ROUNDTABLE ON EVIDENCE BASED MEDICINE

# VALUE IN HEALTH CARE

Accounting for Cost, Quality, Safety, Outcomes and Innovation

AN IOM LEARNING HEALTHCARE SYSTEM WORKSHOP PRELIMINARY DISCUSSION BRIEF

March 2009



Introduction
Motivating issues
Common themes
Highlights in the sounds, sights and numbers
Presentation summaries
Next steps

## I. Introduction

The Institute of Medicine's Roundtable on Evidence-Based Medicine provides a neutral venue for key stakeholders to work cooperatively on innovative approaches to the generation and application of evidence that will drive improvements in the effectiveness and efficiency of medical care in the United States. Participants seek the development of a learning healthcare system that enhances the availability and use of the best evidence for the collaborative healthcare choices of each patient and provider; drives the process of discovery as a natural outgrowth of patient care; and ensures innovation, quality, safety, and value in health care. Roundtable members have set a goal that, by the year 2020, ninety percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence on what works best for whom, under what circumstances.

While the U.S. has the highest per capita spending on health care of any industrialized nation, health outcomes lag those achieved elsewhere. The increasing costs of care are reducing access to care and constitute an ever heavier burden on employers and consumers. To address both the costs and the performance of the health care system, greater consensus will be required on what constitutes value in health care, and how to measure and increase that value. A variety of strategies are beginning to be employed throughout the health system, ranging from value-based payment design to improved systems of care delivery. To facilitate public discussion of the value proposition in health care, and how it can be advanced, the Roundtable convened a workshop on November 17-18, 2008, entitled *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes and Innovation.* The meeting explored the approaches to assessing and improving value, including case studies of tools that are currently being used to increase value, as well as both near-term and long-term approaches to align the system to better promote value. Its stated goal was to provide a forum for discussion of stakeholder perspectives on measuring

and improving value in health care, and to identify the key barriers, opportunities and suggested next steps.

This workshop gathered leading participants from the patient, payer, provider, employer, manufacturer, government, research communities and practitioners in health insurance, the employer, health policy, economics, technology assessment, informatics, health services research, and health professions communities to consider the perspectives of key stakeholders on what constitutes value in health care, the approaches to its assessment, and ways to improve health care with respect to value returned for an investment made. Throughout the course of the workshop, a number of common themes and implications emerged, indicated below, along with a number of possible follow-up actions to be considered for ongoing multi-stakeholder involvement through the IOM Roundtable on Evidence-Based Medicine.

### II. Motivating issues for the discussion

- 1. Healthcare costs comprise an increasing percentage of both U.S. GDP 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 health care costs.
- 3. For those who are uninsured or 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 under-utilization of medical treatments 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 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 health care.

#### III. Common themes heard about value

• Mandate: The urgency to achieve greater value from health care is clear and compelling. The persistent growth in health care costs at a rate greater than inflation is squeezing out employer health care coverage, adding to the uninsured, doubling out-of-pocket payments—all without producing commensurate health improvements. We heard that perhaps one-third to one-half of health expenditures is 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. To the patient, perceived value in health care is often described in terms of the quality of their relationship with their physician. 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, as patients are more likely driven by the sensitivity to the value of time and of ensuring that out-of-pocket payments are targeted to their goals. To the provider, value improvement means developing diagnostic and treatment tools and approaches that offer them increased confidence in the effectiveness of the services they offer. To the employer, value improvement means keeping workers and their families healthier and more productive at lower costs. For health insurers, value improvement means emphasizing interventions that are crisply and coherently defined and supported by a high level of evidence as to effectiveness and efficiency. For health product innovators and manufacturers, value improvement means products that are better for the individual patient, more profitable, and contribute to product differentiation and innovation.

#### Value in Health Care: Common Themes

- **Mandate:** 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.
- Elements: Identifying value in health care is more than simply the right care for the right price. 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. Value determination then begins with learning the benefits—what works best, for whom, under what circumstances. 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, 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, appropriate investment is required in the infrastructure and processes for initial determination and continuous improvement of insights on 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 to be vague and poorly tailored to the evidence. The starting point for tailoring decisions to circumstances is with information on costs, outcomes, and strength of the information. Assessing value at the societal level uses best available information and analytics to generate broad perspective and guidance for decision-making on availability, use, and pricing. But we also heard that value assessment at the individual patient level takes account of context and patient preference, conditioned on openness of information exchange and formal learning from choices taken under uncertainty. We 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 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 discussions was that rewards and incentives prevalent in the American health care 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. If emphases are placed on individual services that are often high cost and inadequately justified, rather than on outcomes, quality and efficiency, 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 was 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. health care system. 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 don't 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 isn't 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. 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.

- Providers: Provider-level value improvement efforts depend on culture and rewards focused on outcomes. The presentations identified several examples of some encouraging results from various programs in progress to improve provider sensitivity to, and focus on, value from health care. They ranged 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, specialized in the care of the poorest and sickest patients and could provide services that in fact had better outcomes and lower costs because they were geared to focus on inter-provider communication, continuity of care, and links with social welfare organizations. But they had also negotiated the necessary flexibility with payers. We heard that the clearest barriers to provider level value improvement certainly lie in the lack of economic incentives for a focus on outcomes (both an analytic and structural issue) and likely 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, hinges on the success of programs that improve practical, ongoing, and seamless access to information on best practices and costs, and payment structures that reward accordingly. Discussion offered insights on the use of various financial approaches to sensitize and orient patient decisions on health care prices—individual diagnostics and treatments, providers, or health plans—according to the evidence on the value delivered. Successful broad-based application of such approaches will likely hinge on system-wide transformation in the availability and use 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 were reminded that product demand is embedded 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.
- 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 health care process, and commitment to make it a priority, the basic analytic 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 mentioned are noted below.

## IV. Highlights in the sounds, sights and numbers

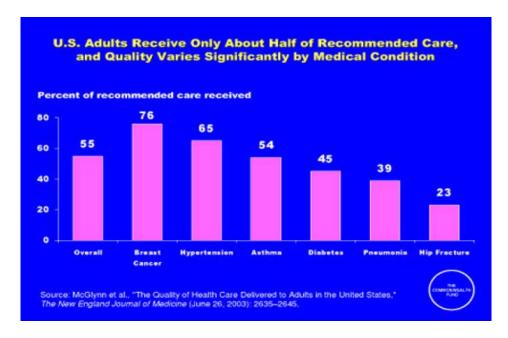
Noted below are examples of points made by presenters during the course of the meeting—through observations, graphics, and data. Summaries and links to slide presentations are included in the next section.

## On perspectives:

"Except for self-pay situations, medical bills are paid by taxpayers, employers and consumers together—so **value to society is critical**, as is value to the patient."

-Christine K. Cassel, American Board of Internal Medicine

## On use of high-value services:



"U.S. adults receive only about half of recommended care."
-A. Mark Fendrick, University of Michigan

#### On system fragmentation:

"A Center for Payment Reform has been established because nationally there are dozens – 13 in Boston alone – *separate, largely uncoordinated* payment reform efforts, creating **confusion**, **diluting lessons**, and **potentially alienating providers**."

-Robert Galvin, Global Healthcare/General Electric

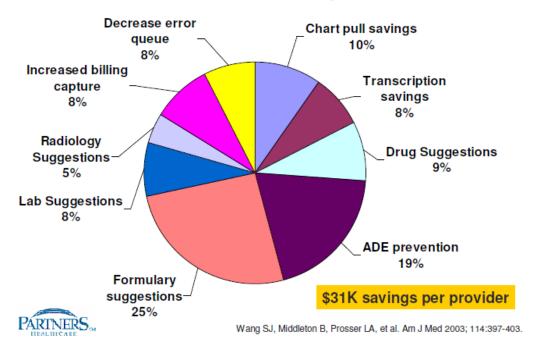
#### On care coordination:

"Primary care practices focusing on hospitalization prevention for high-risk chronically-ill patients can reduce costs by 15-20%."

-Arnold Milstein, Pacific Business Group on Health

### On electronic health records:

# ROI for Partners' Outpatient EHR



"Electronic health records can improve care and save money in many ways."
-Douglas Johnston, Center for IT Leadership

## On wellness programs:

# JOHNSON & JOHNSON HEALTH & WELLNESS PROGRAM IMPACT ON MEDICAL COSTS



"Employee health and wellness programs can reduce employer health costs."

-Ronald Z. Goetzel, Emory University

### On provider incentives:

"We do not yet have either the incentive system or the sustainable infrastructure to enable the achievement of real efficiency and quality."

-Carolyn M. Clancy, Agency for Healthcare Research and Quality & Roundtable Member

#### On coverage and reimbursement decisions:

"Washington State's Health Care Authority demonstrates the **increasing linkage of policy to evidence** on safety, effectiveness and comparative value."

-Steven D. Pearson, Institute for Clinical and Economic Review

#### V. Agenda and presentation summaries

#### DAY ONE

#### 8:30 WELCOME AND INTRODUCTIONS

Denis A. Cortese, Mayo Clinic & Chair, IOM Roundtable on Evidence-Based Medicine

## 8:45 KEYNOTE: THE NEED TO IMPROVE VALUE IN HEALTH CARE

What are the key challenges facing 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

This session provided context for the workshop discussions, reviewing how the concept of value is viewed from different sectoral perspectives. Chair: J. Michael McGinnis, Institute of Medicine

- September 2008 Roundtable Panel Summary—Session chair to offer brief summary of panel discussion at the September 2008 Roundtable meeting in which the notion of value was discussed from the vantage points of different participants: patient, provider, payer, employer, manufacturer, and economist.
- ➤ **Reactor panel**—Brief comments from panel members on their thoughts about priority issues to be resolved in developing and refining approaches to establishing and improving value.

## 10:45 Session 2: Approaches to Assessing Value – illustrative examples

Session 2 featured presentations on the approaches taken to assessing value in various contexts. Speakers will highlighted 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, NCOA

Measurement of value in health care is an increasingly important goal given assessments of both questionable benefit and high cost in the U.S. However, value is very difficult to define in a way that can be practically measured, especially in a field like health care where neither benefits nor resources used to create the benefit are easily defined. The concept of "measurable clinical efficiency" examines the relationship of composite quality measures as a proxy to benefit, and resource use measures using standardize 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 with implementation and use. Resource use can be measured using either 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 a defined period of time, each approach with its pros and cons. Transparency and problems with reliability of measurement hinder resource use measurement. 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 health care system to attribute measures of quality and resource use is also a major challenge with important tradeoffs. Finally, research to explore the relationships between quality and cost and what elements of the system effect these measures is critical, as is setting reasonable "rules" and standards for fairness and accuracy of measurement.

### Surgery and other procedures

#### Justin B. Dimick, University of Michigan

The value of surgical care can be considered from two perspectives. The first considers the effectiveness of surgery, relative to other approaches, for treating medical conditions. Value assessment in this context is the domain of evidencebased medicine, where comparative effectiveness is evaluated by critical evaluation of randomized clinical trials and observational studies. Ensuring patients receive surgery only when the evidence indicates the benefit outweighs the risk clearly improves patient value. The second perspective is motivated by the widespread variations in quality and costs across providers. 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. However, for these efforts to be successful, good measures of quality and cost are needed. Good measures of surgical quality are closer on the horizon. For some conditions, good measures are already available and are being applied. 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, 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

### Howard P. Forman, Yale University

Diagnostic imaging spending has exceeded overall healthcare expenditure growth, straining public (primarily Medicare) and private (primarily employersponsored health benefit) sector contributions to healthcare delivery. 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). 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 their application (e.g., lumbar spine imaging and knee MR). Value to the referring clinician has only peripherally been explored and never explicitly 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. Further research and/or demonstration projects may be necessary in order to better assess the role of gain-sharing or global payments for imaging delivery in the inpatient, outpatient and ER settings.

#### 12:30 LUNCH PRESENTATION: PERSPECTIVES ON VALUE FROM THE U.K.

Sir Michael Rawlins, National Institute for Clinical Excellence, United Kingdom

## 1:45 Session 2 (CONTINUED)

### Preventive services/wellness

David O. Meltzer, University of Chicago

Prevention is an important contributor to improvements in population health. Prevention can also sometimes prevent the need for costly future medical treatments, causing some to focus on prevention as a potential mechanism to control healthcare costs. This presentation will review the use of medical cost-effectiveness analysis to address these questions. The primary conclusion is that prevention can be, but is not always, a cost-effective approach to improving health, but is infrequently a powerful approach to controlling healthcare costs, either in the short term or in the long-term. Moreover, the value of prevention can be profoundly influenced by the context in which it is used, with patient preferences and other characteristics often playing a major role in the value of prevention.

#### Pharmaceuticals/biologicals

#### Newell E. McElwee, Pfizer, Inc.

Value has been defined by the IOM Roundtable on Evidence-Based Medicine as "the benefit relative to the cost." However clear this definition may seem, value has different meanings to different people. This presentation will specifically focus on assessment and appraisal of the value of healthcare technologies. Assessment and appraisal of the value of healthcare technology varies greatly depending on what decision is being made, who the decision-

makers (stakeholders) are, what the stakeholder's preferences/utilities are, whether the focus is on clinical value or economic value, and many other factors such as unmet medical need and the strength of the evidence supporting the value proposition. One framework is therefore to view value in the context of specific decisions and their respective stakeholders. Several key decisions during the lifecycle of a healthcare technology will be used to illustrate 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/diffusion decision by the payer, and the individual treatment decision by the patient and their physician.

## Personalized diagnostics

## Ronald E. Aubert, Medco Health Solutions, Inc.

As a result of the growth of molecular diagnostics, there has been a tremendous wealth of information gained about the molecular characteristics of the human genome. In the past few years, we have also gained a clearer understanding of the functional aspects of the genome. The concept underlying pharmacogenomics is that 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. The use of pharmacogenomics (PGx) testing has the potential to help physicians and patients achieve more predictable and better outcomes. Given the potential benefits and increasing use of PGx testing, careful consideration should be given to the evaluation of testing strategies, including the determination of overall value.

#### Devices

## Parashar B. Patel, Boston Scientific Corp.

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, the standards used in device evaluations appear to be becoming more similar to those used in evaluating pharmaceuticals. While devices have a faster cycle of innovation than drugs, the adoption rates and short-term economic impacts are slower, and the evaluation approach should differ accordingly. 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. They are typically reserved for a later stage when there is potential for broader adoption, expansion of patient indications, and head-to-head comparisons with alternative treatments are desired and more practical. Measuring the value of device interventions raises several unique challenges, including difficulties with randomization and blinding, with methods of comparing different treatment modalities, and with 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. 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 timelines with fewer, but more expensive, technologies and fewer choices for patients.

#### 4:00 Session 3: Approaches to improving value – Consumer Incentives

Sessions 3, 4 and 5 presented specific examples of current approaches to improve value in health care in three main areas. Each session explored the nature of the efforts, and the best practices and results to date. Speakers particularly focused on the evidence of impact and the future potential to improve value with each approach. The first session focused on the use of a variety of consumer-oriented strategies to promote value. Each presentation was followed by a reactor.

Chair: Michael E. Chernew, Harvard University

## Consumer-directed/high deductible health plans

Melinda I. Beeuwkes Buntin, RAND

The presentation will discuss the experience with and the potential of improving value through consumer-directed/high deductible health plans. I will start with the RAND Health Insurance Experiment and then discuss the newer literature on the effects of evolving 'consumer-directed' plan designs on cost, access to care, and ultimate health outcomes. I will also point out the many remaining gaps in the literature and what conclusions can be drawn for policy and practice at this point.

## Value-based insurance design

A. Mark Fendrick, University of Michigan

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. Instead, the dialogue focuses on two trends-quality improvement and cost containment. Efforts to lower costs such as rising premiums or increased copays can create financial barriers that discourage the use of recommended services and the overuse of interventions of questionable benefit. Patient copayments for services designated as quality indicators have risen dramatically and at the same rate as less valued services. This is a concern since studies show that patients who are required to pay more for their health care buy less – of essential and excessive therapies alike. Valuebased insurance design (VBID) offers a potential incremental solution to enhance efficiency in healthcare spending. VBID programs adjust patients' outof-pocket costs for health services on 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. VBID Programs encouraging the use of high quality services have been implemented with a controlled evaluation demonstrating significant increases in patient compliance. The net financial impact of copayment relief on healthcare spending and non-medical expenditures remains unclear. In summary, efforts to control costs should not produce preventable reductions in quality of care. 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/provides incentives to encourage desired behaviors for patients and providers. By aligning financial incentives, this strategy 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 health care expenditure.

## Tiering

## Dennis P. Scanlon, Pennsylvania State University

One approach to steering consumers and patients towards the use of highvalued healthcare services and health providers is "tiering." Broadly defined, tiering refers to the classification of healthcare providers (e.g., hospitals and physicians), pharmaceuticals, or treatments/therapies, based on objective or subjective criteria such as cost, quality and value. Tiering systems typically allow the patient/consumer to select a provider, service or therapy in any tier, with the required out-of-pocket cost to the consumer/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 will examine the research evidence for tiering programs in health care and several examples of tiering programs will be provided. One example to be 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% 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 indicate that the HSI influenced the selection of hospital for one of the two union groups, for 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 (compared to before the HSI 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 ends with a discussion of the key policy issues associated with tiering programs in health care.

#### Wellness

#### Ronald Z. Goetzel, Emory University

The scientific evidence is mounting that worksite health promotion and chronic disease prevention programs can reduce health risks and produce a positive return on investment (ROI) for employers. However, challenges arise in designing and implementing effective programs that achieve the best results, documenting program achievements in ways that scientists and lay people can readily understand and accept research findings, and communicating results to the broad health care community. This session will discuss these challenges with particular emphasis on how to disseminate timely information to the

business community. The session will highlight examples of large-scale research studies previously conducted and those currently underway that are supported by federal and private sector grants. For example, in a project funded by the National Heart, Lung and Blood Institute (NHLBI), 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 will evaluate 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, health care 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, Wellness at Work Program, and several New York City employers. As above, health impacts are being assessed and an ROI analysis is planned. Another major initiative by the CDC is focused on developing Health and Productivity Management (HPM) benchmarks and best practices that emphasize the employer's role in promoting the health and well-being of workers. The CDC is conducting studies that document characteristics of exemplary worksite health promotion programs, identifying appropriate benchmarks relating to program effects, developing frameworks and guidelines for designing, implementing, and evaluating state-of-the art programs, establishing realistic program objectives, and identifying successful worksite programs with proven health and financial impact results.

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#### DAY TWO

#### 8:30 WELCOME AND RE-CAP OF THE FIRST DAY

Denis A. Cortese, Mayo Clinic & Chair, IOM Roundtable on Evidence-Based Medicine

# 9:00 Session 4: Approaches to improving value – Provider and Manufacturer Payments

Continuing from session three, 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. The first two presentations were each followed by a reactor.

Chair: Samuel R. Nussbaum, Wellpoint, Inc.

#### > Pay for performance

Carolyn M. Clancy, Agency for Healthcare Research and Quality & Roundtable Member
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. As a result,
payers have, in recent years, 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. Although some research is being done on the alignment of payment incentives with quality, critical gaps in our collective knowledge exist. Those 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 will address issues such as: 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.

## Coverage and reimbursement decisions

## Steven D. Pearson, Institute for Clinical and Economic Review

Coverage and reimbursement policies are among the most visible tools by which public and private payers in the U.S. seek to enhance the value of healthcare delivery. Consideration of payers' approaches must begin with an understanding of the opportunities and barriers presented by the language of statutes or contracts that sets the legal context for medical policy decisions. The next element considers how payers use evidence, both scientific and contextual, for distinguishing among healthcare interventions. The final component considers the set of medical policy "tools" - including benefit design, coding, provider contracting, and reimbursement models - that are at the disposal of payers to modulate the use of healthcare services. This presentation will analyze 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 costeffectiveness information, and various risk-sharing agreements with manufacturers. Several specific case examples will be discussed in detail, and three overarching goals among these efforts will be 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.

#### Incentives for product innovation

Donald A. Sawyer, AstraZeneca LP (Industry Perspective)

The presentation will address 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. The speaker will begin with an overview of the facts and figures behind pharmaceutical research and development (R&D). Innovative medicines are an important part of the solution to chronic disease and controlling healthcare costs. However, the value of innovative therapies is often not realized by current incentive structures (e.g. Physician Quality Reporting Initiative). The need to change current budget and contracting processes with payers will be discussed with the use of specific examples. The presentation will conclude with options to recognize the long-term value to patient health while maintaining an environment that rewards and encourages innovation of life

saving medicines. Examples will be provided of how AstraZeneca and other manufacturers incorporate the value proposition into decisions throughout the drug development process.

## Reed V. Tuckson, UnitedHealth Group (Payer Perspective)

Our 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, 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. This talk will explore some of the perspectives, tools, and requirements necessary to advance responsible use of new innovations in service to the American people.

# 11:00 Session 5: Approaches to improving value – Organization and Structure of Care

Continuing from sessions three and four, the final session on approaches to improving value focused on changing the organization and structure of care to improve value. Each presentation was followed by a reactor.

Chair: John C. Rother, AARP & Roundtable Member

#### > Electronic health records

#### Douglas Johnston, Center for IT Leadership

This session will discuss, at a high level, the definitions and evidence on the value of electronic health records (EHRs) and the central issues associated with measuring and realizing this value. To help frame the review of evidence on EHR value, this session will start by defining the types of value widespread adoption of EHRs might produce, and review basic and advanced EHR functions within the context of healthcare information technology. Selected empirical evidence on the quality, safety, and financial impact and costs of EHRs will then be discussed, with examples from case studies and the peerreviewed literature. Projections of potential EHR value based upon this evidence will also be reviewed, as will other areas of possible value for which no evidence is currently available. The session will conclude 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 S. Milstein, Pacific Business Group on Health

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 payment 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 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. Observation of four such practices suggests that these design features are likely to enhance, rather than to conflict with current principal medical home quality objectives of improved access, patient-centeredness, and effectiveness of care. While they cannot alone solve our health care affordability challenges, medical homes can substantially reduce total near-term healthcare spending in addition to raising 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. Their numbers and preventable health deterioration will continue to mount.

## Disease management

## Tracey A. Moorhead, DMAA: The Care Continuum Alliance

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 health care teams and stakeholders, and adheres to new evaluation methodologies. This presentation will outline this evolution and highlight case studies from both public and commercial populations that demonstrate the significant value of population health improvement.

#### 1:30 Session 6: Aligning the system for value – now and in the future

This 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.

Chair: Karen L. Smith, AstraZeneca

## > On the horizon

#### Christine K. Cassel, American Board of Internal Medicine

This session considered 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 tradeoffs.

#### > Panel discussion

Ezekiel J. Emanuel, National Institutes of Health Samuel R. Nussbaum, Wellpoint, Inc. John C. Rother, AARP & Roundtable Member Panelists drew together themes and conclusions from meeting on how the health system could be aligned to promote value, both in terms of improvements that can be achieved within the existing system, and in terms of the longer term changes that need to be made.

- O Near term/quick hits Approaches to improve value over the next 3-5 years, within the existing system and using available data.
- Long term Long term approaches to improve value, including the role of health IT, economic incentives, health system structure and coordination.
- Political considerations Political considerations that will impact efforts at health reform, and discuss options to provide insulation from the political process.

## 3:30 CONCLUDING SUMMARY REMARKS AND ADJOURNMENT

Denis A. Cortese, Mayo Clinic & Chair, IOM Roundtable on Evidence-Based Medicine J. Michael McGinnis, Institute of Medicine

## VI. Next steps: possible follow-up actions by the Roundtable

Much of the discussion at the workshop played to the notion that full attainment of the value needed from the U.S. health care system delivered was dependent on broad financing reform that ensured health insurance coverage for all who needed 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 health care dollars, including the following issues as particular possibilities the further attention and action of the members of the Roundtable on Evidence-Based Medicine.

#### 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 adoption and use?
- Transparency as to cost, quality, and outcomes. What efforts by the various sectors represented by Roundtable members—patients, providers, health care delivery organizations, insurers, employers, manufacturers, regulators, information technology, and researchers—might help bring about the true transparency necessary to sharpen the focus on the key elements of the value equation?
- Lifecycle evidence development for interventions. How might Roundtable professional societies, manufacturers, insurers, and regulators help move the process of monitoring

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 decide on the interventions most appropriate for structured introduction, the criteria for expansion, and the approaches to ongoing monitoring?
- ➤ <u>Value-based insurance design</u>. 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

- ➤ <u>Identification of high value services</u>. 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?
- ➤ <u>Care organization incentives</u>. What issues and incentives are needed to expand the development of a medical home model most conducive to the development of more efficient and better coordinated care?
- Lustered 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 awareness growing 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 5 big 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 on 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?
- ➤ <u>Structured information-sharing on high value services</u>. How might insights and information generated on services identified as high value be most effectively disseminated to help inform and motivate patients?
- ➤ <u>Value-based payment/reimbursement structures</u>. 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 focused on actual outcomes (i.e., results achieved), how might such an approach be best developed and tested?
- ➤ <u>Value-engaged regulatory approval processes</u>. 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?
- ➤ <u>High cost service evidence</u>. Similarly how might an inventory be developed of the top 10 high cost services for which comparative effectiveness studies that need to be done?
- ➤ <u>Capacity for comparative-effectiveness research</u>. What additional issues need to be engaged to improve the prospects for successful development of a deeper national capacity for comparative effectiveness research?
- Analytics for value assessment. What are the most important analytic challenges to assessing value and how might they best be engaged, especially with health care costs reaching near crisis levels in the context of a weak economy?

These general themes, insights, and possible activities are drawn from the presentations, observations and suggestions coursing throughout the workshop discussions. They complement the content of the individual presentations that will represent the core material of the published workshop summary, do not constitute findings or recommendations, and serve only to inform Roundtable discussions and possible collaborative activity among members and their sectoral colleagues. As this is an "open source" process, additional suggestions and observations are welcome and encouraged as the Roundtable members identify which, among the many compelling issues, are best suited to their capacities.

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#### 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 Smith, AstraZeneca Samuel R. Nussbaum, Wellpoint

#### THE IOM ROUNDTABLE ON EVIDENCE-BASED MEDICINE

The Institute of Medicine's Roundtable on Evidence-Based Medicine provides a neutral venue for key stakeholders to work cooperatively on innovative approaches to the generation and application of evidence that will drive improvements in the effectiveness and efficiency of medical care in the United States. Participants seek the development of a *learning healthcare system* that enhances the availability and use of the best evidence for the collaborative healthcare choices of each patient and provider; drives the process of discovery as a natural outgrowth of patient care; and ensures innovation, quality, safety, and value in health care. Roundtable members have set a goal that, by the year 2020, ninety percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence on what works best for whom, under what circumstances.

Summary publications are produced for each workshop to provide expert opinion and in-depth exploration of workshop topics to Roundtable members, the general public, and policy makers. A publication is being developed from the proceedings of this workshop, including papers submitted by speakers, commissioned papers, and a summary of workshop discussions. *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes and Innovation* will be the ninth publication in the Learning Healthcare System series.

## Meetings and publications in the Learning Healthcare System series

- Concepts. The Learning Healthcare System (July 2006)
- Evidence standards. Judging the Evidence: Standards for Determining Clinical Effectiveness (Feb 2007)
- Sector strategies. Finding Common Ground: Leadership Commitments to Improve Value in Health Care (Jul 2007)
- IOM Annual Meeting. Evidence-Based Medicine and the Changing Nature of Health Care (Oct 2007)
- Clinical research. Retooling the Knowledge Engine: Improving the Efficiency and Utility of Clinical Effectiveness Research (Dec 2007)
- Clinical data. Clinical Data as a Public Good: Creating and Protecting the Basic Staple of Health Learning (Feb 2008)
- System change. Engineering a Learning Healthcare System: A Look at the Future (Apr 2008)
- Infrastructure. Learning What Works: Infrastructure Required to Learn Which Care Is Best (Jul 2008)
- Value. Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes and Innovation. (Nov 2008)
- 2008 summary. Learning Healthcare System Concepts v. 2008 (Annual Report)

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