Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation

Pierre L. Young, LeighAnne Olsen, and J. Michael McGinnis; Roundtable on Evidence-Based Medicine; Institute of Medicine

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THE LEARNING HEALTHCARE SYSTEM SERIES

ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

VALUE IN HEALTH CARE

Accounting for Cost, Quality, Safety, Outcomes, and Innovation

Workshop Summary

Pierre L. Yong, LeighAnne Olsen, and J. Michael McGinnis

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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ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE[1]

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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 process. We wish to thank the following individuals for their review of this report:

Michael Chernew, Harvard Medical School
Mary Kay Henry, SEIU
Ronald A. Paulus, Geisinger Health System
Vincenza Snow, American College of Physicians

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 **Robert Graham,** University of Cincinnati College of Medicine. 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 healthcare 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

For decades, the rise in healthcare costs in the United States has outpaced growth in the economy as a whole. The United States spends per capita on health almost double the average of other Organisation for Economic Co-operation and Development countries. Over the years, it has become increasingly clear that Americans are not gaining benefits commensurate with these higher expenditures: dozens of countries today boast superior life expectancy and lower infant mortality.

Among many efforts to enhance value from health expenditures, the Institute of Medicine in 2006 created a Roundtable on Evidence-Based Medicine, now called the Roundtable on Value & Science-Driven Health Care. Its purpose was to bring together patients and consumers, providers, manufacturers, payers, researchers and policy makers in a neutral venue to discuss ways evidence about how well interventions work could transform delivery of care in this country. The Roundtable developed a vision of a *learning healthcare system* where evidence is both applied and generated as a natural course of care. Building on this work, the Roundtable convened leaders, researchers, and policy makers from across the healthcare field on November 17-18, 2008, for the workshop *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation.*

This volume summarizes the presentations and discussions from the workshop. These explore the meaning of value in health care from a variety of perspectives, present methods to measure value, and describe ways to give value-enhancing incentives to the provider, consumer, manufacturer, payer, and other stakeholders in the healthcare system. The insights and ideas shared in this volume are germane to the healthcare reform efforts

currently ongoing in this country and, specifically, can help achieve the dual goals of controlling healthcare expenditures and improving health outcomes.

I would like to offer my thanks to the members of the Roundtable who champion better health for Americans, to the Roundtable staff who coordinate and enable Roundtable activities, and to the sponsors who support this vital activity: the Agency for Healthcare Research and Quality, America's Health Insurance Plans, AstraZeneca, Blue Shield of California Foundation, Burroughs Wellcome Fund, California Health Care Foundation, Centers for Medicare and Medicaid Services, Department of Veterans Affairs, Food and Drug Administration, Johnson & Johnson, the Moore Foundation, the National Institutes of Health, sanofi-aventis, and Stryker.

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

Preface

Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation summarizes a two-day workshop held in November 2008, convened by the Institute of Medicine (IOM) Roundtable on Value & Science-Driven Health Care as part of its Learning Healthcare System workshop series. While the purpose of the workshop was not to yield a single definition of value, and, as a result, no single consistent definition of value was identified by the participants, this meeting did provide a forum for the broad spectrum of stakeholders in health to discuss the range of issues relevant to defining, assessing, and measuring the benefits received from our healthcare investments. This collection of papers and insights reflect the serious, reflective engagement of patients, providers, manufacturers, economists, payers, and employers—from both public and private sectors—in the central issues of value in health care. Participants discussed issues such as the mandate for improving value given rising expenditures on health care and the turbulent economic climate; the importance of perspective when defining value; the importance of communication between all involved stakeholders—but especially between patients, consumers, and providers—in order to improve outcomes while reducing costs; the tools available to incentivize value creation, including pay-for-performance, value-based insurance design, and electronic health records; and the opportunities and barriers for implementation and change.

The vision of the IOM Roundtable on Value & Science-Driven Health Care is to help foster the development of a *learning healthcare system*—a system in which the processes and information systems used throughout health care engineer both the natural delivery of best care practices and the

real-time generation of new evidence. With the engagement and support of senior leadership from the nation's key healthcare sectors, the work of the Roundtable has advanced this vision through concerted efforts, including public workshops and published proceedings. The focus of this workshop emerged from prior discussions among Roundtable members and participants which highlighted the nation's lagging outcomes despite increasing expenditures on health—concerns which have only been underscored as the nation continues to battle economic turmoil. This workshop provided a forum for stakeholders to discuss their perspectives on value, discover areas of difference and commonality, and identify topics for further discussion and collaboration. As described in the Summary, a number of fundamental ideas about the impetus for change as well as the challenges, considerations, and opportunities paramount to achieving value emerged.

The workshop discussions made clear the belief in a compelling and urgent mandate to achieve greater value in health care. Yet participants also quickly identified the lack of a uniform definition of value to guide progress while also underscoring the importance of perspective, as value holds different meaning to different stakeholders. Challenges such as the fragmentation of the current service delivery system, a payment system that rewards volume over outcomes, and the lack of communication between patients, consumers, providers, and payers impede progress in targeting services to those most likely to benefit. Despite these challenges, participants seized the opportunity to explore utilization of existing efforts in the field. Presenters explored measurement tools in a variety of facets and specialties of medicine. Discussions focused on the possibilities of utilizing current tools such as health information technology, payment and reimbursement incentives, and organizational structures such as the medical home model as mechanisms for change. A clear concern was the preservation of incentives for innovation and the need to maintain a central focus on the patient as we proceed down the path towards value. The workshop also laid out a number opportunities and challenges requiring the attention and action of stakeholders such as those represented on the Roundtable, including the development of a comprehensive, coordinated system-wide approach to assess and improve the value of health care. The Roundtable will follow this workshop with deeper consideration of many of the highlighted issues through future workshops, commissioned papers, collaborative activities, and public communication efforts. While the challenges are significant, many opportunities exist for the committed members of Roundtable.

Multiple individuals and organizations donated their valuable time toward the development of this workshop summary. In particular, we would like to acknowledge the contributors to this volume for the insights they provided at the workshop as well as their efforts to develop their presentations into the manuscripts included in this summary publication.

In this regard, we should emphasize that this summary is an assemblage of individually authored papers and is intended to convey only the views and beliefs of those participating in the workshop, not the express opinions of the Roundtable on Evidence-Based Medicine, its sponsors, or the Institute of Medicine. We would also like to acknowledge the counsel and efforts of the Planning Committee for this workshop, including Michael E. Chernew (Harvard Medical School), Ezekiel J. Emanuel (National Institutes of Health), Arthur Garson, Jr. (University of Virginia School of Medicine), Samuel R. Nussbaum (Wellpoint), John C. Rother (AARP), and Karen Smith (AstraZeneca). A number of IOM staff were instrumental in coordinating the two-day workshop, including Mark Peterson and Adam Schickedanz. Roundtable staff, including Pierre Yong, Kate Sharaf, LeighAnne Olsen, Catherine Zweig, Kate Vasconi, Ruth Strommen, Kiran Gupta, Jane Fredell, and Daniel O'Neill, helped to translate the workshop proceedings and discussion into this summary. Florence Poillon also contributed substantially to publication development. We would also like to thank Jackie Turner, Vilija Teel, Bronwyn Schrecker Jamrok, and Jordan Wyndelts for helping to coordinate the various aspects of review, production, and publication.

The issue of value looms only larger as we proceed into the twenty-first century. While progress has been made in recognizing the need to improve the clinical outcomes obtained for dollars spent on health care, further efforts need to be devoted to engender value as reality. We look forward to continuing the conversations started during this workshop, learning from its insights, and further contributing to the vision of *The Learning Healthcare System*.

Denis A. Cortese, M.D.
Chair, Roundtable on Value & Science-Driven Health Care

J. Michael McGinnis, M.D., M.P.P.
Executive Director, Roundtable on Value & Science-Driven Health Care

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Summary

The United States has the highest per capita spending on health care of any industrialized nation—50 percent greater than the second highest and twice as high as the average for Europe (Peterson and Burton, 2009). Current U.S. healthcare costs are projected at nearly $2.5 trillion, about 17 percent of the entire economy (Sisko et al., 2009). The Congressional Budget Office estimated that Medicare and Medicaid alone will account for nearly a quarter of the economy by 2050 if healthcare costs grow at just 2 percent more than GDP per capita each year (Congressional Budget Office, 2007). At these levels of spending, healthcare expenditures have begun to restrict the ability of federal and state governments to fund other priorities such as education (White House, 2009).

Yet despite the unprecedented levels of spending, harmful medical errors abound (IOM, 2000), uncoordinated care continues to frustrate patients and providers, and U.S. healthcare costs continue to increase (Sisko et al., 2009). With the growing ranks of the uninsured, the nation faces significant social costs, with lost productivity and increasing disparities in health outcomes (IOM, 2003). An aging population with a higher prevalence of chronic diseases and many patients with multiple conditions together constitute another complicating factor in the trend to higher costs of care (Martini et al., 2007; Meara et al., 2004; Strunk and Ginsburg, 2002).

The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by Roundtable staff as a factual summary of what occurred at the workshop.

It has been estimated that 20-30 percent of expenditures dedicated to health care employ either over-, under-, or misutilization of medical treatments and technologies, relative to the evidence of their effectiveness (Skinner et al., 2005). Despite 60 percent more frequent physician visits, testing, procedures, and use of specialists and hospitals in high-spending areas in the United States, no differences in quality result (Fisher et al., 2003). Perhaps up to two-thirds of spending increases in recent years have been due to the emergence of new medical technologies that may yield marginal enhancement of outcome or may benefit only a small number of patients (Cutler, 1995; Newhouse, 1992; Smith et al., 2000). All of these findings raise basic questions about the orientation and incentives of health-care training, financing, and delivery.

A variety of strategies are beginning to be employed throughout the health system to address the central issue of value, with the goal of improving the net ratio of benefits obtained per dollar spent on health care. These approaches, ranging from value-based payment design to improved systems of care delivery, have garnered growing attention in the midst of the national and international economic crisis. However, despite the obvious need, no single agreed-upon measure of value or comprehensive, coordinated system-wide approach to assess and improve the value of health care exists. Without this definition and approach, the path to achieving greater value will be characterized by encumbrance rather than progress (Leavitt, 2008; Paulus et al., 2008).

ABOUT THE WORKSHOP

To address the issues central to defining, measuring, and improving value in health care, the Institute of Medicine (IOM) Roundtable on Value & Science-Driven Health Care convened a workshop entitled "Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation" in November 2008 at the National Academies in Washington, DC. This workshop was part of the Learning Healthcare System workshop series and aimed to assemble prominent authorities on healthcare value and leaders of the patient, payer, provider, employer, manufacturer, government, health policy, economics, technology assessment, informatics, health services research, and health professions communities. In this context, the IOM provided a forum for the discussion of stakeholder perspectives on measuring and improving value in health care, identifying the key barriers, and outlining the opportunities for next steps. The first day of the workshop focused on illuminating stakeholder perspectives on health care and describing approaches to defining and measuring value. The second day highlighted a number of different approaches to obtaining value in both the present and the future. The workshop agenda is provided in Appen-

dix A, speaker biosketches appear in Appendix B, and a listing of workshop participants can be found in Appendix C. The following synopsis briefly highlights the common themes that arose during the workshop as well as summaries of each presentation.

COMMON THEMES

During the workshop discussions, a number of converging issues emerged. These common themes explored the exigency and facets of the value proposition in health care, the diversity of perspectives on value, and the possibility of implementation and change. Themes touching on the need to improve value and the elements that have to be addressed in achieving this goal included the following:

- **Urgency:** *The urgency to achieve greater value from health care is clear and compelling.* The persistent growth in healthcare costs at a rate greater than inflation is squeezing out employer healthcare coverage, adding to the uninsured, and doubling out-of-pocket payments—all without producing commensurate health improvements. We have heard that perhaps one-third to one-half of health expenditures are unnecessary for targeted health outcomes. The long-term consequences for federal budget obligations driven by the growth in Medicare costs have been described as nearly unfathomable, amounting to an estimated $34 trillion in unfunded obligations, about two-thirds of the total of $53 trillion as yet unfunded for all mandatory federal entitlements (including Social Security and other civilian and military benefits).
- **Perceptions:** *Value means different things to different stakeholders, so clarity of concepts is key.* We have heard that for patients, perceived value in health care is often described in terms of the quality of their relationship with their physician. It has been highlighted that value improvement means helping them better meet their personal goals or living lives that are as normal as possible. It does *not* necessarily mean more services or more expensive services, since it was stated patients are more likely driven by sensitivity to the value of time and ensuring that out-of-pocket payments are targeted to their goals. Provider representatives suggest that value improvement means developing diagnostic and treatment tools and approaches that offer them increased confidence in the effectiveness of the services they offer. Employers discuss value improvement in terms of keeping workers and their families healthier and more productive at lower costs. Health insurers assert that value improvement means emphasizing interventions that are crisply and

coherently defined and supported by a high level of evidence as to effectiveness and efficiency. Representatives from health product innovators and manufacturers have spoken of value improvement as products that are better for the individual patient, are more profitable, and contribute to product differentiation and innovation.

- **Elements:** *Identifying value in health care is more than simply the right care for the right price as it requires determination of the additional elements of the applicability and circumstances of the benefits considered*. We have heard that value in any endeavor is a reflection of what we gain relative to what we put in, and in health care, what is gained from any given diagnostic or treatment intervention will vary by individual. Participants believe that value determination begins with learning the benefits—what works best, for whom, and under what circumstances—as applied to individuals because value is not inherent to any service but rather specific to the individual. Value determination also means determining the right price, and we heard that, from the demand side, the right price is a function of perspective—societal, payer, and patient. From the supply side, the right price is a function of the cost of production, the cost of delivery, and the incentive to innovation.
- **Basics:** *Improving value requires reliable information, sound decision principles, and appropriate incentives*. Since the starting point for determining value is reliable information, workshop discussants underscored the importance of appropriate investment in the infrastructure and processes for initial determination and continuous improvement of insights on the safety, efficacy, effectiveness, and comparative effectiveness of interventions. Action to improve value, then, also requires the fashioning and use of sound decision principles tailored to the circumstances and adequate incentives to promote the desired outcome.
- **Decisions:** *Sound decision principles center on the patient, evidence, context, transparency, and learning*. Currently, decision rules seem to many stakeholders to be vague and poorly tailored to the evidence. Workshop participants contended that the starting point for tailoring decisions to circumstances is with information on costs, outcomes, and strength of the information. They also discussed assessing value at the societal level using best available information and analytics to generate broad perspective and guidance for decision making on availability, use, and pricing. Yet we also heard that value assessment at the individual patient level takes account of context and patient preferences, conditioned on openness of information exchange and formal learning from choices made under uncertainty. We also heard that an informed

patient perspective that trumps a societal value determination can still be consistent with sound decision principles.

- **Information:** *Information reliability derives from its sources, methods, transparency, interpretation, and clarity.* We have heard about the importance of openness on the nature, strengths, and limitations of the evidence and the processes of analysis and interpretation—and of tailoring decision principles according to the features in that respect. 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 are paramount.
- **Incentives:** *Appropriate incentives direct attention and rewards to outcomes, quality, and cost.* Often noted in the workshop discussions was that the rewards and incentives prevalent in the American healthcare system are poorly aligned—and even oppositional—to effectiveness and efficiency, encouraging care that is procedure- and specialty-intensive and discouraging primary care and prevention. We heard that if emphases are placed on individual services that are often high cost and inadequately justified, rather than on outcomes, quality, and efficiency, the attainment of system-wide value is virtually precluded.
- **Limits:** *The ability to attain system value is likely inversely related to the level of system fragmentation.* Transforming health care to a more direct focus on value is frequently noted as an effort that requires broad organizational, financial, and cultural changes—changes ultimately not attainable with the level of fragmentation that currently characterizes decision making in the U.S. healthcare system. 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:** *System-level value improvement requires more seamless communication among components.* Related to system fragmentation, among the primary barriers to achieving better value are the communication gaps noted among virtually all parties involved. Patients and providers do not communicate well with each other about diagnosis and treatment options or cost implications, in part because in complex administrative and rapidly changing knowledge environments, the necessary information is not readily available to either party. Communication, voice or electronic, is often virtually absent between and among multiple providers and provider systems

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. Accordingly, communication between the many groups involved in developing evidence and the practitioners applying it is often unstructured and may be conflicting.

The diversity of stakeholder perspectives on value was highlighted from multiple vantage points.

- **Providers:** *Provider-level value improvement efforts depend on culture and rewards focused on outcomes.* Workshop presentations identified several examples of some encouraging results from various programs in terms of progress to improve provider sensitivity to, and focus on, value from health care. These range from improving the analytic tools to evaluate the effectiveness and efficiency of individual providers, institutions, and interventions, to incentive programs such as pay-for-performance, the patient-centered medical home, and employer-based programs for wellness, disease prevention, and disease management. We heard, for example, that certain provider organizations, in effect, specialize in the care of the poorest and sickest patients and can provide services that in fact have better outcomes and lower costs because they are geared to focus on interprovider communication, continuity of care, and links with social welfare organizations. However, they have also negotiated the necessary flexibility with payers. 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 (both an analytic and a structural issue) 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:** *Patient-level value improvement stems from quality, communication, information, and transparency.* It was noted that patients most often think of value in terms of their relationship with their provider—generally a physician—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—individual diagnostics and treatments, providers, or health

plans—according to the evidence of the value delivered. Successful broad-based application of such approaches will likely hinge on system-wide transformation in the availability of the information necessary and transparency as to its use.

- **Manufacturers:** *Manufacturer-level regulatory and purchasing incentives can be better oriented to value added.* Health product manufacturers and innovators naturally focus on their profitability—returning value to shareholders—but we are reminded that product demand is embedded in the ability to demonstrate advantage with respect to patient value—better outcomes with greater efficiency. Hence, manufacturers expressed an interest in exploring regulatory and payment approaches that enhance performance on outcomes related to product use.

The possibility of change, including the tools and opportunities needed to capitalize on the possibilities, is also a continual theme throughout the report.

- **Tools:** *Continually improving value requires better tools to assess both costs and benefits in health care.* Despite the broad agreement on the need to get better value from all the elements of the healthcare process and the commitment to make this a priority, we heard that the analytical tools and capacity to evaluate both of the basic elements of value—outcomes and costs—in either absolute or comparative terms are substantially underdeveloped and will need greater attention.
- **Opportunities:** *Health system reform is essential to improve value returned, but steps can be taken now.* 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. Some are noted below.

PRESENTATION SUMMARIES

Each presentation at the workshop, including panel discussions, is briefly summarized below.

The Need to Improve Value in Health Care

David M. Walker of the Peter G. Peterson Foundation opened the workshop with a keynote address. Speaking of the key challenges facing the U.S. healthcare system in terms of costs, performance, and value, he highlighted the $53 trillion of debt for unfunded promises for Social Security

and Medicare (Social Security and Medicare Boards of Trustees, 2008). He further discussed the implications of U.S. healthcare costs for the economic crisis, the nation's ability to recover, and the welfare of the American people, before concluding by elaborating on four objectives that should be cornerstones of health reform as we look toward the future: (1) universal coverage for basic and essential health care that meets societal needs, not unlimited individual wants; (2) a defined budget for federal healthcare expenditures that sets limits on spending; (3) the establishment of national evidence-based standards for the practice of medicine and the issuance of prescription drugs in order to improve consistency, enhance quality, reduce costs, and dramatically reduce litigation; and (4) enhanced personal responsibility and accountability for health and wellness.

Perspectives on Value

Drawing on stakeholder comments on value in health care presented at the IOM Roundtable on Value & Science-Driven Health Care meeting in September 2008, a panel of representatives from various sectors of the healthcare enterprise further expanded on sectoral perspectives on value in health care. Seeking to understand the meaning of value and the approaches to assessment among different groups, the panel gathered representatives from patient, provider, economic, health product and device manufacturer, payer, and employer perspectives. Identifying priority issues to be resolved in developing and refining approaches to establishing and improving value, the participants emphasized the importance of perspective, underscoring that value has a different meaning depending on the stakeholder. In contrast to the aggregate view of value adopted by the economists on the panel, patient representatives keenly identified with the ability of health care to help them obtain maximal health and productivity. Employer panelists discussed the value of healthy workers as well as healthy communities. Provider discussants considered value in terms of appropriateness of care rather than cost controls, while payer representatives oriented themselves around the delivery of effective, evidence-based interventions that improve patient outcomes. Meanwhile, manufacturing representatives spoke of the value of innovation and the need to preserve incentives that stimulate creativity and the improvement of health.

Approaches to Assessing Value—Illustrative Examples

Physician Evaluation and Management Services

Measurement of value in health care has become an increasingly important goal given assessments of both questionable benefit and high cost in the United States. However, value can be very difficult to define in a way

that can be measured practically, especially in a field such as health care where neither the benefits nor the resources used to create them are easily defined, stated L. Gregory Pawlson of the National Committee on Quality Assurance. The concept of "measurable clinical efficiency" examines the relationship of composite quality measures as a proxy for benefit and resource use measures, employing standardized prices as the cost function. Quality measures include clinical structure, process and outcome measures of overuse, underuse, and misuse, and patient experiences of care—each with barriers and problems to implementation and use, he asserted. Pawlson said that resource use could be measured either by using episodes delineated by "clean claims periods" and sorting costs into those episodes or by looking at total costs for all services for a defined group of patients for a defined period of time, each approach with its pros and cons. Transparency and problems with reliability of measurement hinder resource use measurement, he continued. Measurable clinical efficiency can then be defined by combining composites of quality with resource use-cost measures in the same population of patients displayed in various combinations (ratios, scatter plots, etc.). The choice of what level (individual clinicians, sites, groups, integrated delivery systems, health plans) of the healthcare system to attribute measures of quality and resource use is also a major challenge with important trade-offs. Finally, Pawlson stated that research to explore the relationships between quality and cost and the elements of the system that affect these measures is critical, as is setting reasonable "rules" and standards for fairness and accuracy of measurement.

Surgery and Other Procedures

Justin B. Dimick of the University of Michigan considered the value of surgical care from two perspectives. The first considered the effectiveness of surgery, relative to other approaches, for treating medical conditions. He stated that value assessment in this context is the domain of evidence-based medicine, where comparative effectiveness is assessed by critical evaluation of randomized clinical trials and observational studies. Ensuring that patients receive surgery only when the evidence indicates the benefit outweighs the risk clearly improves patient value, he said. The second perspective is motivated by the widespread variations in quality and costs across providers. Dimick stated that value assessment in this context—provider profiling—is particularly timely and is the focus of several public reporting and value-based purchasing efforts. Eliminating variations across providers would undoubtedly lead to large gains in patient value, he asserted. However, for these efforts to be successful, good measures of quality and cost are needed. Dimick suggested that good measures of surgical quality are close on the horizon. For some conditions, good measures are already available and are being applied, he continued. Although good measures of cost are

not currently available, there is a growing body of evidence showing that quality and costs are related. Thus, ensuring high-quality care will also lead to lower-cost care. Finally, Dimick concluded that despite a growing emphasis on profiling the technical quality of surgery, there is very little focus on the decision to perform surgery in the first place. To fully assess the value of providers, it will be important to incorporate appropriateness criteria into provider profiling.

Imaging Technologies

Diagnostic imaging spending has exceeded overall healthcare expenditure growth, straining public (primarily Medicare) and private (primarily employer-sponsored health benefits) sector contributions to healthcare delivery. Howard P. Forman of Yale University suggested that value to the beneficiary has been measured in terms of cost-effectiveness for a very small proportion of total imaging. Further, "indication creep" results in a broader application of these services than originally tested (resulting in a lower relative cost-effectiveness than supported in the literature), he stated. Even in situations where imaging is proven *not* cost-effective (or not effective at all), private and public payers have had a difficult time limiting its application (e.g., lumbar spine imaging, knee magnetic resonance imaging). Forman said that value to the referring clinician has only peripherally been explored and never explicitly been measured. Whether due to defensive medicine (e.g., ordering a marginal study in order to increase certainty) or pecuniary motivations (e.g., doing an imaging test in lieu of a more extensive physical examination), the relative contribution of physician (as opposed to patient) derived value represents a confounding variable in efforts to use more consumer-directed solutions. He concluded that further research and demonstration projects may be necessary to better assess the role of gain sharing or global payments for imaging delivery in the inpatient, outpatient, and emergency room settings.

Preventive Services and Wellness

David O. Meltzer of the University of Chicago stated that prevention is an important contributor to improvements in population health. Prevention can also sometimes avert the need for costly future medical treatments, causing some to focus on prevention as a potential mechanism to control healthcare costs, he continued. This presentation reviewed the use of medical cost-effectiveness analysis to address these questions. Meltzer suggested that although prevention can be, but is not always, a cost-effective approach to improving health, it is infrequently a powerful approach to controlling healthcare costs, either in the short term or in the long term.

He concluded that, moreover, the value of prevention can be influenced profoundly by the context in which it is used, with patient preferences and other characteristics often playing a major role in its value.

Pharmaceuticals and Biologicals

Newell E. McElwee of Pfizer, Inc., suggested that value has been defined as "the benefit relative to the cost." However clear this definition may seem, value has different meanings to different people. McElwee stated that assessment or appraisal of the value of healthcare technology varies greatly depending on what decision is being made, who the decision makers (stakeholders) are, what the stakeholders' preferences are, whether the focus is on clinical or economic value, and many other factors such as unmet medical need and the strength of the evidence supporting the value proposition. He discussed how one framework views value in the context of specific decisions and their respective stakeholders. Descriptions of several key decisions during the life cycle of a healthcare technology illustrated how value is considered in decision making, including the early-phase investment decision by the technology developer, the marketing approval decision by the regulatory agency, the adoption or diffusion decision by the payer, and the individual treatment decision by the patient and the physician.

Personalized Diagnostics

As a result of the growth of molecular diagnostics, a tremendous wealth of information has been gained about the molecular characteristics of the human genome, according to Ronald E. Aubert of Medco Health Solutions, Inc. In the past few years, we have also gained a clearer understanding of the functional aspects of the genome. Aubert explained the concept underlying pharmacogenomics (PGx)—that the response to drug therapy varies, in part due to genetic variation. This interaction between genetics and drug therapy allows us to understand how drugs may work more effectively or safely. This presentation reviewed the use of PGx testing and its potential to help physicians and patients achieve more predictable and better outcomes. Given the potential benefits and increasing use of PGx testing, Aubert concluded that careful consideration should be given to the evaluation of testing strategies, including the determination of overall value.

Devices

The clinical and economic evaluation of medical device interventions varies greatly across the spectrum of existing devices. While therapeutic devices achieve many of the same effects as surgical procedures, Parashar B. Patel of

Boston Scientific Corp. discussed how the standards used in device evaluation appear to be becoming more similar to those used in evaluating pharmaceuticals. Although devices have a faster cycle of innovation than drugs, their rates of adoption and short-term economic impacts are slower, and the evaluation approach should differ accordingly, asserted Patel. New device interventions are typically studied and reserved for use in small, highly refractory patient populations after other treatment options have failed. Early life-cycle device evaluations thus focus on clinical safety and effectiveness from societal, payer, and facility perspectives. While many models have been produced to estimate the economic value of device interventions, it is still uncommon to conduct comprehensive economic evaluations for devices, stated Patel. These are typically reserved for a later stage when there is potential for broader adoption and expansion of patient indications, and head-to-head comparisons with alternative treatments are desired and more practical. This presentation discussed measurement of the value of device interventions and its unique challenges, including difficulties with randomization and blinding, methods of comparing different treatment modalities, and accurately assessing economic value in the face of rapid technological and procedural improvements. Given these challenges, measuring and comparing the value of therapies across treatment modalities can be difficult. Patel concluded that a key challenge facing patients, clinicians, payers, and other decision makers in the age of "comparative effectiveness" will be to develop and interpret value measurements in the appropriate contexts without creating longer development time lines with fewer, but more expensive, technologies and fewer choices for patients.

Approaches to Improving Value

The next set of speakers presented specific examples of current approaches to improve value in health care in three main areas: (1) consumer incentives; (2) provider and manufacturer payments; and (3) the organization and structure of care, respectively. Each session explored the nature of the efforts, and the best practices and results to date. Speakers focused particularly on the evidence of impact and the future potential to improve value with each approach.

Consumer Incentives

The first session focused on the use of a variety of consumer-oriented strategies to promote value.

Value-based insurance design A. Mark Fendrick of the University of Michigan suggested that healthcare reform discussions increasingly focus on

how escalating medical costs impact multiple stakeholders. Unfortunately, value—the clinical benefit achieved for the money spent—is frequently excluded from the dialogue on how to solve the healthcare dilemma, he added. Instead, the dialogue focuses on two trends—quality improvement and cost containment. Fendrick asserted that efforts to lower costs such as increasing premiums or increased copays can create financial barriers that discourage the use of recommended services and the overuse of interventions that are of questionable benefit. Patient copayments for services designated as quality indicators have risen dramatically and at the same rate as less valued services. Fendrick stated that this is a concern because studies show that patients who are required to pay more for their health care buy less—of essential and excessive therapies alike. He described how value-based insurance design (VBID) offers a potential incremental solution to enhance efficiency in healthcare spending. VBID programs adjust patients' out-of-pocket costs for health services according to an assessment of the clinical benefit to the individual patient, based on population studies. The basic VBID premise is that patient contributions for high-value services remain low, mitigating the concern that higher cost sharing will lead to deleterious clinical outcomes. Higher cost sharing will apply to interventions with little or no proven benefit. This presentation reviewed examples of VBID programs that encourage the use of high-quality services and demonstrate significant increases in patient compliance. The net financial impact of copayment relief on healthcare spending and nonmedical expenditures remains unclear, stated Fendrick. This presentation concluded that efforts to control costs should not lead to preventable reductions in quality of care. Fendrick suggested that payers desiring to optimize health gains per dollar spent should avoid "across-the-board" cost sharing and instead implement a "value-based" design that removes barriers or provides incentives to encourage desired behaviors on the part of patients and providers. By aligning financial incentives, he asserted, this strategy would encourage the use of high-value care while discouraging the use of low-value or unproven services and ultimately would produce more health at any level of healthcare expenditure.

Consumer-directed, high-deductible health plans Melinda Beeuwkes-Buntin of RAND discussed the experience with and the potential for improving value through consumer-directed, high-deductible health plans (CDHPs). Starting with the RAND Health Insurance Experiment and then discussing the newer literature on the effects of evolving "consumer-directed" plan designs on cost, access to care, and ultimate health outcomes, gaps in the literature were identified. Buntin stated that CDHPs should be shaped to increase value by promoting the collection and dissemination of information about the cost and quality of care. Additionally, the value of CDHPs could

be increased through the dissemination and deployment of "best practices" in CDHP design, as well as increased research about the effects of different CDHP designs on care use and outcomes. Building on this overview, conclusions for policy and practice were offered.

Tiering One approach to steering consumers and patients toward the use of high-value healthcare services and health providers is "tiering." Broadly defined, tiering refers to the classification of healthcare providers (e.g., hospitals, physicians), pharmaceuticals, and treatments or therapies based on objective or subjective criteria such as cost, quality, and value. Dennis P. Scanlon of Pennsylvania State University described how tiering systems typically allow the patient or consumer to select a provider, service, or therapy in any tier, with the required out-of-pocket cost to the consumer or patient varying based on the tier selected. Most tiering programs provide some information about the criteria used to define the tiers, though to varying degrees of detail. By providing better coverage (i.e., lower out-of-pocket costs) for better-value providers through the use of financial incentives (e.g., reduced coinsurance, copayments, or deductibles), proponents argue that tiering is an efficient way of using consumer incentives to improve value in the healthcare system. This presentation examined the research evidence for tiering programs in health care, and several examples of tiering programs were provided. One example discussed in detail is a hospital tiering program, called the hospital safety incentive (HSI), implemented by a large midwestern employer. Under the HSI, eligible employees and their beneficiaries associated with two union groups were required to pay hospital coinsurance, set at 5 percent of total approved hospital charges, up to an annual out-of-pocket maximum. However, the coinsurance was waived (i.e., no coinsurance was charged) if employees received care at a hospital that met certain patient safety standards. Salaried non-union employees and their beneficiaries were not eligible for the HSI and served as a control group in the analysis. The results indicated that the HSI influenced the selection of hospital for one of the two union groups—beneficiaries admitted to the hospital with a medical diagnosis. Specifically, beneficiaries in this category were 2.92 times more likely to choose a hospital that qualified for the HSI after the incentive took effect (versus before it took effect). These beneficiaries were also significantly more likely to choose a hospital that qualified for the HSI relative to the control group as a result of the incentive. The presentation ended with a discussion of the key policy issues associated with tiering programs in health care.

Wellness Ronald Z. Goetzel of Emory University suggested that the scientific evidence is mounting that worksite health promotion and chronic disease prevention programs can reduce health risks and produce a posi-

tive return on investment (ROI) for employers. However, challenges arise in designing and implementing effective programs that achieve the best results, documenting program achievements so that scientists and lay people can readily understand and accept research findings, and communicating results to the broad healthcare community. This presentation discussed those challenges with particular emphasis on how to disseminate timely information to the business community. Goetzel highlighted examples of large-scale research studies previously conducted and those currently under way that are supported by federal and private sector grants. For example, in a project funded by the National Heart, Lung, and Blood Institute, several research organizations are working with employers to design, implement, and evaluate an environmental and ecological intervention program aimed at preventing and managing overweight and obesity in the workplace. A study at the Dow Chemical Company evaluated program impacts on key outcome measures, including trends in body mass index and other weight-related biometric measures, behavioral health risk factors, weight-related health conditions, healthcare utilization and medical expenditures, employee productivity measured in terms of absenteeism and on-the-job "presenteeism," and ROI. Other worksite studies funded by the Centers for Disease Control and Prevention (CDC) are looking at the effectiveness of employer-based programs. One specific initiative is testing a private-public partnership between the New York City Department of Health and Mental Hygiene's Wellness at Work Program and several New York City employers. Another major initiative by the CDC is focused on developing Health and Productivity Management benchmarks and best practices that emphasize the employer's role in promoting the health and well-being of workers. In addition to discussing how workplace wellness programs can serve as vehicles for health behavior change, recommendations to increase employer engagement in providing evidence-based health promotion programs to their employees were offered.

Provider and Manufacturer Payments

This session explored examples of approaches to improve value in health care, with a focus on the use of payment design and coverage and reimbursement policy to improve value.

Pay-for-performance Although the current healthcare financing system encourages the provision of more care, it does little to ensure that individuals receive appropriate care or that the care they receive is effectively or efficiently provided, asserted Carolyn M. Clancy of the Agency for Healthcare Research and Quality. She discussed how, in recent years, payers have implemented an array of strategies aimed at using financial incentives

to promote higher-quality care, with the expectation that this will lead to a better return on their spending. She suggested that although some research is being done on the alignment of payment incentives with quality, critical gaps in our collective knowledge exist. These gaps include evidence related to the impact of payment mechanisms that reward healthcare providers for improving quality and evidence on financial incentives aimed at rewarding patients for choosing high-quality providers. This presentation addressed the issues of what we know and do not know about performance-based value and reaching a stage where people are paying for value and collecting data in ways that address the potential benefits for all stakeholders.

Incentives for product innovation Donald A. Sawyer of AstraZeneca LP spoke from the industry perspective and addressed incentives for product innovation and the benefits of moving toward a healthcare system that puts patients' health first and focuses on health outcomes across the full continuum of patient care. He began with an overview of the facts and figures behind pharmaceutical research and development. He stated that innovative medicines are an important part of the solution to chronic disease and controlling healthcare costs. However, he added that the value of innovative therapies is often not realized by current incentive structures (e.g., Physician Quality Reporting Initiative). Sawyer also discussed the need to change current budget and contracting processes with payers by the use of specific examples. The presentation concluded with options to recognize the long-term value of a product to patient health while maintaining an environment that rewards and encourages innovation for lifesaving medicines.

Reed V. Tuckson from UnitedHealth Group, representing the payer perspective, stated that the nation has an impressive history of stimulating and translating innovation in health and medical care that has led to demonstrable improvements in relief of suffering, enhanced longevity, and reductions in mortality. As new knowledge, pharmaceuticals, and technologies become available, he asserted, it is essential that the science, infrastructures, and processes that inform their translation into practice be responsive and robust. The context of unsustainable healthcare costs and related rates of uninsured people, unacceptable deviation of care delivery from evidence-based standards, inappropriate use of expensive healthcare assets, and safety concerns exert significant pressure on all stakeholders to make responsible choices regarding the incorporation of new healthcare assets. Health plans, given their responsibility to organize affordable access to healthcare services on behalf of consumers and their desire to work with care providers to improve quality and appropriateness in care delivery, have special opportunities and responsibilities in this regard, continued Tuckson. He additionally explored some of the perspectives, tools, and requirements necessary to advance responsible use of new innovations in service to the American people.

Coverage and reimbursement decisions Steven D. Pearson of the Institute for Clinical and Economic Review suggested that coverage and reimbursement policies are among the most visible tools by which public and private payers in the United States seek to enhance the value of healthcare delivery. He stated that consideration of payers' approaches must begin with an understanding of the opportunities and barriers presented by the language of statutes or contracts that set the legal context for medical policy decisions. He stated that another element considers how payers use evidence, both scientific and contextual, for distinguishing among healthcare interventions. Pearson added that the final component considers the set of medical policy "tools"—including benefit design, coding, provider contracting, and reimbursement models—with which payers can modulate the use of healthcare services. Pearson's presentation analyzed the experience to date with recent innovations in coverage and reimbursement policies by Medicare, state governments, and private payers. These innovations are extremely diverse and include the "medical home," bundling of billing codes, new forms of tiering copayments and coinsurance, explicit use of cost-effectiveness information, and various risk-sharing agreements with manufacturers. Several specific examples were discussed in detail, and three overarching goals among these efforts were highlighted: (1) the use of best existing evidence at the time of initial coverage and reimbursement to "sculpt" the use of new medical interventions, targeting only those patients for whom the benefits are best known; (2) the alignment of financial incentives and payments to support appropriate use; and (3) the exploration of new ways to link coverage and reimbursement to the development and evaluation of better evidence on the value of medical interventions for different types of patients.

Organization and Structure of Care

This final session on approaches to improving value focused on changing the organization and structure of care to improve value.

Electronic health records Focusing on the definitions and evidence on the value of electronic health records (EHRs), Douglas Johnston from the Center for IT Leadership discussed the central issues associated with measuring and realizing this value. To help frame the review of evidence on EHR value, he started by defining the types of value that widespread adoption of EHRs might produce, and reviewed basic and advanced EHR functions within the context of healthcare information technology. Johnston examined selected empirical evidence of the quality, safety, and financial impact and costs of EHRs, considering examples from case studies and the peer-reviewed literature. Projections of potential EHR value based on this evidence were reviewed, as were other areas of possible value for which no evidence is currently avail-

able. The session concluded with an overview of some of the issues associated with EHR value measurement and realization, including the current state of EHR adoption, development of valid measures, definition of best practices, unintended consequences of EHR use, misalignment of incentives, access to capital, and the development of data standards.

Patient-centered medical home Arnold Milstein from the Pacific Business Group on Health posited that if medical homes deliver better quality without increasing total healthcare spending, they will generate social benefit. Continuing, he argued that social benefit will also increase if medical homes shift physician payment toward primary care. However, for medical homes to profoundly benefit non-affluent adults who do not qualify for Medicaid and persuade most purchasers to pay higher medical home fees, they must also lower total near-term healthcare spending. To achieve such "home run" status, medical homes' design, certification standards, and criteria for reward from payers must explicitly incorporate features from existing primary care practices that achieve low total cost of care and favorable performance on other domains of quality, Milstein stated. His observation of four such practices suggested that these design features are likely to enhance, rather than conflict with, current principal medical home quality objectives of improved access, patient-centeredness, and effectiveness of care. He suggested that while medical homes cannot alone solve our healthcare affordability challenges, they can substantially reduce total near-term healthcare spending in addition to elevating the quality of care. Milstein stated that roughly 60 million uninsured and underinsured lower-income Americans need physician and health plan leaders to jointly pursue this higher aspiration for medical homes. Otherwise, their numbers and preventable health deterioration will continue to mount.

Disease management Tracey A. Moorhead of DMAA: The Care Continuum Alliance discussed how traditionally conceived "disease management" has evolved dramatically in recent years to improve clinical quality and value. Today, "population health improvement" addresses larger populations, places greater emphasis on wellness and health promotion, supports expanding healthcare teams and stakeholders, and adheres to new evaluation methodologies. The presentation outlined this evolution and highlighted case studies from both public and commercial populations that demonstrate the significant value of population health improvement.

Aligning the System—Now and in the Future

This concluding session discussed how the health system could be better aligned to promote value in all aspects of health care, both now

and in the future. Sir Michael Rawlins of the United Kingdom's National Institute for Health and Clinical Excellence highlighted four particular challenges in the consideration of value in health care: (1) the dearth of direct comparative effectiveness studies between interventions; (2) the limitations in applying the results from clinical trials to the real world; (3) the translation of clinical effectiveness into value; and (4) the complexities of drawing conclusions that are based, in part, on considerations of cost-effectiveness. Christine K. Cassel of the American Board of Internal Medicine considered the future in two dimensions: (1) anticipation of likely advances in medicine and (2) creation of a framework to understand the additive value of these advances in the important context of resource constraints and value trade-offs. In conclusion, a panel comprised of Ezekiel J. Emanuel from the National Institutes of Health, Samuel R. Nussbaum from Wellpoint, Inc., and John C. Rother from AARP closed the workshop by drawing together themes and conclusions from the meeting on how the health system could be aligned to promote value, in terms of both improvements that can be achieved within the existing system and the longer-term changes that need to be made. The panelists discussed the importance of health information technology in enabling changes in the healthcare system and the pivotal role that reliable, quality data will play in transforming the current system into a value-based system. Focusing on long-term goals, the panelists echoed previous presentations by highlighting the continued need to reorganize both the payment system to reward outcomes over volume and the clinical care delivery system to better facilitate management of chronic illnesses.

Next Steps

System-Level Efforts

Health information technology Since promoting health information technology was the most commonly mentioned priority as a prerequisite for sustained progress toward greater value in health care (improving quality, monitoring outcomes, clinical decision assistance, developing evidence, tracking costs, streamlining paperwork, improving coordination, facilitating patient engagement), how might Roundtable members and the Electronic Health Record Innovation Collaborative help accelerate its adoption and use?

Transparency as to cost, quality, and outcomes What efforts by the various sectors represented by Roundtable members—patients, providers, healthcare delivery organizations, insurers, employers, manufacturers, regulators, the information technology sector, and researchers—might help bring about the true transparency necessary to sharpen the focus on the key elements of the value equation?

Life-cycle evidence development for interventions How might Roundtable professional societies, manufacturers, insurers, and regulators help transform the process of monitoring the value achieved from various interventions from what amounts to a snapshot in time to an ongoing capacity?

Payer-Level Efforts

Coverage with evidence development If coverage with evidence development amounts to a beta-test of the learning healthcare system's concept of real-time evidence generation from clinical practice, what vehicle might facilitate development of the decision rules needed to determine the interventions most appropriate for structured introduction, the criteria for expansion, and the approaches to ongoing monitoring?

Value-based insurance design How might the conditions be identified that may be best suited to further testing the notion of adjusting payments to the level of evidence in support of the effectiveness and efficiency of a particular approach?

Outcome-focused bundled payment approaches What means might best be considered to identify conditions and services most amenable as bundled components in payment-for-outcomes approaches?

Value-based payment or reimbursement structures How might better information be developed for tailoring payment for care to the likely value of the outcome, and once available, what strategies will be most effective in developing the information and incentives necessary for its promotion?

Provider-Level Efforts

Identification of high-value services Might the members of the Roundtable's Best Practices Innovation Collaborative consider criteria for identifying high-value services in their respective arenas, as well as innovative approaches to their delivery?

Care organization incentives What issues and incentives are needed to expand the development of a medical home model most conducive to more efficient and better-coordinated care?

Clustered care for the very sick If, as was presented, there are demonstrated effectiveness and efficiency advantages from certain organizations specializing in the care of the poor and very sick, how can that model of heroism be taken to scale?

Incentives for triage and coordination functions Because the ancillary services of triage, care coordination, and follow-up are so key to improving outcomes and reducing costs, what can be done to introduce them as a routine into the culture of care?

Decision assistance at point of choice With growing awareness of the challenges to providers of keeping up with changes in the knowledge base, what might the Roundtable do to explore expanded decision assistance at the point of choice?

Appropriateness score for five important diseases Since five conditions—heart disease, cancer, stroke, diabetes, and chronic lung disease—account for three-fourths of health expenditures, can an appropriateness of care score be developed and applied for their management?

Patient-Level Efforts

"Push" strategies for patient-provider communication on value Since it is both necessary and inevitable that patients and providers become stronger partners in the care process, what strategies might be most effective in achieving that result?

Structured information-sharing on high-value services How might insights and information generated on services identified as high value be disseminated most effectively to help inform and motivate patients?

Manufacturer-Level Efforts

Purchasing models focused on outcomes Since it was proposed by a representative of the manufacturing sector that consideration be given to the development of product purchase models that focus on actual outcomes (i.e., results achieved), how might such an approach best be developed and tested?

Value-engaged regulatory approval processes What approaches might make it easier for manufacturers, payers, and the Food and Drug Administration to engage earlier in the testing and approval process around value issues relevant to a product's ultimate approval and use?

Research Analytics and Information Mobilization

High-value service gaps Because some high-value services—for example, certain preventive services—are underutilized, what criteria might be used to develop an inventory of the top 10 services for which the gaps between evidence in-hand and delivery patterns are most substantial?

High-cost service evidence Similarly how might an inventory be developed of the top 10 high-cost services for which comparative effectiveness studies need to be done?

Capacity for comparative effectiveness research What additional issues need to be engaged to improve prospects for the successful development of a deeper national capacity for comparative effectiveness research?

Analytics for value assessment What are the most important analytical challenges to assessing value and how might they best be engaged, especially with healthcare costs reaching near crisis levels in the context of a weak economy?

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The Need to Improve Value in Health Care

INTRODUCTION

Health care in the United States can, in certain circumstances, be the best in the world. Technology and innovation have allowed immense progress in clinical care. Yet, in this milieu of progress, U.S. per capita national health expenditures are far greater than those of any other country—50 percent higher than the second highest and twice as high as the average for Europe (Peterson and Burton, 2007). U.S. healthcare costs are projected at nearly $2.5 trillion, about 17 percent of the entire economy (Sisko et al., 2009), and the Congressional Budget Office estimated that Medicare and Medicaid alone will account for nearly a quarter of the economy by 2050 if healthcare costs grow at just 2 percent more than GDP per capita each year (Congressional Budget Office, 2007). Despite the amount of spending on health care, uncoordinated care has led to frustration for patients and providers, fostered an unacceptable level of harmful medical errors—many of which are serious (IOM, 2000), and resulted in overall national performance that ranks us below at least three dozen other countries on basic health parameters, despite our health spending (Peterson and Burton, 2007).

The challenges of improving health outcomes while curbing rising healthcare expenditures and maintaining incentives for innovation among providers, pharmaceutical and medical device manufacturers, insurers, and employers have become especially acute in the face of the current economic state of both the U.S. and the global economy. World financial markets have been thrown into a precarious state of instability, and the United States and many other countries are in a period of sustained recession. The

U.S. government has to contend with these challenges while also facing an aging population, many with multiple medical conditions (Martini et al., 2007; Meara et al., 2004; Strunk and Ginsburg, 2002), medical care entitlement payouts of unprecedented and unparalleled cost (Social Security and Medicare Boards of Trustees, 2008), and an underlying absence of a single agreed-upon measure of value in health care.

The need to enhance the value obtained from health care led the Institute of Medicine's (IOM's) Roundtable on Value & Science-Driven Health Care to host a workshop entitled "Value in Health Care: Accounting for Costs, Quality, Safety, Outcomes, and Innovation," part of the Learning Healthcare System series, in November 2008. Through a multistakeholder forum for discussion of key perspectives on measuring and improving value in health care, presenters and attendees identified the key barriers, opportunities, and next steps necessary to improve value in health care in the United States.

Presenters at this workshop specifically discussed various approaches to assessing and improving value, in terms of both maximizing what we gain in patient outcomes and minimizing what we give up, especially the opportunity costs of expenditures on less effective treatments. The sessions also addressed a number of new and promising tools and organizational arrangements currently being used in the United States in an attempt to increase value, as well as both near-term opportunities and long-term strategies to align the many elements of the healthcare system to promote value. The chapters in this report highlight common themes from the discussions and provide summaries of the presentations from a variety of perspectives.

The principal purpose of each of the 8 Roundtable workshops and reports so far is to establish a conceptual framework within which to consider important dimensions of a value-driven health system and to develop an agenda for action to facilitate moving forward. In the three years since the Roundtable was established, the calls for increasing health system value have increased, in large part because of growing evidence that continuing to provide health services in the way we currently do is financially unsustainable and does not result in optimal patient outcomes (Fisher et al., 2003; Peterson and Burton, 2007). The following summary of a keynote address by David M. Walker of the Peter G. Peterson Foundation eloquently expresses the bleak financial trajectory of current healthcare spending in the United States and its implications for the future welfare of the American people and provides the economic and financial context driving the need for action.

THE NEED TO IMPROVE VALUE IN HEALTH CARE

David M. Walker, Peter G. Peterson Foundation

On March 4, 1789, the Constitution of the United States of America established a new national government for this country. The Founding Fathers believed that the federal government had a limited and specific role in American life. Responsible only for matters of national concern, the federal government presided over such areas as national defense, foreign policy, national finances, the postal service, and the federal judicial system.

At that time, the federal government accounted for 2 percent of the nation's economy. Today, the federal government's budget accounts for approximately 21 percent. Sixty-two percent of the current budget is devoted to entitlement programs—Social Security, Medicare, and Medicaid—and expenditures unrelated to the express and enumerated powers that the Founding Fathers envisioned (Peter G. Peterson Foundation, 2008). Some of these expansions can easily be justified; others are questionable.

Many things change over time, but certain principles and values should be timeless.

In the late 1700s, Americans believed in thrift. Two hundred years ago, Americans believed in individual opportunity and the need to provide a level playing field to ensure that each person could maximize his or her innate abilities. In the beginning, the citizenry believed in stewardship (Steigerwald, 2008).

In recent years, the words "thrift" and "stewardship" have disappeared from the English lexicon. The government has encouraged Americans to spend money and to charge as much as possible. Starting in the 1980s, the government and the public became "addicted to debt." Debt became tolerable and acceptable regardless of the prevailing state of the economy. Americans started using credit cards to buy a cup of coffee. The stigma of declaring bankruptcy at both individual and corporate levels has almost disappeared (Steigerwald, 2008).

Individual opportunity has yielded to a belief in entitlement to a broad array of costly benefits. Worse, some efforts to provide equal opportunity through our tax system and social insurance programs resulted in middle- and upper-class welfare.

Our perspective as a country and as individuals has fundamentally shifted. Our public morality has been transformed. The beginning of the Republic was inculcated with the notion of stewardship—a sense of our collective and individual responsibilities not only to make today better but also to better position ourselves for future generations. It is in that basic regard that our elected officials have failed.

We face a number of serious sustainability problems, and health care

is the largest of the challenges before us today. We have built an amalgam of healthcare policies and structures based on a myopic view of today. We have fallen far short of creating a forward-looking, integrated, and sustainable system—one that *aligns incentives* to encourage people and institutions to behave properly; *fosters transparency* by providing information about both cost and quality so that providers, patients, payers, and purchasers can understand the value of services and make better choices; and *increases accountability* for poor choices.

Our current healthcare "system" could, if not reformed, bankrupt this nation. The United States is the only country that writes a blank check for health care. Even Sweden, which has socialized medicine from cradle to grave, limits how much of its federal budget and how much of its economy will be dedicated to health care. At the end of September 2007, the U.S. government had amassed $53 trillion of debt on the crest of unfunded promises for Social Security and Medicare (Social Security and Medicare Boards of Trustees, 2008). This translates to $175,000 for every person in the United States and 90 percent of the net worth of every American household (Walker, 2008).

So, how do we fix our healthcare "system"? The answer does not lie in a single piece of sweeping legislation, but an integrated plan with many parts, all aimed at these four objectives:

1. *Universal coverage for basic and essential health care* that meets societal needs, not unlimited individual wants. Basic care includes wellness promotion, preventive services such as immunizations, and protection against catastrophic events. It should not include taxpayer-paid futile care.
2. *A budget for federal healthcare expenditures* that sets limits. Without checks and balances in place, our healthcare expenditure outlays will bankrupt our government. Today, those costs grow 2.6 percent faster than the rest of the economy every year (Congressional Budget Office, 2007). We need to explore strategies such as competitive bidding in government-sponsored healthcare programs, limiting access to high-cost drugs, reimbursing lower-cost alternative treatments, and streamlining administration.
3. *National evidence-based practice standards* for the practice of medicine and for the issuance of prescription drugs in order to improve consistency, enhance quality, reduce costs, and dramatically reduce litigation.
4. *Enhanced personal responsibility and accountability* for health and wellness. We have to reverse the perversity of our incentives today and stop subsidizing bad behavior and health choices. The United

States is first in the world in cost, but we are also first in the world in obesity.

The United States is on an imprudent and unsustainable path. More blank checks for health care will lead us into deeper debt and culminate in a bankrupt government. Comprehensive healthcare reform must rest on these four principles: universal coverage for basic and essential health care, limits on federal healthcare spending, national evidence-based practice standards, and enhanced personal accountability. More fundamentally, however, we must return to the basic tenets of the nascent Republic of the United States. We have to judge the success of our policies and reforms not only by the benchmark of how they will address problems today but by asking ourselves: How can we fulfill our roles as stewards of a better, more equitable, more effective, and more responsible United States for the generations to come?

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2

Stakeholder Perspectives on Value

INTRODUCTION

An increasing number of signs indicate that our health system, at its current rate of growth, threatens to engulf the federal budget (Congressional Budget Office, 2007). As expenditures on health care continue to swell, our society's ability to invest in education, infrastructure, energy, and additional aspects of the economy becomes ever more limited (White House, 2009). Since September 2008, new economic realities have changed the nation's financial picture dramatically, and our concept of value has to change accordingly. The concept of value must expand its focus, looking beyond the desires of individual patients, providers, or industries, toward meeting societal needs. The value proposition in health care should reflect not just economic value, but also the societal principles that undergird our approach to economic analysis (Persad et al., 2009).

This workshop has focused on providing a forum for discussing solutions to the healthcare crisis, where discussions focused on increasing value—defined as the ratio of benefits to cost—as a cornerstone of not just controlling, but reducing, the rising costs of health care. In September 2008, the Institute of Medicine (IOM) Roundtable on Value & Science-Driven Health Care met to explore key stakeholders' perspectives on value in health care, seeking to understand the meaning of value and the approaches to assessment among patients, providers, economists, health product and device manufacturers, payers, and employers. The September presentations formed a starting point for much of the conversations during this workshop's stakeholder panel session, enabling further definition

of the broad commonalities and the subtle differences between stakeholder views on value.

This chapter presents a synthesis of both workshop and Roundtable discussions of stakeholder perspectives (see Table 2-1 for participants).

Both discussions emphasized the importance of perspective in discussing value questions, indicating that different stakeholders perceive costs and benefits differently. Economic viewpoints on the panel considered value in terms of the aggregate impact on society as a whole. In contrast, it was highlighted by participants that patients particularly value the ability of health care to help them obtain optimal health in order to meet personal goals. Yet it was also mentioned that patients do not necessarily believe they need more care to achieve better health provided that transparency of information, evidence, and treatment options exists. Overlapping with these views, representatives from the employer sector asserted that they value not only maintaining healthy and productive workers and families at the lowest cost possible, but also focusing on enhancing community health.

Meanwhile, providers on the panel desired evidence-based, effective diagnostic interventions and treatments that are delivered efficiently. They also considered value in terms of focusing principally on appropriateness of care discussions that fully engage providers and consumers together, rather than conversations about controlling costs. Participating payer representatives emphasized a value orientation around evidence-based medical

TABLE 2-1 Participants in Stakeholder Perspectives Panels

Perspective	September 2008 Roundtable Meeting Panel	Value in Health Care Workshop Panel
Economic Viewpoint	A. Mark Fendrick, University of Michigan	Paul B. Ginsburg, Center for Studying Health System Change
Patient	Sabrina Corlette, National Partnership for Women & Families	Gail Griffith, Patient Representative
Employer	Martín-J. Sepúlveda, IBM	Helen Darling, National Business Group on Health
Provider	Howard Beckman, Rochester Individual Practice Association	Bruce Ferguson, East Carolina Heart Institute
Payer	Troy A. Brennan, Aetna, Inc.	Murray N. Ross, Kaiser Permanente Institute for Health Policy
Manufacturer	Harlan F. Weisman, Johnson & Johnson	Jean P. Gagnon, sanofi-aventis

interventions that are highly effective and around structuring incentives to encourage the use of these interventions. Manufacturers on the panel focused on maintaining incentives for product innovation while simultaneously considering the impact of their products on individual patients' health in terms of costs and benefits over time.

Despite these differences in perspectives, many stakeholders indicated areas of commonality, suggesting that beneficial social outcomes, such as improved school performance and productivity, may be hard to monetize yet could be considered in assessments of value in health care. Importantly, several presenters also separately identified problems with the current delivery system, indicating a misalignment of payment incentives with the goals of value.

Economic Perspectives

A. Mark Fendrick suggested that while healthcare reform discussions focus predominantly on controlling costs, it is the concept of *health* that should be uppermost. Unlike assessments of spending in other economic sectors, value in health care—that is, the clinical benefit achieved for the money spent—is frequently excluded from the current dialogue on how to solve the nation's healthcare dilemma, he explained. Despite the relative lack of attention to the value proposition, Paul B. Ginsburg stated that rigorous methodologies to measure health outcomes per level of expenditure are available, transparent, and well accepted.

Both discussants underscored the misalignment between the current health delivery and financing system and the achievement of value. Fendrick asserted that we instead have two streams of concern—quality improvement and cost containment—that create conflicting incentives for patients and clinicians. Some quality improvement initiatives are designed to improve patient self-management by increasing participation in specific high-value interventions that are becoming costlier to patients. Yet rising out-of-pocket costs discourage the use of recommended services and the overuse of interventions of questionable benefit. He commented that studies demonstrate that when patients are required to pay more for their health care, they buy less of both essential and excessive therapies alike (Newhouse, 1992). Meanwhile, current clinician reimbursement systems create additional financial barriers to providing adequate primary care and follow-up services.

Fendrick stated that consumers require education about the value of the services they are consuming and payers can assist by providing financial incentives to encourage the use of high-value services. He advocated that the current "one-size-fits-all" benefit design be abandoned and replaced by value-based insurance design. Using this approach, the promotion of ser-

vices and interventions with high benefit-to-cost ratios will produce greater value—defined as health per dollar spent—at any level of aggregate health expenditure. Value-based insurance design offers a potential incremental solution to enhance efficiency in healthcare spending, suggested Fendrick. These insurance packages adjust patients' out-of-pocket costs for specific health services based on an assessment of their clinical benefit (net of cost). The more beneficial a therapy is likely to be, the lower is the cost share. By aligning financial incentives in this way, high-value care is encouraged, while low-value or unproven services are discouraged. Ultimately, Fendrick asserted that such a strategy would produce more benefits at any level of expenditure.

Ginsburg asserted that pursuing a value-based strategy that discourages low-value interventions will be much less successful. He specified that to implement these strategies successfully, consumers, providers, payers, and researchers must be involved. Expanding on this idea, he said that since value determination will require extensive knowledge of the outcomes and costs of the services being evaluated, it will necessitate enhancing the commitment to effectiveness research.

Ginsburg also cautioned that while it is conceptually appealing to consider a medical intervention as either valuable or not, value is a continuous outcome, not a binary one. Medical services span a continuous scale, ranging from those with positive benefits to those without benefit and even to those that cause harm. Ginsburg said that although some may argue that enough evidence exists to enable distinguishing useless and harmful interventions from those that could provide utility, recent history has demonstrated our inability to determine the harms of many medical products prior to their widespread use in clinical practice.

Beyond identifying a need to form consensus about the best methods of measuring and utilizing value assessments, a common theme discussed by both discussants was the critical need to reform the healthcare provider payment system to reward outcomes over volume. Without this, they suggested, we will continue to struggle against powerful incentives that work counter to the achievement of better value.

Perspectives from Patients

Sabrina Corlette stated that the patient community is not monolithic and there is a wide range of consumer and patient perceptions of value. The distinction between a "patient" and a "consumer" is something to keep in mind, she said, because the perspective of a patient actively undergoing a course of treatment for a particular illness may differ significantly from the perspective of a healthcare consumer who may acquire goods and services over the course of a lifetime but not be actively in treatment.

Both Gail Griffith and Corlette spoke of how patients are often perceived as believing that more medical care and newer treatments are better, although patients' views are more complex than this. Corlette expanded on this idea, saying that people generally do not question the quality of care they receive, even if their attention is called to the epidemic of medical errors and the huge geographic variations in quality in the United States. She stated that there is an unwillingness to accept the idea that the doctor they see and personally chose is not a high-quality doctor. She cited a recent poll by the National Business Group on Health that found that 72 percent of the employees surveyed thought their doctors were very or completely trustworthy sources of health information compared to 66 percent for nurses, 43 percent for health plans, and only 22 percent for employers (National Business Group on Health, 2008).

Given the emergence of health information technology (HIT), Griffith stated that patients have legitimate concerns about the privacy and security of their health information and the use of this information in ways that they do not understand and have not authorized. However, the general public will be willing to accept some privacy risks because it recognizes the benefits of interoperable health records, she continued. With new leadership for the nation, she believes there is hope that the focus on HIT will bring a concurrent focus on the protection and privacy of medical records.

The discussants stated that patients are often suspicious that there may be a hidden agenda of cost cutting behind the concept of "evidence-based" medicine and are concerned that it may restrict the treatment options available to their doctors. Yet as consumers face escalating cost exposure and bear more out-of-pocket costs, there is both an increasing recognition that costs are rising at too high a rate and, over time, an increasing acceptance of some elements of the value agenda. Griffith asserted that as recently as the 2008 Presidential election, spurred by the economic meltdown, American consumers and patients shifted from a mindset of "more is better" to an emphasis on access to care, equity, and value.

Yet health care is *different* from other industries, Corlette maintained. Because of the complexity of the provider-patient relationship, the asymmetry of knowledge, and patient vulnerability, health care will never be a purely commercial transaction in which patients seek the best "deal." She indicated that a value-based agenda will fail with patients if the focus is on cost. She continued that proponents of value need to focus on quality and access and that any cost savings should just be an ancillary benefit of improved quality.

Perspectives from Employers

Martín-J. Sepúlveda stated that employers are an important, but reluctant, change agent in health care. He explained that unrelenting market competition and the imperative of competitive labor costs have driven employers to unprecedented levels of engagement in healthcare transformation and cost control. The marginal impact of employer innovations—for example, pay-for-performance and total health management to address chronic conditions such as diabetes and the exploding epidemic of obesity—together with logical limits to employee cost shifting in the face of escalating healthcare expenditures, referred to as the "PacMan" of the federal budget by Helen Darling, have compelled employers to demand accountability for value in current healthcare expenditures.

This demand in the healthcare marketplace has brought attention to deficiencies and defects in the healthcare industry that thwart accelerated value improvements, said Sepúlveda. Expanding on this idea, Darling discussed the specific target areas of waste in the healthcare delivery system—the 20-30 percent of overuse, underuse, and misuse in a $2.5 trillion dollar spending budget (Skinner et al., 2005). Other areas of waste include the complete lack of consistency or consensus on what "value" means in health care and confusion about the high leverage loci of value creation in health care, related Sepúlveda. He added that unrealistic expectations of the state of the "evidence" for so-called value-based coverage and inadequate attention to comprehensive, person-focused (not condition-focused) care delivery with revitalized and transformed primary care also continue to pervade the system.

The discussants agreed that evidence generation is foundational to value acquisition in health care. Yet there exists a gross imbalance in focus and funding between translational research (from discovery to randomized clinical trial) and applied community- and practice-based research and intervention, asserted Sepúlveda. The panelists stated that failure to remedy this irrational imbalance—by not significantly shifting resources toward community- and practice-based behavioral change, along with investments in data collection and quality assessment through HIT implementation and education on the comparative efficacy of treatment options—will perpetuate both the current T1 ("bench to bedside") bottleneck of effective new interventions and the suffering, disability, and expense resulting from the deplorable state of our population's health.

With respect to the investment in the health care of their employees, Sepúlveda suggested that most employers think that the key elements of value are costs that can be justified by improved patient clinical and functional outcomes, minimization of services re-work (medical errors, duplication of services), and reduced cycle time resulting from improved access

and coordination of care. These factors, he said, have been demonstrated to deliver better performance at work, reduced absenteeism, and increased workplace productivity.

Darling concluded that employers and other stakeholders must be bold in their efforts to increase the value obtained from health care in this country. In the milieu of a sagging economy and rising unemployment, she articulated that the nation can address the deficiencies of the system and drive higher achievements in value only by shifting its focus from providing more care to a goal of delivering higher-quality, more effective, and more efficient care that can not only decrease the growth of healthcare spending but actually *reduce* it.

Perspectives from Providers

Physicians view value in a different dimension than other stakeholders, noted Howard Beckman. He added that when cost is presented as distinct from an assessment of quality, physicians view those who promote cost reduction as largely motivated by dollar savings that do not accrue to either providers or patients. The result is the perception that these cost-saving programs are untrustworthy. The discussants agreed that professionalism demands considering the needs of patients first. Confronted with talk of cost reductions, Beckman asserted that physicians hear two important messages: (1) plans or employers may be more interested in saving money than ensuring that needed services are provided, and (2) provider incomes and current styles of practice are at risk from those more interested in cost reductions than improving quality.

Beckman suggested that the IOM has created a more integrated model of value that places cost within the context of quality by defining quality as reducing overuse, misuse, and underuse of services. This model requires that each service offered be evaluated for appropriateness based on the best available evidence. Expanding on this idea, Bruce Ferguson articulated that evidence generated by comparative effectiveness studies can inform the development of appropriateness guidelines, and HIT resources can be designed to collect information about the quality of care delivered and potentially be utilized as a tool for the dissemination of guidelines.

Simultaneously, provider representatives also focused on the need for reform of the payment and delivery systems to reflect the patient's perspective and to reward longitudinal outcomes. If payment can be justified only for appropriate care, expanding the definition of quality to include efforts to identify and reduce overuse and misuse of services successfully shifts the focus from defining quality merely as reducing underuse to increasing the value of care in a way that is professionally acceptable to physicians. They articulated the belief that focusing on appropriateness more effectively

engages physicians in changing their behaviors while reducing cost and improving quality.

Recognizing differences in perspectives on value, the panelists stated that successful programs involving practitioners to improve value should focus on reducing overuse and misuse of services. Ferguson provided the example of the collaborative efforts of the American College of Cardiology, the Society of Thoracic Surgeons, and the American Heart Association, which have already started to recognize the importance of engaging these aspects of medical care by shifting their paradigm for defining value and creating appropriateness criteria for a number of cardiac services and conditions. Sharing variation in a group's utilization patterns in the framework of appropriateness criteria is another example of how value can effectively be addressed in collaboration with physicians. He stated that providers additionally need access to a combination of clinical quality data and cost data at the point of care, which is being done by the Virginia Cardiac Surgery Quality Improvement Project; otherwise healthcare providers lack knowledge of a critically important denominator of the value equation. The discussants concluded that without the implementation of these changes in focus, payment structure, and information delivery, providers will not be able to make the right decisions in terms of value for the patients with whom they are entrusted.

Perspectives from Payers

Troy A. Brennan noted that while payers broadly see the same components of value as other stakeholders, they have significant differences as well. Often in the medical arena, he related, emergent technologies—such as Intensity-Modulated Radiation Therapy or, more recently, proton beam therapy—are widely adopted for treatment without demonstration of clinical superiority to less expensive alternatives. However, he asserted that payers do have a role in improving value in health care by making coverage decisions based on the evidence.

Yet significant challenges exist for payers as they tackle the issue of value. The first is the lack of trust from consumers and providers, stated Murray N. Ross. He explained that for these stakeholders, attempts to drive an increase in value will be considered as all about the bottom line, not about providing the best, most efficient, and oftentimes very expensive care to very sick people. Continuing, he suggested that payers, like patients, are not monolithic. Many different business models exist, some of which are not predicated on obtaining value but rather on obtaining profit. He also discussed the difficulties of convincing consumers that the need for comparative effectiveness research will not decrease the quality of their care, but rather potentially improve it, when most consumers do not realize that most of the care provided in this country is anything but evidence based.

The panelists asserted that a keystone to tackling these challenges will be the availability of better evidence of the effectiveness, including cost-effectiveness, of different treatments. Insurers currently do not factor cost-effectiveness information into coverage decisions, making these decisions based solely on efficacy, asserted Brennan. However, a government program likely would have the stature to incorporate cost into its analyses for cases in which multiple treatment options exist, he continued. Without using these types of information, the discussants concluded, we will continue to have irrational decisions in the healthcare system, the costs of care will continue to rise at unsustainable rates, and we will be unable to control the actual dollars spent on health care. Without considering these types of factors, they said, it will be even harder to achieve higher rates of healthcare coverage.

Perspectives from Manufacturers

In these times of burgeoning healthcare costs, discussions of what value means in health care are common, stated the participants. The product company view of value in health care is based on the understanding that value is multifunctional and must take into account a number of perspectives, but value from a patient perspective should come first, noted Harlan F. Weisman. He asserted that manufacturers offer specific value to the healthcare enterprise through the development and discovery of effective treatments that are supported by evidence on outcomes and comparative efficacy. Jean P. Gagnon expanded on this, stating that the value to patients of these pharmaceutical and technological innovations relates to the actual improvement in health through the appropriate use of such products, achieved through the proper education of providers, patients, payers, and researchers about their safe and effective use.

Weisman believes that cost alone should not be used to assess the value of treatments or to limit access. Rather, value should consider the individual patient, should consider actual improvements in patient health and costs over time, and should include assessment of patient satisfaction for services provided. The need for comparative effectiveness should be balanced by the need to introduce innovations addressing unmet medical needs, he added. Weisman continued, suggesting that initial approval and reimbursement should be based on standards of efficacy and safety that depend on the seriousness of the condition and the relative unmet need, with post-approval commitment by the manufacturer to ongoing data collection and analysis to increase information about safety, efficacy, and real-world comparative effectiveness.

At the same time, incentives need to be preserved to support the full spectrum of incremental and substantial innovation that adds value to

health care, said Gagnon. He suggested that integrated care, supported by appropriate reimbursement and evidence, is the most appropriate enabler of value-based decision making. Continuing, he specified that decisions should be informed by the most comprehensive and up-to-date information available, including observational data where appropriate. Standards of evidence should be sensitive to the seriousness of the condition to be treated and to the relative unmet need of treatments for that condition.

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3

Approaches to Assessing Value—Illustrative Examples

INTRODUCTION

The rising healthcare costs in the United States in the face of global economic turmoil underscore the necessity for a health system that identifies and eliminates low-value services, minimizes inappropriate use of medical services, and responds to the explosion of costly new technologies, thus positioning value as a key cornerstone to improving the quality of care delivered in this country (Clancy, 2008; Leavitt, 2008; Paulus et al., 2008). In workshop discussions, participants repeatedly suggested that creating a system that encourages and incentivizes the delivery of high-value services relies first on creating a common approach to defining and assessing value in health care.

Emerging from the presentations and dialogue at the workshop session on approaches to assessing value was the importance of perceptions and perspectives—the meaning of value changes as the stakeholders change. L. Gregory Pawlson discusses methods of estimating the value of physicians on both individual and group levels and the importance of measuring quality, resource use, and cost. He discusses the strides made in value measurement of providers and outlines the steps necessary to expand on prior work in a manner that will allow accurate, informative, and comparative assessments of efficiency and value in health care.

Since surgical care accounts for more than 40 percent of overall spending for inpatient care (National Center for Health Statistics, 2006), developing approaches to assess and estimate the value of individual surgical and interventional procedures is paramount. Justin B. Dimick highlights two

domains of surgical value: the value of surgical interventions and the value of individual providers, including both surgeons and hospitals. He discusses methods of measuring costs and outcomes in both of these domains and additionally surveys public policy options for improving value in surgery.

Howard P. Forman explores the challenges to determining the cost-effectiveness of diagnostic imaging and argues that better, more widely available, cost-effectiveness information could be an important component of stemming the growth of unnecessary imaging. David O. Meltzer focuses on the medical cost-effectiveness of preventive services and wellness approaches, concluding that prevention can be, but is not invariably, a short- or long-term cost-effective approach to improving health. Newell E. McElwee examines the issue of determining the value of pharmaceuticals, specifically discussing decision points along the pharmaceutical life cycle. He also emphasizes that the value of pharmaceuticals varies depending on the specific decision considered and the preferences of the stakeholder making that decision.

Presenters also focus on assessing the value of diagnostic tools and devices. Ronald E. Aubert proposes a framework for evaluating the potential value of pharmacogenetic diagnostics, providing a case study of how applying pharmacogenetic data to the dosing of warfarin, a blood thinner, could reduce adverse events and yield cost savings to the healthcare system. Parashar B. Patel concludes the chapter by discussing the impact of evidence requirements for medical devices on innovation and assessment of value from a device manufacturer's perspective and the need for cross-stakeholder collaborative efforts in order to preserve incentives for innovation and discovery.

MEASURING VALUE OF AMBULATORY CARE SERVICES

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Measurement of value in health care is an increasingly important goal, given assessments that indicate less benefit from and higher cost for services provided in the United States versus countries of comparable wealth, as well as multiple studies pointing out apparent waste and less than desirable quality of care (Fisher et al., 2003; McGlynn et al., 2003). However, defining value, let alone measuring it, is very challenging in health care, where neither benefits provided nor resources used to create the benefits are straightforward. Although there have been a considerable number of research studies using various econometric approaches to cost and benefit determination in health care, there is as yet no standard practice for measuring value or even an agreed-upon definition of value.

Regardless of the challenge, accurate, valid, and reliable formulations of both the benefit and the cost portions of the value equation are absolutely critical to any hope of creating a "value-based" or value-driven healthcare system.

Limitations of Current Approaches

The most widely available and relatively easily accessible data sources for determination of quality and cost are so-called claims data (data on services—visits, procedures, laboratory services, and medications dispensed) provided by clinicians or others and submitted for payment to insurers. Claims data are intended to document the minimal data required for payment (most often under fee for service) and in many instances do not accurately reflect the actual services provided, the diagnoses to which the services were actually linked, or in some instances, which clinician actually provided the services. Moreover, major gaps in the completeness of claims data can seriously affect their utility in either quality or resource use-cost determinations (Pawlson et al., 2007). Careful audit procedures that look at such areas as sampling framework, completeness of data extraction, and other oversight are critical to using claims data for resource use-cost purposes. To provide valid and reliable information for most quality measures, intensive effort is required to abstract information from existing paper medical records. While the increasing use of electronic medical records (EMRs) may ameliorate this issue to some degree, many current EMRs lack adequate documentation and search capabilities that are crucial for their potential use in quality measurement. This gap is largely due to the fact that many EMRs were designed to mirror billing systems or paper records, not to facilitate systemic data collection on clinical care. Surveys, although a critical source of information on some aspects of patient experience of care, are of necessity based on patient recall and interpretation of events and, because of this, provide limited information in some instances.

Even where reliable and valid measures exist, limitations of the data are also reflected in the narrow breadth of available quality measurements. Until recently, except for a short-lived effort by the Centers for Medicare and Medicaid Services (CMS; the Health Care Financing Administration at the time) to generate national standardized comparison data from hospitals on coronary artery bypass graft surgeries, there are very few widely available standardized comparison data at any level (physician, group, hospital, or health plan) beyond regional or national comparisons. The Healthcare Effectiveness Data and Information Set (HEDIS) is one example of a widely available standardized set of comparison data, but it is available only at the health plan level. Moreover, since the development of HEDIS was driven primarily by consumers and purchasers concerned about the potential nega-

tive impact of health plans and capitation on quality through underuse of services (e.g., not providing screening for breast cancer), HEDIS measures, until recently, were focused almost exclusively on problems of underuse at the plan level.

There has been substantial recent effort by CMS and others to extend publicly available quality measurement to other levels of the system. In some instances these efforts have been accompanied by calls (and, in some cases, funding) for the development of a broader range of clinical structure, process, and outcome measures of quality and measures related to overuse, misuse, resource use-cost, and patient experiences of care. However, we are still far behind where we need to be to assess value broadly in the healthcare system. Moreover, creating measures in areas such as overuse, appropriate use, misuse, and resource use-cost is proving to be very challenging. Consider that Brook and colleagues demonstrated in the 1980s that much care cannot be categorized definitively as appropriate or inappropriate and little correlation exists between rates of inappropriate care and service utilization in a given region (Chassin et al., 1987; Park et al., 1986). David Eddy has noted that structural issues related to the nature of clinical medicine, such as relative rarity of key outcomes, remote times between interventions and outcomes, the heterogeneity of practice populations of different physicians, and inherent uncertainty in disease outcomes, pose major barriers to measurement, especially at more granular levels of the system such as hospitals or physician office practices (Eddy, 1998). While risk adjustment offers some hope of adjusting for some of the differences created by these factors, there is broad consensus that current risk adjustment approaches are far from ideal or adequate. Finally, research looking at the relationship between relative quality achieved and relative resources used has shown that the relationship is complex. Fisher and colleagues found that despite the use of 60 percent more care for hospitalizations, specialist care, and major tests in the last six months of life of Medicare patients in high-cost regions of the United States, the quality of care in high-cost regions appears actually to be lower (Fisher et al., 2003). Our own research has suggested small but significant negative correlations between higher quality and lower resource use for inpatient hospitalizations and positive correlations between higher quality and higher resource use for medications at the health plan level (O'Connor et al., 2008).

Measuring Value at What Level of Care?

The National Academy of Engineering and Institute of Medicine (2005) report *Building a Better Delivery System: A New Engineering/Health Care Partnership* described multiple levels of the healthcare system, ranging from the patient to the environment (defined as entities such as insurers

or regulators that do not deliver health care directly but influence the care delivered). In ambulatory care, quality could be examined at the individual physician, group, integrated delivery system, regional, or national level. Measurement at the individual physician level is appealing from the standpoint of accountability and "actionability." Moreover, if information generated from a given physician's patient chart is used, there is no problem with relating a given action to a specific patient and physician. However, both quality and costs are often "generated" at a higher level of the system. For example, many, if not most, patients with multiple chronic conditions interact with a substantial number of clinicians over the course of a single year. These multiple interactions represent a web of health care that cannot be captured by examining individual physician-patient interactions in a group of patients. Attribution of clinical measurement and cost to a single clinician is also problematic because much of the variance in costs or quality does not appear to reside at the level of the individual physician (O'Connor et al., 2008). This, coupled with the inherently wide variation in resource use-cost, especially where inpatient or surgical-procedure use is involved, the aforementioned heterogeneity of patients among practices, and the relatively small numbers of patients with a given condition in an individual physician practice, places severe limits on measurement, especially for public reporting or accountability at the individual physician or even the small-group level. The National Committee for Quality Assurance (NCQA), as promulgated in its Physician-Hospital Quality reporting standards, has indicated, based on a number of studies within and external to NCQA, that for quality measures, at least 30 patients are needed to obtain a reasonably low probability of misclassification, but adherence to the more stringent criterion of a 90 percent confidence interval or a reliability coefficient of 0.7 is highly desirable (Scholle et al., 2008). For resource use-cost measures, given widely variable confidence intervals depending on the specific resource use category and disease, there is no defined minimal sample size; thus, only a calculated confidence interval (CI) of 0.9 or greater or a reliability coefficient of 0.7 would be acceptable. Indeed, to achieve a calculated CI of 0.9 appears to require a sample size of more than 100 patients for even the most reliable resource use measures, and in most instances the number required exceeds 500. Thus, while physician-level measurement may provide important feedback for individual practitioners, data derived from small sample sizes cannot reliably be generalized to the practice of medical care at the broader system level.

To overcome these problems with sample size requirements and misclassification, both quality and resource use related to accountability should most often be measured at some level higher than the individual physician, such as the group or integrated delivery system (contractual or virtual) level. By examining clinical care patterns and use from the organizational

level of physician practice groups, much richer information about the relationships between quality and care emerge, especially for patients with multiple chronic conditions. System-level measurements also promote a sense of shared accountability for healthcare costs and outcomes. Within a system, data on individual physician performance, although not sufficiently robust for public reporting, can serve as the basis for feedback and discussion of performance. While there are relatively few functionally integrated health delivery systems that can facilitate these system-level assessments of value, research is critically needed to explore how to create or assign individual clinicians to virtually determined delivery systems (on the basis of hospital use, referrals to other physicians, etc.).

Moving to Measurable Clinical Efficiency

The concept of "measurable clinical efficiency" addresses using a set of quality measures as a proxy for benefit and a set of resource use measures as a proxy for the cost function (Table 3-1).

As illustrated in Table 3-1, such value assessments would include measurements of misuse, overuse, and underuse in evaluating the quality function and use of various types of resources for the resource use-cost function. Resource use in this respect can be measured using disease- or condition-specific claims, defined episodes delineated by "clean claims periods," and sorting costs exclusively into those episode groups or by looking at total costs for all services for a defined group of patients for a defined period of time. Either actual (defined by claims paid or allowable charges) or standardized prices can be used since both have their advantages and disadvantages. All of these approaches imply looking at both quality and cost over

TABLE 3-1 Measurable Clinical Efficiency—Measures of Quality and Their Associated Outcomes

Measures of quality of care	Underuse: needed services *not* provided	Appropriate use: provision of needed services	Overuse: provision of unnecessary services	Misuse: provision of potentially harmful services
Cost-waste outcomes	Avoidable consequences	Excess cost-use for appropriate care	Cost of overuse	Cost of misuse
Clinical outcomes	Clinical outcomes and patient experience			
Total cost-use	Aggregate cost-relative resource use			

time and different entities, rather than in a single place at a single time as with most current quality measurement.

Measurable clinical efficiency can be reported for improvement or accountability purposes by combining composites of quality with resource use-cost measures in the same population of patients. The composites can be displayed in various combinations (ratios, scatter plots, relative "star" ratings, etc.). As noted before, the choice of what level of the healthcare system (e.g., individual clinicians, sites, groups, integrated delivery systems, health plans) to attribute measures of quality and resource use needs to be balanced with important trade-offs. Finally, further research to explore the relationships between quality and cost and what elements of the system have an impact on these measures is critical, as is continuing to set reasonable rules and standards for fairness and accuracy of measurement.

Conclusion

Limited transparency and problems with reliability of measurement hinder resource use-cost and quality measurements, and current tools provide only an initial starting point for combining these areas to determine value. Further research and development to develop reliable and valid measures of appropriateness of care and additional measures of overuse and misuse of clinical care as well as resource use measurement, is critical. Consideration must also be given to the development of measures of clinical outcomes at group, network, and plan levels. "Composite" measures incorporating clinical performance and intermediate outcomes in quality and resource use measures at multiple system levels need to be developed to allow comparative assessment of efficiency and value. As electronic medical records evolve and their capacity expands, attention should be paid to the types of data needed to assess the aspects of care related to value. Only with concerted and sustained attention to these interim steps can actual value to health care can be measured and used to improve quality and reduce waste in our healthcare system.

ASSESSING THE VALUE OF SURGICAL CARE

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Surgery accounts for a large proportion of healthcare services in the United States. The number of patients undergoing inpatient surgery doubled from 2000 through 2006 (from 23 million to 46 million) (National Center for Health Statistics, 2006). Surgical care also comprises a major component of healthcare expenditures, exceeding 40 percent of overall spend-

ing for inpatient care (National Center for Health Statistics, 2006). With healthcare costs skyrocketing, any effort to curtail their growth will have to include surgical care. Payers and purchasers also increasingly recognize that costs must be controlled without sacrificing quality. Consequently, their focus has shifted to optimizing value, rather than considering quality or costs in isolation.

When assessing the value of surgical care, there are two perspectives to consider. The first perspective—the value of surgical *interventions*—considers the value of surgery, relative to other approaches, for treating specific conditions. Often referred to as "technology assessment," this perspective uses the tools of evidence-based medicine to evaluate the effectiveness and cost-effectiveness of new interventions. Identifying and eliminating surgical services of no value (waste) or low value will reduce healthcare spending without impacting quality.

Motivated by the widespread variations in outcomes and costs across providers, the second perspective assesses the value of specific surgical *providers* relative to others. Value assessment in this context, provider profiling, is particularly timely and is the focus of several public reporting and value-based purchasing efforts. Value can be optimized by directing patients to the highest-value hospitals and surgeons—those that provide high-quality, efficient health care.

Assessing the value of surgical care is challenging. This paper surveys existing tools—what we have—and tools on the immediate horizon—what we need—for value assessment in surgery. Within each perspective, we consider the evaluation of two key domains: outcomes and cost. We close by considering policy approaches for using the tools discussed to improve value in the context of surgical care.

Assessing the Value of New Surgical Inventions

The last decade has seen explosive growth in new medical technology. While this trend is pervasive in medicine, it is disproportionately focused in procedural specialties, especially surgery. There are new surgical procedures for conditions that were previously not treated. For example, bariatric surgery for morbid obesity has increased tenfold over the past decade and is now the second most common abdominal operation in the United States (Santry et al., 2005). There are also new, less invasive procedures that replace existing surgical procedures. For example, endovascular repair of aortic aneurysms has largely replaced the conventional, open surgical procedure (Schermerhorn et al., 2008).

New technology is an important driver of healthcare cost growth (Baker et al., 2003; Fuchs, 1999). There is general consensus among economists, policy makers, and healthcare purchasers that the introduction of new

surgical procedures, pharmaceuticals, and diagnostic imaging increases healthcare spending. However, there is extensive debate regarding the value of this new technology—whether the benefits are worth the costs (Cutler and McClellan, 2001). Understanding the value of new surgical interventions requires an evaluation of both outcomes and costs.

Evaluating Outcomes

Comparing the effectiveness of new surgical interventions is traditionally the domain of evidence-based medicine. Principles of evidence-based medicine are central to the assessment of the value of novel therapies, including pharmaceuticals, medical devices, and surgical procedures. The goal of this assessment is to understand the comparative effectiveness and cost-effectiveness of new interventions. Because these tools are no different for surgery than for other new technologies or interventions and are considered elsewhere in this report, we consider them only briefly here.

Comparative effectiveness is evaluated by critical examination of randomized clinical trials and observational studies. The goal of these studies is to quantify the net benefit, in terms of healthcare outcomes, of the new surgical intervention compared to the next best alternative. Randomized trials, which minimize baseline differences in comparison groups, are widely considered the gold standard for evaluating new interventions. However, observational studies are important for two reasons. First, observational trials are sometimes the only option. In many situations, randomized trials are not feasible due to expense or a lack of clinical equipoise. Second, observational studies, particularly if they are population based, provide an estimate of the effectiveness of an intervention in the "real world." In contrast, randomized trials provide evidence of efficacy in a narrow, carefully selected subpopulation.

Carotid endarterectomy, a procedure to prevent stroke, is one example in which observational studies made a contribution beyond the randomized trials. For this procedure, randomized clinical trials and population-based studies yielded very different estimates of surgical risk. Using the national Medicare population, Wennberg and colleagues demonstrated that outcomes after carotid endarterectomy were much better in hospitals that participated in the randomized trials compared to other, lower-volume facilities (Wennberg et al., 1998). Because surgical decisions are made by weighing the risks versus the benefits of the procedure, these population-based estimates of surgical outcomes are necessary to guide decision making and to understand the value of a surgical intervention in the real world.

Although the basic tools for evaluating comparative effectiveness exist, several challenges must be overcome. First, we need to address the paucity of evidence evaluating new interventions (Phillips, 2008). In the United

States, we have an undeveloped infrastructure for evaluating evidence. For primary evidence of benefit, we often rely on trials initiated by investigators or industry. For synthesis studies, such as meta-analysis, we rely on networks of volunteers, such as the Cochrane Collaborative. A national infrastructure for setting priorities and funding studies is a necessary first step in filling the evidence void. The second challenge we need to address is the rapid uptake of unproven surgery. New surgical techniques often become widespread prior to good evidence of their benefit. This premature diffusion may be due to the lack of regulatory oversight of surgical techniques and devices. There is currently no gatekeeper, analogous to the Food and Drug Administration (FDA), to prevent new surgical technologies from being adopted prior to good evidence of their benefit.

Strengthening the link between evidence and insurance coverage would also help slow the premature adoption of new technology. Currently, we rely on individual payers to evaluate and make coverage decisions on most interventions. The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) was recently created to advise the Centers for Medicare and Medicaid Services on national coverage decisions (Holloway et al., 1999). While this effort is no doubt a good start and provides a framework on which to build, it currently evaluates a small fraction of new interventions.

Evaluating Costs

The costs of new interventions must also be considered. In assessing new technologies, the costs of an intervention must be considered in the context of its clinical benefit. While some new interventions are actually cost-saving, most result in an incremental increase in healthcare costs. Cost-effectiveness is a formal method for integrating evidence of benefit with information on costs. The cost-effectiveness of new interventions is evaluated as the incremental benefit divided by the incremental cost, relative to the next-best alternative. Most often, cost-effectiveness is evaluated using decision analytic techniques, and reported as the cost (in dollars) per quality-adjusted life-year (QALY). The best evidence regarding effectiveness, as described in the section above, is used in the numerator. The incremental cost (the denominator) is often the most challenging estimate to obtain. Good estimates of intervention costs must be performed from the societal perspective; these often include the costs of the intervention itself, other healthcare costs, and indirect costs to society (e.g., time lost from work).

Although the tools of cost-effectiveness are also well developed, there are still important challenges to overcome. First, we must address the inconsistent application of cost-effectiveness methods. For example,

a recent review of studies focusing on the cost-effectiveness of carotid endarterectomy found tremendous differences across studies. Divergent conclusions of cost-effectiveness were reported from studies that addressed the same questions and used similar inputs (Holloway et al., 1999). For an asymptomatic patient, the cost-effectiveness varied from 1.8 months at a cost of $52,700 per QALY to 3 months at a cost of $8,004 per QALY. Until this problem is addressed, critics will continually point to the inconsistent results of cost-effectiveness studies.

Although we have the necessary tools to evaluate effectiveness and cost-effectiveness, we clearly need a central organization for applying them in a uniform manner. There are obvious precedents. For example, the National Institute for Health and Clinical Excellence (NICE) was established as a part of the British National Health Service in 1999 (Pearson and Rawlins, 2005). NICE was created to set standards for the adoption of new health-care technologies and explicitly take into account both clinical effectiveness and cost-effectiveness. Some advocate the creation of a similar organization in the United States. With the creation of such an organization, we would make the necessary first step toward improving the value of surgery by identifying and potentially reducing the use of surgical services with small (or expensive) marginal benefits.

Assessing the Value of Hospitals and Surgeons

The second perspective to consider is the value of surgical providers—surgeons and hospitals. Motivated by the widespread variations in use, quality, and costs across surgical providers, this perspective is particularly timely and is the focus of several public reporting and value-based purchasing efforts.

Profiling Outcomes

Empirical data from numerous sources reveal widespread variations in morbidity and mortality after surgery. Recent data from the 123 hospitals participating in the National Surgical Quality Improvement Program show that morbidity rates after colon surgery range from 3 to 23 percent, even after adjusting for differences in patient's baseline risk (Figure 3-1). Knowledge of these variations has led to an unprecedented number of efforts aimed at measuring surgical quality. Unfortunately, these efforts are hindered by a lack of good measures.

The measures we currently have—individual quality indicators—are severely limited (Birkmeyer et al., 2004). Hospital morbidity and mortality rates are often too "noisy" due to the small number of cases performed at individual hospitals (Dimick et al., 2004). Hospital volume, widely used in

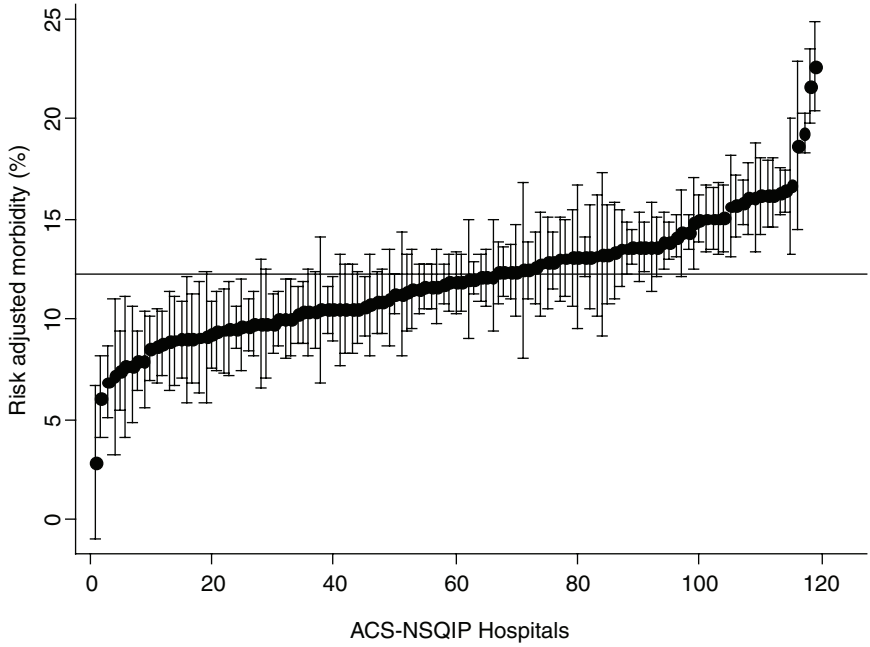

FIGURE 3-1 Ratio of observed to expected morbidity for colon resection at all hospitals participating in the American College of Surgeons NSQIP (2005-2006).
SOURCE: American College of Surgeons National Surgical Quality Improvement Program (NSQIP).

surgery, is an imperfect proxy for individual provider performance. Process measures, widely used for measuring the quality of medical diagnoses, are not as useful in surgery. Unfortunately, processes that are strongly related to outcomes (i.e., high leverage) are not known for most surgical procedures (Hawn et al., 2008). Finally, with the growing number of measures currently used, it is difficult to know how to interpret multiple, conflicting, quality indicators (O'Brien et al., 2007).

With these limitations of individual measures, we need a better approach for assessing surgical quality. Composite measures, which combine multiple individual indicators, can overcome many of these limitations (AHRQ, 2006; O'Brien et al., 2007; Staiger et al., 2009). By pooling multiple measures, they become less "noisy" and provide more reliable estimates of hospital performance. Composite measures also address the problem of multiple competing or conflicting quality indicators. They provide a single, easy-to-interpret, assessment of global quality. One challenge with composite measures is to optimally weight the input measures. The most

common approach to weighting measures is to provide equal weight or rely on expert opinion.

However, there is a growing trend toward the empirical weighting of input measures. With this technique, each of the inputs is weighted according to how reliably it is measured and how closely it relates to a gold standard quality measure. Staiger and colleagues recently published the methods for creating these measures using aortic valve replacement (Staiger et al., 2009). They found that a composite measure of risk-adjusted mortality and hospital volume with aortic valve replacement combined with risk-adjusted mortality for other cardiac procedures explained 70 percent of the hospital-level variation in mortality and was better at predicting future performance than any individual measure (Figure 3-2).

Profiling Costs

Assuming the perspective of a healthcare payer, such as Medicare, the costs of surgical care are a function of price per case and the number of procedures performed. Price, the payment for the episode, varies to some extent. Unfortunately, the tools we have to measure hospital resource use—length of stay and charges—are not useful for profiling providers. For most operations, the efficient use of resources is already incentivized due to bundled payments for physicians and hospitals (e.g., prospective hospital payment for Medicare and most private payers). For example, Medicare

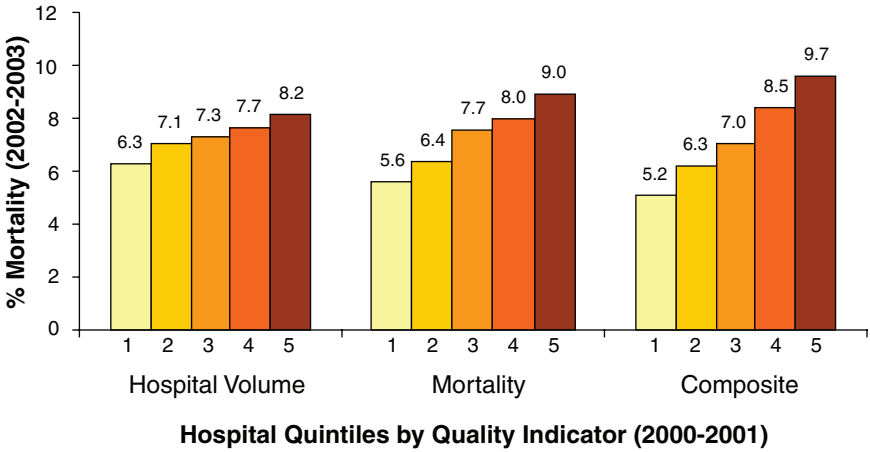

FIGURE 3-2 Ability of hospital volume, mortality, and an empirically derived composite to predict future risk-adjusted mortality. Data are from Medicare beneficiaries undergoing aortic valve replacement, 2000-2003.

payments for coronary artery bypass surgery vary only 13% (from $31,554 to $35,656) from hospitals in the lowest quartile to the highest quartile of resource use (Hackbarth et al., 2008). In contrast, there is much more variation in payment from the top to bottom quartile for readmissions (200%) and postdischarge care (110%). This is not surprising when you consider the potential sources of increased costs across different phases of the surgical episode (Table 3-2). Payments for each phase of care depend on both practice style and the quality of care.

What we need to profile provider efficiency adequately are measures that estimate resource use for the entire episode of surgical care—preoperative, perioperative, and postdischarge. The data and methods for creating such measures already exist. As a starting point, payment data from Medicare could be used. This would require using inpatient, physician, and outpatient files. The first step, and perhaps the most challenging, would be to use claims data to empirically define the surgical episode, either using a defined interval (30, 60, or 90 days) or identifying a natural cutoff where claims drop back

TABLE 3-2 Sources of Variation in the Cost of Surgery for Each Phase of the Surgical Episode

Examples of Practice Style-Related Excess Costs	Phases of Surgical Episodes and Payment Types	Examples of Quality-Related Excess Costs
Excessive rates of discretionary procedures	*Initial decision making* (decision to operate)	Unnecessary surgery
Unnecessary consultations, testing or imaging (higher unbundled payments)	*Perioperative period* (preoperative testing, procedure, and immediate postoperative care) • Hospital (diagnosis-related group or outlier payments) • Physician services	Complications resulting in "bumping" of diagnosis-related group level or outlier status
Excessive cost shifting (from inpatient stay to ancillary services)	*Transition period* (medical services after initial discharge) • Hospital (inpatient and outpatient) • Physician services • Extended care –Home health –Rehabilitation stay	Complications resulting in more hospital, physician, and ancillary services after discharge
	Steady state • Baseline medical costs	

to the presurgical "baseline." Once these episodes are defined, hospitals could be profiled on the total payments during all phases of care.

While the price per case is important, the number of procedures performed is likely a much more important driver of total spending on surgical services. Like variations in outcomes, empirical data support wide variations in the use of surgery. Although decades of research show geographic variations in the use of surgery, this body of work has recently moved into the mainstream. For example, a *New York Times* interactive feature (currently available on its website) provides data on the use of heart bypass, knee replacement, and mastectomy across the United States (data are provided by the Dartmouth Atlas of Healthcare) (*New York Times*, 2007). For all three procedures, the use of surgery varies dramatically across regions; with heart bypass, rates of surgery vary more than fivefold from 1.9 to 9.5 per 1,000 Medicare beneficiaries.

Despite the growing awareness of these variations in the use of surgery, very little has been done to address them. Unfortunately, the existing tools for measuring utilization have problems that limit their widespread use. One approach—used in the *New York Times* feature—was pioneered by John Wennberg and the Dartmouth Atlas working group. The Dartmouth Atlas reports regional rates of utilization for each Hospital Referral Region (HRR) in the United States (Dartmouth University). These regions, which are determined empirically, are determined based on where patients receive complex surgery (i.e., cardiac surgery, neurosurgery) and often include multiple large hospitals within each HRR. As a result, this unit of measurement is much too broad to foster accountability. Simply put, individual hospitals or healthcare systems cannot be held responsible for the use of surgery in the entire region (Fisher et al., 2007).

The appropriate level of analysis—one that could be held accountable—would include only one hospital system. Recently, Fisher and colleagues have developed a novel unit of analysis for this purpose, the physician-hospital network (PHN) (Fisher et al., 2007). Each PHN is made up of a hospital and its extended physician medical staff. PHNs are created by assigning each patient to a primary physician and then assigning each physician to a hospital. Thus, each PHN is a virtual network of physicians clustered around a central hospital. Preliminary data reveal large variations in the use of surgery across PHNs. For example, the use of hip replacement surgery varies threefold across the largest 20 PHNs in the Medicare population (Figure 3-3).

Rates of surgery in each PHN could be used to improve the value of surgery in several ways. First, public reporting of PHN rates of surgery would allow patients to understand the "aggressiveness" profile of their hospital. Patients who are offered surgery in an aggressive system could seek a second opinion in a neighboring PHN that is more conservative.

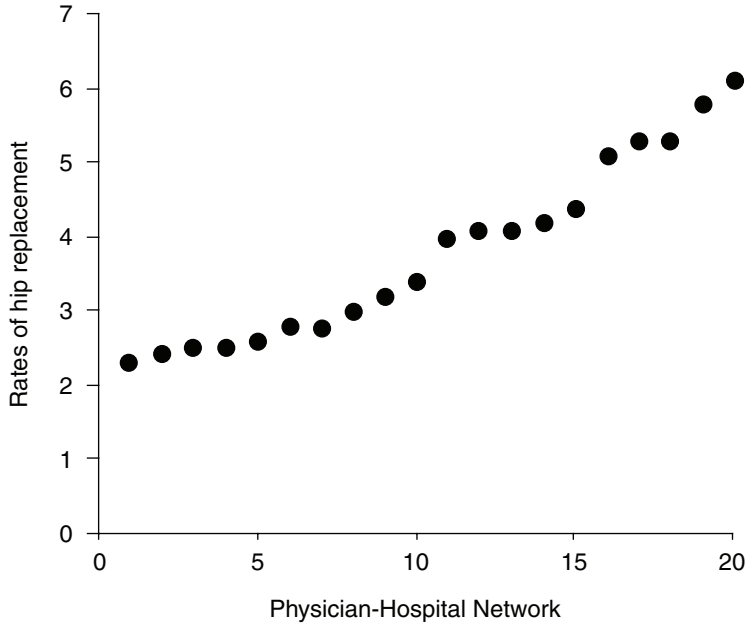

FIGURE 3-3 Variation in the use of hip replacement across the 20 largest physician-hospital networks in the United States. Rates shown are per 10,000 Medicare beneficiaries.

Second, PHNs with high rates could be audited for appropriateness, ensuring that surgery is not being overused in these systems. This approach would incorporate both tools—appropriateness criteria and regional rates of utilization—in an efficient and meaningful way. Finally, hospitals and PHNs with high rates of specific procedures would think twice about hiring another practitioner, which would limit capacity and reduce supply-induced demand.

Unfortunately, even if the right unit of measurement is used, there remain considerable challenges in understanding existing variations in the use of surgery. Specifically, it is hard to know how much surgery should be performed in a given population—which rate is right. One approach, measuring appropriateness of care, is based on the assumption that variations are driven by the inappropriate use of surgery. Pioneered by Robert Brook, measuring appropriateness involves identifying a set of criteria that include all possible clinical indications for a procedure (Brook et al., 1990). There are several reasons why this approach will not help understand existing variations. First, creating appropriateness criteria for every procedure is a

daunting task. Second, even if resources could be marshaled, many clinicians disagree about clinical appropriateness, especially physicians from different specialties (Kahan et al., 1996). Finally, empirical data suggested that regions with high rates of surgery do not necessarily provide more inappropriate care (Leape et al., 1990).

Dealing with this problem is no simple task. Most decisions to perform surgery are in the middle of the spectrum, somewhere between frankly inappropriate and clearly indicated. Empirical evidence indicates that shared decision making between patients and physicians results in lower rates of discretionary surgery (Dartmouth University, 2009). To address these variations, we therefore need effective strategies for incorporating patient preferences and evidence into decision making. Ensuring that patients, rather than surgeons, make the decision to proceed with discretionary surgery will clearly improve value.

Policy Approaches to Improving Value

The measurement tools discussed above will have to be translated into policy to improve the value of surgical care. The policy remedy for eliminating or minimizing low-value surgical services depends on the perspective. When considering surgical interventions, the leading policy remedy is value-based insurance design (Chernew et al., 2007). This approach is considered in detail elsewhere in this report. In brief, value-based insurance design makes the patient pay more out of pocket for less valuable services. For example, healthcare interventions considered "high value" are free (e.g., diabetes medications and supplies), whereas "low-value" interventions would require a high copayment. This type of benefit design has been shown to encourage the use of high-value services. Although mostly applied to pharmaceuticals thus far, this approach could also be applied to surgical interventions. Of course, addressing the challenges of assessing the value of new surgical interventions, discussed earlier, will be necessary before value-based insurance design can be applied to surgery.

When considering low-value surgical providers, the most promising policy solution is value-based purchasing. Value-based purchasing is a general term encompassing several different mechanisms for realigning provider incentives to reward higher-quality and/or lower-cost health care, including pay-for-performance, tiered copayments, and others. These payment mechanisms are considered in detail elsewhere in this report. With pay-for-performance, physicians are given a bonus payment for meeting certain quality benchmarks, usually adherence to evidence-based processes of care (Rosenthal et al., 2007). With tiered copayments, patients would pay less to obtain care from high-quality providers and pay more to obtain care from low-quality providers. While these efforts are gaining momentum and are

applied by both private and public payers, better measures of outcomes, cost, and utilization are needed before they can reach their full potential.

INFORMATION FLOW IN DIAGNOSTIC IMAGING: CONSUMER, CLINICIAN, FACILITY, PAYER? WHY IMAGING VALUE IS DIFFICULT TO MEASURE

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Frank Levy, Ph.D., Massachusetts Institute of Technology

With national healthcare expenditures at an all-time high, public and private payers are increasingly looking at component spending to quantify relative value in order to improve the efficiency of spending and, ultimately, to improve health at any given spending level. Spending for diagnostic imaging (DI)[1] is already a substantial component of total spending and is growing rapidly, thus consuming ever-larger pieces of the total (Baker et al., 2008; Government Accountability Office, 2008). In an environment where insurance design has taken center stage in efforts to "rationalize" the spending on health care from public and private sources, the limited information and various incentives that underlie the decision to order an image are important areas for study. Cost-effectiveness and comparative effectiveness analysis have been suggested as a necessary first step in this direction.

Before even considering such evaluation, one must be cognizant that such analyses can have impact only if payers are directly or indirectly capable of using such information. In the private insurance market, this is certainly within the realm of possibility, as radiology benefit management (RBM) companies have come to play a major role. In the Medicare market, such direct intervention has only recently been contemplated, but not implemented on any scale (Government Accountability Office, 2008). In the long run, however, these provider-based solutions will be most effective if they can also use cost-effectiveness information gleaned to reshape patient expectations. If quality and value are in fact measurable, the consumer may rationally be expected to play a role in reducing low-value spending and, perhaps, reducing overall spending.

In this paper, we begin by exploring the current state and challenges to imaging cost-effectiveness analysis. In the second section, we explore the factors that underlie a decision to order an image, emphasizing the reasons why a rational decision model may fail in the real world. Finally, we sug-

[1] For the purposes of this report, DI includes all noninvasive diagnostic imaging, irrespective of the provider. Thus, cardiac imaging and obstetric imaging are considered to follow similar patterns.

gest avenues that might be pursued to ameliorate these market failures in an effort to counter this effect.

Technology Assessments in Radiology

Some of the earliest seminal work in cost-effectiveness analysis focused on imaging and screening, with early studies of lung cancer and breast cancer screening dominating the dramatic increase in available technologies (Blackmore and Magid, 1997; Fineberg et al., 1977; Shapiro et al., 1966; Taylor et al., 1981). During the 1980s and 1990s, formal trials evaluating the effectiveness of imaging in screening and diagnostic utility were begun, some with public sector funding. Subsequently, studies of clinical utility have flourished with some notable limitations, generally related to the inability to connect imaging directly to outcome (Blackmore and Magid, 1997; Hollingworth, 2005; Singer and Applegate, 2001).

In the past few years, several papers and a book have been published summarizing and evaluating the existing cost-effectiveness and value-based imaging literature (Eddy, 2006; Hollingworth, 2005; Hunink, 2008; Otero et al., 2008).Their findings suggest limitations in the existing literature as well as practical explanations for why imaging may be less amenable to traditional studies. In the forward to the book *Evidence-Based Imaging*, Hillman states, "Despite our best intentions, most of what constitutes modern medical imaging practice is based on habit, anecdotes, and scientific writings that are too often fraught with biases," a point we return to below. Even in Blackmore and Medina's book, the majority of clinical applications appear to have limited or insufficient evidence to truly inform decision making, and it is rare to find an indication for which "strong evidence" is present.

In their review and meta-analysis of cost-effectiveness analysis in medical imaging, Otero and colleagues (2008) note that there has been an increase in the number of analyses over the last decade but not in analytical quality. They go on to describe and reference (Singer and Applegate, 2001) the multiple reasons why cost-effectiveness analysis in radiology may be more difficult: (1) imaging technologies evolve more rapidly than the ability to gather clinical evidence supporting their use and (2) the inability to accumulate sufficient data prior to widespread adoption.

In her accompanying editorial to Otero and colleagues, Hunink (2008) reviews the history of imaging cost-effectiveness research and raises additional cautions. She points out the variation between different experts in assumptions (including the dramatic variation in discount rates as used by UK and U.S. policy boards). Further, she notes the exclusion of increasing longevity from total costs, despite the impact this may have from the societal perspective. She amplifies on the concern that while DI cost-

effectiveness analyses have increased in number, they have not kept pace with other disciplines in methodological improvements in quality.

Ultimately, the evidence for imaging cost-effectiveness (and, presumably, value) is best in the category of breast imaging and generally poorer in other areas (Eddy, 2006). While numerous investigators have performed studies targeted at neuroimaging, musculoskeletal imaging, and cardiac imaging (among others), one major limitation has been the relatively narrow indications that are studied versus the application in clinical practice.

Ideal Versus the Reality—Why an Image Is Ordered

In a rational choice framework, the image ordering decision would be based on a social cost-effectiveness analysis that compares the cost of the image to the expected value of improvements in patient health that the image produces. The actual ordering decision falls short of this ideal for at least four reasons.

1. As noted above, the necessary relevant cost-effectiveness information is often unavailable.
2. Patients may exert pressure to receive an image based on their overestimate of the image's benefits.
3. The ordering physician may face financial and psychological incentives to order the image.
4. The doctor-patient relationship—a principal-agent relationship—mitigates against correcting overestimated benefits and misaligned incentives.

With respect to patients, research demonstrates a statistically significant improvement in "well-being" and a reduction in anxiety after receiving a diagnostic workup, irrespective of positive or negative findings (Lucock et al., 1997; Mushlin et al., 1994). Thus, while there may be no meaningful impact on outcome or even a long-term impact on perceived well-being, information may, under certain circumstances, provide benefit in and of itself that is difficult to measure in traditional survey instruments.

It is possible that some of this benefit is based on patient misperception—for example, an underestimate of the risks associated with a false positive or an overestimate of the costs of two weeks of watchful waiting. Nonetheless, the part of the benefit that remains after exposure to this information should, in theory, be included in a social cost-effectiveness calculation.

With respect to physician incentives, various clinical settings may offer the physician financial and/or nonfinancial incentives—potential "payoffs"—to order the image. In the category of financial payoffs, we generally think of areas where a true economic rent is recovered (Winter

and Ray, 2008). If the physician is ordering a study where the payment exceeds the cost, there is a true profit potential. Even in the presence of strong ethical adherence to the Hippocratic oath and similar constructs, the physician may have incentives to over-order imaging studies. This fits under the rubric of supplier-induced demand.

In the absence of direct financial gain, there may be additional, non-financial payoffs including the following:

- The ordering physician may be able to reduce effort by having a briefer or less intense physical examination.
- The ordering physician may be able to have a shorter operating room commitment.
- The ordering physician may avoid potential malpractice costs (real or perceived)—this being the defensive medicine argument.
- The payoff may have no fungible equivalent but may be reflected in decreased physician concern or uncertainty regarding the patient in question.

From a cost-effectiveness perspective, these different payoffs carry different weights. The ordering physician's profit (if any) should carry no weight. The reduced effort may or may not carry weight depending on the use of the saved time (see the example below).

The physician's desire for reduced uncertainty is potentially important. Behavioral economists emphasize the way in which decisions can be driven by a desire to avoid "regret"—the guilt and responsibility one feels upon recognizing that one has made the wrong choice in an uncertain situation (Thaler, 1994). In a clinical setting, regret would arise from a misdiagnosis that could have been avoided by ordering an image.[2] The psychic value of regret avoidance may be insufficient to justify the image's cost, but it remains a benefit that should be included in a social cost-effectiveness analysis.

Problems in the doctor-patient relationship begin from the position that a fundamental element of an economically competitive market is full information for buyers and sellers. In such a market, information about price, value, and quality is necessary and symmetric. This implies that the buyer and the seller each have sufficient information about their product and/or service to enter into an exchange.

[2] For example, having a car's brakes checked involves visible money and time costs, so a physician is unlikely to have them checked every day even though it would reduce uncertainty about the car's safety. The drive to reduce uncertainty is reinforced by the human tendency to exaggerate the recurrence probability of rare but vivid events—an incorrect diagnosis that could have been avoided by an image (Nisbett and Ross, 1980).

While there are few perfect markets in health care, the prescription drug industry offers a relevant comparison and basis for discussion. Prescription drugs, although protected for a period of time by a government-sanctioned monopoly (patents and FDA exclusivity, both of which confer the ability to collect monopoly economic rents), exist in a market where good (not great) information about efficacy, price, and outcome exists. In such a market, an empowered consumer may make rational decisions about purchasing drugs directly. In the presence of insurance (the most frequent situation), information may be used to steer patients to individual branded and generic drugs, using economic incentives and value-based approaches. In this market, pricing and spending growth has been muted and dramatic gains in market share have been seen for generic drugs, in particular. As a further consideration, the pharmacy benefit management (PBM) industry has risen up to incorporate economic and informational incentives targeted at steering patients to lower-cost options.

In imaging, value is best represented by our traditional metrics of effectiveness (limited at best and noted above); quality can vary considerably across practices; and pricing information is often limited or completely opaque. As Blackmore and Medina have tried to do, efforts at organizing information for clinicians are emerging. This brings us to the infrequently discussed topic of the principal-agency problem.

The principal-agent framework applies whenever one party (the agent) is hired by another (the principal) to take actions or make decisions that affect the payoff[3] to the principal (Besanko et al., 2003). In health care, this paradigm is further complicated by third-party payers. However, for all intents and purposes, it fits the physician-patient relationship: the physician is most often the agent, with the patient being the principal. While the Hippocratic oath may seem to sterilize the pecuniary risk in the relationship, there is ample evidence of genuine conflict. For example, providing patients with information on physician incentives, the risk of false positives, and so forth, might reduce patient pressure for images that are medically unnecessary. The principal-agent problem reduces the likelihood that the physician will provide such information.

While not often described in this manner, the findings of the group at Dartmouth and their well-known presentation at the www.dartmouthatlas.org site support the informational and prinicipal-agency issues in healthcare. Their group suggests that the variation in healthcare use fits into three categories: (1) systematic underuse of effective care such as beta-blockers after heart attack, or diabetic eye care; (2) misuse of preference-sensitive care such

[3] This payoff need not exclude the possibility that the patient is made better off, as well. The principal-agent problem does not require that the payoff flows only to the agent, but merely that there are additional payoffs to the agent beyond the "agency fee."

as discretionary surgery (as documented by striking variations among neighboring communities in rates of surgery); and (3) overuse of supply-sensitive care such as physician visits and hospitalization rates among chronically ill patients (Dartmouth University, 2009). There are no necessary conflicts between this typology and the suggestion that principal-agency issues may, in fact, be an overriding concern with regard to imaging. Further, the addition of this issue to the usual description begins to explain why growth in imaging may be greater than would be expected merely by direct financial gains.

The Radiology Benefit Management Industry: A Solution or an Interim Palliation?

The radiology benefit management industry has risen up in response to the rising cost of imaging and the difficulty of applying traditional managed care mechanisms for controlling utilization (Appleby, 2008). Using a combination of network control and monitoring, as well as more traditional means of pre-authorization and pre-certification, RBM companies attempt to control the principal-agent problem while relying on evidence. In the absence of strong direct evidence, they are forced to use consensus approaches to decision making.

The industry is an interesting parallel to the pharmacy benefit industry in that it generally takes no risk in its contracting and is paid, mostly, on a transactional and performance basis. By judging the growth of the industry and its penetration in the presence of low switching costs, one would assume that RBM companies perform well; but in the absence of statistically valid data, one can only infer this.

The RBM industry's greatest strength lies in its ability to validate and disseminate information as well as oversee the "agents." This last point is, perhaps, most difficult to directly address and verify because the relative payoff (as described above) to the referring clinician is difficult to measure. Still, it does imply an additional check on the ordering practices of referring clinicians and, theoretically at least, patient care.

The Road Forward

As we have argued, better cost-effectiveness information, distributed more widely, could be an important element in slowing the growth of unnecessary imaging. At the outset, such information would improve the "value added" by RBMs. The information would also make physicians more aware of both the costs of an image and the chances that it would, in fact, reduce diagnostic uncertainty. Similarly, access to this information would allow patients to take a more active role in the image ordering decision.

A realistic goal involves producing cost-effectiveness information that can serve as general decision guidelines. The more ambitious goal—cost-effectiveness analyses leading to detailed rules—is impractical because of hard-to-measure benefits (e.g., increase in the patient's feeling of well-being). In addition, detailed rules are difficult because cost-effectiveness calculations for a given image critically depend on context. A few explanatory (and not infrequent) scenarios illustrate the point.

Three trauma patients simultaneously arrive at the hospital, all with moderate risk of nonpenetrating traumatic injury. A dedicated physical examination may reduce the need for further imaging. However, given resource constraints, computed tomography of the brain, cervical spine, chest, abdomen, and pelvis is performed on each. While this approach has minimal risk and should improve the outcome for the patient, it also will reduce the need for dedicated primary and secondary evaluation by the trauma surgeons and clinical staff. In this case, nursing resources (in addition to those of the trauma surgical team) may also benefit from reduced demand. Thus, the value flow (payoff to agent in the parlance of the principal-agent situation) includes the hospital (which can reduce staffing in this scenario) and the physician staff (which may reliably manage more such patients in the setting of additional imaging).

A sexually active patient is admitted to the emergency room with fever and lower abdominal pain. The emergency room physician is concerned that the pain is pelvic and perhaps related to pelvic inflammatory disease. The physical examination suggests, but is not definitive for, cervical motion tenderness. Consultation with the obstetrics-gynecology service is sought. The physician consult requests a transvaginal ultrasound prior to physically examining the patient. In this situation, the new consult can avoid making multiple trips to see the patient and may, ultimately, be able to make a remote decision to admit the patient without necessarily seeing the patient on an emergent basis. Again, while the outcome for the patient is not harmed, the payoff is to the consulting service.

A patient presents to the orthopedic surgeon with signs and symptoms of internal derangement of the knee. Arthroscopy is indicated. The orthopedic surgeon obtains a magnetic resonance imaging study in order to facilitate the procedure and provide a roadmap to the injuries. There may be a true advantage to the patient in limiting the intervention and also detecting rare complications. However, the orthopedic surgeon additionally gains from a shorter procedure.

In all scenarios, there is no violation of the Hippocratic oath. There is, however, a lack of perfect information and a principal-agent conflict. In each case, the payoff to the provider and the cost to the payer are seemingly disconnected in the absence of additional monitoring.

Once the goal is agreed to, cost-effectiveness information for the most frequent imaging settings can be obtained in a number of ways: studies that record the physician's decision-making process to see in which circumstances (and with what likelihood) an image changes a decision; comparisons of the use of imaging in the United States and Canada (where highly restricted capacity limits imaging in certain situations), and efforts at discerning the incremental non-patient care payoff to the referring clinician, perhaps in settings where fee-for-service reimbursement is discouraged or absent. Current efforts by public and private payers to utilize the concept of the "patient-centered medical home" (Deloitte Center for Health Solutions, 2008) would fit in this latter category.

In summary, there is nothing truly extraordinary about diagnostic imaging that can explain its outsized growth in spending. Rather than the nature of the technology, it is the nature of the relationship between the flow of value to the patient, the referring clinician, other providers, and the presence of third-party payers that may increase the use of low-value (to the patient) imaging. Efforts to measure and, perhaps, capture the flow of value to the responsible clinician may allow for improved overall patient outcomes at lower costs. At present, the RBM industry plays a temporizing role in attempting to achieve this goal.

ASSESSING THE VALUE OF PREVENTION

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Prevention is widely recognized as a critical part of good health care and is a foundational principle of numerous aspects of the health professions, including the fields of preventive medicine and public health. Indeed, prevention can produce important health benefits in both length and quality of life and may have favorable effects on healthcare costs in some instances. However, prevention is not always beneficial or a desirable use of limited resources. As a result, there is a strong case for the application of principles of cost-effectiveness to the analysis of prevention. Medical cost-effectiveness analysis can provide a systematic framework for determining whether the benefit of a medical intervention of any type—whether preventive or not—is worth its cost. For this reason, medical cost-effectiveness analysis is an important tool to apply to all healthcare spending. Nevertheless, several aspects of prevention make it especially important that preventive services be analyzed through the lens of cost-effectiveness.

First, benefits that accrue in the future, such as those that come from prevention, are less valuable than similar benefits that could occur in the present. Cost-effectiveness analysis provides a well-developed framework

in which to balance benefits and costs occurring over varying periods of time. Indeed, because future benefits of prevention may be high and some prevention efforts may be associated with risks in the present, it is important to have a tool such as cost-effectiveness analysis to create aggregate measures that combine potential current harms and potential future benefits into a single measure of net benefit. Similar issues arise on the cost side because prevention may often generate costs in the short run yet have the potential to reduce costs over the long run, although the latter is by no means guaranteed or even the norm. Second, because benefits and costs may be uncertain in both the short and the long run, at individual and population levels, the framework of cost-effectiveness analysis can be particularly important for determining the value of prevention, especially since it is well suited to integrating uncertain outcomes into decision making.

Third, since the benefits and costs of prevention can also be borne by multiple parties, issues of perspective are important in the assessment of preventive services.

All of these factors can be captured within the context of medical cost-effectiveness analysis and make its application to the assessment of preventive services especially useful and important.

The application of medical cost-effectiveness analysis to preventive services has a long and distinguished history, including most notably Weinstein and Stason's (1976) pioneering work on the cost-effectiveness of the treatment of hypertension and Louise Russell's *Is Prevention Better Than Cure?* (Russell, 1986). This paper does not seek to synthesize or summarize that immense body of work but instead to briefly introduce the key concepts of medical cost-effectiveness analysis for users unfamiliar with it and to highlight four key points about the cost-effectiveness of prevention that may be less familiar even to readers highly familiar with the field.

A Brief Introduction to Medical Cost-Effectiveness Analysis

Medical cost-effectiveness analysis seeks to provide a logically coherent framework in which to maximize the health benefits of spending on health care subject to resource constraints. Medical cost-effectiveness analysis has roots in decision science, economics, and psychology but dates in its current form most clearly to the work of Weinstein and Stason (1976) on the cost-effectiveness of the treatment of hypertension.

Calculating Health Benefits

Following the most commonly used approach, health benefits are measured in terms of their effects on the quality and length of life, as combined

into quality-adjusted life-years. QALYs are a weighted form of life expectancy, where each year of life in any given health state (h) is weighted by a quality-of-life weight ($Q(h)$) between 0 and 1, where 0 is equivalent to death and 1 is equivalent to perfect health. These quality-of-life weights (also known as utilities) can be derived by a number of psychometric techniques that generally ask patients to rate their health in various health states relative to each other or relative to perfect health. Quite often the quality of life associated with a health state of interest for a given medical intervention has already been studied, and there are published libraries of such quality-of-life weights, such as the one included in the Tufts registry of published cost-effectiveness studies (Tufts University, 2009).

The uncertain nature of health in QALYs is captured by the probability that persons survive in health state h at time t, which can be written as $S(h,t)$. The probabilities of various health states at various times in the future can either be measured directly through the use of clinical trials or estimated based on the analysis of existing data and then modeled mathematically.

A final element in the calculations of QALYs is that people may value outcomes at future times (t) less than outcomes in the present. To account for this mathematically, outcomes in the future may be weighted by a term β^t, where $\beta < 1$ and t is the time from the present; therefore as time into the future increases, β^t decreases and the future receives less weight in the present. This is known as discounting. For example, with future benefits discounted at 3 percent so $\beta = 0.97$, a benefit worth 1 unit today would be 0.97 unit if received one year in the future and 0.94 (0.97×0.97) if received two years in the future.

Combining all these elements, QALYs can then be calculated as the sum of future years lived in various health states weighted by their quality of life, probability, and time into the future. Thus QALYs can be calculated as

$$\text{QALYs} = Q(h,t = 0) + \Sigma_{t,h}\, \beta^{t} \times S(h,t) \times Q(h,t),$$

where $\Sigma_{t,h}$ is the sum over all possible times and future health states.

To illustrate with a simple example, assume a person who is thought to be in fair health with $Q = 0.6$ health this year. Also assume this person has a 70 percent chance of surviving until next year with an associated quality of life of 0.1 and a 30 percent chance of dying by next year and therefore an associated quality of life of 0. Finally, assume that the person has a discount rate of 3 percent and therefore $\beta = 0.97$. Given these values, this person would have

$$\text{QALYs} = 0.6 + 0.97\,(0.7 \times 0.1 + 0.3 \times 0) = 0.6679 \text{ QALYs}.$$

Calculating Costs

To calculate cost-effectiveness, a measure of cost is needed, and this may be derived by a variety mechanisms, including direct collection of data as part of a clinical trial or use of published data on utilization and/or costs. A critical idea is the concept of incremental costs—the extra costs that occur because of one intervention compared to another. For example, if the choice being made is between a newer, more expensive treatment that costs $10,000 and an older one that costs $8,000, the relevant incremental cost is $2,000. Another critical idea in cost-effectiveness is the idea of perspective—that is, the question of costs and benefits to whom.

Most experts suggest that for most purposes, a societal perspective is appropriate, including all costs and benefits regardless of to whom they accrue. This has a variety of implications for measuring costs. One obvious implication is a preference for using direct measures of cost rather than price or charges for a service since the markup of the latter two over cost is simply a transfer payment from the entity buying the service to the entity that produced it, not a real social cost. More subtle examples of this issue that are relevant for prevention relate to future medical and nonmedical costs, which are discussed further below.

The case for taking a societal perspective is most fully articulated in a 1996 volume entitled *Cost-Effectiveness in Health and Medicine* edited by Marthe Gold and others, which represents the work of a Public Health Service panel asked to develop consensus on core methods in cost-effectiveness analysis. Although the field has advanced since the publication of that book more than a decade ago, it remains a very valuable reference for anyone wishing to learn more about this area.

Calculating and Utilizing Cost-Effectiveness Ratios

Having assembled data on the health effects of an intervention in QALYs and its costs, the next step is typically to calculate the cost-effectiveness ratio by dividing the cost by the number of QALYs gained. Such ratios are then often put into what is called a league table, which lists these interventions in order of increasing cost per QALY so that the most cost-effective interventions are at the top of the table and the least are at the bottom. Table 3-3 is a league table that reports the cost per life-year saved for a number of preventive services.

Reviewing the table, one sees that some interventions, such as screening neonates for phenylketonuria, may both produce health benefits and save money and are therefore certainly desirable from the perspective of cost-effectiveness. Other interventions may not produce health benefits and are costly. Those interventions are dominated and should not be pursued.

TABLE 3-3 Cost per Life-Year Saved for Preventive Services

Intervention	Cost per Life-Year Saved
Neonatal screening for phenylketonuria	<0
Secondary prevention for hypercholesterolemia in men ages 55-64	2,000
Secondary prevention for hypercholesterolemia in men ages 75-84	25,000
Primary prevention for hypercholesterolemia in men ages 55-64	99,000
Screening exercise test for coronary disease in men age 40	124,000
Screening ultrasound every 5 years for abdominal aortic aneurism	907,000

Most interventions, however, will have positive costs and benefits and will therefore be like the remaining interventions in the table, with the decision about whether they are cost-effective determined by the threshold one uses in terms of the cost per QALY (or cost per life-year if quality of life is not accounted for). While there is no specific agreement about what cost per QALY should define the threshold for cost-effectiveness, estimates in developed countries often range from about $50,000 per QALY to $200,000 per QALY and are justified by comparisons to implicit values that people place on risks to health in other contexts. One example of such an approach involves examination of the wage premiums that people have to be paid to accept jobs that have increased risk of death. Another examines the cost-effectiveness of medical interventions considered to be of borderline cost-effectiveness, such as dialysis among older adults, and compares other interventions to that point of reference. Yet another approach starts at the top of the table and funds interventions up until the point at which available funds for health care are exhausted. However, this approach is not useful when there is no explicit budget for health care or when one takes the perspective that nonmedical costs that would accrue outside such a budget are also appropriate considerations for cost-effectiveness analysis.

In practice, there is also often uncertainty about the cost-effectiveness of an intervention, so that precisely defining a threshold may not be as relevant as looking for extreme results on either end of the spectrum that provide opportunities for more effective resource allocation. For example, in Table 3-3, both increasing the use of cholesterol-lowering drugs for secondary prevention in men aged 55-64 years with hypercholesterolemia and reducing the use of screening ultrasound exams to search for abdominal aortic aneurism in the general population are clearly outside on one side or the other of the cost-effectiveness threshold.

While this general approach of promoting the use of interventions that are highly cost-effective and discouraging the use of those that are clearly not cost-effective is the correct one, it is also worth noting that the scale of the intervention considered is a very important concern if there

is limited ability to promote the use of cost-effective interventions over ones that that are not cost-effective. For example, if the cost-effectiveness threshold were $100,000 per QALY, it might be far more important to promote the use of an intervention with a cost-effectiveness ratio of $90,000 that could apply to many people than to promote an intervention with a cost-effectiveness ratio of $10,000 per QALY that could apply to a much smaller population. One relatively recently developed approach to address this problem is to emphasize the "net health benefits" of an intervention, which calculates the benefits produced by an intervention across the population net of the potential health benefits that could otherwise be produced by reallocating the costs of the intervention to pay for interventions that are at the threshold that defines cost-effectiveness (Stinnett and Mullahy, 1998).

Cost-effectiveness analysis can be criticized on a large number of methodological bases, ranging from how benefits and costs are defined, to how distributional issues are addressed. There is no question that many of these concerns about the approach are substantive. Nevertheless, the value of the approach is suggested by the more than 1,000 applications that have now been published (Tufts University, 2009) and the number of specific examples that have helped inform public policies. One favorite example is the use of Pap smears at varying frequencies, which cost-effectiveness analysis has suggested is highly cost-effective if done every three years, but less so when done every other year or annually. Annual testing costs almost $1,000,000 per life-year saved while adding only hours to life expectancy. Evidence such as this has been important in shaping national recommendations about the frequency of Pap smears, as evidenced by the move away from annual screening and increased emphasis on increasing the fraction of women having Pap smears performed at three-year intervals, if appropriate. As discussed below, the Pap smear example is bittersweet with respect to the value of cost-effectiveness analysis because much of the use of Pap smears in the United States remains at frequencies that are not cost-effective. Still, the small cost of performing cost-effectiveness analyses relative to the large cost of health care itself means that it does not take many examples of even partial success in better targeting or reducing spending to justify the use of cost-effectiveness in policy making.

It should also be pointed out that cost-effectiveness analysis alone should not be the only criterion for decision making. There are a wide variety of other concerns that policy makers, clinicians, and others who might use cost-effectiveness analysis should also consider in making decisions. Thus, the limitations of cost-effectiveness analysis can be compensated for to some extent by understanding that it should not be the only factor in decision making. Indeed, some have argued that one of the most valuable contributions of cost-effectiveness is forcing examination of the

factors the analysis can, and cannot, account for. While the United States has used cost-effectiveness analysis in policy making to a relatively small extent, the experience of many countries around the world, perhaps most notably the United Kingdom's National Institute for Health and Clinical Excellence, suggests that incorporating cost-effectiveness analysis into the policy-making process can promote discussion of the benefits and costs of medical interventions.

Four Key Points About Prevention and Cost-Effectiveness Analysis

As noted above, there is a long and distinguished history of the application of cost-effectiveness analysis to the analysis of prevention. Rather than to attempt to replicate that literature, the goal of this paper is to highlight a few key parts of it and extend it in the context of recent discussions of the potential of prevention to address key concerns around the control of healthcare costs in the United States.

Point 1: If prevention produces health benefits then it should be worth paying for. Therefore, prevention need not—and generally will not—save money.

During the 2008 presidential primaries and general election, many of the candidates suggested that prevention might be an important source of cost control. Certainly it is true that if future healthcare costs can be averted, it is possible that prevention could reduce healthcare costs, and there are, indeed, examples of disease management programs that have saved costs. Nevertheless, a quick review of the sampling of healthcare interventions in Table 3-3, and the much broader list of preventive measures in the Tufts registry suggests that most preventive health care costs money (Cohen et al., 2008). However, this is not to say these are not worthwhile expenditures. Indeed many preventive healthcare interventions are highly cost-effective. By and large, rather than focusing on the cost savings of preventive health care, we have to take a comprehensive approach that generally will begin with the magnitude of its benefits rather than the magnitude of any reductions in downstream healthcare costs. The key point is that the idea that preventive health care saves money, while perhaps politically attractive, is a very incomplete perspective on the benefits and, hence priorities, for prevention. This point is by no means new (Russell, 1993). Nevertheless it seems to require repeated reinforcement. Perhaps this is a reflection of the difficulty in controlling healthcare costs by other means.

Point 2: If prevention extends life, it can affect costs in the future—medical and nonmedical. This produces economic advantages of emphasizing prevention that improves quality of life rather than length of life.

When prevention extends life, it can often produce costs in future years in terms of both medical and nonmedical costs, both of which can significantly change the cost-effectiveness of the intervention. Such costs have often been neglected in studies of preventive health care, but work by myself (Meltzer, 1997) and others has shown that including those costs can significantly change the cost-effectiveness ratio, often improving the cost-effectiveness of interventions that improve quality of life compared to interventions that increase length of life. This suggests that if one wanted to strengthen the economic case for prevention, focusing on interventions that primarily improve quality of life might be preferred to focusing on those that primarily increase length of life. However, this is less true for younger persons who are still in the workforce, and it may become less true even for older persons if working lives extend as people live longer—but the trend in retirement ages in the United States over the past decades has been the opposite. It should be noted that this is *not* to say that the goal of prevention should be to save money, but rather that accounting for future costs may make interventions that improve quality of life likely to be more cost-effective compared to those that increase length of life.

Point 3: The value of prevention depends on how we use it—not just which approaches but in whom.

Preventive services are a diverse set of interventions, some highly cost-effective and others not so, but many interventions vary in their cost-effectiveness depending on the context in which we use them. This makes general claims about "prevention's" effect on costs, health, or the cost-effectiveness of health care overall inherently misleading. Policy discussions require a much more nuanced conversation of the specific approaches to prevention being advocated and the specific population and context in which they will be used. The earlier Pap smear case study provides an excellent example for illustrating the importance of context, since Pap smears are highly cost-effective if received once every three years but have almost no incremental value if done more frequently. Because the majority of Pap smears in the United States are given at frequencies that are not cost-effective, most of the money we spend on Pap smears would be better spent in other ways (Meltzer and Alexander, 2009). This said, providing Pap smears every three years produces benefits that are so substantial and so cost-effective that, even though we waste most of the money we spend on Pap smears, their overall cost-effectiveness remains very high. While eliminating these more frequent Pap smears that are not cost-effective could produce a more efficient healthcare system overall, one must be cautious in eliminating inefficient use if there is risk that efficient use might be reduced as well.

In cases where the benefits of targeted use are more modest, non-selective use can turn a potentially cost-effective intervention into non-cost-

effective one. This has been seen most strikingly in studies of intensive therapy for diabetes, where great heterogeneity in patient preferences about the value of intensive treatment exists (Meltzer et al., 2003). Interestingly, these variations are driven heavily by patients' feelings about the quality of life associated with the therapy itself. Patients who feel that intensive therapy (with its more frequent fingersticks, injections of insulin, and risk of hypoglycemic events) reduces quality of life are much less likely to experience a net benefit from intensive therapy. Interventions such as this whose benefits depend heavily on patient preferences are often known as "preference sensitive." A study of the cost-effectiveness of physical exercise found similar results in that exercise was found to be cost-effective only as long as the person exercising considered the time spent to be of reasonably good quality. Because prevention very often involves applying a service to a large number of people in order to prevent illness in a much smaller number, it is likely that many preventive services are highly sensitive to preferences about receipt of the service itself. It may be for reasons such as this that interventions that can be relatively unpleasant, such as colonoscopy, Pap smears, and mammograms, are far less than universally utilized despite strong evidence of their benefits.

Another important implication of the importance of patient preferences in prevention is a behavioral one. Patients whose preferences do not favor an intervention may indeed reject it, potentially improving both the net effectiveness and the cost-effectiveness of the intervention as it is used in practice. We have found that this is true for intensive therapy for diabetes, with patients who find the therapy itself more unpleasant rejecting the intervention. This effect is so dramatic, in fact, that if intensive therapy were used by all older patients, it would actually be harmful. However, as it is used in practice, we find intensive therapy both beneficial and cost-effective (Meltzer et al., 2003).

This is not to say that current patterns of use are ideal. We find that benefits would be great even if intensive therapy were adopted only by people whose preferences suggest they are expected to benefit from it. This makes the case for approaches, such as decision aids, that may help patients make better decisions. Some of our analyses suggest that the value of information that can result in better decision making at the individual level (i.e., the value of individualized or "personalized" care) may be much greater than the value of information that seeks to inform decision making only at the population level (i.e., the single treatment), which has been the focus of most cost-effectiveness analyses (Basu and Meltzer, 2007).

Point 4: If the value of prevention depends on how and in whom we use it, we must evaluate technologies as they are used in practice and seek to improve their use if it is not ideal.

The idea that the value of prevention depends on how we use it, whether this is misuse or overuse or the failure to individualize care, suggests that we need to think carefully about how to use cost-effectiveness analysis in policy making. If a cost-effectiveness analysis suggests that an intervention could be cost-effective if used in one way but it is not used that way in practice, should the intervention be considered cost-effective or not? This may be one area where the judgment of policy makers could be especially important, particularly if there are available policy options that can alter patterns of use in ways that could change the cost-effectiveness of the intervention. Examining these questions of how to think about cost-effectiveness in the context of how technologies are used is a very new area of inquiry and one worthy of substantial attention by cost-effectiveness researchers and policy makers.

If one accepts the idea that the value of interventions should be assessed in the context in which they are used, one is immediately drawn to consider approaches that may alter the use of technologies. There are myriads of possibilities available to influence behavior, ranging from patient-focused methods (e.g., copayments, patient decision aids) to provider-focused methods (e.g., payment incentives, practice guidelines, health information systems, opinion leaders). The extensive discussion of value-based pricing at this meeting can readily be understood in this context as an effort to try to influence the cost-effectiveness of therapies by better targeting them to the populations in which they will be most beneficial and cost-effective.

Conclusion

Prevention is a critical part of modern health care and has great potential to influence health and perhaps even help control certain aspects of healthcare costs. However, the value of prevention varies tremendously depending on the approach considered, and on how and in whom it is used. Although cost-effectiveness analysis must be only one consideration in the policy-making process, the tools of cost-effectiveness analysis can provide insight into efforts to maximize the value of prevention. The United States, to date, has used the tools of cost-effectiveness analysis less than other countries. Yet the United States may have more to gain than any other nation because of its exceptionally high level of healthcare spending, the increasing pressures to control that spending, and the harm that ill-informed controls on spending could cause. While the tools of cost-effectiveness analysis will continue to be refined and will never be perfect, it will be critical to utilize the insights gained from cost-effectiveness analysis and apply them to prevention and to the entire healthcare system as we seek to maximize the value of health care in this country.

EVIDENCE-BASED DECISION MAKING OR DECISION-BASED EVIDENCE MAKING? EVIDENCE AND DECISIONS ALONG THE LIFE CYCLE OF PHARMACEUTICAL PRODUCTS

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The IOM's Roundtable on Value & Science-Driven Health Care established the concept of "value" as an early priority (IOM, 2008). Value in health care was characterized by the Sectoral Strategies Working Group as "the right care to the right patient at the right time for the right price" and expressed as "the physical health and sense of well-being achieved relative to the cost" of healthcare interventions. The costs of these interventions are related to the total resources used, whether expressed in economic or monetary terms or otherwise.

In theory, value is a relatively simple concept. In practice, measuring value, especially in health care, is difficult. The Sectoral Strategies Working Group alluded to this, noting that measuring health benefits and healthcare costs is particularly challenging and that there may be substantial variability between the perspectives of individuals and those of the general population. Indeed, value is often in the eye of the beholder. This paper is intended to supplement the previous IOM Roundtable work on value and focuses on stakeholder perspectives of key decisions that must be made during the life cycle of a pharmaceutical product.

Overview of Decision Making and Key Decisions

The conceptual framework of making decisions under uncertainty and with incomplete information has been studied in the business world since the 1950s (Grayson, 1960). Eddy (1990) has described a similar framework for medical decisions and suggested that they consist of two components: scientific judgments and preference judgments (Figure 3-4).

Scientific judgments involve analysis of the scientific evidence on benefits and costs for each decision option. To the extent possible, scientific judgments are objective, analytical processes—a left-brain activity. Analysis of evidence is done by scientists who rely on established rules of evidence and who can generally reach consensus. In contrast, preference judgments involve personal values and preferences and are more of a subjective process—a right-brain activity. The stakeholders who ultimately make decisions about pharmaceutical products may not always be scientists and may not always have a goal of reaching consensus with others. Their decision reflects a combination of their interpretation of the scientific evidence and their own personal preferences.

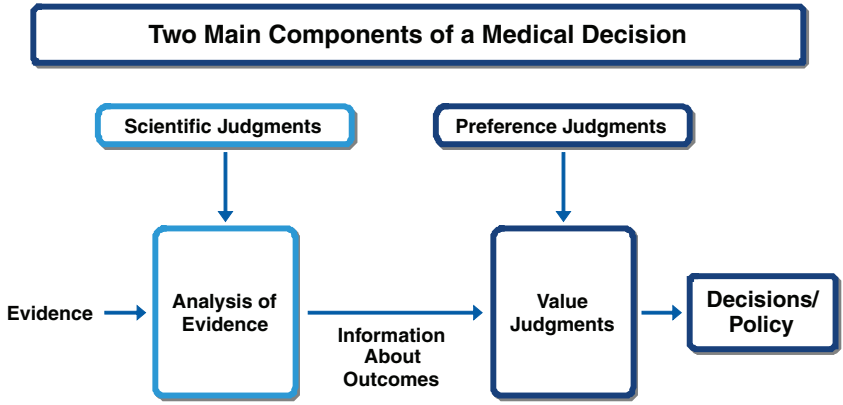

FIGURE 3-4 The anatomy of a medical decision.
SOURCE: Eddy, 1990.

Teutsch and Berger (2005) have developed a similar framework for medical decisions and added other variables such as budget constraints, equity, and acceptability to the preference judgment component. They refer to the scientific component as evidence synthesis and the preference component more generically as evidence-based decision making. Health technology assessment (HTA) agencies refer to the scientific component as the assessment phase and the preference component as the appraisal phase. By and large, however, these different descriptions refer to the same overall framework. While much of the debate about the quality of medical decisions has been focused on improving the scientific evidence base, there has been relatively little debate about how decisions are made, what evidence is necessary for specific decisions, and what role individual and societal preferences play in those decisions.

There are many decisions in the life cycle of a pharmaceutical product, but this paper focuses on only four: (1) the investment decision to advance a product in development from Phase 2 to Phase 3; (2) the regulatory decision to approve a product for marketing; (3) the decision to adopt and subsequently allow use of a product in a patient population; and (4) the treatment decision to prescribe a product for an individual patient (Figure 3-5). The stakeholders for each of these decisions are the product developers, the regulatory agency, the payers and their intermediaries, and the patients and their physicians, respectively.

Investment Decisions

Pharmaceutical companies make many decisions during drug development. Examples include "go/no-go" decisions for first advancing products into humans (Phase 1 studies, usually in normal volunteers), for determining the dose range and early indicators of efficacy (Phase 2 studies in selected patients), and for determining safety and effectiveness in large groups of patients (Phase 3 studies). Investment costs and complexity increases with each subsequent phase, with the greatest increase in costs occurring in Phase 3. Therefore one of the key development decisions for a pharmaceutical product is the decision to advance the product from Phase 2 to Phase 3. While many factors are taken into account, advancement decisions are based on opportunity costs for the development portfolio and are often informed by financial calculations such as expected net present value (eNPV), which is a metric that represents how much value will result from an investment. The calculations for eNPV are based on forecasts for revenue and expenses over the lifetime of the product. Revenue and expenses that occur in the future are discounted back to the present according to standard accounting practices.

The decision to advance a product from Phase 2 to Phase 3 also depends on estimates of the other key decisions already mentioned, that

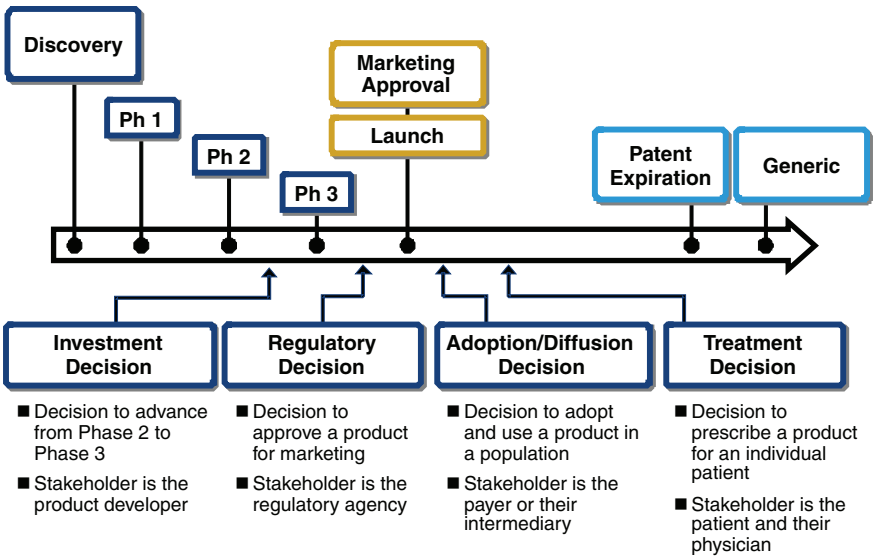

FIGURE 3-5 Key decisions in the life cycle of a drug.

is, the probability of technical and regulatory success, the probability of adoption and subsequent use by payers, and the probability that if the product is made available by payers, physicians will utilize it. Historically, financial calculations have been driven mostly by the probability of technical and regulatory success. In recent years there has been an effort to provide more granular input on adoption and diffusion. Indeed, we have recently done simulation modeling on the impact of policies that might restrict adoption and diffusion (such as coverage with evidence development) on eNPV. Coverage with evidence development (CED) is a federal program administered by the Centers for Medicare and Medicaid Services that requires additional data collection as a condition of coverage for national coverage decisions. CED restricts coverage to patients enrolled in the study—the decision for covering other patients is delayed until the new evidence is available. Our unpublished results suggest that this type of policy may significantly lower the eNPV of Phase 2 products, therefore emphasizing the importance of understanding the evidence required for adoption decisions at the time of marketing approval.

The overall goal of incorporating more granularity in investment decision inputs is to provide more accurate eNPV estimates and minimize the risk of either developing a product that companies cannot sell (false positive) or stopping development of a product that is beneficial for society (false negative). I think all pharmaceutical companies are attempting to adapt to this new evidence-based environment by making smarter development decisions earlier. However, they will require better eNPV estimates, which in turn will require better forecasting ability for marketing approval and, importantly, for adoption and diffusion by payers.

Regulatory Decisions

The evidentiary requirements for a given product label and the subsequent marketing approval decision by a regulatory agency are relatively predictable. Regulatory agencies put a lot of emphasis on Phase 3 study results in their marketing approval decisions. To better ensure that the evidence from Phase 3 studies will meet regulatory requirements, pharmaceutical companies hold meetings with regulatory agencies near the end of Phase 2 to discuss the type and strength of evidence needed in Phase 3. When the studies have been completed and the results are known, the agency may use an external expert advisory committee to provide advice if the agency anticipates questions surrounding interpretation of the results. While the regulatory approval process is not perfect, it is generally predictable.

The evidence requirements for regulatory agencies often differ from those of payers, patients, and physicians. Regulatory agencies typically focus on clinical value and not economic value. They are usually willing to

trade off external validity for internal validity—hence, their focus on data from randomized clinical trials. Their research question is often focused on whether a product is safe and effective, which may not require an active comparator to answer.

Adoption Decisions

Adoption decisions are not as predictable as regulatory decisions, primarily because payers do not have clearly defined evidence requirements. Historically, pharmaceutical companies have proactively received informal input from payer advisory boards on developmental compounds for the purpose of Phase 3 study planning, but there is often considerable variability in the input from both within a given health plan and between health plans. Recently the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom has begun a formal consultation service for pharmaceutical companies that is based on the end of Phase 2 meetings with the regulatory UK approval agency. This program is in its infancy, and it is too early to know whether this process will result in better predictability for adoption decisions, but it is a step in the right direction. In part, the uncertainty about the predictability of the process is because the evidentiary requirements identified in the process are nonbinding but done in "good faith." Some of the larger payers and health plans in the United States are just beginning to think about a more formal process for determining the evidence necessary for adoption decisions and various benefit designs, but they have not yet come as far as NICE.

Better predictability of adoption decisions will depend in part on better-defined evidence requirements, that is, the left side of Figure 3-4, but there remains significant variability in the preference (or appraisal) component of adoption decisions, that is, the right side of Figure 3-4. Indeed, the preference component of adoption decisions may have more of an impact on predictability than the evidence itself. Few studies have formally addressed this issue, but we know that there are areas for potential improvement. For example, there are no generally accepted guidelines for how pharmacy and therapeutics (P&T) committees should approach adoption decisions, and very few plans have formal orientation and training for committee members. This issue has implications for patients choosing a health plan: they will want to know not only whether the medicines they need are on the formulary but also whether a new product they may need in the future is likely to be available based on their understanding of the P&T committee's decision-making process. We have a project in progress that uses a modified RAND Appropriateness Criteria approach to assess how a group of adoption decision experts rate hypothetical scenarios where the quality and strength of scientific evidence on benefits, harms, and cost are varied. The

lack of studies in the preference or appraisal component of adoption decisions makes it ripe for additional research.

One specific issue related to adoption decisions has to do with "specialty pharmaceuticals." These are typically injection and infusion therapies with a high cost (>$5,000 per year). The evidence requirements for the scientific assessment component of these adoption decisions is no different than for other pharmaceuticals, but the preferences and values of decision makers may differ. Health plans have responded to specialty pharmaceuticals by shifting a percentage of the cost directly to the patient in the form of a co-insurance copayment (Tier 4). This class of drugs is growing (3 percent Tier 4 in 2004 [Kaiser Family Foundation and Health Research and Family Trust, 2004] versus 7 percent in 2007 [Kaiser Family Foundation and Health Research and Family Trust, 2007]) and may create a situation in which many Americans face a choice of no medication or possible financial ruin (Kolata, 2008). This situation is an affordability issue that is independent of value.

Treatment Decisions

Sackett and colleagues (2001) have defined evidence-based medicine as the integration of best research evidence with clinical expertise and patient values. Ideally, this should be standard for treatment decisions. Formal incorporation of patient values and preferences is rarely done but can be important. Fraenkel (2008) has shown that preferences may be important in selecting treatments for rheumatoid arthritis. Treatment decisions made by African-American patients were more likely to be based on preferences regarding adverse events, particularly rare, catastrophic adverse events, whereas treatment decisions made by Caucasians were more likely to be based on preferences regarding benefits. Preferences may also impact incremental cost-effectiveness ratios. Meltzer and colleagues (2003) have shown that patients' self-selection, based on their own treatment preferences, changed the incremental cost-effectiveness ratios for aggressive glucose control among diabetic patients from above the threshold for "good value" to coming within the range of "good value."

One challenge for individual patient treatment decisions is the application of population averages from study results when heterogeneity of treatment effects exists (Fraenkel, 2008). In Figure 3-6, photographs of 24 individuals are represented by the 12 pictures in the periphery of the figure—each picture is a digital composite of two people. The picture in the center is a digital composite of all 24 individuals and is analogous to the average results from a clinical trial where important differences existed between patients. The study results would be applicable to a given patient only to the extent that the patient was like the "average patient." This problem of averages makes

FIGURE 3-6 The problem of averaging population data.

it difficult in practice to get to the ideal of "best research evidence" as proposed by Sackett.

There are generally two approaches to reducing uncertainty around the heterogeneity of treatment effects. One is the use of genotyping and bioassays to reduce uncertainty at the individual patient level. The second is the use of subgroup analysis or actuarial diagnostics to reduce uncertainty at the subgroup level. Both have important roles, and it is expected that their use will increase.

Summary

The value of pharmaceuticals may be assessed and appraised differently depending on the type of decision being made and the preferences of the stakeholder making the decision. The type of evidence required for the decision and the stakeholder's tolerance for uncertainty surrounding the evidence may also vary according to the decision being made. This implies that, ideally, evidence generation should be specific to the decision

and to stakeholder requirements—that is, decision-based evidence making should precede evidence-based decision making. In practice, this approach works relatively well for some types of decisions (regulatory), but there is still work to be done in understanding the evidence needs of payers making adoption decisions and the evidence needed to better inform individual treatment decisions. Investment decisions by pharmaceutical companies depend, in part, on their ability to predict regulatory, adoption, and treatment decisions. As we develop policies that balance the need for cost control with society's desire for broad access to new, innovative medical treatments, it will be important for pharmaceutical companies to be able to better predict these other key decisions so that they can make smarter investment decisions earlier in the drug development process. This will require pharmaceutical companies to work closely with health plans and payers during early development and to better understand their requirements for evidence. Finally, individual treatment decisions could be improved by better incorporating individual preferences and heterogeneity of treatment effects into the decision.

APPROACHES TO ASSESSING VALUE: PERSONALIZED DIAGNOSTICS

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The mapping of the genome in 2003 and the dissemination of more efficient and less costly technology to detect DNA sequences led to a rapid series of completed genome-wide association studies (GWAS) and pharmacogenomic evaluations. The GWAS not only brought potential new targets for drug development, but also brought new diagnostics to more quickly and easily determine genetic predisposition to both disease and drug response. Because many of these new diagnostics were not deterministic (i.e., neither 100 percent associated with a given condition nor 100 percent predictive) but probabilistic in nature, their uptake in the clinic was not immediate. Additionally, studies to determine their impact on the natural history of disease or even treatment outcome were rarely assessed, leaving clinicians unclear about their relative value. These are frequently referred to as clinical utility studies.

Equally absent from the dialogue has been the perspective of payers, who bring their own determination of value. Along with the need for clinical utility, payers are anxious to evaluate value, balancing both cost and outcome differences in a trade-off. Because many of these diagnostics range in retail price between $200 and $3,000 (Human Genome Project, 2008), payers need to understand what downstream value they are receiv-

ing for coverage, in terms of either clinical improvement or cost avoidance or both.

The purpose of this paper is to outline some of the key methodological considerations in determining the value of personalized diagnostics. Although these are not necessarily different methods from those used to evaluate other healthcare technologies, there are nuances in personalized medicine that make some of these key considerations more or less challenging, and these are highlighted and explored. Also, while there is no single method to necessarily determine value, transparency around study approach and careful consideration of key methodological questions would make these value determinations more relevant to decision makers.

Perspective of the Evaluation

The first consideration for the conduct of these studies is to predetermine the perspective of the decision maker for the knowledge to be gleaned. This drives which end points are to be considered and also under what time period the evaluation will be conducted. For example, if the perspective is to be that of self-insured employers and the candidate diagnostic is to be used among their actively working population, the employers may be interested in trading off the diagnostic-associated costs with an understanding of total healthcare costs avoided (e.g., doctor visits, drug costs avoided or increased, ER visits, hospitalizations); differences in absenteeism, "presenteeism," and short- and long-term disability; and any other metric that influences their bottom line. If however, the decision maker is the caregiver of an elderly patient, the caregiver may be interested in examining not only the relative clinical benefits that accrue by virtue of testing, but also the impact of those benefits on caregiver burden and the accompanying savings in terms of cost and human burden that can accrue. A listing of decision-maker perspectives and candidate end points is provided in Table 3-4.

The most challenging area for this issue within personalized diagnostics is the value assessment of those tests that determine the relative risks of developing a chronic illness in the far future (i.e., predisposition testing). The determination of ultimate value would have to explore the long-term natural history impact of testing versus not testing, but the perspective for many decision makers may not be consonant with this type of long-term outcome avoidance. For example, there are now personalized tests that can provide the long-term probability of developing Alzheimer's disease in patients with mild cognitive impairment (Shaw et al., 2009). The value for an employer to cover the costs of these tests would have to trade off the incremental cost with the benefit of providing the probability to the employee. If the hypothetical value might include a hypothetical treatment in 20 years, the value might be the avoidance of all the current symptomatology and ensuing

TABLE 3-4 Listing of Perspectives and Potential Value End Points

Decision Maker	Direct Medical Costs	Indirect Medical Costs	Intangible Costs	Other
Employer	X	X		Productivity
Health plan	X			
Consumer	X		X	Productivity
Government plan	X	X		Productivity
Providers	X		X	Opportunity
Societal (taxpayer)	X	X	X	Opportunity, productivity

costs associated with Alzheimer's care as we experience it today. However, this could be a 40-year net benefit on a test conducted and reimbursed today, with uncertainty around the probability from the test itself, the value of the hypothetical treatment, its costs, and the time horizon. All of this might make the value equation, even if conducted properly, irrelevant to the employer who may not necessarily bear the financial risk for this employee in 40 years. On the other hand, for the consumer, the net benefits could be improved peace of mind, improved quality of life, or even an influence on life planning. All of these considerations could impact the study design.

Study Designs and Sensitivity Analyses

The value of personalized diagnostics can be determined from a variety of study designs commonly considered in healthcare economic evaluations (Table 3-5).

Most decision makers in the United States are interested in cost-benefit analysis, where both the costs and the benefits are stated in economic terms. For example, the American Enterprise Institute (AEI) and the Brookings Institution published a study of the value of warfarin testing from the perspective of national healthcare costs (i.e., not a particular payer and excluding indirect and intangible costs) (McWilliam et al., 2006). Warfarin, a blood thinner, can cause significant adverse effects, including strokes and hemorrhaging. They estimated the costs associated with genotyping and forecasted an expected savings from avoiding 18,000 strokes and 85,000 serious bleeds, with assumptions and sensitivity analysis provided. This led to a base case assumption of $1.1 billion saved netting out the projected costs of testing, with the sensitivity analysis ranging between $100 million and $2 billion in savings.

What is important about this paper is that all the estimates are made explicit, and the sensitivity analyses allow for modifying these assumptions.

TABLE 3-5 Study Designs of Value in Personalized Diagnostics

Cost-benefit	Weighs the total expected costs of the intervention against the total expected benefits (both costs and benefits are estimated in dollars)
Cost-effectiveness	Costs are estimated in dollars, but benefits are estimated in terms of outcomes such as years of life gained or premature deaths averted
Cost-utility	A special case of cost-effectiveness in which costs are estimated in dollars but benefits are measured in full health lived and expressed in quality-adjusted life-years or disability-adjusted life-years

For example, their base case assumes a 50 percent reduction in strokes with genotyping. However, one of their sensitivity analyses provides a revised net benefit estimate if only 5 percent of strokes are reduced ($487 million). Likewise, they provide a projected net benefit if the assumed bleeding rates are reduced by only 5 percent ($387 million in projected savings). The transparency around study design and aspects therein allows for interpretation by the particular decision maker. Interestingly, even with this relatively straightforward type of study design, Zarnke and colleagues found that 68 percent of published cost-benefit papers did not use standard methods of assessment in their research and more than 50 percent were incomplete (Zarnke et al., 1997).

What can be confusing are conflicting study designs that provide opposite apparent answers to the same research question. For example, a recent cost-utility assessment of warfarin testing came to the conclusion that warfarin genotyping was not cost-effective (Eckman et al., 2009). In this study, the authors took the perspective of society in that they valued the benefits not only in terms of costs avoided, as the AEI-Brookings Institution had done, but also the quality impact of having had these events as expressed by quality-adjusted life-years. Since they too were transparent about their assumptions, the opposite conclusion from this study can be readily examined. For instance, they assumed in their base case a one-month benefit from genotyping. Thus, they did not consider avoided bleeds or strokes that may occur after a month of therapy. Had they considered even three months as a reasonable time frame for assessing net benefit, their paper shows that warfarin genotyping would be cost-effective. Additionally, they estimated costs accrued to genotyping for delaying initiation of therapy until the genotype test results were completed. Most clinicians would start the loading dose when the need occurred and not wait for genotyping. This biased against genotyping in their model. Last, the expected incidence of bleed or stroke was highly conservative, so the avoidance of events was

minimal even if they decreased by 50 percent. Varying any of those assumptions would have made genotyping cost-effective.

Since base case assumptions for either study drove their overall conclusions, this is a worrisome issue for personalized diagnostics. The study design in its execution can provide only an estimate of net value; what is most important is transparency about the study design itself, all assumptions, and all sensitivity analyses. The decision maker should be allowed to make a judgment based on his or her particular inputs or perspective; thus, overall conclusions could vary. So for evaluating the value of warfarin genotyping, academic medical centers that enforce frequent international normalized ratio (INR) testing—a test to monitor the effects of warfarin—may ultimately not find genotyping of net value since their avoidable event rates may already be quite low, whereas rural healthcare centers where frequent INR testing is not practical may find it extremely valuable.

Scenarios, Populations, and Subgroups

There is generally a need to evaluate at least two scenarios: the treatment patterns and outcomes as they exist today and the changed environment in which a new personalized diagnostic would be used. This entails understanding the natural history of the condition or situation that exists today without personalized diagnostics, on which the future presumed state is layered.

For personalized diagnostics, this can be particularly challenging. Take, for example, the current diagnosis and management of Type 2 diabetes. Let us assume the base case examines a population over age 40 which undergoes routine screening for diabetes and then manages it once diagnosed. There is a predictable natural history that has been well elucidated on which to model the costs and routine interventions from pre-diabetic all the way to frank diabetes as well as the probabilities of various ensuing complications. If we were to examine the role of a new gene marker that is highly predictive of developing Type 2 diabetes, the scenario under which it is used might consider incremental costs for broader population screening at an earlier age than usual (since predictive markers might signal an even earlier scheme of lifestyle change), earlier interventions that could be diet or medication related, some estimated number of diabetic cases avoided through this genetic screening, at what age, and so forth. The comparison of these scenarios can be upended with personalized diagnostics, because personalized diagnostics can change our view of when to intervene with "typical" patients. Standard comparative evaluations today generally start at the same point—when the person is diagnosed.

Subgroups pose another challenge for personalized diagnostics. Take the example of *K-ras* mutations and the drug cetuximab. The value of the drug in providing two extra months of life was originally determined from clinical trials of metastatic colon cancer patients but without respect to a biomarker (Jonker et al., 2007). As genomic information was gleaned that the drug may not work for patients with *K-ras* mutations, post hoc analyses were conducted on the original clinical trial participants (Karapetis et al., 2008). The overall finding was that there was no benefit in the 30 percent of patients with mutations, leaving the results with the wild-type patients even better than those for the original overall cohort (Karapetis et al., 2008). However, to date, the Food and Drug Administration has not relabeled the drug, presumably because the patients were not stratified by *K-ras* status before randomization. Thus, the value of the drug is presumed to be lower overall than perhaps it should be if used in a targeted manner. Both the National Comprehensive Cancer Network and the American Society of Clinical Oncology guidelines suggest genomic testing despite the unchanged label, but this provides an example of value as determined in subgroups and the controversies in determining causation.

Time Horizon

The impact of the time horizon on the value proposition is important and again challenging, particularly for personalized diagnostics. As described earlier, for those diagnostics that are pre-disposition tests, the value would have to acknowledge the downstream effects, which may occur so far away in the future that the decision maker is essentially indifferent. Alternatively, as also illustrated earlier in the study of the cost utility of warfarin, the time horizon of benefit could be truncated into such a short time period that there would not be enough events witnessed for any benefit to accrue.

For pharmacogenomics, the time horizon for value estimation relates to the downstream influence of the biomarker on the selection, dose, or duration of therapy and its ensuing outcomes. If, for example, value were to be determined for tamoxifen users with breast cancer, the time horizon from the 10-year outcomes trials where cytochrome P-450 2D6 metabolism status was related to breast cancer recurrence could be used (Goetz et al., 2007). If the 10 percent of women who were poor metabolizers of tamoxifen were assumed to be tested by year 1 and switched to an aromatase inhibitor, their outcomes could be estimated to be what has been shown with aromatase inhibitors. The 10-year calculated costs of recurrent cancers avoided would be compared to the increased costs associated with testing and incremental drug costs (since branded aromatase inhibitors are more expensive than generic tamoxifen).

Costing

The imputation of cost is probably one of the most important aspects of value estimation for most decision makers. Which costs matter is tied to the perspective (e.g., health plans generally focus on direct medical care costs, employers may also value work loss, consumers may also value quality of life). This does not differ for evaluations of personalized diagnostics. All of the usual methodological considerations for estimating direct, indirect, and intangible costs would apply in the usual fashion here.

What is challenging specifically for this field is to estimate a fixed cost of particular tests, given the accelerated pace of improvement in technology with associated reductions in prices for many of the tests. So while whole genome sequencing was $300 million just six years ago, it is predicted to decrease to $1,000 in the next five years (Next Big Future, 2008; Wade, 2006). Also, given that patients may someday have inexpensive whole-genome scans conducted as a matter of public health in childhood (like vaccinations), there would be no incremental cost due to testing later in life because genes do not change. The remainder of costing for these value equations would focus on the costs and benefits associated with changing the natural history of the condition under consideration, not the testing fees.

Conclusion

Determining the value for personalized diagnostics requires the same methodological considerations for determining value as considered in other healthcare interventions. However, there are nuances for personalized diagnostics. These nuances include upending the timing and determination of when someone is ill; the implied treatment course; estimating cost for tests in a changing environment with cheaper and cheaper tests; the need for assuming value even if information is not derived from pristine, randomized controlled trials (example of cetuximab above); and special attention to the time horizon for estimated benefits and costs. The term "evidenced-based" should not be limited to the evidence derived from randomized trials alone. More studies are needed that use alternative research designs, are conducted in more typical practice settings, and enable the measurement of outcomes such as provider adoption and time to optimal therapy. This is particularly true for personalized diagnostics where the knowledge of the technology and benefits among many providers is still minimal and the interest among the consumer and payer is quickly increasing.

MEDICAL DEVICE VALUE AND INNOVATION

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Modern society places a high value on the advancement of medical technology, and stories of medical device innovations extending and improving patients' lives are celebrated as modern miracles. Yet such devices including implantable defibrillators, drug-eluting stents, and cochlear implants are also visible embodiments of medical technology advancements that are criticized for driving the high costs of medical care (Newhouse, 1992).

Other criticisms levied at medical device technologies relate to gaps in clinical evidence and regulatory requirements, clinical uses for unproven indications, the need for comparative effectiveness research trials, and questions about the affordability and value of new technologies, among others (Deyo and Patrick, 2005; Kessler et al., 2004).

Despite, or perhaps arising from, these criticisms, profound changes have taken place in the medical device arena over the past decade, including increased emphasis on evidence-based medicine. Device innovators have stepped up to the challenges raised by regulators, payers, professional societies, and technology assessment organizations to rigorously demonstrate the clinical and economic value of their therapies. While additional reforms remain ahead, many proposed solutions are in place or rapidly emerging.

Close examination of key medical device inventions reveals that in many respects, their development has represented a "vindication of the scientific method" (Mueller and Sanborn, 1995). Early serendipitous discoveries and the synthesis of advancements across diverse disciplines often proceed in a nonlinear and discontinuous pattern, eventually resulting in the development of beneficial new technologies and procedures. Despite the perception of rapid device development and proliferation, innovation frequently requires decades of research and development before devices are first made available to patients. In many cases, physician pioneers and device inventors must overcome conventional wisdom and resistance by the medical establishment before new approaches are even considered. Only after new devices are introduced into clinical practice does their use spawn the iterative process of technological, procedural, and other clinical practice improvements that continuously improve quality and outcomes.

A large body of rigorous research evidence using a wide range of designs (appropriate to the stage of technology evolution and the nature of research questions at the time) has demonstrated that many of these device innovations provide both clinical and health economic benefits. Increasingly, randomized controlled device trials form the evidentiary standard for regulatory approval, reimbursement, and professional adoption.

That said, there are examples, such as cochlear implants, where experts widely agree that randomized controlled trials to demonstrate efficacy would have been unethical. Large-scale registries and surveillance studies are becoming the norm to identify safety concerns and track real-world patient outcomes. While it is inherently challenging to gauge the economic value of device technologies at the earliest stages of their life cycle, many studies have demonstrated cost-effectiveness and sometimes cost savings.

Despite progress in ensuring that medical technology innovations are grounded in solid evidence, the research agenda will always remain unfinished and health policy makers should recognize that there are limits to the clinical evaluative process (Gelijns et al., 2005). We encourage attention to the potential impact of additional reforms on medical innovation. Ultimately, device innovators need a predictable framework to foster new innovations that benefit patient care.

Clinical Benefits of Medical Devices

Sometimes lost amidst criticisms of medical device industry shortcomings are the many proven, evidence-based, and often dramatic benefits of medical devices in extending and improving the lives of millions of patients. The following are examples of medical device inventions that have revolutionized the treatment of a variety of deadly or debilitating conditions.

- *Cardiac pacemakers*: Patients developing complete heart block experience repeated syncopal episodes leading, in many cases, to cardiac arrest. Although isolated reports of artificial pacemakers being used to successfully resuscitate patients from cardiac arrest date back to the 1920s, they were ignored as completely impractical until advances in electronics coincided with the new era of open heart surgery. The introduction of the first cardiac pacemakers by Paul Zoll, Wilson Greatbach, and others in the 1950s and 1960s built on decades of earlier research, enabling the pacemakers to sustain the lives of patients experiencing acute heart block episodes that would otherwise have been fatal. Huge advances in pacemaker technology, including fully implantable devices, interactive sensing and pacing algorithms, and remote device monitoring, have since taken place that vastly improved patient outcomes (Jeffrey, 2001).
- *Implantable defibrillators*: Sudden cardiac death represents a serious national health problem, accounting for more than 300,000 deaths annually—or 13 percent of all natural deaths—because of deadly ventricular arrhythmias (Myerburg et al., 1993). The development of the implantable defibrillator by Michel Mirowski and

his research team from 1969 through 1980 built on earlier success with cardiac pacemakers, but required major research advancements to create implantable devices that could shock and restart the heart's normal rhythm after episodes of ventricular fibrillation. Implantable cardioverter defibrillators (ICDs) save one life for every 3 to 11 patients implanted by reducing sudden cardiac death and mortality among implanted patients (Camm et al., 2007). More than a dozen landmark randomized controlled trials involving more than 8,000 patients have shown reductions in overall mortality of 23 to 55 percent with ICD therapy compared to optimal medication therapy (Ezekowitz et al., 2007). ICDs have also benefited from technology advancements including pacing capabilities to prevent deadly arrhythmias, algorithms to resynchronize multiple chambers of the heart, endocardial defibrillation leads, remote device and patient management capabilities, and smaller implants with extended battery longevity (Jeffrey, 2001).

- *Cochlear implants*: Severe, profound deafness imposes a tremendous burden on both the hearing impaired and society, and afflicts an estimated 500,000 Americans. The deaf require specialized schooling and costly social welfare services, and they are the lowest-wage earners of all disabled patients. Even with specialized support, most never graduate high school, and graduates on average attain only a third grade reading level (Parisier, 2003). Beginning in the mid-1950s, William House and others undertook research and development that, over three decades, finally culminated in the FDA's approval of the first cochlear implant in 1984 (Foote, 1992). Substantial obstacles needed to be overcome, including lack of research funding by the National Institutes of Health (NIH) and professional society refusal to publish research results due to concerns over ethics and long-term effects of permanent implants. While the first-generation single-channel implants provided very limited hearing benefits, technological advancements over the next two decades—including multichannel and bilateral implants with sophisticated speech processing algorithms—have been so dramatic that cochlear implants are now widely described as a miracle treatment. Prelingually deaf children can now be implanted at 12 months of age, enabling them to participate fully in the hearing world. Studies have demonstrated that patients with cochlear implants can hear and understand speech in challenging listening environments that approach the levels of their normal-hearing counterparts (Cheng and Niparko, 1999; Cheng et al., 2000a).
- *Percutaneous coronary interventions, including drug-eluting stents*: Percutaneous coronary interventions (PCIs) subsume a number

of catheter-based procedures—including coronary balloon angioplasty and stenting—that are used to clear narrowed or blocked coronary arteries. Coronary artery disease remains the leading cause of death in both the United States and Europe, and it imposes major costs on society. When percutaneous transluminal coronary angioplasty (PTCA) was introduced by Dr. Andreas Gruentzig in 1976, its viability was met with widespread skepticism in the physician community even though cardiac catheterization procedures had already become common after their introduction in the 1940s. Yet since commercialization in 1980, balloon angioplasty and coronary stenting have revolutionized cardiology by enabling effective, minimally invasive treatments and becoming the dominant form of coronary revascularization (nearly 3 to 1 over coronary bypass grafting) for patients with coronary artery disease (Mueller and Sanborn, 1995; Smith et al., 2001). Multiple generations of technology improvements have led to greatly improved results, and PCI devices have now been studied in more rigorous clinical studies than any other medical intervention in history. Patient outcomes have been carefully tracked since the inception of the procedure in NIH-sponsored clinical registries (Detre et al., 1988; Williams et al., 2000), and a large number of randomized controlled trials rigorously demonstrated benefits of PTCA, coronary stents, and drug-eluting stents. For example, 39 randomized trials including more than 16,000 patients showed clinical superiority of stents over PTCA (Hill et al., 2004), and 19 randomized trials involving 9,000 patients showed clinical superiority of drug-eluting stents over traditional stents (Roiron et al., 2006).

- *Neurovascular coiling*: Ruptured brain aneurysms are devastating events that have an extremely poor prognosis, with a one-year mortality rate of 50 percent, and an additional 30 percent suffering permanent neurological and cognitive deficits (Lindberg et al., 1992; Sacco et al., 1984). Neurovascular coils for occluding intracranial aneurysms were developed by Guido Guglielmi in the 1980s and commercially introduced in 1995 as a minimally invasive alternative to open neurosurgery (Guglielmi, 1997). Originally developed to provide a treatment option for patients at high risk for surgery, coiling has now largely supplanted surgical clipping as first-line treatment for these patients. The randomized International Subarachnoid Aneurysm Trial found that the minimally invasive coiling treatment reduced mortality and significant disability by 23 percent compared to surgery, leading to major changes in clinical practice (Derdeyn et al., 2003; Molyneux et al., 2002). Since its inception, coiling embolization has evolved through clinical experience,

with improved patient selection and introduction of technological improvements. Technological advancements include introduction of new coil sizes and shapes, microcatheters, bioactive coils, and new detachment mechanisms that have improved outcomes.

- *Cardiac ablation*: Numerous heart arrhythmias can now be cured using minimally invasive catheters to ablate damaged heart tissue using radio-frequency energy, with success rates of around 90 percent versus less than 40 percent for treatment with medical therapy (Blomstrom-Lundqvist et al., 2003; Center for Devices and Radiologic Health, 2002). When introduced in the early 1990s for specific atrial arrhythmias, radio-frequency catheter ablation was shown to be so much more effective than alternative treatments that randomized controlled trials were determined to be unethical. When catheter ablation was later studied for broader application to treat atrial fibrillation, multiple randomized trials showed huge benefits of ablation over drugs, improving the treatment prognoses for these patients (Nair et al., 2008; Noheria et al., 2008). A series of additional head-to-head randomized trials of different ablation approaches have subsequently refined evidence and practice consistent with FDA recommendations (U.S. Food and Drug Administration, 2008b).

These and many other highly efficacious device-based treatments—including prosthetic heart valves, artificial joint replacements, advanced imaging technologies, wound management devices, and implantable neurostimulators for a variety of conditions—form the basis for the often described explosion of medical technology innovation that has extended and improved quality of life for millions of Americans.

Medical Device Regulatory Trends

Regulation of medical devices represents an inherently complex challenge that has evolved dramatically over the past three decades since Congress provided the FDA with broad authority to do so in 1976. Congress and experts have explicitly concluded, after years of study and oversight, that no single regulatory evidentiary standard is appropriate to encompass the vast diversity of devices ranging from simple and ancillary devices (e.g., bandages, splints, surgical drapes) to extremely complex permanent implants (e.g., cardiac pacemakers, defibrillators, cochlear implants). Instead, Congress consciously adopted a flexible, tiered standard that provided the FDA with substantial regulatory discretion to develop valid evidence requirements to ensure that devices are safe and effective and to adjust requirements for specific devices based on expert

input reflecting current scientific standards and knowledge (Advanced Medical Technology Association, 2008; Feigal et al., 2003; Merrill, 1994; Munsey, 1995).

Congress has closely overseen the FDA regulatory process for medical devices and enacted major legislative reforms over time to expand and modernize the agency's regulatory framework in a manner that protects public health while enabling access for patients to beneficial new device technologies. The FDA has developed processes that require evidentiary development both before and after regulatory approval.

Pre-market Requirements

Although some critics have questioned the degree of clinical evidence required by the FDA to establish the safety and effectiveness of medical devices, Congress has repeatedly and concertedly rejected adoption of the same regulatory standards as applicable for drugs. Instead, recognizing the important differences between drugs and devices, Congress provided the FDA with discretional authority to develop and adjust requirements, based on input from well-qualified experts, well-controlled clinical trials, and other valid scientific evidence for devices (Advanced Medical Technology Association, 2008). Over time, the FDA has moved toward requiring randomized controlled trials for many high-risk devices as well as expanding clinical trial requirements for some 510(k) devices before approval. This has contributed to a large number of randomized device trials. Issuance of a series of FDA Guidance Documents has further documented the evolution of randomized controlled trial requirements for approval of various device types, including drug-eluting stents (U.S. Food and Drug Administration, 2008c), cardiac ablation devices (U.S. Food and Drug Administration, 2004a, 2008b), vertebroplasty devices (U.S. Food and Drug Administration, 2004b), and total artificial disks (U.S. Food and Drug Administration, 2008d).

As device interventions and technologies evolve, regulatory standards have been adapted for specific devices in recognition that different types of clinical evidence have been appropriate during different stages in the development of these technologies. For example, after randomized controlled trials demonstrated benefits of coronary stents versus alternative treatments in 1994, the FDA began accepting randomized equivalency trials demonstrating equivalency to approved stents rather than comparisons to angioplasty or placebo. As technology matured, the FDA required later-generation products to document performance consistent with objective performance criteria (OPC) based on clinical evidence from single-arm studies while requiring randomized trials for new technologies such as drug-eluting stents (U.S. Food and Drug Administration, 2008a). The FDA has adopted similar OPC standards for other mature device technologies

including prosthetic heart valves and joint replacements, and evaluations have concluded that this approach is safer and more efficient for patients than randomized controlled trials (Grunkemeier et al., 2006). In other cases, such as cochlear implants, it has been widely accepted that clinical evidence from single-arm (compared to randomized controlled) trials was appropriate to demonstrate safety and effectiveness from the outset since the natural history of treatment was well understood.

Post-approval Surveillance

Post-approval clinical studies are increasingly required by the FDA to demonstrate safety and long-term outcomes of devices in large real-world treatment populations. While the FDA has required more than 80 post-market surveillance studies of different devices since 2005, some have called for a significant expansion of post-approval studies to evaluate real-world treatment outcomes in the recognition that pre-market trials have limitations and the medical device reporting (MDR) system for adverse events has major deficiencies and provides inconsistent data. Expanding on past experiences with FDA-mandated surveillance studies in addition to post-approval studies voluntarily developed under the sponsorship of the NIH, professional societies, foreign governments, and manufacturers could provide more high-quality data to evaluate safety and effectiveness (Mehran et al., 2004).

Cross-Stakeholder Collaborative Efforts

There are many instances in which landmark randomized controlled trials have been sponsored by the NIH and other government agencies to strengthen evidence regarding the comparative effectiveness of devices. Examples include NIH-sponsored randomized trials of implantable defibrillators (MUSTT, AVID, SCD-HeFT) (Camm et al., 2007), left-ventricular assist devices (REMATCH) (Rose et al., 2001), and deep-brain stimulators (Weaver et al., 2009), among others. In some instances, device manufacturers and independent researchers have proactively sponsored randomized trials to strengthen the evidence basis for approved indications even after widespread coverage and adoption are in place. Examples include randomized trials of spinal cord stimulation that have confirmed its efficacy and cost-effectiveness for chronic neuropathic pain (Kemler et al., 2004; Kumar et al., 2007; North et al., 2005) and trials of vertebroplasty for osteoporotic vertebral compression fractures (Gray et al., 2007; Voormolen et al., 2007). Many of these examples serve as excellent models of "comparative effectiveness" research trials that should be expanded into other areas of medicine.

In addition, the NIH and others have sponsored a variety of real-world device registries (e.g., National Heart, Lung, and Blood Institute

PCI Registries [Detre et al., 1988; Hill et al., 2004; Williams et al., 2000], Swedish National Hip Replacement Registry [Malchau et al., 2002]) to systematically track real-world clinical outcomes and support adoption of evidence-based improvements as device technology and practice evolve over time. These efforts complement registries sponsored by manufacturers and professional societies to track patient outcomes for a variety of devices. In the case of the recent NIH Wingspan Intracranial Stent Registry, data are supporting development of a definitive randomized controlled trial to rigorously evaluate clinical efficacy (Zaidat et al., 2008).

Reimbursement Trends

Perhaps the most profound trend impacting medical devices has been the escalation of both the evidence standards required by payers to provide coverage and the adequate funding levels needed to support clinical adoption.

As the largest payer in the world, the Medicare program exerts a huge influence on medical technology innovation. Numerous coverage decisions and other developments in the Medicare coverage process have made clear that the evidence bar has risen substantially over the past decade for reimbursement of new technologies. Since 1998, the Medicare Coverage Advisory Committee (MEDCAC) has provided expert reviews of scientific and clinical evidence in a public forum that increased the visibility of several major Medicare coverage decisions. The strength of the evidence used by the CMS in making decisions, while perhaps not yet at levels desired by many critics, is improving. Importantly, CMS declined to provide coverage in one-third of national coverage decisions from 1999 to 2007 and, when granting coverage, issued conditions in almost 60 percent of cases (Neumann et al., 2008).

One example of the increased strength of evidence required is the 2003 CMS decision to approve coverage for defibrillators only for a subgroup of the patient population studied in the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II trial. This was despite having received FDA approval, unanimous approval from MEDCAC, and practice guidelines written jointly by three physician societies supporting the clinical benefits of defibrillators for the entire MADIT II population. While CMS recognized that MADIT II was a well-designed randomized trial, it was hesitant to provide broad coverage based on results from a single trial (Centers for Medicare and Medicaid Services, 2003). CMS did not cover the entire MADIT II population until results were confirmed by another large, well-designed trial (Sudden Cardiac Death in Heart Failure Trial [SCD-HeFT]).

Two other major examples of a higher evidentiary standard are CMS coverage decisions for left ventricular assist devices (LVADs) and carotid

artery stenting (CAS), both of which impose narrow coverage criteria. For example, CMS agreed to extend coverage for LVADs as "destination therapy" for end-stage heart failure patients meeting the REMATCH study criteria. However, CMS authorized coverage only at designated heart transplant facilities that have performed a threshold volume of LVAD procedures and met other criteria established by CMS (Ursula et al., 2007). For CAS, CMS restricted coverage to 24 percent of patients within the FDA-approved patient population.[4] Coverage for CAS is further restricted to Medicare-certified sites and only if the site collects data on all CAS procedures performed at the site (Centers for Medicare and Medicaid Services, 2008a).

CMS has issued several other coverage decisions mandating participation in CMS-approved clinical trials or registries for devices as a condition of Medicare coverage (Tunis et al., 2007). The most highly publicized was the 2005 National Coverage Determination for implantable defibrillators—based on the SCD-HeFT trial—that led to the creation of a national ICD registry to track real-world outcomes and is being managed jointly by the American College of Cardiology and the Heart Rhythm Society. More recently, CMS has issued guidance documents explaining the rationale and conditions for requiring study participation as a condition of Medicare coverage. While coverage in the context of post-approval registries may be a desirable means to track outcomes and ensure efficient use of technology, it is important that such studies be designed to efficiently answer the important research questions that exist (Gillick, 2004).

CMS is raising the evidentiary standard through payment policy as well. Since 2001, Medicare has made available special payments under the hospital inpatient prospective payment system for new technology that demonstrates "substantial clinical improvement" and meets certain cost and other criteria. In 2002, Medicare added a similar clinical criterion for the new technology payment mechanism under the hospital outpatient prospective payment system. Transitional pass-through payments in the outpatient setting and new-technology add-on payments in the inpatient setting represent a type of pay-for-performance for new technologies. To be eligible for these payments, new technologies must be FDA approved, meet stringent cost criteria, and demonstrate a substantial clinical improvement for Medicare beneficiaries among other requirements (Centers for Medicare and Medicaid Services, 2001a,b). Technologies can meet the clinical criteria by demonstrating reduced mortality, lower rates of therapeutic interventions, reduced hospitalizations, and similar clinical outcome improvements. A recent study found that since 2001, CMS has determined that only 8 of 18 new technology add-on payment applications satisfied the substantial clinical improvement criterion. Seven of the 18 did not meet the substan-

[4] Internal Boston Scientific calculation based on Boston Scientific trial enrollment data.

tial clinical improvement criteria and three are still pending FDA approval (Clyde et al., 2008).

Even when new technologies meet CMS criteria, hospitals do not automatically receive "full" payments that cover the incremental cost of the new technology. In the inpatient setting, new technology payments are designed to cover, at most, only 50 percent of the incremental cost associated with the technology. In the outpatient setting, hospital pass-through payments are designed to cover the full incremental cost of a new technology. However, in many instances, hospitals have not received pass-through payments covering their actual incremental costs due to a variety of coding and billing problems, including charge compression, where hospitals typically have lower mark-ups for higher-cost devices, and lag in updating hospital billing systems.

In sum, through the use of coverage and payment policy, Medicare is raising evidentiary standards for hospitals and other providers to receive payment for using new technologies. We expect this trend to continue. For example in July 2008, CMS issued a list of potential future coverage decision topics that demonstrates its interest in revising existing coverage decisions for established treatments, including off-label use of drug-eluting coronary stents, vertebroplasty and kyphoplasty, lumbar fusion, and artificial cervical disks (Centers for Medicare and Medicaid Services, 2008b). These reimbursement trends are likely to accelerate in the future as Congress considers creation of a comparative effectiveness research entity and a host of other healthcare reforms.

Health Economic Evaluations

Considerable attention has been paid to the high costs of advanced medical technologies as a driver of medical expenditures. Yet these analyses typically do not take into account the value of technology and therefore do not answer the question of whether the expenditures are worthwhile. Research examining the overall health economic value of advanced medical technologies has concluded that they are generally worthwhile to society (Cutler, 2004).

Over the past decade, formal health economic evaluations of specific device interventions have become commonplace, with most attention being paid to assessments conducted by the National Institute of Health and Clinical Excellence in the United Kingdom. Device sponsors recognize that planning for economic assessments early in a new device's life cycle can be a critical factor to commercial viability. While many economic studies of devices have found they are cost-effective for typical patient populations within commonly referenced thresholds of $50,000 or $100,000 per quality-adjusted life-year, the long-term value of devices may be underestimated

and improve over time as real-world experience leads to technological and other advancements. Further, economic assessments are extremely complex, with studies producing widely varying findings that are highly dependent on technical modeling decisions, including the analysis time horizon, effectiveness parameters, cost inputs, and specific patient subgroups chosen for analysis. Even rigorous economic studies have important weaknesses, and they are often difficult to compare.

Following are examples of economic evaluations demonstrating the cost-effectiveness of common therapeutic device treatments (see also Table 3-6):

- *Implantable defibrillators*: Based on the analysis of eight landmark ICD trials on the primary prevention of sudden cardiac death, ICDs have been shown to be cost-effective (with a range of $25,000 to $50,000 per QALY) in populations where significant reductions in mortality have been demonstrated (Sanders et al., 2005). A more recent iteration of the defibrillator that includes cardiac resynchronization, otherwise known as a CRT-D, not only has been shown to be cost-effective in the COMPANION patient population, but has also been shown to reduce two-year follow-up hospitalization costs by 29 percent (Feldman et al., 2005).
- *Cochlear implants*: Several independent studies have found that cochlear implants are cost-effective in both children and adults ($5,000 to $13,000 per QALY) (Cheng and Niparko, 1999; Cheng et al., 2000a). When indirect cost savings are taken into account, such as the reduced need for special education services when children are mainstreamed into regular classrooms, overall cost savings of more than $50,000 accrue per child (Cheng et al., 2000a).
- *Percutaneous coronary interventions*: Numerous economic studies have assessed the cost-effectiveness of PCI technologies compared to clinical alternatives (Bakhai et al., 2003; Firth et al., 2008; Kupersmith et al., 1995). Studies of coronary stenting versus PTCA found that the higher initial costs of stents were almost completely offset by savings due to the reduced need for revascularization. More recent economic evaluations of drug-eluting stents have been marked by controversy because they demonstrate wide ranges of cost-effectiveness depending on technical modeling decisions (Firth et al., 2008).
- *Cardiac ablation*: Several studies have demonstrated that cardiac ablation produces overall cost savings compared to chronic medical therapy for supraventricular tachycardias (SVTs), and recent economic evaluations of randomized studies have found high cost-effectiveness for atrial fibrillation (Cheng et al., 2000b; Hogenhuis

TABLE 3-6 Examples of Medical Device Cost-Effectiveness

Medical Device Intervention	Source	ICER (Cost/QALY)
Cardiac Ablation		
SVT or severe WPW	Cheng et al. (2000)	Cost-saving
Atrial fibrillation	McKenna et al. (2008)	$11,500
Cochlear Implants		
Cochlear implant vs. NoTx, children (all costs or direct only)	Cheng et al. (2000)	Cost-saving or $6,000
Cochlear implant vs. NoTx or hearing aid, adults	Cheng et al. (2000)	$13,000
Implantable Defibrillators and Pacemakers		
Cardiac resynchronization pacemaker vs. CMM for heart failure	Feldman et al. (2005)	$19,600
Cardiac resynchronization defibrillator vs. CMM for heart failure	Feldman et al. (2005)	$43,000
ICD vs. CMM, primary prevention of SCD	Sanders et al. (2005)	$24,500-$50,700
Neurovascular Coiling		
Coiling vs. surgical clipping, ruptured	Bairstow et al. (2002)	Cost-saving
Coiling vs. NoTx, unruptured ≥10 mm or <10 mm symptomatic	Johnston et al. (1999)	$5,000-$12,000
Coiling vs. NoTx, unruptured <10 mm asymptomatic	Johnston et al. (1999)	$42,000
Percutaneous Coronary Interventions		
PTCA vs. CMM, severe angina	Kupersmith et al. (1995)	$12,500
Cardiac stent vs. PTCA AMI	Bakhai et al. (2003)	$11,000
DES vs. stent long lesions, diabetics, or small vessels	Firth et al. (2008)	$13,000-$263,000
Prosthetic Hip Replacement		
Hip replacement vs. CMM younger adults (45-50)	O'Shea et al. (2001)	Cost-saving
Hip replacement vs. CMM older adults	O'Shea et al. (2001)	$2,000
Spinal Cord Stimulation		
SCS vs. CMM or surgical reoperation, FBSS	Bala et al. (2008)	Cost-saving
SCS vs. PT, CRPS	Kemler and Furnee (2002)	Cost-saving

NOTE: AMI = acute myocardial infection; CMM = conventional medical management; CRPS = chronic regional pain syndrome; DES = drug-eluting stent; FBSS = failed back surgery syndrome; ICD = implantable cardioverter defibrillator; ICER = incremental cost-effectiveness ratio; NoTx = no treatment; PT = physical therapy; PTCA = percutaneous transluminal coronary angioplasty; SCD = sudden cardiac death; SCS = spinal cord stimulation; SVT = supraventricular tachycardia; WPW = Wolff-Parkinson-White syndrome.

et al., 1993; McKenna et al., 2008). Despite the higher initial costs of treatment, the elimination of symptoms and the averted need for chronic medications and associated medical care utilization leads to a reduction or neutrality in treatment costs over time.

- *Neurovascular coiling*: Coiling of brain aneurysms has been found to be cost-saving for subarachnoid hemorrhage and cost-effective for large and symptomatic unruptured aneurysms (range of $5,000 to $12,000 per QALY) (Bairstow et al., 2002; Johnston et al., 1999).
- *Spinal cord stimulation*: Multiple economic studies based on randomized controlled trials have found that spinal cord stimulation produces cost savings compared to conventional medical management or surgical reoperation for chronic neuropathic pain conditions (Bala et al., 2008; Kemler and Furnee, 2002).
- *Prosthetic hip replacements*: Prosthetic hip replacements have been found to be cost-saving in younger adults and essentially cost-neutral in older adults (O'Shea et al., 2002).

Given the reality of current budgetary and cost constraints, it appears likely that rigorous economic evaluations of new medical technologies will become a permanent fixture in the healthcare arena. However, the many limitations of economic assessment methods should preclude their use as a mechanistic tool to guide reimbursement and funding decisions. Real dangers can result from the use of cost-effectiveness modeling as a blunt instrument for coverage and adoption of new technologies that could ultimately undervalue the benefit of these innovations and restrict the development of breakthrough technologies that are highly beneficial to society and patients.

Evidence and Innovation in Medical Devices

Evidence-based medicine trends have had a profound impact in the medical device arena over the past decade. Device innovators recognize the need to rigorously demonstrate clinical and economic value, and compelling evidence has demonstrated beneficial outcomes in many areas. Calls for additional high-quality evidence from randomized controlled trials have been answered by a dramatic increase in pre-approval and post-approval randomized studies for therapeutic devices. Many of these studies represent real-world examples of comparative effectiveness research that can serve as a model for future studies (Tunis et al., 2003; Wilensky, 2006).

Expanding the use of post-market clinical registries can also provide the additional evidence needed for safety surveillance and tracking patient outcomes in real-world treatment environments and patient populations. Recent actions by Medicare indicate that reimbursement may be increas-

ingly tied to participation in such studies, and this appears to be a promising concept in certain instances if research can be efficiently and adequately designed to answer critical questions regarding clinical value.

As pressure has grown for rational prioritization in health care as a means to control spending, economic evaluations have greatly increased for high-cost device technologies. While there is broad understanding that interventions should be worth their costs to society, methods for assessing economic value remain immature and we caution against simplistic use of blunt instruments such as cost-effectiveness in reimbursement and funding decisions.

Methods to assess the clinical and economic value of device interventions must take into consideration the nature of innovation in the medical device arena. For example, newly developed procedures may not be ripe for a fair assessment since the procedural technique may still be undergoing refinement. Similarly, there may be only a small cadre of skilled and experienced physicians performing the intervention. On the other hand, waiting until the technology matures may result in faster dissemination than desired by policy makers, particularly among populations that may not receive the greatest clinical benefits.

We recognize that policy makers must assess and refine methods to determine the value of all types of treatment modalities, including device interventions. The goal is to provide comparative information to clinicians, payers, and patients. However, ultimately, medical innovators need a predictable and reasonable framework in order to support development and commercialization of new medical devices in a society that still values technology advancement. While the bar continues to be raised in terms of clinical and economic evidence, we caution that the desire for additional evidence from clinical trials will always outpace our ability to perform them (Gelijns et al., 2005). Without proper application by policy makers to tailor requirements for different devices, there will be longer development time lines, reduced innovation, and fewer treatment options for patients.

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4

Approaches to Improving Value—Consumer Incentives

INTRODUCTION

Previous discussions at this workshop series, such as the stakeholder perspectives described in Chapter 2, highlight the importance of consumers in reorienting health care in the United States toward a value-driven system. It was heard that consumers play a critical role in the medical decision-making process and make multiple decisions in the path of care that ultimately impact the value of care delivered on both individual and societal levels. The presentations in this session focused on specific examples of consumer-focused approaches to achieve greater value, exploring the research to date and the evidence of impact.

A. Mark Fendrick emphasizes the continued underutilization of high-value health services, with research indicating that U.S. adults receive only about 50 percent of recommended care (McGlynn et al., 2003). He discusses the potential for value-based insurance design—which focuses on consumer choices, adjusting patients' out-of-pocket costs for specific services based on an assessment of the clinical benefit achieved (with the more clinically beneficial interventions associated with lower out-of-pocket costs)—to be utilized as a tool for increasing value in health care.

Building on the concept of value-based insurance design, Melinda Beeuwkes-Buntin discusses consumer-directed, high-deductible health plans (CDHPs). This presentation elaborated on the mechanisms though which CDHPs attempt to provide patients with financial incentives to make wiser healthcare choices while spurring them to take greater responsibility for their care. The impact of evolving "consumer-directed" plan designs on

expenditures, access to care, and clinical outcomes is also reviewed, with gaps in knowledge and future areas of needed research identified.

Approaches such as pharmaceutical or hospital tiering programs have attempted to increase the transparency of value of different medical interventions and providers. Dennis Scanlon describes in further detail how tiering classifies healthcare providers, pharmaceuticals, or treatments on the basis of objective or subjective criteria such as cost, quality, and value, and engages patients and consumers in making informed decisions. One example discussed in detail is a hospital tiering program and the impact of the program on consumer choices and quality of care.

Concluding the session, Ronald Goetzel details the value of worksite health promotion and chronic disease prevention programs, indicating that they can yield significant health and economic benefits for employers and employees. In addition to discussing how workplace wellness programs can serve as vehicles for health behavior change, he outlines recommendations to increase employer engagement in providing evidence-based health promotion programs to their employees.

VALUE-BASED INSURANCE DESIGN: RESTORING HEALTH TO THE HEALTHCARE COST DEBATE

A. Mark Fendrick, M.D., University of Michigan Medical Center, and Michael E. Chernew, Ph.D., Harvard Medical School

As healthcare premiums escalate, both private and public purchasers are forced to decide how best to address this unsustainable economic burden. Unfortunately, value—the clinical benefit achieved for the money spent—is frequently excluded from the dialogue on how to manage the growth of healthcare spending.

If the desirable clinical effects of health insurance are ignored, constraining healthcare cost growth can be achieved simply by providing less generous coverage or no coverage at all. In fact, the numbers of Americans who are uninsured or underinsured is at an all-time high, reflecting the trade-off between the high cost of health benefits and remaining viable in today's economy (Kaiser Family Foundation, 2005). Although rising healthcare costs are the main impetus behind the redesign of health benefits, concerns regarding the quality of care share the limelight. This clear and unresolved tension between cost containment and suboptimal quality of care has led to two prevailing trends in benefit design:

1. *Cost containment strategies that use financial incentives to alter patient and provider behavior*: This approach includes increases in cost sharing (e.g., deductibles, copays, coinsurance rates) in exist-

ing plan designs and the introduction of high-deductible health plans that allow employees to set aside tax-free money for health expenses. A recent Kaiser Foundation Employer Benefit Survey showed relative moderation in the growth in healthcare premiums, largely attributable to increasing cost shifting from employer to beneficiary (Kaiser Family Foundation, 2005).

2. *Improving the quality of care and keeping individuals healthier longer*: Employers and insurers are implementing wellness and disease management (DM) initiatives to help individuals manage their health in an effort to avoid more costly care. Pay-for-performance (P4P) programs, which pay providers more for adhering to evidence-based clinical practices and delivering specific health outcomes, are disseminated widely. While many proponents of these initiatives contend that better health will lead to lower spending, fiscal savings from quality-oriented interventions have not materialized.

Since higher patient cost sharing discourages use of high-value medical services, these two trends inherently conflict. The main challenge is to devise benefit packages that openly address the problem of spending growth, yet explicitly aim to optimize the health of beneficiaries through the incorporation of features that complement each other in the effective and efficient delivery of care.

Role of Cost Sharing

From the patient perspective, increased cost sharing is the principal instrument of change. There is little debate over the economic theory that an increase in out-of-pocket expenses will lead to less consumption of healthcare services. Many studies demonstrate that when confronted with higher costs, individuals will purchase less care (Gibson et al., 2005). Ideally, higher patient copayments would discourage only the utilization of low-value care. For this important assumption to be achieved, patients must be able to distinguish between high-value and low-value interventions. However, when this ability to differentiate among services does not exist, increased cost sharing has the potential to cause negative clinical outcomes. A large and growing body of evidence demonstrates that in response to increased cost sharing, patients decrease the use of both high-value (e.g., immunizations, cancer screening, appropriate prescription drug use) and low-value services, and may have worse health outcomes as a result (Figure 4-1).

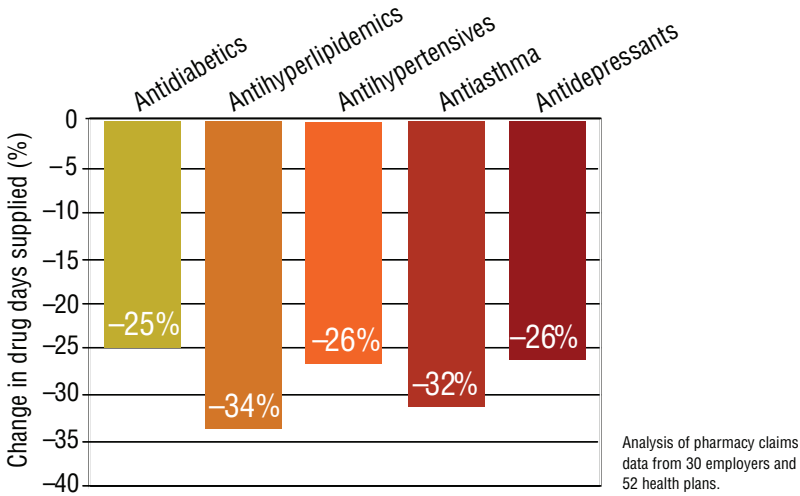

FIGURE 4-1 Impact of out-of-pocket costs on adherence.
SOURCE: Goldman et al., 2004.

Value-Based Insurance Design

In response to the adverse clinical effects of "one-size-fits-all" cost shifting, we propose "value-based insurance design" (VBID), a system that bases patients' copayments on the relative value—not the cost of the clinical intervention (Chernew et al., 2007; Fendrick and Chernew, 2006). In this setting, cost sharing is still utilized, but a "clinically sensitive" approach is explicitly employed to mitigate the adverse health consequences of high out-of-pocket expenditures. Originally referred to as the "benefit-based copay" for prescription drugs, VBID has broadened to all sectors of healthcare delivery. The principle tenets of a VBID program are that (1) medical services differ in the clinical benefit achieved and (2) the value of a specific intervention likely varies across patient groups. We believe that more efficient resource allocation can be achieved when the amount of patient cost sharing is a function of the value of the specific healthcare service to a targeted patient group.

Although cost sharing may be ill advised in certain clinical circumstances, it would be absurd to completely ignore the need for interventions to reign in spending. Increased cost sharing seems inevitable given the lack of demonstrated savings from, or unwillingness to adopt, other approaches. In the VBID paradigm, patients' out-of-pocket costs are determined by the costs and benefit of care—zero or low copayments for interventions of highest value (e.g., mammogram for women with a first-degree relative

with breast cancer, lipid-lowering therapy for an individual with a history of myocardial infarction) and higher cost sharing for interventions with little or no proven healthcare benefit (e.g., total body computed tomographic scanning). This more sophisticated benefit design is made possible by advances in health information technology and comparative effectiveness research. While some believe that such benefit packages are too complex to be accepted by consumers or too difficult to create in certain clinical conditions, the inability to construct the perfect program should not lead to abandonment of key VBID principles. The cost of maintaining the status quo, in terms of higher spending and worse health outcomes, is staggering.

Barriers to VBID implementation certainly exist and create several challenges (Chernew et al., 2007). From experience in the field, VBID programs are feasible, are acceptable to all stakeholders, and have been very well received by beneficiaries. VBID can address several important inconsistencies in the current system and work synergistically with other initiatives such as high-deductible health plans, disease management, patient-centered medical home, and P4P programs. By allowing different cost-sharing provisions for different services, value can be enhanced without removing the role of cost sharing in the system overall.

Types of VBID Programs

In practice, there are two general approaches to VBID programs. *The first simply targets services known to be of high value* (e.g., ACE [angiotensin converting enzyme] inhibitors). While some users of the services have the target high-value condition(s) (e.g., congestive heart failure, myocardial infarction), others do not (e.g., essential hypertension), and the system does not attempt to differentiate between these patient groups.

The second approach targets patients with select clinical diagnoses (e.g., coronary artery disease) and lowers copays for specific high-value services (e.g., statins, beta-blockers) only for those patient groups. This diagnosis-driven strategy, which requires more sophisticated data systems to implement, creates a differential copay based on patients' health conditions.

A controlled evaluation of a VBID program that lowered copayments for all users of five high-value pharmaceutical classes, demonstrated significant increases in patient compliance (Chernew et al., 2008) (Table 4-1).

The financial impact of VBID programs on healthcare spending is under investigation. Economic effects depend on the level and precision of targeting and the extent or direction of the changes in copayments. Since many clinical services provide higher value for a select subset of patients, the better the system is at identifying those patients, the greater is the likelihood of achieving a high financial return. Employers with more targeted

TABLE 4-1 Copay Reductions Increase Adherence to High-Value Drug Classes[a]

Medication	MPR Increase	Baseline MPR	% MPR Increase	% Reduction in Nonadherence
ACE/ARB	2.59 ($p < .001$)	68.4	3.8	8.2
β-blockers	3.02 ($p < .001$)	68.3	4.4	9.5
Diabetes	4.02 ($p < .001$)	69.5	5.8	13.2
Statins	3.39 ($p < .001$)	53.0	6.3	7.1
Steroids	1.86 ($p = .134$)	31.6	5.9	2.7

NOTE: ACE = angiotensin coverting enzyme; ARB = angiotensin receptor blocker; MPR = medication possession ratio.

[a] When a large services industry employer reduced copays for certain classes of drugs, nonadherence rates decreased by 7-14%. Copayment rates for generic medications were reduced from $5 to $0; copayments for brand-name drugs were cut in half for five classes of drugs. A similar employer with identical disease management offerings and similar, but stable, copayments served as a control group.

SOURCE: Copyrighted and published by Project HOP/Health Affairs as Chernew, M. E., M. Shah, A. Wegh, S. Rosenberg, I. Juster, A. Rosen, M. Sokol, K. Yu-Isenberg, and M. Fendrick. 2008. Impact of decreasing copayments on medication adherence within a disease management environment. *Health Affairs* 27(1):103-112. The published article is archived and available online at www.healthaffairs.com.

programs incur lower treatment costs, because fewer individuals are eligible for copay reductions and the targeted patients who receive copay relief are most likely to benefit from increased utilization.

Offsetting these direct costs of copay reduction are the savings incurred by reductions in future services avoided due to better clinical outcomes. For example, savings due to fewer emergency room visits for acute asthma exacerbations would offset the direct costs of lower copays for asthma controller medications, at least partially. The net financial benefit improves if the underlying risk of an adverse outcome is high, if the cost of that adverse outcome is high, if consumers are responsive to lower copays, and if the service is effective at preventing the adverse outcome. Additional return on investment accrues if the nonmedical benefits of improved health (e.g., reduced disability and absenteeism, enhanced productivity) are included.

The following financial scenarios are likely to occur, depending on the goals of the VBID program and the willingness to raise copayments on low-value services:

- Targeted copay reductions will result in higher value for each market basket of services only if there are incentives to use services that produce high levels of health benefit. There will be an uncertain effect on total healthcare cost trends.

- Copay reductions with global or targeted copayment increases to offset short-term costs of increased utilization of targeted services (actuarial equivalence) will result in higher value for each market basket of services due to incentives to use services that produce high levels of health benefit. Total healthcare costs will be equal or lower, depending on the extent of savings yielded due to offsets from improved health and lower utilization of low-value services as a result of higher copays.

Efforts to control costs should not produce preventable reductions in quality of care. Multiple private and public sector employers, health plans, and pharmacy benefit managers have implemented VBID programs encouraging the use of high-quality services. In 2001, Fortune 500 employer Pitney Bowes lowered copayments for asthma and diabetes medications, reporting to the *Wall Street Journal* a $1 million savings from reduced complications (Furhrman, 2007). The city of Asheville, North Carolina, Marriott Corporation, Mohawk Carpets, Wal-Mart, CIGNA, the State of Maine, and the University of Michigan are among those who have implemented VBID. Leading health plans and health benefit consultants are working to make these packages accessible nationwide.

Conclusion

Payers desiring to optimize health gains per dollar spent should avoid "across-the-board" cost sharing and instead implement a "value-based" design that removes barriers and provides incentives to encourage desired behaviors for patients and providers. Targeted efforts to reduce utilization of low-value services are more likely to contain cost growth while maintaining quality of care.

We do not expect VBID to solve the nation's healthcare crisis. Technological advances will continue to generate upward pressure on costs, and the ability of individuals and their employers to afford such coverage will increasingly be strained. That said, the alignment of financial incentives—for patients and providers—would encourage the use of high-value care, while discouraging the use of low-value or unproven services, and *ultimately produce more health at any level of healthcare expenditure.*

CONSUMER-DIRECTED HEALTH PLANS: WHAT ARE THEY, WHAT DO WE KNOW ABOUT THEIR EFFECTS, AND CAN THEY ENHANCE VALUE?

Melinda J. Beeuwkes-Buntin, Ph.D., RAND Health

The health insurance options available to Americans have changed dramatically in the last five years. Higher deductibles and personal health savings accounts—either health reimbursement accounts (HRAs) or health savings accounts (HSAs)—are increasingly popular features that are intended to make patients more cost conscious in their healthcare choices. Plans with these features, often referred to as consumer-directed health plans, are intended to engage consumers in understanding the costs of care and in making healthcare choices.[1] Critics charge, however, that they are currently little more than a device to shift costs to enrollees. This paper sketches the scope of consumer-directed care, discusses what is known about the effects on CDHPs to date, and concludes with some thoughts about how consumer-directed care might be used to increase the value of the healthcare services we receive.

Scope of Consumer-Directed Care

Consumer-directed health plans emphasize the role consumers can play in making decisions about their healthcare choices. These plans usually provide patients with upfront financial incentives to choose care wisely in the form of deductibles that are typically higher than those of traditional plans—the typical consumer-directed plan has a single deductible of $1,000 or more. In addition, as mentioned above, they are often coupled with personal savings accounts that roll over if funds in them are not spent; this gives patients additional incentives to save for future expenses rather than consume care in the current period. Proponents of consumer-directed plans hope these measures will spur patients to take greater responsibility for their own care and seek information about care options. They also point out that more informed and motivated consumers can in turn spur healthcare providers to compete for their business on the basis of higher quality and/or lower costs.

Since the advent of CDHPs early in the decade, an increasing number of employers have offered them either exclusively or as a choice among

[1] In this discussion, the term "consumer-directed health plans" refers to private plans that have higher-than-average deductibles, but may not necessarily meet federal requirements for a plan that can be paired with an HSA. The term "high-deductible health plan" (HDHP) refers specifically to HSA-qualified plans that meet the requirements set out in regulations issued by the U.S. Treasury.

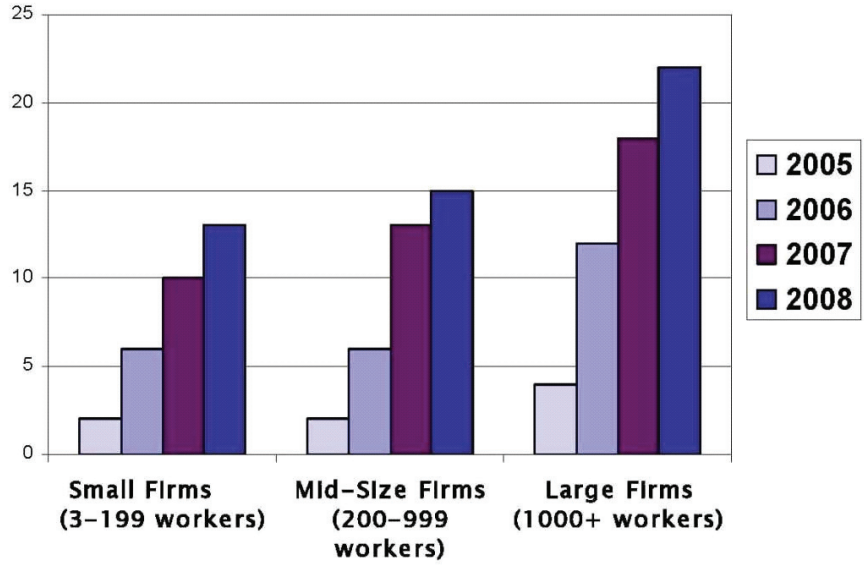

FIGURE 4-2 Proportion of firms offering a CDHP option, by size.
SOURCE: Kaiser Family Foundation and the Health Research Educational Trust, 2008b.

other types of insurance. Large employers are more likely than midsize and small businesses to provide CDHPs as an option. In 2008, almost a quarter of firms with 1,000 or more workers offered CDHPs, compared to 15 percent of midsize and 13 percent of small firms (Figure 4-2). Half of very large firms with more than 5,000 enrollees offer a CDHP option (Watson Wyatt/RAND, 2007). Across the board, the rate of firms offering CDHPs has increased substantially since 2005 when U.S. Treasury regulations laid out the criteria for HSAs. However, despite employer enthusiasm for CDHPs, consumer take-up remains relatively low. In 2007, 11 percent of Americans were enrolled in a high-deductible health plan (HDHP). Only 2 percent of Americans were enrolled in a CDHP featuring an HDHP plus an HRA or an HSA (EBRI/Commonwealth, 2008).

Economic forces, employer choices, and evolving plan designs all have the potential to change this picture. Even before the extent of the economic downturn was known, a survey of human resources executives in early 2008 indicated that companies are still warming to the idea of CDHPs and see them becoming more important in the future. Nearly nine-tenths of respondents were optimistic about the future of CDHPs at their firms: 34 percent anticipated more employees in a CDHP, 26 percent anticipated

offering a "full replacement" CDHP (i.e., offering only a CDHP to their employees), and 29 percent anticipated a "majority" of employees in a CDHP (Figure 4-3). All of these rates represented an increase from 2007, and now that companies are more financially stressed, they are reportedly even more interested in CDHPs (Watson Wyatt/RAND, 2007). Finally, given that CDHPs are still relatively new products in the market, it may not be surprising that interest in them is growing as offerings are refined. For example, most CDHP plans now exempt some or all preventive care services from the deductible and vendors are offering more sophisticated incentive programs designed to help people stay healthy and manage chronic illnesses. In short, although CDHP enrollment has been lower than many in the industry had initially expected, it is still growing and forces may now be aligned to help it expand more quickly.

Research to Date on CDHPs

Given the growing enrollment in CDHPs and the increased focus on improving the value of health services delivered, what is known about the effects of CDHPs on healthcare costs and quality? The most authoritative estimates of their likely effects come from the decades-old RAND Health Insurance Experiment (HIE). The HIE found that higher deductibles could reduce spending by about 5-10 percent (Newhouse, 1992). The reductions in care use implied by these savings came through reductions in patient-initiated visits, however, not through the choice of more cost-effective treatments. Indeed, the reductions occurred in all types of services—preventive care, routine chronic care, and care deemed necessary by physician experts as well as care deemed unnecessary. Yet these reductions in care use had little effect on health outcomes during the evaluation period. The exception was for patients who were both sick and poor; their health declined more in the higher cost-sharing plans.

There are reasons, however, why the effects of today's CDHPs might differ from the high-deductible plans studied in the RAND experiment. First, medical technology has advanced dramatically since the experiment began in the early 1970s and, thus, the consequences of going without care could be more severe. Second, the Internet has made medical information much more widely available, potentially increasing the ability of patients to make informed decisions about care. Third, new consumer-driven designs often emphasize prevention and are coupled with other programs such as disease management programs and health risk assessments. Finally, personal savings accounts could provide patients with the liquidity they need to initiate care. Still, despite these changes, it is important to know that the overall financial risk borne by CDHP enrollees is likely greater than that borne by the original HIE participants, because the latter were compensated for enrolling in

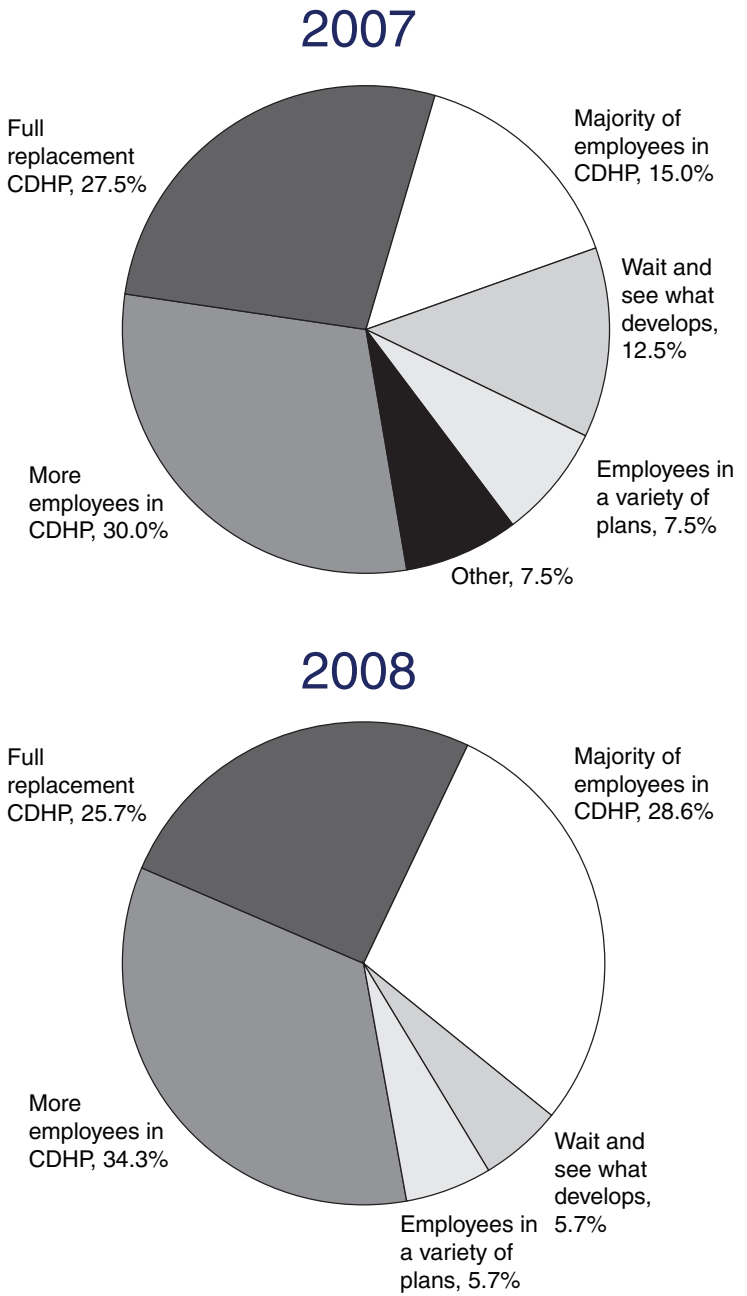

FIGURE 4-3 Most human resources executives remain committed to CDHPs. SOURCE: Watson Wyatt/RAND, 2007.

the experiment and had their financial exposure limited to a percentage of their income. Thus, the question of whether modern CDHP designs can spur consumers to seek higher-value care—rather than indiscriminately cut back on care when faced with higher costs—remains an open one.

So what does the recent literature suggest about CDHPs? Unfortunately, evidence is still largely limited to early adopters of these plan types and to studies of the experience of a single employer or a single insurance carrier. A review in 2006 of the evidence to date about CDHPs concluded that moving consumers from traditional plans to high-deductible plans would result in a one-time reduction in service utilization of about 4-15 percent (Buntin et al., 2006), but that coupling these plans with funded savings accounts could reduce this effect by half. Some evidence supported lower average spending, smaller premium increases, and lower use of care across a range of services, but mixed results were found for changes in individual spending over time and for quality of care.

Recent work has largely confirmed these findings—mixed as they are. A follow-on study by Feldman and colleagues (Feldman et al., 2007) suggested that after the initial cost savings, CDHP enrollees might actually spend more in subsequent years (Figure 4-4). The authors also found that expenditures for hospitalizations were higher for CDHP members than for members of preferred provider organizations (PPOs) and that the savings within the CDHP group came only through reduced pharmacy costs. However, Feldman and colleagues concluded that the CDHP they studied did not have high enough cost sharing to limit care use—in particular, it had an HRA account to which the employer made a substantial contribution.

Other studies have found mixed results for different types of care use. Wharam and colleagues (Wharam et al., 2007) showed that emergency room (ER) visits, hospitalizations, and hospital days all decreased among CDHP patients and increased among members of traditional plans. Interestingly, they also found that CDHP enrollees were much less likely to have a second ER visit, indicating that they learned something about the costs of ER use during their first visit. However, the average cost for a CDHP member's hospital stay compared to the costs for members in traditional plans was higher, suggesting that CDHP consumers may delay care until reaching a critical point. Rowe and colleagues (Rowe et al., 2008) found that preventive care visits decreased among both Aetna CDHP and PPO enrollees, but the decrease among the PPO enrollees was actually slightly larger (Figure 4-5).

Preventive service use and screening rates among CDHP participants are comparable to those of members of traditional plans if their CDHP offers first-dollar coverage for preventive services. Rowe and colleagues (2008) found that preventive service use for diabetes and preventive screen-

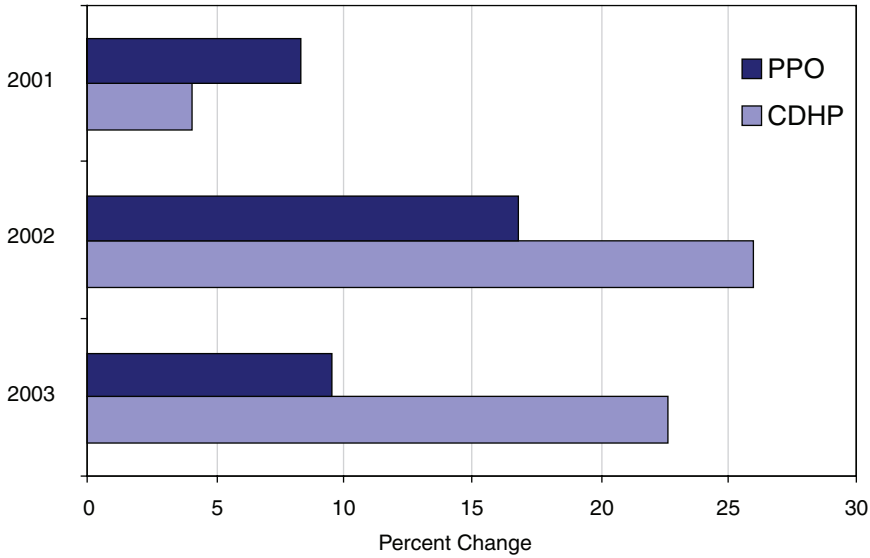

FIGURE 4-4 Recent estimates: effects of CDHPs on spending.
NOTE: Includes employer and employee expenses. Figures show increase in spending in preferred provider organizations (PPOs) and CDHPs versus the control point-of-service (POS) plan.

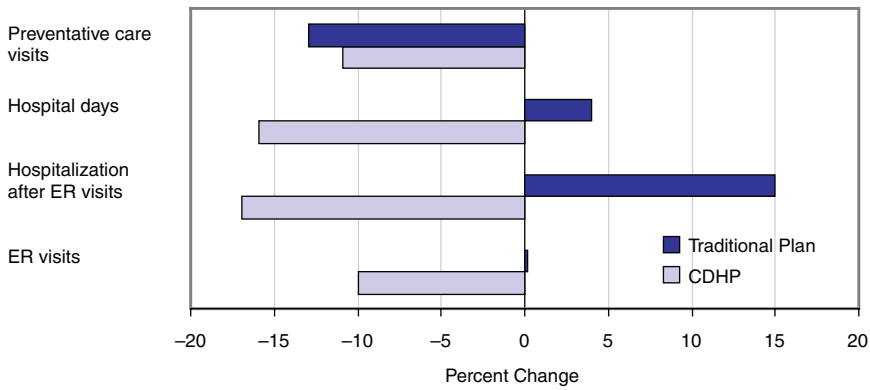

FIGURE 4-5 Recent estimates: effects of CDHPs on medical utilization.
NOTE: Emergency room (ER) and hospitalization figures represent change from 2001 to 2005 for consumers in an HDHP versus a health maintenance organization (HMO); preventive care visits represent change from 2003 to 2005 for consumers in a health reimbursement account versus a preferred provider organization.

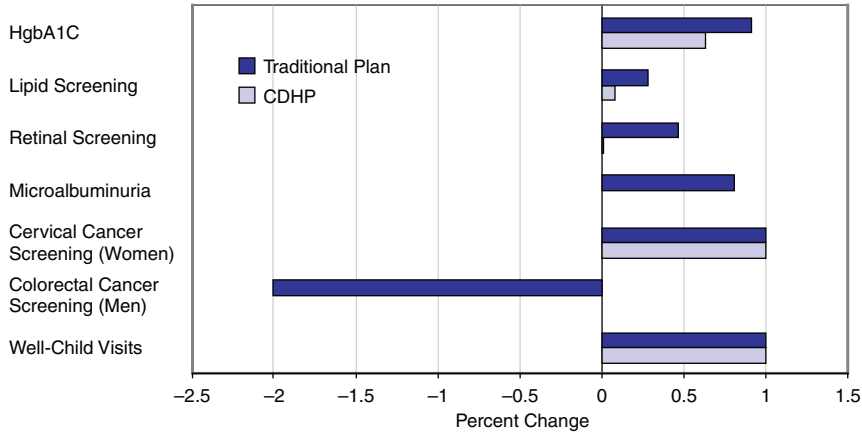

FIGURE 4-6 Recent estimates: effects of CDHPs on preventive service use.
NOTE: Mammogram and Pap smear differences were not significant in Rowe et al. (2008).
SOURCE: Well-child and cancer screenings: Busch et al., 2006; change in CDHP participants vs. PPO from 2003 to 2004 and diabetes management.

ings rates showed no consistent pattern of association with CDHP enrollment. Busch and colleagues (2006) also found either no effect or a positive effect of CDHP enrollment on the rate of cancer screenings and well-child visits (Figure 4-6). It is worth noting, however, that rates of use of preventive care for both the CDHP and the comparison plan show substantial room for improvement.

One area in which CDHPs do compare unfavorably to traditional plans is appropriate prescription drug use. Building on prior work reporting that CDHP members are more likely to forgo filling a prescription because of cost than those in traditional plans, Greene and colleagues (2008) established that CDHP enrollees are more likely to discontinue using medication for chronic diseases than consumers in a basic three-tier copayment plan (Figure 4-7). However, these authors also found that CDHP consumers have the same rates of medical adherence if they do continue their medication and are no more likely to substitute to generic drugs.

While the section above summarizes the recent published literature, it is important to note a few limitations in what has been learned to date. First, all of the studies mentioned are observational studies of a single insurer or employer, most with a pre/post design and an attempt to control statistically for selection into different plans. Given that favorable selection into CDHPs is now fairly well documented (e.g., Busch et al., 2006; Dixon et

al., 2008; Government Accountability Office, 2006), the results should be interpreted in that light. Second, CDHP vendors have conducted their own internal studies that paint a brighter picture of CDHP cost savings and health outcomes than the results discussed here. These industry studies have the benefits of larger sample sizes and more recent data. However, most of these publications are not peer-reviewed so their methods and assumptions have not been subject to outside scrutiny. Third, there is considerable variation in benefit design among CDHPs. Plans have different constellations of coinsurance rates, deductibles, and personal accounts—all of which can affect care use. Most of the CDHPs studied in the published literature have moderately high deductibles and are coupled with employer-funded HRA accounts. Newer plans may be coupled with HSA accounts and may employ a broader array of incentives and information tools that can facilitate consumer decision making and potentially increase value.

How Could CDHPs Be Shaped to Increase Value?

Consumer-directed health plans are predicated on the idea that informed and incentivized consumers can make decisions about their healthcare use that yield better outcomes at lower cost: in other words, their goal is to improve value. Putting aside whether or not CDHPs are currently doing this, the goal is a good one. CDHPs should be shaped to increase their ability to reach that goal. One way to do this, which is entirely in keeping

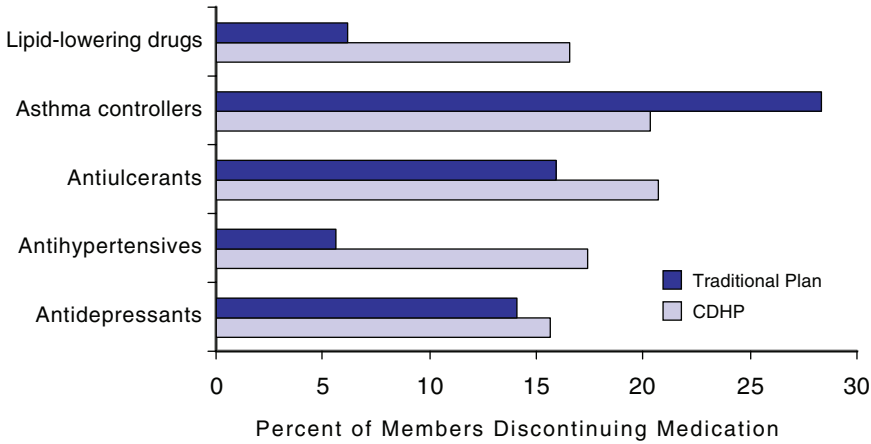

FIGURE 4-7 Recent estimates: effects of CDHPs on medication discontinuation. NOTE: Comparison is a high-deductible CDHP to a PPO with a three-tier copayment scheme.

with the philosophy of consumer-directed care, is promoting the collection and dissemination of information about the cost and quality of care. Such information can change behavior and increase value. For example, when provided with information and faced with differential cost sharing, people do switch from brand-name medications to generic drugs. However there is relatively little information available about the cost and quality of hospital procedures and services, and even less on the outpatient side. Human resources executives at firms offering CDHPs to their employees nearly universally agreed that the information tools available to their employees were of fair or poor quality (Watson Wyatt/RAND, 2007). Worse, they did not cite any improvements in them between 2007 and 2008 (Figure 4-8). Without such information, it is hard for consumers to make meaningful choices among providers that take value into account.

A second way to increase the value of CDHPs is to disseminate and deploy "best practices" in CDHP design. For example, many CDHPs cover preventive services before the deductible is met, but not all do. This should be encouraged, especially for high-value preventive services (Masciosik et al., 2006). In addition, it would be beneficial to define some drugs and services that support secondary prevention—such as drugs for the prevention of the sequelae of diabetes and foot exams for those with diabetes—as preventive care exempt from the deductible. Many CDHPs currently offer financial incentives to participate in health improvement programs (Figure 4-9). It could be valuable to expand the combination CDHPs with these and other

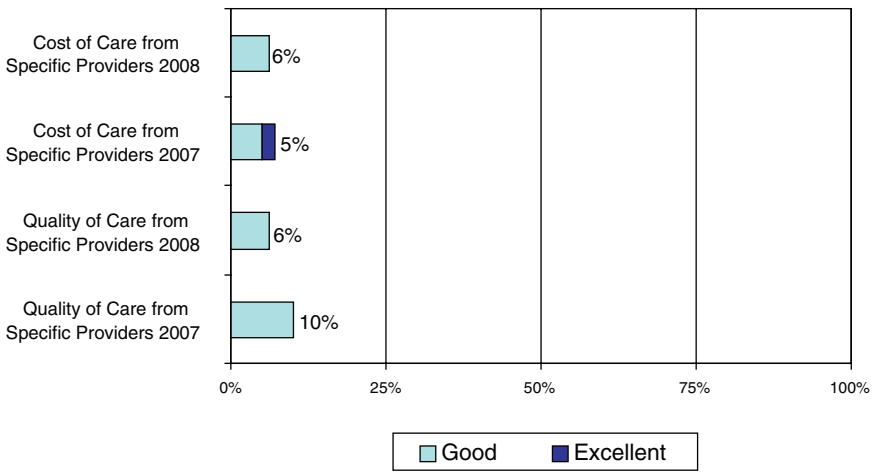

FIGURE 4-8 Human resources executives' ratings of information tools.
SOURCE: Watson Wyatt/RAND, 2007.

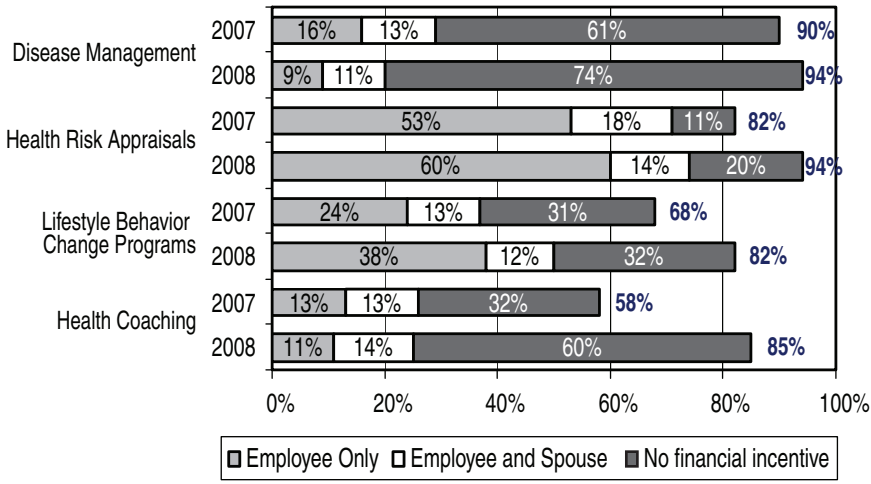

FIGURE 4-9 CDHP financial incentives to participate in health improvement programs.
SOURCE: Watson Wyatt/RAND, 2007.

value-oriented approaches that are discussed in this volume, including value-based benefit designs, tiering, and workplace-based wellness initiatives.

Finally, value could be increased with more research about the effects of different CDHP designs on the use and outcomes of care. This includes research on the specific aspects of CDHP design such as deductible levels, deductible exemptions, and personal savings accounts. It also includes research on the value of health improvement programs that are being promoted under the broad rubric of "consumerism." The effectiveness of these programs alone, in conjunction with CDHPs and in combination with other value-based programs, is not yet known, but the need for strategies that can yield improvements in value is clear.

THE ROLE OF TIERED BENEFIT DESIGNS FOR IMPROVING VALUE IN HEALTH CARE

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Definition and Motivation for Tiered Benefit Programs

As discussed in this report and many other sources, the healthcare system in the United States suffers from substantial deficits in quality, safety,

efficiency, and value (IOM, 2000, 2001; McGlynn, 1997). Policy makers, academics, and clinicians from across the ideological spectrum have proposed a wide array of strategies to improve value in the healthcare system, many of which are discussed in other chapters of this volume. For example, improvement efforts may come through the regulatory system, utilizing mechanisms such as accreditation and professional licensure (Brennan, 1998). Other strategies include providing "supply-side" incentives to hospitals, physicians, and health plans to improve the quality of their care. These incentives may include both financial (e.g., pay-for-performance programs; Rosenthal et al., 2005) and nonfinancial or "reputational" incentives (e.g., public reporting systems; Marshall et al., 2000).

There has also been a growing interest in "demand-side" interventions to address quality, safety, and value deficiencies. For example, increasing attention has been paid to the notion of "consumer engagement," which describes a variety of activities designed to help patients become more active in their care. These activities may include helping consumers utilize public reports and providing self-management education (Hurley et al., 2009). Another "demand-side" strategy that is garnering significant attention is the concept of "tiering." Tiering can be defined as the classification of healthcare providers (e.g., hospitals, physicians) or treatments (e.g., pharmaceuticals, durable medical equipment, physical therapy) into different groups—or tiers—based on objective or subjective criteria such as measures of cost, quality, safety, or value.

Prevalence of Tiering Programs

Tiering of prescription drugs is the most prominent form of tiering program and is emerging as a nearly universal benefit characteristic. In 2008, the Kaiser Family Foundation found that 92 percent of beneficiaries face some type of differential cost sharing. This is equal to a 21 percent increase from 2000 (76 percent) (Kaiser Family Foundation and the Health Research Educational Trust, 2008a). Furthermore, in 2000, only 27 percent of beneficiaries were in plans with three tiers and no plans reported four tiers (Kaiser Family Foundation and the Health Research Educational Trust, 2000). By 2008, 77 percent of all beneficiaries were in plans with at least three tiers, an increase of 185 percent. Four-tier structures are also growing in popularity as 7 percent of all beneficiaries in 2008 were enrolled in such plans (Kaiser Family Foundation and the Health Research Educational Trust, 2008a).

Although far less prevalent than tiered prescription drug benefits, health plans are also beginning to institute tiered benefit designs for hospital care and physician services. There are few estimates of the prevalence of tiered benefit structures for providers, but in 2005, the Kaiser Family Foundation estimated that 13 percent of beneficiaries were enrolled in plans with

tiered provider benefits (Kaiser Family Foundation and the Health Research Educational Trust, 2005). Historically, provider tiering has been advanced by large employers or purchaser coalitions. Therefore, markets with firms that are active in health benefit reform are more likely to see these design changes (Draper et al., 2007).

Although provider tiering programs are not prevalent, employers continue to be somewhat interested in instituting these benefit changes. In Kaiser's 2008 Employer Health Benefits Survey, 18 percent of firms stated that they were at least somewhat likely to adopt tiered copayments for office visits or hospital stays (Kaiser Family Foundation and the Health Research Educational Trust, 2008a). Multistakeholder quality improvement collaboratives are also beginning to investigate the possibility of developing provider tiering programs in local communities (Anthem Blue Cross Blue Shield, 2007; Maine Health Management Coalition, 2008).

There is no published evidence that tiering has been used for other types of therapies or services such as durable medical equipment, physical therapy, or long-term care, but it is conceivable that tiering could be utilized in these sectors of health care as well.

Goals of Tiering Programs

By assigning providers or products to different tiers and offering information about the tiering method and the financial implications of choosing a tier, healthcare purchasers and payers seek to accomplish several goals. Commonly cited goals of tiering programs include (1) engaging patients and consumers in making informed decisions about providers or therapies; (2) steering patients toward better-quality or safer hospitals and doctors; (3) cost savings through the use of lower-cost providers or therapies; and (4) helping patients to better self-manage their health conditions and to receive appropriate care. Thus, the "first-order" goal of a tiering program is to influence a decision such as the choice of a prescription drug or the use of the best doctors and hospitals. This choice is important only in so far as it leads to the "second-order" goal(s), which include improved quality, value, or safety.

Although many different methods can be used to place providers into tiers, these decisions are generally based on cost, quality, or safety measures or a combination of these. As part of their tiering programs, employers or health insurance plans generally provide consumers with information about how the tiers are constructed and which options are in each tier. Consumers often, but not always, face financial incentives in tiering programs, such as reduced premiums or copayments for choosing the tiers with preferred providers or treatments (Draper et al., 2007).

Although the popular press might suggest otherwise, tiering is not a

new concept in health care, but instead originates from methods used previously. For example, a strict pharmaceutical formulary essentially establishes a "two-tiered" prescription drug benefit since if a patient chooses a drug that is not on the formulary, the health plan simply does not pay for it. Similarly, closed-model health maintenance organizations (HMOs) essentially offer a "two-tiered" provider benefit. The first tier would include in-network providers, whereas out-of-network providers would be in the second tier and would not be covered. One key distinction however is that modern tiering systems, having learned from the "managed care backlash," generally do not place hard limits on consumer choice. Instead, beneficiaries are allowed to choose any provider but face differential cost sharing based on the tier in which the provider is placed. Another distinction from historical managed care programs is that today's tiering programs increasingly incorporate quality and safety as factors used to define tiers. In short, tiering programs are attempting to utilize the cost-sharing benefits of managed care to drive improvements in value, safety, and quality without restricting consumer choice or focusing exclusively on costs.

Stakeholders' Perspectives on Tiering Programs

While tiering programs are increasing in popularity, stakeholders vary in their perspective on these programs. Purchasers (e.g., self-insured employers, government healthcare programs) and payers (e.g., health insurance plans) view tiering as a potentially attractive way to reward high-value providers and give other providers incentives to improve their outcomes. They also view tiering as a way to increase the utilization of more cost-effective treatments or therapies, such as the substitution of generic drugs for brand-name drugs. Tiering is also attractive to purchasers and payers because it allows these entities to continue to offer broad provider networks, thus avoiding the negativity that comes with restricting consumer choice (Draper et al., 2007). The perspective of other stakeholders is likely mixed. For example, physicians or hospitals may differ in their assessment of tiering on either philosophical or empirical grounds. Philosophically, some providers are opposed to differential consumer incentives, such as lower copayments or coinsurance, for the same types of providers. On the other hand, some providers view tiering as an opportunity to demonstrate value and to be rewarded with increased market share and reimbursement. For this latter group, the primary concern is making sure that the methods used to develop tiering programs are scientifically valid and robust.

Patients and manufacturers of drugs and other medical devices are also likely to have mixed views on tiering. On the one hand, tiering programs may provide incentives for all parties in the healthcare system to demonstrate better value, making the primary concern the validity and fairness

of the tiering criteria. On the other hand, since tiering is a departure from historical norms, many patients, providers, and producers view it as an attempt to resurrect the old-style managed care programs.

Requirements and Technical Considerations for Tiering Programs

Several factors and considerations are important when designing and implementing tiered benefits programs. These are discussed in turn.

Measurement and Data Availability

Because tiering programs distinguish providers, drugs, or therapies based on cost, quality, or safety, it is important that these dimensions can be measured accurately and reliably from readily available data. The risk of faulty measurement is significant for all stakeholders since, for example, inaccurate measurement can lead to the false classification of providers, resulting in unintended consequences for payers, purchasers, and patients, not to mention reputational, revenue, and market share consequences for providers.

Measuring and comparing the quality of brand-name drugs and generics within the same class is relatively straightforward as is measuring drug costs, but even so there are still many important technical details to consider when establishing a pharmaceutical tiering program (e.g., how to handle discounts and rebates when computing pharmacy costs). Healthcare costs are also notoriously difficult to measure and as such can potentially lead to erroneous tiering classifications (Fishman et al., 2004). When it comes to hospital care and physician services, measurement is more difficult. For quality and safety, national consensus measures are emerging through the efforts of groups such as the National Quality Forum (NQF, 2009) and should eventually serve to alleviate concerns about the measurement aspect of tiering programs. For now, however, there remain substantial debate regarding the ability of these consensus measures to accurately capture the quality and safety of care and concerns about the appropriateness of the available measures for use in tiered hospital and physician benefits programs.

In some cases the measurement science is ahead of purchasers' and payers' practical abilities to collect the necessary data to measure and classify providers into tiers. In these cases the technical issues often relate to issues such as data availability, data source (claims vs. electronic record vs. provider self-report), ability to attribute patients to providers, and necessary minimal sample size required for accurate measurement (Fishman et al., 2004; Iezzoni, 1997; Krein et al., 2002). Since most general acute care and tertiary care hospitals provide a broad range of treatment and services,

including medical and surgical care, there is also the decision about whether to tier hospitals across an entire range of services or to tier separately based on specific clinical services (e.g., cardiac or cancer care) within a hospital.

Market-Level Provider Capacity

Although tiering programs are appealing conceptually, they will not be successful without a sufficient number of providers in the preferred tiers or unless providers in the preferred tiers are operating at full capacity. The first issue, while potentially mutable over time, can be a limiting factor if few options are available in the preferred tier. When this is the case, it is a matter of judgment about when to proceed with a tiering program. In some cases, sponsors may proceed immediately to provide an incentive for providers to qualify for the preferred tier (i.e., presumably through improving quality or value), while others may wait until there is a viable set of options in the preferred tier that can be selected at the launch of the program. The second situation is more challenging and not easily mutable in the short term. In other words, if physicians or hospitals in the preferred tiers are operating at capacity, such that they cannot take on new patients, then the effect of the tiering program is inherently limited. This is an important consideration because there are locations in the United States where both hospitals and physicians are operating at full capacity or are facing significant physician shortages in primary care and other specialties (Bazzoli et al., 2003; Cooper et al., 2002; Trude, 2003).

Budgetary Implications

Tiering programs, particularly those that include financial incentives, have budgetary implications for the program sponsor since changes in the distribution of providers, drugs, or products used have real actuarial implications. It is impossible to make firm general statements about the direction and magnitude of actuarial implications of tiering programs. Instead, each program must be assessed individually. For example, tiered pharmaceutical benefit programs that encourage generic substitution would have to estimate the impact on overall cost to the plan sponsor of varying copayment amounts by tier. This estimate would depend on the baseline utilization and cost of drugs in each tier as well as the rate by which patients substituted drugs in different tiers. Although this projection is still subject to some uncertainty regarding the substitution rate, plan sponsors should have reasonable information about the costs of drugs in the various tiers. The same is often not true for physician or hospital tiering, where the link between quality and safety measures and costs is not as well established and often depends on probabilistic expectations regarding complication

rates and length of stay. In this case, plan sponsors should make budgetary projections based on the best available evidence and in consultation with actuaries, while accounting for the uncertainty and also considering an appropriate time horizon for achieving a return.

The Evidence Base for Tiered Benefit Programs

Pharmaceutical Tiering

Tiered benefit designs for prescription drugs have emerged in response to growing prescription drug costs and represent the most common type of tiering program, although drug tiering is clearly different from hospital and physician tiering. While the details of the benefit structures differ between plans, there are common characteristics. Drugs tend to be divided into either two or three tiers (and sometimes four) based on cost and clinical efficacy criteria. In two-tier plans, generic drugs are placed in Tier 1 while brand-name drugs are placed in Tier 2. In three-tier plans, the brand-name drugs are further differentiated into preferred and nonpreferred drugs, which are brand-name drugs with similar clinical indications and effectiveness but different prices. Patients can choose from any of the drug types but face increasing copayments as they move up the tiering ladder. The copayments for each of the tiers vary by health plan but average $11, $25, and $43, respectively, for Tier 1, Tier 2, and Tier 3 (Kaiser Family Foundation, 2008).

Because pharmaceutical tiering strategies have grown in popularity, there is a substantial collection of literature investigating their effect. The literature focuses on both "first-order" goals, such as changes in drug choice, and "second-order" goals, such as total expenditures and clinical outcomes (e.g., drug discontinuation rates). The literature does suggest that tiered drug benefits affect drug choice. The effect is most apparent for preferred brand-name drugs. Specifically, introducing a third tier tends to decrease spending for nonpreferred drugs and increase spending for preferred drugs (Gibson et al., 2005). For example, one study shows that the use of preferred drugs increased for ACE inhibitors (13 percent), protein pump inhibitors (8.9 percent), and statins (6 percent) (Rector et al., 2003). However, Gibson and colleagues (2005) suggest that tiering has been less effective in encouraging switching to generic medications, perhaps because generic brand price differentials have been too small to induce substitution of generics for brand-name drugs.

The literature also suggests that the prescription drug switching induced by tiering schemes tends to reduce total expenditures on prescription drugs (Fairman et al., 2003; Gilman and Kautter, 2007; Motheral and Fairman, 2001). However, these reductions in expenditure tend to be captured by

health plans, while beneficiary costs may actually increase (Gibson et al., 2005; Hodgkin et al., 2008; Huskamp et al., 2003, 2005). For example, Landon and colleagues (2007) show that as overall drug spending decreased by 5-15 percent, health plan spending decreased around 20 percent, while out-of-pocket payments for beneficiaries increased by at least 20 percent to more than 100 percent.

Literature investigating the effect of tiered benefit designs on clinical outcomes, such as morbidity, is scant. However, some literature does focus on intermediate outcomes such as drug discontinuation. There is some evidence that tiering may lead to drug discontinuation in certain drug classes, among certain groups of patients, and within certain benefit designs, but these results have not been consistent across a diversity of settings (Gibson et al., 2005; Huskamp et al., 2003, 2005, 2007; Landsman et al., 2005).

Physician Tiering

Although there are no estimates on the exact prevalence of physician tiering, it is believed that the prevalence of these programs is small. Health plans and employers have introduced physician tiering schemes in only a limited number of markets (Draper et al., 2007). Despite its low prevalence, physician tiering has garnered quite a bit of critical media attention.

Existing physician tiering strategies vary but commonly employ a two- or three-tiered system, which groups physicians based on either cost or quality or a combination of both. Tiering strategies have been used for both primary and specialist services. There is not only substantial variation in the criteria (cost, quality, or both) used to classify physicians but also in the methodology used to determine the tier placement. Depending on the methodology, plans place anywhere from 25 to 80 percent of physicians in the highest tiers. In some plans, beneficiaries are required to pay different copayments depending on the tier in which their physician is placed, whereas other plans simply use the tiers as informational tools for beneficiaries (Draper et al., 2007).

One employer that has been out in front of physician tiering has been the Commonwealth of Massachusetts, thus providing a useful case study of how physician tiering programs have been executed in the real world. Health benefits for state employees in Massachusetts are overseen by a quasi-governmental organization called the Group Insurance Commission (GIC). GIC contracts with a variety of health plans including Unicare, Harvard Pilgrim, and Tufts Health Plan to administer the benefits. In June 2006, GIC introduced a physician tiering program called the Clinical Performance Improvement (CPI) Initiative, which was designed to both reduce costs and increase quality while maintaining provider choice for

beneficiaries (Commonwealth of Massachussetts Group Insurance Commission, 2007).

Each of the plans provided claims data to GIC for all of its members. Based on clinical guidelines, GIC established process performance standards for each of the specialties. From the claims dataset, GIC used a novel algorithm to assess the quality of care for each physician in Massachusetts. Quality is essentially based on the percentage of eligible patients for which a physician complies with the clinical guidelines. Similarly, GIC was able to use the claims dataset to determine the cost of care provided by each physician for similar conditions, adjusted for geographic and market characteristics (Wellpoint, Inc., 2008).

Each of the GIC plans has the freedom to execute CPI in its own way. Some of the plans' programs tiered all Massachusetts physicians, while others only tiered certain specialties. One example of how a plan has executed CPI comes from Unicare, which placed physicians in one of three tiers using standard benchmarks for cost and quality. Unicare classified physicians as "excellent" and placed them in Tier 1 if they have performed at or above the benchmark for both cost and quality. Physicians are considered "good" and placed in Tier 2 if they are below (but not more than 25 percent below) the benchmark for either cost or quality. Physicians are considered "standard" and placed in Tier 3 if they are at least 25 percent more expensive or at least 25 percent lower in quality than comparable physicians (Wellpoint, Inc., 2008).

Based on the tier placement, beneficiaries are rewarded for choosing high-quality, efficient providers by being subject to lower copayments for physicians in higher tiers. Basic members in the Unicare plan face copayments of $10, $20, and $25 for primary care physicians respectively in Tier 1, 2, or 3. For specialty care, beneficiaries face copayments of $10, $20, and $30 (Wellpoint, Inc., 2008). Although the GIC program has received substantial publicity, other plans, such as Regence Blue Cross in Washington as well as UnitedHealthcare and Cigna in Connecticut, have also experimented with physician tiering (King, 2008).

To our knowledge there is no peer-reviewed literature examining the effect of this or similar physician tiering strategies on any kind of outcome, including physician choice, quality improvements, clinical outcomes, costs, or expenditures. However, there is a single study investigating the potential effects of physician tiering on care inequities for minorities, which the authors conclude is likely minimal (Brennan et al., 2008).

Physician tiering systems have been extremely controversial, leading to a series of lawsuits across the nation. In November 2006, the Washington State Medical Association filed suit against Regence Blue Shield, claiming that the tiering methodology did not adequately measure the quality of physician care. The suit was ultimately settled in August 2007 and Regence

agreed to postpone the tiering program until it could receive sufficient input from physicians. In 2007, the Fairfield County Medical Society in Connecticut filed a similar suit against UnitedHealthcare and Cigna (King, 2008). GIC has not been immune from legal action. In May 2008, the Massachusetts Medical Society filed suit against GIC, Unicare, and Tufts Health plan claiming both defamation and fraud (Krasner, 2008).

These lawsuits illustrate the importance of measurement and data in physician tiering programs. In each of the suits, the plaintiffs claim that the measurement of care quality was arbitrary or did not represent the actual quality of care provided by physicians. Bruce Auerbach, the president of the Massachusetts Medical Society stated that "the GIC has refused to correct the CPI's most glaring problem, which is its ranking of individual physicians using inaccurate, unreliable, and invalid tools and data" (Krasner, 2008).

Even as lawsuits continue, there is some indication that progress is being made toward consensus on physician tiering methodologies. In July 2007, Attorney General of New York Andrew Cuomo sent letters to CIGNA, Aetna, and UnitedHealthcare expressing concern that physician tiering methodologies were based on inaccurate data and were disproportionately based on cost rather than quality (King, 2008). The health plans quickly agreed to adopt Cuomo's "Doctor Ranking Model Code." Among other provisions, the code required plans to disclose tiering methodology, to use risk adjustments, and to use national consensus measures (New York State Office of the Attorney General, 2007). Similar codes have been adopted in other states including Colorado (Berry, 2008).

A coalition of consumer, labor, and employer organizations called the Consumer-Purchaser Disclosure Project, which includes AARP, the Leapfrog Group, and the National Business Coalition on Health, has been working on a similar initiative. This coalition has agreed on a set of principles that will guide future efforts in performance measurement, reporting, and tiering. Called the "Patient Charter," this set of principles includes reliance on national consensus measures and disclosure of measurement methods (Robert Wood Johnson Foundation, 2008). The Robert Wood Johnson Foundation recently funded a study by George Washington University investigating the legality of tiering programs. That study has affirmed that these types of transparency provisions should ensure the legality of tiering programs (Robert Wood Johnson Foundation, 2007). These, and similar, agreements may facilitate the expansion of physician tiering.

Hospital Tiering

There are also a variety of methods used to place hospitals in specific tiers, but placement is generally based on cost and/or quality measurements. Blue Cross and Blue Shield of California (BCBSCA) introduced a tiered hos-

pital network in 2002 based purely on costs (cost per inpatient episode and cost per outpatient procedure) (Robinson, 2003). Boeing, in its self-funded plan, placed hospitals in tiers based on compliance with the safety goals outlined by the Leapfrog Group (Rosenthal et al., 2007). However, other health plans have attempted to create composite indices. For example, the Tufts Health Plan uses quality measures that have been required by Medicare and the Joint Commission (JCAHO) for regulatory purposes as well as cost data to place hospitals into tiers (Rosenthal et al., 2007). Hospitals are then rated as "good" if they meet no cost or quality standards, "better" if they meet one of the standards, or "best" if they meet all standards for cost and quality (Rosenthal et al., 2007).

These measurement details prove to be very important in hospital tiering programs. Rosenthal and colleagues (Rosenthal et al., 2007) tested whether or not rating methodology had an effect on hospital tier placement. The authors tested two "extreme" strategies based on only cost or quality as well as two hybrid strategies— one that used cost data with minimal quality data and another that weighted cost and quality equally. This study found that there was little agreement between the four strategies, even the hybrid strategies, suggesting that measurement methodology is extremely important.

Clearly, the grouping methodology can have a great effect on health plans' tiering programs. However, if done correctly, there is some early evidence that if the financial incentives lead patients to higher-quality hospitals, the tiering structures may actually lead to improved quality of care for patients. In a study released in November 2008, the Blue Cross/Blue Shield Association (BCBSA) showed that hospitals that were awarded a "Blues Distinction" had lower readmission rates for cardiac patients. "Blues Distinction" is a designation developed by the BCBSA that is used by local Blues plans to structure quality-based tiering schemes (Nylen, 2008). However, wider evidence of the effect of quality designation on outcomes has yet to emerge and there are no similar studies on cost-based designations.

Much of the empirical evidence on the effect of tiering programs on hospital choice has emerged from an evaluation of a single firm's hospital tiering initiative. In July 2004, this firm changed the standard hospital benefit for union employees from 100 percent to 95 percent coverage. However, if the beneficiaries used a "safe" hospital, defined as one that complied with the Leapfrog Group's three safety "leaps," the benefit would return to 100 percent (Scanlon et al., 2008). The evaluation has tested the effect of the tiering program on awareness and attitudes regarding patient safety as well as its actual impact on hospital choice (Scanlon et al., 2008).

The results of this intervention were mixed. There was no evidence to suggest that the education associated with the tiering program had any effect on beneficiaries' awareness and attitudes. The intervention group

was no more likely than the control group to seek information on health benefits and quality of care, acknowledge variation in medical errors among hospitals, or express willingness to go to a different hospital (Scanlon and Christianson, 2008). Despite no significant changes in awareness and attitudes, there were some effects on hospital choice among members of the engineers' union admitted for medical conditions. Specifically, this group was 2.92 times more likely to visit a so-called "safe" hospital after the intervention than before. However, there was no significant effect for surgical admissions or within the machinist union's employees, who were less well educated and earned less than the engineers (Scanlon et al., 2008).

The effects of this study may have been mediated by the limitations of the program. Only 17 percent of all hospitals were placed in the top tier. Perhaps, there would have been a greater effect if the patients had more hospitals to choose from in the preferred tier. Also, because the analysis was limited to a single payer, it is reasonable to assume that the results cannot be generalized to other plans or firms. Regardless of these limitations, the results do draw into question the effectiveness of "demand-side" interventions executed by employers and plans for the purpose of influencing provider choice, particularly when considered in relationship to alternative approaches such as changing supply-side behavior or providing supply-side incentives (Scanlon et al., 2008).

Conclusions and Policy Implications

Tiered benefit designs are now commonplace for pharmaceuticals, and while not nearly as prevalent for other healthcare products or services, this type of benefit design is becoming increasingly popular for physician and hospital care. Tiering is theoretically appealing because it provides an incentive for patients to select high-value providers, which in turn is expected to stimulate supply-side improvement for fear of losing revenue and market share. Yet with the exception of tiered drug benefits, there is unfortunately little published evidence about the impact of tiering, making it difficult for purchasers and payers to easily predict the outcome of adopting tiering strategies. Like many advances in healthcare finance and insurance design, while there is a dearth of evidence in the published literature, it is likely that some of the more innovative private sector payers and purchasers who have implemented tiering programs have amassed unpublished evidence on the topic. Despite this dearth of evidence, our analysis has highlighted some key considerations when thinking about the potential benefit and impact of tiered benefit design programs.

Consider alternative strategies to achieve goals As discussed above, tiered benefit designs are considered a means to achieving the ultimate end of

improved value, quality, and safety. As such, it is important to consider alternative approaches to accomplish these goals, including regulation, pay-for-performance, professional development, and continuing education in the areas of quality of care and efficiency. While the evidence base for improving value in these areas may not be strong either, those considering tiering programs should also understand the cost-benefits of these different options.

Evidence from pilot studies is needed The currently scant evidence base will be improved only if purchasers and payers implementing tiered benefit programs study the financial and clinical impact of these programs, including the return on investment to program sponsors. Thus, program sponsors may want to implement programs gradually, allowing first for a pilot phase to gauge the likely outcomes of full-scale program implementation.

Healthcare market characteristics matter Providing incentives for consumers presumes a set of viable options. Therefore, the impact of tiered benefit programs, particularly on physicians and hospitals, will depend on local market characteristics, including the supply and capacity of healthcare providers. This is particularly important in markets where there are shortages of physicians or hospital beds.

Targeting the incentive at the decision maker Tiered benefit designs provide incentives to consumers for decisions that are made primarily (or at least heavily influenced) by physicians or specialists. For example, patients are referred and admitted to a hospital by a physician and often in a weakened state where time is of the essence. In this case, a tiered benefit design may have limited impact if aimed at the patient rather than the admitting physician. Likewise, while physicians heavily influence hospital admission decisions and referrals to specialists, the degree to which they are able to consider alternative hospitals or specialists is increasingly dictated by admitting privileges, contractual affiliations, distance and geographic location, and ownership interest in healthcare facilities (Scanlon et al., 2006). All of these factors can be extremely important in the overall success of a tiering program.

Methods matter As discussed above, tiering programs are only as good as the methods and data used to define the tiers. Related to this point, program developers need to consider the "appropriate unit" for tiering programs. For example, should hospitals be tiered across their entire range of services or for a specific subset of services? Likewise, should individual physicians be subject to tiered benefit programs or only physician practices comprised of multiple physicians? The answers to these questions need to be made

after considering both the practical goals and objectives of the program and the data requirements needed to construct reliable and valid performance measures.

Communication matters Many consumers and patients have insufficient knowledge of health insurance plan benefits let alone the various plan options that might be available to them (Hibbard et al., 1998). Because tiered benefit plans often require information at the point of service, when either filling a prescription or making a decision about doctors and hospitals, it can be challenging to communicate this information to beneficiaries. While it is not clear that a perfect communication strategy exists, plan sponsors should develop a robust strategy for communicating information about tiered benefit designs to program beneficiaries.

A critical mass is important One potential problem with existing tiered benefit designs and other health finance innovations is that they have not reached a critical enough mass in the marketplace to be taken seriously by healthcare providers. In other words, the threat of losing market share may not be that great when a single, self-insured employer implements a tiered hospital benefit program in a community. However, if many other employers, health plans, and even the state and federal governments' health programs implement similar tiering strategies, the threats and incentives become very real. Thus, those developing tiered benefit design programs should consider the need for a critical mass and seek leverage by partnering with others in the market.

POLICY PERSPECTIVES: HEALTH PROMOTION AND DISEASE PREVENTION (AKA WELLNESS)

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We are at a pivotal point in our nation's history. Not only are we ushering in a new administration, headed by a charismatic and visionary leader, we are also at a juncture in American history where dramatic and significant changes in our healthcare system are not only possible, but probable. The manner in which health system reform unfolds during the coming months and years can and should be influenced by all Americans. As a collective, Americans are presented with a wondrous opportunity to transform a clunky, inefficient, and at times harmful healthcare delivery system to one that provides quality and cost-effective care, with an increased emphasis on prevention and health promotion.

Employers can play a significant role in improving peoples' lives and their health. Their part has not been fully vetted in discussions of healthcare

reform, although the promise and potential for achieving large-scale health and economic impacts among working-age adults is undeniable.

Why employers? About 160 million Americans go to work every day, spending a significant portion of their waking hours in the work environment. In fact, more than ever before, work spills over past the traditional office hours in the form of e-mails, voicemails, and Blackberries. Work influences health, and in turn, workers' health influences work performance. Astute employers wishing to improve the health and well-being of their workers can reach large segments of the population who would not normally be exposed to and engaged in organized health improvement efforts. Thus, an opportunity presents itself to positively influence population health and, at the same time, mitigate the rise in healthcare costs through workplace health promotion programs.

In many ways, the workplace represents a microcosm of society and an ideal setting for introducing and maintaining health promotion programs. Employers establish work rules and procedures that reflect the distinct norms and culture of the organization. Six key employer attributes supporting the potential of using workplaces as a venue for improving workers' health include the following: (1) workplaces often contain a concentrated group of people who share a common purpose; (2) communication with workers is well established and straightforward; (3) social and organizational support for behavior changes is available; (4) data on program impacts can be tracked using existing organizational health surveillance programs; (5) certain policies, procedures, and practices can be introduced and organizational norms can be shaped; and (6) financial or other types of incentives can be offered to gain participation in programs.

Certain employers have recognized the benefits of worksite health promotion and are already far along in providing effective health improvement programs. Over the past 30 to 40 years, there has been a noticeable rise in the number of employers engaged in health promotion and, more broadly, health and productivity management programs at their workplaces. However, many of these initiatives have design and implementation flaws that reduce their potential for effective and positive change. A recent federally funded study published by Laura Linnan (Linnan et al., 2008), a professor at the University of North Carolina, found that although about 90 percent of employers say they have health promotion programs in place, only 6.9 percent actually offer effective programs containing these essential ingredients to make them successful: (1) health education, (2) links to related employee services, (3) supportive physical and social environments for health improvement, (4) integration of health promotion into the organization's culture, and (5) employee screenings with adequate treatment and follow-up. In other words, most employers do not offer evidence-based programs that achieve clear health and financial objectives. Furthermore,

even those who do implement well-structured and evidence-based programs may not always be sure these programs work because they have not put effective measurement systems in place.

Making the Business Case for Workplace Health Promotion

Many employers are familiar with a growing body of literature showing that theory-based and empirically sound programs can improve workers' health, lower their risk for disease, save businesses money, and improve an organization's competitiveness (Goetzel and Ozminkowski, 2008). However, others lack the hard evidence necessary to convince program sponsors and company management that investing in workers' health is "worth it"—not just from a humanitarian point of view but also because it is good for their business.

How might a health promotion program champion respond when confronted by the boss who says, "Convince me—why should a business invest in the health and well-being of its workers?" The response may take the form of a series of statements supported by a growing body of empirical evidence.

The logic flow for worksite health promotion can be articulated as follows. A large proportion of the diseases and disorders affecting workers is preventable (Partnership to Fight Chronic Disease, 2008). Modifiable health risk factors are precursors to a large number of diseases and disorders and, at the extreme, premature death (Amler and Dull, 1987). Many modifiable health risks are associated with increased healthcare costs and reduced worker productivity within a relatively short time window (Goetzel et al., 1998a). By utilizing a workplace-sponsored health promotion and disease prevention program, employers can target modifiable health risk factors and achieve improvements in the health risk profile of their population that can lead to reductions in healthcare costs and improvements in productivity (Goetzel et al., 2002; Heaney and Goetzel, 1998; Ozminkowski et al., 1999). Finally, worksite health promotion and disease prevention programs thus save companies money and produce a positive return on investment (ROI) (Aldana, 2001).

Where is the evidence supporting each of the above statements? What follows is a synopsis of the research linked to each of the major points.

There is little argument that poor health costs employers significant amounts of money and that many chronic health conditions, such as heart disease, Type 2 diabetes, and certain cancers, are largely caused by behavior and lifestyle (Mokdad et al., 2000). Excess spending has its source in increased and avoidable healthcare services, employee absenteeism, short- and long-term disability payments, higher accident rates, and diminished worker productivity (Goetzel et al., 2004). There is also growing evidence that workers

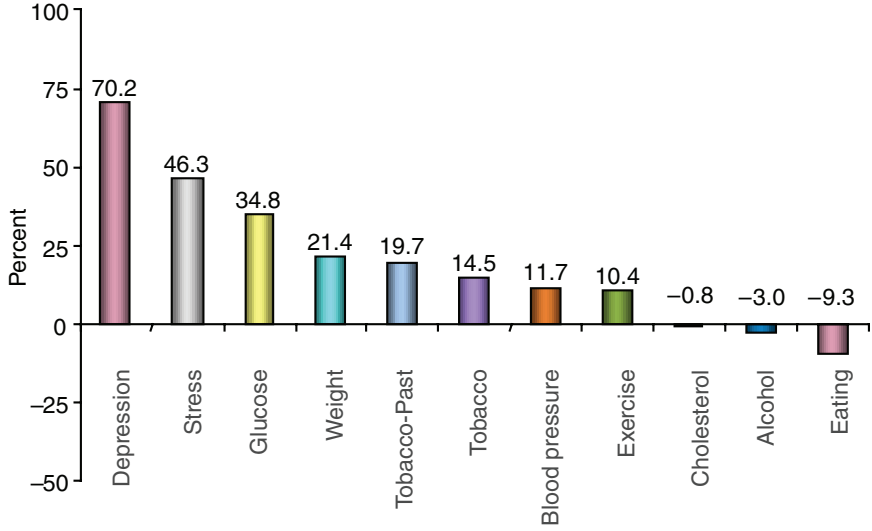

FIGURE 4-10 Incremental impact of 11 modifiable risk factors on medical expenditures.
NOTE: Independent effects after adjustment, N = 46,026.
SOURCE: Goetzel et al., 1998a.

at higher risk for modifiable conditions such as obesity, inadequate physical activity, smoking, poor diet, unmanaged stress, and high biometric values for cholesterol, blood pressure, and glucose also cost more than those lacking these risks (Anderson et al., 2000) (Figure 4-10). Further, employees exhibiting several risk factors cost significantly more than employees with fewer risk factors. These higher costs affect not only employers but also employees, since the dollars spent on health care and other employee benefits are subtracted from employee salaries and total compensation. Thus, improving the health risk profile of workers can benefit employers and employees alike.

Workplace Programs as a Vehicle for Behavior Change

What is the evidence supporting the positive effects of workplace health promotion on health risks and behaviors? A systematic literature review commissioned by the U.S. Centers for Disease Control and Prevention (CDC) in 1995, and more recently in 2007, concluded that well-designed, evidence-based programs built on behavioral theory can achieve long-term health and productivity improvements in employee populations (Soler et al., 2009). In an earlier review, Catherine Heaney and I examined 47 peer-

reviewed studies over a 20-year period and found that workplace programs, in spite of their variability in terms of comprehensiveness, intensity, and duration, achieved long-term behavior change and risk reduction among workers (Heaney and Goetzel, 1998). The most effective programs were those that offered individualized risk reduction counseling to the highest-risk employees within a "healthy-company" workplace environment in which broader health awareness initiatives were already under way.

The review released in 2007 by the CDC Community Guide Task Force examined data from more than 50 studies that reported workplace program participation outcomes based on a range of health behaviors, physiological measures, and productivity indicators. The review was largely positive with sufficient and strong evidence supporting the view that workplace programs exerted a positive effect on poor behaviors and biometric values. When measured at an individual level, many of the changes in these outcomes were small, but at the population level they were considered substantial (Centers for Disease Control and Prevention, 2007) (Table 4-2).

Workplace Programs' Financial Outcomes

What, then, is the evidence of cost savings? Here too several literature reviews that weigh the evidence from experimental and quasi-experimental study designs suggest that workplace programs using tailored communications and individualized counseling for high-risk individuals are likely to produce a positive ROI; that is, for every dollar invested over a three-year period, the ROI ranges from about $1.40 to $4.70 (Chapman, 2005; Goetzel et al., 1999). Studies often cited for the strongest research designs and the largest numbers of subjects include those performed at Johnson and Johnson, Citibank, Dupont, Bank of America, Tenneco, Duke University, the California Public Retirees System, Procter & Gamble, Highmark, and Chevron Corporation (Figure 4-11). Even when taking into consideration the inconsistencies in design and results across these studies, most of these workplace studies have shown positive financial outcomes.

TABLE 4-2 Evaluation of Worksite Health Promotion Programs—February 2007 Analysis Summary Results

Outcome	Body of Evidence	Consistent Results	Magnitude of Effect	Finding
Estimated risk	15	Yes	Moderate	Sufficient
Healthcare use	6	Yes	Moderate	Sufficient
Worker productivity	10	Yes	Moderate	Strong

SOURCE: Soler et al., 2007.

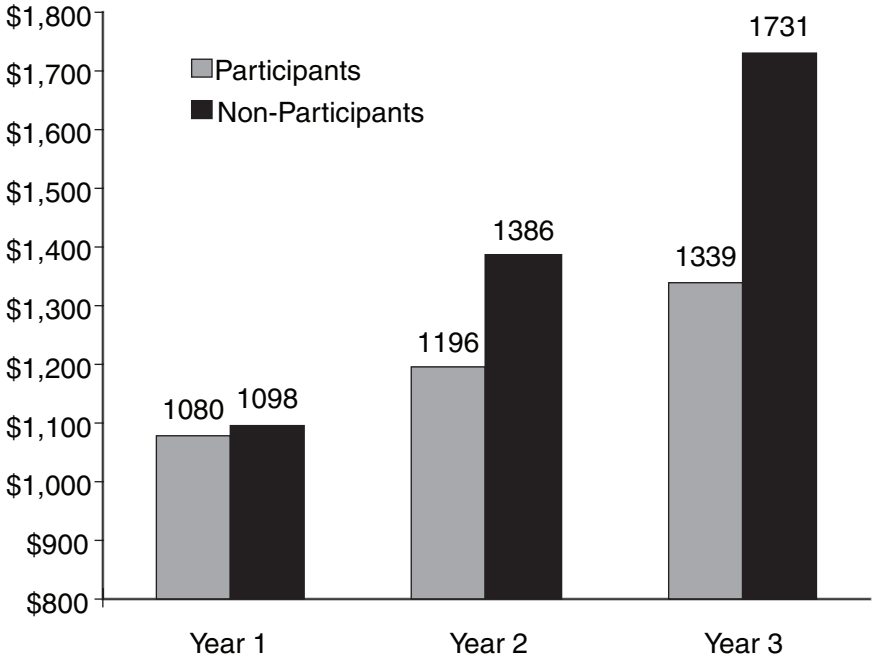

FIGURE 4-11 Total annual medical costs for participants and nonparticipants in health check: Proctor & Gamble (1990-1992).
SOURCE: Goetzel et al., 1998b.

Suggestions

With the above discussion as background, following are personal suggestions for employer-directed initiatives as part of healthcare reform. The overall aim of these recommendations is to increase employer engagement in providing state-of-the-art and science-based health promotion programs to their employees.

Improve employer communication and education about the benefits of effective health promotion programs We need to do a better job communicating the human and economic costs associated with poor health, the effects of not achieving health improvements, and the options available to reduce health risks. Federal, state, and local health agencies, in partnership with businesses, should leverage their extensive marketing and communication networks to share information about exemplary programs to employers. This means a broader dissemination of results from scientific studies and translation of findings into understandable business language;

convening business group meetings on workplace topics; and speaking before legislators and policy makers with testimonial evidence regarding program successes.

Increase funding for applied research in "real-world" settings There are not enough federally funded, applied research studies that examine real-world applications of health promotion programs in the workplace. Until recently, much of the workplace research came from the private sector and was paid for by private sources. This research is improving but is still relatively primitive and limited. To enhance knowledge of best practices, more government support is needed for studying the science underlying workplace-based programs and the relative effectiveness of various component parts in improving health, lowering costs, and increasing worker productivity.

Develop tools and resources to support employer efforts in health promotion Several tools and resources have already been developed and disseminated with the support of government funding. However, additional ones are needed to help employers design, implement, and evaluate their workplace programs.

Pilot innovative health promotion programs at federal, state, and local health departments and agencies It is ironic that most government agencies do not have state-of-the-art programs for their own employees and dependents. Some noteworthy exceptions can be found in King County, Washington, and the State of Delaware, where experimental health promotion programs are now being implemented and evaluated. Public agencies should serve as laboratories for testing innovative approaches to improving workers' health as well as role models that other employers can emulate.

Honor and reward America's healthiest organizations We need to recognize and reward employers who are the champions of health improvement. Innovative organizations that have successfully implemented extraordinary programs deserve recognition. There are good award programs already in place, including those at the National Business Group on Health, the Health and Human Services Secretary's Innovation in Prevention Award, and the Health Project's C. Everett Koop National Health Award. These efforts should be further supported and expanded.

Create an employers' health promotion resource center A government-supported resource center would collect, develop, and disseminate objective, easy-to-use, and accessible information and act as a clearinghouse for resources, tools, and expertise to support employer efforts.

Establish a public-private technical advisory council The council would be set up just like other government advisory panels, such as the U.S. Preventive Services Task Force and the Community Guide Task Force.

Establish collective purchasing consortia for small employers These consortia would define common health and business objectives for employers in a given community, achieve consensus on health promotion program designs, issue requests for proposals to vendors and health plans, and establish performance guarantees related to the success of these programs.

Support establishment of health promotion program certification and accreditation programs Several established review and accreditation organizations, such as the National Committee for Quality Assurance (NCQA), the Utilization Review Accreditation Committee (URAC), and the Health Enhancement Research Organization (HERO), have recently introduced review processes focused on workplace vendors and health plans. These organizations should be encouraged because they will improve the quality of health promotion programs and introduce a level playing field of competition across programs and vendors.

Provide financial incentives for employers to adopt evidence-based programs An immediate and effective way to capture the attention of businesses is to provide them tax credits for implementing bona fide health promotion programs. These tax credits would partially offset the costs of providing a qualified program. (See Senator Tom Harkin's Healthy Workforce Act—S. 1753; Library of Congress, 2009.)

Conclusion

In sum, we need to make sure that there is a clear focus on workplaces as a venue for health system reform. The current U.S. healthcare system has major flaws. We are spending more than $2 trillion per year on health care, with three-fourths of this amount being directed toward the treatment of chronic diseases. Almost two-thirds of the growth in spending is attributable to Americans' worsening health habits, particularly the epidemic rise in obesity. Our healthcare delivery system favors paying for treatment rather than prevention. For the United States to continue to be an economic leader worldwide, supported by a healthy and productive workforce, we need to direct our national attention and energy toward concerted health promotion and disease prevention. We can start by focusing on improving the health and well-being of employees who work within our organizations. Prevention and health promotion are essential to comprehensive health

system reform because improving the health of Americans will reduce the social and financial burdens imposed by preventable illnesses.

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5

Approaches to Improving Value—Provider and Manufacturer Payments

INTRODUCTION

Payment design, coverage policies, reimbursement rules, and other financial incentives and disincentives are powerful motivators when attempting to steer the healthcare system toward more desirable care patterns (Guterman et al., 2009). Experiments with payment design and coverage and reimbursement policies are currently going on in both public and private healthcare sectors, with varying results. Speakers in this session of the workshop explored current payment design experiments and discussed the efficacy of utilizing these reimbursement tools to improve the value received from health care.

In this chapter, Carolyn M. Clancy details the pay-for-performance (P4P) model, an effort to more explicitly link provider payments to quality of care. She highlights the lack of coherent approaches to P4P and the variable success this approach has had in fundamentally changing provider practice patterns. For example, while financial incentives for individual physicians have shown that P4P can induce quality improvements for diabetic patients (Beaulieu and Horrigan, 2005), group-level incentives have had no impact on mammography screening or hemoglobin A_{1c} testing rates (Rosenthal et al., 2005). After underscoring that the current incentive system and healthcare infrastructure fail to accommodate the achievement of real efficiency and quality, she outlines recommendations for rethinking medical training, measurement, system design, and the reward system.

Building on Clancy's recommendations, Donald A. Sawyer identifies how the current healthcare system stymies innovation in product develop-

ment. He suggests refocusing the myopic view of innovation on the horizon of long-term health improvements and financial savings. Reed V. Tuckson discusses the alignment of manufacturers, technologists, payers, patients, and providers necessary to establish a system that continues to provide incentives for innovation and maintains an open market for the development of promising but unproven interventions. He elaborates specifically on a joint effort between UnitedHealth Group and the American College of Cardiology to develop appropriateness criteria for cardiac single-photon emission computed tomography myocardial perfusion imaging—a new and very expensive technology—based on best evidence as an example of how the interests of diverse stakeholder groups could be aligned.

In conclusion, Steven D. Pearson likens coverage and reimbursement tools to a blunt knife that lacks subtlety in effecting value improvements, but he also expands on coverage innovations in public and private arenas that could sharpen these tools. He specifically describes Washington State's Health Technology Assessment Program—which considers efficacy, safety, and cost-effectiveness in making coverage decisions for all of the state's public programs—and physician edits—which limit the prescription of certain drugs to specific physicians or specialists in an effort to target medications to those patients most likely benefit from them—before elaborating on the future of payment and reimbursement as a tool to improve value.

PAY FOR PERFORMANCE

Carolyn M. Clancy, M.D., Agency for Healthcare Research and Quality

For health reform advocates, this is a very exciting time—one that is driven by a sense of urgency. However, despite many significant efforts at reform, we do not yet have an effective incentive system or a sustainable infrastructure that would allow us to achieve real efficiency and quality. As we search for the answer to "system transformation," I worry about several issues:

1. We create and apply more and more tools to an already chaotic system,
2. We fail to delve into the fundamental problems of healthcare infrastructure, and
3. We confuse short-term tactics and long-term strategy.

Given these difficulties, let me envision what a transformed healthcare system may look like in 10 years. By then we could have a system that:

- Rewards physicians and patients for making the right choices,
- Reports and measures quality electronically,
- Shares best practices rapidly with providers and offers knowledge of how to apply the evidence to individual patients, and
- Focuses increasingly on improving quality and value outcomes for episodes of care.

Pay for Performance

Perhaps seen as one of the keys to system transformation, P4P and value-based purchasing programs have experienced rapid growth in the past decade. There are now literally hundreds of these programs in the private sector. They include any type of performance-based provider payment arrangement, including those that target performance on cost measures. P4P and value-based purchasing extend beyond individual healthcare providers. The Centers for Medicare and Medicaid Services (CMS) and Congress have also extensively discussed launching performance-based reimbursement approaches for hospitals.

However, we still do not know how to design effective pay-for-performance programs, much less how to do so in our very large, very chaotic healthcare system. Some demonstration projects are encouraging (e.g., the Premier demonstration). Yet even the best of these do not yield groundbreaking improvements in patient outcomes. Generally, evaluations of P4P programs find that payment incentives have demonstrated a positive effect, but the effect is relatively modest—and sometimes counterintuitive.

For example, the Agency for Healthcare Research and Quality (AHRQ) funded the Palo Alto Medical Foundation (PAMF) to study different models of P4P. The study involved five sites that have had electronic medical records since 2000 and utilized physician payment tiers based on relative value units of service. Studies of financial incentives for individual physicians have shown that, bundled with other care management tools, P4P can lead to improvement in quality of care for diabetic patients (Beaulieu and Horrigan, 2005). The impact of group-level incentives and a patient registry-intervention system improved documentation of tobacco use but led to no change in the provision of quitting advice (Roski et al., 2003). Group-level incentives also led to small increases in cervical cancer screening but no change in mammography screening or hemoglobin A_{1c} testing rates (Rosenthal et al., 2005). In this study, since the largest relative improvements were seen in those with higher baseline performance, this raises additional questions of how best to distribute the rewards. That is, should already (relatively) high performers receive the largest rewards—or those who improve the most?

This research on P4P has additionally shown that the frequency of

payment by itself may not make a difference in performance. In the context of organizational-level quality improvement efforts, relatively small financial incentives to individual physicians have limited incremental effects on well-established measures. Interestingly the PAMF has also found some spillover effects, where improvements occurred in both incentivized and nonincentivized measures. However, we do not fully understand the processes underlying this outcome and need to learn more about why these spillover effects occurred in order to capitalize on their potential.

AHRQ's quality report last year found that overall quality of care improved in all U.S. populations and settings by 2.3 percent (Agency for Healthcare Research and Quality, 2007). Unfortunately, health costs concurrently increased 6.7 percent. You do not have to know about technical quality measures to see the problem. Something clearly must be done not only to reduce the costs of care but also to improve clinical outcomes. Don Berwick often says that our payment system is not just quality neutral, it is actually pretty toxic. It is easy to make glib statements that our current reimbursement policies reward volume rather than value. Yet those rewards translate into income for a lot of people who are doing very well in the current system. Making dramatic changes in the reward system will be, to say the least, challenging.

Challenges and the Road Ahead

How do we transform a chaotic system that accounts for 16 percent of our economy? We need a road map. We need to rethink our training, measurement, and system design. We also need to change our reward system.

Our challenges include engaging the research and provider communities in developing quality and value measures quickly while creating a sustainable infrastructure for collecting, analyzing, and disseminating information about performance and outcomes. Gaps in value-based measures, measures across episodes of care, and patient-centered outcomes need to be addressed. Incentives must align rewards with quality and value. In one promising activity, the Bridges to Excellence program has tried to determine what it would take to build at least part of the needed infrastructure that would make pay-for-performance work. This includes exploration of cost-savings distribution plans with doctors who deliver high-quality care, such as lowering rates of avoidable hospital admissions.

The evolution of our healthcare infrastructure to a learning healthcare system—one in which real-time feedback on quality creates value for providers and patients—is not possible today. We know that people will not continue to provide data to a collection system or value the feedback they receive unless it is timely and relevant. Take Hospital Compare, a public reporting system of how well hospitals care for patients with certain medi-

cal conditions or surgical procedures. When a hospital currently sends its reports to CMS, it takes nine months to get feedback—much too long to imagine that the data will have an impact on quality. As a result, people on the front lines of care delivery have no sense of how their daily work connects to those report cards.

We also will need policies and regulations for information governance because patient-centered assessment and improvement require data sharing and care coordination. Right now the mindset and relevant laws are framed around paper medical records (or their digitized incarnation) and reflect the limitations of these records. We cannot begin to collect the kinds of information that would inform pay-for-performance or allow the creation of a learning healthcare system without clear policies on data ownership, the rules for sharing data, and protocols for providing feedback to patients and doctors in real time.

Recently, several colleagues of mine published an article in the *Journal of the American Medical Association* (Dougherty and Conway, 2008) that discussed the time lag between new biomedical breakthroughs and their widespread application to clinical care. Take, for example, the 25-year delay in getting consistent, appropriate use of β-blockers for patients after heart attacks (Lee, 2007). In order to transform the system into one without delays in the translation of research to practice, healthcare providers must align with the research enterprises that are trying to improve health care.

More research and better research will not help us obtain better health care unless such research focuses on top priorities and the results are linked strategically to an infrastructure that helps us scale both promises and best practices.

INCENTIVES FOR PRODUCT INNOVATION—PRODUCT MANUFACTURER PERSPECTIVE

Donald A. Sawyer, J.D., AstraZeneca Pharmaceuticals

We all know that America is at a critical crossroads in health care. We can continue with business as usual and suffer the consequences, or we can take on the issues at the root of the problem. We're here today because we have chosen the latter, and we understand that to be part of the solution, we must be part of the conversation.

Like every other party at the table, we have opinions on how health care *should be* structured. We believe that any reform package should promote market competition that leads to improved health outcomes. It should maintain and enhance patient safety. It should expand coverage for the uninsured. Healthcare reform should provide incentives for product

innovation—specifically innovation that paves the way to pharmaceutical breakthroughs.

Incentives for innovation are imperative to patient health and the future of American health care. I am fortunate to be part of an organization whose priorities are to keep people healthy and to keep care accessible, while also promoting an environment that encourages innovation. As a company, we believe that a good healthcare system should support these goals. Yet the reality is that the system in place doesn't do that very well.

The question is: How are we going to change it? How are "we"—we meaning the pharmaceutical and biological industry and all payers—going to ensure that innovative, meaningful medicines are discovered, developed, and delivered to the right patients, to ensure optimal patient outcomes, and ultimately to improve the healthcare system?

A Word About Research and Development and Return on Investment

Before we discuss ways to work collaboratively to improve the healthcare system, it is essential to talk about what really goes into innovation. Pharmaceutical firms spend most of their resources on drug development. To develop a single drug takes anywhere from 10 to 15 years. So if we started work on a new drug today, that would put us at the finish line in 2023—by then, Barack Obama would qualify for Medicare.

To bring that single drug from lab to pharmacy costs more than $1 billion in current dollars, not to mention the investment in drugs that never make it to market. For every 5,000 compounds tested, only five ever make it to clinical trials, and only one receives FDA approval (Pharmaceutical Research and Manufacturers of America, 2008). Let me give you a real example. You've probably never heard of a diabetes drug called Galida. You have not heard of it because after spending tens of millions of dollars and dedicating hundreds of employees to bring it to market, we decided not to continue with the process. Why? Because we did not believe it offered a significant benefit for patients over existing therapies. Of the drugs that are approved and do make it to market, only 2 in 10 will ever recoup their cost of development.

Instead of focusing on innovation in the short term through the lens of a microscope, if we—and all players in the system—were to view innovation through a telescope and take a long-term view, the rewards of the time and financial investment of bringing a new drug to market would be substantial. For example, for every $1 spent on cholesterol medicines, more than $5 is saved on disease-related costs. With diabetes, the return is even greater. For every $1 spent on diabetes medicines, the system realizes a $7 return on investment (Pharmaceutical Research and Manufacturers of America, 2008).

Neither Payers nor Manufacturers Are Demanding Change

Innovation is integral to reducing our healthcare costs and improving patient health, but our current system provides little incentive for innovation.

Over the years, American health care has evolved into a system whose primary goal is not patient health outcomes, but rather containing short-term costs. If achieving better patient outcomes were the goal, the painstaking, time-intensive research and development just described would have all of the encouragement and backing it needs. Unfortunately, it does not. The current system does little to provide for innovation, and we all have equal responsibility for this problem: payers, manufacturers, and policy makers.

The fact is that both payers and drug manufacturers are responsible for the current situation. Both parties are living in a short-term environment focused on delivering results to our shareholders. However, if we maintain this short-term perspective, we cannot unlock the true potential of innovation.

For the last 20 years, the relationships between payers and the pharmaceutical industry have been focused largely on financial arrangements that are short term and transactional in nature. Manufacturers and payers engage in contract negotiations intended to agree on a price that will enable patients to access our products. These contracts also drive market share. This is logical behavior for companies focused on creating shareholder value. Yet as we know, the value of innovative therapies is not often realized within a single budget cycle.

Florida's Medicaid program and Pfizer tried to address this issue through an innovative program that ended abruptly in 2005 due to legislative changes. Pfizer guaranteed $33 million of savings over two years. Instead of paying supplemental rebates to secure placement of its products on the Medicaid formulary—money that does not always end up going toward health care—Pfizer implemented a disease management program. The true impact on savings and patient outcomes was never realized (Pfizer, 2004).

Today, we are beginning to recognize that if we take a longer-term view and hold each other accountable for delivering on health outcomes in addition to our quarterly financial results, we can do a better job for patients. So what can we do to foster a long-term, holistic approach that encourages increased innovation?

At AstraZeneca, we are starting to talk with like-minded payers about concepts that will transform our business relationships, have a positive impact on patient health, provide the incentives for pharmaceutical inno-

vation, and still deliver on payer business results. These objectives do not have to be mutually exclusive.

Some of these concepts include tying discounts to metrics other than market share, such as medication adherence, lower copays for essential medicines, and attainment of treatment goals. We are finding that we will have to try some of these concepts by piloting them with payers who have integrated medical and pharmacy data and are comfortable with defining and assuming risk. Gradually, we are starting to see signs of a shift to a focus on outcomes. Today, leading-edge companies such as Pitney Bowes and Marriott are experimenting with the concept of "value-based insurance design," a model that encourages the use of high-value products and services when the benefits outweigh the costs. The success has been tangible, creating a real savings for those organizations willing to step outside of the box and do something different.

Pitney Bowes, for instance, reduced copayments for drugs prescribed for diabetes and asthma. As reported in the several publications including the *Wall Street Journal*, the company realized a $1 million net savings in the first year from reducing complications that are common in patients with those diseases (Fuhrman, 2004, 2007; Mahoney, 2005).

A growing number of employers—Marriott, Mohawk Industries, University of Michigan, and even my own employer AstraZeneca—are beginning to incorporate the lessons learned form Pitney Bowes and other experiments, such as the well-known Asheville Project, into their own health benefit plans. Some health insurers are too. This kind of innovation on the part of payers provides the incentive for innovators to bring to market high-value healthcare products, be they pharmaceuticals, devices, or biologics.

The advantage of value-based benefit designs such as these is that they not only allow companies to better manage their costs, but also result in a healthier, more productive workforce, which, for any company, *should be* the objective of health care.

Where Do Providers and Patients Fit In?

We can talk as much as we want about paying for outcomes, but it does not really become meaningful until we start talking about the potential to improve the health of patients.

In reality, the current system focus on cutting costs in the short term over achieving long-term results is standing between providers and their patients and better outcomes. I will share one example. Earlier this year, a Wilmington, Delaware, cardiologist was invited to give an overview of acute coronary syndrome to members of one of our development teams. During the question-and-answer session, the doctor was asked whether he

had the autonomy to use the treatments he thinks are most appropriate for the individual patient. The short answer was "no."

The doctor responded that today he is confronted with reimbursement methods that work against each other and ultimately do not put the patient first. Formularies require the use of generic statins and make branded statins, which are often more effective especially in high-risk patients, more difficult to prescribe. At the same time, the Centers for Medicare and Medicaid Services is asking doctors to report on outcomes such as: Are these same high-risk patients reaching certain cholesterol goals? This doctor knows that generic options are not likely to get his high-risk patients to that goal, putting the doctor in a frustrating spot.

In short, we have a payment system that manages inputs instead of encouraging outcomes. What is clear to this doctor is that we need a system that focuses on patient outcomes, not input components. The prevailing "one-size-fits-all" approach does not allow doctors to do what they are trained to do: exercise their best clinical judgment for the individual patient.

This physician is frustrated because he is aware of the inherent conflict of competing reimbursement methods. The patient's behavior, however, is shaped by those financial incentives—unaware that the benefit design may not support his or her health and welfare—and all too often leads to negative health consequences.

Let me explain what I mean. Over the last decade, patients have been asked to shoulder a greater percentage of their prescription drug costs. On average, the out-of pocket copayment for prescription drugs is 22 percent. For doctors' visits, it is 10 percent, and for hospital stays, the copayment is 3 percent. There is ample evidence that patient cost sharing lowers spending and decreases pharmaceutical utilization. Evidence also shows that these effects are more pronounced as the copayments increase.

Yet does cost sharing decrease overall healthcare costs? Evidence from studies by Dana Goldman of RAND (Goldman et al., 2004), Mark Fendrick of the University of Michigan and Michael Chernew of Harvard University (Chernew et al., 2008), and others (Kessler et al., 2007) tell us that cost sharing decreases patient compliance with essential medications in chronic disease and actually increases utilization of other services, such as hospital admissions and acute doctor or emergency room visits.

Conclusion

What I have described today is a current system that is unsustainable: a system where a patient sees no other choice than to split pills in two or not take them at all. The economic downturn will only intensify the patient's dilemma. As former U.S. Surgeon General C. Everett Koop said, "Drugs

don't work in patients that don't take them" (Osterberg and Blaschke, 2005).

The current system simply will not drive the incremental *and* breakthrough innovation we need to continue to bring patients groundbreaking, and sometimes lifesaving, therapies. We are quickly approaching a stalemate where the current system will either drive or stop innovation. The risk, then, is not finding potentially lifesaving therapies or changes that could drastically improve patient outcomes. Modern medicine has advanced tremendously over the last 30 years, to the point where we are asking, "Do you really need another drug to treat hypertension or diabetes? Can this disease really be managed any better at this point?"

Before answering, a statement attributed to Charles Deull, Commissioner of the U.S. Patent Office in 1899, should be considered: "Everything that can be invented has been invented."

We cannot afford to be short-sighted.

Every day at pharmaceutical companies, hundreds of decisions are made around innovation. When we invest, there is no guarantee that the scientific investigation will result in products we can bring to the market. Frequently we conduct the research and analyze the data only to conclude that our investment in a particular molecule will not yield the expected value. However, to continue to forge ahead, we need a system where that risk and those "go/no-go" decisions, such as the ones involving Galida, are ultimately rewarded. We need a system that rewards innovative therapies. We also need a system that is focused on delivering the greatest long-term value to patients.

> Our timing is right. To echo the words and the charge of now former Health and Human Services Secretary Michael Leavitt when he spoke in this very room, we are called "to be an instrument of change and to try and solve the issues resulting from the current Medicare payment system. . . . [We are called] to work together to propose a system that will not compromise patient outcomes for short-term savings and will not compromise innovation to make short-term budgets." (Leavitt, 2008)

INCENTIVES FOR PRODUCT INNOVATION—PAYER PERSPECTIVE

Reed V. Tuckson, M.D., FACP, UnitedHealth Group

In my work at UnitedHealth Group, I am routinely excited by the opportunities that we have to facilitate access to the full range of comprehensive health and medical services that people need. Coordinating wellness, prevention, early diagnostic, therapeutic, and restorative care services is exciting and stimulating. However, the context for our work is shaped significantly by the dramatic escalation in healthcare costs and the related

challenges to affordability faced by millions of our customers and other Americans. As such, we have a responsibility to work with all healthcare stakeholders to ensure that new innovations in health and medical care delivery work effectively, are cost-effective, and are used in a manner consistent with scientific evidence and expert physician-derived clinical guidance.

Unfortunately, our experiences mirror the published literature that describes significant waste of expensive healthcare assets (Fisher et al., 2003; Welch et al., 1993; Wennberg et al., 2007). This is unfair to people such as our small-employer customers, many of whom may have mortgaged their homes two or three times to make a go of it and who tenuously employ five or six other dependent people. So, while I am excited about innovation and the potential that it can deliver, we also have a responsibility to be extremely vigilant in determining what is adopted and how it is utilized within the total context of the delivery system.

It is clear from our experience that the existing care delivery infrastructure is suboptimal in this regard in several important ways:

- The availability of a robust and clinically relevant basic science research agenda;
- The ability of expert physicians and medical specialty societies to analyze and translate science into clinical guidance;
- The ability to define specific population groups for which new knowledge and innovations are appropriate;
- The dissemination of knowledge to the profession and its incorporation into appropriate clinical practice through mechanisms such as continuing medical education and information technology; and
- The available support for appropriate patient decision making in the context of the patient-physician relationship.

Given this context, we have important work before us. First, the Institute of Medicine needs to be more active in providing guidance for the prioritization of prevention research on the nation's research agenda. It is frustrating and inappropriate that so few of our research dollars are devoted to population, community, and individual prevention. It seems that somehow we have made a national decision to value high-intensity and complex medical innovation much more than finding and testing new and creative ways of preventing disease and promoting wellness. Given the escalation of preventable chronic disease and its associated costs, we need a much more robust research base regarding what works in prevention and the cost-effectiveness of those interventions.

Second, the ability to prioritize the agenda and the infrastructure for the conduct of clinical trials remains suboptimal. Inadequate funding for high-

value opportunities and insufficient supply of researchers with available time are but two of the challenges to this infrastructure.

Third, as widely recognized, comparative effectiveness research is essential. However, support for these studies and analytics needs to include not only *clinical* comparisons of new innovations against existing treatment interventions in the context of the total management of a condition, but also *cost-effectiveness* comparisons. Additionally, care should be taken to ensure that the funding mechanisms for new comparative effectiveness studies do not threaten the viability and centrality of the Agency for Healthcare Research and Quality (AHRQ) in its leadership role for health services research.

Fourth, medical specialty societies are poorly prepared and significantly underresourced to translate clinical research into guidance and performance assessment measures. The culture of medicine requires expert physician leadership and peer-to-peer consultation in determining clinical guidance. For example, I am excited about the work we are doing with the American College of Cardiology to support the creation of appropriateness criteria, clinical guidance, performance assessment, and continuing education in the use of the rapidly growing and expensive single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI) for cardiac imaging. Unfortunately, very few other societies are positioned to carry out these types of analyses expeditiously and to do so in a cost-effective way. Therefore, it is important that AHRQ be provided with funding that can be used to support our specialty societies to accomplish this important work. If physicians are going to exert the leadership that we expect, our society needs to support their societies with the necessary resources.

Finally, we also need to educate the American people to better prepare them to make the personally appropriate choices regarding the use of new and expensive interventions, while also being respectful of the economic consequences of ill-advised decisions. In this new genetic era, the decisions and choices that people are required to make will be more complex than ever. Unfortunately, they are poorly prepared to do so. It is in everyone's interest to better assist people in their role as responsible stewards of their own health, in addition to the use of expensive technologies.

In conclusion, innovation in any field brings with it excitement and optimism. In health care, at its best, innovation can help people to live healthier lives, prevent hospitalizations, and reduce the misery and economic consequences of debilitating disease. However, innovation, for its own sake, is not particularly exciting, especially if it contributes irresponsibly to misaligned priorities and waste of precious healthcare assets. As such, all stakeholders in health care have a responsibility to think carefully about what we are trying to achieve, the priorities for the use of resources, and the accountability that each sector has for maximizing access to affordable,

quality, health interventions that assist people in realizing their greatest possible state of health.

APPROACHES TO IMPROVING VALUE: COVERAGE AND REIMBURSEMENT

Steven D. Pearson, M.D., M.Sc.,
Institute for Clinical and Economic Review

The sequel to Philip Pullman's book *The Golden Compass* was entitled *The Subtle Knife*. The subtle knife was a knife so sharp that it could find the tiniest crevices in the fabric of the universe and slice openings to serve as passages between different worlds. Its ability to distinguish minute differences in space and time was beyond human understanding. Its precision was absolute (Pullman, 1997).

Coverage

No one, certainly, would argue that coverage policy is a subtle knife. Coverage policies made by public and private insurers cannot be designed to distinguish minor differences between individual clinicians and individual patients; rather, coverage policies are generated for populations. Interventions are judged upon their known effects for populations of patients. Historically—and legally—the dividing line between covered and noncovered interventions for private insurers is usually determined by whether interventions are deemed "medically necessary." Any further definition of this dividing line commonly includes requirements for interventions to fall within generally accepted standards of medical practice, to be clinically appropriate in terms of type and frequency, and to not be primarily for the convenience of the patient. Even the sum of these criteria provides a relatively weak tool for achieving improved value in the healthcare system. Under these terms, frankly "quack" treatments can be denied coverage, as can wildly "inappropriate" interventions such as month-long hospital stays to reduce weight through monitored diets. But what about fine-tuning of the use of costly interventions with questionable risk-benefit ratios? Or encouraging the use of less expensive and less invasive treatment or diagnostic options that offer comparable net benefits? Coverage by itself cannot hope to advance these value goals.

Public insurers face the same problems. Coverage within the Medicare system is guided by its own statutory language requiring that payments not be made for interventions that are not "reasonable and necessary" (double negative in the original). Despite more than 50 years of experience, Medicare's "reasonable and necessary" dividing line for coverage has

proven an even blunter tool for improving value than the "medically necessary" language of private payers. Over the years there have been periodic attempts to define the boundaries of "reasonable and necessary" in a more rigorous and transparent fashion. CMS has scheduled hearings and offered draft language to give the term "reasonable and necessary" a stronger basis. Yet each time an effort has been launched, healthcare interests have found reason to push back against what they view will be tighter restrictions on coverage. Until recent years, in fact, it has been felt by most that the history of Medicare's coverage decisions implies that strong evidence of harm is required before coverage will be denied. Denial of coverage has rarely been used when evidence of benefit over other options is lacking or even when evidence of any benefit is lacking; the default has been to provide coverage unless there is fairly clear and incontrovertible evidence of harm for most patients—a blunt knife, indeed.

However, there are ways for coverage policies to be designed and implemented in order to be more powerful tools for improving value. Some private health insurance contracts include a clause to the effect that services may not be considered medically necessary if they are more costly than an alternative service or sequence of services that is at least as likely to produce equivalent therapeutic or diagnostic results. Medicare has a similar regulation that allows it, in limited circumstances, to cover only the "least costly alternative" for durable medical equipment and injectable drugs.

Although this basic concept sounds like a potentially powerful tool to improve value, in practice it is seldom used. When used by private insurers, it is very rarely employed to deny coverage for a specific service; instead, the term is used to deny coverage for a service that is used at a higher frequency or intensity than considered appropriate. For example, a payer may deny coverage for injections provided weekly when monthly injections suffice. At Medicare, even limited use of the "least costly alternative" policy hit a major roadblock recently when a court ruled that Medicare's statutory language did not in fact allow its application in the consideration of medication coverage. Therefore, although many have hoped that better value could be achieved through limiting coverage to less costly but comparable options, the practical and legal challenges have blunted the actual impact.

Reimbursement

If coverage has proven to be a blunt knife, what are the chances that reimbursement policy can prove more effective? It is easy to assume that private payers could negotiate their own reimbursement rates, paying more for high-value services and less for low-value services. Yet payers often have broad contracts with providers that outline reimbursements rates based on

Medicare rates plus or minus 5 to 10 percent. This policy makes Medicare the 800-pound gorilla in reimbursement. As a result, payers' and providers' "value" discussions are dominated by the coding and relative value units (RVUs) used to determine Medicare reimbursement. The basic premise that Medicare "reimburses" according to a formula based on physicians' time, the complexity of the service, and the cost of any material involved makes it clear that reimbursement is divorced from any consideration of the degree of clinical benefit produced by the intervention.

Highlights of Policies from Public and Private Payers

Public Payers

Medicare Medicare is eagerly employing coverage with evidence development (CED) as a reimbursement tool. CED refers to the linkage of Medicare coverage of specific, promising technologies to a requirement that patients participate in a registry or clinical trial. In recent years this approach has been applied by CMS to the coverage of several biologics approved for colorectal cancer, implantable cardioverter defibrillators for prevention of sudden cardiac death, and positron emission tomography for patients with malignancies. The policy was framed as having a dual purpose: (1) to ensure at the time of service that the care met the Medicare standard of reasonable and necessary and, most notably, (2) to provide the basis for longitudinal data collection that would ultimately assist doctors and patients in better understanding the risks, benefits, and costs of alternative diagnostic and treatment options.

Yet CED has proven challenging to use. There remains uncertainty about whether CED is meant to expedite diffusion of services while gathering evidence about the service or whether it is simply an auxiliary stipulation beyond standard evidence requirements. This uncertainty hinders rather than helps. However, CED continues to evolve and will likely play an even greater role in the future.

Medicare also has tried to reap improved value by bundling Healthcare Common Procedure Coding System (HCPCS) payment codes to allow blended payment rates. If two HCPCS codes are determined by Medicare to be essentially identical even though they have significantly different prices, Medicare can pay a blended rate for both of the codes. A blended payment rate gives greater incentive for providers to utilize the lower-priced option because its lower base cost to the provider will mean a higher marginal profit from the payment. Blended payment is not based on the same regulation as the "least costly alternative" approach, but it serves much the same purpose: using the coverage and payment system to favor lower-priced options that have the same clinical performance.

The most recent coverage innovation developed by Medicare to foster value is its approach to denying coverage for "never events"—adverse events such as postoperative infections and blood clots that are judged to be fully preventable. Although this mechanism by itself is unlikely to produce significant cost savings in the short term, it serves as a reminder that Medicare views itself on a path toward becoming a strategic value-based purchaser of services. Through nonpayment for "never events," Medicare is progressing on the road to paying for outcomes, not just services. Great advances in value are likely as Medicare continues down this path.

State governments The states also play important roles in seeking new ways to use coverage and reimbursement to promote value. One example is Washington State, which passed legislation creating a Health Care Authority (HCA) responsible for performing health technology assessment to guide coverage decisions. The Washington HCA has an 11-member panel that makes coverage decisions for all of the state's public programs on the transparent basis of safety, efficacy, and cost-effectiveness. In the face of limited resources, the program's mandate is to increase value for the state's healthcare dollars.

Consider its decision regarding computed tomographic colonography (CTC), which is a screening test for colorectal cancer. The HTA commissioned the Institute for Clinical and Economic Review (ICER) at Massachusetts General Hospital to conduct an evidence review for CTC compared to traditional colonoscopy. Assessing both comparative clinical effectiveness and comparative value, ICER's evidence review concluded that CTC was clinically comparable to colonoscopy for cancer screening but likely of low value because of the higher costs and frequent need for repeat testing. Yet the review suggested that if the cost for CTC was lowered to one-third of the cost of a colonoscopy, as is the case in parts of Wisconsin, where several private insurers cover CTC, CTC could be considered to be a high-value service. In Washington State, since the reimbursement rates for CTC and colonoscopy were equivalent, the HCA decided not to cover CTC for colorectal cancer screening at that time.

Private Payers

For private payers, tiered drug formularies, prior authorization, centers of excellence, and tiered networks of hospitals and providers represent a few of the mechanisms they have developed to apply evidence through benefits design and the management of medical services to increase value. For example, through tiering—now a near-universal part of drug coverage—private payers increase out-of-pocket payments for lower-value services and drugs. Many private payers also employ what are called step programs—or

step edits—in which patients with a particular condition must start with a particular (lower-cost) drug and have inadequate results with that drug before the payer will extend coverage to a second, more expensive drug.

Alongside step edits are often found physician edits, which limit the prescription of certain drugs to specific types of medical specialists who, it is assumed, are more likely to have the clinical experience to judge when a more expensive, and sometimes more dangerous, drug is appropriate for an individual patient.

Two publicly known examples of conditional coverage provide a sense of how these approaches can be used to improve value. One example involves the drug trastuzumab, also known as Herceptin, which is effective in the treatment of breast cancer only among patients who have a specific tumor marker. Herceptin can have significant side effects and is also a very expensive medication, making it important on many levels that it be used only in patients who are likely to benefit. In a study reported by UnitedHealthcare, however, approximately 20 percent of enrolled patients being treated with trastuzumab lacked the relevant tumor marker (Culliton, 2008). A considerable number of patients were receiving the drug without any hope of benefiting from it. As a result of this study, UnitedHealthcare developed a new policy requiring documentation of the tumor marker before extending coverage for the drug (Phillips, 2008).

Another example of conditional coverage involves adalimumab (Humira), a biological agent used to treat rheumatoid arthritis. HealthPartners, a not-for-profit payer in Minnesota, requires prior approval for the medication, restricts its use to rheumatologists, and sets dose limits of 40 mg every other week. Additionally, adalimumab is reserved for patients with rheumatoid arthritis who have previously tried and failed at least a three-month trial of an alternative agent. After these criteria are met and approval is provided, the drug must be obtained though a specific specialty pharmacy. Through the integrated application of physician edits, step edits, and dosage limits, payers hope to increase value by targeting this expensive medication to those patients who need it and will most likely benefit from it.

Future Considerations for Coverage and Reimbursement

The future of reimbursement and coverage among private payers may include risk-sharing arrangements, such as the adoption of population capitation arrangements. In these arrangements a payer may contract with a pharmaceutical manufacturer for a specific price to cover an entire population. The goal of this arrangement is to provide a reasonable profit to manufacturers while incentivizing them to work toward appropriate use of the drug within the population who will benefit from it. Another type

of risk-sharing arrangement that may be seen in the future is one in which provisional approval for coverage is given with initial reference pricing for a new drug; the potential for price increases in the future is tied to whether future data evaluation demonstrates increased efficacy over other options. Other types of risk-sharing agreements that are likely to be considered can be drawn from the experience in the United Kingdom, where a value-based evaluation process has led to various types of agreements. In one example, a pharmaceutical company received coverage for its drug only when it agreed to reimburse the National Health Service when the medication proves to be ineffective for a patient.

The future of Medicare's ability to use coverage and reimbursement to improve value will depend on its collaboration with manufacturers and physicians. All parties should work together to determine the role evidence will play in coverage, reimbursement, and physician payments. It will be helpful if CMS can provide clearer guidance to manufacturers and others about general guidelines for the evidence requirements needed for coverage and reimbursement determinations—for example, details regarding the recommended length of and outcomes for clinical trials. With the seeming demise of the least-costly-alternative reimbursement approach, hopefully Congress will take the opportunity to reformulate reimbursement policies in light of evidence of clinical value in order to give Medicare the tools it needs to obtain the highest value possible for every dollar spent.

State governments should continue to serve as important laboratories for using evidence in coverage and reimbursement in ways that advance value. They may benefit from collaboration in the commissioning of evidence reviews and can share their lessons learned in translating evidence into coverage and reimbursement to help guide states just starting out on this path.

Finally, all stakeholders will benefit from an enhanced national commitment to comparative effectiveness research. A comparative effectiveness initiative that produces and effectively disseminates authoritative evidence on clinical and cost-effectiveness will help patients and clinicians make more "value-oriented" decisions on a day-to-day basis. Better evidence will also support innovative coverage and reimbursement policy that can align all interests in providing higher value. Coverage and reimbursement are relatively blunt knives, but there are many ways to control costs that are more subtle. With transparent links to good evidence, coverage and reimbursement have great potential to help patients and the United States achieve a high-quality, sustainable healthcare system.

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6

Approaches to Improving Value—Organization and Structure of Care

INTRODUCTION

At the present moment in U.S. political history, the possibility of health reform seems more likely than it has for the past decade and a half (Iglehart, 2009), making the capitalization of value in health care—and the organizational and structural changes that would help achieve it—particularly timely. The current fragmentation and disarray of the healthcare system greatly affect costs, quality of care, and patient and provider satisfaction (Stange, 2009; Wiggins, 2008). Some of the attempts to promote reorganization of the delivery of care—such as pay-for-performance and value-based insurance design—have been explored earlier in this summary. Yet prior discussions have also highlighted the need to specifically focus on organizational and structural issues in the healthcare system.

This chapter delves into three promising tools specifically intended to improve healthcare organization and structure. Electronic health records (EHRs), discussed by Douglas Johnston, are considered a key piece of infrastructure for overall health system improvements. EHRs can enable increased coordination across multiple service providers, augment patient engagement, decrease medical errors, and facilitate overall efficiency improvements (Chaudhry et al., 2006; Kaushal et al., 2003). Yet, despite their obvious value and ability to enable progressive strides in care delivery, Johnston argues that, ultimately, EHRs are a necessary but not a sufficient tool for reform of the health system.

Arnold Milstein focuses on medical "home runs," describing four primary care practices that were able to deliver high-quality care while simul-

taneously enabling their patients to consume 15-20 percent less total payer spending per year on a risk-adjusted basis than patients being treated by regional peers—all within the current payment environment that rewards volume over outcomes. He identifies two common characteristics of these practices: (1) a focus on preventing urgent and emergent hospitalization for chronic illnesses and (2) a concentration on referral care to high-quality specialists who consciously consider resource use. Yet, he asserts, to achieve these "home runs," the design of medical homes—a model of delivering primary care that engages individual patients in forming partnerships with their personal physicians in an accessible, continuous, comprehensive, patient-centered, coordinated, compassionate, and culturally effective manner (American Academy of Family Physicians et al., 2007)—must explicitly incorporate the lessons learned from these successful examples before they can improve quality while lowering total costs of care in a sustained fashion.

Concluding the chapter, Tracey A. Moorhead explores the evolution from "disease management" to "population health improvement," which ranges from a focus on individuals with chronic illness to an emphasis on health promotion in larger populations. Through case studies demonstrating positive returns on investment in public and private healthcare settings, she parses a process that aligns providers and services with the common goal of improving the health of populations and concurrently yields significant economic savings.

THE VALUE OF ELECTRONIC HEALTH RECORDS

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Has the U.S. healthcare system finally reached an inflection point in the decades-long effort to adopt health information technology (IT)? Very likely, given unprecedented state, regional, and federal initiatives to support and fund health IT. Many states and regions have invested in consortia and collaborations to further the use of electronic prescribing, electronic health records, and health information exchange (Healthcare Information and Management System Society, 2008).[1] At the federal level, most significant is the recently passed American Recovery and Rehabilitation Act (ARRA), whose provisions show the federal government's commitment to a multi-

[1] For current status on state and regional health IT programs, see http://www.himss.org/StateDashboard/.

year, multibillion-dollar investment in health IT (American Recovery and Reinvestment Act, 2009).

The value and feasibility of health IT continue to be debated widely, although evidence from a variety of sources—experimental and observational studies, case studies, expert opinion, and analytic models—suggests that, implemented well and used appropriately, these technologies improve quality and safety and potentially reduce costs. The questions of whether, how, and to whom health IT produces value are central to this debate and are as complicated and thorny as other issues such as privacy and security and technical standards.

Health IT is comprised of a broad range of information systems and computer-based functions (Blumenthal and Glaser, 2007). This paper discusses issues associated with the value of a central health information technology: EHRs. We begin by defining EHRs and reviewing the characteristics that may impact the creation and capture of EHR value. We then review a selection of the published evidence and projections of EHR benefits and costs and conclude by discussing key issues in assessing the value of this technology.

Generally, EHRs and their related functions have been shown to improve the quality, safety, and efficiency of care. Moreover, there is evidence, although limited, that EHRs can produce significant financial benefits if implemented well. Projections of EHR value, based on the current evidence from the literature and experts, suggest that widespread adoption and use of EHRs and systems containing EHR functions could produce substantial clinical and financial benefits to the U.S. healthcare system. The Center for IT Leadership's (CITL's) own projections suggest that millions of avoided medication errors and hundreds of billions in avoided costs are possible from widespread adoption of EHR-related functions such as order entry, decision support, and electronic healthcare information exchange (Bu et al., 2007; Walker et al., 2005).

However, given the range of available evidence, we assert that creating and then capturing value from EHRs is a matter of conditions and degrees, because value is likely to accrue differently, and at relatively different rates and levels, depending on the context in which it is adopted. As care providers move toward widespread EHR adoption, the need for more robust evidence on EHR impacts and costs that reflects different characteristics of the U.S. healthcare system is more acute than ever.

Defining EHRs and Related Benefits

EHRs have been defined in many ways. Common to these definitions is the idea that EHRs are, fundamentally, electronic tools for collecting clinical data from multiple sources and for using these data at the point of

care to support clinical decision making. One commonly cited definition of EHRs (NAHIT, 2008) is:

> An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.

In 2003, the Institute of Medicine (IOM) convened a Committee on Data Standards for Patient Safety, one product of which was a statement on the key capabilities of EHRs (IOM, 2003). The committee's letter report listed eight core EHR functions:

1. *Health information and data* (clinical documentation): a defined dataset including patient demographics, medical and nursing diagnoses, problems, current medications, allergies, test results, clinical narratives, and other important patient data.
2. *Results management*: automated, electronic display of current and previous results from laboratory tests, radiology procedures, and other sources.
3. *Order entry or order management*: electronic entry and management of medication, lab test, radiology, procedure, and other orders.
4. *Decision support*: computer-based tools that assist clinicians with managing knowledge and decisions about patients and their care. Decision support can be *passive*, as in static information about a drug's effectiveness, or *active*, as in automated alerts about potential drug interactions and reminders to deliver recommended care.
5. *Electronic communication and connectivity*: electronic sharing of patient's health information and data among care providers and other stakeholders. This sharing ranges from unstructured, free text approaches (e-mail) to fully structured, machine-readable, standards-based exchanges.
6. *Patient support*: electronic tools that give patients access to their health records, provide interactive education, and help monitor and manage their conditions remotely.
7. *Administrative processes*: functions that support patient scheduling, verification of insurance status, and electronic claims processing—including automated capture of charges for care services.
8. *Reporting and population health management*: aggregation, reporting, and analysis of data across patients for multiple purposes including monitoring and managing chronic conditions, tracking key quality indicators, and reporting disease statistics.

These functions can be further organized into three categories: those that support different activities in episodes of patient care (functions 1-7); those

that enable monitoring and interventions across populations of patients (functions 1, 5, and 8); and those that support clinical decision making for individuals and groups of patients (functions 1, 2, and 4). While clinicians' workflows and data needs may differ by care setting and medical specialty, the need for appropriate documentation of a patient's history, current problems, medications, allergies, test and study results, and demographic information is consistent, as are needs to order medication, tests, and procedures and to share patient data and coordinate with other caregivers. Likewise, the need to identify, intervene, and monitor a group of patients with a given set of characteristics[2] is important to ensure both therapeutic consistency (i.e., that all patients with similar conditions, comorbidities, and severity of illness receive the same recommended care) and collective improvement in the care these patients receive (Greenlick, 1995; Wagner, 1995). Finally, the ability to apply clinical logic to this information in support of diagnosis and treatment of individuals and cohorts of patients, and the ability to offer relevant disease and treatment information to clinicians in real time at the point of care, are also important EHR functions.

Used consistently and appropriately, EHRs containing these functions are postulated to produce significant value in the form of the following:

- Improved quality—decision support may result in increased adherence to care guidelines;
- Improved patient safety—interaction and allergy checking at the time of drug orders may decrease rates of medication errors;
- Improved outcomes—decreases in the morbidity and mortality associated with acute and chronic conditions;
- More integration and better care coordination—improved availability of patient data at the point of care and communication among caregivers and patients;
- Improved efficiency—decreases in the frequency of unnecessary and duplicative care and in the costly manual exchange of clinical data;
- Decreased costs—both in administrative costs to support clinical operations (maintaining paper medical records) and in the costs of care;
- Increased provider revenues—from improved coding and documentation; and
- Better research data—creating longitudinal data stores on patient's conditions, histories, and outcomes.

[2] Characteristics include sex, age, diagnosis, disease severity, insurance type, geography, and others.

For many of these value categories, experimental and observational studies have found significant, positive changes in the quality, safety (Kaushal and Bates, 2001; Kaushal et al., 2003), and efficiency of care (Chaudhry et al., 2006; Goldzweig et al., 2009) and, in limited instances, financial impacts in terms of cost savings and improved revenues (Middleton, 2005; Miller et al., 2005). However, in some instances, the evidence of the value of EHRs (or of specific EHR capabilities) is equivocal. One study of EHRs reported no conclusive changes in the use of laboratory and radiology services and slight to no changes in intermediate measures of healthcare quality (Garrido et al., 2005). Other studies have suggested that in some care settings, the use of EHR functions such as computerized physician order entry (CPOE) may have actually caused errors (Han et al., 2005; Koppel et al., 2005). As we look from the promise of EHRs to the evidence of EHR impact, a few questions are important to consider: How is value created from EHRs? How is it captured or realized? To whom does EHR value accrue?

EHR Value Creation and Value Capture

Value creation through EHRs is the process of using these tools to support positive changes in the processes, outcomes, and costs of care; value capture is the process of realizing these changes as benefits as well as determining to whom these benefits accrue. EHRs can create value through producing process efficiencies, replacing manual paper-based clinical and administrative methods with those automated through computers and electronic information networks. Depending on their capabilities, EHRs can also create value through changes in the utilization of services, either by increasing care known to be beneficial and appropriate or by decreasing care that is potentially inappropriate (unnecessary) and even harmful. Certain reductions (or increases) in the costs of care may then follow from these efficiencies and changes in utilization. This potential value is expressed in terms of the benefits listed above: improved quality, safer and more efficient care, and so forth.

However, the ability of caregivers, patients, and others to capture this value—to actually change processes of care, avoid medication errors, and decrease costs—is another matter. Some EHR benefits are, arguably, relatively easier to capture (or more likely to be captured) than others. For example, revenue enhancements from EHRs that improve coding are more likely to be recognized than efficiency-related cost savings that require a reduction in clinical or support staff. While physician practices may automate documentation and coding through EHRs and therefore require fewer staff for these tasks, anecdotal evidence suggests that—for certain care settings—they are less likely to shed these resources than to reassign them to other productive tasks.

EHR stakeholders encompass a broad range of health system actors. The most proximal EHR stakeholders include clinician users, patients, and ancillary providers; more distal are those who finance, regulate, and monitor care (i.e., health plans, government administrators, and public health organizations, respectively) as well as those who research the effects of care delivery.[3] EHR adoption and use may result in value to some of these actors, but not others. From the perspective of the U.S. healthcare system, the effects of EHR adoption and use—and the dynamics of value capture—may be experienced and distributed differently depending on several key characteristics. For instance, in the previous example, the benefits of improved coding (i.e., increased revenues) would accrue to providers under the predominant fee-for-service payment system. Changing the payment system to capitation, where providers would be at risk for the costs of care, would limit the accrual of value since they would not be able to bill for improved services.

In addition to payment systems, the sophistication of an EHR system, the settings in which this system is adopted, the size of the organization, the presence or absence of strong leadership and quality improvement programs, and other dimensions impact the type and amount of value EHRs may produce and to whom this value ultimately accrues. Table 6-1 provides a summary of many of the key characteristics that impact EHR value creation and capture.

To illustrate the ways in which some of these characteristics may combine to effect the creation and capture of EHR value, consider the following expanded example. A physician practice of 10 clinicians adopts an EHR with clinical documentation and administrative support features. This practice is based in an urban setting with a high volume of relatively complex patients and is reimbursed on a largely fee-for-service (FFS) basis. Successfully adopted and used, an EHR with these functions in this context may decrease the high costs associated with maintaining paper records and producing insurance claims, thereby saving this practice money. Moreover, electronic documentation may improve coding for visits and consequently increase this practice's revenues. In both of these examples, the practice may receive financial benefit from EHR adoption—one in savings, one in revenues. Health plans, however, may share only in savings related to claims processing (they no longer receive and manually process paper-based claims), but these plans may actually experience increased costs due to improved provider coding.

[3] In a report on the costs and benefits of health IT, the Congressional Budget Office (CBO) provides a useful distinction between *internal benefits* that accrue to providers and *external benefits* that are enjoyed by entities interacting with providers (see U.S. Congress, 2008, p. 7).

TABLE 6-1 Types of Characteristics Impacting EHR Value

EHR system	• Basic to advanced functions • Commercial vs. institutional (i.e., "home-grown")
Care setting	• Inpatient vs. outpatient • Primary vs. specialty
Organization setting	• Community vs. academic • Open vs. closed model • Urban vs. rural
Organization size	• Large, medium, or small
Organization leadership	• Experience with health IT and EHRs • Commitment to success
Financial issues	• Revenue mix (e.g., risk contracting vs. fee-for-service payments) • Financial incentives (e.g., pay-for-performance, reporting) • EHR adoption and maintenance costs
Workflow and practice patterns	• Care process variation • Level of EHR adoption and "meaningful" use
Populations served	• Pediatric, geriatric, or condition-specific

Changing a few characteristics in this example would change the dynamics of EHR value creation and capture. If this same practice added order entry and robust decision support capabilities to its EHR, most medication orders would now be entered electronically. Decision support features would check these orders for drug allergies and drug-drug interactions, alerting clinicians of possible adverse drug events (ADEs). If clinicians act on these alerts, they decrease the amount of medication errors. This decrease, in turn, reduces visits or hospitalizations stemming from ADEs—clearly, an improvement in safety that benefits both patients and providers. Also, since this practice is reimbursed on a FFS basis, any costs avoided due to reductions in ADE-related events accrue to payers. However, if order entry and decision support features improve adherence to guideline-based care, then this would increase the amount of services delivered to patients—correcting for underuse of proven preventive and chronic care measures. In this instance, care quality would increase, again benefiting patients and clinicians, but so would the costs of care in the short term—costs borne by payers. In the long term, however, improvements in the quality of care might actually precipitate a net decrease in care costs if more serious clinical events were avoided as a result. Here then, all parties—patients, providers, and payers—would likely benefit.

This example starts out simply enough, but then value creation and capture become more complicated—seeming to flip-flop once more characteristics are changed or introduced. The illustration above is intended

to show how EHR value is complex and influenced by a wide range of attributes. Accordingly, the evidence on EHR impact should be considered in light of these characteristics.

Evidence of EHR Value: Research Studies and Cost-Benefit Projections

Evidence of EHR value generally falls into two categories: (1) research study data[4] and (2) projections of EHR costs and benefits based on this data. The former category answers specific questions about the actual impact of EHRs; the latter addresses questions about their possible impact. Both are important for understanding EHR value. This section reviews summaries of the evidence on EHR value from both categories. We present data from review articles that included studies examining EHRs as well as key EHR capabilities contained in the IOM definition above.

Research Studies Related to EHR Impacts on Quality, Safety, and Efficiency

In 2006, researchers at RAND published a systematic review on the impact of health information technology (health IT) on the quality, efficiency, and costs of medical care (Chaudhry et al., 2006). Subsequently, they published a follow-on review of the evidence on HIT costs and benefits from 2004 to 2007 (Goldzweig et al., 2009). Since EHRs are an important combination of systems and functions within the broader realm of health IT, we selected findings from these reviews that included studies of the key EHR capabilities included in the IOM definition. Generally, RAND found improvements in care quality and safety, but little evidence on costs or cost savings. Findings relevant to EHR functionality are the following:

- Increased adherence to guideline-based care: absolute improvements in the range of 5 to 66 percent (most clustering in the 12 to 20 percent range). This was particularly the case for preventive care guidelines (e.g., vaccinations and screenings).
- Improved medication safety: decreases in serious medication errors in the range of 55 to 86 percent and improvements in the accuracy of drug dosing from 12 to 21 percent.
- Enhanced surveillance and monitoring.

Evidence in both these review studies was mixed in terms of the impact of health IT and EHR impact on the efficiency of care. The major benefit in terms of efficiency was decreased utilization of care—absolute reductions

[4] This includes data from and includes experimental, observational, and case studies using quantitative and/or qualitative methods.

of between 8.5 and 24 percent, particularly for lab tests and image studies. Since much of the evidence on HIT and EHR impact came from four institutions—three of which were part of academic medical centers—and since many of the systems studied were developed by these institutions (i.e., homegrown), study authors could not say for certain whether or not this evidence would readily translate to other institutions that might use commercial systems.

Recent evidence published as late as January 2009 indicates that the benefits of EHRs would be realized through the adoption of commercial systems in urban hospitals. Amarasingham and colleagues (2009) performed a cross-sectional study of 72 urban hospitals in Texas and hypothesized that those with higher rates of adoption and use of clinical information technologies would have better outcomes and lower costs of care. Specifically, they examined the degree to which hospital use of many EHR functions—including clinical documentation, order entry, results reporting, and decision support—was associated with mortality, complications, costs, and length of stay for patients with four medical conditions: myocardial infarction, congestive heart failure, coronary artery bypass grafting, and pneumonia. Patients at hospitals who had adopted and used systems with EHR functions more intensively had lower rates of hospital-based fatalities and lower risk of complications. Of special note is that, for nearly all conditions, greater use of EHR functions was associated with lower hospital costs. Although this study was limited to hospitals and did not determine whether or not clinical automation was the *cause* of decreased risk of negative outcomes and lower costs, it provides an important piece of evidence for EHR value stemming from the use of commercial systems (Bates, 2009).

Research Studies Related to EHR Costs

Financial impact—in terms of both costs and revenues—is an important aspect of EHR value. EHR cost considerations include the funds to acquire and maintain systems as well as the savings resulting from EHR adoption and use. Revenues include the ability of EHRs to increase payments to provider organizations through improved coding and greater provider productivity.

Data on EHR system costs are very limited, vary widely, differ by setting of care, and are often the product of estimations and models—not actual costs incurred. In outpatient settings, the widest range of EHR adoption costs reported in a single study by Miller and colleagues is $14,500 to $63,600 per provider, with a median of nearly $46,000 (Miller et al., 2005). Annual EHR maintenance costs from this same study range from approximately $6,000 to nearly $12,000 per provider, with a median of $7,200. Miller's adoption estimates include opportunity costs: the decrease in revenues resulting from lost productivity during EHR adoption. Creating

a similar range of acquisition costs for outpatient EHRs from other studies yields $25,000 to $45,000 per provider, with a range of support costs from $3,000 to $9,000 per provider annually (U.S. Congress, 2008). In inpatient care settings, acquisition costs for clinical information systems with order entry and decision support capabilities—a proxy for EHR costs—ranged from $2.8 million to $4.1 million for a 200-bed hospital to $9.7 million to $14.7 million for a 1,000-bed hospital; support costs ranged from $174,000 to $468,000 annually for a 200-bed hospital, and $747,000 to $1.5 million for a 1,000-bed hospital annually (Birkmeyer et al., 2002). A cost-benefit analysis of an inpatient CPOE system estimated $11.8 million in costs over 10 years to develop, implement, and operate the system (Kaushal et al., 2006). Other sources have reported inpatient system acquisition costs of $14,500 to $63,000 per bed,[5] with annual maintenance costs of approximately 20 to 30 percent of acquisition costs (U.S. Congress, 2008).

Research Studies Related to the Financial Impact of EHRs

There are several examples of cost savings and revenue gains from case studies of EHRs and their related functions (Kaushal et al., 2006; Middleton and Janas, 2000; Miller et al., 2005; Wang et al., 2003) and some published evidence from observational and experimental studies (Chaudhry et al., 2006; Goldzweig et al., 2009).[6] In general, sources of cost savings from EHR functions include those from elimination or reduction of manual administrative processes (e.g., reduced chart pulls and transcription costs) and from changes in the utilization of services (e.g., reduced duplicate and inappropriate diagnostic tests, more appropriate ordering of medications and image studies, reduced hospital stays, avoidance of error-related visits and hospitalizations). Revenue gains typically stem from improvements in coding and provider productivity.

Some of the best examples of case studies on EHR financial impact include work completed by Robert Miller and colleagues. In a study of EHR adoption in 14 solo and small-group practices, Miller found that most practices enjoyed a $33,000 financial benefit, approximately half of which was from improved coding and half from practice efficiencies. After EHR adoption cost, providers accrued an average of $23,000 net financial gain, with an average of 2.5 years to break even. Of the 14 practices participating in this study, 2 did not break even within the period of analysis (five years)

[5] Though nearly identical to the range of outpatient EHR costs reported by Miller et al. (2005), the range of per bed costs for inpatient CPOE systems was derived from different sources (see **First Consulting Group, 2003; Girosi et al., 2005**).

[6] As RAND researchers note, much of the evidence on financial value from these studies is based upon monetizing changes in administrative processes and in utilization of different care services.

(Miller et al., 2005). In a case study of EHR adoption and use in an integrated delivery network, Middleton and Janas found more than $30,000 in net EHR-related savings per provider (Middleton and Janas, 2000).

Another study performed by Miller and colleagues found that EHRs in community health centers did not produce enough cost savings and increased revenues to completely recoup the costs of EHR investment and to maintain these systems. Substantial quality improvements were recognized, however, suggesting the need for external support in order to continue to realize EHR-based quality gains (Miller and West, 2007).

Generally, the available data suggest that significant financial benefit from EHRs is possible—enough in some instances and care settings to cover EHR system costs and to provide a positive return on investment. While the generalizability of these studies is limited by their small sample sizes, it is important to note that many of these studies were conducted in circumstances lacking a specific financial or other EHR incentive program and were in organizations where FFS payment methods are common.

Cost-Benefit Projections Related to Clinical and Financial Impacts of EHRs

Distinct from research studies are cost-benefit analyses that use study and other data to project the impact of EHR systems or specific EHR functions (Wang et al., 2003). Generally, the intent of cost-benefit projections (normally computer-based analytic models) is to provide order-of-magnitude estimates of the potential clinical and financial impact of EHRs, given their broad adoption and appropriate use by clinicians. Another, less quantitative but important product of these studies is the development of conceptual models or frameworks that describe the range of features, functions, and uses of emerging health information technologies.

CITL has projected the potential impacts of several key EHR functions, including the following:

- *Order entry* with *decision support* in outpatient care settings (ambulatory computerized provider order entry, or ACPOE);
- *Electronic communication and connectivity* between providers and other healthcare stakeholders (health information exchange and interoperability, or HIEI); and
- *Population health management* using clinical decision support to manage patients with Type 2 diabetes (IT-enabled diabetes management, or ITDM).

In the ACPOE and HIEI models, CITL projected substantial clinical benefits in the form of improved patient safety from decreased ADEs and more appropriate utilization of medications and tests. CITL also projected a

net positive financial benefit from widespread use of these technologies over 5 to 10 years. In the third model, ITDM, CITL predicted significant reductions in diabetes-related clinical events and improvements in morbidity.

Regarding ACPOE, CITL projected the impact of increasing levels of order entry and decision support sophistication on the reduction of adverse drug events, ADE-related hospitalizations and visits, and finally ACPOE adoption costs and financial benefits. Nationwide adoption of advanced ACPOE systems has the potential to eliminate more than 2 million ADEs and avoid more than 190,000 hospitalizations per year. Moreover, the most advanced ACPOE systems could save the U.S. healthcare system $34 billion per year in reduced medication, radiology, laboratory, and ADE-related expenditures. Given the predominance of FFS reimbursement, CITL calculated that the majority of ACPOE financial benefit—almost 90 percent—would accrue to payers who are at risk for the costs of patient care (Johnston et al., 2003).

CITL's study of the value of HIEI examined the costs and impact of increasing levels of standardized electronic sharing of health data between provider organizations and other stakeholders: health plans, pharmacies, laboratories, imaging centers, and public health entities. Interoperability levels ranged from 1 (paper-based, manual exchange of data) to 4 (fully standardized, electronic health information exchange). Over a 10-year implementation period, CITL projected that level 4 HIEI would produce a cumulative net value of $337 billion, with a potential annual net benefit of nearly $78 billion thereafter. It is important to note that less standardized electronic health information exchange (HIEI level 3) would produce a cumulative net loss of more than $34 billion over the same time period (Table 6-2).

CITL's analysis of the value of IT-enabled diabetes management simulated the progression of Type 2 diabetes in a population of virtual patients over time. Using novel methods of bridging the evidence on changes in care processes to clinical outcomes (Kendrick et al., 2007), this model predicted changes in specific physiological states, diabetes care processes, morbidity and mortality-related outcomes, and costs for different forms of IT-enabled interventions, including EHRs with diabetes-specific decision support. CITL's projections found that the decision support-based interventions, adopted widely and used over 10 years, would improve adherence to guideline-based care and would avoid thousands of cases of end-stage renal disease, lower-extremity amputations, blindness, and deaths while saving $10.7 billion in related costs (Bu et al., 2007). The costs of implementing and maintaining diabetes-specific decision support (Adler-Milstein et al., 2007), however, exceeded these savings—resulting in a net increase in costs for substantial quality improvements.

TABLE 6-2 Net Value of Health Information Exchange and Interoperability

Level	Implementation, Cumulative Years 1-10 ($ billion)	Steady State, Annual, Starting Year 11 ($ billion)
Level 2		
Benefit	141	21.6
Cost	0.0	0.0
Net value	141	21.6
Level 3		
Benefit	286	44.0
Cost	320	20.2
Net value	–34.2	23.9
Level 4		
Benefit	613	94.3
Cost	276	16.5
Net value	337	77.8

NOTE: For explanation of levels see text; all results are stated to three significant digits.
SOURCE: Walker et al., 2005.

Examining the possible costs and benefits of electronic medical records[7] adopted and used over a 15-year period, researchers at RAND projected a cumulative net savings of $371 billion for inpatient settings and $142 billion for outpatient settings and, overall, annual net savings of $81 billion from EHR-related efficiencies and improvements in patient safety (Hillestad et al., 2005). This analysis extrapolated evidence from studies showing positive results from adoption of electronic health records and modeled wide adoption and effective use of EHR functions.

Indications from CITL and RAND are that substantial investment in EHRs and in systems supporting EHR functions could provide significant improvements in the quality of care and net reductions in costs over time. However, cost-benefit projections are not meant to replace empirical studies; rather, they use the best available evidence from the literature and experts to inform those potentially investing in the development or acquisition of these systems about the type and magnitude of potential EHR costs and benefits. However, given the limited evidence base, these analyses have not been able to account for every characteristic that may impact EHR value. Nonetheless, cost-benefit projections provide an important component in

[7] The definition of electronic medical records in the RAND cost-benefit analysis largely overlaps the IOM definition of EHRs.

making the vision for an EHR-enabled healthcare system more concrete and for assisting public and private sector decision makers in judging the impact of EHR investments and outcomes. By making their assumptions, inputs, and calculations explicit, cost-benefit projections allow for comparisons of scenarios that test the effects of different levels of adoption, cost, and impact on EHR value.

Issues in Assessing EHR Value

Perhaps the greatest issue with assessing the value of EHRs is the current low adoption across care settings. The most recent data on outpatient and inpatient EHR use indicate that, on average, only 13 percent of physicians practicing in outpatient care settings (DesRoches et al., 2008) and about 8 percent of hospitals (Jha et al., 2009) have successfully adopted basic EHR systems. Adoption of fully functional EHRs that include the key functions and characteristics of the IOM's definition is even lower: at most, 4 percent of outpatient providers and less than 2 percent of hospitals have EHRs with broad functionality, such as clinical documentation, electronic data sharing, and order entry for drugs, as well as lab tests, image studies, and robust decision support.[8]

There are many reasons behind low EHR adoption, including the relatively high cost of purchasing and maintaining EHRs (Hersh, 2004) and provider's limited access to capital. Coupled with concerns over vendor continuity, misalignment of incentives (i.e., where proportionally more EHR benefits accrue to stakeholders other than providers who bear EHR adoption costs) (Middleton, 2005), and substantial changes in care workflow needed to successfully incorporate EHRs into clinical practice (Ash and Bates, 2005; Miller and Sim, 2004), providers have been either unable or reticent to adopt them. Low adoption has, in part, kept the evidence base on EHR value more limited.

In addition, evidence on the "unintended consequences" of EHRs and their functions—notably CPOE—has been published in recent years. This work has focused on the ways in which EHR functions such as order entry with decision support may result in workflow difficulties, increased demands on clinician users, unexpected and unintended changes in institutional power structures, overdependence on technology, and generation of new kinds of errors and even harm to patients (Campbell et al., 2006; Han

[8] Important to note, however, is the difference in adoption by size of organization: up to half of practices with more than 50 providers have adopted either basic (33 percent) or fully functional (17 percent) EHRs, while 19 percent of hospitals with more than 400 beds have adopted basic (16 percent) and fully functional (about 3 percent) EHRs. Clearly, as with value, EHR adoption differs by several important characteristics.

et al., 2005; Koppel et al., 2005; Sittig et al., 2006). This research is important since it indicates the need for robust evaluations of health IT and EHRs during and after adoption in order to ensure value to clinicians and patients alike. These studies may also provide important data on EHR adoption barriers and the strategies applied to address them (Bates, 2009).

Policy makers and researchers note that EHRs are a necessary but not sufficient component of reforming health care in the United States. Since EHRs, like all of health IT, are tools designed to enhance, better coordinate, and document clinician's activities, their adoption is but one piece of a larger effort to update and modernize a fractured system. Many note the lack of robust randomized controlled trials on EHR impact and costs and urge caution about viewing EHRs—and health IT more broadly—as a panacea for issues concerning high costs and poor quality (Diamond and Shirky, 2008). Some doubt the veracity of cost-benefit projections (Himmelstein and Woolhandler, 2005) or their inputs and assumptions (Baker, 2005), whereas others note their lack of application to answering more narrow questions about the impact of federal legislation on EHR adoption (U.S. Congress, 2008). In addition, some doubt that health IT and EHRs will produce cost savings absent significant health system reforms (Sidirov, 2006; U.S. Congress, 2008). Like any issue within the larger debate on healthcare reform, the value of EHRs has both supporters and critics. Both agree, however, with the need to evaluate EHR impact more rigorously.

The evidence base for health IT and EHRs is evolving (Blumenthal and Glaser, 2007). Assessing the value of EHRs is challenging, since it spans clinical and financial domains and is contingent upon a complex interaction of characteristics. The sample of research study data and cost-benefit projections reviewed in this paper comes from a range of care and organizational settings, involving different levels of EHR functions and examining different types of EHR-related impact and costs. As would be expected, the value of EHRs and related functions varies as well. Moreover, new forms of EHR value, such as enabling comparative effectiveness research and biosurveillance through aggregation of electronic patient data, have yet to be studied. What the existing evidence has not been able to determine and what is not well understood are which combinations of characteristics are able to achieve relatively greater value from EHRs and which interactions are most important in creating and sustaining EHR value. To maximize the benefit of federal investments in health IT generally and EHRs specifically, more research targeting these areas is needed. Understanding the combination of characteristics—those factors that most determine EHR value—should be a central focus of research on EHRs.

MEDICAL HOMES AND MEDICAL "HOME RUNS"

Arnold Milstein, M.D., M.P.H.,
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The primary objective of the medical home being defined by physician organizations and accreditors is quality improvement, but unless medical homes also fulfill their considerable potential to reduce total per capita health spending, they will elude the financial reach of many adults in the lower half of the income distribution. An increasing fraction of these adults can no longer afford their current share of health insurance premiums and average point-of-service cost sharing, especially if they are chronically ill, and most do not qualify for Medicaid coverage. Medical homes that fail to substantially reduce total per capita health spending will also find it difficult to persuade public and private sector purchasers to support substantial new medical home fees.

Lower-income adults and employer, union, and government health benefit program sponsors need the medical home to be a "medical home run"—a care delivery innovation that substantially reduces near- and long-term total healthcare spending while improving quality of care. Medical homes can be medical home runs, but I worry that most will not be.

My concern is partly because medical homes are not being designed explicitly for this purpose and partly because the near-term cost of correcting underuse is likely to substantially exceed savings from eliminating overuse. Ironically, my strongest concern originates in my observations of several exceptional, existing primary care practices that are indeed medical home runs.

Scouting for Existing Medical Home Runs

With support from the Robert Wood Johnson Foundation, the California HealthCare Foundation, and employee health plan sponsors, I scouted for and found four primary care physician-led practices with average or above-average quality scores whose care enables their patients to consume 15-20 percent less total payer spending per year on a risk-adjusted basis than patients being treated by regional peers. Mobilizing impressive business ingenuity, they achieved this result in a U.S. payment environment that typically punishes physicians who invest to prevent costly near-term health crises. I found them in both large and small physician practices in Massachusetts, Florida, and California. I am certain they exist elsewhere.

If the ingredients and accomplishments of these four medical home runs rapidly spread, many underinsured and uninsured lower-income Americans could be covered without increased healthcare spending or lower quality

of care. In addition, health benefit plan sponsors would gladly support the higher primary care physician payments that were required to attain such results.

However, these four physician practices contain two key features that are not well addressed in current medical home blueprints: (1) personal zealotry in preventing urgent and emergent hospitalization for chronic illnesses and (2) equally zealous concentration of referral care to high-quality medical specialists who are sparing in their use of "supply-sensitive services," as defined in the Dartmouth Atlas.

Personal Zealotry in Preventing Unplanned Hospitalization for Chronic Illness

All four primary care medical home runs operate as de facto "hospitalization prevention organizations" for their chronically ill patients; they make prevention of unplanned hospitalization of these patients a primary objective; and they redesign their practice models accordingly. A key element of this prioritization is clinical mindset: the physicians and their office staff regard urgent and emergent hospitalizations for patients with chronic illnesses as personal and organizational failure events, study their root causes, and evolve their practice model to prevent recurrences.

While the specific clinical innovations to prevent unplanned hospitalizations vary somewhat across the four practices and are discussed elsewhere, they converge in two ways. At least one primary care team member demonstrates saliently to each chronically ill patient that he or she cares deeply and personally about that person and the protection of the patient's health. This usually includes mobilizing family members, social services, and other resources required for successful patient self-management. In addition, as soon as a chronically ill patient senses an impending health crisis, a member of the healthcare team familiar with that patient's history is readily reachable and prepared "to go the extra mile" to prevent hospitalization, including actively coordinating with emergency room physicians and hospitalists in exploring alternatives to hospitalization (Milstein and Gilbertson, 2009).

An attitude of "protection of your health matters to me personally" and "I'm prepared to invest special effort to spare you a health crisis" was memorably captured in Atul Gawande's 2004 *New Yorker* magazine portrait of Dr. Warren Warwick in "The Bell Curve." It is the exception rather than the rule in American healthcare delivery. Because it reflects a personality characteristic of clinical team members rather than a readily teachable behavior or a structural enhancement of a primary care practice, ensuring this expression of patient-centeredness requires new selection criteria for medical home team members serving the chronically ill. Given the

prolonged time frames required to integrate patient-centeredness robustly into medical student selection and into graduate and postgraduate physician training, near-term improvement implies selecting for this attitude among nonphysician team members. Other organizations, such as the retail giant Nordstrom, have shown that selecting employees for high natural service orientation is feasible.

Concentrating Referral Care with High-Quality, Conservative Medical Specialists

Current methods of comparing specialists on quality and total spending per episode of acute illness care and per year of chronic illness care are imperfect. Nonetheless, each of the four primary care medical home runs used available performance assessments of specialists on quality and total cost of care in order to concentrate specialist referrals with one well-performing specialist or specialist group per specialty. In two of the medical home run practices, conservative resource use by these specialists was reinforced by payer capitation payment of specialists.

An estimate of potential healthcare spending reduction associated with preferential use of such highly ranked specialists in Seattle—a low-spending Dartmouth Atlas region—was prepared by Mark Rattray. He found no relationship between low spending and quality for care delivered by most non-primary-care specialties. When he modeled savings from preferential referral to low-spending specialists with above-average quality scores, he found that the opportunity for savings constituted approximately 15 percent of total payer spending controlled by specialists. The savings opportunity is likely greater in the higher-spending Dartmouth Atlas regions.

Concentration of referrals also enables more effective care via greater standardization of treatment protocols among physicians treating the same patient, more reliable transfers of patient information between primary and specialist care, and greater clarity regarding the division of responsibility among physicians involved in a patient's ongoing management.

Closing Comment

If medical homes deliver better quality without increasing total healthcare spending, they will generate social benefit. Social benefit will also increase if medical homes shift physician payments toward primary care. However, for medical homes to profoundly benefit non-affluent adults who do not qualify for Medicaid and to persuade most purchasers to pay higher medical home fees, they must also lower total near-term healthcare payer spending. To achieve such home run status, medical homes' designs, certification standards, and criteria for reward from payers must explicitly

incorporate features from existing primary care practices that achieve low total cost of care and favorable performance on other domains of quality. Observation of four such practices suggests that these design features are likely to enhance, rather than conflict with, current principal medical home quality objectives of improved access, patient-centeredness, and effectiveness of care.

While they cannot alone correct the major shortfalls in the value of U.S. health care, medical homes can substantially reduce total near-term healthcare spending while improving quality of care. Today, roughly 60 million uninsured and underinsured lower-income Americans need physician and health plan leaders to jointly pursue this higher aspiration for medical homes. Otherwise, their numbers and preventable health deterioration will continue to mount.

DISEASE MANAGEMENT

Tracey A. Moorhead, DMAA: The Care Continuum Alliance

Improving health and achieving meaningful system reform demands that we rethink our most basic ideas of how—and when—to provide the best care. Population health improvement in its many forms—prevention, wellness, chronic disease management, and others—offers important direction for this task by demonstrating how good health often is simply a matter of good timing.

Population health improvement learned long ago that keeping people healthy and identifying risk, rather than waiting for hospitalization or diagnosis of chronic disease, brings greater rewards than reactionary care—the all-too-common approach. This is how population health has evolved over the past decade, from managing existing conditions (still an important component of what we do) to a broad spectrum of services and solutions across the continuum of care for chronic disease. These interventions are many and varied: wellness, health promotion, prevention, and even complex case management and palliative care. The tools of the trade have expanded greatly too, encompassing health risk assessment, advanced predictive modeling services, personal health record portals, electronic medical records, remote patient monitoring, and other technological innovations that all contribute in some form to stopping a problem before it starts.

Underlying all are three core components of population health improvement: the central leadership role of the physician, a patient-centered focus, and emphasis on patient and physician engagement. Reform must recognize that physicians and patients cannot go it alone. They need the support of a variety of services and professionals, especially in the sphere of chronic condition prevention and care. Population health can bring to bear the

technological and staffing resources all too often out of reach for the typical practice, especially small practices. Bringing together all stakeholders this way allows us to align providers and services with the shared goal of improving the health of populations and, in turn, moving more people off the rolls of the at-risk and into the ranks of the chronically well.

Often, though, we lose sight of this goal in the debate about whether disease management "works"—a debate that usually starts with the wrong questions: Does disease management save money? is typical and, more often than not, what is meant is: Does disease management always work in every case for every population using the same intervention? The answer is no. If you have seen one disease management program, you have seen only one disease management program. Successful chronic disease programs employ tailored interventions and measurements that reflect the unique needs of the population served and unique resources available to it.

Drilling down further, sometimes the question is: What are the short-term medical cost savings for this program? However, this question overlooks the long-term value of sustaining and improving health status and, again, assumes that disease management is a one-size-fits-all, monolithic process that can serve any population in any setting regardless of the resources or the training required.

A much better question reformers must consider is: Do population health improvement programs improve quality and deliver value? The population health improvement industry, through its representative organization DMAA: The Care Continuum Alliance has worked diligently over the past three years to answer this question through an evidence-based, consensus approach. The Outcomes Guidelines project has sought, in a rigorously transparent way, to establish the appropriate parameters for answering more productive questions: In what population settings will these strategies have their greatest impact? For which conditions? Which outcomes show positive change and in what sequence? Over what time frame?

The Outcomes Guidelines project has further defined the measurement of the impact of population health programs. Recognizing a gap in the understanding of best practices in outcomes measurement for population health improvement, DMAA launched the Outcomes Guidelines project in 2006. While the project sought to bring clarity to the confusion caused by a host of competing methodologies in outcomes measurement, it also deliberately avoided advocating a single approach. Rather, it set forth guidelines for best practices and for adjusting an evaluation based on population and program variations, all the while keeping a balance between scientific rigor and practicality.

The Outcomes Guidelines Report (DMAA, 2008), the work product of this project, now comprises three volumes. The collection incorporates

comment and counsel from a wide variety of quality and research leaders, both public and private sector, including the National Committee for Quality Assurance, URAC, the Joint Commission, and the federal Agency for Healthcare Research and Quality. The most recent volume, Volume 3, refines and expands earlier work and explores new areas, notably medication adherence, trends, and small populations. It also reflects the broader industry shift toward keeping people healthy with extensive new work on measuring success in wellness programs, an area DMAA will continue to develop in a fourth phase of the project.

With this tool in hand, we can look critically at those relevant questions for population health discussed earlier and narrow our focus on programs that produce the results we seek, based on industry consensus, evidence-based approaches to evaluation. With a clear understanding of best practices in evaluation, we can overcome the challenge of differing expectations and varying populations—the source of so much confusion in the past—and move closer to erasing doubt about the value of population health improvement to a reformed delivery system.

Little doubt remains among employers and other private sector purchasers of health care. Chief financial officers, health benefits executives, and other human resources professionals need only look at their bottom line to see the value of employee health promotion and wellness programs. They also see the value in improved productivity and presenteeism and reduced absenteeism. The Southern Company, a large southeastern U.S. utility, offers a good case study. It engaged 10,000 employees of an eligible population of about 20,000 and provided, based on the needs of the individuals in this population, wellness, prevention, and disease management services. This successful initiative lowered hospital admission rates for the population by 57 percent for those with chronic obstructive pulmonary disease (COPD) and 100 percent for workers and beneficiaries suffering from depression. For those who did need hospitalization, average length of stay decreased by a similar range. Emergency department visits dropped, too, by a range of 29 to 100 percent. What was the return on investment (ROI)? Southern Company calculated a 2.37:1 ROI, net of program costs: $2.37 back for every dollar invested across the board for this program.

Another case study comes to us from J. B. Hunt, a leading national trucking company. J. B. Hunt enrolled 3,200 participants—mostly truck drivers—in a program targeting high blood pressure, which impacted drivers' ability to stay on the job, created safety issues, and generated unacceptable turnover at the company. The three-year lifestyle health promotion program resulted in a 37 percent smoking cessation rate and an average 15-pound weight loss among 49 percent of the targeted population. Disease management generated $213,000 in savings for four chronic condi-

tions. Equally important to the company, the program reduced preventable accidents by 25 percent and increased employee retention by 6.2 percent.

The public sector has seen similar positive results from population health programs. Medicaid, in particular, has served as a breeding ground for extraordinary innovation and flexibility to reach specific populations with tailored programs.

Illinois initially engaged nearly 2 million beneficiaries for primary care case management and disease management and provided disease management for 220,000 chronically ill Medicaid recipients. Working with nurses, social workers, and physicians to support patients and reduce admissions, Illinois realized a net savings in 2007 of $34 million through an 8.5 to 20 percent reduction in admissions and a 13 percent drop in emergency department visits. The program worked so well that the state expanded it to additional populations.

Through its EqualityCare program, Wyoming enjoyed similar savings. The program reduced inpatient admissions by 40 percent and created net savings of $13 million in 2005 and $17 million the following year. Like Illinois, on the strength of these results, Wyoming expanded its program to oral health, maternal weight, and childhood behavioral issues in 2007.

Florida provides another compelling example: $97 million in savings over three years in a program that brought coaching, education, and other interventions to 180,000 chronically ill residents. Attacking rising rates of asthma, diabetes, hypertension, and congestive heart failure (CHF), Florida reduced CHF admissions by 22 percent and emergency department visits by 12 percent. Florida made a particularly strong effort to work with hospitals, physicians, and community organizations, recognizing the broad base of support necessary to effectively fight chronic conditions.

Our experience with chronic care coordination and disease management in Medicare has been somewhat mixed. Medicare fee-for-service beneficiaries present significant challenges to traditional care management interventions, and the program's mammoth size complicates the task further by hampering the flexibility and midcourse corrections needed to quickly adapt a program to a population's changing needs. Even so, we have seen some success in fee-for-service Medicare and noteworthy progress in Medicare Advantage plans, which more closely align with the private sector care management models in which population health thrives. Medicare Advantage special needs plans, for example, exhibit the sort of program design flexibility, collaboration, and coordination that we could extend to other segments of the Medicare program to better deliver services to all beneficiaries.

Much of our recent experience in fee-for-service Medicare comes from the Medicare Health Support (MHS) pilot, which was launched in 2005 and abruptly ended in 2008 based on initial reports of marginal improve-

ments in clinical outcomes and costs savings. Those initial assessments, though, rested on relatively limited data—fewer than three months' worth, in some cases. Generally, populations served in these pilots were far sicker than anticipated by even the Centers for Medicare and Medicaid Services, and many beneficiaries became ineligible for the program before the pilots could begin interventions. This fact alone would indicate that a longer intervention time, where possible, would be required to derive clinical improvements or financial savings given the severe health status of many of these beneficiaries. Even still, these pilots can offer important lessons to be leveraged in reform efforts. Some pilot programs did report clinical improvements and cost savings, and this should be where we direct our attention for the lessons we can learn about chronic condition care in the FFS population. To dismiss these positive results as anomalies rather than the learning opportunities they surely are is to throw the baby out with the bathwater. We simply cannot afford to ignore promising results when true reform demands so much more. We also must not ignore the strong anecdotal evidence of high beneficiary satisfaction and high provider engagement in MHS.

Provider satisfaction with chronic care coordination and population health likely will play an influential role in how these services fit in a reformed healthcare system—a point the population health industry has learned quite a bit about in the past decade. Population health programs must engage physicians and demonstrate clearly how they support the physician's practice and the patients it serves. Fortunately for the industry, it has innumerable examples of collaboration with physicians. Population health's prospects for a central place in the medical home appear strong, particularly given its ability to provide the health information technology infrastructure that small practices often cannot afford and to dovetail well with medical home certification requirements.

As we look to the continued influx of baby boomers to our healthcare system, population health improvement becomes an increasingly important component of coordination and collaboration with physicians and other medical providers. We know that with appropriate design, flexibility, accurate and timely data, and sound approaches to program evaluation, population health improvement makes for a powerful weapon in our fight against chronic disease—a fight we must win to achieve lasting health system reform.

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7

Aligning the System to Promote Value—Now and in the Future

INTRODUCTION

The nation and our healthcare system are at a critical juncture. If overall national expenditures for health care continue to rise, other priorities such as education and energy will suffer (White House, 2009). Consensus among stakeholders—patients, healthcare providers, payers, manufacturers, and legislators—continues to grow that the healthcare infrastructure in the United States needs transformative change (Oberlander, 2007). Investments, both short and long term, involving the public and the private sectors, will be crucial to achieving control over escalating healthcare expenditures while preserving incentives for innovation and enhancing quality of care.

The U.S. healthcare system needs many fundamental changes in order to create a coherent, efficient care delivery system that delivers value to Americans (IOM, 2007). Many of the tools necessary to achieve this vision—such as value-based insurance design, tiering, workplace wellness programs, electronic health records, patient-centered medical homes, and disease management programs—were discussed at this workshop. However, mobilizing stakeholders into agreement about the specific policy levers necessary to obtain increased value in health care also depends on the framing of the message, John C. Rother asserted as part of a panel that discussed the challenges and opportunities confronting the value movement. He encouraged focusing on clinical excellence and improvements in health rather than just cost savings; otherwise he feared a repetition of prior mistakes that occurred with the implementation of capitation and managed care.

As part of that concluding panel, Ezekiel J. Emanuel cautioned that no single one of the tools discussed during the entire workshop is a "magic bullet." He described how many economists believe that proper provider incentives and payment design will fix the system; how some stakeholders speak of the panacea of health information technology (HIT); how health services researchers tout comparative effectiveness as a generator of data that will inform healthcare decision making and reshape the delivery of health care in this country; and finally, how others believe that educating consumers about the total costs of healthcare interventions and increasing cost sharing with patients will stimulate changes in behavior that will yield cost savings.

Emanuel posited that all of these elements simply constitute pieces of a toolbox that need to be engaged simultaneously and synergistically to create disruptive evolution in health care. The difficulty lies in engaging all of these tools effectively to produce incremental changes that eventually coalesce into enduring system-wide, synergistic innovations.

In this chapter's first paper, Sir Michael Rawlins provides lessons for U.S. efforts drawn from his experiences leading the United Kingdom's National Institute for Health and Clinical Excellence (NICE). He describes four particular challenges faced by NICE as it attempted to obtain value for patients, families, and UK society: (1) the need for direct comparative effectiveness studies between interventions, (2) the limitations in translating clinical trial results to real-world settings, (3) the difficulties in valuing treatments across clinical conditions, and (4) the incorporation of cost-effectiveness into value determinations. Although these challenges are global, he cautions that ultimately value assessments must consider the societal context, culture, and preferences of the country in which the decisions are made.

Christine K. Cassel continues with a consideration of likely future advances in medicine and a framework for understanding the value proposition in the context of these innovations, suggesting that the current environment might present a moment of disequilibrium that could catalyze reengineering of the healthcare system. Ezekiel J. Emanuel, Samuel R. Nussbaum, and John C. Rother discussed short- and long-term investment opportunities that would foster synergistic innovations and disruptive evolution toward increasing value in health care.

PLENARY ADDRESS: PERSPECTIVES ON VALUE FROM THE UNITED KINGDOM

Sir Michael Rawlins, M.D.,
National Institute for Health and Clinical Excellence

The United Kingdom's National Health Service (NHS) came into existence in 1948. Funded from general taxation, it provides care from "the

cradle to the grave" and is free at the point of use. The small private sector provides less than 5 percent (mainly elective surgery) of the nation's healthcare needs.

Although the structure and political context of the NHS is unique, the problems it faces are global. The tension between the increasing demands for health care and the limits on the available resources underscores—for all nations—the importance of obtaining value for patients, their families, and society.

NICE was created, as part of the NHS, in 1999. It is required to provide NHS healthcare professionals with advice on achieving the highest quality of care for patients at an affordable cost. In doing so, NICE faces four particular challenges:

1. The dearth of direct comparative effectiveness studies between interventions;
2. The limitations in applying the results from clinical trials to the real world;
3. The translation of clinical effectiveness into value; and
4. Drawing conclusions that are based, in part, on considerations of cost-effectiveness.

Comparative Effectiveness

Assessments of comparative effectiveness, between alternative therapeutic or diagnostic strategies, are critical for examining both clinical and cost-effectiveness. A placebo-controlled trial provides information about the absolute efficacy of an intervention but does not necessarily give much indication about a product's performance in comparison to other available treatments for the same condition. Although head-to-head trials with an active comparator offer richer data for informing routine clinical care, most drug regulatory authorities do not require them for registration purposes. This occurs, in part, because comparative studies will necessarily be larger and hence more costly, but also because what constitutes the current standard of care varies widely both within, and between, healthcare organizations.

In the absence of direct evidence of comparative effectiveness, NICE is often forced to use indirect comparisons in its assessments. An indirect comparison between drug A and drug B can be undertaken by analyzing the results of each against placebo. While there is evidence to show that some types of indirect comparison provide more reliable evidence than others, the approach is often challenging. More head-to-head comparative studies would allow physicians and patients to select appropriate treatments. This particularly applies to studies involving comparisons of pharmaceuticals with devices, physical therapies, or psychological approaches.

Limitations of Randomized Controlled Trials

Randomized controlled trials usually involve relatively small numbers of people from homogeneous patient populations for brief periods of time. The generalizability of these findings to the use of an intervention in routine clinical care is often uncertain. Many drugs, for example, are given to elderly patients with multiple conditions for which they are receiving other necessary medications. Polypharmacy therefore creates additional difficulties that will rarely be resolved from the results of randomized controlled trials. Physicians are thus left to weigh these potential interactions with little empirical data to inform their decisions.

The increasing use of interim and subgroup analyses, in the analysis of the results of randomized controlled trials, poses further problems. There is no consensus among statisticians about how—or, indeed, whether—these should be undertaken. Interim analyses, in particular, more frequently lead to early termination of studies in the field of oncology. While emerging evidence of serious toxicity or significant benefits during a study is a valid reason for premature termination of the trial, there are also concerns that interim findings may represent—by chance—either false positive or false negative results (known, respectively, as "random highs" or "random lows").

Measuring ultimate end points in clinical trials can also be difficult, especially over the long term, and surrogate markers are often an attractive proposition. In oncology, for example, investigators have frequently used tumor response rates as predictors of long-term clinical outcomes. Tumor response rates, however, tend to be weak markers of ultimate end points such as overall survival or quality of life, and greater faith has been placed in them than is warranted.

Valuing Treatments Across Clinical Conditions

NICE faces challenges when translating clinical effectiveness into "value." There is, however, an imperative to do so in order to avoid the provision of cost-ineffective treatments for a few patients with one condition at the expense of others with another condition, for whom cost-effective care would be denied. NICE therefore expresses the health gain produced by a particular intervention as a gain in "utility." This takes account of both the increased quality of life and the time for which it is enjoyed.

There is substantial research to support the use of the EuroQol-5D (EQ-5D)[1] as an appropriate approach to assessing utility gains. More

[1] The EuroQol-5D is a standardized instrument used for measuring healthcare outcomes that produces a single measure (utility) of health status. Increasingly used as a stand-alone measure in many countries, the United Kingdom weights the instrument's variables to reflect the values of the population as a whole. For more information see http://www.euroqol.org/.

recently the Short-Form 36 (SF-36)[2] has also been shown to be capable of assessing utility gains. The EQ-5D considers societal preferences (derived from large population surveys) for various health states that enable comparisons of health gains to be made of different interventions across different conditions.

The use of measures of utility, derived from instruments such as the EQ-5D and the SF-36, is not without problems. Randomized controlled trials rarely include the capture of overall quality-of-life measures let alone ones that can be expressed as utilities. Measures of utility may sometimes fail to capture significant elements that are critical for some conditions (e.g., fatigue, exhaustion, poor cognition). Societal preferences about the burden associated with a particular condition may also differ markedly from those of individuals with the disorder. For example, fully sighted people regard the loss of one eye as causing a significant reduction in the quality of life. For those with monocular vision, however, blindness in one eye is much less of a burden.

Taking Cost into Account

When considering the cost of an intervention, NICE takes into account the full range of costs and savings that are relevant to the NHS. These include the acquisition costs of the product, any special monitoring requirements, and the treatment of complications. In addition, the cost considerations also include savings, for example, from reduced hospitalization or delayed nursing home admission.

NICE does not take into account the broader costs and savings to society as a whole, such as those incurred by sickness benefits and lost productivity. There are obviously potential benefits from using such a wider economic perspective. However, NICE's Statutory Instruments, which form its legal basis, specifically deny such an approach. Moreover, providing advantages to those who are economically active would inevitably disadvantage those who are economically inactive, such as the elderly. This, in the United Kingdom, would be unacceptable.

NICE generally expresses the additional costs, for the additional health gains, as the incremental cost-effectiveness ratio (usually as the cost per quality-adjusted life-year gained or cost per QALY). The Institute, in distinguishing cost-effective from cost-ineffective interventions, does not how-

[2] The Short-Form 36 (SF-36) is a "multipurpose, 36-item survey that measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health." These can be combined into a single measure of utility. See http://www.iqola.org/instruments.aspx.

ever use a strict cost per QALY "cutoff." Instead, it provides its advisory committees with a range of preferred values and asks these committees to exercise their judgment about whether the specific circumstances should allow the preferred value range to be exceeded. In particular, committees are asked to take account of whether the intervention adds demonstrable and substantial benefits that may not have been captured adequately in the measurement of health gain. In this approach, the cost per QALY is used as "a tool not a rule."

Of the 350 decisions that NICE has made about the clinical and cost-effectiveness of new and established interventions (including pharmaceuticals, devices, and procedures), it has rejected only 9 percent. A further 6 percent have been recommended for use "only in research" (i.e., coverage with evidence development).

Conclusion

The global interest in NICE is suggested by the more than 2,000 articles about its work in peer-reviewed journals and the 450,000 monthly visits to its website. This suggests that there is an appetite for the role the Institute undertakes in distinguishing between cost-effective and cost-ineffective interventions. It is important to appreciate that such distinctions, though informed by evidence, require a degree of judgment on the part of decision makers, and the social and cultural environment in which decision makers work will, rightly, condition the conclusions they reach.

VALUE IN HEALTH CARE: THE PATH TO VALUE

Christine K. Cassel, M.D., American Board of Internal Medicine

As we look at how to achieve value in health care, I have been asked to consider the future in two dimensions: (1) to anticipate likely advances in medicine and (2) to create a framework to understand the additive value of these advances in the important context of resource constraints and value trade-offs.

Categories of Technology Advancement

As we look toward the world of health care in the future, for example in the year 2025, the advances we envision are in areas where rapid progress is already occurring, such as imaging technologies, specialty pharmaceuticals, genetic targeting and personalized medicine, nanotechnology, robotics, and telemedicine. Just as advances in these fields will continue to emerge, there are very likely to be some advances in fields that we cannot even imagine.

As we consider these future advances, I believe it will be helpful to consider the different categorical types of technological advances in medicine. The first category of advances includes interventions that prevent disease. Immunizations—which mobilize the body's own defenses through the immune system to prevent illness—represent the ideal cost-effective technology. Immunizations have been used most effectively against infectious diseases, such as polio and measles, but recently also have been successfully employed as a prevention tool for cervical cancer, possible because it is caused by a virus.

Some advances can lead to early detection and, with appropriate treatment, a cure of illness. We see evidence of this in the early detection of many malignancies as well as early treatment of infectious illnesses, such as community-acquired pneumonias. Early detection can also identify a chronic condition for which there is not a cure, but for which early detection can lead to prolonged survival if treatment is available. Examples of these diseases are diabetes, hypertension, and coronary artery disease. The concept of using modern interventions—not for cure, but to stave off decline—is possible not just in diabetes and heart disease, but increasingly in other chronic conditions such as cancer, Alzheimer's disease, heart disease, renal failure, diabetes, vascular disease, and treatment of mood disorders such as depression or bipolar conditions. In these conditions, advances occur not only in the early detection methods, but just as importantly in the interventions.

Another category of technological advance is rescue technology. These are primarily therapeutic interventions where the natural history of life-threatening conditions can be interrupted and altered in order to avert death. The most dramatic of these have been utilized among the elderly. For example, previously an individual who developed a severe pneumonia or a dissecting aneurysm at the age of 80 and subsequently died of that condition would not have been considered to have died prematurely. Yet, aggressive interventions can now often prevent that death and lead to prolonged survival for the patient.

However, while rescue technologies can avert death, they do not necessarily return patients back to their premorbid baseline physiological and functional status. Patients sometimes suffer from additional post-condition disability. One stark example of this is hip fracture, which occurs with escalating frequency in the eighth and ninth decades of life. Even after repair of the hip fracture, there is a significant likelihood that the individual will not return to independent function and a more than 50 percent chance of needing prolonged nursing home care, with subsequent likely complications leading to death.

Medical advances also include interventions that are not treating a disease necessarily but do enhance normal function and, therefore, quality

of life—a current, exciting example of which is cognitive enhancers. Neurocognitive research has led to an increased understanding of medications that can enhance normal memory as well as normal alertness and reduce the need for sleep. Research is also improving mobility, in terms of both muscle strength without the adverse consequences of anabolic steroids and improving cartilage and synovial function in aging joints to avoid the need for joint replacement.

Another example in this category involves sensory conditions, which are rarely considered serious medical problems. Yet vision and hearing impairments can lead to lack of independence, lack of mobility, and greater risk of depression, all of which can reduce quality of life and be potentially life-threatening. Treatments for hearing disorders can dramatically improve an otherwise functional older person's ability to continue working and engage in community and family activities. All of these interventions that enhance normal functioning lead to improved quality of life. Additionally, by keeping people active and engaged as they age, they also reduce the accretion of other kinds of chronic illnesses.

Finally, we must also acknowledge the tremendous boom in cosmetic surgery and cosmetic dermatology that has been driven by the combination of scientific advances and the market of aging baby boomers.

More Than Biomedical Progress

All that I have just discussed has considered categories of advances in biomedical science. Yet in light of the inevitable growth of additional advances, we need to consider two other developments as equally important. The first one is information technology advances and the second is healthcare delivery advances.

We already have seen major advances in the ability to manage healthcare information electronically, and yet we have not invested as a nation in making sure that this technology is used more widely and more effectively. In fact, we may have more mandates for the use of sildenafil than we have for health information technology. Effective information management cannot only reduce overuse, particularly in the diagnostic arena, but also better coordinate care across providers to reduce errors and missed opportunities for appropriate interventions. In addition to information management, information technology allows us to perform wireless monitoring of conditions such as arrhythmias. It has also made possible robotic surgery, robotic healthcare support for the home-bound, and telemedicine. We ought to think about the value that is placed on healthcare information technology advances every bit as critically and thoughtfully as we do with biomedical advances.

Delivery system advances are generally not thought of in the same way as technology—either information technology or biomedical technology—

and yet almost every healthcare expert looking at the next chapter of healthcare reform in the United States points out that our delivery system is broken, fragmented, ineffective, redundant, inefficient, and wasteful. It is also inequitable and unable to deal effectively with healthcare disparities and cultural complexity.

Yet there are established effective delivery systems in the United States as well as in other countries from which we can learn. There are also major efforts under way to reestablish systems that coordinate care on behalf of patients with complex conditions. The most notable of these are the medical home demonstrations now under way, supported by healthcare payers and purchasers and soon to be an initiated under a major Medicare demonstration. In addition, there are small sites of innovation around transition management from hospital to home or to nursing home, as well as a drive for greater integration between specialists caring for a single individual. Finally, because many aspects of the delivery system have become global, we must also include efforts to better integrate and coordinate these global services as we think about the next steps for health care.

Categorical Questions of Value

As we think about how to determine the value of new and all-too-often very expensive technologies in the categories I have just described, we can think of evaluating them on the basis of two factors. One factor is the prolongation of life, where technology prolongs survival although sometimes with significant, ongoing, serious illness or disability. The other factor is quality of life, where interventions that do not necessarily prolong life can increase quality of life—quality in terms of function at any level, such as physical mobility, mental function, emotional health, or pain control.

In addition, there are categorical questions that are useful in the determination of value from technologies. These include the following:

- *Magnitude of the impact*: We need to consider the relative impact on various segments of the population, the impact on life prolongation and on quality of life.
- *Magnitude of the risk*: In diagnostic studies, the risk of false positives needs to be thoroughly evaluated. Adverse consequences need to be weighed against gains on both individual and societal levels.
- *Downstream effects*: Similar to joint replacement or other interventions leading to enhanced mobility or improvement in vision and hearing, and thus reducing depression and increasing social engagement, one has to consider the potential impact on other comorbid chronic conditions.

- *Ethics and fairness*: We need to ask about the ethics and fairness of value as part of these considerations. Is the access to life prolongation or functional improvement part of the social contract? For example, when we insist through Emergency Medical Treatment and Active Labor Act laws that critically ill patients be treated in emergency rooms regardless of their ability to pay, are we saying as a society that we value life enough to provide rescue technology? Does this suggest that if it were more cost-effective to treat those individuals before the condition got to the extreme, we should create an environment in which prevention were possible? Not only must we ask about the social contract, we have to ask about the insurance contract. As we have multiple approaches to healthcare insurance throughout the country, should there be a basic minimum benefits package to which every insured patient is entitled? Also, how should these benefits be insulated from special interests or political concerns that add costs but do not add value for a significant portion of the population?

Value and Values in Health Care

Finally, as we think about *value* in health care, it is important to first ask about *values* in health care. When we think of value, we think of efficiency, evidence-based medicine, and cost-effective treatments. When ethicists talk about values, however, they talk about fairness, compassion, and respect for individuals.

So where do value and values intersect in health care? Every national survey shows that the American public supports major healthcare reform. In a 2008 survey, 93 percent of respondents said the quality and affordability of health care were equally important (Employee Benefit Research Institute, 2008). Yet in the United States, an unresolved issue is the degree to which social justice is part of the fairness equation, as it is in other developed countries where the debate starts with the assumption that everyone should have coverage for basic health care. The United States has never agreed to that assumption, yet the argument from an efficiency standpoint seems to suggest that this direction is a good one.

It is worth raising the question again whether this unresolved issue stems from a concern for justice and fairness or for efficiency. Regardless of the root of the issue, we know that we have the following realities to deal with: 45 million uninsured and perhaps twice as many underinsured. Both of these facts lead to medical bankruptcy continuing to be the primary cause of the collapse of families, which of course is even more important in the current, difficult economic times. We now have good documentation of

the multiple causes of healthcare disparities, but adding fairness and justice components to our determination of value could significantly narrow those disparities.

So what kind of themes can help us advance value-based health care? One is comparative effectiveness, which is receiving a lot of attention now. Although this is not a new idea, it is hopefully an idea whose time has come. Lessons of the past have shown how vitally important it is for a comparative effectiveness entity to be both authoritative and free of political pressure. Secondly, financial incentives must be aligned for value not for volume. This will inevitably lead to some provider risk mechanism, whether it is global or bundled payments or a prepaid model, such as a capitated or concierge model. It is clear that a straight fee-for-service payment system misaligns value in an unacceptable fashion. Finally, the modern context has taught us the importance of utilizing multistakeholder processes that create a level playing field in which consumers, patients, and purchasers, as well as providers and payers, can develop and implement policies and payment approaches based on a common value system. Examining and establishing values needs to be an ongoing process that is inherent and consistent with the daily work of providers, hospitals, and physicians and built around both individual patients and their communities.

Perhaps this will be a moment in time when the Nash Equilibrium breaks down. John Nash, the Nobel Prize–winning mathematician, posited that there is a social equilibrium reached when multiple parties are frozen in current relationships because no party can change its own strategy while the strategies of the other parties remain unchanged. With the current economic crisis in the United States, the Nash Equilibrium could break down when the pain of the status quo for multiple parties, including consumers, patients, and purchasers, begins to exceed the fear of the unknown. If all the stakeholders in health care can seize that moment of disequilibrium, the opportunity could provide a catalyst for clinical reengineering of the healthcare system in a manner that deems it as important as biomedical advances. When system reengineering and biomedical advances finally synergize, it will much more likely that we can have a value-based approach to the adoption of new technology.

OPPORTUNITIES FOR CHANGE

The following is a summary comments made by the workshopís concluding panelists, which included Ezekiel J. Emanuel from the National Institutes of Health, Samuel R. Nussbaum from Wellpoint, Inc., and John C. Rother from AARP. Their comments focused on the short- and long-term investment opportunities that would foster synergistic innovations and disruptive evolution towards increasing value in health care.

Short-term Investments

The panel identified several opportunities for short-term investments that can yield improvements in the current health care system. Emanuel discussed the necessity to generate high-quality, reliable dataódata that addresses the comparative efficacy of medical interventions and minimizes the safety and risks of these interventions. Nussbaum cited a recent editorial co-authored by Billy Beane, Newt Gingrich, and John Kerry, which described the revolution in baseball enabled by the collection of data (Beane, et al., 2008), and argued that data and evidence-based medical practice could drive a similar evolution towards value in health care.

The panel further pinpointed electronic health records as an implementable tool to collect the necessary data. Nussbaum discussed the benefits of engaging all health care providers in e-prescribing, which could provide a quick gateway to broader adoption of HIT and real-time decision support. HIT could also provide a starting point for tailoring decisions to individual clinical circumstances while considering additional information on costs, outcomes and strength of the available evidence.

Nussbaum additionally emphasized the importance of directly educating consumers in the decision-making process while engaging stakeholders about the necessity to obtain greater value in health care. Rother built on this idea by encouraging trust building among stakeholders through transparency. Considering the differing perspectives on value, he also asserted the importance of providing opportunities for feedback and incorporating these viewpoints into the reform process. He suggested that engaging these stakeholdersóincluding, importantly, public consumersóin the short-term in this manner will likely yield substantive long-term gains.

Long-term Investments

Focusing on long-term opportunities, Nussbaum identified payment reform as a cornerstone to re-organizing the current health system. He discussed the necessary innovations to incentive improved outcomes rather than volume of services. Nussbaum also specifically cited the need to utilize payment restrictions to address the overuse of unnecessary services, such as the 20 to 50 percent of duplicative or unnecessary imaging studies that costs billions of dollars (Americaís Health Insurance Plans, 2008). He described payment for bundles of services as a potential method for reducing unnecessary services while refocusing clinical care on improving quality and outcomes.

The panel also discussed reorganizing care delivery systems to facilitate chronic disease management that will enable progressive quality improvement beyond current standards. Referencing Arnold Milsteinís discussion of

medical home runs during this workshop, Nussbaum spoke of the importance of emphasizing care coordination, and its potential for preventing hospitalizations and cost savings. Identifying missed opportunities for prevention and improving the delivery of these preventive services could also yield significant savings by emphasizing wellness and preventing costly disease complications.

As a final point, Rother raised the specter of funding these investments. Offering the possibility of joint public-private ventures, he encouraged an honest assessment of feasible and sustainable sources of financing. He stated that identifying these sources and investing in the tools discussed during this workshop will be necessary to realizing the long-term savings and improved clinical outcomes achievable through their implementation.

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8

Common Themes and Opportunities for Action

INTRODUCTION

The general themes, insights, and possible activities presented in this chapter and throughout this report are drawn from the presentations, observations, and suggestions coursing through workshop discussions. They are intended to complement the content of the individual presentations, which represent the core material of the published workshop summary. This material does not constitute findings or recommendations, and serves only to inform Roundtable discussions and possible collaborative activity among members and their sectoral colleagues. Since this is an "open source" process, additional suggestions and observations are welcome and encouraged as Roundtable members identify which, among the many compelling issues, are best suited to their capacities.

COMMON THEMES

A number of common themes emerged during workshop discussions. These converging ideas explored the urgency to obtain greater value from our investments in health care, the ideas and actions that need to be considered as stakeholders pursue the value proposition, the diversity of perspectives on value, and the possibility of implementation and change (Box 8-1). The themes focusing on the exigency and facets of value include the following:

- **Urgency:** *The urgency to achieve greater value from health care is clear and compelling.* The persistent growth in healthcare costs at

BOX 8-1
Value in Health Care: Common Themes

- **Urgency:** *The urgency to achieve greater value from health care is clear and compelling.*
- **Perceptions:** *Value means different things to different stakeholders, so clarity of concepts is key.*
- **Elements:** *Identifying value in health care is more than simply the right care for the right price.*
- **Basics:** *Improving value requires reliable information, sound decision principles, and appropriate incentives.*
- **Decisions:** *Sound decision principles center on the patient, evidence, context, transparency, and learning.*
- **Information:** *Information reliability derives from its sources, methods, transparency, interpretation, and clarity.*
- **Incentives:** *Appropriate incentives direct attention and rewards to outcomes, quality, and cost.*
- **Limits:** *The ability to attain system value is likely inversely related to the level of system fragmentation.*
- **Communication:** *System-level value improvement requires more seamless communication among components.*
- **Providers:** *Provider-level value improvement efforts depend on culture and rewards focused on outcomes.*
- **Patients:** *Patient-level value improvement stems from quality, communication, information, and transparency.*
- **Manufacturers:** *Manufacturer-level regulatory and purchasing incentives can be better oriented to value added.*
- **Tools:** *Continually improving value requires better tools to assess both costs and benefits in health care.*
- **Opportunities:** *Health system reform is essential to improve value returned, but steps can be taken now.*

a rate greater than inflation is squeezing out employer healthcare coverage, adding to the uninsured, and doubling out-of-pocket payments—all without producing commensurate health improvements. We have heard that perhaps one-third to one-half of health expenditures are unnecessary for targeted health outcomes. The long-term consequences for federal budget obligations driven by the growth in Medicare costs have been described as nearly unfathomable, amounting to an estimated $34 trillion in unfunded obligations, about two-thirds of the total of $53 trillion as yet unfunded

for all mandatory federal entitlements (including Social Security and other civilian and military benefits).

- **Perceptions:** *Value means different things to different stakeholders, so clarity of concepts is key.* We have heard that for patients, perceived value in health care is often described in terms of the quality of their relationship with their physician. It has been highlighted that value improvement means helping them better meet their personal goals or living lives that are as normal as possible. It does *not* necessarily mean more services or more expensive services, since it was stated patients are more likely driven by sensitivity to the value of time and ensuring that out-of-pocket payments are targeted to their goals. Provider representatives suggest that value improvement means developing diagnostic and treatment tools and approaches that offer them increased confidence in the effectiveness of the services they offer. Employers discuss value improvement in terms of keeping workers and their families healthier and more productive at lower costs. Health insurers assert that value improvement means emphasizing interventions that are crisply and coherently defined and supported by a high level of evidence as to effectiveness and efficiency. Representatives from health product innovators and manufacturers have spoken of value improvement as products that are better for the individual patient, are more profitable, and contribute to product differentiation and innovation.
- **Elements:** *Identifying value in health care is more than simply the right care for the right price as it requires determination of the additional elements of the applicability and circumstances of the benefits considered.* We have heard that value in any endeavor is a reflection of what we gain relative to what we put in, and in health care, what is gained from any given diagnostic or treatment intervention will vary by individual. Participants believe that value determination begins with learning the benefits—what works best, for whom, and under what circumstances—as applied to individuals because value is not inherent to any service but rather specific to the individual. Value determination also means determining the right price, and we heard that, from the demand side, the right price is a function of perspective—societal, payer, and patient. From the supply side, the right price is a function of the cost of production, the cost of delivery, and the incentive to innovation.
- **Basics:** *Improving value requires reliable information, sound decision principles, and appropriate incentives.* Since the starting point for determining value is reliable information, workshop discussants underscored the importance of appropriate investment in the infrastructure and processes for initial determination and continu-

ous improvement of insights on the safety, efficacy, effectiveness, and comparative effectiveness of interventions. Action to improve value, then, also requires the fashioning and use of sound decision principles tailored to the circumstances and adequate incentives to promote the desired outcome.

- **Decisions:** *Sound decision principles center on the patient, evidence, context, transparency, and learning.* Currently, decision rules seem to many stakeholders to be vague and poorly tailored to the evidence. Workshop participants contended that the starting point for tailoring decisions to circumstances is with information on costs, outcomes, and strength of the information. They also discussed assessing value at the societal level using best available information and analytics to generate broad perspective and guidance for decision making on availability, use, and pricing. Yet we also heard that value assessment at the individual patient level takes account of context and patient preferences, conditioned on openness of information exchange and formal learning from choices made under uncertainty. We also heard that an informed patient perspective that trumps a societal value determination can still be consistent with sound decision principles.
- **Information:** *Information reliability derives from its sources, methods, transparency, interpretation, and clarity.* We have heard about the importance of openness on the nature, strengths, and limitations of the evidence and the processes of analysis and interpretation—and of tailoring decision principles according to the features in that respect. 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 are paramount.
- **Incentives:** *Appropriate incentives direct attention and rewards to outcomes, quality, and cost.* Often noted in the workshop discussions was that the rewards and incentives prevalent in the American healthcare system are poorly aligned—and even oppositional—to effectiveness and efficiency, encouraging care that is procedure- and specialty-intensive and discouraging primary care and prevention. We heard that if emphases are placed on individual services that are often high cost and inadequately justified, rather than on outcomes, quality, and efficiency, the attainment of system-wide value is virtually precluded.
- **Limits:** *The ability to attain system value is likely inversely related to the level of system fragmentation.* Transforming health care to a more direct focus on value is frequently noted as an effort that requires broad organizational, financial, and cultural changes—changes ultimately not attainable with the level of fragmentation

that currently characterizes decision making in the U.S. healthcare system. 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:** *System-level value improvement requires more seamless communication among components*. Related to system fragmentation, among the primary barriers to achieving better value are the communication gaps noted among virtually all parties involved. Patients and providers do not communicate well with each other about diagnosis and treatment options or cost implications, in part because in complex administrative and rapidly changing knowledge environments, the necessary information is not readily available to either party. Communication, voice or electronic, is often virtually absent between and among multiple providers and provider systems 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. Accordingly, communication between the many groups involved in developing evidence and the practitioners applying it is often unstructured and may be conflicting.

The diversity of stakeholder perspectives on value was highlighted from multiple vantage points.

- **Providers:** *Provider-level value improvement efforts depend on culture and rewards focused on outcomes*. Workshop presentations identified several examples of some encouraging results from various programs in terms of progress to improve provider sensitivity to, and focus on, value from health care. These range from improving the analytic tools to evaluate the effectiveness and efficiency of individual providers, institutions, and interventions, to incentive programs such as pay-for-performance, the patient-centered medical home, and employer-based programs for wellness, disease prevention, and disease management. We heard, for example, that certain provider organizations, in effect, specialize in the care of the poorest and sickest patients and can provide services that in

fact have better outcomes and lower costs because they are geared to focus on interprovider communication, continuity of care, and links with social welfare organizations. However, they have also negotiated the necessary flexibility with payers. 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 (both an analytic and a structural issue) 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:** *Patient-level value improvement stems from quality, communication, information, and transparency.* It was noted that patients most often think of value in terms of their relationship with their provider—generally a physician—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—individual diagnostics and treatments, providers, or health plans—according to the evidence of the value delivered. Successful broad-based application of such approaches will likely hinge on system-wide transformation in the availability of the information necessary and transparency as to its use.
- **Manufacturers:** *Manufacturer-level regulatory and purchasing incentives can be better oriented to value added.* Health product manufacturers and innovators naturally focus on their profitability—returning value to shareholders—but we are reminded that product demand is embedded in the ability to demonstrate advantage with respect to patient value—better outcomes with greater efficiency. Hence, manufacturers expressed an interest in exploring regulatory and payment approaches that enhance performance on outcomes related to product use.

The possibility of change, including the tools and opportunities needed to capitalize on the possibilities, is also a continual theme throughout the report.

- **Tools:** *Continually improving value requires better tools to assess both costs and benefits in health care.* Despite the broad agreement on the need to get better value from all the elements of the healthcare process and the commitment to make this a priority, we heard that the analytical tools and capacity to evaluate both of the

basic elements of value—outcomes and costs—in either absolute or comparative terms are substantially underdeveloped and will need greater attention.

- **Opportunities:** *Health system reform is essential to improve value returned, but steps can be taken now.* 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. Some are noted below.

LOOKING AHEAD TOWARD NEXT STEPS

Much of the discussion at the workshop played to the notion that full attainment of the value needed from the U.S. healthcare system was dependent on broad financing reform that ensured health insurance coverage for all who need it; yielded greater consistency and rationale in the governance, operating, and payment principles of public and private health insurers; and insulated care and value decisions from inefficient political influence. These are all important and fundamental considerations, but outside the scope of the meeting.

Nonetheless, the meeting's discussions identified a number of promising suggestions for ways to facilitate attainment of greater value for our healthcare dollars, including the following issues as particular possibilities for the further attention and action of the members of the Roundtable on Value & Science-Driven Health Care.

System-Level Efforts

Health information technology Since promoting health information technology was the most commonly mentioned priority as a prerequisite for sustained progress toward greater value in health care (improving quality, monitoring outcomes, clinical decision assistance, developing evidence, tracking costs, streamlining paperwork, improving coordination, facilitating patient engagement), how might Roundtable members and the Electronic Health Record Innovation Collaborative help accelerate its adoption and use?

Transparency as to cost, quality, and outcomes What efforts by the various sectors represented by Roundtable members—patients, providers, healthcare delivery organizations, insurers, employers, manufacturers, regulators, the information technology sector, and researchers—might help bring about the true transparency necessary to sharpen the focus on the key elements of the value equation?

Life-cycle evidence development for interventions How might Roundtable professional societies, manufacturers, insurers, and regulators help transform the process of monitoring the value achieved from various interventions from what amounts to a snapshot in time to an ongoing capacity?

Payer-Level Efforts

Coverage with evidence development If coverage with evidence development amounts to a beta-test of the learning healthcare system's concept of real-time evidence generation from clinical practice, what vehicle might facilitate development of the decision rules needed to determine the interventions most appropriate for structured introduction, the criteria for expansion, and the approaches to ongoing monitoring?

Value-based insurance design How might the conditions be identified that may be best suited to further testing the notion of adjusting payments to the level of evidence in support of the effectiveness and efficiency of a particular approach?

Outcome-focused bundled payment approaches What means might best be considered to identify conditions and services most amenable as bundled components in payment-for-outcomes approaches?

Provider-Level Efforts

Identification of high-value services Might the members of the Roundtable's Best Practices Innovation Collaborative consider criteria for identifying high-value services in their respective arenas, as well as innovative approaches to their delivery?

Care organization incentives What issues and incentives are needed to expand the development of a medical home model most conducive to more efficient and better-coordinated care?

Clustered care for the very sick If, as was presented, there are demonstrated effectiveness and efficiency advantages from certain organizations specializing in the care of the poor and very sick, how can that model of heroism be taken to scale?

Incentives for triage and coordination functions Because the ancillary services of triage, care coordination, and follow-up are so key to improving outcomes and reducing costs, what can be done to introduce them as a routine into the culture of care?

Decision assistance at point of choice With growing awareness of the challenges to providers of keeping up with changes in the knowledge base, what might the Roundtable do to explore expanded decision assistance at the point of choice?

Appropriateness score for five important diseases Since five conditions—heart disease, cancer, stroke, diabetes, and chronic lung disease—account for three-fourths of health expenditures, can an appropriateness of care score be developed and applied for their management?

Patient-Level Efforts

"Push" strategies for patient-provider communication on value Since it is both necessary and inevitable that patients and providers become stronger partners in the care process, what strategies might be most effective in achieving that result?

Structured information-sharing on high-value services How might insights and information generated on services identified as high value be disseminated most effectively to help inform and motivate patients?

Value-based payment or reimbursement structures How might better information be developed for tailoring payment for care to the likely value of the outcome, and once available, what strategies will be most effective in developing the information and incentives necessary for its promotion?

Manufacturer-Level Efforts

Purchasing models focused on outcomes Since it was proposed by a representative of the manufacturing sector that consideration be given to the development of product purchase models that focus on actual outcomes (i.e., results achieved), how might such an approach best be developed and tested?

Value-engaged regulatory approval processes What approaches might make it easier for manufacturers, payers, and the Food and Drug Administration to engage earlier in the testing and approval process around value issues relevant to a product's ultimate approval and use?

Research Analytics and Information Mobilization

High-value service gaps Because some high-value services—for example, certain preventive services—are underutilized, what criteria might be used

to develop an inventory of the top 10 services for which the gaps between evidence in-hand and delivery patterns are most substantial?

High-cost service evidence Similarly how might an inventory be developed of the top 10 high-cost services for which comparative effectiveness studies need to be done?

Capacity for comparative effectiveness research What additional issues need to be engaged to improve prospects for the successful development of a deeper national capacity for comparative effectiveness research?

Analytics for value assessment What are the most important analytical challenges to assessing value and how might they best be engaged, especially with healthcare costs reaching near crisis levels in the context of a weak economy?

Appendixes

Appendix A

Workshop Agenda

VALUE IN HEALTH CARE
Accounting for Cost, Quality, Safety, Outcomes, and Innovation

A LEARNING HEALTHCARE SYSTEM WORKSHOP
IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

NOVEMBER 17-18, 2008
LECTURE ROOM, NATIONAL ACADEMY OF SCIENCES
WASHINGTON, DC 20001

Issues motivating the discussion

1. Healthcare costs comprise an increasing percentage of both U.S. gross domestic product and federal spending, crowding out other spending priorities, and are often cited as a threat to the competitiveness of U.S. companies.
2. Health outcomes on many key measures in the United States lag behind those achieved in other countries with significantly lower healthcare costs.
3. Both for uninsured and for underinsured, cost is a prominent factor in reducing access to care and increasing disparities in health outcomes.
4. Concerns exist about patient safety and quality of care, and the many examples of both over- and underutilization of medical treat-

ments and technologies, relative to the evidence of their effectiveness, raise basic questions about the orientation and incentives of healthcare training, financing, and delivery.

5. An aging population with a higher prevalence of chronic diseases, and of many patients with multiple conditions, is a complicating but not determining factor in the trend to higher costs of care.
6. Emerging as a challenge is the use of high-cost technologies and provider services (e.g., certain diagnostic imaging, medical devices, pharmaceuticals, elective procedures) that may yield marginal enhancement of outcome or are targeted to the benefit of only a small set of patients.
7. A single agreed-upon measure of value is not available.
8. A comprehensive, coordinated system-wide approach to assess and improve the value of health care does not exist in the U.S. healthcare system.

Goals: Provide a forum for discussion of stakeholder perspectives on measuring and improving value in health care, and identify the key barriers, opportunities, and suggested next steps.

DAY ONE

8:30 WELCOME AND INTRODUCTIONS
Denis A. Cortese, Mayo Clinic & Chair, IOM Roundtable on Value & Science-Driven Health Care

8:45 KEYNOTE: THE NEED TO IMPROVE VALUE IN HEALTH CARE
What are the key challenges facing the U.S. healthcare system in terms of costs, performance, and value? What are the implications of U.S. healthcare costs for the economic crisis, the nation's ability to recover, and the welfare of the American people?
David M. Walker, Peter G. Peterson Foundation

9:30 SESSION 1: PERSPECTIVES ON VALUE
To provide context for the workshop discussions, this session will focus on reviewing how the concept of value is viewed from different sectoral perspectives.
Chair: J. Michael McGinnis, Institute of Medicine

- **September 2008 Roundtable Panel Summary**
- **Reactor panel**
  Helen Darling (National Business Group on Health), Bruce Ferguson (East Carolina Heart Institute), Jean-Paul Gagnon

(sanofi-aventis), Paul Ginsburg (Center for Studying Health System Change), Gail Griffith (FDA patient representative), Murray Ross (Kaiser Permanente)

DISCUSSION

[Break 10:30 to 10:45]

10:45 SESSION 2: APPROACHES TO ASSESSING VALUE – ILLUSTRATIVE EXAMPLES

Session 2 will feature presentations on the approaches taken to assessing value in various contexts. Speakers will highlight the analytic approaches and tools that are used to characterize and measure value—e.g., outcome measures, cost measures, time horizons, their use, limitations and needed refinements.
Chair: Ezekiel J. Emanuel, National Institutes of Health

- **Physician evaluation and management services**
  L. Gregory Pawlson, NCQA
- **Surgery and other procedures**
  Justin B. Dimick, University of Michigan
- **Imaging technologies**
  Howard P. Forman, Yale University

REACTOR PANEL
Dan Campion (Outcome Sciences), Martha Sylvia (Johns Hopkins), Philip Wang (National Institute of Mental Health)

DISCUSSION

12:30 LUNCH PRESENTATION: PERSPECTIVES ON VALUE FROM THE UNITED KINGDOM
Sir Michael Rawlins, National Institute for Clinical Excellence, United Kingdom

1:45 SESSION 2 (CONTINUED)

- **Preventive services/wellness**
  David O. Meltzer, University of Chicago
- **Pharmaceuticals/biologicals**
  Newell E. McElwee, Pfizer, Inc.
- **Personalized diagnostics**
  Ronald E. Aubert, Medco Health Solutions, Inc.

- **Devices**
  Parashar B. Patel, Boston Scientific Corp.

REACTOR PANEL
Elise Berliner (Agency for Healthcare Research and Quality), Steve Phurrough (Centers for Medicare & Medicaid Services), Paul Rudolf (Arnold & Porter, LLP)

DISCUSSION

[Break 3:45 to 4:00]

4:00 **SESSION 3: APPROACHES TO IMPROVING VALUE – CONSUMER INCENTIVES**
Sessions 3, 4, and 5 will present specific examples of current approaches to improve value in health care in three main areas. Each session will explore the nature of the efforts, and the best practices and results to date. Speakers will particularly focus on the evidence of impact and the future potential to improve value with each approach. The first session will focus on the use of a variety of consumer-oriented strategies to promote value. Each presentation will be followed by a reactor.
Chair: Michael E. Chernew, Harvard University

- **Consumer-directed/high-deductible health plans**
  Melinda J. Beeuwkes Buntin, RAND
- **Value-based insurance design**
  A. Mark Fendrick, University of Michigan
- **Tiering**
  Dennis P. Scanlon, Pennsylvania State University
- **Wellness**
  Ronald Z. Goetzel, Emory University

DISCUSSION
Initial post-presentation responses:
- *Francois Sainfort (University of Minnesota School of Public Health)—Consumer-directed health plans*
- *Kavita Patel (United States Senate)—Value-based insurance design*
- *Caroline Rossi Steinberg (American Hospital Association)—Tiering*
- *Seth Serxner (Mercer)—Wellness*

5:45 RECEPTION

DAY TWO

8:30 WELCOME AND RECAP OF THE FIRST DAY
Denis A. Cortese, Mayo Clinic & Chair, IOM Roundtable on Value & Science-Driven Health Care

9:00 SESSION 4: APPROACHES TO IMPROVING VALUE – PROVIDER AND MANUFACTURER PAYMENTS
Continuing from Session 3, this session will explore examples of approaches to improve value in health care, with a focus on the use of payment design and coverage and reimbursement policy to improve value. The first two presentations will each be followed by a reactor.
Chair: Samuel R. Nussbaum, Wellpoint, Inc.

- **Pay-for-performance**
  Carolyn M. Clancy, Agency for Healthcare Research and Quality & Roundtable Member
- **Coverage and reimbursement decisions**
  Steven D. Pearson, Institute for Clinical and Economic Review
- **Incentives for product innovation**
  Donald A. Sawyer, AstraZeneca
  Reed V. Tuckson, UnitedHealth Group

DISCUSSION
Initial post-presentation responses:
- ***Robert Galvin (General Electric)—Pay-for-performance***
- ***Amy Miller (Personalized Medicine Coalition)—Coverage***

[Break 10:45 to 11:00]

11:00 SESSION 5: APPROACHES TO IMPROVING VALUE – ORGANIZATION AND STRUCTURE OF CARE
Continuing from Sessions 3 and 4, the final session on approaches to improving value will focus on changing the organization and structure of care to improve value. Each presentation will be followed by a reactor.
Chair: John C. Rother, AARP & Roundtable Member

- **Electronic health records**
  Douglas Johnston, Center for IT Leadership
- **Patient-centered medical home**
  Arnold S. Milstein, Pacific Business Group on Health

- **Disease management**
  Tracey A. Moorhead, DMAA: The Care Continuum Alliance

DISCUSSION
Initial post-presentation responses:
- *Ronald Paulus (Geisinger Health System)—EHRs*
- *Sarah Scholle (National Committee for Quality Assurance)—Medical home*
- *Linda Magno (Centers for Medicare & Medicaid Services)—Disease management*

[Lunch 12:30 to 1:30]

1:30 SESSION 6: ALIGNING THE SYSTEM TO PROMOTE VALUE – NOW AND IN THE FUTURE
How could the health system be better aligned to promote value in all aspects of health care, both now and in the future?
Chair: Karen L. Smith, AstraZeneca

- **On the horizon**
  Christine K. Cassel, American Board of Internal Medicine
- **Panel discussion**
  Ezekiel J. Emanuel, National Institutes of Health
  Samuel R. Nussbaum, Wellpoint, Inc.
  John C. Rother, AARP & Roundtable Member

  - Near term/quick hits
  - Long term
  - Political considerations

DISCUSSION

3:30 CONCLUDING SUMMARY, REMARKS, AND ADJOURNMENT
J. Michael McGinnis, Institute of Medicine

PLANNING COMMITTEE

Michael E. Chernew, Harvard Medical School
John C. Rother, AARP
Ezekiel J. Emanuel, National Institutes of Health
Arthur Garson, Jr., University of Virginia School of Medicine
Karen L. Smith, AstraZeneca
Samuel R. Nussbaum, Wellpoint

Appendix B

Biographical Sketches of Workshop Participants

Ronald E. Aubert, Ph.D., M.S.P.H., is currently vice president of Clinical Analytics and Outcomes Research (CAOR), at Medco Health Solutions, Inc. His responsibilities include directing and implementation of outcome research studies, managing client and product support and reporting, and providing consultation to internal and external clients. Areas of focus for CAOR include analyses to identify pharmacogenomic opportunities and evaluate the impact of pharmacogenomic testing on clinical outcomes, the impact of plan design changes on drug utilization, health disparities in medication adherence, and integrated medical and pharmacy claims studies to monitor quality of care indicators for external clients. CAOR supports the development and evaluation of new products such as Specialty Pharmacy, Medicare Part-D pharmacy benefit, and clinical safety products. Prior to coming to Medco Health, Dr. Aubert was a senior health care analyst at U.S. Quality Algorithms (USQA) Center for Health Care Research where he was principal investigator on randomized trials evaluating the effectiveness of nurse case management and a study evaluating screening and case management in high-risk Medicare enrollees. He was chief of the Epidemiology Section, Division of Diabetes Translation at the Centers for Disease Control and Prevention (CDC). Dr. Aubert received a B.A. from Oberlin College and an M.S.P.H. and a Ph.D. from the University of North Carolina at Chapel Hill, and he completed the Epidemic Intelligence Service fellowship at the CDC. He holds or has held the following appointments: faculty at the University of Medicine and Dentistry of New Jersey, Emory University School of Medicine, the Medical College of Georgia and Morehouse School of Medicine, the National Advisory Committee for the Robert Wood

Johnson Foundation Improving Chronic Illness Care Initiative, and chairman of the Robert Wood Johnson Foundation National Diabetes Initiative advisory committee.

Howard B. Beckman, M.D., is medical director of the Rochester Individual Practice Association (RIPA)—a 3,200-practitioner community-wide physician organization—which has contracted both for capitated care and consulting services since 1998. Dr. Beckman is also a clinical professor of medicine and family medicine at the University of Rochester School of Medicine and Dentistry, where he conducts health services research and maintains a small internal medicine and geriatrics practice. Dr. Beckman received his undergraduate degree from Brandeis University and his M.D. from the Wayne State University School of Medicine. His primary administrative and research interests are creating and evaluating effective partnerships. Dr. Beckman served as a co-investigator for the Excellus/RIPA Robert Wood Johnson Rewarding Results grant. This work led to publications under his co-authorship that address the effects of pay-for-performance on reducing overuse, underuse, and misuse of services. Recently published work in the *Journal of Healthcare Management*, for example, demonstrated a positive return-on-investment for the pay-for-performance initiative and improved quality measures in treating diabetes and coronary disease.

Melinda Beeuwkes Buntin, Ph.D., is a senior health economist at RAND, deputy director of RAND Health's Economics, Financing, and Organization Program, and director of Public Sector Initiatives for RAND Health. She specializes in insurance benefit design, health insurance markets, provider payment, and the care use and needs of the elderly. Her current projects include a study of the effects of consumer-directed health care on healthcare access, costs, and quality involving more than 40 employers offering consumer-directed plans; an assessment of national policy reform options involving extensive literature reviews and a microsimulation model; and an National Institute of Aging (NIA)-funded study of the effects of Medicare payment changes on post-acute care costs and outcomes. Dr. Buntin is also currently leading a study for Assistant Secretary for Planning and Evaluation of the determinants of increases in Medicare spending for physicians' services. She was principal investigator (PI) on RAND's recently completed project to monitor the effects of Medicare's new inpatient rehabilitation facility prospective payment system and to refine that payment system. Her work on that project included developing an access-to-care monitoring system for Medicare post-acute care, focusing on the effects of the inpatient rehabilitation prospective payment system. Dr. Buntin also completed work for the Medicare Payment Advisory Committee (MedPAC) on the costs and outcomes of PAC for lower-extremity joint replacement patients. She has

also worked on projects and published in the areas of disease management, the market for individual health insurance policies, Medicare physician payment rates, the financing of end-of-life care, and Medicare managed care plan design and payment. She graduated from the Ph.D. program in health policy at Harvard University, where she concentrated in health economics and specialized in the economics of the Medicare program. Her dissertation was entitled "Risk Selection in the Medicare Program" and included chapters on techniques for modeling healthcare costs, the effect of benefit packages on risk selection among Medicare+Choice Plans, and the costs of Medicare beneficiaries at the end of life.

Troyen Brennan, M.D., J.D., M.P.H., is Executive Vice President and Chief Medical Officer of CVS Caremark. In this role, Dr. Brennan directs CVS Caremarkís clinical affairs and oversees strategy development. Prior to joining CVS Caremark, Dr. Brennan was Chief Medical Officer of Aetna Inc. From 2000 to 2005, Dr. Brennan served as President and CEO of Brigham and Women's Physician's Organization. In his academic work, he was Professor of Medicine at Harvard Medical School, and Professor of Law and Public Health at Harvard School of Public Health. Dr. Brennan received his M.D. and M.P.H. degrees from Yale Medical School and his J.D. degree from Yale Law School. He completed his internship and residency in internal medicine at Massachusetts General Hospital. He is a member of the Institute of Medicine of the National Academy of Sciences.

Christine K. Cassel, M.D., is president and chief executive officer (CEO) of the American Board of Internal Medicine (ABIM) and the ABIM Foundation, and a leading expert in geriatric medicine, medical ethics, and quality of care. Dr. Cassel, board certified in both internal medicine and geriatric medicine, has achieved a number of firsts for women in medicine—she was the first female board chair of ABIM from 1995 to 1996, the first female president of the American College of Physicians from 1996 to 1997, and the first female dean of Oregon Health & Science University in Portland in 2002. An active scholar and lecturer, she is the author or coauthor of 14 books and more than 150 journal articles on geriatric medicine, aging, bioethics, and health policy. She chaired influential Institute of Medicine (IOM) reports on end-of-life care and public health. Her most recent book is *Medicare Matters: What Geriatric Medicine Can Teach American Health Care*. Dr. Cassel is a representative to the National Quality Forum's National Priorities Partnership, a member of the Commonwealth Fund's Commission on a High Performance Health System, and the IOM Governing Council. She also sits on the board of directors of the Greenwall Foundation, Kaiser Permanente, Premier, Inc., and other organizations with quality healthcare agendas. She was appointed by President Clinton

to serve on the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry and has been central to other national leadership efforts to inspire quality of care. Dr. Cassel has served as the president of the American Federation for Aging Research, dean of the School of Medicine and vice president for medical affairs at Oregon Health & Science University, and chair of the Department of Geriatrics and Adult Development at Mount Sinai School of Medicine in New York, where she was also professor of geriatrics and medicine. She spent a decade at the University of Chicago Pritzker School of Medicine, as chief of General Internal Medicine and a founding health policy director of the Harris School of Public Policy. Dr. Cassel received her bachelor's degree from the University of Chicago and her medical degree from the University of Massachusetts Medical School. She is the recipient of numerous honorary degrees and is an honorary fellow of the Royal Colleges of Medicine of the United Kingdom and Canada and the European Federation of Internal Medicine, and she was elected a master of the American College of Physicians in 1997.

Michael E. Chernew, Ph.D., is a professor in the Department of Health Care Policy at Harvard Medical School. One major area of his research focuses on assessing the impact of managed care on the healthcare marketplace, with an emphasis on examining the impact of managed care on healthcare cost growth and on the use of medical technology. Other research has examined determinants of patient choice of hospital and the impact of health plan performance measures on employee and employer selection of health plans. Dr. Chernew is a member of the Commonwealth Foundation's Commission on a High Performance Health Care System. In 2000 and 2004, he served on technical advisory panels for the Centers for Medicare and Medicaid Services (CMS) that reviewed the assumptions used by Medicare actuaries to assess the financial status of Medicare trust funds. 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. Dr. Chernew is a research associate of the National Bureau of Economic Research and is on the editorial boards of *Health Affairs* and *Medical Care Research and Review*. He is also coeditor of the *American Journal of Managed Care* and senior associate editor of *Health Services Research*. Dr. Chernew received an A.B. from the University of Pennsylvania College of Arts and Sciences, a B.S. from the University of Pennsylvania Wharton School (economics), and a Ph.D. in economics from Stanford University, where his training focused on areas of applied microeconomics and econometrics.

Carolyn M. Clancy, M.D., is director of the Agency for Healthcare Research and Quality (AHRQ). Prior to 2002 she was Director of AHRQ's Center for Outcomes and Effectiveness Research (COER). Dr. Clancy, a general internist and health services researcher, is a graduate of Boston College and the University of Massachusetts Medical School. Following clinical training in internal medicine, Dr. Clancy was a Henry J. Kaiser Family Foundation fellow at the University of Pennsylvania. She was also an assistant professor in the Department of Internal Medicine at the Medical College of Virginia in Richmond before joining AHRQ in 1990. Dr. Clancy holds an academic appointment at George Washington University School of Medicine (clinical associate professor, Department of Medicine), is the senior associate editor of *Health Services Research*, and serves on multiple editorial boards (currently, *Annals of Family Medicine*, *American Journal of Medical Quality*, and *Medical Care Research and Review*). She has published widely in peer-reviewed journals and has edited or contributed to seven books. She is a member of the Institute of Medicine and was elected a master of the American College of Physicians in 2004.

Sabrina Corlette, J.D., is the director of Health Policy Programs at the National Partnership for Women & Families. As such, Ms. Corlette leads the organization's efforts to promote access to quality, affordable health care. Before joining the National Partnership, Ms. Corlette was an attorney with the law firm of Hogan & Hartson, LLP, advising clients on health care issues relating to Medicare, Medicaid, health information technology, health privacy, and medical research laws and policies. Prior to joining Hogan & Hartson, Ms. Corlette served on the U.S. Senate Health, Education, Labor and Pensions Committee. There, she served as senior health policy adviser to Senator Tom Harkin, providing guidance on short- and long-term legislative strategy, drafting legislation, and building and maintaining coalitions on health care issues. Before her tenure on Capitol Hill, Ms. Corlette served as a research assistant and speechwriter to First Lady Hillary Rodham Clinton. Ms. Corlette received her law degree with high honors from the University of Texas at Austin and her Bachelor of Arts, cum laude, from Harvard University. Before law school, she spent a year in Nairobi, Kenya, assisting with efforts at the United States International University to develop an HIV/AIDS prevention program.

Denis A. Cortese, M.D., is president and CEO of Mayo Clinic and chair of the Executive Committee. He has been a member of the Board of Trustees since 1997 and previously served on that board from 1990 to 1993. Following service in the U.S. Naval Corps, he joined the staff of Mayo Clinic in Rochester, Minnesota, in 1976 as a specialist in pulmonary medicine. He was a member of the Board of Governors in Rochester before moving to

Mayo Clinic in Jacksonville, Florida, in 1993. From 1999 to 2002 he served as chair of the Board of Governors at Mayo Clinic and chair of the Board of Directors at St. Luke's Hospital in Jacksonville, Florida. He is a director and former president of the International Photodynamic Association and has been involved in the bronchoscopic detection, localization, and treatment of early-stage lung cancer. He is a member of the Healthcare Leadership Council and the Harvard-Kennedy School Healthcare Policy Group, and is a former member of the Center for Corporate Innovation. He served on the Steering Committee for the RAND Information Therapy (Ix) Project Using Information Technology to Create a New Future in Healthcare, and the Principals Committee of the National Innovation Initiative. He also is a charter member of the Advisory Board of World Community Grid and a founding member of the American Medical Group Association Chairs/Presidents/CEOs Council. Dr. Cortese is a graduate of Temple University, completed his residency at the Mayo Graduate School of Medicine, and is a professor of medicine in Mayo Clinic College of Medicine. Dr. Cortese is a member of the Institute of Medicine, a fellow of the Royal College of Physicians in England, and an honorary member of the Academia Nacional de Mexicana (Mexico).

Helen B. Darling, M.A., is president of the National Business Group on Health (formerly the Washington Business Group on Health). Ms. Darling also currently serves as co-chair of the Committee on Performance Measurement of the National Committee on Quality Assurance. She is a member of: the Medical Advisory Panel, Technology Evaluation Center, run by the Blue Cross Blue Shield Association; the Institute of Medicine's Board on Health Promotion and Disease Prevention; the Cancer Care Measures Steering Committee of the National Quality Forum; the Board of the VHA Health Foundation, along with a number of other advisory and editorial boards. From 1992 through 1998, Ms. Darling directed the purchasing of health benefits and disability for the Xerox Corporation, and was previously a principal at William W. Mercer. Earlier in her career, Ms. Darling was an adviser to Senator David Durenberger, the ranking Republican on the Health Subcommittee of the Senate Finance Committee. Ms. Darling received a master's degree in demography/sociology and a bachelor's of science degree in history/english, cum laude, from the University of Memphis.

Justin B. Dimick, M.D., M.P.H., is a graduate of Cornell University and Johns Hopkins Medical School; he completed his residency training in general surgery at the University of Michigan and joined the faculty as an assistant professor of surgery in 2007. During his training, he completed a fellowship in health services research and received his M.P.H. degree at Dartmouth. Dr. Dimick's research focuses on quality measurement and

improvement. His previous work elucidated the strengths and limitations of existing quality measures, particularly hospital volume and risk-adjusted mortality rates. With funding from AHRQ, his current research is focused on developing better measures of surgical performance. This work applies statistical methods that combine information from multiple quality domains to create composite measures of performance. He is a quality measurement consultant to the Leapfrog Group, a coalition of private payers. He also serves on the Measurement and Evaluation Committee of the American College of Surgeon's National Surgical Quality Improvement Program.

Ezekiel J. Emanuel, M.D., Ph.D., is chair of the Department of Clinical Bioethics at the Warren G. Magnuson Clinical Center at the National Institutes of Health (NIH). He is also a breast oncologist. After graduating from Amherst College, Dr. Emanuel received his M.Sc. degree in biochemistry from Oxford University. He received his M.D. degree from Harvard Medical School and his Ph.D. degree in political philosophy from Harvard University, receiving the Toppan Award for the finest political science dissertation of the year. From 1987 to 1988, Dr. Emanuel was a fellow in the Program in Ethics and the Professions at the Kennedy School of Government at Harvard. After completing his internship and residency in internal medicine at Boston's Beth Israel Hospital and his oncology fellowship at the Dana-Farber Cancer Institute (DFCI), he joined the DFCI faculty. He was associate professor at Harvard Medical School before joining the National Institutes of Health. Dr. Emanuel developed the Medical Directive, a comprehensive living will that has been endorsed by *Consumer Reports on Health*, *Harvard Health Letter*, the *New York Times*, the *Wall Street Journal*, and many other publications. He has published widely on the ethics of clinical research, healthcare reform, international research ethics, end-of-life care issues, euthanasia, the ethics of managed care, and the physician-patient relationship in the *New England Journal of Medicine*, *Lancet*, *JAMA*, and many other medical journals. Dr. Emanuel's book on medical ethics, *The Ends of Human Life: Medical Ethics in a Liberal Polity*, has been widely praised and received honorable mention for the Rosenhaupt Memorial Book Award by the Woodrow Wilson Foundation. He also has published *No Margin, No Mission: Health-Care Organizations and the Quest for Ethical Excellence* and coedited *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*. Dr. Emanuel has received numerous awards, including election to the Institute of Medicine and to the Association of American Physicians. *Hippocrates Magazine* selected him as Doctor of the Year in Ethics. He received the American Medical Association-Burroughs Wellcome Leadership Award and a Fulbright Scholarship (which he declined). Dr. Emanuel served on President Clinton's Health Care Task Force, the National Bioethics Advisory Commission, and the bioethics panel of the Pan American Health

Organization. He has been visiting professor at the University of Pittsburgh School of Medicine and the University of California, Los Angeles, and Brin Professor at Johns Hopkins Medical School.

A. Mark Fendrick, M.D., is a professor of internal medicine in the School of Medicine and a professor of health management and policy in the School of Public Health at the University of Michigan. Dr. Fendrick received a bachelor's degree in economics and chemistry from University of Pennsylvania and his medical degree from Harvard Medical School. Dr. Fendrick completed his residency in internal medicine at the University of Pennsylvania where he was a fellow in the Robert Wood Johnson Foundation Clinical Scholars Program. He is co-director of the Center for Value-Based Insurance Design at the University of Michigan. Dr. Fendrick's research focuses on the clinical and economic assessment of medical interventions with special attention to how technological innovation influences clinical practice and impacts healthcare systems. He has authored more than 200 articles and book chapters and lectures frequently on the health and cost implications of medical interventions to diverse audiences around the world. Dr. Fendrick remains clinically active in the practice of general internal medicine. He is the coeditor-in-chief of the *American Journal of Managed Care* and is an editorial board member for three additional peer-reviewed publications. His perspective and understanding of clinical and economic issues have fostered collaborations with numerous government agencies, health plans, professional societies, and healthcare companies. He serves on the Medicare Coverage Advisory Committee. Dr. Fendrick has served on the Board of Directors of the International Society for Technology Assessment in Health Care and the International Society for Pharmacoeconomics and Outcomes Research.

T. Bruce Ferguson Jr., M.D., is professor and chairman of the Department of Cardiovascular Sciences at the East Carolina Heart Institute and the Brody School of Medicine at ECU in Greenville, North Carolina. He is also the clinical chief of the Integrated Comprehensive Cardiovascular Service Line at the ECHI-PCMH. Dr. Ferguson graduated from Medical School at Washington University in St. Louis, Missouri, and finished his General and Cardiothoracic Surgery training at Duke University Medical Center under David C. Sabiston, Jr., M.D., in 1988. He then returned to Washington University where he achieved the rank of associate professor with tenure until 2006. He was subsequently professor of Surgery and Physiology in the Department of Surgery at LSUHSC in New Orleans until early 2006, when he was recruited by Dr. W. Randolph Chitwood to assist in the establishment of the East Carolina Heart Institute. In 2007, Dr. Ferguson became the inaugural chair of the completely integrated Department of Cardiovascular Sciences, which combined cardiovascular medicine, cardiothoracic surgery,

and vascular surgery into a single academic organizational structure, which is also mirrored by the organizational structure of the Integrated Service Line. Dr. Ferguson was chair of the STS Council on Quality, Research and Patient Safety for 6 years, and in this capacity was involved extensively with the STS National Databases. He was the PI on a 7-year grant addressing QI in CABG, funded by the Agency for Healthcare Research and Quality. He is currently chair of the Joint STS-AATS Workforce on Government Relations and Advocacy, a highly visible and volatile effort in the current era of Health Care Reform in the United States.

Howard P. Forman, M.D., M.B.A., is a health services researcher focusing on diagnostic radiology, health policy, and healthcare leadership. His most recent publications address teleradiology, international outsourcing, the incentives that medical students respond to in choosing a specialty, and ensuring quality in imaging services. Professor Forman teaches healthcare policy in the Yale School of Public Health and healthcare economics in the Yale College Economics Department. He is the faculty founder and director of the M.D.-M.B.A. program between Yale School of Medicine and Yale School of Management, as well as the co-director of the School of Management's M.B.A. for Executives Program. As a practicing cross-sectional and emergency-trauma radiologist, he is actively involved in patient care and issues related to financial administration, healthcare compliance, and contracting. He has worked in the U.S. Senate, as a health policy fellow, on Medicare legislation. He is the treasurer of the American Roentgen Ray Society.

Jean Paul Gagnon, Ph.D., is director of Public Policy at sanofi-aventis in Bridgewater, New Jersey. He received a B.S. in pharmacy, an M.S. in pharmacy administration from the University of Connecticut, and a Ph.D. in pharmacy administration from Ohio State University. He is a former professor and division head of Pharmacy Administration in the School of Pharmacy at the University of North Carolina and has worked for sanofi-aventis for 17 years. He has written more than 60 articles in peer-reviewed journals and has made presentations on a variety of issues including Medicare, Part D, Evidence-Based Medicine, and the effect of federal policy on the pharmaceutical industry and pharmacy practice. In 2002, he received the APhA Hugo H. Schaefer Award for outstanding volunteer contributions to the profession of pharmacy. In 1981-1982, he was a Robert Wood Johnson Health Policy Fellow in Washington, DC, and worked as a committee staff person on the Energy and Commerce's Subcommittee on Health. He was chairman of the Health Outcomes Committee of the Pharmaceutical Research Manufacturers of America (PhRMA) from 1997 until 2001, president of the American Association of Colleges of Pharmacy

for the 1985-1986 year, served as treasurer and a Board of Trustee member of the American Pharmaceutical Association from 1991 until 1997, served as president of the International Association of Pharmacoeconomics and Outcomes Research from 1996 until 1997 and was its treasurer from 1998 until 2004, and was a member of the Board of Trustees and treasurer for the U. S. Pharmacopeia from 1995 until 2005. In his present position, he is involved in public policy activities for sanofi-aventis. His interests include pharmacoeconomic and health outcomes research, the Medicare Prescription Drug Improvement and Modernization Act, importation of prescription drugs, health policy issues affecting prescription drugs, and the pharmaceutical industry.

Arthur (Tim) Garson, Jr., M.D., M.P.H., is provost of the University of Virginia in Charlottesville and former dean of the School of Medicine. He graduated (Phi Beta Kappa, summa cum laude) from Princeton University in 1970 and received his M.D. (Alpha Omega Alpha) from Duke University in 1974, remaining at Duke for pediatric residency through 1976. In 1979, he completed his pediatric cardiology fellowship at Baylor College of Medicine in Houston, becoming chief of pediatric cardiology in 1988. He has been a visiting professor in more than 100 institutions. He is the author of more than 450 publications, including 7 books. In 1992, he received a master's degree in public health from the University of Texas, Houston. Also in 1992, he joined the faculty at Duke University, becoming associate vice chancellor for health affairs, where he served as medical director of government relations for the Medical Center and professor in the Sanford Institute of Public Policy. He has served as special consultant in health programs and policy to the State of Texas Department of Health and the North Carolina Vocational Rehabilitation Commission. He chaired the North Carolina Health Planning Commission Committee charged with drafting legislation on practice guidelines, report cards, and malpractice reform.

Paul B. Ginsburg, Ph.D., is president of the Center for Studying Health System Change (HSC). Founded in 1995 by Dr. Ginsburg, HSC conducts research to inform policy makers and other audiences about changes in organization of financing and delivery of care and their effects on people. HSC is widely known for the objectivity and technical quality of its research and its success in communicating it to policy makers and the media, as well as to the research community. Ginsburg is particularly known for his understanding of health care markets and health care costs. In 2007, for the fifth time, Dr. Ginsburg was named by Modern Healthcare as one of the 100 most powerful persons in health care. Dr. Ginsburg served as the founding executive director of the predecessor to the Medicare Payment

Advisory Commission. Widely regarded as highly influential, the Commission developed the Medicare physician payment reform proposal that was enacted by the Congress in 1989. Dr. Ginsburg was a senior economist at RAND and served as deputy assistant director at the Congressional Budget Office. Before that, he served on the faculties of Duke University and Michigan State University. He earned his doctorate in economics from Harvard University.

Ronald Z. Goetzel, Ph.D., M.A., is both the director of the Emory University Institute for Health and Productivity Studies (IHPS) and the vice president of consulting and applied research for Thomson Reuters. The mission of the IHPS is to bridge the gap between academia, the business community, and the healthcare policy world—bringing academic resources into policy debates and day-to-day business decisions and bringing health and productivity management issues into academia. Before moving to Emory, Dr. Goetzel was at Cornell University. Dr. Goetzel is responsible for leading innovative research projects and consulting services for healthcare purchaser, managed care, government, and pharmaceutical clients interested in conducting cutting-edge research focused on the relationship between health and well-being and work-related productivity. He is a nationally recognized and widely published expert in health and productivity management (HPM), return-on-investment (ROI), program evaluation, and outcomes research. Before joining Thomson Reuters (formerly Medstat) in 1995, Dr. Goetzel was vice president of Assessment, Data Analysis and Evaluation Services at Johnson & Johnson Health Care Systems. Earlier in his career, Dr. Goetzel was the medical school education program evaluator at the Albert Einstein College of Medicine, where he was appointed to the psychiatry faculty. Dr. Goetzel earned his doctorate in organizational and administrative studies and his M.A. in applied social psychology from New York University and his B.S. degree in psychology from the City College of New York.

Gail Griffith is a writer and communications consultant to mental health organizations focused on suicide prevention. Throughout her career, she has been engaged in advocacy, public relations, and fundraising designing and implementing international humanitarian programs and cause-related campaigns. She is a graduate of University of California, Berkeley, and holds a graduate degree from Georgetown University. She is the author of *Will's Choice*, published by HarperCollins in May 2005. *Will's Choice,* which examines the paucity of treatment options for families with children with mental illnesses, was a finalist for the publishing industry's 2005 Books for a Better Life Award. In June 2006 Ms. Griffith received the Tipper Gore, Remember the Children Award from Mental Health America

for her advocacy. She is a member of a number of mental health advocacy organizations and from 2005 to 2008 served on the board of the American Foundation for Suicide Prevention. In 2004, she was appointed patient representative to the U.S. Food and Drug Administration's (FDA's) scientific advisory committee charged with investigating the possible link between antidepressant medication and suicidal thinking in young people. She continues to consult for the FDA as a permanent consumer representative to the psychopharmacological drugs committee and recently served as lead author of an assessment of the 2001 Surgeon General's National Strategy on Suicide Prevention.

Douglas Johnston, M.A., is the executive director of the Center for Information Technology Leadership (CITL) at Partners HealthCare System. Mr. Johnston has diverse experience as a health systems researcher and consultant. As the executive director, he leads the development and execution of strategy and operations for a research center focused on examining the value that information technology brings to health care. Previously, as the director of research for the New England Healthcare Institute, Mr. Johnston managed a team of researchers and policy analysts in assessing the impact of innovations in drugs, medical devices, and information technologies on the healthcare system in New England and nationally. Mr. Johnston has also been a senior analyst at CITL, an analyst at Forrester Research, and a consultant at Ernst & Young, LLP. He has published widely in the general healthcare trade press and in peer-reviewed journals and has been awarded research grants from the Robert Wood Johnson Foundation, the California HealthCare Foundation, and the eHealth Initiative. Mr. Johnston received his B.A. from the University of Massachusetts, Amherst, and a master's from Harvard University focusing on medical ethics and health policy. He has also served as an instructor in medicine at Harvard Medical School.

Newell E. McElwee, Pharm.D., M.S.P.H., is vice president of evidence-based strategies at Pfizer where he leads a group of scientists focused on evidence-based medicine, health technology assessment, the use of observational data for assessing clinical effectiveness, and the application of evidence to coverage decisions. He has worked in the pharmaceutical industry since 1992 following a career in academia. His educational background is in pharmacy (B.S., University of Louisiana; Pharm.D., Mercer University) and epidemiology (M.S.P.H., University of Utah). Newell also completed a clinical pharmacy residency and a research fellowship in clinical pharmacology and toxicology. He currently serves on the AHRQ Effective Healthcare Stakeholder Group, the AHRQ Centers for Education, Research, and Training (CERT) Steering Committee, the board of the Center for Medical Technology Policy, the Academy of Managed Care Pharmacy "Format"

Steering Committee, the Center for the Evaluation of Value and Risk in Health Advisory Board (Tufts), the Pharmaceutical Outcomes Research and Policy Advisory Board (University of Washington), the Health Sector Advisory Council (Duke), and the Health Industry Forum Steering Committee. Newell has had leadership roles in the International Society for Pharmacoeconomics and Outcomes Research and the Society for Medical Decision Making. He has a faculty appointment at Tufts School of Medicine in Boston.

J. Michael McGinnis, M.D., M.P.P., is a long-time contributor to national and international health policy leadership, now a senior scholar at the Institute of Medicine, and executive director of the IOM Roundtable on Value & Science-Driven Health Care. He is also an elected member of the IOM. He previously was senior vice president at the Robert Wood Johnson Foundation (RWJF) and, unusual for political posts, held continuous appointments through the Carter, Reagan, Bush, and Clinton administrations, with responsibility for coordinating activities and policies in disease prevention and health promotion. Programs and policies created and launched at his initiative include the *Healthy People* process setting national health objectives, the U.S. Preventive Services Task Force, the *Dietary Guidelines for Americans* (with the U.S. Department of Agriculture), the Ten Essential Services of Public Health, the RWJF Health and Society Scholars Program, the RWJF Young Epidemiology Scholars Program, and the RWJF Active Living family of programs. Internationally, he chaired the World Bank-European Commission Task Force on postwar reconstruction of the health sector in Bosnia and worked as both field epidemiologist and state coordinator for the World Health Organization's successful smallpox eradication program in India.

David O. Meltzer, M.D., Ph.D., is an associate professor in the Department of Medicine and an associated faculty member in the Harris School and the Department of Economics. Meltzer's research explores problems in health economics and public policy with a focus on the theoretical foundations of medical cost-effectiveness analysis and the effects of managed care and medical specialization on the cost and quality of care, especially in teaching hospitals. Meltzer is currently completing a randomized trial comparing the use of doctors who specialize in inpatient care ("hospitalists") with traditional physicians in six academic medical centers. Meltzer received his M.D. and Ph.D. in economics from the University of Chicago and completed his residency in internal medicine at Brigham and Women's Hospital in Boston. He is director of the Center for Health and the Social Sciences at the University of Chicago and also co-director of the Program on Outcomes Research Training and the M.D.-Ph.D. program in the social sciences. He serves on

the faculty of the Graduate Program in Health Administration and Policy, the Population Research Center, and the Center on Aging. Meltzer is a research associate of the National Bureau of Economic Research, an elected member of the American Society for Clinical Investigation, and past president of the Society for Medical Decision Making. He has served on panels examining the future of Medicare for the National Academy of Social Insurance and the Department of Health and Human Services (HHS) and U.S. organ allocation policy for the IOM. He recently served on an IOM panel examining the effectiveness of the U.S. drug safety system and current serves on the HHS Secretary's Advisory Committee on Healthy People 2020, which aims to established health objectives for the U.S. population.

Arnold Milstein, M.D., M.P.H., is the medical director of the Pacific Business Group on Health (PBGH) and the chief physician at Mercer Health & Benefits. PBGH is the largest employer healthcare purchasing coalition in the United States. His work and publications focus on healthcare purchasing strategy, the psychology of clinical performance improvement, and clinical innovations that reduce total healthcare spending. He co-founded both the Leapfrog Group and the Consumer-Purchaser Disclosure Project. He heads performance measurement activities for both initiatives and is a congressional MedPAC commissioner. The *New England Journal of Medicine* series on employer-sponsored health insurance described him as a "pioneer" in efforts to advance quality of care. He was selected for the highest annual award of the National Business Group on Health (NBGH), for nationally distinguished innovation in healthcare cost reduction and quality gains. He was elected to the Institute of Medicine and is a faculty member at the University of California-San Francisco (UCSF) Institute for Health Policy Studies. He was educated at Harvard (B.A., economics), Tufts (M.D.), and UC-Berkeley (M.P.H., health services evaluation and planning).

Tracey A. Moorhead is president and CEO of DMAA: The Care Continuum Alliance. DMAA convenes all stakeholders providing services along the care continuum toward the goal of population health improvement. These care continuum services include strategies such as health and wellness promotion, disease management, and care coordination. Based in Washington, DC, DMAA represents more than 200 corporate and individual members in promoting the role of population health improvement to raise the quality of care, improve health outcomes, and reduce preventable healthcare costs for people with chronic conditions and those at risk for developing chronic conditions. Ms. Moorhead is recognized as a leading healthcare advocate with considerable experience in public policy and coalition management. She effectively directs policy formulation and strategic advocacy efforts, as well as represents the disease management community

before the media, allied organizations and constituents, and all levels of government. Ms. Moorhead previously served as executive director of the Alliance to Improve Medicare (AIM), a bipartisan coalition advocating comprehensive Medicare improvements. AIM supported enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. As AIM's executive director, Ms. Moorhead coordinated and moderated educational and policy briefings for congressional staff; directed AIM's policy research, development, and communications efforts; and developed grassroots programs in conjunction with AIM member organizations. In addition to her role with AIM, Ms. Moorhead served as vice president, Government Relations, for the Healthcare Leadership Council (HLC). In this role, she coordinated a nationwide grassroots outreach campaign to senior citizens and partner organizations to increase awareness and participation in new Medicare benefits.

Samuel R. Nussbaum, M.D., is executive vice president and chief medical officer for WellPoint, Inc. He oversees corporate medical policy, clinical pharmacy programs, health improvement and quality resources, programs for clinical excellence, disease and care management, and clinical informatics to optimize care for members. Dr. Nussbaum also has responsibility for the Health Management Corporation (HMC) and HealthCore subsidiaries. His principal responsibilities continue to include serving as chief spokesperson on medical issues, guiding the corporate vision regarding quality of care and its measurements, leading efforts to assess cost of care performance, and developing a strategy to foster further collaboration with physicians and hospitals to strengthen and improve patient care. Dr. Nussbaum earned his medical degree from Mount Sinai School of Medicine. He trained in internal medicine at Stanford and Harvard and in endocrinology and metabolism at Massachusetts General Hospital and Harvard Medical School, where he served on the faculty for 20 years. His clinical and basic research has led to new therapies to treat skeletal disorders and new technologies to measure hormones in blood. He has served as president of the Disease Management Association of America, chairman of the National Committee for Quality Health Care, chair of America's Health Insurance Plan's (AHIP's) Chief Medical Officer Leadership Council, and a member of the AHIP Board, and he is professor of medicine at Washington University School of Medicine.

Parashar B. Patel, M.P.A., joined Boston Scientific Corporation (BSC) as vice president of health economics and reimbursement for BSC's Healthcare Strategies and Programs Group in 2003. Parashar is responsible for the company's corporate and site health economics and reimbursement functions, chiefly focusing on the development and implementation of

global strategic and reimbursement and legislative initiatives. He is also closely involved in health economics analysis and outcomes research for the BSC. Prior to joining, Parashar was deputy director of the Hospital and Ambulatory Policy Group in the CMS Center for Medicare Management. The group was responsible for Medicare payment policy for a wide range of acute and ambulatory care services including inpatient and outpatient hospital services and physician services. He has extensive experience in healthcare financing policy through his work with the American Association of Health Plans, the Office of (then) Senate Majority Leader George J. Mitchell, the U.S. Office of Management and Budget, and Connecticut's Medicaid agency. He holds a B.A. in political science and a master of public affairs from the University of Connecticut.

L. Gregory Pawlson, M.D., M.P.H., is the executive vice president of the National Committee for Quality Assurance (NCQA). NCQA is a leading evaluator of healthcare services and is especially well known for its development of HEDIS clinical performance measures. At NCQA, beyond his role as a senior member of the leadership team, Dr. Pawlson has oversight and responsibility for research and analysis, federal and state contracting, and performance measure development. While at NCQA, Dr. Pawlson has played a major role in the development and maintenance of the current set of HEDIS measures and other NCQA measures including those used in physician recognition programs and pay-for-performance projects. Before joining NCQA in January 2000, Dr. Pawlson was senior associate vice president for health affairs and worked with the quality and utilization management efforts of the George Washington (GW) Health Plan and Faculty Practice. Prior to that Dr. Pawlson had served as chairman of the Department of Health Care Sciences (DHCS) and director of the Institute for Health Policy, Outcomes and Human Values at GW. During a sabbatical year at GW in 1987, Dr. Pawlson served as a Robert Wood Johnson Health Policy fellow and health policy aide on the staff of Senator George Mitchell (D-Maine) and in 1997-1998 was a scholar in residence at the American Association of Medical Colleges, at its Center for the Assessment and Management of Change in Academic Medicine. Within organized medicine, Dr. Pawlson has served as president or on the board of a number of organizations including the American Geriatrics Society, the Society for General Internal Medicine, the Bon Secours Health System, and the American College of Medical Quality. Dr. Pawlson has more than 100 publications in peer-reviewed journals and has received numerous awards and citations for his teaching and research.

Steven D. Pearson, M.D., M.Sc., is the founder and president of the Institute for Clinical and Economic Review (ICER) at Massachusetts General Hospital and Harvard Medical School. Dr. Pearson also serves as the cur-

rent vice chair of the Medicare Evidence Development and Coverage Advisory Committee, and he is a senior scientist in the Department of Bioethics at the National Institutes of Health. He attended UCSF School of Medicine and completed his residency in internal medicine at Brigham and Women's Hospital in Boston. An internist, health services researcher, and ethicist, he was awarded an Atlantic Fellowship from the British government in 2004 to pursue policy studies at the National Institute for Health and Clinical Excellence (NICE) in London, England. He returned to the United States to serve as special adviser, Technology and Coverage Policy, within the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services from 2005 to 2006. He also served as senior fellow at America's Health Insurance Plans from 2006 to 2008. His published work includes more than 75 peer-reviewed articles and the book *No Margin, No Mission: Health Care Organizations and the Quest for Ethical Excellence,* published in 2003 by Oxford University Press.

Sir Michael Rawlins, M.D., has been chairman of the National Institute of Health and Clinical Excellence (NICE) since its formation in 1999. He is also chairman of the Advisory Council on the Misuse of Drugs (since 1998). He is an honorary professor at the London School of Hygiene and Tropical Medicine, University of London, and emeritus professor at the University of Newcastle upon Tyne. He was the Ruth and Lionel Jacobson Professor of Clinical Pharmacology at the University of Newcastle upon Tyne from 1973 to 2006. At the same time he held the position of consultant physician and consultant clinical pharmacologist to the Newcastle Hospitals National Health Service (NHS) Trust. He was vice chairman (1987-1992) and chairman (1993-1998) of the Committee on Safety of Medicines.

Murray N. Ross, Ph.D., is vice president, Kaiser Foundation Health Plan, and director of the Kaiser Permanente Institute for Health Policy in Oakland, California. His current work focuses on how the U.S. health system can use new medical technologies more effectively. Before joining Kaiser Permanente in 2002, Dr. Ross was an adviser to the U.S. Congress. He served almost 5 years as the executive director of the Medicare Payment Advisory Commission, a nonpartisan agency charged with making recommendations on Medicare policy issues to Congress. Previously, he spent 9 years at the Congressional Budget Office, lastly heading up the group charged with assessing the budgetary impact of legislative proposals affecting Medicare and Medicaid. Dr. Ross earned his doctorate in economics from the University of Maryland, College Park, and completed his undergraduate work in economics at Arizona State University.

John C. Rother, J.D., is the group executive officer of policy and strategy for AARP. He is responsible for the federal and state public policies of the association, for international initiatives, and for formulating AARP's overall strategic direction. He is an authority on Medicare, managed care, long-term care, Social Security, pensions, and the challenges facing the boomer generation. Prior to coming to AARP in 1984, Mr. Rother served eight years with the U.S. Senate as special counsel for labor and health to former Senator Jacob Javits (R-N.Y.), then as staff director and chief counsel for the Special Committee on Aging under its chairman, Senator John Heinz (R-Pa.). He serves on several boards and commissions, including Generations United, the National Health Care Quality Forum, the American Board of Internal Medicine Foundation, National Academy on Aging, and Civic Ventures. He is frequently quoted in the news and an invited speaker at conferences and congressional briefings. Throughout 1996, Mr. Rother was on special sabbatical assignment to study the consumer implications of the managed care revolution and the economic challenges facing the boomer generation. John Rother is an honors graduate of Oberlin College and the University of Pennsylvania Law School.

Donald A. Sawyer, J.D., joined AstraZeneca in 2003 as counselor to meet the legal needs of the Managed Care Business Group, but from there moved into the business in various roles, all in support of managed markets. Don held the role of director of Managed Markets Contract Operations. There, Don led the department responsible for administration and payment of private payer rebate and charge-back contracts. Moving forward, Don held the position of contract strategy director for Nexium with responsibility for the creation, negotiation, and implementation of contract strategies associated with the Nexium brand with respect to commercial and government customers. Don advanced into the role of senior director in Contract Strategy, where he provided leadership for the development and launch of the Medicare Access Standard Contract Offer and was responsible for negotiations across our commercial and Part D portfolio. Don held the position of area sales director in the Southeast Business Center prior to joining the USBC Managed Markets Team as executive director of Managed Markets in May 2007. On July 1, 2008, he was promoted to vice president, Managed Markets Sales and Strategy, where he has continued to serve as an integral member of the Marketing and Sales Operations leadership team. In October 2008, Don accepted an invitation to serve on the Center of Value-Based Insurance Design (V-Bid) Advisory Board at the University of Michigan, where he provides expertise, insight, and direction in the adoption of health insurance principles that balances cost and quality. Don's educational background includes a bachelor of arts degree in economics

from the University of Delaware. He also holds a J.D. from Widener University School of Law, Wilmington, Delaware.

Dennis P. Scanlon, Ph.D., is a researcher focusing on health systems improvement, including the role of information, incentives, and behavior change for improving healthcare outcomes. He led a federally funded research project examining the state of quality improvement activities at managed care plans, focusing on the degree to which health plans were using performance measures for quality improvement activities. He was awarded the Investigator in Health Care Policy Research Award from the Robert Wood Johnson Foundation to study whether private and public sector healthcare purchasers are able to effectively use their health purchasing leverage to drive improvements in quality and reductions in medical errors. Dennis also served as an investigator on a five-year AHRQ-funded project with researchers from the University of California-San Francisco and the University of Michigan examining the impact of insurance market competition on the quality of care. More recently, Dr. Scanlon is the principal investigator for the Center for Health Care Strategies' Regional Quality Improvement demonstration, and he is also leading the research for the RWJF Aligning Forces for Quality Initiative, a $300 million program to bring together stakeholders for improved quality, efficiency, and value in 14 communities across the United States. Scanlon is also working with the Commonwealth Fund and the Institute for Healthcare Improvement to plan a demonstration to reduce preventable and avoidable hospital readmissions. Dr. Scanlon has been on the faculty at Penn State for 13 years in the Department of Health Policy & Administration and has taught courses at the undergraduate and graduate levels. Currently he serves as the professor in charge of the doctoral program in health policy and administration. He received his bachelor's degree in economics from Villanova University, his master's in economics from the University of Pittsburgh, and his Ph.D. in health services organization and policy from the University of Michigan with a concentration in economics and public health.

Martín-J. Sepúlveda, M.D., FACP, is vice president of Global Well-Being Services and Health Benefits for the IBM Corporation. He leads a worldwide team of professionals providing health care policy, strategy and design, and comprehensive employee well-being services to IBM's global businesses. He serves on the Institute of Medicine's Board on Population Health and Public Health Practice, the Board of Directors of the Employee Benefits Research Institute, the Board of Advisors to the School of Public Health at the University of Iowa, the Board of the National Business Group on Health, and chairs its Global Health Benefits Institute. He received his B.A. from Yale University; his M.D. and M.P.H. degrees from Harvard University; completed his inter-

nal medicine residency at the University of California Hospital & Clinics; completed his occupational medicine residency and epidemic intelligence service at NIOSH, CDC; and completed his internal medicine fellowship at the University of Iowa Hospitals and Clinics. He is a fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, and the American College of Preventive Medicine.

Karen Smith, M.D., Ph.D., M.B.A., is vice president of External Medical Affairs (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 lead EMR in the creation of strategic partnerships with key organizations and stakeholders across the U.S. market. Immediately prior to joining AZ, Dr. Smith held 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 senior management and medical roles in a number of large pharmaceuticals companies, Dr. Smith was the CEO-managing director of Boron Molecular, a start-up biotech company focused on R&D and production of biopharmaceuticals and fine chemicals. Dr. Smith holds an M.D. from the University of Warwick (UK) specializing in cardiology, a Ph.D. in oncology molecular genetics from the University of Western Australia, a master's in business administration from the University of New England (Australia), and a master's in law (medical law major) in spring 2008 from the University of Salford (UK). A permanent citizen of the United States, Dr. Smith holds dual citizenship in Australia and Great Britain.

Reed V. Tuckson, M.D., is a graduate of Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania's General Internal Medicine Residency and Fellowship Programs. Dr. Tuckson is currently executive vice president and chief of medical affairs at UnitedHealth Group, a Fortune 25 diversified health and well-being company. He is responsible for working with all of the company's business units to improve the quality and efficiency of health services. Formerly, Dr. Tuckson served as senior vice president, Professional Standards, for the American Medical Association (AMA). He is former president of the

Charles R. Drew University of Medicine and Science in Los Angeles; has served as senior vice president for programs of the March of Dimes Birth Defects Foundation; and is a former commissioner of public health for the District of Columbia. Dr. Tuckson is an active member of the Institute of Medicine and served as chairperson of its Quality Chasm Summit Committee and a member of the Committee on the Consequences of the Uninsured. He is immediate past chair of the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society. Additionally, he recently served as a commissioner, Certification Commission on Health Information Technology, and is currently a member of the Performance Measurement Workgroup, Ambulatory Care Quality Alliance (AQA) and of the Quality Workgroup, American Health Information Community. Dr. Tuckson has also held other federal appointments, including cabinet-level advisory committees on health reform, infant mortality, children's health, violence, and radiation testing. Most recently, he was named one of *Modern Healthcare's* "Top 25 Minority Executives" in health care for 2008 and to *Ebony* magazine's "2008 Power 150: The Most Influential Blacks in America" list.

David M. Walker is president and CEO of the Peter G. Peterson Foundation, where he advocates for specific solutions, works proactively with grantees and other partners to build strong coalitions, and encourages and engages in grassroots efforts to bring pressure on Washington to act. As comptroller general of the United States and head of the Government Accountability Office (GAO) from 1998 to 2008, spanning both Democratic and Republican administrations, Dave served as the federal government's chief auditor. Appointed by President Bill Clinton and confirmed unanimously by the U.S. Senate, he was an outspoken, nonpartisan advocate for addressing the major fiscal and other sustainability challenges facing the country. He also enacted transformational reforms at the agency and within the accountability profession. Prior to his appointment to run the GAO, Dave served as a partner and global managing director of Arthur Andersen, LLP, and in several government leadership positions, including as a public trustee for Social Security and Medicare from 1990 to 1995 and as assistant secretary of labor for Pension and Welfare Benefit Programs during the Reagan administration. He also serves on the boards of the Committee for a Responsible Federal Budget and the Partnership for Public Service. He has authored two books, is a regular commentator, and is the subject of the critically acclaimed documentary *I.O.U.S.A.*, which arrived in theatres around the country in August 2008.

Harlan F. Weisman, M.D., is the Chief Science and Technology Officer, Medical Devices & Diagnostics, Johnson & Johnson. In this role, Dr. Weisman is a member of the Johnson & Johnson Medical Devices & Diagnostics

Group Operating Committee (GOC). He supports the GOC in steering the Group's scientific and technical agenda, leading the Group's investments in Group-level technologies, and sponsoring the Group's research and development (R&D) talent agenda. Prior to this, he was company group chairman, Research & Development, Pharmaceuticals, for Johnson & Johnson, where he had executive oversight of the ALZA Corporation, Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), and TransForm Pharmaceuticals, Inc. Previously, Dr. Weisman was President of J&JPRD. Prior to this, he was president, Research & Development, at Centocor, another member of the Johnson & Johnson family of R&D companies. Before joining Centocor in 1990, Dr. Weisman was assistant professor of Medicine at the Johns Hopkins University School of Medicine, consultant cardiologist at Johns Hopkins Hospital, and director of the Experimental Cardiac Pathology Laboratory there. He is a graduate of the University of Maryland and the University of Maryland School of Medicine. After his residency in Internal Medicine at Mount Sinai Hospital in New York, he did his postgraduate fellowship training in cardiovascular disease at Johns Hopkins Hospital. Dr. Weisman is a Fellow of the American College of Cardiology, the American College of Chest Physicians, and the Councils on Clinical Cardiology and Arteriosclerosis, Thrombosis, and Vascular Biology of the American Heart Association. He is also a member of the American College of Physicians, the American Federation for Clinical Research, the American Medical Association, and the New Jersey Medical Society. Dr. Weisman is an author of more than 90 journal articles and book chapters in the fields of cardiovascular disease and medical product development.

Appendix C

Workshop Attendee List

Patricia Adams
The National Pharmaceutical Council

Julia Adler-Milstein
Harvard University

Jill Arent
Wyeth

Ronald Aubert
Medco Health Solutions, Inc.

Dan Ball
Eli Lilly and Company

Mercedes Barrs
Amylin Pharmaceuticals Inc.

Mara Benner
Gentiva Health Services

Marc Berger
Eli Lilly and Company

Elise Berliner
Agency for Healthcare Research and Quality

Margaret Blasinsky
The Madrillon Group Inc.

Douglas Boenning
Department of Health and Human Services

Marilyn Sue Bogner
Institute for the Study of Human Error, LLC

Robert Borotkanics
Agency for Healthcare Research and Quality

Warren Brennan
SMA Informatics

Shannon Brownlee
National Institutes of Health

Lynda Bryant-Comstock
GlaxoSmithKline

Melinda Beeuwkes Buntin
RAND

Kathy Buto
Johnson & Johnson

Kevin Cain
National Health Council

Daniel Campion
Outcome Sciences, Inc.

Linda Carter
Johnson & Johnson

Christine Cassel
American Board of Internal Medicine

Christine Chang
Agency for Healthcare Research and Quality

Stephanie Chang
Agency for Healthcare Research and Quality

Michael Chernew
Harvard Medical School

Stanley Chin
Altarum Institute

Carolyn Clancy
Agency for Healthcare Research and Quality

Thomas Concannon
Tufts Medical Center

Joanne Conroy
Association of American Medical Colleges

Sabrina Corlette
National Partnership for Women & Families

Denis Cortese
Mayo Institute

Dennis Cotter
Medical Technology and Practice Patterns Institute

Brian Currie
Long Island Health Network

Helen Darling
National Business Group on Health

Louis Diamond
Thomson Reuters

Justin Dimick
University of Michigan

Victoria Dohnal
Biotechnology Industry Organization

David Domann
Ortho McNeil Janssen Pharmaceuticals, Inc.

Johnston Douglas
Center for Information Technology Leadership

Victoria A. Doyon
Independent Public Health Policy Consultant

Mark Elder
Department of Health and Human Services

Ezekiel Emanuel
National Institutes of Health

Peter Fagan
Johns Hopkins Healthcare, LLC

Shalen Fairbanks
American College of Cardiology

April Falconi
AcademyHealth

Jeff Farkas
National Institutes of Health

W. Gregory Feero
National Institutes of Health

Laurie Feinberg
Department of Health and Human Services

Stuart Feldman
Sanofi Pasteur

Mark Fendrick
University of Michigan

Bruce Ferguson
Brody School of Medicine, East Carolina University

Larry Fields
Worldwide Public Affairs & Policy

Leslye Fitterman
Centers for Medicare and Medicaid Services

Howard Forman
Yale University

Raymond Formanek
Office of the Surgeon General

Renee Fox
University of Maryland School of Medicine

Steven Fox
Agency for Healthcare Research and Quality

Sarah Frayne
Avalere Health, LLC

Susan Friedman
American Osteopathic Association

Jean Paul Gagnon
sanofi-aventis

Robert Galvin
General Electric Company

Barry Gershon
Wyeth

Mark Gibson
Milbank Memorial Fund

Paul Ginsburg
Center for Studying Health System Change

Ronald Goetzel
Institute of Health and Productivity Studies

Don Goffena
WL Gore and Associates, Inc.

Marthe Gold
City University of New York Medical School

Merrill Goozner
Center for Science in the Public Interest

Shefa Gordon
National Institutes of Health

Gail Griffith
FDA Patient Representative

Atul Grover
Association of American Medical Colleges

Stuart Guterman
Commonwealth Fund

Jenissa Haidari
American Academy of Otolaryngology

Michael Handrigan
Deparment of Health and Human Services

Susan Hardy
Kaiser Permanente Mid Atlantic

Alex Hathaway
GlaxoSmithKline

Kathy Hayes
National Institute of Dental and Craniofacial Research

Jan Heinrich
Health Policy R&D

Roger Herdman
Institute of Medicine

Susan Hinck
Senate Committee on Finance

Ari Hoffman
National Institutes of Health

Chantal Holy
Johnson & Johnson

Carmen Hooker Odom
Milbank Memoral Fund

Jane Horvath
Merck & Co., Inc.

Julianne Howell
Centers for Medicare and Medicaid Services

Belinda Ireland
BJC HealthCare

Gretchen Jacobson
Congressional Research Service

Elizabeth Jahn
Center for Healthcare Research & Transformation

Amber Jessup
Department of Health and Human Services

Priti Jhingran
GlaxoSmithKline

Rima Jolivet
Childbirth Connection

Jamie Jolly
Daiichi Sankyo, Inc.

Aranthan "AJ" Jones II
U.S. Congress, Office of the Majority Whip

Mary Kapp
Centers for Medicare and Medicaid Services

Randee Kastner
Center for Medical Technology Policy

Marcia Kean
Feinstein Kean Healthcare

Bruce Kelly
Mayo Clinic

Elizabeth Kittrie
Department of Health and Human Services

Arnold Kuzmack
FDA Patient Representative

Jeanne Larsen
Georgetown University Medical Center

Jean LeMasurier
Gorman Health Group

Daniel Leonard
National Pharmaceutical Council

Sandra Leonard
AstraZeneca

Jeffrey Lerner
ECRI Institute

Hallie Lewis
Cepheid

Sarah Lieber
National Institutes of Health

Karen Linscott
National Institutes of Health

Muoi Loi
Johns Hopkins Bloomberg School of Public Health

Benjamin Lum
Department of Health and Human Services

Linda Magno
Centers for Medicare and Medicaid Services

Carole J. DeSpain Magoffin
Health Quality Institutes of America

Brian Maloney
AstraZeneca

Danica Marinac-Dabic
Food and Drug Administration

Jay Markowitz
T. Rowe Price

Norman Marks
Food and Drug Administration

William Martin
National Institutes of Health

Joseph Martinez
Amylin Pharmaceuticals

Elliot Maxwell
Johns Hopkins University

Michael McCaughan
FDC-Windhover

Newell McElwee
Pfizer, Inc.

Bob McNellis
American Academy of Physician Assistants

Arthur Meltzer
Centers for Medicare and Medicaid Services

David Meltzer
University of Chicago Department of Medicine

Amy Miller
Personalized Medicine Coalition

Nancy Miller
National Institutes of Health

Wilhelmine Miller
George Washington University

Arnold Milstein
Pacific Business Group on Health

Carol Monaco
American Osteopathic Association

Kim Montgomery
Columbia University

Eliza Moody
Microsoft

Tracey Moorhead
DMAA: The Care Continuum Alliance

Rachel Morgan
National Conference of State Legislatures

Dina Moss
Agency for Healthcare Research and Quality

Carmen Moten
National Institute of Mental Health/NIH

Sharon Murphy
Institute of Medicine

Anne Mutti
Medicare Payment Advisory Commission

Barbara Myklebust
George Washington University

Keisuke Nakagawa
Congressional Budget Office

Katherine Navarro-McKay
Partnership for Quality Care

Sam Nussbaum
WellPoint, Inc.

Nour Obeidat
University of Maryland

Eduardo Ortiz
National Institutes of Health

Katie Pahner
Health Policy Source, Inc.

Kavita Patel
United States Senate

Parashar Patel
Boston Scientific

Ron Paulus
Geisinger Health System

Greg Pawlson
National Committee for Quality Assurance

Steven Pearson
Institute for Clinical and Economic Review

Gary Persinger
National Pharmaceutical Council

Mark Peterson
Institute of Medicine

Raymond Petryshyn
National Cancer Institute

Steve Phurrough
Centers for Medicare and Medicaid Services

Susan Pingleton
University Healthsystem Consortium

Kathryn Pontzer
Heart Rhythm Society

Eleanor M. Powell
Pfizer, Inc.

Wayne Powell
The Society for Cardiac Angiography and Interventions

Charlene Quinn
University of Maryland School of Medicine

Carrie Raffaelli
Microsoft

Michael Rawlins
National Institute for Clinical Excellence

Margaret Reagan
Premier, Inc.

John C. Ring
American Health Information Management Association

Jodi Robinson
Department of Health and Human Services

Rebecca Roper
Agency for Healthcare Research and Quality

Alan Rosenberg
WellPoint, Inc.

Murray Ross
Kaiser Foundation Health Plan

John Rother
AARP

Patricia Rowell
Department of Veterans Affairs

Paul Rudolf
Arnold & Porter, LLP

Benjamin Sachs
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François Sainfort
University of Minnesota School of Public Health

Susan Samson
UCSF Breast SPORE Advocacy Core

Karen Sanders
American Psychiatric Association

Amanda Sarata
Congressional Research Service

Donald Sawyer
AstraZeneca

Dennis Scanlon
Pennsylvania State University

Adam Scheffler
University of Chicago

Adam Schickedanz
Institute of Medicine

Victor Schneider
NASA

Sarah Scholle
National Committee for Quality Assurance

Michele Schoonmaker
Cepheid

Justine Seidenfeld
Center for Medical Technology Policy

Sara Selgrade
National Human Genome Research Institute

Seth Serxner
Mercer

Belinda Seto
National Institute of Biomedical Imaging and Bioengineering

Lynn Shepherd
Vox Medica

David Siegel
Meridian Health

Dee Simons
Biogen Idec, Inc.

Isabella Sledge
Strata

Karen Smith
AstraZeneca

Michael Sokol
GlaxoSmithKline

Peter Sonnenreich
Kikaku America International

Alan Spotnitz
Robert Wood Johnson Medical School

Anil Srivastava
iBharti Foundation

Caroline Steinberg
American Hospital Association

Mark Stewart
American College of Cardiology

Tara Straw
American College of Obstetricians & Gynecologists

Prasun Subedi
Pfizer, Inc.

Nora Super
Kaiser Permanente

Martha Sylvia
Johns Hopkins Health Care

Betty Tai
Center of Clinical Trials Network

Nina Thomas
Eli Lilly & Company

Nicholas Torsiello
Booz Allen Hamilton

Deborah Trautman
Office of Congresswoman Nancy Pelosi

Reed Tuckson
UnitedHealth Group

Thomas Valuck
Centers for Medicare and Medicaid Services

Jennifer Villani
National Institutes of Health

Francis Visco
National Breast Cancer Coalition

Benedetto Vitiello
National Institute of Mental Health

Greg Volkar
Burson-Marsteller

Patricia Wahl
BJC HealthCare

David Walker
Peter G. Peterson Foundation

Richard Walther
Plan Room

Philip Wang
National Institute of Mental Health

Timothy Ward
Department of Veterans Affairs

Kimberly Westrich
National Pharmaceutical Council

Danielle Whicher
Center for Medical Technology Policy

Kendal Williams
University of Pennsylvania Health System

Dave Wong
Noblis