

The Road to Value-based Healthcare: Destination Apparent, Journey Uncertain

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In healthcare, the destination is apparent: improve quality and control costs. But it is the journey to that point that remains uncertain. Many stakeholders are intensely focused on identifying solutions that address the double-digit annual spending growth that has launched healthcare to the forefront of our nation's priority list. Of equal concern is that we do not have a good handle on what we truly obtain for our investment.

In the words of Tom Scully, former administrator of the Centers for Medicare and Medicaid Services (CMS): "In an era of change in which the annual healthcare budget in the U.S. exceeds the Department of Defense budget by a factor of four, it is imperative that the American public receives the greatest value for its hard-earned dollars."¹ Although the overall costs of healthcare are unlikely to go down, we can hope to improve quality and use resources more efficiently. To accomplish these goals and maintain a sustainable healthcare system, it will be necessary to develop better means of measuring *value* and aligning system incentives to reward it.

To fill this "value gap," we have embarked on restructuring efforts that will fundamentally alter systems of care. Evidence-based medicine (EBM), economic and outcomes research, and other tools are being

integrated into health reimbursement processes.² A variety of pay-for-performance approaches have emerged, offering incentives for physicians and hospitals to standardize use of technologies and services with well-established value. Health plan benefit designs are encouraging consumer selection of high-quality, cost-effective services. Evolving databases, registries, and information networks will significantly influence the way that we evaluate, monitor, and direct the use of health services in the future.

Although value is the common thread among these approaches, in reality they are a patchwork of disparate efforts—not a systematic approach to value integration. Certainly providers, payers, manufacturers, and others are moving toward collaboration, transparency, and common standards—establishing the "rules of the road" for value-based healthcare—but we are only at the beginning stages of this journey. As the vanguard advances to usher in this new value-based world, a variety of factors will influence the success and overall impact of these efforts.

A number of key issues relate to value-based healthcare, including considerations for emerging genomic and biotechnology products.

What Is Value?

For purposes of this discussion, we will consider value in the academic sense, as understood by healthcare purchasers and policy makers, as well as in the broader applied context of healthcare purchasing strategies (see Exhibit 1).

As it pertains to a particular technology or service, most purchasers of healthcare would define value as quality/outcomes divided by the cost required to obtain those outcomes. Some might think that conventional EBM enables comparative assessment of the value associated with a particular intervention, but this is not technically true. EBM can

be considered a component of "value," but it does not fully reflect value because it mainly emphasizes the clinical/outcomes portion of the value equation. Value measurement most often involves econometric methods, such as cost-effectiveness or cost-utility analysis that integrate both outcomes and cost information. Although these methods have been around for a long time, methodological and policy concerns have historically delayed broader adoption of such techniques in health decision-making. Others would argue that even these measures fall short of informing real value-based medicine because they do not adequately incorporate patient perceptions of quality or quality-of-life factors.²

Value-based purchasing (VBP) is a relatively new term. VBP emphasizes activities that aim to improve both the quality and cost of care by a) purchasing/use of health technologies or services with demonstrated value and b) applying "system controls" that encourage the desired purchasing behavior or other changes.³ In other words, VBP uses value information to influence the decision making of consumers, plans, and providers. System controls, defined broadly, can include pay-for-performance, health benefit and reimbursement restructuring, total quality improvement, and knowledge transfer. Whether VBP actually results in quality or cost benefits will largely depend on how we define and apply value in practice—beyond the academic definition above—and the capacity of our health system and system controls to truly deliver value.

Exhibit 1: What Is Value?

$$\text{Value} = \frac{\text{Quality (Outcome)}}{\text{Cost}}$$

$$\text{Value-based Purchasing} = \frac{\text{Quality (Outcome)}}{\text{Cost}} + \text{System Controls}$$

Destination Value: Uncertain Implications for New Health Technologies

It's no secret that we frequently deliver costly services of marginal value, while other more cost-effective services are grossly underutilized.⁴ Development of methods to better estimate and compare the value of health services will narrow this gap in the future. However, efforts to advance value-based healthcare have exposed potential challenges for new health technologies—including those that promise to usher in new paradigms of health delivery—warranting careful implementation of tomorrow's health solutions today. Though not a comprehensive list, some of these challenges are as follows.

What Is the Right Measuring Stick?

Finding a common measure to compare similar technologies has long been debated in economics and outcomes research. Scholars have considered various economic measures that blend quality and cost information, including whether they are comprehensible and useful in health decision-making. In the quest for an adequate measure of value, a single standard would be ideal. However, the one-size-fits-all approaches to value estimation that have largely been applied to drugs may not be practicable for all technologies, particularly emerging medical devices and diagnostics.

Devices and diagnostics generally have shorter realized patent lives and greater technology turnover than drugs, which can diminish incentives to conduct the extensive randomized controlled trials (RCTs) and economic studies often required for drugs. Many technical challenges also exist. For example, recent discussions on estimating the value of pharmacogenomics cite significant barriers to assessment, such as lack of causal and comparative effectiveness data and the multi-factorial complexities

of evaluating diagnostic/drug combinations.⁵ Likewise, it is often difficult for diagnostic studies to generate direct evidence of impacts on health outcomes. This is because the link between treatment use and outcomes is more straightforward than for diagnostics. One renders a treatment and can then measure the short- and long-term outcomes. A diagnostic study geared to measure health outcomes, on the other hand, is subject to a wider variety of confounding effects, including multiple treatment options and variation in care delivery.

For which technologies do we need more or different evidence than others? What standards will we adopt in value measurement? When should we adopt other approaches such as patient registries or patient-reported outcomes? When is data modeling more efficient than direct evidence collection and how can we best use these results in practice? Many questions remain unanswered. As we refine our approach to measuring value, it remains important to consider both the need to readily compare value among similar services and the need to adopt methods that account for variability among technology types and applications.

When Is the Right Time to Assess Value?

Once we agree on a means to measure value, when should we evaluate it? Payers and technology assessment organizations (e.g., BCBS TEC, Hayes, ECRI) are now considering new technologies much earlier in the product life cycle. Some payers also employ "horizon scanning" approaches that identify technologies anticipated to have a significant impact on beneficiary care—even before they emerge on the market. It is essential that the potential of these technologies be reasonably tested in practice, without prematurely rendering a decision about value.

In scenarios where early technology assessment is necessary, but evidence of value is incomplete, what options exist to explore promising but unproven technologies?

The "coverage with evidence development" (CED) guidance recently released by the Center for Medicare and Medicaid Services (CMS) appears to be one option. Although it is anticipated that CED will be limited to only a few applications per year, eligible technologies engaged in the National Coverage Determination (NCD) process will be temporarily covered and reimbursed while additional data are collected. CED also reflects an approach where the manufacturer and payer share the financial burden associated with data collection to better field-test the value of new technologies post-FDA approval.

In an environment where the consumer will increasingly drive purchasing decisions, CMS and other payers are beginning to view these types of investments in new technology assessment as good business for their beneficiaries. Such approaches also support innovation for high-potential services, help decision makers gain answers to questions on value not covered by studies for market clearance, and ensure that patients can access those technologies that truly improve quality and costs of care.

How Much Evidence of Value Is Enough?

Most clinical practice guidelines and health quality measures integrate technologies with supporting evidence developed through years of clinical study and application. New health technologies such as pharmacogenomics, molecular imaging, and targeted biotechnologies do not yet have the same deep evidentiary support. Nevertheless, they offer opportunities to improve the quality and precision of healthcare—to personalize medicine—in ways that we are only beginning to understand.

As health decision makers struggle with quality and cost constraints, evidentiary expectations for new health technologies appear to be expanding. How do we best align our “need to know” with the timing and resource constraints inherent to new technology development?

The value dossier, of the type often developed under the Academy of Managed Care Pharmacy (AMCP) format, is one example of an approach to conveying the value of new drugs and biologics. These dossiers, familiar to the managed care community, communicate clinical and economic outcomes associated with a particular intervention. Evidence of value is presented in a manner that enables payers to assess implications for their beneficiary populations and make real time health decisions without unnecessarily delaying patient access. This approach also integrates modeling to account for lack of direct evidence at the time of product launch. Although this approach would likely need to be altered for medical devices and diagnostics, it does represent a standardized means of communicating value that most stakeholders accept.

In our efforts to assess value, we must continually ask ourselves how much information do we need to render a decision and how accurate do we need to be? When setting new thresholds for value, against which we will measure new health technologies and services, we must not create unnecessary barriers to innovation or access or “break the bank.” This means setting value expectations for new technologies in a manner that is sensitive to level of maturity and technological change. It also means requiring sufficient value information to inform rational selection among available healthcare alternatives and integration into systems of care.

How Do We Reward Value?

When it comes to rewarding value in the health system, we find

ourselves at the earliest stages of trial and error versus other U.S. industries. Once we have defined and measured value, how do we align incentives to drive desired results? What type and level of incentives are required to alter consumer, practitioner, and hospital behavior? These and other questions loom large over initial attempts to focus on value. But it is where the rubber truly meets the road if we are to succeed in value-based healthcare.

Recent pay-for-performance (P4P) and other quality initiatives are forerunners of the broader approaches to value integration yet to come. These efforts have been driven by a variety of payers, large employers, and consumer coalitions and largely operationalize quality and performance measures aimed at improving various aspects of care (e.g., safety, effectiveness, efficiency). Perhaps the most widely accepted set of such measures is the Health Plan Employer Data and Information Set (HEDIS), used by 90 percent of managed care organizations today. Although current P4P models generally focus at the hospital level, the Medicare Payment Advisory Commission (MedPAC) and other influential groups are now exploring ways to encourage individual physicians to select care options with established value.² Additionally, consumer-directed methods will continue to shift responsibility and financial burden to the patient in an attempt to balance value and choice. In this evolving system, it may be possible to choose technologies that do not offer proven value, but this will increasingly occur at a cost.

Despite the tremendous potential of such performance- and value-based purchasing strategies, it is currently uncertain whether or how such mechanisms will address emerging technologies. Presumably new technologies, such as genomic testing and targeted therapies, will offer value through improved

outcomes and efficiencies in care delivery. However, if the role of such technologies in meeting performance goals is unclear, it is conceivable that evolving systems may create unanticipated disincentives for their use. Incentive structures will influence whether providers offer certain services or decline others—it is hoped in ways that improve patient care and outcomes. It will be important for the new value infrastructure to anticipate potential care gaps and build in safeguards that foster prudent provider and patient choices without precluding advancement of emerging technologies and services.

Conclusion

As Steven Teutsch and Marc Berger have pointed out: “balancing our investment in the promise of tomorrow versus the needs of the present is a tricky business.”⁵ On the road to value in U.S. healthcare, we are finding that there are just as many questions as answers. The journey is far from over and far from certain. Identifying the solutions will require collaborative communication and the will to address the formidable healthcare challenges that affect all stakeholders, including payers, providers, purchasers, and manufacturers. **JMCM**

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