in 1910 helped establish the fundamental elements of how physicians are trained and how care is delivered to patients (Beck, 2004; Flexner, 1910). That system of training has survived fundamentally intact to this day. Much as Gutenberg's movable type changed the power structure of society in the Middle Ages, the Internet and Google have fundamentally changed the balance of knowledge and the ability, as well as the expectations, of patients to be engaged in their health care. Rapid advances in science and technology, coupled with the complexity of 21st-century care, make the old paradigms of learning and caring for patients obsolete. The old underlying assumptions about what it means to be a physician—which continue to be reinforced in training—are in conflict with what is

needed to provide care that is aligned with the six aims of the *Chasm* report as well as foster a learning health system (Table 8-2).

Changes to the culture must start in medical school (Table 8-3). Today, two years of basic science followed by two years of clinical science form the backbone of physician training. This system is largely unchanged from the days of the 19th century. In this hierarchical system, physicians in training also pick up the underlying assumptions and attitudes about medicine and patients of their residents and attending physicians. A recent Lucian Leape Institute report calls for a change in medical education from the current focus on "courses" and content to a focus on examining patient care processes, systems thinking, leadership, and teamwork (Lucian Leape Institute, 2010). Team learning for medical students has until now been

TABLE 8-2 Changing Provider Culture in Health Care

20th Century	21st Century
Taking care of the sick	Promoting health and well-being
Physician-centered	Patient-centered
Gestalt	Evidence-based
See one, do one, teach one	Simulation, simulator
Know it all	Know what to ask and how to find the answer
Autonomy	Collaborative/team
The health of my patient	The health of a population of patients
My fault	Faulty systems
Total patient care commitment, 24/7	Work hour restrictions, physician wellness
Learning: batched, episodic	Learning: continuous, embedded

TABLE 8-3 Changing Culture: Medical School

20th Century	21st Century
Unidirectional learning	Interactive, team learning
Knowing everything	Knowing essentials, asking questions, finding answers
Individual accountability	Team accountability
Departments	Service line training
Role models: lengthy resumés and grants	Role model: "quality provider"
Passing boards	Competency- and milestone-based training and certification

limited. The use of Team STEPPS by Emory University School of Medicine and Woodruff School of Nursing is an example of what is possible in training. All third-year medical students and fourth-year nursing students now participate in team training (Morrison et al., 2010).

Much of the "content" that students learn is out of date by the time they graduate. Instead of requiring medical students to memorize large amounts of material that they may never use and will soon forget, it is time for medical schools to decide what *not* to teach. Medical schools should be teaching students how to ask the right questions and leverage information systems to provide just-in-time answers that are evidence based and reflect best practices. These are the skills that are needed for life-long learning.

It may also be necessary to look at the basic organizational structures of medical schools. Traditional departments such as medicine and surgery encourage and reward siloed thinking and training. Academic advancement and funding are integrated into the department structure. The formation of cardiovascular, neuroscience, and cancer institutes represents a move toward more collaborative care models. Ideally, medical student training would include training in working in interdisciplinary teams that cross service lines.

Role models for medical students and residents should be providers who are highly accomplished in the competencies outlined by the IOM: patient-centered care, the ability to work in interdisciplinary teams, evidence-based practice, understanding and application of quality and safety improvement concepts, and skill in using and applying information technology in the care of patients (IOM, 2003). Successful completion of medical school should require demonstration of competency in those core areas.

Residency training reinforces what students learn in medical school. In 1999, the Accreditation Council for Graduate Medical Education (ACGME) approved six general competencies that would be required of all residents. They included the traditional medical knowledge and patient care, but also included practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice (ACGME Outcome Project, 1999; Meyers et al., 2007; Sachdeva et al., 2007). Training in these competencies has been gradual and varied, depending on the institution.

Virginia Mason Medical Center (VMMC) in Seattle, Washington, adopted the Toyota Production System philosophies and practices and applied them to health care in 2001. The system focuses process design work on the patient and the care processes, which results in improved quality and safety. Value streams are used to help analyze processes, and the team develops standard work processes around best practices and mistake proofing for safety and quality. Rapid process improvement workshops (RPIWs) are one of the tools used to implement process improvement at VMMC. All

residents must be a member of at least one workshop during their residency. The workshops involve taking a team of people offline for a week to work on a problem. A typical team comprises all the people involved in the process, including, ideally, a patient. On the first day, the team is trained in the tools, the problem to be tackled is reviewed, and the team applies innovation techniques to generate improvement ideas. The next four days are spent on the floor conducting trials of these ideas, followed by a report to the medical center on Friday. Follow-up reports after 30, 60, and 90 days ensure rigor.

An RPIW held on ambulatory teaching demonstrates the power of this work. The teaching process for residents in the specialty clinic had remained largely unchanged from the 1920s, despite changes in the complexity of the work. Cardiology was chosen for the workshop because it was the rotation in the department of medicine ranked lowest by the residents. The attendings viewed teaching as a burden that lengthened their day, and in-service test scores were low. For the RPIW, the team included a cardiologist, residents, medical assistants, and a scheduler. The solutions were simple and included developing clear rotation expectations; an orientation for residents; daily huddles of the resident with the medical assistant and attending; visual control so everyone could easily see where the patient, attending, and resident were located; anticipation of "flow busters," such as getting called away to the cath lab; and the development of parallel rather than sequential processes. A year and a half later, residents ranked cardiology as one of the top rotations, and 70 percent of the attendings were rated as "top teachers." A powerful lesson learned for the residents was that improving processes is part of a provider's job and that there are tools and science to help achieve that improvement.

Training across silos to ensure the best care for patients is another lesson residents learn. An example is the work on door-to-balloon time for cardiac patients. The team includes medics, emergency department staff, residents, cath lab staff, and cardiologists. Work is standardized, including single-pager notification of the entire team; external setup with kits; and standardized processes, including where to put EKG patches and IVs. Regular drills are held, as well as debriefs with the team to identify improvements for the future.

Training in the internal medicine residents' continuity clinic is another example of the power of the LEAN management system. Several years of process improvement work have centered on improving the primary care experience for patients, providers, and staff. The improvements have included skill-task alignment and the provision of patient-centered care as a team. A collaborative practice model was developed for the internal medicine residents' continuity clinic. The residents practice in the same flow station with the same attending for the duration of their residency.

They learn to work with a "flow manager" who performs preliminary activities—including medication reconciliation, taking and recording of vital signs in the electronic medical record (EMR), teeing up of the health maintenance module, and agenda setting—before the resident sees a patient. While the resident is in with the patient, the flow manager sets up indirect work for the resident, such as phone messages, lab results, and medication refills. When the resident finishes with the patient visit, he/she will do the indirect work that is already set up before seeing the next patient. Visits related to chronic diseases such as diabetes or congestive heart failure are linked to visits with the nurse. The EMR has built-in mistake proofing to ensure that patients receive the screenings they need; safe medications; and appropriate, value-added labs. Evidence-based guidelines and pathways and patient teaching aids are readily available online for both patient and provider to use in discussions about care. Residents learn communication skills (huddles, warm hand-offs to care nurses) and how to provide efficient evidence-based care in flow. As they gain skill in providing care in flow, they find that at the end of the session, they do not face batches of charts to dictate or lab letters to send. The residents begin to see internal medicine as a sustainable career and gain an appreciation of the importance of improving processes to improve care for patients.

These examples demonstrate that training in the ACGME competencies can be accomplished as an integral part of providing safe, quality care for patients. They reinforce the importance of continuous improvement and learning among the entire healthcare team. ACGME also recommended outcome-based assessment of residents during their training. Years after the initial recommendations, however, educational outcome measures remain rudimentary. It is said that what is measured is what is considered important. Further progress in training residents and changing the culture of care will require progress in measuring educational outcomes (Table 8-4).

TABLE 8-4 Changing Culture: Evaluation of Resident

20th Century	21st Century
In-service exams	Medical content: critical elements that must be known
Board exams	Skill in asking the right clinical questions and finding answers
Rotation evaluations • Subjective • Evaluators not trained or skilled in feedback	Educational outcomes to include • Patient and staff satisfaction • Team skills (leadership/following) • Communication skills • Training in giving and receiving feedback

For an organization or practice to evolve into a learning system, training of medical students and residents is critical but not sufficient. Practices and organizations need to recruit not just for medical and technical knowledge but also for the other dimensions outlined by ACGME. At VMMC, a physician compact makes explicit the expectations around patient care, including the focus on patients, collaboration, and communication with the team. The physician compact is used in the recruitment process, and providers are chosen for both technical and cultural fit.

Once in practice, physicians would ideally find themselves in an environment that supports continuous learning and provides tools to help them apply evidence and best practices to the care they provide. The evolution of the EMR from a documentation and ordering tool to one that supports learning is critical for physicians who are overwhelmed by the volume of new learning, along with uncertainty about the efficacy of current treatments. Embedding such capabilities as risk calculators, checklists, automatic feedback, online information search engines, and patient educational material into the EMR can enable physicians and patients to learn just-in-time during the care process (Davenport and Glaser, 2002; Enthoven and Vorhaus, 1997; Schiff and Bates, 2010).

Most physicians practicing today began practice before EMRs were available. For physicians, who have been trained to have all of the answers, reluctance to ask for help is often a barrier to learning how to use available tools. It is important to provide training that is designed for individual learning styles, easy to access, and efficient with regard to time. At VMMC, more than half of providers have taken the "Getting On-Line and Up to Speed in Evidence Based Medicine" course. The course is taught by physicians, it is hands-on, and there is one teacher for every two learners. The course is grounded in a four-step, case-based model. Providers learn how to form search questions; find evidence (search primary studies, vetted sites, consensus tools); appraise information (level of evidence/strength); and save the sites so that they will appear on their exam room computers and can begin to be used with patients the next day.

Learning organizations also need to find ways to engage physicians in guideline development, patient safety initiatives, and leadership/team training. Physicians are data driven, and providing accurate data on clinical outcomes and patient satisfaction can lead to organizational and individual improvement. In order to help physicians improve, it is important that this data sharing be coupled with courses/tools in such areas as shared decision making.

Knowledge assessment for physicians in practice continues to be based on multiple-choice tests, which serves to reinforce the need to know the right answer every time (Brooks, 2010). Certification tests that allow the use of online resources; that are primarily case based; and that test the

ability to use guidelines, evidence, and statistics in making clinical decisions would come closer to measuring the skills needed for continuous learning and improvement. Maintenance of certification should be seamless and not another barrier and add-on for physicians. Continuing medical education credits should be automatically updated in a database that would be available to all credentialing bodies. Instead of more work, recertification could become embedded in the daily work of the provider.

The movement to a learning health system will also require a change in the current payment system. The current system rewards primarily the amount of work done by individuals. The result is a system that is too expensive, of variable quality, and inequitably distributed. If healthcare systems are to move to a care model that is evidence based and focuses on outcomes, quality, and safety, a payment model that is aligned with those goals will be necessary.

Ensuring clinical excellence and continuous improvement will require letting go of traditional ways of teaching and learning. It will require engaging every member of the healthcare team, including the patient. Finally, it will require major institutional leadership in medical schools, in graduate medical education, and in specialty groups for continuing medical education.

CARE COOPERATION AND CONTINUITY ACROSS CLINICIANS, FACILITIES, AND SYSTEMS

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The Massachusetts Strategic Plan for Care Transitions: A Model for a Learning Health System

The healthcare system in the United States demonstrates significant patient safety and quality deficiencies (Snow et al., 2009) and therefore fails to provide value for those who use and pay for it. The United States spends more on health care than any other country in the world. In the past, it was generally agreed that higher costs signaled better quality of care. However, emerging research is beginning to question this assumption by demonstrating that higher-cost regions of the country experience worse quality of care and lower patient satisfaction (Elmendorf, 2009). The opportunity exists to make significant changes in the healthcare system that can enhance both quality and efficiency.

The Institute of Medicine (IOM) has helped characterize a learning health system as the most promising approach for addressing the complex array of healthcare decisions facing the nation in the future (IOM, 2007). Achieving this vision will require fundamental changes, including better synchronization of efforts, use of shared EMRs, and public engagement. At the core of a learning health system is the goal of transforming the current system from one that operates for the convenience of providers and institutions to one that is patient-centered. Nowhere is this need more evident than when patients transition from one setting or one set of providers to another during an episode of care. Furthermore, it has become increasingly clear that no single entity can achieve significant changes in healthcare delivery on its own. The involvement of the public sector is crucial as a means for fragmented providers to interact—especially in efforts aimed at improving the management of transitions that cross treatment silos.

Given the range of healthcare settings and the number of providers involved in treating patients, it is not surprising that communication problems and other errors in treatment persist as patients move across the continuum of care (see Box 8-1). Patients and families are unassisted as they navigate different providers and care settings.

BOX 8-1
Barriers to Effective Care Transitions

Structural
- Lack of integrated care systems
- Lack of longitudinal responsibility
- Lack of standardized forms and processes
- Incompatible information systems
- Lack of care coordination and team-based training
- Lack of established community links

Procedural
- Ineffective communication
- Failure to recognize cultural, educational, or language differences
- Processes neither patient-centered nor longitudinal

Performance Measurement and Alignment
- Underuse of measures to indicate optimal transitions
- Compensation and performance incentives not aligned with care coordination and transitions
- Payment for volume of services rather than incentivized for outcomes

Massachusetts state leaders believe that poor communication and a lack of clear accountability for patients among multiple providers lead to medical errors, waste, and duplication. Adverse events often occur during care transitions, most often with complex, chronically ill, and vulnerable patients. Such events can result from failure to communicate critical information related to a patient's medical care, safety, medications, advance directives, in-home support services, and social situation. Failure to identify issues in such areas as health literacy and cultural preferences may also lead to higher rates of hospitalization, particularly in vulnerable populations. The result is high expenditures for the chronically ill, driven primarily by hospital admissions and readmissions.

We envision a future in which interdisciplinary teams deliver safe, effective, and timely care that is culturally and linguistically appropriate—within and across settings. This vision calls for care that is organized around regions and communities; that is delivered by integrated systems coordinated across settings; and in which the flow of patient information is seamless and secure among all of a patient's providers, insurers, and patients themselves. To accomplish this transformational change, the Massachusetts healthcare community will require collaboration and effective partnerships focused on the creation of a patient-centered care model delivered within learning healthcare systems and encompassing the entire continuum of care. This paper describes the process undertaken by the Commonwealth of Massachusetts to identify and quantify issues associated with care transitions, and to develop and implement a statewide strategic plan for beginning to address those issues. This strategic plan is designed to delineate actionable steps to help the Massachusetts healthcare community realize the vision of integrated, high-value, coordinated, and efficient healthcare delivery.

Background and Significance

Health care in the United States has evolved into a complex array of settings, providers, payers, and procedures. Settings of care include hospitals; subacute and postacute nursing facilities; the patient's home; primary and specialty care offices; community health centers; rehab facilities; home health agencies; hospice; long-term care facilities; and other institutional, ambulatory, and ancillary care providers. In each setting, multiple clinicians care for each patient, sometimes independently and at other times as part of an interdisciplinary team. Figure 8-2 depicts the interdependencies among many different organizations and settings involved in realizing this vision in Massachusetts.

Improving care transitions has the potential to save lives, reduce adverse events and disability due to gaps or omissions in care, and reduce unnecessary costs. Several national clinical and policy models were

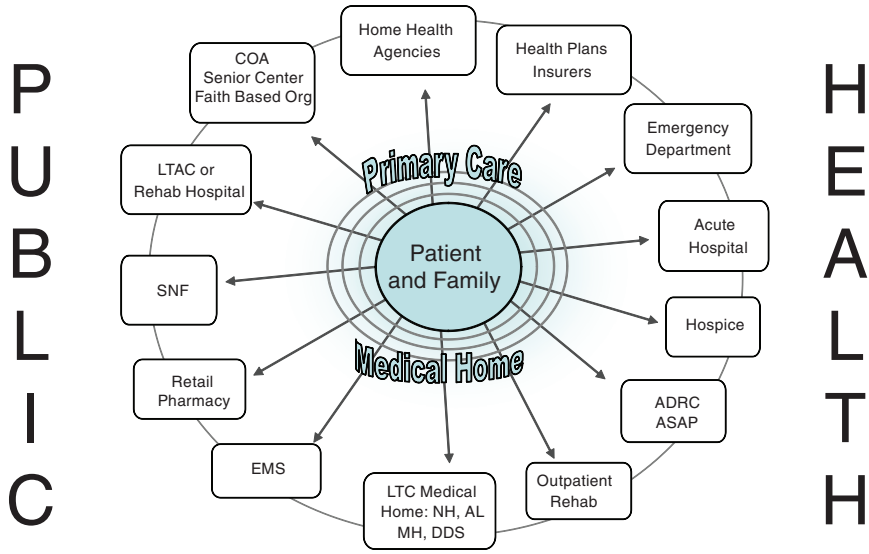

FIGURE 8-2 Interdependencies among organizations: settings of care that must work together and be interdependent to achieve a patient-centered, integrated health system.
SOURCE: Reprinted with permission from the Massachusetts Care Transitions Forum.

reviewed in developing the strategic plan, three of which are highlighted here.

First was the University of Colorado "Care Transitions Intervention," which employs an interdisciplinary team model using a transitions coach. The intervention focuses on four pillars: (1) medication self-management, (2) use of a dynamic patient-centered record, (3) timely primary care/specialty follow-up, and (4) recognition of red flags.

The model was tested on 750 patients aged 65 and older at the University of Colorado Health Sciences Center, randomized at the time of hospitalization to receive either the coaching intervention or usual care. Intervention patients experienced significantly lower rehospitalization rates at 30 and 90 days relative to control subjects, as well as lower rates of rehospitalization for the condition precipitating the index admission at 90 and 180 days. Mean hospital costs were lower for intervention patients than for controls at 180 days (Coleman et al., 2006).

Second was the Transitional Care Model, which focuses on several components, including screening, engaging the elder/caregiver, managing symptoms, educating and promoting self-management, collaborating, ensur-

ing continuity, coordinating care, and maintaining relationships. The model is implemented by a single advanced practice nurse using evidence-based protocols and with a focus on long-term outcomes. The model was initially tested in a randomized controlled trial of 276 older adults at the University of Pennsylvania Hospital (Naylor et al., 2004). It resulted in fewer hospital readmissions, fewer total days rehospitalized, lower readmission charges, and lower charges for healthcare services after discharge.

The final model emerged from a collaboration among the American College of Physicians, the Society of Hospital Medicine, the American Geriatric Society, the American College of Emergency Physicians, and the Society for Academic Emergency Medicine to develop consensus standards to address quality gaps in care transitions. The Transitions of Care Consensus Conference, held in fall-winter 2006, developed several principles and clinical standards for care transitions: accountability, communication of treatment plans and follow-up expectations, timely feedback, involvement of the patient and family, respect for the hub of coordination of care, the patient's ability to identify a medical home, patients knowing who is responsible at every point along the transition, national standards for transitions in care, and standardized metrics for continuous quality improvement and accountability (NTOCC, 2009; Snow et al., 2009).

Creating the Plan

Although efforts to improve care transitions had been ongoing for some time, those efforts were fragmented and uncoordinated. About 3 years ago, a small group of clinicians, healthcare administrators, and government agency staff, coordinated by the Massachusetts Health Data Consortium and Massachusetts Senior Care Foundation, came together to discuss gaps in such efforts and how to disseminate individual work more broadly. That group grew to more than 100 stakeholders and is now known as the Care Transitions Forum, representing a community of interest that meets quarterly to share best practices and provide mentorship to institutions and organizations across the state. Concurrently, senior policy staff from the Massachusetts Executive Office of Health and Human Services had been developing statewide initiatives around patient-centered medical homes and accountable care organizations. They determined that none of these reforms would attain maximum effectiveness unless coordination across care settings was improved. The policy staff members were active participants in the Care Transitions Forum, and with the Secretary's approval, the idea of creating a strategic plan was put forth. The development work was a learning process involving public and private stakeholders from across the Commonwealth. A working group composed of senior administration officials working together with the policy community began by reviewing the

BOX 8-2
A Vision for the Future of Health Care

- Interdisciplinary teams delivering safe, effective, and timely care that is culturally and linguistically appropriate within and across settings
- Aligning of
  - — Clinical care (individuals)
  - — Public health (populations)
  - — Health policy (payment and organization of services)

literature and identifying best practices in care. To effect system change, the group explored innovations along multiple dimensions—medical practice, public health, and healthcare financing—and eventually composed a vision for the future (Box 8-2). A strategic plan was drafted over the subsequent months.

Content of the Strategic Plan

The strategic plan[2] contains five main sections. An introduction defines care transitions and identifies the healthcare system's problems in this area. The next section reviews what is known about effective transitions based on national models and randomized trials. The next two sections summarize current projects in Massachusetts that form the infrastructure for future work, and place them in the state and federal policy context. The final section presents the vision for improving care transitions, including principles, recommendations, action steps, and measures for consideration. One goal is to weave the many currently fragmented care transition projects in Massachusetts into a fabric that covers the state. We believe Massachusetts can be a model healthcare learning state and can lead the nation in improving care transitions and reducing avoidable hospitalizations.

Objectives

We had a number of objectives in writing the strategic plan. A central tenet of the process was ensuring the patient's voice. To this end, we

[2] The document referred to in this section can be found at: https://www.mass.gov/Ihqcc/docs/meetings/stratetic_plan_for_care_transitions.doc.

included patients, families, and advocates in the development and review of each stage of the plan. Still, the first few drafts appeared to lack a strong enough patient focus, so an unfolding case study was added to the document. This enabled us to tell a story from the patient's point of view, and put a very real face on the problem of unsafe care transitions and rehospitalizations.

Another objective was to build consensus among the many stakeholders as to the most important care transition principles; to this end, it was necessary to get people to agree to work together outside of their individual institutions for the good of state health policy. For example, many institutions have their own patient transfer form or process. Numerous forms, very similar but each somewhat unique, exist. To improve consistency and institute a standardized, evidence-based process, each institution must agree to give up some customization so that a unified form and process can be adopted statewide. Bringing stakeholders in early, obtaining their input, and listening to their concerns have been essential parts of our process. We are currently moving forward with final development and deployment of our statewide resident transfer form, which we anticipate will be posted on the Massachusetts Department of Public Health website in the next few months.

A third objective was to include guidance addressing accountability between sending and receiving institutions. When a patient leaves one setting of care, someone must be prepared to receive that patient in the next setting of care. Longitudinal responsibility rests with the sending provider until the receiving provider has acknowledged and accepted the patient. While we anticipated that hospitals and physicians would be resistant to this concept, they accepted the significance of this component of care transitions and the need to address this difficult problem. Ongoing discussions in 22 communities are currently under way as part of the State Action to Avoid Rehospitalizations project, supported by a grant from the Commonwealth Fund.

Measurement

As a learning healthcare system and state, we must be able to measure performance improvement in care transitions. Put simply, how will we know a safe and effective transition when we see it?

The Massachusetts strategic plan for care transitions outlines a strategy for tracking progress and measuring successes and challenges. Performance measurement is essential if the best practices and lessons learned from state demonstrations and national research and care models are to be implemented effectively on a statewide basis. The measures described in the plan have been endorsed by recognized national and state panels of experts. The

plan presents a menu of options for measurement, and proposes that the selection process involve providers, payers, and patients/advocates to ensure that measurement is balanced and reflects the essential roles of providers, insurers, and patients in improving the process.

The National Quality Forum has endorsed several measures for care transitions: the three-item Care Transitions Measure, the 30-day all-cause risk-standardized readmission rate following hospitalization for heart failure developed by the Centers for Medicare & Medicaid Services (CMS), the CMS 30-day all-cause risk-standardized readmission rate following hospitalization for acute myocardial infarction, the CMS 30-day all-cause risk-standardized readmission rate following hospitalization for pneumonia, and the all-cause readmission index (NQF, 2007).

Certain process measures are linked to successful outcomes: the timely transfer of information across settings and professionals involved in care transitions, the effective coordination of transitions across settings and professionals, the timely delivery of care, improvement in patient understanding of and adherence to the treatment plan, improvement in patient awareness of emergency provider contact information, and improvement in patient engagement in care (ABIM, 2009). Ongoing work to refine measures is part of the Massachusetts strategic plan.

Dissemination and Next Steps

In his book *Agendas, Alternatives, and Public Policies,* John Kingdon explains how policy issues rise and fall on public agendas (Kingdon, 2003). He describes three independent streams of activities—problems, policies, and politics—that must occur before effective decision making takes place in government. For a problem to be identified, there must at some point in time be agreement that solutions exist. Policies are generated by specialists, staffers, academics, and interest groups. The creation of the strategic plan accomplished these first two activities. The third required careful vetting of the plan with interested parties. The most prominent of these was the Health Care Quality and Cost Council, which had been established under Massachusetts' landmark healthcare reform law in 2006.

With the Kingdon policy hurdles passed, Massachusetts has now moved into the implementation phase, with workgroups already engaged in the refinement and deployment of a statewide interfacility transfer form and process, as well as state surveyor education around effective care transitions. As more cross-continuum teams are established in more communities, Massachusetts will continue to evolve as a learning health system at the state level.

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9

Incentives Aligned with Value and Learning

INTRODUCTION

The present structure of the American healthcare system rewards volume over value and performing procedures over achieving the best outcomes. Transforming the health system will require a radical change in key precepts—including incentive schemes—and has the potential to elevate national healthcare statistics from mediocre to excellent. If this is to occur, commitments must be made by all stakeholders, and incentives will need to encompass both monetary and professional rewards. Incentive programs already are scattered across the country, but the system as a whole should be reengineered so that all stakeholders—for example, physicians, patients, health systems, payers, advocacy groups, and insurers—provide incentives for constant improvement, science-driven care, and value.

Papers in this chapter illustrate approaches to realign incentives to reward value and learning over volume and excess. In the first paper, Michael E. Chernew of Harvard University argues that cost containment and payment for value, not volume, should rank high in strategies to effect transformative change. He shows how global payment models offer promise for building a system based on science and value. Integral to realigning the health system are comprehensive performance measures that are based on solid evidence and observability as well as incentives that reward positive health outcomes.

The second paper, presented by Richard Gilfillan, formerly of Geisinger Health System, makes a business case for practicing evidence-based, integrated care rather than the high-volume, fragmented care typical in much of the United States. He notes that the business model for providers and hos-

pitals should be the main focus as it can trump *à la carte* incentives in determining whether individuals or organizations focus on volume vs. value. Additionally, Gilfillan highlights how systems approaches can produce reliable processes that minimize errors and how systems can be designed to put evidence-based knowledge in the real-time care workflow.

Anne F. Weiss and Bianca M. Freda of The Robert Wood Johnson Foundation describe the Aligning Forces for Quality (AF4Q) initiative. Active in 17 regions around the country, leadership teams of multiple stakeholders are involved in crafting performance measures, building quality improvement infrastructure, and assessing ways to better engage the public in the concept of a learning health system. The authors state that through the AF4Q initiative, the Foundation hopes to learn how to improve messaging, encourage community participation, and stimulate a learning culture.

PAYING FOR VALUE AND SCIENCE-DRIVEN CARE

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All stakeholders agree that the healthcare system should promote value: the amount of benefits received per dollar spent. Clinical improvements are likely the most significant benefit, but nonclinical benefits, such as reassurance, are important as well. Admittedly, benefit is in the eye of the beholder, but it is useful in this context to define benefits from a patient-centric perspective. Value calculations should use a broad definition of costs, including medical and nonmedical costs associated with care. Many tools can be used to promote value, including the design of provider payment and benefits, the focus of this paper.

The general theory of how value is created in competitive markets is straightforward. Consumers know their preferences. They face prices. They make choices. In a perfectly competitive setting, economists define the outcomes of those choices as reflecting value. This model is subject to extensions and caveats as markets deviate from perfect competition, but for the most part, it captures how market economies work.

In imperfect markets, consumers may not be making the right choices (in their diet, for example), but solutions often require more paternalism than economists typically prefer. When problems arise within such markets, private or public information is often provided to improve choice, or markets are regulated to prevent the most serious problems. But in most markets, interventions are modest, and market forces are the benchmark strategy used to generate value. The problem in health care is that for a number of reasons related to imperfect markets and the salience of health, the problems are more severe.

A key problem is that consumers do not observe quality in health care. Quality measurement and communication in health care may be improved, but for the foreseeable future, the information available will be woefully inadequate to support a perfect market. Moreover, in part because of poor information, providers have weak incentives to improve quality. For example, if a provider works in a hospital and is paid per admission, he/she has little incentive to improve quality and prevent readmissions. On the patient side, apart from the information problem, insurance distorts the choices because incentives to avoid high-cost treatments and providers are typically very weak.

The issue of obtaining value on the provider's side generally focuses on changing provider incentives and combining those incentives with information. Payment reform, including value-based purchasing, is largely a provider-centric way of promoting value. This is in contrast with value-based benefit design, which is patient-centered. The two are not mutually exclusive, and they should be synergistic. For example, it would be problematic if all services were free for patients but providers were discouraged from providing those services. Recognizing where to use patient versus provider incentives and how to integrate them is important.

Despite the focus on value, the overarching concern of the healthcare system must be spending growth. In the President's budget, the ratio of debt to gross domestic product (GDP) becomes 90 percent by 2020 (Figure 9-1) (CBO, 2010). That ratio is not good, and it also is on an upward trajectory,

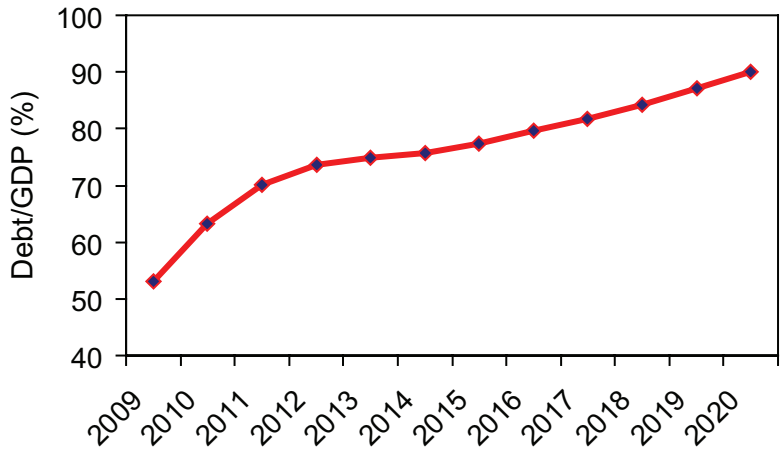

FIGURE 9-1 Expected trajectory of ratio of U.S. debt to gross domestic product (GDP). Payment must do more than promote value; it must also control costs.
NOTE: Cited from CBO Analysis of the President's 2011 Budget.
SOURCE: CBO, 2010.

which is even more concerning. Much of the forecast is based on projected healthcare spending. This fiscal imbalance must be resolved, the mechanisms used will define the healthcare system of the future, ideally promoting value while constraining spending.

Alternate Payment Systems

Incentives and payment for promoting value must be designed to control aggregate spending. This is important when considering payment systems because they must be evaluated not simply on the basis of whether they promote value (which is important), but also on the basis of whether they contribute to a fiscally sustainable healthcare system.

One prominent payment strategy for promoting value is pay for performance (P4P). It is almost cliché to observe that one will get what one pays for. Currently, because value is not being paid for, value is not being delivered. The idea behind P4P is that high-value services can be defined and paid for. P4P raises several concerns. One example is the comprehensiveness of measures. Everything cannot be measured. Current measure sets can be expanded, but they will remain incomplete. The result is a multitasking problem. If one thing is paid for, providers may stop doing other things, even if some of those things are high-value. Another concern is the size of the reward. How big a reward is needed to change behavior meaningfully? There are also issues of design. Should providers be paid for relative or absolute performance? Existing evidence for the success of P4P programs is limited, much more limited than the proponents of P4P would have thought 5 to 10 years ago. Richard Frank and Kathleen Mullen conclude an evaluation of a P4P program in California by noting, "Our results cast doubt on the promise of pay for performance as a transformative mechanism for improving the general quality of the healthcare system" (Mullen et al., 2010). Overall, P4P should be considered a tool to be used in the context of broader payment reform. The fundamental concern in health care is the spending trajectory, and it is unlikely that P4P programs alone will be able to change that trajectory sufficiently. Moreover, the technical concerns are sufficiently great that P4P is unlikely to be the foundation of an incentive program designed to promote value.

Another payment approach involves bundling payments. One bundling strategy is episode-based payment. The idea behind episode-based payment is that payment should be made for episodes of care, bundled across as many services and providers as possible. This approach contrasts with fee-for-service, which encourages fragmented care. Hospitals and their physicians should be included in the bundle, and in many cases, other services, such as post–acute care, should be bundled in as well. Payment should be defined based on what consumers care about (care for a particular ailment

or collection of ailments), as opposed to the detailed services that are part of that care.

Episode payment requires good performance standards to ensure that people are actually receiving good-quality care. Obviously, the least costly way to provide care is not to provide it. As with P4P, technical issues arise about how to implement episode payment. Episodes must be defined, and it must be recognized that people have multiple episodes. Establishing payment rates is problematic if a patient has multiple episodes concurrently. Another concern is who controls the payment (who is the residual claimant). Finally, it remains to be seen how much of health care is amendable to episode definition and how payments would be updated over time. Episode-based payment has been implemented, at least on a limited scale, demonstrating its feasibility. For the reasons cited above (comprehensiveness, dealing with multiple episodes), however, it is probably best to view episode-based payment as a tool, as opposed to the fundamental way of solving cost and quality problems.

Another bundled payment approach is global payment, which entails a single risk-adjusted payment to providers (or a provider group). This approach should be defined to include performance standards, which address the incentive to provide less care and distinguishes this strategy from past capitation approaches. Global payment also must deal with the risk faced by providers. Doing so may require a transformation of practice organization, which, while challenging, is feasible. Many accountable care organization models, which use gain sharing, are a form of this approach. Implementation issues, such as how the money flows and who is the residual claimant, would have to be considered carefully. As with episode-based payment, the process for updating fees over time is important. Nevertheless, because of its global nature, this approach is a much more likely starting point for solving the fundamental cost problem than some of the other payment strategies.

One example is the Alternative Quality Contract that is offered by Blue Cross Blue Shield of Massachusetts. A global payment is made to a physician organization that assumes accountability for the full continuum of care—from preventive to end-of-life care and everything between. The global budget is updated over 5 years, in general by the consumer price index, so providers agree to a global payment trajectory for 5 years. This is not a 1-year capitation. Providers can receive performance bonuses, and there is a comprehensive set of ambulatory and inpatient performance measures. Payment flows to providers just as in a fee-for-service system, but it is oriented to the primary care physician group (which could be a multispecialty group), which is the residual claimant (and bearer of the risk). This makes the approach consistent with medical home models.

Performance Measures in a Learning Health System

All of the new payment models require performance measurement which will need to be able to identify bad performers; be supported and informed by a strong clinical research base; and adjust for risk. Meeting many of these requirements is facilitated by larger care systems and better information systems, suggesting that care systems are likely to become larger.

The question at hand is how to deal with this issue in a learning environment, especially in a healthcare system that is constantly evolving with new evidence being generated. New approaches are good, but quality measures are unlikely to incorporate cutting-edge care directly. Evidence takes time to develop and to be accepted. Some outcome measures, however, such as patient satisfaction, complications, and readmission rates, hold potential for capturing innovation. A set of outcome measures may be broad enough to capture providers who significantly underutilize high-value, cutting-edge care.

Updating measures for innovative care will be a particular challenge. New measures will have to be incorporated as new data emerge. The measure set will always lag. A core set of measures that are transparent and developed through some public or quasi-public process will be necessary. Additionally, some expansion and experimentation by purchasers will have to be allowed as they devise new measures. This will be an ongoing process among purchasers and other quality-focused entities.

Updating bundled payment for new services will be a particular challenge that will require considerable clinical knowledge. Payers will have to develop a system for increasing payments if particularly valuable services are developed, but the system will need to maintain overall fiscal restraint.

In the context of any fiscally sensible system, maintaining quality will require ongoing effort. However, if the concern is not to diminish quality in any way and thus to pay for whatever people (or their doctors) want, the system will collapse by its own weight, and quality will suffer.

Conclusion

In summary, the economy is the goose that lays the golden egg (the healthcare system). If spending increases enough that it destroys the economy, the healthcare system will be degraded. A quick recipe for going forward is to (1) start with cost containment, probably moving to global payment; (2) build as comprehensive a performance system as possible; (3) incentivize patients appropriately; (4) provide as much information as possible to everyone in a manageable way; and (5) encourage organizational reform. Taking these steps will entail a great deal of work, but we may have no choice but to start the journey.

GENERATING EVIDENCE TO GUIDE CARE

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Center for Medicare and Medicaid Innovation

America's healthcare industry is highly innovative in sectors that reward innovation. The development of electronic health records (EHRs) and other data management innovations will speed learning and innovation, but these innovations could produce either more or less value for patients depending on the industry's business model. The current business model focuses learning and innovation on increasing the volume of and revenue for services provided. To focus learning on innovation and produce more value for patients, new business models are needed that reward patient-centered value. There are ample opportunities to improve the value produced by the healthcare system, and there is much to be learned. The recent healthcare reform legislation includes a number of alternative reimbursement approaches for Medicare and Medicaid. Private payers could work closely with the Centers for Medicare & Medicaid Services (CMS) to develop robust partnerships with providers committed to learning to deliver higher-value care. Such organizations, with a preponderance of their business dependent on delivering high-value outcomes, will demonstrate how much more value the healthcare system can deliver.

Patient-Centered Value as the Vision

The good news is that the United States already spends $2.6 trillion annually on health care. That amount should be more than enough to cover everyone. Yet the nation has 40 million people uninsured, experiences frequent medical expense–driven personal bankruptcies, and is characterized by highly variable clinical outcomes. From a patient perspective, we have a low-value system. The problem is that too much of the value produced by the system flows to producers, including insurers, hospitals, physicians, and other providers of care.

The Institute of Medicine's (IOM's) learning health system, the Institute for Healthcare Improvement's (IHI) triple aim framework (population health, experience of care, per capita costs), and The Commonwealth Fund's high-performance delivery system constitute alternative visions of a system that would optimize the quality, affordability, and experience of care for patients (Berwick et al., 2008; Commonwealth Fund, 2010; IOM, 2007). All are based on a patient-centered, value-driven healthcare system. The Affordable Care Act (ACA) of 2010 assumes that higher-value care would help finance coverage for millions of uninsured Americans. These

visions all rely on increased innovation and knowledge to create higher-value care.

But are innovation and knowledge necessarily drivers of value? Should we press for more innovation and systems of learning without addressing the business context in which they occur?

The Healthcare Industry Business Model

Businesses produce what is rewarded. Industries evolve from business models that align incentives with desired outcomes. The healthcare industry's fee-for-service business model is perfectly aligned with the rewarded outcomes: more revenue from more services. The dictum "no margin, no mission" recognizes that not-for-profit healthcare organizations operate within the same context and generally produce the same high-cost outcomes.

In policy discussions, the U.S. healthcare system is expected to produce efficient, high-quality care and is referred to as broken because it does not. Yet no rewards are provided for high-value care, and no one is held accountable for producing it. By rewarding piecework, the current business model encourages fragmentation of care. If no one is in charge, no one can be accountable for the outcomes that occur. The automobile industry is more accountable for health outcomes than is the healthcare industry. When accelerator problems in its cars were found to cause 3.5 deaths per year, Toyota was forced to recall and fix 8.5 million cars. When the IOM identified 90,000 unnecessary deaths per year caused by medical errors, there was no one to call (IOM, 1999). Ten years later, despite a great deal of work and attention, medical errors continue to cause thousands of deaths annually (Sebelius, 2010).

If high-value outcomes are desired, business models that reward providers for delivering those outcomes are needed. The right business models to produce high-value care are unknown, although proposals abound. Congress has included a variety of new payment initiatives in the healthcare reform legislation so that different models can be evaluated. One thing is certain: if we are going to achieve the visions of the IOM, IHI, and The Commonwealth Fund, the primary challenge for policy makers and healthcare managers over the next decade will be driving and managing the transition of the healthcare business model from producer-centered volume to patient-centered value. Key attributes of these models are listed in Box 9-1.

The Role of Innovation and Learning

Policy makers have identified a lack of innovation and knowledge of what treatments work as reasons for the current low-value system. But

BOX 9-1
A Choice of Healthcare Business Models

Producer-Centered Volume	vs.	Patient-Centered Value
• Uncoordinated		• Coordinated
• Fragmented		• Integrated
• High-cost		• Lower-cost
• Fair quality		• High quality
• Minimal accountability		• Triple aim accountability

innovation and learning do not occur in a vacuum. Dynamic industries learn because innovative business practices are rewarded. Moore's law for the semiconductor industry states that the number of transistors that can efficiently be placed on an integrated circuit board doubles every 2 years. This law has held true for 45 years because faster, smaller processing chips produce large margins for Intel and other focused producers. Learning and innovation follow the business model.

Producer-Centered Volume Innovation and Learning

The current healthcare business model directs innovation in three ways. Businesses proactively select innovation and learning opportunities based on the expected business development opportunity. An example is the focus on new drugs to treat chronic diseases that are prevalent in developed countries. Businesses typically do not invest in learning that offers no return. Businesses also avoid innovations that might compromise their success. Hospitals traditionally have not invested in programs to decrease readmissions.

Rapid innovation occurs in health care. I recently heard a presentation by a medical device sales representative who proudly displayed four iterative versions of her company's spinal fusion screws. The cycle time was 9 months. The speaker had no information demonstrating improved outcomes for patients.

Case mix adjustment for Medicare Advantage (MA) plans provides another example. CMS began the rollout of Hierarchical Condition Categories (HCC) coding for case mix adjustment in 2004. Over the next 3 years, an entire new industry segment of HCC coding optimization erupted. The innovation was driven by a fundamental change in the business model for MA plans. When revenue became a direct function of population risk, investments in systems to fully identify the burden of patient risk became a necessity.

Innovation in the pharmaceutical industry continues to produce important advances in specialty drugs. Unfortunately, the pace of value-adding discoveries in the more traditional pharmaceutical sector has slowed. Much of the learning and innovation has produced "me too" drugs that provide high margins for producers but little incremental value for patients.

Why does the healthcare system invest in non-value-added medical devices, coding systems, and purple pills, but not programs for care transitions? The obvious answer is that the former are driven by strong business cases, while the latter are not. In the current business model, innovation is much more likely to decrease than to increase patient-centered value. The United States does not have low-value health care because it lacks knowledge about delivering high-value care, but because the healthcare business model rewards and thereby drives low-value care. Innovation and learning need to be focused on patient-centered value business models that reward them.

Patient-Centered Value Innovations

Geisinger Health System (GHS) includes a Clinical Enterprise with 800 physicians and three hospitals and a 240,000-member Geisinger Health Plan (GHP). The system has EHRs that connect all sites of care and GHP. Neither entity works exclusively with its GHS partner. Both rely on non-Geisinger relationships for the majority of their business. GHS physicians do provide primary care for 40 percent of GHP members. This shared population provides an opportunity for joint pursuit of innovative care delivery and financing initiatives.

Five years ago, the GHS board of directors and leadership made "Geisinger Quality" the central strategic goal. There were four reasons for this approach:

- It is the right thing for our patients and our community.
- It inspires our staff.
- Our integrated system is well positioned to create knowledge about higher-value care.
- The current model is not sustainable.

Quality was broadly defined to include the IOM's six aims for quality improvement (IOM, 2001) and several other dimensions. Generally, the goal was to deliver high-value patient-centered care.

To execute this strategy, we developed a series of care transformation initiatives as joint projects of our Clinical Enterprise and GHP teams. These initiatives target care models of high frequency and costs that also demonstrate high variance in care and outcomes—models that could be significantly improved to deliver higher-value outcomes for patients.

Once care models have been identified for improvement, evidence-based best practices are researched, agreed upon, and implemented. The EHR is used to enable this reengineered care and to collect data with which to document results. A new GHP contractual arrangement also is put in place to align reimbursement with the expected higher-value outcomes. The payment approaches are aligned with the nature of the clinical process of care. Global, bundled payments are used for patient-based episodic care, while pay for performance and shared savings incentives are used for population-based improvements. Each care model innovation, then, is accompanied by a new business model that rewards high-value outcomes.

Each initiative typically tracks process, outcome, efficiency, and patient satisfaction metrics. Process metrics demonstrate compliance with evidence-based care. Outcome metrics show the impact of the new care pathways on patients' health status. Efficiency metrics track improvements in the total payer cost or in the cost of delivering a service. Patient satisfaction metrics monitor the patient experience of care.

Improvement in these measures of success leads to better financial results for the Clinical Enterprise. Physicians and operational managers are directly impacted as well because their performance evaluations and incentive payments are based on the same outcomes. The effect of these changes in clinical and reimbursement models, then, is to bring the value dimensions of patient experience, health status, and efficiency into the managerial mainstream. Clinical managers and physicians are directly accountable for, and therefore attentive to, outcomes. Outcome measures for the population are the measures of operational success tracked directly by managers. Value garners managerial attention.

The standard reimbursement arrangement between the parties is a straightforward fee-for-service contract. For the clinical enterprise, these programs move the business model from volume toward value. For GHP, the better outcomes, more satisfied patients, and lower costs provide an opportunity for growth in market share. Accordingly, GHP provides additional payments to help the physicians and practices finance the care transformation. The revised business models establish a "virtuous cycle" that drives a provider–payer partnership to deliver better patient outcomes and higher-value health care.

Examples of this approach include the following:

ProvenCare Acute:

- Population—those undergoing acute surgical and medical procedures
- Care model innovation—evidence-based redesigned care pathways for acute hospital services
- Business model innovation—bundled payment for an episode of care

- Measures of success—outcome metrics, compliance with guidelines, patient satisfaction, cost of services
- Result—improved outcomes and cost of services (Table 9-1)

Chronic Disease Care Optimization:

- Population—primary care office patients with chronic diseases
- Care model innovation—evidence-based care pathways and EHR-based registries and reminders for patients with diabetes, high blood pressure, and hyperlipidemia
- Business model innovation—pay-for-performance incentives
- Measures of success—bundled metrics for diabetes, hypertension, cholesterol and preventive services, patient satisfaction
- Results—marked improvement in all metrics (Table 9-2)

ProvenHealth Navigator:

- Population—all Medicare beneficiaries seen in primary care offices
- Care innovation—value-driven medical home model based on partnership between primary care providers and GHP
- Business model innovation—fee for service supplemented with stipends and a quality-driven shared savings model
- Measures of success—triple aim outcome metrics for health status, patient experience of care, cost of care
- Results—improvements in Healthcare Effectiveness Data and Information Set, patient satisfaction, and cost metrics (Table 9-3)

Patient-Centered Value Learning

This patient-centered value business model focuses learning on systems to improve outcomes. This is best seen in our ProvenHealth Navigator medical home model. The measures of success for this model are improvements in the dimensions of health status, patient experience of care, and total cost of care. Physicians are rewarded explicitly for improvements along these dimensions. As a result, the practices and GHP are tightly focused on monitoring outcomes together. The entire practice team, including GHP in-office case managers, reviews outcome results at monthly meetings. The practice managers produce monthly reports demonstrating the results of chronic disease care and patient satisfaction for each physician. GHP staff report on patients admitted to the hospital, all readmissions, and the total cost of care. Admissions, readmissions, and concerns for specific patients or care systems are discussed with the entire staff. The whole team, including office staff and GHP payer staff, is engaged in conversations about what could be done

TABLE 9-1 Value Learning: ProvenCare

Results	Improvement (%)
Patients with more than one complication	28
Atrial fibrillation	17
Any pulmonary complication	43
Deep sternal wound infection	25
Readmission within 30 days	44

Innovation: Evidence-based best practice surgical case redesign
Evidence Development: Process and outcome metrics for surgical care
Incentive: 90 global payment, including complications

TABLE 9-2 Value Learning: Chronic Disease Care Optimization

Results	Improvement (%)
Diabetes bundle	30
Coronary disease bundle	20
Preventive care bundle	75

Innovation: EHR-driven registries and reminders
Evidence Development: Physician-specific monthly Healthcare Effectiveness Data and Information Set (HEDIS) metrics
Incentive: Straight pay for performance

TABLE 9-3 Value Learning: ProvenHealth Navigator

Results	Improvement
Admissions	Decreased 16%
Readmissions	Decreased 30%
Quality metrics	Improved as noted in Table 9-2

Innovation: Medical home with population management built into the primary care office
Evidence Development: Process and outcome metrics for surgical care
Incentive: Fee for service, pay for performance, stipends and shared savings paid based on quality outcomes

better. Examples of best practices from other offices are diffused rapidly. In this environment, the team members can see the impact they are having across an entire population. Every member knows that good outcomes will be celebrated and poor outcomes scrutinized to learn important lessons.

In the ProvenHealth Navigator model, outcome measurement flows directly and naturally from the delivery of care. Understanding the patient

experience, quality outcomes, and the cost of care is a central management function of the practice. Learning to improve these outcomes is built directly into the operations of the practice.

Lessons Learned

We have made mistakes and learned important lessons over the past 5 years. The most significant lessons learned are as follows:

- It is possible to improve delivery systems to optimize the quality, patient experience, and efficiency of care simultaneously.
- Change is difficult to accomplish in the context of daily practice; it requires ongoing attention, additional dedicated staff, and a good motivation.
- Financial support and rewards are essential to make the business case, but:
  - — individuals respond to multiple drivers, not just payment; and
  - — transparency, constant feedback, and celebration of success drive staff engagement.
- Clinical and business leadership are critical.
- The provider–payer partnership is central.
- Transparency works: sharing results within and across practices drives improvement.
- Engagement and accountability work best in small units—groups of four to five physicians.
- Clinical transformation is hard work—focusing on initiatives with broad impact delivers the most added value.
- Timely analysis of results is essential to rapid-cycle innovation.
- Innovations affecting small numbers of patients provide limited data for analysis and learning.

The innovations described in this paper impact a relatively small portion of the overall clinical activity of our system. Other parts of the system operate with a more traditional volume-based model, albeit within the culture of a not-for-profit multispecialty group practice. The results demonstrate what is possible within an organization operating two business models. How much more value could be produced in an environment where every operational area was working to optimize patient-centered value? Given the synergistic effects among initiatives that we have seen, we believe it would be possible to produce much more value in a simplified business environment.

Implications for Health Systems

Our experience leads to the following suggestions for organizations, providers, and payers that make a strategic commitment to delivering higher-value care to their communities:

- Make patient-centered value an explicit strategic commitment, and communicate it clearly to the organization.
- Make patient-centered value innovation objectives important drivers of senior leaders' incentive plans.
- Include the innovation goal in all employee incentive plans.
- Build population registries and other tools with which to manage a population, not just those in the hospital.
- Form payer partnerships to align reimbursement and agree on joint initiatives and R&D investments.
- Explicitly identify the source of added value before selecting a particular initiative.
- Maximize the leverage of care redesign and reimbursement changes to drive the broadest clinical impact with the least administrative work.
- Shorten the learning cycle time:
  — build evidence-based guidelines into the flow of care;
  — build data capture into standard care processes; and
  — measure and feed back results frequently.
- Extend initiatives to as many patients as possible to create mass and momentum for change, as well as meaningful data.
- Establish analytical resources close to the innovation activities to provide rapid evaluation and feedback.
- Celebrate success.

Public Policy Implications

The most significant public policy opportunity to improve value innovation and learning is to create the will for healthcare organizations to deliver high-value outcomes. The reimbursement innovations for providers and MA plans in the recent healthcare reform legislation will drive movement in that direction. The greatest impact would result if public and private payers developed a common approach that gave providers an unambiguous context in which to deliver higher-value care. Other suggestions include the following:

- Begin a public campaign to legitimize patient-centered value as an explicit aim.

- View CMS and the Center for Innovation as payer partners working with providers to deliver patient-centered value.
- Make outcome data rapidly available to providers operating under value-based contracts.
- Increase transparency and stimulate learning by providing claims data to third parties for provider profiling.
- Challenge payers and providers to step up to accountability.
- Develop partnerships with private payers to provide greater patient mass for care transformation efforts by providers.
- Build a rapid learning network; use the EHR capabilities of multiple integrated systems to establish a learning web that can mine current and future data to evaluate treatment impacts.
- Be cautious about evaluating initiatives that occur in provider systems with mixed business models.

Conclusion

Opportunities to improve the value of health care abound, even with the limited knowledge we have today. As the healthcare system becomes digitized, shorter learning and innovation cycles become desirable and inevitable. We will learn from other industries that use refined data management capabilities to adjust their operations in real time. Whether innovation will drive higher value for patients or more revenue and volume for producers is unclear. The most significant step we can take to ensure that innovation serves patients is to reward higher-value outcomes. Public–private payer initiatives with specific providers committed to an unambiguous patient-centered value business model would provide the most robust learning environment. This is the model that can teach us what is possible when every employee wakes up every day committed to learning how to better deliver high-value care for patients and the community.

CREATING A LEARNING CULTURE

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The American healthcare system faces critical challenges, including poor quality, skyrocketing costs, and troubling racial and ethnic disparities. The ACA of 2010 arguably should provide tools to address many of these challenges. But it is unrealistic to expect that the nation's healthcare system need only undergo a one-time transformation. Rather, the healthcare system will need the ability to identify problems proactively, develop solutions for those problems quickly, and create a culture that rewards

solutions and promotes the ongoing search for problems and their respective solutions. Essentially, real reform requires that health care become an ongoing learning enterprise. Unfortunately, health care currently is not that sort of system. In fact, American health care offers few incentives for, and indeed poses formidable barriers to, learning and problem solving. There is, however, hope. Work supported by The Robert Wood Johnson Foundation (RWJF) is helping the field understand some of the important necessary next steps toward such a learning system. Many observers have noted that the current system of paying for health care in the United States creates disincentives for high-quality care: it encourages wasteful and fragmented care and does not reward providers who struggle to deliver good care (Miller, 2009). RWJF's work to improve healthcare quality suggests that there are, however, powerful nonfinancial incentives that can be used to influence behavior and shape a learning culture.

RWJF launched its Quality/Equality strategy and its signature initiative, Aligning Forces for Quality (AF4Q), in 2008. RWJF's board of directors has made a $300 million commitment to the strategy through 2015. The strategy was designed around two principles: first, that while quality is a national problem, health care is delivered locally, and fixing it requires local action; second, that those who receive, give, and pay for care—consumers, providers, and purchasers—need to team up and align their efforts to create lasting change (Painter and Lavizzo-Mourey, 2008).

AF4Q is being implemented in 17 targeted regions. Three are states (Minnesota, Wisconsin, and Maine); one is a rural county in California; and most of the rest are multicounty or metropolitan areas. In each region, a multistakeholder team of healthcare leaders, physicians, nurses, consumers, health plans, business, and others carry out three key activities: they issue public performance reports on hospitals and physicians, develop a sustainable capacity or infrastructure to help physicians improve, and work to engage consumers in using healthcare information.

For this strategy to succeed, different stakeholder groups need to reach fundamental agreement on difficult tasks, such as defining and measuring good care, engaging professionals in efforts to improve care, and getting patients and consumers more involved in different aspects of their care. And they have to accomplish these tasks in the absence of any meaningful policy, social, or economic incentives. Although there is certainly overwhelming evidence of various kinds of healthcare quality problems, different groups generally understand those problems differently (AHRQ, 2009).

The challenge of getting different stakeholders aligned around common goals in AF4Q is very much like the challenges to creating a learning health system. RWJF and its partners have addressed these challenges by using strategic communications, engaging health system leaders, and engaging consumers.

Using Strategic Communications

During 2007–2009, RWJF, in partnership with several strategic communications firms, embarked on a series of message research projects with the general public, physicians, consumers, and employers. In general, these projects involved a review of existing research, individual interviews, focus groups, and telephone or online surveys. The firms developed evidence-based messages, which were extensively sourced to ensure that they would be credible. Messages were distributed widely to AF4Q community teams and other grantees, who were trained in using the messages and were given interactive tools, such as a slide builder. The messages, training, and tools have been extremely well received by the AF4Q communities. There are lessons to be learned about each audience for these communications and ways to reach them effectively, which should also prove useful in efforts to create a learning culture.

Research on the general public was conducted in part by a firm, Olson Zaltman Associates, with a unique methodology based on theories of cognitive learning: that people learn and perceive the world according to a few universal frames or metaphors, and these metaphors help them derive meaning from a wide range of related concepts. Therefore, the firm's approach is to identify these universal emotional metaphors and use them as the foundation for messaging and engagement efforts. In the case of health care, Olson Zaltman Associates' research reveals that people view health care as a journey from a state of confusion and complexity to one of relief and simplicity, and they see quality health care as a patient–provider relationship that takes them to their goal, around multiple barriers, and results in comfort and peace of mind. The essence of quality health care from patients' perspective is having a close relationship with their medical provider that is based on trust.

Subsequent message research with a physician audience emphasized AF4Q's focus on measuring and publicly reporting on the quality of care. This research revealed that physicians are understandably focused on how performance data are collected, adjusted, and analyzed and how the data will be used; they expressed the greatest confidence in initiatives led by their peers. Physicians were interested in how they compared with their colleagues but did not want this information made public. They did not expect their patients to use public performance information. The results of this research were used to develop messages that acknowledge problems with previous efforts to measure and report quality and physicians' frustration with the healthcare system. These messages give physicians reasons to participate in the project and ask them to contribute their leadership, expertise, and influence to help improve care and make their patients better partners in care. It is also important to link the process of measuring and reporting on quality with payment reform.

Messages were developed for employers as well, based on insights provided by AF4Q communities. These insights revealed the need to communicate very basic reasons why employers should take an interest in poor healthcare quality and offer specific ways they can contribute. Major messages used with the employer audience include both the direct and hidden, indirect costs of poor health care; the added premium costs of wasteful, poor-value care; and examples of companies that have made a difference.

Engaging Health System Leaders

Health system leaders, such as hospital board members, do not always make quality a strategic priority (Jha and Epstein, 2010). Fewer than half of hospital board members rate quality of care as a top priority, and only a minority have been trained in quality. A number of quality improvement initiatives sponsored by RWJF have explored ways to engage board members and senior executives in efforts to measure and improve quality (RWJF, 2008). Based on those experiences, a number of recommendations can be made for engaging health system leaders in a learning community:

- Make the case based on both mission and margin: build evidence for how learning is "the right thing to do" but also is good for the bottom line.
- Use a trusted intermediary, not a consultant, to reach hospital leaders.
- Make learning activities a standing agenda item, with dashboard metrics that align with other institutional goals.
- Ask health system leaders to play a role in publicly showcasing and communicating about results, as well as in motivating staff.

Engaging Consumers

Consumer engagement is a critical strategic component of AF4Q, as it should be in a learning healthcare system. RWJF's goal is for consumers to access and use health and performance information to make healthcare decisions at key points. Consumer representation in all aspects of a learning organization, including governance and decision making, is critical to achieving the goal of patient-centered care (Regenstein and Andres, 2010). Consumer representatives may require ongoing training and support to play a meaningful role.

Authentic consumer representation involves individuals who do not have a financial stake in the healthcare system. They may represent a specific constituency, be it faith-based, disease-based, or population-based (NPWF, 2009). Individuals who are current or retired employees of a

healthcare organization and their spouses are often tagged as "consumer" representatives but may not be able to play that role convincingly.

Too often, healthcare improvement initiatives focus on what is technically and politically feasible rather than what is of greatest importance to patients and families. This is due, in part, to the relative absence of information on meaningful outcomes that capture patients' experience over time and in different settings, compared with an abundance of information on specific clinical processes and transactions. For example, while it is costly to collect information on patient experience, these measures provide direct information about the patient-centeredness of care at both the practice and provider levels, and positively correlate with processes of care for both prevention and disease management (Shaller et al., 2010). AF4Q sites are working to make the results of patient experience surveys more widely available, despite the difficulty of finding a sustainable business model for doing so. A learning health system should focus on and promote the issues that matter to patients and families.

Creating a Learning Culture: Some Conclusions

Although not backed by rigorous research results at this point, some insights about how to create a learning culture within the healthcare system have emerged from RWJF's experience in promoting social change and AF4Q's experience to date:

- *Test change in local markets*—Although healthcare quality is obviously driven by federal and state policy, as well as private market developments at every level, health care is delivered locally, and it is important to gain experience in different market environments around the country.
- *Invest in message research and adhere rigorously to tested messages*—Strategic communication is a proven critical component for achieving social change (Hurley et al., 2009).
- *Insist on participation by multiple stakeholders* (Sequist et al., 2008).
- *Engage authentic consumer participation.*
- *Measure and focus on what matters.*
- *Value transparency.*
- *Do not neglect financial incentives*—Although this paper has focused on nonfinancial ways to create a learning culture, creating such a culture is difficult in the face of payment systems that often punish, rather than reward, learning and improvement (RWJF, 2010).

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10

Common Themes and Opportunities for Action

INTRODUCTION

As noted in Chapter 1, the discussions summarized here had broad objectives: to review the state of play with respect to the foundational elements of a learning health system; to explore the hallmarks of patient engagement for care that must keep science, patients, and value in focus; and to discuss strategies important for improving the awareness and patient-focused action necessary for the transition to a learning health system.

With a scope this broad, the discussions spanned many issues, but certain elements served as frequent reference points throughout the discussions. This chapter provides a review of those common themes, and also summarizes a session entitled Strategies and Priorities in which panelists were asked to reflect on what they heard about compelling policy issues moving forward.

Emerging from workshop discussion is the notion that a learning health system should focus on patients and their family, caregivers, or agents; should default to openness; should listen to the patient's voice; and should promote respect, transparency, and patient feedback.

COMMON THEMES

Common themes that emerged during the course of the 2 days of discussion (see Box 10-1) are summarized below.

Listening. *Each patient–clinician interaction starts with uninterrupted atten-*

BOX 10-1
Patient-Anchored Care: Common Themes

- **Listening.** Each patient-clinician interaction starts with uninterrupted attention to the patient's voice on issues, perspectives, goals, and preferences.
- **Participatory.** Health outcomes improve when patients are engaged in their own care.
- **Reliable.** All patients should expect proven best practice as the starting point in their care.
- **Personalized**. With proven best practice as the starting point, science-based tailoring is informed by personal biological traits, circumstances, and preferences.
- **Seamless.** Care delivered by multiple providers in multiple settings should be fully integrated and seamless.
- **Efficient.** Patients, their families, and clinicians should expect care to be appropriate to the need, available resources, and time required.
- **Accountable.** All relevant aspects of the clinical experience, including patient perspectives, should be captured and routinely assessed against expectations.
- **Transparent.** Information on the outcomes of care—both effectiveness and efficiency—should be readily accessible and understandable to patients and their families.
- **Trustworthy.** Patients should expect a strong and secure foundation of trust on all dimensions—safety, quality, security, efficiency, accountability, and equity.
- **Learning.** In a learning health system, the patient is an active contributor to and supporter of the learning process.

tion to the patient's voice on issues, perspectives, goals, and preferences. These patient views should then be used to guide clinical decisions, which often involve choices among multiple treatments that have both benefits and risks. Workshop participants reported that care often improved when staff and providers listened carefully to the concerns of patients and their families. Yet, it has been noted that physicians tend to interrupt patients within about 15 seconds of beginning to speak at the outset of the visit. On the other hand, an uninterrupted patient tends to conclude their remarks in under a minute (Beckman and Frankel, 1984). Listening fully to the patient, then, does not cause any significant delays in the physician's schedule, and adds substantially to creating an environment where patients feel comfortable sharing their health information. Achieving this goal will require a new focus on patient communication starting early in provider education to ensure that providers have the tools they need to share complex health information with patients and help them with these decisions.

Participatory. *Health outcomes improve when patients are engaged in their own care.* In addition to improving health outcomes and patient adherence,

participants noted that engagement can increase employee satisfaction and financial performance. People are eager to play a strong role in their own health care when given the right tools, as evidenced by the rapid uptake of Web 2.0 health information applications. Yet as one speaker mentioned, surveys indicate that only half of patients receive clear information on the benefits and trade-offs of the treatments under consideration for their condition. Patients' involvement may be increased by providing them with additional information tools for learning about their health, helping them see the impact of their efforts, and acquainting them with new technologies with which to monitor their health and assist with lifestyle changes. Public participation is not limited to the clinic; the workshop highlighted new initiatives to provide access to health data and allow individuals to create new applications to improve their health.

Reliable. *Each patient should expect proven best practice as the starting point in their care.* The current variability in medical practice impacts patient care and results in uneven quality and safety for patients. Participants described tools that minimize this variation, such as dashboard displays that highlight the interventions that are due, done, or overdue and improve the consistency of the delivery of interventions to patients; other technologies that show promise include clinical decision support systems that present best practices to clinicians. Several participants also noted that, while technologies provide new opportunities, incentives, such as bundled payments and pay for performance, are needed to promote reliability and effectiveness in healthcare organizations and ensure accountability.

Personalized. *With proven best practices as the starting point, science-based tailoring is shaped by personal biological traits, genetics, circumstances, and preferences.* Since the sequencing of the human genome was accomplished, medical science has sought to personalize treatments to specific biological traits and genetics, in addition to personalizing care based on individual patient circumstances and preferences. This effort challenges the traditional approach of giving the highest priority to evidence gathered by means of large randomized controlled clinical trials, in which treatments are measured in a large population with a diverse genetic profile. Using multiple types of complementary evidence could better guide medical decisions and account for these personal factors. This new approach focuses on the applicability of results to the clinic, rather than automatically giving priority to the results of randomized controlled trials.

Seamless. *Care delivered by multiple providers in multiple settings should be nonetheless expected to be fully integrated and seamless.* As patients move among providers and settings, they often encounter communication

problems, which may result in treatment errors and duplicative services. Participants described how team-based care offers the potential to rectify this disconnected care and limit human error. Effective teams are aided by an appropriate information technology infrastructure, which facilitates efficient and effective communication of health information. Encouraging the use of such teams will likely require the use of financial incentives, including bundled payments and payments that focus on outcomes; applying disincentives for poor outcomes, such as for preventable hospital readmissions; and creating incentives for delivery system reforms, including medical homes and accountable care organizations.

Efficient. *Patients, their families, and clinicians should expect care to be appropriate to need, resources, and time required.* Participants underscored the fact that currently, much of the care that is delivered is neither necessary nor efficient, with patients facing increasing out-of-pocket costs and lost time in the care process. This finding is not surprising given that the current incentive structure, focused on volume over value, encourages overuse and waste. As multiple participants noted, the United States spent roughly 17 percent of its gross domestic product on health care last year, yet this investment does not yield the health outcomes commensurate with the costs. To gain greater value, many participants stressed that the costs and outcomes of care should be more transparent to patients, and new payment models—ranging from bundling payments for an entire episode of care, to pay-for-performance systems, to global payment—need to be implemented.

Accountable. *All relevant aspects of the clinical experience, including patient perspectives, should be captured and routinely assessed against expectations.* This information is vital not only to achieving effective patient management, but also to judging whether experiments with new delivery system models, payment incentives, or standards of care are having their intended effect on improving patient health and promoting efficiency. Measuring performance and disseminating innovations that work (and eliminating those that do not) constitute a systematic way of improving healthcare delivery. One presentation highlighted how this systematic approach to improvement allowed the speaker's organization to enhance care by conducting comprehensive reviews of interventions for different conditions, adopting the best practices identified by that review, and measuring the performance of the revised standard of care.

Transparent. *Information on the outcomes of care—both effectiveness and efficiency—should be readily accessible and understandable to patients and their families.* Several speakers mentioned the frustration felt by patients regarding the lack of understandable information on the costs,

quality, and outcomes of care, especially in light of reports about medical errors and the increasing personal burden of costs and inefficiencies of care. It was noted that, when offered a choice, patients do not routinely choose more costly or more intensive interventions. However, patients rarely have choice or information about alternatives. It is clear that information needed to improve value—better outcomes at lower cost—requires transparent information on the costs and outcomes of care.

Trustworthy. *Patients should expect a strong and secure trust fabric on all dimensions—safety, quality, security, efficiency, accountability, and equity.* In few areas of human endeavor is trust on each of these dimensions more important. Yet one presenter noted that, even though 50,000 to 90,000 deaths per year are caused by medical errors, health care lacks the basic trust elements of transparency and accountability needed to drive improvements in quality and safety. In a learning system that draws lessons from each care experience, public trust must be bolstered in all aspects of the healthcare enterprise: equitable access to reliable clinician knowledge and skills, safeguards on clinical processes, the privacy and security of medical records, and the validity and safety of clinical trials.

Learning. *In a learning health system, the patient is an active contributor to, and supporter of, the learning process.* Each patient experience offers the potential to deepen the knowledge base that drives care quality and outcomes—at the individual, practice, and societal levels. A focus of the workshop was the stake of the patient in fostering a digital health utility that provides needed information to patients and their clinicians, ensures synchronization among providers, and generates knowledge for progress—for example, for comparative effectiveness insights, public health activities, or postmarket monitoring of approved technologies and drugs. Reference was made, for example, to the need for a common core data set for electronic health record–based data that would allow reliable, platform-independent research across large patient populations. These are issues in which patients have a strong stake, and they must have confidence in the system's functionality for the generation of timely and reliable new insights.

STRATEGIES FOR MOVING FORWARD

Throughout this workshop, participants reflected on the state of play of health care today; identified the opportunities and impediments for transforming health care into a continuously evolving, learning health system; considered the needs of different stakeholders—patients, family members, the public, physicians, healthcare teams, or leaders; and addressed the impediments for achieving this vision.

The Need to Engage Patients and the Public

Developing active learning skills, rejecting patronizing attitudes to patients and inviting patients to the table on all matters pertinent to health and health care were often raised in discussions as crucial in moving ahead. Early in the workshop, participants made clear their priority for re-engineering the healthcare system around the needs of patients. Frequently suggested strategies for patient engagement included: involving patients as partners in the design of research, inviting patients to technology assessment and coverage-decision making meetings, stimulating dialogue between patients and industry, asking patients about their opinions of the health system, fostering shared decision making, and sharing information in the most transparent way.

Focus on Learning

The Roundtable vision of a learning health system was frequently referenced by participants. Speakers envisioned a system in which advancing science and clinical research would be natural, seamless, and a real-time byproduct of each individual's care experience; highlighted the need for a clinical data trust that fully, accurately, and seamlessly captures health experience and improves society's knowledge resource; recognized the dynamic nature of clinical evidence; noted that standards should be tailored to the data sources and circumstances of the individual to whom they are applied; and articulated the need to develop a supporting research infrastructure.

Often noted was the imperative to make sure that learning encompasses all groups. Particularly striking was the repeated emphasis on learning for patients, learning for clinicians and clinician teams, and learning for organizations. Learning must be customized for each group. Patient learning must be tailored depending on health problems, literacy levels, and interest in self-management in order to affect patient behavior, maximize clinical adherence, and improve health outcomes. Similarly, presenters highlighted that clinicians learn differently depending on their career stage. Medical students might be blank slates for learning teamwork, electronic health systems, and collaboration, while experienced clinicians may need to have materials adjusted to their practice patterns. Finally, organizations vary in their ability to adjust, with some organizations having substantial resources to devote to innovation while others try to cope with their current practice load.

Public Communications Vital to Success

One of the key challenges identified in the workshop was the need for better communication strategies. Information about science and medi-

cal care often is presented in an oversimplified format where risks and uncertainty are not discussed. This is compounded by media strategies that dramatize health information or are shaped by groups that shape messages based on their own self-interest. As noted by Fran Visco of the National Breast Cancer Coalition, messages that are over-simplified or under-interpreted can lead to public controversies instead of rational discussions about evidence, as occurred during the update of the U.S. Preventive Services Task Force recommendations on breast cancer screening.

Health communications could be improved by learning from other sectors with expertise in public communications, ranging from the media to advertising to new media firms. These organizations have conducted substantial research into the efficacy of different communications strategies and whether they influence public behavior. Building on this expertise, more research is needed on how science and medical evidence are absorbed by the public and the impact of different messaging methods.

These initiatives also should take advantage of new media technologies. One example discussed was Text4baby, a service for pregnant women. Provided to any woman who enrolls, it provides weekly health messages targeted to a woman's due date and the first year of a baby's life via text message. The service is a partnership where cellphone companies have agreed to pay for costs of the text messages. Early anecdotal reports suggest positive reactions from the participants.

Although these targeted campaigns produce successes, further improvements require a stronger investment in widespread health literacy. Health literacy has a stronger impact on a patient's health than age, income, race, or other factors (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999). A key opportunity for teaching health concepts is the primary and secondary educational system, where children could be taught concepts such as risk, evidence uncertainty, and disease prevention along with the skills to analyze health information.

Public understanding of health issues is heavily influenced by news media reporting. Current health reporting entails covering complex financial, public policy, and scientific issues, ranging from health insurance structures to clinical trial results to legislative proposals. Journalists must cover this broad range of complex issues and make them accessible and understandable while ensuring the stories remain accurate and comprehensive. Achieving these aims requires increased education of journalists that cover health issues to assist them in their work. However, as noted by presenters, traditional media channels are not the only venue for delivering information to patients, and patients and consumers now receive most of their medical and health information from the Internet. The volume of knowledge available will increase in the future because of open access journals, public access policies, and collaborative web forums.

LOOKING AHEAD TO NEXT STEPS

The IOM Roundtable on Value & Science-Driven Health Care provides a trusted venue for sustained discussion and collaboration between national experts and health system stakeholders on issues important to improving the generation and application of evidence in healthcare decisions. It has advanced these discussions through five Innovation Collaboratives on clinical effectiveness research, electronic health records, best practices, evidence communications, and value incentives. With the passage of the Affordable Care Act, the Roundtable has new opportunities to engage in those five areas and promote the creation of a *learning health system*. The meeting's discussions identified a number of promising suggestions for continuing the Roundtable's work to achieve a learning health system, with the following issues deserving further attention and action by the members of the Roundtable.

Clinical Effectiveness Research

- How do various research methodologies produce results that contribute to personalized treatments, real-time learning, and clinical relevance? Should the Roundtable and its Clinical Effectiveness Research Innovation Collaborative develop a new taxonomy of research approaches that advance these goals?
- What steps can encourage greater patient involvement in the evidence process, from fostering participation in clinical trials, to initiating data collection for disease research, and developing applications from existing data?

Evidence Communication

- How can the Roundtable and its Evidence Communications Innovation Collaborative encourage the development of best practices in health communications, whereby complex information is delivered in simple and easy-to-understand formats? What steps can be taken to compile information on successful concepts, such as patient coaching, question checklists, and patient decision aids?
- What steps can be taken to encourage the education system to teach students how to analyze health information as well as related concepts, such as how to gauge risks and benefits, in order to promote broader health literacy?
- How can the Roundtable connect leaders from enterprises with expertise in consumer communications, such as media outlets and advertising, with health system leaders to transfer the lessons they have learned?

- Given that the media are a key supplier of health information, what steps can be taken to enhance the health literacy of journalists so as to improve the information delivered to the public?
- With more Americans obtaining health information from the Internet, how can the Roundtable encourage the development of websites with authoritative medical information for consumers?

Best Practices

- Given the benefits of engaging patients and families in their medical care, how might patient-centered care be encouraged throughout the medical system?
- What steps can the Roundtable and its Best Practices Innovation Collaborative take to encourage the use of technologies, such as dashboard displays or procedure checklists, that reduce variability in care management and improve the reliability of the use of best practices?
- What impediments prevent patient preferences and goals from being considered in all care decisions?
- Given the advantages of team-based care in promoting coordinated care and quality improvement, how can a team approach to care delivery be encouraged?

Electronic Health Records

- Developing a learning health system will require the use of clinical data as a reliable source for clinical research. How might the Roundtable and its Electronic Health Record Innovation Collaborative encourage the development of standards and approaches to assure the quality of these data?
- Since an effective health information utility was identified as a prerequisite for care coordination, continuous learning, and measurement of outcomes, what steps could Roundtable members and its Electronic Health Record Innovation Collaborative take to accelerate the adoption and use of such a utility?
- Given the accelerated development of medical evidence, what might the Roundtable do to explore expanded decision support at the point of care?

Value

- With the creation of new reimbursement incentives to promote value, how might the Roundtable and its Value Incentives Learn-

ing Collaborative develop a framework for ongoing assessment of the efficacy of these reimbursement experiments with respect to increasing value?
- What specific actions could be taken to reduce healthcare costs and increase value? What incentives are needed to encourage those actions?
- What incentives, financial or otherwise, are needed to encourage providers to place greater emphasis on engaging patients in their care?

As these issues are considered, it is important to note that the focus of the workshop was ultimately for and about the patient. Addressing these specific issues will help to move the health system toward one that provides the right care to the right person at the right time and for the right price. There is an opportunity to reach this ideal, but it will take commitment from all stakeholders, leadership, and diligence to reach a health system where patients are able to chart their own course.

REFERENCE

Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, A.M.A., 1999. Health literacy. *Journal of the American Medical Association* 281(6):552-557.

Appendixes

Appendix A

Workshop Agenda

Patients Charting the Course:
Citizen Engagement and the Learning Health System

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

April 1–2, 2010
Keck Center of the National Academies
Washington, DC 20001

Motivating issues and assumptions underlying the discussion

1. *Advances*. Progress in medical science, basic research, information technology, and operations research offers the potential for immediate, continuous, and transformative improvement in health care.
2. *Performance*. In terms of both effectiveness and efficiency, the nation's healthcare system is underperforming. The United States has the highest health expenditures per capita—twice the *per capita* average for other developed countries—yet consistently rates no better than the middle tier of developed nations on such key indicators as infant mortality, life expectancy, and overall health system performance.
3. *Core aim*. The core aim of health care is improved outcomes: to maintain or enhance patient status with respect to disease, injury, functional status, or sense of well-being. Yet often the dominant characteristics are more oriented to clinician preferences or interests, and economic rewards for volume over value.
4. *Anchor foci*. The primary foci of care in a manner that emphasizes outcomes should be on the mutually dependent aims of patient-centeredness, better science, better value, and continuous improvement.
5. *Key elements*. Efforts of the IOM and others have fostered a better understanding of the foundation stones of the Learning Health System, and, as discussions continue on health reform, special

consideration is warranted on the current priorities and strategies to accelerate progress.

6. *Communication.* Central to progress are the communication strategies necessary to inform and engage the public and patient communities as understanding advocates, partners, and change agents.

Objectives

1. Identify the state of play with respect to the foundation stones of the Learning Healthcare System, and the most important priorities and policy levers necessary to accelerate progress.
2. Explore and clarify the integral links among the three key aims of care delivered: science-driven, patient-centered, and value-enhancing.
3. Discuss communication and public engagement strategies important to improving awareness and action necessary for transformation to a Learning Health System.

DAY ONE

9:00 Keynote: the learning health system—now and to come
Overview of the nature and promise of the learning healthcare system for advancing a culture of patient-centeredness, science, and value. Discuss approaches to the key challenges and identify health reform priorities to make a learning healthcare system possible.
Harvey Fineberg, Institute of Medicine

9:30 Session 1: Clinical research, patient care, and learning that is real-time and continuous
What is needed to improve the efficiency, effectiveness, and volume of clinical research; and, how might capacity be structured to support a system of real-time and continuous learning that anticipates research needs and produces and applies evidence that is timely, relevant, and applicable to real-world care?
Chair: Joel Kupersmith, Veterans Health Administration

- **Comparative effectiveness research—accounting for patient, clinician, and policy needs**
  Patrick Conway, Office of the Secretary, Department of HHS
- **Health systems as research platforms—enhancing science, value and innovation**
  Sherine Gabriel, Mayo Clinic

- **Enhancing the culture of patient contributions to learning in health care**
  Diane Simmons, Center for Information & Study of Clinical Research Participation

11:00 Session 2: Clinical data as a public good for discovery
What is meant by the notion of clinical data as a public good, what is the potential, and how can issues such as de-identification, data integrity, and privacy and security concerns be best addressed? What strategies are needed to better engage patients and the public as advocates?
Chair: Karen Smith, AstraZeneca

- **Information needs for the learning healthcare system**
  Farzad Mostashari, Office of the National Coordinator for HIT
- **Opening access to high-value data sets**
  Todd Park, Department of Health and Human Services
- **Ensuring data integrity—implications of privacy protection and proprietary concerns**
  Don Detmer, University of Virginia

[Lunch 12:30–1:00]

1:00 Session 3: Engaging patients to improve science and value in the Learning Health System
What is meant—theoretically and practically—by patient engagement in health care, how might health systems better learn from patient participation across health system activities—as consumers, actors and research subjects—and what are the implications related to clinical science, healthcare delivery, and patient engagement strategies?
Chair: Myrl Weinberg, National Health Council

- **Investing patients in the research and continuous improvement enterprise—related to clinical science, health services, value, and patient orientation**
  Sharon Terry, Genetic Alliance
- **Public and patient communication strategies to improve health system performance—encouraging patient engagement and participation**
  James Conway, Institute for Healthcare Improvement

- **Communicating with patients about their concerns, preferences, and expectations–evidence translation, dissemination, application**
  Karen Sepucha, Harvard Medical School

2:30 Session 4: Health information technology as the engine for learning
What are the trends and strategies for HIT adoption and how can this infrastructure resource be developed simultaneously as a knowledge engine, a tool for care improvement, and a portal for practical patient engagement?
Chair: Murray Ross, Kaiser Permanente

- **Meaningful use of health information technology**
  David Blumenthal, Office of the National Coordinator for HIT
- **Data linkage, distributed data networks, and infrastructure for clinical research**
  Daniel Masys, Vanderbilt University
- **HIT and Web 2.0 as a vehicle for patient engagement—at the clinical encounter and beyond**
  Joseph Kvedar, Center for Connected Health

4:00 Session 5: Patients, clinical decisions, and health management in the information age
What lessons can be learned about patient/caregiver needs and expectations from efforts to support active engagement of patients in their healthcare decisions and management; and how might these factors inform priorities and strategies for improving patient involvement and investment in health care?
Chair: Michael Fordis, Eisenberg Center and Baylor College of Medicine

- **Public and patient information access and use as a core care component**
  George D. Lundberg, former editor-in-chief (JAMA, eMedicine, and MedScape)
- **HIT-based approaches to care management and shared decision-making**
  Paul Tang, Palo Alto Medical Foundation
- **Health and disease management outside the clinic doors**
  Doriane Miller, University of Chicago Medical Center

5:30 WRAP-UP COMMENTS

5:45 RECEPTION

DAY TWO

9:00 Session 6: Applying evidence for patient-centered care—standards and expectations
How do the key precepts of patient-centered care, personalized medicine, and evidence-based medicine interplay and complement each other to yield care that is more effective and efficient; and, what are the implications for shaping a health system to meet these expectations?
Chair: William Novelli, Georgetown University

- **The role of evidence in patient-centered care—"whatever the patient wants"?**
  Dale Collins Vidal, Dartmouth Institute for Health Policy and Clinical Practice
- **Evidence standards and application approaches that help get the right care to the right patient at the right time**
  Clifford Goodman, The Lewin Group
- **Translation and communication needs for care under evidence uncertainty**
  Fran Visco, National Breast Cancer Coalition

10:30 Session 7: Team-based care and the learning culture
What is meant by team-based care, how might it look in a learning healthcare system, and should, or how should, caregiver culture and practice vary by circumstance? What are the implications for health professions education and training?
Chair: J. Michael McGinnis, Institute of Medicine

- **Practical experience with collaborative models in the health professions**
  Allan Frankel, Brigham and Women's Hospital
- **Measures and strategies for clinical excellence and continuous improvement**
  Joyce Lammert, Virginia Mason Medical Center
- **Care cooperation and continuity across clinicians, facilities, and systems**
  Alice Bonner, Massachusetts Department of Public Health

[Lunch 12:00–12:30]

12:30 Session 8: Incentives aligned with value and learning
What are the key opportunities to better align incentives with elements important for care that is effective, efficient, and adds to learning?
Chair: Helen Darling, National Business Group on Health

- **Paying for value and science-driven care**
  Michael Chernew, Harvard University
- **Generating evidence to guide care**
  Richard Gilfillan, Geisinger Health Plan
- **Creating a learning culture**
  Anne Weiss, Robert Wood Johnson Foundation

2:00 Session 9: Strategies and priorities moving forward
A policy-oriented panel to pull together and discuss key themes from workshop presentations on next steps, public perception and opinion and reflect on key opportunities, possible messages, and approaches to encourage greater public engagement in driving system improvements
Moderator: J. Michael McGinnis, Institute of Medicine

- *Kathy Buto, Johnson & Johnson*
- *Helen Darling, National Business Group on Health*
- *Deborah Trautman, Johns Hopkins Medicine Center for Health Policy*
- *Myrl Weinberg, National Health Council*

Appendix B

Biographical Sketches of Workshop Participants

David Blumenthal, M.D., M.P.P., formerly served as the National Coordinator for Health Information Technology under President Barack Obama. In this role he was charged with building an interoperable, private and secure nationwide health information system and supporting the widespread, meaningful use of health information technology (IT). Dr. Blumenthal received his undergraduate, medical, and public policy degrees from Harvard University and completed his residency in internal medicine at Massachusetts General Hospital. Prior to his appointment to the administration, Dr. Blumenthal was a practicing primary care physician; Director, Institute for Health Policy; and the Samuel O. Thier Professor of Medicine and Professor of Health Policy at the Massachusetts General Hospital/Partners HealthCare System and Harvard Medical School. Dr. Blumenthal is a renowned health services researcher and national authority on health IT adoption. With his colleagues from Harvard Medical School, he authored the seminal studies on the adoption and use of health IT in the United States. He is the author of more than 200 scholarly publications, including most recently, "Heart of Power: Health and Politics in the Oval Office," which tells the history of U.S. presidents' involvement in health reform, from Franklin D. Roosevelt through George W. Bush. A member of the Institute of Medicine and a former board member and national correspondent for the *New England Journal of Medicine*, Dr. Blumenthal has held several leadership positions in medicine, government, and academia including Senior Vice President at Boston's Brigham and Women's Hospital; Executive Director of the Center for Health Policy and Management and Lecturer on Public Policy at the Kennedy School of Government; and as a professional staff

member on Senator Edward Kennedy's Senate Subcommittee on Health and Scientific Research. He was the founding Chairman of AcademyHealth and served previously on the boards of the University of Chicago Health System and of the University of Pennsylvania Health System. He is recipient of the Distinguished Investigator Award from AcademyHealth, and a Doctor of Humane Letters from Rush University.

Alice Bonner, Ph.D., R.N., FAANP, has been a gerontological nurse practitioner for the past 20 years. From 1997 to 2005 she was the Clinical Director of Long Term Care and Geriatrics at the Fallon Clinic in Worcester, Massachusetts. From 2005 to 2009, Dr. Bonner was Executive Director at the Massachusetts Senior Care Foundation, an organization that works to improve the lives of older adults and persons with disabilities through research, education, and quality improvement. She is also an Assistant Professor at the Graduate School of Nursing, University of Massachusetts in Worcester, MA. Dr. Bonner is currently the Director of the Bureau of Health Care Safety and Quality at the Department of Public Health in Boston, MA. Her research interests include patient safety culture in healthcare organizations, safe medication prescribing and management, and improving care transitions across settings.

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

Michael E. Chernew, Ph.D., is a Professor in the Department of Health Care Policy at Harvard Medical School. Dr. Chernew's research activities have focused on several areas including the causes and consequences of growth in healthcare expenditures. Ongoing work explores geographic variation in

spending growth and the relationship between individual and market factors in predicting rises in spending growth. Another branch of Dr. Chernew's research focuses on the theory and evaluation of Value Based Insurance Design (VBID) packages that attempt to minimize financial barriers to high-value healthcare services. Several large companies have adopted these approaches, and Dr. Chernew's ongoing work includes evaluations of these programs. Dr. Chernew received his B.A. from the University of Pennsylvania and his Ph.D. in economics from Stanford University, where his training focused on areas of applied microeconomics and econometrics. He is the Co-Editor of the *American Journal of Managed Care* and Senior Associate Editor of *Health Services Research*. Dr. Chernew is a member the Medicare Payment Advisory Commission (MedPAC), which is an independent agency established to advise the U.S. Congress on issues affecting the Medicare program. He is also a member of the Congressional Budget Office's Panel of Health Advisors and The Commonwealth Foundation's Commission on a High Performance Health System. In 2000 and 2004, he served on technical advisory panels for the Centers for Medicare & Medicaid Services (CMS) that reviewed the assumptions used by the Medicare actuaries to assess the financial status of the Medicare trust funds. On the panels, Dr. Chernew focused on the methodology used to project trends in long-term healthcare cost growth. In 1998, he was awarded the John D. Thompson Prize for Young Investigators by the Association of University Programs in Public Health. In 1999, he received the Alice S. Hersh Young Investigator Award from the Association of Health Services Research. Both of these awards recognize overall contribution to the field of health services research. His 2008 article in *Health Affairs* "Impact of Decreasing Copayments on Medication Adherence within Disease Management Program," was awarded the Research Award from the National Institute for Health Care Management. Dr. Chernew is a Faculty Research Fellow of the National Bureau of Economic Research, and he has served on the Editorial Boards of *Health Affairs* and *Medical Care Research and Review*.

James B. Conway, M.S., is an adjunct faculty member of the Harvard School of Public Health and a Senior Fellow at the Institute for Healthcare Improvement (IHI). He has served IHI as Senior Vice President from 2006–2009 and Senior Fellow from 2005 to 2006. From 1995 to 2005, he was Executive Vice President and Chief Operating Officer of Dana-Farber Cancer Institute (DFCI). Prior to joining DFCI, he had a 27-year career at Children's Hospital, Boston in Radiology Administration, Finance, and as Assistant Hospital Director. His areas of expertise and interest include governance and executive leadership, patient safety, change management, and patient-/family-centered care. He holds an M.S. from Lesley College, Cambridge, MA. Jim is the winner of numerous awards including the 1999

ACHE Mass. Regents Award, the 2001 first Individual Leadership Award in Patient Safety by the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance. In 2008, he received the Picker Award for Excellence in the Advancement of Patient Centered Care and in 2009 the Mary Davis Barber Heart of Hospice Award from the Mass. Hospice and Palliative Care Federation. A Fellow of the American College of Healthcare Executives, he is a member of the Clinical Issues Advisory Council of the Massachusetts Hospital Association, and is a Distinguished Advisor to the Lucian Leape Institute for the National Patient Safety Foundation. Board service includes: Chair, The Partnership for Healthcare Excellence; board member, Winchester Hospital; member, Medically Induced Trauma Support Services (MITSS); member, Health Research and Education Trust (HRET); member NICHQ and Board of Advisors, American Cancer Society, New England Region. In government service, he is a member of the Commonwealth of Massachusetts Quality and Cost Council.

Patrick Conway, M.D., M.Sc., is currently an Assistant Professor of Pediatrics at the University of Cincinnati College of Medicine. From 2008 to 2010, he was Chief Medical Officer at the Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Planning and Evaluation, the policy division for the Office of the Secretary. In 2007–2008, Dr. Conway was a White House Fellow assigned to the Office of Secretary in HHS and the Director of the Agency for Healthcare Research and Quality. As Chief Medical Officer, he has a portfolio of work focused primarily on quality measurement and links to payment, health information technology, and research and evaluation across the entire Department. He also served as the Executive Director of the Federal Coordinating Council on Comparative Effectiveness Research, coordinating investment of the $1.1 billion for this type of research in the American Reinvestment and Recovery Act Act. He was a Robert Wood Johnson Clinical Scholar and completed an M.S. focused on health services research at the University of Pennsylvania. Previously, he was a management consultant at McKinsey & Company, serving senior management of mainly healthcare clients on strategy projects. He has published articles in journals such as *Journal of the American Medical Association, New England Journal of Medicine,* and *Pediatrics* and has given national presentations on topics including healthcare policy, quality of care, comparative effectiveness, hospitalist systems, and nurse staffing. He completed pediatrics residency at Children's Hospital Boston. Dr. Conway is currently transitioning back to Cincinnati Children's as Director of Hospital Medicine, leading more than 40 faculty and staff who are involved in the care of approximately a third of hospital

admissions to a system with more than $1 billion in revenue per year and a mission to improve outcomes for children.

Helen Darling, M.A., is President of the National Business Group on Health, a nonprofit, membership organization devoted exclusively to providing solutions to its employer-members' most important healthcare problems and representing large employers on health policy issues. Its 283 members, including 59 of the Fortune 100 in 2010, purchase health benefits for more than 50 million employees, retirees, and dependents. She was the 2009 recipient of the WorldatWork's prestigious Keystone Award, in recognition of sustained contributions to the field of Human Resources and Benefits. Ms. Darling 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 Boards of the National Quality Forum and the congressionally created Reagan-Udall Foundation; and the Medicare Coverage Advisory Committee. Previously, she directed the purchasing of health benefits and disability at Xerox Corporation. Ms. Darling was health advisor to Senator David Durenberger on the Senate Finance Committee. She directed three studies at the Institute of Medicine. Ms. Darling received a master's degree in demography/sociology and a B.S. in history/English, cum laude, from the University of Memphis.

Don Eugene Detmer, M.D., M.A., is Professor Emeritus and Professor of Medical Education in the Department of Public Health Sciences at the University of Virginia, Senior Advisor to AMIA, and Visiting Professor at CHIME, University College of London. He is the Founder and Co-chair of the Blue Ridge Academic Health Group, chair of the IOM membership committee, and chair of the board of MedBiquitous. He is a member of the IOM, a lifetime Associate of the National Academies, and a fellow of AAAS, American College of Medical Informatics, American College of Surgeons, and American College of Sports Medicine (emeritus). He sits on the Strategic Plan Work Group of the Policy Advisory Committee to the Office of the National Coordinator for HIT. He is the immediate past President and CEO of AMIA and chairs the Steering Committee of the AMIA Global Partnership Program and he is a past chairman of the IOM Board on Health Care Services, NLM Board of Regents, and the NCVHS. His M.D. degree is from the University of Kansas and his M.A. is from Cambridge University, U.K. His education and training included work at Kansas, Johns Hopkins, National Institutes of Health, Duke, IOM, and Harvard Business School. Faculty appointments have been held at University of Wisconsin-Madison, University of Utah, University of Virginia, and Cambridge University. He served as Vice-President for Health Sciences at Utah and Virginia. He

chaired the IOM committee that produced the Computer-based Patient Record reports of 1991 and 1997 and was a member of the IOM Errors and Quality Chasm reports. Dr. Detmer's research interests include national and international health information and communications policy, quality improvement, administrative medicine, vascular surgery, education of clinician-executives, and leadership of academic health sciences centers.

Harvey V. Fineberg, M.D., Ph.D., is President of the Institute of Medicine. He served as Provost of Harvard University from 1997 to 2001, following 13 years as Dean of the Harvard School of Public Health. He has devoted most of his academic career to the fields of health policy and medical decision making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Dr. Fineberg helped found and served as President of the Society for Medical Decision Making and also served as consultant to the World Health Organization. At the Institute of Medicine, he has chaired and served on a number of panels dealing with health policy issues, ranging from AIDS to new medical technology. He also served as a member of the Public Health Council of Massachusetts (1976–1979), as Chairman of the Health Care Technology Study Section of the National Center for Health Services Research (1982–1985), and as President of the Association of Schools of Public Health (1995–1996). Dr. Fineberg is co-author of the books *Clinical Decision Analysis, Innovators in Physician Education,* and *The Epidemic That Never Was,* an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, and understanding risk in society. He has also authored numerous articles published in professional journals. Dr. Fineberg is the recipient of several honorary degrees and the Joseph W. Mountin Prize from the U.S. Centers for Disease Control and Prevention. He earned his bachelor's and doctoral degrees from Harvard University.

Michael Fordis, M.D., is the founding director of the Center for Collaborative and Interactive Technologies at Baylor College of Medicine, Houston, Texas; the Director of the John M. Eisenberg Center for Clinical Decisions and Communication Sciences, the single national center supported by AHRQ for translation of comparative effectiveness research findings produced by the Effective Healthcare Program into actionable products for dissemination and use by clinicians, consumers, and policy makers to support decision making; Director of the Education Core of the AHRQ-funded Houston Center for Education and Research in Therapeutics; and the Senior Associate Dean for Continuing Medical Education and Senior Associate Dean for Continuing Medical Education at Baylor College of

Medicine. Dr. Fordis' interests focus on applying technology to healthcare provider and patient learning, decision making, and behavioral change; clinical decision support; quality improvement; and development and use of resources for faculty engaged in teaching. He is nationally active in educational and technology efforts, serving or having served in leadership and/or committee and task force positions for the Society for Academic Continuing Medical Education; the American Heart Association; the Association of American Medical Colleges; the Conjoint Committee for CME of the Council of Medical Specialty Societies; the Accreditation Review Committee for the Accreditation Council on Continuing Medical Education; and the MedBiquitous Consortium—the ANSI-accredited developer of information technology standards for healthcare education and competence assessment.

Allan Frankel, M.D., trained as a pediatric anesthesiologist and practiced for 25 years as a cardiac and then general anesthesiologist in Boston hospitals—academic and community. He became in 1999 among the first U.S. Patient Safety Officers, helping develop the role for Harvard hospitals and Partners Healthcare in Boston. The focus of his research, journal publications, and 3 books has been studying effective leadership, teamwork, communication and improvement to achieve operational excellence. Through his affiliation with two groups—the Institute for Healthcare Improvement and Pascal Metrics—and through his research, he works directly with hospital departments from Saudi Arabia to Scotland to Western Canada.

Sherine E. Gabriel, M.D., is Professor of Medicine and of Epidemiology and the William J. and Charles H. Mayo Professor at Mayo Clinic. Her research has focused on the risks, determinants, costs, and outcomes of the rheumatic diseases, with a recent emphasis on cardiovascular comorbidity in rheumatoid arthritis. At Mayo Clinic, Dr. Gabriel serves as Co-Principal Investigator and Director of Education for the NIH-funded Center for Translational Sciences. She is also the Medical Director of the Mayo Clinic Office for Strategic Alliances and Vice-Chair of the Business Development Council. Extramurally, she serves on the Executive Board of the Observational Medical Outcomes Partnership and is the recent past President of the American College of Rheumatology.

Richard Gilfillan, M.D., is former President and CEO of Geisinger Health Plan (GHP) and Executive Vice President for System Insurance Operations at the Geisinger Health System. Dr. Gilfillan was responsible for Geisinger's three managed care companies that provide a full spectrum of health benefit programs for individuals, employers, and Medicare beneficiaries. With $1 billion in revenues, GHP and its affiliated companies provide health

coverage to more than 225,000 members. He began his career as a family practitioner for the Georgetown University Community Health Plan. After establishing a family practice group in Massachusetts, he became Medical Director for Medigroup Central HMO, a Blue Cross of New Jersey managed care company in 1985. He was Chief Medical Officer for Independence Blue Cross from 1992 until 1995, when he became the General Manager of AmeriHealth New Jersey managed care subsidiary. Prior to joining Geisinger, Dr. Gilfillan was the Senior Vice President for National Network Management at Coventry Health Care. Dr. Gilfillan received his undergraduate and medical degrees from Georgetown University in Washington, DC. He completed a family practice residency at Hennepin County Medical Center in Minneapolis. He also earned an M.B.A. from the Wharton School of the University of Pennsylvania. Dr. Gilfillan has served on numerous community and corporate boards.

Clifford Goodman, Ph.D., is a Vice President at The Lewin Group, a healthcare policy and human services consulting firm based in Falls Church, VA. He has more than 25 years of experience in such areas as health technology assessment, evidence-based health care, comparative effectiveness research, health economics, and studies pertaining to healthcare innovation, regulation, and payment. He directs studies and projects for an international range of government agencies; pharmaceutical, biotechnology, and medical device companies; healthcare provider institutions; and professional, industry, and patient advocacy groups. His recent work has involved such areas as oncology, cardiovascular disease, diabetes, obesity, end-stage renal disease, pandemic influenza, follow-on biologics, systemic lupus erythematosus, wound care, low-back pain, health information technology, pharmacogenomics, diagnostic testing, organ donation and transplantation, personalized medicine, and policy applications of cost-effectiveness analysis. Dr. Goodman is acting director of the new Lewin Group Center for Comparative Effectiveness Research (CER). For HHS, Dr. Goodman has directed a contract for Lewin to provide a CER inventory and strategic framework for the Federal Coordinating Council for Comparative Effectiveness Research. He is chair (through May 2011) of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) for the Centers for Medicare & Medicaid Services. He has testified to Congress on issues pertaining to Medicare coverage of health care technology. Dr. Goodman also is a nationally recognized health policy issues moderator and facilitator of expert panels and health industry advisory boards. He is a founding board member of Health Technology Assessment International and is a Fellow of the American Institute for Medical and Biological Engineering. He did his undergraduate work at Cornell University, received a master's degree from the Georgia

Institute of Technology, and earned his doctorate from the Wharton School of the University of Pennsylvania.

Joel Kupersmith, M.D., currently Chief Research and Development Officer at the Veterans Health Administration, is a graduate of New York Medical College, where he also completed his clinical residency in internal medicine. Subsequently, he completed a cardiology fellowship at Beth Israel Medical Center/Harvard Medical School. After research training in the Department of Pharmacology, Columbia College of Physicians and Surgeons, he joined the faculty of the Mt. Sinai School of Medicine where he rose to the rank of Professor and was Director of the Clinical Pharmacology section. After this he became Chief of Cardiology and V.V. Cooke Professor of Medicine at the University of Louisville and then Professor and Chairperson, Department of Medicine at the College of Human Medicine at Michigan State University. Dr. Kupersmith has been on many national and international committees involved in heart disease and on editorial boards of the *American Journal of Medicine* and two heart disease journals. 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. Dr. Kupersmith was elected to the Governing Council, Medical School Section of the American Medical Association, is a member of the Association of American Medical Colleges Task Force on Fraud and Abuse, and has been a Site Visit Chair for the Liaison Committee on Medical Education.

Joseph C. Kvedar, M.D., is the Founder and Director of the Center for Connected Health, applying communications technology and online resources to increase access and improve the delivery of quality medical services and patient care outside of the traditional medical setting. In his role with the Center for Connected Health, Dr. Kvedar is leading important research in the use of a combination of remote-monitoring technology, sensors, and online communications and intelligence to improve patient adherence, engagement, and clinical outcomes. Dr. Kvedar is internationally recognized for his leadership and vision in the field of connected health. Dr. Kvedar is co-editor of the book *Home Telehealth: Connecting Care within the Community*, the first book to report on the applications of technology to deliver quality health care in the home. He is a past President and board member of the American Telemedicine Association (ATA), and in 2009, Dr. Kvedar was honored by the ATA with its Individual Leadership Award, recognizing his significant contributions to connected health and telemedicine. Last

year, *Mass High Tech, The Journal of New England Technology* also named Dr. Kvedar an All-Star in the field of health care.

Joyce Lammert, M.D., Ph.D., received her M.D. and Ph.D. from the University of North Carolina at Chapel Hill and completed her Asthma, Allergy Fellowship at the University of Washington. She is the Chief of the Department of Medicine at Virginia Mason Medical Center in Seattle, WA, and a Clinical Associate Professor, University of Washington. She became a certified LEAN leader in 2002 and leads and sponsors many improvement events in support of the strategic goals for the organization. Dr. Lammert is a frequent speaker on the topic of physician compacts as a result of her role in leading the compact work at Virginia Mason in 2000. She is also actively involved in graduate medical education. She serves as President of the Board of NeighborCare Health.

George D. Lundberg, M.D., a 1995 "pioneer" of the medical internet, Dr. Lundberg was born in Florida, grew up in rural southern Alabama and holds earned and honorary degrees from North Park College, Baylor University, the University of Alabama (Birmingham and Tuscaloosa), the State University of New York, Syracuse, Thomas Jefferson University, and the Medical College of Ohio. He completed a clinical internship in Hawaii and a pathology residency in San Antonio. He served 11 years in the U.S. Army during the Vietnam War Era in San Francisco and El Paso. Dr. Lundberg was Professor of Pathology and Associate Director of Laboratories at the Los Angeles County/USC Medical Center for 10 years, and for 5 years was Professor and Chair of Pathology at the University of California, Davis. Dr. Lundberg has worked in tropical medicine in Central America and forensic medicine in New York, Sweden, and England. He is past President of the American Society of Clinical Pathologists. From 1982 to 1999, Dr. Lundberg was at the American Medical Association as Editor-in- Chief, Scientific Information and Multimedia with editorial responsibility for its 39 medical journals, *American Medical News*, and various Internet products, and *JAMA*. In 1999, Dr. Lundberg became Editor-in-Chief of Medscape, and the founding Editor-in-Chief of both *Medscape General Medicine* and CBS HealthWatch.com. In 2002, Dr. Lundberg was Special Healthcare Advisor to the Chairman and CEO of WebMD for 2 years. Later, he served as the Editor-in-Chief of The Medscape Journal of Medicine, the original open access general medical journal, and beginning in 2006, Editor-in-Chief of eMedicine from WebMD, the original open access comprehensive medical textbook. A frequent lecturer, radio, television and webcasting guest and host, and a member of the Institute of Medicine, Dr. Lundberg was a Professor at Harvard University from 1993 to 2008. Dr. Lundberg left WebMD in 2009 and is now Editor-in-Chief, Cancer Commons; Editor-at-

Large, *MedPage Today*; a Consulting Professor at Stanford; and President and Board Chair of The Lundberg Institute. In 2000, the Industry Standard dubbed Dr. Lundberg "Online Health Care's Medicine Man."

Daniel R. Masys, M.D., is Professor and Chair of the Department of Biomedical Informatics and Professor of Medicine at the Vanderbilt University School of Medicine. Dr. Masys is an honors graduate of Princeton University (biochemistry and molecular genetics) and the Ohio State University College of Medicine. He completed postgraduate training in internal medicine, hematology and medical oncology at the University of California, San Diego, and the Naval Regional Medical Center, San Diego. Prior to joining Vanderbilt, Dr. Masys was Director of Biomedical Informatics and Professor of Medicine at the University of California, San Diego. He also previously served as Director of the Lister Hill National Center for Biomedical Communications, which is a research and development division of the National Library of Medicine. Dr. Masys' research interests span a number of areas of informatics, including genome-phenome correlation using electronic medical records data, the pooling and meta-analysis of HIV epidemiology data from multilingual international sources, creation of tools for clinical and translational research, and design and implementation of patient portals. Dr. Masys is an elected member of the Institute of Medicine. He is a Fellow of the American College of Physicians and the American College of Medical Informatics. He was a founding Associate Editor of the *Journal of the American Medical Informatics Association*, and has received numerous awards including the NIH Director's Award and the U.S. Surgeon General's Exemplary Service Medal.

Michael McGinnis, M.D., M.P.P., is a physician, epidemiologist, and longtime contributor to national and international health programs and policy. He now is Senior Scholar and Director of the Institute of Medicine's Roundtable on Value & Science-Driven Health Care, as well as an elected IOM member. Much of his policy leadership stems from his four-administration tenure, perhaps unique among federal appointees, with continuous service through the Carter, Reagan, Bush, and Clinton administrations as the key point person for disease prevention and health promotion. Several still prominent initiatives were launched under his guidance, including the *Healthy People* national goals and objectives process, the *Dietary Guidelines for Americans* and the U.S. Preventive Services Task Force. Internationally, he served as Epidemiologist and State Director for the successful WHO smallpox eradication program in India, and more recently as Chair of the international task force to rebuild the health and human services sector in post-war in Bosnia.

Doriane Miller, M.D., is the inaugural Director of the Center for Community Health and Vitality at the University of Chicago Medical Center. The Center for Community Health and Vitality's mission is to improve population health outcomes for residents on the south side of Chicago through community-engaged research, demonstration and service models. Prior to joining the University in January 2009, she served as National Program Director of New Health Partnerships, a demonstration project funded by The Robert Wood Johnson Foundation and the California Health Care Foundation on collaborative self-management support. Dr. Miller is also a faculty member of the Institute for Healthcare Improvement in Cambridge, MA. She joined Stroger Hospital of Cook County in March of 2005, as Associate Division Chief for General Internal Medicine, focusing her attention on mentoring and staff development, while serving as a community provider at Woodlawn Adult Health Center. Prior to going to Stroger, she served 2 years as the Senior Director for Quality and Clinical Research of the Health Research and Educational Trust of the American Hospital Association where she focused on quality and patient safety demonstration projects. Dr. Miller also worked for 5 years as a program Vice-President at The Robert Wood Johnson Foundation where she was responsible for strategic planning and program design in the clinical quality improvement area, using clinical and community-based strategies. Programs developed under her direction include demonstration projects designed to help improve the quality of care for people with chronic health conditions such as asthma, diabetes, and depression. Dr. Miller's work in the area of improving asthma outcomes through school and community interventions was noted by the American Academy of Asthma, Allergy and Immunology with a 2006 Special Recognition Award. Dr. Miller was a member of the 2002 Institute of Medicine committee that produced the report, *Guidance for the National Healthcare Disparities Report*. Dr. Miller was recognized by The Robert Wood Johnson Foundation's Community Health Leadership Program in 1993 for her community-based efforts in improving the health and well-being of grandparents raising their grandchildren through an initiative called, Grandparents Who Care. Dr. Miller also brings more than 20 years of experience as a community-based primary care provider who has worked with under-served, minority populations, with a special interest in behavioral health. She served as Medical Director of the Maxine Hall Health Center of the San Francisco Department of Health, while also serving as Assistant Clinical Professor of Medicine in the Department of Medicine at San Francisco General Hospital, University of California, San Francisco. Dr. Miller received her medical degree from the University of Chicago. She completed a primary care internal medicine residency and a general medicine/clinical epidemiology fellowship at the University of California, San Francisco.

Farzad Mostashari, M.D., Sc.M., currently serves as a Senior Advisor for policy and programs with the Office of the National Coordinator for Health Information Technology at the U.S. Department of Health and Human Services. Previously, he served at the NYC Health Department (DOHMH) as Assistant Commissioner for the Primary Care Information Project, with the goal of encouraging and facilitating the adoption of prevention-oriented health information technology in underserved communities. Dr. Mostashari also led the CDC-funded NYC Center of Excellence in Public Health Informatics, and an AHRQ-funded project focused on quality measurement at the point of care. Prior to this he established the Bureau of Epidemiology Services at the DOHMH, charged with providing epidemiologic and statistical expertise and data for decision making to the Agency. He was one of the lead investigators in the outbreaks of West Nile virus and anthrax in NYC, and among the first developers of real-time electronic disease surveillance systems nationwide.

William D. Novelli, M.A., is a professor in the McDonough School of Business at Georgetown University. In addition to teaching in the M.B.A. 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 more than 40 million people aged 50 and older. During his tenure, the organization achieved important policy successes at national and state levels in health, financial security, good government, and other areas. It also doubled its budget, added 5 million new members, and expanded internationally. 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 United Staes 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. Porter Novelli was founded to apply marketing to social and health issues, and grew into an international marketing/public relations agency with corporate, not-for-profit, and government clients. He retired from the firm in 1990 to pursue a second career in public service. He was named one of the 100 most in-

fluential 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 he 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 United States 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 he 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. Mr. Novelli serves on a number of boards and advisory committees.

Todd Park joined HHS as Chief Technology Officer in August 2009. In this role, he is responsible for helping HHS leadership harness the power of data, technology, and innovation to improve the health and welfare of the nation. Mr. Park co-founded Athenahealth in 1997 and co-led its development over the following decade into one of the most innovative, socially oriented, and successful health information technology companies in the industry. Prior to Athenahealth, he served as a management consultant with Booz Allen & Hamilton, focusing on healthcare strategy, technology, and operations. Mr. Park has also served in a volunteer capacity as a Senior Fellow at the Center for American Progress, where he focused on health IT and health reform policy, and as senior healthcare advisor to Ashoka, a leading global incubator of social entrepreneurs, where he helped start a venture to bring affordable telehealth, drugs, diagnostics, and clean water to rural India. Mr. Park graduated magna cum laude and Phi Beta Kappa from Harvard College with an A.B. in economics.

Murray Ross, Ph.D., is the Vice President of the Kaiser Foundation Health Plan and the Director of the Kaiser Permanente Institute for Health Policy in Oakland, CA. Kaiser Permanente (KP) is the nation's largest private integrated delivery system, providing health care to over eight million people in nine states and the District of Columbia. The Institute for Health Policy supports research, expert roundtables, and conferences intended to increase

understanding of policy issues and help identify solutions. Dr. Ross brings the valuable ability to absorb and synthesize complex healthcare issues, and to explain the practical implications of market developments and public policies to government leaders and healthcare industry decision makers. As a result, he is sought after as a speaker to national and international audiences on a wide range of healthcare topics. He holds a wealth of knowledge of the intricacies of Medicare and advises KP's leadership on business and public policy issues arising from ongoing changes in that program. His current policy research focuses on how the U.S. health system can make more effective use of new drugs, devices, and medical procedures and how to encourage greater integration of care delivery to improve quality. Dr. Ross holds a number of internal and external advisory positions. Before joining KP in 2002, Dr. Ross spent most of his professional career as a policy advisor to the U.S. Congress. He served almost 5 years as the Executive Director of the Medicare Payment Advisory Commission, an influential nonpartisan agency charged with making recommendations on Medicare policy issues to the Congress. Previously, he spent 9 years at the Congressional Budget Office, most recently heading up the group charged with assessing the budgetary impact of legislative proposals affecting the Medicare and Medicaid programs. Dr. Ross earned his doctorate in economics from the University of Maryland, College Park, and completed his undergraduate work in economics at Arizona State University.

Karen R. Sepucha, Ph.D., is a Senior Scientist in the Health Decision Research Unit in the General Medicine Division at Massachusetts General Hospital and an Instructor in Medicine at Harvard Medical School. Her research and clinical interests involve developing and implementing tools and methods to improve the quality of significant medical decisions made by patients and clinicians. She focuses on situations where there is more than one medically appropriate option, and where the "best" choice depends not only on the science but also on integrating the patient's preferences for different health outcomes. Dr. Sepucha was the medical editor for a series of five breast cancer patient decision aids (PtDAs) developed by the not-for-profit Foundation for Informed Medical Decision Making. The PtDAs have won seven media awards, and Dr. Sepucha has led the dissemination of these programs to more than 80 academic and community cancer centers across the country. Her most recent work is focused on developing instruments to measure the quality of decisions. The decision quality instruments assess the extent to which patients are informed, involved, and receive treatments that reflect what's most important to them. Dr. Sepucha has been active in local, national, and international efforts to improve decision quality, including the International Patient Decision Aids Standards collaboration.

Diane Simmons is President and CEO of the Center for Information & Study on Clinical Research Participation, and she has extensive experience in managing a nonprofit. For more than ten years, she ran a $5 million United Way agency where she was responsible for the development and implementation of the agency's strategic plan and she managed the functions of membership, marketing, programming, and finance. Prior to her involvement in running a nonprofit, she rose through the ranks of Citibank/Citigroup to Vice President of Management Development and Training, then Chief of Staff to the head of Citibank Visa/MasterCard, and then to Vice President of Citigroup Insurance Marketing generating $80 million business income annually.

Karen Smith, M.D., Ph.D., M.B.A., is Vice President of External Medical Relations (EMR) for the U.S. business of AstraZeneca PLC (AZ), headquartered in London, England. As one of the world's largest pharmaceutical companies with healthcare sales of $29.5 billion, AZ is a leader in the research, development, manufacture, and marketing of prescription pharmaceuticals and the supply of healthcare services. Through the combined benefits of global capabilities and local market relationships, AZ is able to respond quickly and effectively to changing business needs in the targeted therapeutic areas of gastrointestinal, cardiovascular, neuroscience, respiratory, oncology, and infection. Dr. Smith joined the company in 2007 to build and lead EMR in the creation of strategic partnerships with key organizations and stakeholders across the U.S. market. EMR's focus on clinical and scientific exchange through external relations maximizes opportunities to elevate patient health outcomes in clinical, societal, and policy arenas. Immediately prior to joining AZ, Dr. Smith held key management roles with Bristol-Myers Squibb (BMS) in Australia, Canada, and the United States. Most recently, Dr Smith was responsible for developing and managing post-marketing clinical trials across all brands and therapeutic areas for the BMS U.S. operation. In addition to holding executive management and medical roles within a number of large pharmaceuticals companies, she was the CEO/President of Boron Molecular, a start-up biotech company focused on R&D as well as the production of biopharmaceuticals and fine chemicals. Dr. Smith has worked globally in Asia-Pacific, Japan, Canada, Australia, Europe, UK, and the United States. Dr. Smith holds an M.D. from the University of Warwick specializing in cardiology, a Ph.D. in oncology molecular genetics from the University of Washington, M.B.A. from the University of New England, and will receive her master's degree in law this year from the University of Salford. She is a published scientist and reviewer for several clinical journals and currently holds several board seats as well as serving as the Co-Chair of the Coalition Against Major Disease, a collaboration between the biopharmaceutical industry, government agency scientists, patient groups, and other key stakeholders working together to

bring greater speed, efficiency, safety, and predictability to medical product development.

Paul C. Tang, M.D., M.S., is an Internist and Vice President, Chief Medical Information Officer at the Palo Alto Medical Foundation (PAMF) and Consulting Associate Professor of Medicine (Biomedical Informatics) at Stanford University. He received his B.S. and M.S. in electrical engineering from Stanford University and his M.D. from the University of California, San Francisco. He is Vice Chair of the federal Health Information Technology Policy Committee created by the American Recovery and Reinvestment Act and Chair of its Meaningful Use Work Group. Dr. Tang is an elected member of the IOM and serves on its Health Care Services Board. He chaired an IOM patient safety committee that published *Patient Safety: A New Standard for Care* and *Key Capabilities of an Electronic Health Record System*. Dr. Tang is a past Chair of the Board for the American Medical Informatics Association. He chairs the National Quality Forum's (NQF) Health Information Technology Expert Panel and is a member of the NQF Consensus Standards Approval Committee. He is a member of the National Committee on Vital and Health Statistics (NCVHS) and Co-Chair of the NCVHS Quality Subcommittee. He co-chairs the Measurement Implementation Strategy Work Group of the Quality Alliance Steering Committee and chairs The Robert Wood Johnson Foundation's National Advisory Council for ProjectHealth Design. Dr. Tang is a Fellow of the American College of Medical Informatics, the American College of Physicians, the College of Healthcare Information Management Executives, and the Healthcare Information and Management Systems Society.

Sharon F. Terry, M.A., is President and CEO of the Genetic Alliance, a network transforming health by promoting an environment of openness centered on the health of individuals, families, and communities. She is the founding Executive Director of PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE). Following the diagnosis of their two children with PXE in 1994, Ms. Terry, a former college chaplain, and her husband, Patrick, founded and built a dynamic organization that enables ethical research and policies and provides support and information to members and the public. She is at the forefront of consumer participation in genetics research, services, and policy and serves as a member of many of the major governmental advisory committees on medical research, including the HIT Standards Committee for the Office of the National Coordinator for Health Information Technology, liaison to the Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children, and the National Advisory Council for Human Genome Research, NHGRI, NIH. She serves on the boards of GRAND Therapeutics Foundation, the Center for Information

& Study on Clinical Research Participation, The Biotechnology Institute, National Coalition of Health Professional Education in Genetics, and the Coalition for 21st Century Medicine. She is on the steering committees of Genetic Association Information Network of NHGRI, the CETT program, and the EGAPP Stakeholders Group, the editorial boards of *Genetic Testing and Biomarkers* and *Biopreservation and Biobanking*, and the boards of Google Health and Rosalind Franklin Society Advisory. She is the Chair of the Coalition for Genetic Fairness that was instrumental in the passage of the Genetic Information Nondiscrimination Act. She is a member of the IOM Roundtable on Translating Genomic-Based Research for Health. In 2005, she received an honorary doctorate from Iona College for her work in community engagement and haplotype mapping; in 2007 received the first Patient Service Award from the UNC Institute for Pharmacogenomics and Individualized Therapy; and in 2009 received the Research!America Distinguished Organization Advocacy Award. She has recently been named an Ashoka Fellow. Ms. Terry is a co-founder of the Genetic Alliance Biobank. It is a centralized biological and data (consent/clinical/environmental) repository catalyzing translational genomic research on rare genetic diseases. The BioBank works in partnership with academic and industrial collaborators to develop novel diagnostics and therapeutics to better understand and treat these diseases. Along with the other co-inventors of the gene associated with PXE (ABCC6), she holds the patent for the invention. She co-directs a 33-lab research consortium and manages 52 offices worldwide for PXE International.

Deborah Trautman, Ph.D., R.N., has held clinical and administrative leadership positions at the University of Pittsburgh Medical Center and the Johns Hopkins Medical Institutions. Most recently, she has served as the Vice President of Patient Care Services for Howard County General Hospital, part of the Johns Hopkins Health System, and as Director of Nursing for Emergency Medicine at the Johns Hopkins Hospital, and she has a Joint Appointment at the Johns Hopkins University School of Nursing. She received a B.S.N. from West Virginia Wesleyan College, an M.S.N. with emphasis on education and administration from the University of Pittsburgh, and a Ph.D. in health policy from the University of Maryland's Department of Public Policy. Her dissertation research examined emergency department screening for intimate partner violence, and her research interests include women's health, healthcare disparities, violence, and clinical service excellence. She has authored and coauthored publications on intimate partner violence, pain management, clinical competency, change management, cardiopulmonary bypass, the use of music in the emergency department, and consolidating emergency services. As a member of the senior leadership at the Johns Hopkins Hospital, she represents the hospital on the Baltimore City Domestic Violence Fatality Review Team. Dr. Traut-

man is a Magnet Appraiser Fellow for the American Nurses Association Credentialing Center Commission on Accreditation. She previously served on the Society for Academic Emergency Medicine's Public Health Interest Group, the Baltimore City Mayor's Task Force on Domestic Violence, and the Johns Hopkins University President's Council on Urban Health Violence Prevention Workgroup. Her health policy interests include emergency patient care, emergency nursing practice, women's health, healthcare disparities, access to health care, and improving healthcare delivery. She is a 2007–2008 Robert Wood Johnson Health Policy Fellow working for the Honorable Nancy Pelosi, Speaker of the House, House of Representatives.

Dale Collins Vidal, M.D., M.S., is Director of the Center for Informed Choice at The Dartmouth Institute for Health Policy and Clinical Practice and Professor of Surgery and Chief of Plastic Surgery at DHMC. As a leader in healthcare transparency and shared decision making, Dr. Vidal's research efforts and expertise involve patients' medical decision making and the use of health information technology systems to promote patient-centered care. She is actively engaged in a number of activities in support of shared decision making in healthcare delivery and healthcare policy reform. She has served as a member of the Agency for Healthcare Research and Quality (AHRQ) Technical Expert Panel on Formative Research to Inform the Development of Preventive Services Tools Based on USPSTF Recommendations for Clinicians and Consumers to improve healthcare quality.

Frances M. Visco, J.D., is the first president of the National Breast Cancer Coalition (NBCC), as well as a member of its Board of Directors and Executive Committee. Prior to NBCC, Ms. Visco was a partner in a Philadelphia law firm. In 1993, President Clinton appointed Ms. Visco as one of three members of the President's Cancer Panel, and she was the first consumer to chair the Integration Panel of the Department of Defense Peer-Review Breast Cancer Research Program. She co-chaired the National Action Plan on Breast Cancer and served on the National Cancer Policy Board. Ms. Visco has testified before Congress, has lectured throughout the US and internationally on the politics of breast cancer issues, and has been a frequent guest on national television discussing women's health. She has been a member of Institute of Medicine panels and has served on other policy committees, including the steering committees of the Breast Cancer International Research Group and the Experts Advisory Panel for the Universal Health Insurance Program at the New America Foundation. Ms. Visco is a more than 20-year breast cancer survivor. She is an honors graduate of St. Joseph's University and of Villanova University School of Law, where she was an Editor of the *Villanova Law Review* and a Chair of the Women's Law Caucus.

Myrl Weinberg, M.A., C.A.E., is President of the National Health Council, an umbrella organization that has served as the place where "the health community meets" for 84 years. The Council's 105 members are national health-related organizations. Its goals are to promote quality health care for all people, to promote the importance of medical research, and to promote the role of voluntary health agencies, also called patient-based groups. Ms. Weinberg's career has focused on health, medical research, long-term care, social security, and related issues that affect persons with chronic diseases and/or disabilities. Before joining the Council, Ms. Weinberg held numerous managerial positions at the American Diabetes Association, including serving as Vice President for Corporate Relations and Public Affairs. Ms. Weinberg has a long history of board and committee service, including serving as a member of the IOM Health Sciences Policy Board. She was honored to be selected to serve on the congressionally mandated IOM committee created to assess how research priorities are established at the NIH. Most recently, she served on the National Research Council/IOM Committee on the Organizational Structure of the NIH. In addition, Ms. Weinberg serves as Vice Chair of the Governing Board of the International Alliance of Patients' Organizations. She also serves on the Roche Genetics Science and Ethics Advisory Committee and as a founding member for the Association for the Accreditation of Human Research Protection Programs. Ms. Weinberg pursued advanced graduate study at Purdue University. She holds an M.A. in special education from George Peabody College and a B.A. in psychology from the University of Arkansas.

Anne F. Weiss, M.P.P., is Team Director and a Senior Program Officer at The Robert Wood Johnson Foundation. She directs the Foundation's Quality/Equality programming, including its signature initiative, *Aligning Forces for Quality*. Before joining the Foundation in 1999, she was Senior Assistant Commissioner in the New Jersey Department of Health & Senior Services, where she oversaw the state's regulation of hospitals and health plan quality. She also served as Executive Director of New Jersey's health reform commission in the mid-1990s and led the design and implementation of Health Access New Jersey, a subsidized health benefits plan. Before going to New Jersey, Ms. Weiss spent 10 years in Washington, DC, where she was a professional staff member of the U.S. Senate Committee on Finance and a Senior Examiner at the Office of Management and Budget. She began her career in the Office of the Assistant Secretary for Planning and Evaluation in the U.S. Department of Health and Human Services. Ms. Weiss holds an M.P.P. from the Kennedy School of Government at Harvard and a B.A. from Wellesley College.

Appendix C

Workshop Attendee List

Madhu Agarwal
Department of Veterans Affairs

Rashmi Agarwal
Washington University in St. Louis

Jody Allen
Medco

Jennifer Alexander
Research Triangle Institute International

Shilpa Amin
Agency for Healthcare Research and Quality

Suresh Arya
National Institutes of Health

Allison Baer
American Society of Clinical Oncology

Mara Baer
BlueCross BlueShield Association

Michael Banyas
Health Resources and Services Administration

Bartley Barefoot
GlaxoSmithKline

Valerie Barton
Avalere Health

Rhonda Robinson Beale
OptumHealth Behavioral Solutions

Aman Bhandari
Office of Science and Technology Policy

Timothy Birner
sanofi-aventis

Meryl Bloomrosen
American Medical Informatics Association

David Blumenthal
Office of the National Coordinator for Health IT

Douglas Boenning
Office of Science and Data Policy

Marilyn Sue Bogner
Institute for the Study of Human Error, LLC

Blair Bolles
AAA Technical Writing

Alice Bonner
Massachusetts Department of Public Health

J. Lyle Bootman
University of Arizona College of Pharmacy

Mary Jo Braid-Forbes
Braid-Forbes Health Research

Normandy Brangan
Centers for Medicare & Medicaid Services

Warren Brennan
SMA Info Partners, LLC

Steven Brotman
AdvaMed

Kathleen Buto
Johnson & Johnson

Daniel Campion
Outcome Inc.

Kristin Carman
American Institutes for Research

Linda Carter
Johnson & Johnson

Kee Chan
Boston University

Michael Chernew
Harvard University

Brenda Cleary
AARP

Alex Clyde
Medtronic Inc.

Vivian Coates
ECRI Institute

Perry Cohen
Parkinson Pipeline Project

Elaine Collier
National Center for Research Resources

Kathleen Connors de Laguna
Centers for Medicare & Medicaid Services

Richard Conroy
National Institutes of Health

James Conway
Institute for Healthcare Improvement

Patrick Conway
Department of Health and Human Services

Hiliary Critchley
Hiliary Critchley Consulting, LLC

Sean Currigan
The American College of Obstetricians and Gynecologists

Helen Darling
National Business Group on Health

Carole DeSpain Magoffin
Health Quality Institutes of America

Patrice Desvigne-Nickens
National Heart, Lung, and Blood Institute

Don Detmer
University of Virginia

Deirdre DeVine
Evidence-based Practice Group

Christopher Dezii
Bristol-Myers Squibb Company

Louis Diamond
Thomson Reuters Healthcare

Michael Dinneen
Office of the Assistant Secretary of Defense (Health Affairs)

John Dodd
Computer Sciences Corporation

Martey Dodoo
American Academy of Family Physicians

Katherine Doermann
American College of Cardiology

Bob Donnelly
Johnson & Johnson

Lynn Etheredge
George Washington University

Peter Fagan
Johns Hopkins HealthCare, LLC

Jeff Farkas
Medtronic Inc.

Reuven Ferziger
Johnson & Johnson

Rosemarie Filart
National Institutes of Health

Michael Fordis
Bayor College of Medicine

Frank Fortier
American Academy of Physician Assistants

Renee Fox
University of Maryland School of Medicine

Allan Frankel
Pascal Metrics

Angela Franklin
American College of Emergency Physicians

Susan Friedman
American Osteopathic Association

Charlene Frizzera
Centers for Medicare & Medicaid Services

Andrea Furia-Helms
Food and Drug Administration

Sandra Fusco-Walker
Centers for Medicare & Medicaid Services

Sherine Gabriel
Mayo Clinic

Jean Paul Gagnon
sanofi-aventis

Lynne Garner
Donaghue Foundation

Reed Gelzer
Advocates for Documentation Integrity and Compliance

Richard Gilfillan
Geisinger Health System

Cliff Goodman
The Lewin Group

Shefa Gordon
National Institutes of Health

Mark Gorman
National Coalition for Cancer Survivorship

Jennifer Graff
National Pharmaceutical Council

Tina Grande
Healthcare Leadership Council

Rachel Groman
American Association of Neurological Surgeons

Stuart Guterman
The Commonwealth Fund

Rosemarie Hakim
Centers for Medicare & Medicaid Services

Andrea Harabin
National Heart, Lung, and Blood Institute

Susan Hardy
Kaiser Permanent Mid Atlantic

John Haughton
DocSite

Allison Hawke
Dartmouth Medical School

Giselle Hicks
National Breast Cancer Coalition

Lindsey Hoggle
Health Project Partners, LLC

Mary Horlick
National Institute of Diabetes and Digestive and Kidney Diseases

Julianne Howell
Centers for Medicare & Medicaid Services

Craig Hunter
United BioSource Corp.

Ferdinand Ibebuchi
Society of Health Policy Young Professionals

Belinda Ireland
BJC Healthcare

Jeff Jacobs
American Society for Clinical Pathology

Marcia Kean
Feinstein Kean Healthcare

James Knutson
Aircraft Gear Corporation

Murray Kopelow
Accreditation Council for Continuing Medical Education

Holly Korda
Altarum Institute

Joel Kupersmith
Veterans Health Administration

Hanns Kuttner
Hudson Institute

Arnold Kuzmack
Food and Drug Administration

Joseph Kvedar
Partners HealthCare

Joyce Lammert
Virginia Mason Medical Center

William Lang
American Association of Colleges of Pharmacy

Christopher Langston
The John A. Hartford Foundation

Rick Larue
University of Florida College of Medicine

Janet Leigh
The Robert Wood Johnson Foundation

Teresa Lee
AdvaMed

James Leonard
Kennell and Associates

Jeffrey Lerner
ECRI Institute

Hillary Lewis
University of Texas Health Science Center at Houston

Svetlana Lisanti
Bio-Medical Resources Group

George Lundberg
MedScape

Erin Mackay
Healthcare Leadership Council

Danica Marinac-Dabic
Food and Drug Administration

Norman Marks
Food and Drug Administration

Stephen Marmaras
Biotechnology Industry Organization

John Martin
Premier Inc.

William Martin
National Institute of Environmental Health Sciences

Daniel Masys
Vanderbilt University

Kathleen McCormick
National Heart, Lung, and Blood Institute

Arthur Meltzer
Centers for Medicare & Medicaid Services

Susan Mende
Robert Wood Johnson Foundation

Todd Michael
sanofi-aventis

Pamela Milberg
National Coalition for Cancer Survivorship

Doriane Miller
New Health Partnerships

Nancy Miller
National Institutes of Health

Thomas Miller
American Enterprise Institute

Wilhelmine Miller
George Washington University

Carol Monaco
American Osteopathic Association

Marilyn Moon
American Institutes for Research

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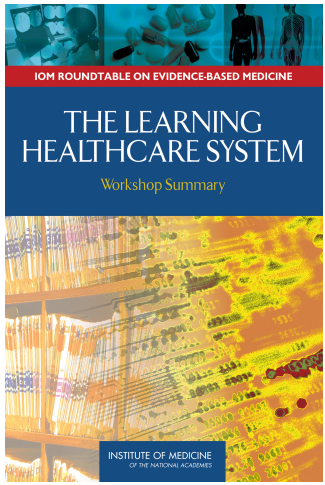
Appendix D

The *Learning Health System* Series: Workshop Common Themes

1. VISION

The Learning Healthcare System



Adaptation to the pace of change: continuous learning and a much more dynamic approach to evidence development and application, taking full advantage of developing information technology to match the rate at which new interventions are developed and new insights emerge about individual variation in response to those interventions.

Stronger synchrony of efforts: better consistency and coordination of efforts to generate, assess, and advise on the results of new knowledge in a way that does not produce conflict or confusion.

Culture of shared responsibility: to enable the evolution of the learning environment as a common cause of patients, providers, and researchers and better engage all in improved communication about the importance of the nature of evidence and its evolution.

New clinical research paradigm: drawing clinical research closer to the experience of clinical practice, including the development of new study methodologies adapted to the practice environment and a better understanding of when RCTs are most practical and desirable.

Clinical decision support systems: to accommodate the reality that although professional judgment will always be vital to shaping care, the amount of information required for any given decision is moving beyond unassisted human capacity.

Universal electronic health records: comprehensive deployment and effective application of the full capabilities available in EHRs as an essential prerequisite for the evolution of the learning healthcare system.

Tools for database linkage, mining, and use: advancing the potential for structured, large databases as new sources of evidence, including issues in fostering interoperable platforms and in developing new means of ongoing searching of those databases for patterns and clinical insights.

Notion of clinical data as a public good: advancement of the notion of the use of clinical data as a central common resource for advancing knowledge and evidence for effective care—including directly addressing current challenges related to the treatment of data as a proprietary good and interpretations of the Health Insurance Portability and Accountability Act (HIPAA) and other patient privacy issues that currently present barriers to knowledge development.

Incentives aligned for practice-based evidence: encouraging the development and use of evidence by drawing research and practice closer together, and developing the patient records and interoperable platforms necessary to foster more rapid learning and improve care.

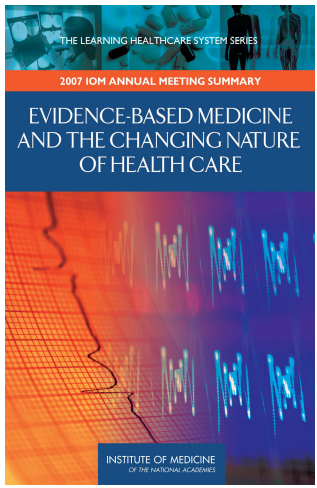
Public engagement: improved communication about the nature of evidence and its development, and the active roles of both patients and healthcare professionals in evidence development and dissemination.

Trusted scientific broker: an agent or entity with the public and scientific confidence to provide guidance, shape priorities, and foster the shift in the clinical research paradigm.

Leadership: to marshal the vision, strategy, and actions necessary to create a learning healthcare system.

2. CARE COMPLEXITY

Evidence-Based Medicine and the Changing Nature of Health Care



Increasing complexity of health care: New pharmaceuticals, medical devices, technologies, and predictive data offer much promise for improving health care, but they also introduce high levels of complexity, requiring changes on the parts of both caregivers and their patients.

Unjustified discrepancies in care patterns: The intensity of healthcare service delivered for similar conditions varies significantly across geographic regions, particularly in areas that require discretionary decision making. However, the higher-spending regions often do not deliver better-quality care, hence offering substantial opportunity for reduced spending without sacrificing health outcomes.

Importance of better value from health care: The current healthcare system is not designed to deliver value, and the nation's long-term fiscal challenges are serious and are being driven predominately by excessive medical spending, often on interventions of no clinical benefit. Opportunities exist to eliminate wasteful spending with no reduction in health care, as well as to improve the overall health outcomes, but agreement is needed both on what constitutes best care and on what constitutes value in health care.

Uncertainty exposed by the information environment: An irony of the information-rich environment is that information important to clinical decision making is often not available, or is provided in forms that are not relevant to the broad spectrum of patients—with differing levels of health, socioeconomic circumstances, and preferences—and the issues encountered in clinical practice. This is due to too little clinical effectiveness research, too poor dissemination of the evidence that is available, and too few incentives and decision supports for evidence-based care.

Pressing need for evidence development: More and better evidence—including comparative and longitudinal data—is needed to determine the effectiveness and usefulness of new medical interventions, treatments, drugs, devices, and genetic information. There is an untapped potential to reduce healthcare costs and improve quality by developing evidence not only for specific medical interventions, but also for the way health care is delivered.

Promise of health information technology: Electronic medical records (EMRs) and clinical data registries offer tremendous potential both to generate new evidence and to augment randomized clinical trials. Addressing privacy and proprietary issues that limit data access and sharing would help to support a system in which electronic medical records, clinical registries, and other types of electronic data could contribute to building a more robust evidence base.

Need for more practice-based research: How might the system better support the notion of a "living textbook of medicine" in which the experience of healthcare diagnosis and treatment is routinely captured in order to better care for those in the future. To develop best evidence for the delivery of medicine that is geared toward the needs of individual patients, investment is needed into infrastructure for the gathering and analysis of healthcare data and information, and standards and protocols to ensure their accuracy and reliability.

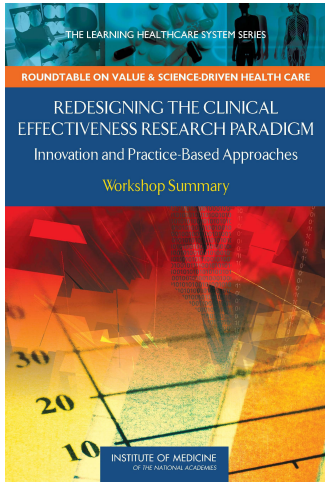
Shift to a culture of care that learns: This changing role will require healthcare providers and patients to adopt a culture that supports the generation and application of evidence. Effective culture change must also be accompanied by insurance and reimbursement system reform that encourages development and application of the systems necessary.

New model of patient-provider partnership: With the increasing complexity of care, and the need and demand for more patient involvement, the traditional "physician-as-sole-authority" model will need to adapt to support patients as integral partners in medical decisions.

Leadership that stems from every quarter: Adapting to and taking advantage of, the changes in the healthcare environment will take broad leadership. A strategic focus on the development and application of evidence will require the involvement of both the public and private sectors working together, and with policy makers, providers, patients, insurers, and other stakeholders in the steps toward change.

3. EFFECTIVENESS RESEARCH

Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches



Address current limitations in applicability of research results: Because clinical conditions and their interventions have complex and varying circumstances, there are different implications for the evidence needed, study designs, and the ways lessons are applied: the internal and external validity challenge. In addition, although our assessment of candidate interventions is primarily through pre-market studies, the opportunity for discovery extends throughout the lifecycle of an intervention—development, approval, coverage, and the full period of implementation.

Counter inefficiencies in timeliness, costs, and volume: Much of current clinical effectiveness research has inherent limits and inefficiencies related to time, cost and volume. Small studies may have insufficient reliability or follow-up. Large experimental studies may be expensive and lengthy, but have limited applicability to practice circumstances. Studies sponsored by product manufacturers have to overcome perceived conflicts and may not be fully used. There is a strong need for more systematic approaches to better defining how, when, for whom, and in what setting an intervention is best used.

Define a more strategic use to the clinical experimental model: Just as there are limits and challenges to observational data, there are limits to the use of experimental data. Challenges related to the scope of inferences possible, to discrepancies in the ability to detect near-term vs. long-term events, to the timeliness of our insights and our ability to keep pace with changes in technology and procedures, all must be managed. For the future of clinical effectiveness research, the important issues relate not to whether randomized experimental studies are better than observational studies, or vice versa, but to what's right for the circumstances (clinical and economic), and how the capacity can be systematically improved.

Provide stimulus to new research designs, tools, and analytics: An exciting part of the advancement process has been the development of new tools and resources that may quicken the pace of our learning and add real value

by helping to better target, tailor, and refine approaches. Use of innovative research designs, statistical techniques, probability and other models may accelerate the timeliness and level of research insights. Some interesting approaches using modeling for virtual intervention studies may hold prospects for revolutionary change in certain clinical outcomes research.

Encourage innovation in clinical effectiveness research conduct: The kinds of "safe harbor" opportunities that exist in various fields for developing and testing innovative methodologies for addressing complex problems are rarely found in clinical research. Initiative is needed for the research community to challenge and assess its approaches—a sort of meta-experimental strategy—including those related to analyzing large datasets, in order to learn about the purposes best served by different approaches. Innovation is also needed to counter the inefficiencies related to the volume of studies conducted. How might existing research be more systematically summarized; or, different research methods organized, phased, or coordinated to add incremental value to existing evidence?

Promote the notion of effectiveness research as a routine part of practice: Taking full advantage of each clinical experience is the theoretical goal of a learning healthcare system. But for the theory to move closer to the practice, tools and incentives are needed for caregiver engagement. A starting point is with the anchoring of the focus of clinical effectiveness research planning and priority setting on the point of service—the patient–provider interface—as the source of attention, guidance, and involvement on the key questions to engage. The work with patient registries by many specialty groups is an indication of the promise in this respect, but additional emphasis is necessary in anticipation of the access and use of the technology that opens new possibilities.

Improve access and use of clinical data as a knowledge resource: With the development of bigger and more numerous clinical data sets, the potential exists for larger scale data mining for new insights on the effectiveness of interventions. Taking advantage of the prospects will require improvements in data sharing arrangements and platform compatibilities, addressing issues related to real and perceived barriers from interpretation of privacy and patient protection rules, enhanced access for secondary analysis to federally sponsored clinical data (e.g., Medicare part D, pharmaceutical, clinical trials), the necessary expertise, and stronger capacity to use clinical data for post-market surveillance.

Foster the transformational research potential of information technology: Broad application and linkage of electronic health records holds the poten-

tial to foster movement toward real-time clinical effectiveness research that can generate vastly enhanced insights into the performance of interventions, caregivers, institutions, and systems—and how they vary by patient needs and circumstances. Capturing that potential requires working to better understand and foster the progress possible, through full application of electronic health records, development and application of standards that facilitate interoperability, agreement on and adherence to research data collection standards by researchers, developing new search strategies for data mining, and investing patients and caregivers as key supporters in learning.

Engage patients as full partners in the learning culture: Access to up-to-date information by both caregiver and patient changes the state of play in several ways. The patient sometimes has greater time and motivation to access relevant information than the caregiver, and a sharing partnership is to the advantage of both. The more patients understand and communicate with their caregivers about the evolving nature of evidence, the less disruptive will be the frequency and amplitude of public response to research results that find themselves prematurely, or without appropriate interpretative guidance, in the headlines and short-term consciousness of Americans.

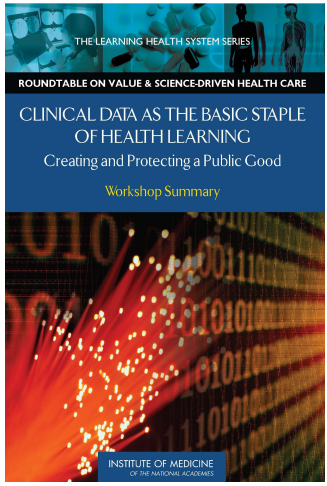
Build toward continuous learning in all aspects of care: This foundational principle of a learning healthcare system will depend on system and culture change in each element of the care process with the potential to promote interest, activity, and involvement in the knowledge and evidence development process, from health professions education to care delivery and payment.

4. DATA UTILITY

Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good

Clarity on the basic principles of clinical data stewardship: The starting point for expanded access and use of clinical data for knowledge development is agreement on some of the fundamental notions to guide the activities for all individuals and organizations with responsibility for managing clinical data. Workshop participants repeatedly mentioned the need for consensus on approaches to such issues as data structure, standards, reporting requirements, quality assurance, timeliness, de-identification or security measures, access and use procedures—all of which will determine the pace and nature of evidence development.

Incentives for real-time use of clinical data in evidence development: Current barriers to the real-time use of clinical data for new knowledge discussed



at the workshop ranged from regulatory and commercial issues to cost and quality issues. Participants suggested the need for a dedicated program of activities, incentives, and strategies to improve the methods and approaches, their testing and demonstration, the cooperative decision making on priorities and programs, and the collective approach to regulatory barriers.

Transparency to the patient when data are applied for research: Patient acceptance is key to use of clinical data for knowledge development, and patient engagement and control are key to acceptance. In this respect, clarity to individual patients on the structure, risks, and benefits of access to data for knowledge development was noted by participants as particularly important. Patient confidence and system accountability may be enhanced through transparent notification and audit processes in which patients are informed of when and by whom their information has been accessed for knowledge development.

Addressing the market failure for expanding electronic health records: Currently, market incentives are inadequate to bring about the expansion of use of electronic health records necessary to make the point of care a locus for the development, sharing, and application of knowledge about what works best for individual patients. Shortfalls noted by participants included demand by providers or patients that is not sufficient to counter the expense to small organizations, competing platforms and asynchronous reporting requirements that work against their utility for broad quality and outcome determinations, and that even the larger payers—apart from government—do not possess the critical mass necessary to drive broader scale applicability and complementarity. It will likely take a deeper, more directed and coordinated strategy involving Medicare leadership to foster such changes.

Personal records and portals that center patients in the learning process: Patient demand could be instrumental in spreading the availability of electronic health records for improving patient care and knowledge development. Such demand will depend upon much greater patient access to, comfort with, and regular use of programs that allow either the maintenance of personal electronic health records or access through a dedicated portal to their provider-maintained electronic medical record. As noted

during the workshop, many consumer-oriented products currently under development give patients and consumers more active roles in managing personal clinical information, and may help to demonstrate value in the speed and ease of personal access to the information, better accommodate patient preference in care, and foster a partnership spirit conducive to the broader EHR application.

Coordinated EHR user organization evidence development work: The development of a vehicle to enhance collaboration among larger EHR users of different vendors was raised during the workshop as a means to accelerate the emergence of more standardized agreements and approaches to integrating and sharing data across multiple platforms, common query strategies, virtual data warehousing rules and strategies, relational standards, and engagement of ways to reduce misperceptions on regulatory compliance issues.

The business case for expanded data sharing in a distributed network: Demonstrating the net benefits of data sharing could promote its use. Benefits suggested by participants included cost savings or avoidance from facilitated feedback to providers on quality and outcomes; quick, continuous improvement information; and improved management, coordination, and assessment of patient care.

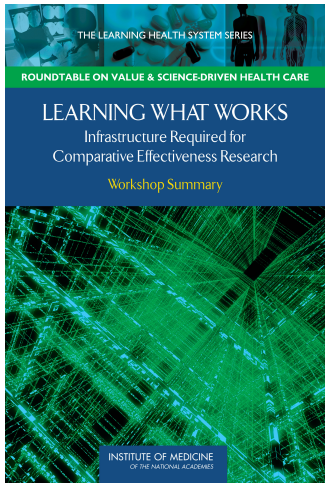
Assuring publicly funded data for the public benefit: Federal and state funds that support medical care, as well as support insights into medical care through clinical research grant funding, are the source of substantial clinical data; yet, many participants observed that these resources are not yet effectively applied to the generation of new knowledge for the common good.

Broader semantic strategies for data mining: Platform incompatibilities for clinical data substantially limit the spread of electronic health records and their use for knowledge development. Yet discussion identified strategies using alternative semantic approaches for mining clinical data for health insights, which may warrant dedicated cooperative efforts to develop and apply them.

Public engagement in evidence development strategies: Generating a base of support for and shared emphasis on developing a healthcare ecosystem in which all stakeholders play a contributory role was noted by many participants as important for progress. Ultimately, the public will determine the broad acceptance and applicability of clinical data for knowledge development, underscoring the importance of keeping the public closely involved and informed on all relevant activities to use clinical data to generate new knowledge.

5. EVIDENCE

Learning What Works: Infrastructure Required for Comparative Effectiveness Research



Coordinating work and ensuring standards are key components of the evidence infrastructure: Infrastructure for evidence development includes the capacity for greater coordination in the setting of study priorities; the development of systematic decisions for the conduct of comparative effectiveness research, systematic reviews, and guideline development; and ensuring the consistent translation of developed information.

Learning about effectiveness must continue beyond the transition from testing to practice: Pre-market testing for the safety and effectiveness of various interventions cannot assess the results for all populations or the circumstances of use and differences in practice patterns, so gathering information as interventions are applied in practice settings should represent a key focus in designing the infrastructure to learn which care is best.

Timely and dynamic evidence of clinical effectiveness requires bridging research and practice: Although historical insulation of clinical research from the regular delivery of healthcare services evolved to facilitate data capture and control for confounding factors, it may not adequately inform the real-world setting of clinical practice. With the prospect of enhanced data capture electronically at the point of care, on real-world patient populations, and statistical approaches to improve analysis, as well as increasing demand to keep pace with technologic innovation, the divide of clinical research from care practice increasingly limits the utility of research results.

Current infrastructure planning must build to future needs and opportunities: Emerging questions include those related to the management of multiple co-occurring chronic diseases of increasing prevalence in an aging population, the improved insights into individual variation relevant to both treatments and diagnostics, and the impact of innovation in shortening the lifecycle of any particular intervention. Emerging tools include innovations in trial design, the development of new statistical approaches to data analysis, and the development of electronic medical and personal health records.

Keeping pace with technological innovation compels more than a head-to-head and time-to-time focus: With the rapid pace of change in the nature of interventions and the difficulty, expense, and time required to develop studies—and the challenges of ensuring the generalizability of results in the face of limitations of traditional approach to randomized controlled trials (RCTs)—a first-order priority for the effectiveness research is the establishment of infrastructure for a more dynamic, real-time approach to learning. Leveraging new tools such as health IT should allow for a more networked and distributed approach to information sharing and evidence creation.

Real-time learning depends on health information technology investment: It was noted that collecting data is the most time-intensive part of trials and studies, and IT is critical to streamlining this work. The increasing complexity of the factors involved in understanding the effectiveness of clinical options under different circumstances requires a blend of database access and computing power that can only be provided from broadly applied health information technology. A policy framework for privacy and security will be necessary to build and maintain public trust that information will be protected as it is shared.

Developing and applying tools that foster real-time data analysis is an important element: The scope and scale of evidence needs suggests that innovation is needed across the range of research methods, from making clinical trials faster and less expensive, to moving beyond randomized trials to better address practical circumstances. To take advantage of health information technology, statistical tools, and analytic algorithms that can be embedded in databases to allow real-time insights will be important. Similarly, tools are needed that will allow findings to be drawn from databases built on different vendor platforms, using semantic technology to integrate currently disparate medical data, and for developing the next generation of statistical tools for the analysis of clinical data, including the building of models that allow insights to be generated by virtual studies.

A trained workforce is a vital link in the chain of evidence stewardship: Given the pace of change in the number and variety of clinical interventions as well as in the tools and approaches to assessing them, there is a need to ensure that these developing opportunities are matched by the skills of the workforce. This includes training and education in the methodologies of research design, translating research, guideline development, and maintaining and mining clinical records. It also includes attention to re-orienting the education of front-line caregivers around their emerging responsibilities for access, interpretation, and discussion with patients of a dynamic evidence

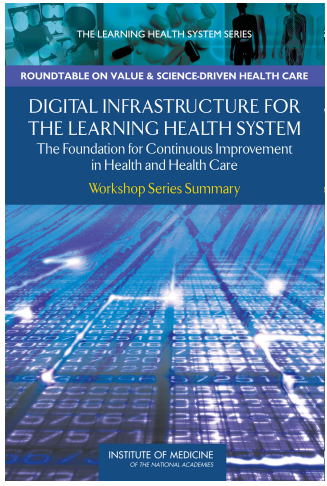
base, as well as helping to ensure the availability and integrity of the clinical data that shape conclusions on evidence.

Approaches are needed that draw effectively on both public and private capacities: Several times in the course of the meeting it was pointed out that although the total investment in clinical effectiveness research in the United States is substantial, it is inefficient because of the absence of a vehicle for common priority setting and coordination of efforts and because the work on effectiveness done by private companies in product development and testing is usually not accessible to the broader community. Several models are in development to establish public–private collaborative efforts to improve the efficiency and effectiveness of the work.

Efficiency and effectiveness compel globalizing evidence and localizing decisions: Reference was made throughout the meeting to work going on elsewhere in the world. This brought clearly into play the need to ensure that, where possible, common work to assess an intervention's clinical effectiveness—or collective work to assess the body of evidence—be collaborative and well-coordinated across boundaries, while also being mindful that different cultural and policy environments may lead to different decisions at the local level.

6. DIGITAL PLATFORM

Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care



Build a shared learning environment: HIT provides an opportunity to change the current environment in which health decisions are made to one of shared input and active participation from patients, caregivers, and the population at large. Approaches to developing this shared learning environment discussed include the direct involvement and support of the patients' and population's roles in the generation of knowledge through the incorporation of user-generated data; understanding the benefits of information use in patient care and population health improvement; and improving patient access to health information to allow for a more active role in care decisions.

Engage health and health care, population and patient: Many participants reiterated that in order to improve health outcomes for the nation, thinking must extend beyond clinical encounters, and even beyond the individual patient, to the population as a whole. This shift of scope brought into clearer focus several issues discussed, including: the opportunity to use HIT and its associated information to build a concept of health that is about more than medical care, and draws on seamless interface with information from non-medical health-related sources to generate knowledge that allows for a more inclusive view of population health improvement.

Leverage existing programs and policies: A foundational assumption during the discussions was the advantage provided by building on the substantial recent progress, both nationally and internationally, with an emphasis on the importance of fostering coordination among these efforts to capture efficiencies and prevent unnecessary duplication and waste going forward. Participants often noted that recent policies and legislation have laid a foundation for this work, and that the resulting investments and progress can be leveraged to move toward long-term system goals.

Embed services and research in a continuous learning loop: Meeting participants often underscored that a digital infrastructure that supports both the generation and use of knowledge cannot be effective unless it is integrated seamlessly within the processes from which it draws and is meant to support: care delivery, research, quality improvement, and population health monitoring. Ease of use for health system stakeholders, attention to the effects on workflow, and the delivery of useful decision support at point of care were often mentioned in discussions.

Anchor in the ultra-large-scale (ULS) system approach: One of the most prominent features of the discussions was the notion that the health system is a complex, socio-technical ecosystem, and therefore requires a new way of thinking. Grounding the approach to coordination and integration of the digital infrastructure for the learning health system in the principles of a ULS system approach was suggested by several workshop participants from the computer science community. The term "ultra-large-scale system" refers to the existence of a virtual system of unprecedented scale and complexity, working from multiple platforms and used by multiple participants and stakeholders with cross-cutting common purpose at some level—e.g., improving health and health care. Overall ULS functionality is therefore facilitated by protocols that allow maximum practical flexibility for participants. Incorporating decentralization of data, development, and operational authority and control, this approach fosters local innovation, personalization, and emergent behaviors. Participants felt that this approach was well

suited to the complex adaptive characteristics of the health system, and that it could serve as an anchoring framework for approaching both the social and technical components of the overall infrastructure.

Emphasize decentralization and specifications parsimony: In line with the complex adaptive qualities of the health system outlined in the Quality Chasm (IOM, 2001) report and reiterated during these workshops, both the social and technical components of the digital health infrastructure require a framework that allows for tailoring to specific needs, local innovation, and evolvability. In this respect, the commonly repeated refrain was a call for the principle of parsimony and minimizing centralization that might constitute a barrier to entry: specify only the minimal set of standards or requirements necessary for key functional utility, and push the maximum amount of control to the periphery. This approach is in line with strategies under consideration for use of metadata for wrapping individual information packets to facilitate interoperability and health information exchange, in which a primary focus would be on development of the metadata standards.

Keep use barriers low and complexity incremental: Similarly, incentives for broad participation in the digital infrastructure by all stakeholders was discussed as a crucial factor to its success. The proposal to keep the barrier for use of the infrastructure low was articulated by workshop participants in order to allow for maximum participation at a basal level, and allow for incremental complexity and sophistication where possible or necessary.

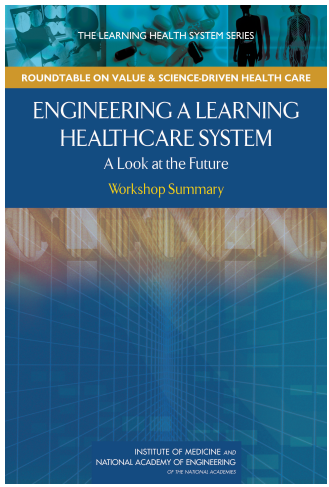
Foster a socio-technical perspective, focused on the population: From the outset of the discussions, participants pointed out that the major barriers to technical progress often lie in social and cultural domains. Acknowledging and engaging this fact was described as being crucial to success, with discussions centering on an approach that reorients future efforts to engage the patient more directly in the collection and use of information in a way that is most useful to them.

Weave a strong trust fabric among stakeholders: Security and privacy concerns represent a strong threat to participation in, and therefore the success of, the socio-technical ecosystem. Accordingly, they must be dealt with from both the social and technical perspectives. Participants emphasized the need for systems security to comply with all current requirements and regulations and retain an ability to evolve to meet future needs. In addition, honest communication to the public and other involved stakeholders about risks and benefits will be crucial to building a foundation of trust.

Provide continuous evaluation and improvement: A learning system is one that assesses its own performance against a set of goals and uses the results of that evaluation to change future behaviors. Workshop participants articulated the importance that all components of a digital infrastructure must themselves function as learning systems.

7. SYSTEMS ENGINEERING

Engineering a Learning Healthcare System: A Look at the Future



Center the system's processes on the right target—the patient: Patient-centered care was defined in the 2001 IOM report *Crossing the Quality Chasm* as providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions. Throughout several sessions, workshop participants emphasized the need to ensure that processes support patients—and patients are not forced into processes. Patient needs and perspectives must be at the center of all process design, technology application, and clinician engagement.

System excellence is created by the reliable delivery of established best practice: In health care, establishing practices from the best available evidence and building them as routines into practice patterns, as well as developing systems to document results and update best practices as the evidence evolves, will integrate some of the best elements from the engineering disciplines into healthcare issues. Participants often cited the need for better integration of best practices development, and communication in healthcare systems, as well as process systems to track care details and outcomes, and feedback to inform practice refinement and lead to better patient outcomes.

Complexity compels reasoned allowance for tailored adjustments: Established routines may need circumstance-specific adjustments, either because of differences among individuals in the appropriateness for them of the established healthcare regimens, variations in caregiver skill, the evolving nature of the science base—or all three. Mass customization and other engineering practices can help assure the consistency that can accelerate the

recognition of the need for tailoring and delivering the most appropriate care, with the best prospects for improved outcomes, for the patient.

Learning is a non-linear process: The focus on an established hierarchy of scientific evidence as a basis for evaluation and decision making cannot accommodate the fact that much of the sound learning in complex systems occurs in local and individual settings. Participants cited the need to bridge the gap between dependence on formal trials, such as randomized clinical trials, and the experience of local improvement, in order to speed learning and avoid impractical costs.

Emphasize interdependence and tend to the process interfaces: A system is most vulnerable at links between critical processes. In health care, attention to the nature of relationships and hand-offs between elements of the patient care and administrative processes is therefore vital and a crucial component of focusing the process on the patient experience and improving outcomes.

Teamwork and cross-checks trump command and control: Especially in systems designed to guarantee safety, system performance that is effective and efficient requires careful coordination and teamwork, as well as a culture that encourages parity among all with established responsibilities. During the workshop several examples were cited of other industries that have used systems design and social engineering to better integrate and strengthen their systems processes with great improvements in efficiency and safety.

Performance, transparency, and feedback serve as the engine for improvement: Continuous learning and improvement in patient care requires transparency in processes and outcomes, as well as capacity to capture feedback and make adjustments.

Expect errors in the performance of individuals, perfection in the performance of systems: Human error is inevitable in any system and should be assumed. On the other hand, safeguards and designed redundancies can deliver perfection in system performance. Mapping processes, embedding prompts, cross-checks, and information loops can assure best outcomes, and allow human capacity to focus on what can not be programmed—compassion and individual patient needs. Several workshop presentations shared success stories and lessons learned from other industries, such as automotive and the airline industry, that have effectively incorporated this strategy.

Align rewards on the key elements of continuous improvement: Incentives, standards, and measurement requirements can serve as powerful change

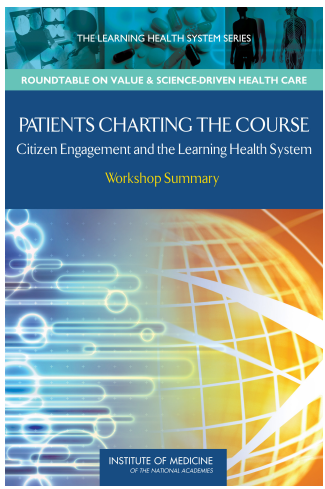
agents. Participants noted that it is vital that incentives be carefully considered and directed to the targets most important to improving the efficiency, effectiveness, and safety of the system and ultimately patient outcomes, as well as taking into consideration the patient and provider experiences.

Development of education and research to facilitate understanding and partnerships between engineering and the health professions: The relevance of systems engineering principles to health care and the impressive transformation brought to other industries speaks to the merits of developing common vocabularies, concepts, and ongoing joint education and research activities that help generate stronger questions and solutions. Workshop participants pointed to the dearth of training opportunities bridging these two professions and spoke of the need to encourage greater collaborative work between them.

Foster a leadership culture, language, and style that reinforce teamwork and results: Positive leadership cultures foster and celebrate consensus goals, teamwork, multidisciplinary efforts, transparency, and continuous monitoring and improvement. In citing examples of successful learning systems, participants highlighted the need for a supportive and integrated leadership.

8. PATIENTS & THE PUBLIC

Patients Charting the Course:
Citizen Engagement and the Learning Health System



Listening: *Each patient encounter starts with the patient's voice fully drawn out on issues, perspectives, goals, and preferences.* These patient views should then be used to guide clinical decisions, which often involve choices among multiple treatments, each of which has both benefits and risks. Workshop participants reported that care often improved when staff and providers listened to the concerns of patients and their families. Achieving this goal will require a new focus on patient communication starting early in provider education to ensure that providers have the tools they need to share complex health information with patients and help them with these decisions.

Participatory: *Health outcomes improve when patients are engaged in their own care*. In addition to improving health outcomes and patient adherence, participants noted that engagement can increase employee satisfaction and financial performance. People are eager to play a strong role in their own health care when given the right tools, as evidenced by the rapid uptake of Web 2.0 health information applications. Yet as one speaker mentioned, surveys indicate that only half of patients receive clear information on the benefits and trade-offs of the treatments under consideration for their condition. Patients' involvement may be increased by providing them with additional information tools for learning about their health, helping them see the impact of their efforts, and acquainting them with new technologies with which to monitor their health and assist with lifestyle changes. Public participation is not limited to the clinic; the workshop highlighted new initiatives to provide access to health data and allow individuals to create new applications to improve their health.

Reliable: *Each patient should expect proven best practice as the starting point in their care*. The current variability in medical practice impacts patient care and results in uneven quality and safety for patients. Participants described tools that minimize this variation, such as dashboard displays that highlight the interventions that are due, done, or overdue and improve the consistency of the delivery of interventions to patients. Other technologies that show promise include clinical decision support systems that present best practices to clinicians. Participants also noted that, while technologies provide new opportunities, incentives are needed to promote reliability and effectiveness in healthcare organizations and ensure accountability.

Personalized: *With proven best practices as the starting point, science-based tailoring is shaped by personal biological traits, circumstances, and preferences*. Since the sequencing of the human genome was accomplished, medical science has sought to personalize treatments and standards of care. This effort challenges the traditional approach of giving the highest priority to evidence gathered by means of large randomized controlled clinical trials, in which treatments are measured in a large population with a diverse genetic profile. Using multiple types of complementary evidence could better guide medical decisions and account for these personal factors. This new approach focuses on the applicability of results to the clinic, rather than automatically giving priority to the results of randomized controlled trials.

Seamless: *Care delivered by multiple providers in multiple settings should be nonetheless expected to be fully integrated and seamless*. As patients move among providers and settings, they often encounter communication

problems, which may result in treatment errors and duplicative services. Participants described how team-based care offers the potential to rectify this disconnected care and limit human error. Effective teams are aided by an appropriate information technology infrastructure, which facilitates efficient and effective communication of health information, as well as by collaborative organizational systems, from medical homes to accountable care organizations.

Efficient: *Patients, their families, and clinicians should expect care to be appropriate to need, resources, and time required.* Participants underscored the fact that currently, much of the care that is delivered is neither necessary nor efficient. Among the chief complaints of patients are increasing out-of-pocket costs and lost time in the care process. This finding is not surprising given that the current incentive structure, focused on volume over value, encourages overuse and waste. As multiple participants noted, the United States spent roughly 17 percent of its gross domestic product on health care last year, yet this investment did not yield the health outcomes commensurate with the costs. To gain greater value, participants stressed, the costs and outcomes of care must be more transparent to patients, and new payment models—ranging from bundling payments for an entire episode of care, to pay-for-performance systems, to global payment—must be implemented.

Accountable: *All relevant aspects of the clinical experience, including patient perspectives, should be captured and routinely assessed against expectations.* This information is vital not only to achieving effective patient management, but also to judging whether experiments with new delivery system models, payment incentives, or standards of care are having their intended effect on improving patient health and promoting efficiency. Measuring performance and disseminating innovations that work (and eliminating those that do not) constitute a systematic way of improving healthcare delivery. One presentation highlighted how this systematic approach to improvement allowed the speaker's organization to enhance care by conducting comprehensive reviews of interventions for different conditions, adopting the best practices identified by that review, and measuring the performance of the revised standard of care.

Transparent: *Information on the outcomes of care—both effectiveness and efficiency—should be readily accessible and understandable to patients and their families.* Several speakers mentioned the frustration felt by patients regarding the lack of understandable information on the costs, quality, and outcomes of care, especially in light of reports about medical errors and the increasing personal burden of costs and inefficiencies of

care. It was noted that, when offered a choice, patients do not routinely choose more costly or more intensive interventions. However, choice and information about alternatives are rarely available. It is clear that action to improve value—better outcomes at lower cost—requires transparent information on the costs and outcomes of care.

Trustworthy: *Patients should expect a strong and secure trust fabric on all dimensions—safety, quality, security, efficiency, accountability, and equity.* In few areas of human endeavor is trust on each of these dimensions more important. Yet one presenter noted that, even in the face of information that 50,000 to 90,000 deaths per year are caused by medical errors, health care lacks the basic trust elements of transparency and accountability needed to drive improvements in quality and safety. In a learning system that draws lessons from each care experience, public trust must be bolstered in all aspects of the healthcare enterprise: equitable access to reliable clinician knowledge and skills, safeguards on clinical processes, privacy and security of medical records, and validity and safety of clinical trials.

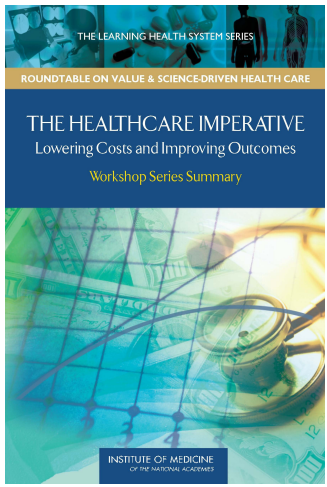
Learning: *In a learning health system, the patient is an active contributor to, and supporter of, the learning process.* Each patient experience offers the potential to deepen the knowledge base that drives care quality and outcomes—at the individual, practice, and societal levels. A focus of the workshop was the stake of the patient in fostering a digital health utility that provides needed information to patients and their clinicians, ensures synchronization among providers, and generates knowledge for progress—for example, for comparative effectiveness insights, public health activities, or postmarket monitoring of approved technologies and drugs. Reference was made, for example, to the need for a common core data set for EHR–based data that would allow reliable, platform-independent research across large patient populations. These are issues in which patients have a strong stake, and they must have confidence in the system's functionality for the generation of timely and reliable new insights.

9. COST AND OUTCOMES

The Healthcare Imperative: Lowering Costs and Improving Outcomes

Challenges for health costs and outcomes

Health cost excesses with personal, institutional, and national consequences. In the past decade, U.S. health costs have increased by 92 percent, representing approximately four times the inflation rate for the economy as a whole. Out-of-pocket costs for individuals have increased by 40 percent.



Overall, Medicaid now takes almost 20 percent of state budgets, crowding out other state priorities such as education.

Health outcomes far short of expectations. Despite health spending double the average for other developed nations, U.S. health outcomes rank below two to three dozen other countries on indices such as life expectancy, care for chronic disease, and persistent disparities in the access and outcomes of care.

Fragmented decision points, inconsistent principles, and political distortions. Barriers to appropriate care include poor care coordination, lack of consistent evidence-based guidelines, payment systems that encourage volume over value, and political influences that sometimes overturn scientific determinations.

Domains of waste and inefficiency in healthcare spending

Unnecessary services: services reflecting choices or levels beyond those supported by evidence or benchmarks.

Inefficiently delivered services: inefficient labor use, time-flow discontinuities, duplicate services, medical errors.

Excess administrative costs: billing and insurance-related costs for payers and providers, inefficient reporting requirements.

Prices that are too high: for medical services, pharmaceuticals, products and devices, relative to benchmarks.

Missed prevention opportunities: for preventable obesity, diabetes, heart disease, stroke, pulmonary disease, cancers, infections.

Medical fraud: systemic over-billing, billing for undelivered services, use of unlicensed providers.

Drivers of the problems

Scientific uncertainty. Clinical evidence development is not keeping pace with new diagnostics, treatments, and insights into individual variation.

Perverse economic and practice incentives. The fee-for-service reimbursement system rewards service volume rather than value.

System fragmentation. Multiple, disconnected, and uncoordinated decision points in healthcare delivery and finance are fundamental challenges to efficient and effective care.

Opacity as to cost, quality, and outcomes. Without meaningful and trustworthy sources of information on costs and outcomes of care, neither patients nor their clinicians can make fully informed decisions.

Changes in health status. An aging population, the growing prevalence of obesity, and increases in multiple co-occurring, complex chronic diseases are accelerating the need for health services.

Lack of patient involvement. The culture of care is not yet conducive to active patient participation in care decisions, despite growing use of web-accessible information and evidence of the positive effect of shared decision making on health outcomes.

Under-investment in population health. Because health status is importantly influenced by behavioral, social, and environmental factors, progress depends on a stronger commitment to population-wide health programs.

Corrective levers

Streamlined and harmonized health insurance regulation. Reduce complexities and inconsistencies in coverage standards and requirements often unique to a jurisdiction.

Administrative simplification and consistency. Streamline and harmonize inconsistent payment and reporting requirements that create unnecessary and excessive administrative costs.

Focus incentives on results and value. Focus payments on outcomes and value, and increase targeting those at highest risk of poor outcomes.

Quality and consistency in treatment. Establish treatment guidelines as the starting point for effective care, tailoring as indicated, and capturing the care experience for continuous improvement.

Evidence that is timely, independent, and understandable. Foster effective care through a dedicated, unified program that provides reliable guidance;

keeps up with innovation and changing science; and improves practice reliability, consistency, and impact.

Clinical records that are reliable, sharable, and secure. Use electronic health records to enhance the effectiveness and efficiency of care, facilitate patient handoffs, provide clinical decision guidance, and foster patient involvement.

Data that are protected but accessible for continuous learning. Create a digital utility with clinical data as a resource for real-time monitoring of the results of treatment, ongoing generation of new evidence for effective care, and continuous care improvement.

Transparency requirements on cost, quality, and outcomes. Build an accessible information resource, with transparency as to cost, outcomes, and value serving as a critical element of system change.

Culture and activities framed by patient perspective. Position patient perspectives and needs as primary—and convenience and interest as secondary—for the design and execution of healthcare organization and delivery.

Medical liability reform. Diminish defensive medicine as a detrimental, significant driver of unnecessary services and procedures—e.g., through harbors for best evidence practices, caps on non-economic damages, specialized tribunals.

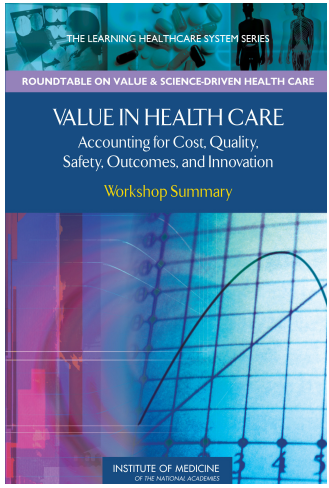
Prevention. Elevate the focus on prevention, ranging from clinical preventive services to community health and wellness.

10. VALUE

Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation

Urgency: Increasing healthcare costs consistently outpace inflation, squeezing out employer coverage, adding to the uninsured, and doubling out-of-pocket payments—without commensurate health improvements. The long-term consequences for federal budget obligations, driven by the growth in Medicare costs, amount to an estimated $34 trillion in unfunded obligations.

Perceptions: We have heard that for patients perceived value in health care is often described in terms of the quality of their relationship with their physicians. Clinicians discussed value as diagnostic and treatment ap-



proaches that offer increased confidence in the effectiveness of services offered. Employers viewed value improvement in terms of keeping workers and their families healthier and more productive at lower costs. For health insurers, we heard that value improvement means emphasizing interventions that are crisply defined and supported by a high level of evidence. Health product innovators spoke of value improvement as a product that is better for the individual patient, more profitable, and contributes to product differentiation and innovation.

Elements: Value from health care has dimensions beyond the nature, cost, and effectiveness of a particular intervention, including those related to elements such as preference, satisfaction, and appropriateness to circumstance. Value determination also means determining the right price, and we heard that, from the demand side, the right price is a function of perspective. From the supply side, the right price is a function of the cost of production, the cost of delivery, and the incentive to innovation.

Gain: Because reliable information is the starting point for improving value, discussants underscored the importance of adequate transparency and continuous improvement of insights on the safety, efficacy, effectiveness, and comparative effectiveness of interventions.

Decisions: Currently, decision rules seem to many stakeholders to be vague, inconsistent, and poorly tailored to the evidence.

Information: Because the quality of evidence varies, as do the methods used to evaluate it, transparency as to source and process, care as to interpretation, and clarity in communication were noted as key.

Incentives: Often noted in the workshop discussions was that the incentives prevalent in the American healthcare system are poorly aligned to effectiveness and efficiency, encouraging care that is procedure- and specialty-intensive and discouraging primary care and prevention.

Limits: We have heard that obtaining the value needed will continue to be elusive until better means are available to draw broadly on information as to services' efficiency and effectiveness, to set priorities and streamline

approaches to filling the evidence gaps, to ensure consistency in the ways evidence is interpreted and applied, and to marshal incentives to improve the delivery of high-value services while discouraging those of limited value.

Communication: Patients and providers do not communicate well with each other about diagnosis and treatment options or cost implications. Communication is often absent between multiple providers for a single patient, increasing the prospect of service gaps, duplications, confusion, and harm, according to discussants. Further, communication between scientific and professional organizations producing and evaluating evidence is often limited, resulting in inefficiencies, missed opportunities, and contradictions in the production of guidance.

Providers: We heard that the clearest barriers to provider-level value improvement appear to lie in the lack of economic incentives for a focus on outcomes and also in cultural and structural disincentives to tend to the critical interfaces of the care process—the quality of the links in the chain of care elements.

Patients: It was noted that patients most often think of value in terms of their relationship with their provider but ultimately the practical results of that relationship, in terms of costs and outcomes, hinge on the success of programs that improve practical, ongoing, and seamless access to information on best practices and costs and of payment structures that reward accordingly. Workshop discussants offered insights into the use of various financial approaches to sensitize and orient patient decisions on healthcare prices according to the evidence of the value delivered.

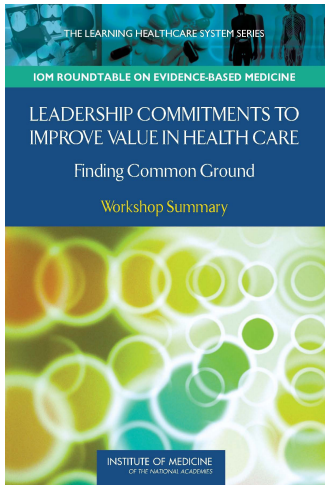
Manufacturers: Health product manufacturers and innovators naturally focus on their profitability but because product demand is also derived from the ability to demonstrate advantage with respect to outcomes and efficiency, manufacturers expressed an interest in regulatory and payment approaches that enhance performance on outcomes resulting from product use.

Tools: Despite the broad agreement on their importance, we heard that the analytical tools and capacity to evaluate, in either absolute or comparative terms, the basic elements of value—outcomes and costs—are substantially underdeveloped and will need greater attention.

Opportunities: Although attaining better value in health care depends on reducing the fragmentation that is its central barrier, we heard a number of examples of measures that might be taken at different levels, both to achieve better value now and to set the stage for future progress.

11. LEADERSHIP

Leadership Commitments to Improve Value in Health Care: Finding Common Ground



Build trust and collaboration: Health care depends for its effectiveness on the close cooperation of all parties involved. Building trust and facilitating transformative change will require broader-based collaboration and cooperative stakeholder engagement.

Foster agreement on "value" in health care: Although all participants agreed on the centrality and importance of the value achieved from health care, different groups often think of value in different ways. A multistakeholder effort might drive clarity and consensus on those principles and elements of value common to all stakeholders.

Improve public understanding of evidence: Too often, people perceive that certain common terms such as "evidence based," "research," "medical necessity," and "risk" suggest a restrictive or experimental element to their care. It will take systematic and coordinated communication strategy to better convey the central concepts that medical evidence is dynamic, that evidence-based medicine is the provision of care that the evidence suggests is best for any given patient at any given point in time, and that health care is a joint patient–provider endeavor.

Characterize the impact of shortfalls in the evidence: Documenting the consequences of provision of care on the basis of too little evidence or the potential benefits of providing care on the basis of the right evidence is a prerequisite to obtaining an improved understanding of and demand for evidence-based care and stakeholder activation.

Identify the priorities for evidence development: The first step to a systematic and coordinated effort to conduct the most important assessments is the identification of the priorities as a sort of consensus national problem list and research agenda of the most pressing issues for medical care decisions.

Improve the level, quality, and efficiency of the research: Policies that facilitate the ability to use clinical data to monitor the effectiveness of in-

terventions are needed. Novel approaches to the conduct of clinical trials are needed. A more structured lexicon for "best practices" in undertaking observational studies may be necessary.

Clarify and promote transparency: Consensus is needed to establish common principles of transparency and standards for how they should be applied in each sector. One starting point might be with principles for evidence interpretation.

Establish principles for the interpretation and use of evidence: Decisions on market approval, insurance coverage, provider use, and patient acceptance are all informed by some interpretation of the evidence. Clarity of the guiding principles is important.

Improve engagement in the full lifecycle of interventions: Many factors are at play for each intervention—for example, similarity to previously tested interventions, the safety and effectiveness of an intervention for some populations but not others, the availability of biomarkers predictive of efficacy, and costs that vary by scale and stage of application or by the need for later services. Facilitating innovation, access, and effective information gathering while emphasizing patient safety, appropriate application, improved outcomes, and efficiency will require a set of lifecycle-oriented decision-making rules that are more carefully considered than they are at present.

Focus on frontline providers: Accelerating the translation of clinical research into practice involves addressing matters of professional education, credentialing, licensure, practice support, economic incentives, patient acceptance, and the culture of care. It will require the central and coordinated involvement of the organizations that represent those providers.

Foster a trusted intermediary for evidence: In this information age, health-related information is constantly presented through news reports, marketing, professional organizations, journals, and the Internet, but it is often confusing and even contradictory. A trusted information source—one that is independent but that engages all stakeholders—is needed to identify gaps; set priorities; establish standards; and guide the development, interpretation, and dissemination of evidence on clinical effectiveness.

Build the capacity to meet the demand: Currently, the combined resources of the various public and private organizations involved in studying comparative clinical effectiveness meet but a small and scattered fraction of the demand. The centrality of the problem to the quality and efficiency—

the viability, according to some—of the nation's healthcare system may require the creation of a new independent entity devoted to the work.

Create incentives for change: Economic and policy incentives to engage the use of the best available evidence and more fully engage patients in the clinical decision-making process include the alignment of purchasing incentives accordingly when value is determined; use of the reimbursement power of insurers and other financial incentives to generate new insights from medical care (e.g., coverage with evidence development); and the linkage of purchaser and payer decisions to performance incentives for best practices, outcomes, and the better secondary use of routinely collected data.

Accelerate advances in health information technology: Health information technology can facilitate the development of learning networks and accelerate the generation of evidence, enable data aggregation and utilization, deliver evidence to the point of care, and expand research capacities. Coordinated stakeholder action—and financial incentives—should be able to speed the progress toward universal application of electronic health records and access to information both on basic interoperability issues (e.g., standards and vocabulary) and, possibly, the development of more radical data search innovations.

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