National Dialogue for Healthcare Innovation

Research Report—Value in Healthcare

Prepared for the Healthcare Leadership Council
by ZS Associates

February 23, 2015

Impact where it matters.

National Dialogue for Healthcare Innovation

Research Report—Value in Healthcare

Prepared for the Healthcare Leadership Council
by ZS Associates

Contents


EMERGENCY
Main Entrance
Entrance A | B

Introduction to the National Dialogue for Healthcare Innovation (NDHI)

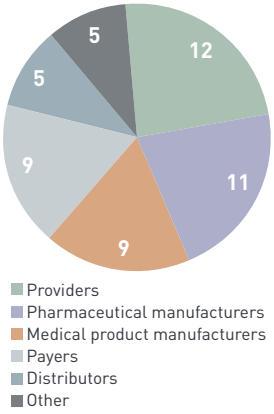
The Healthcare Leadership Council (HLC) has formed the National Dialogue for Healthcare Innovation (NDHI) to bring together leaders from private-sector healthcare, government, academia, and patient and consumer organizations to discuss the critical, complex issues that set the course for healthcare's future.

In preparation for the NDHI summit, to be held in early March 2015, HLC member organization ZS Associates, a healthcare consultancy, interviewed leaders of HLC member organizations to explore and move toward private-sector consensus on the topics of how to best deliver value and innovation in healthcare.

The objectives of these interviews primarily were to explore how best to define value in healthcare, and then to identify the most pressing challenges and promising opportunities related to delivering value and spurring innovation in healthcare. The aim was to crystallize opportunities for HLC to make a positive difference in healthcare, whether through efforts to shape policy, private-sector collaborations or private-public collaborations.

ZS Associates interviewed 51 stakeholders from 26 HLC member organizations, representing various sectors within healthcare, including integrated hospital and provider systems, payers or health insurance plans, medical device manufacturers, biopharmaceutical manufacturers and healthcare data companies. Stakeholders included executive leadership roles within HLC member organizations, and represented functional areas including policy and reimbursement, health economics and medical operations. The interviews were conducted from November 2014 through January 2015, with each discussion lasting 30 to 60 minutes.

Number of Stakeholders Interviewed



Across interviews, stakeholders were passionate about making a positive impact on the U.S. healthcare system, whether via innovative treatments or medical practices, improved consumer and patient engagement, and collaboration with other private- and public-sector entities. Despite the challenges facing our healthcare system and HLC member organizations, optimism prevailed. A number of interviewees were confident that stakeholders could achieve mutual trust and improve value in healthcare by focusing on patients and keeping them at the center of conversations. One health plan executive shared his optimism for the future, noting that, a decade ago, there was little willingness among employer customers to meaningfully discuss "the need for balance between cost and employee choice. Today, he said, "Our purchasers understand that there will have to be trade-offs. What they want are trade-offs that are reasonable." Similar discussions are happening frequently throughout the healthcare system, and such dialogue is important to identifying solutions that help improve the value of our healthcare system.

Defining Value in Healthcare

Much has been written on the topic of value in healthcare, and it continues to be a much-discussed topic across healthcare stakeholders. In most industries, the concept of value tends not to generate much discussion, and delivering significant value to customers is the inherent intent of most business models, and a prerequisite to long-term success.

While delivering value to customers is also inherent to business models in healthcare, the assessment of value is complex. What makes healthcare different?

+ **Disintermediation of payment for services and delivery of services:** Those receiving services (i.e., consumers and patients) are typically insulated from or even blind to the actual total cost of those services. Sometimes, those delivering services (i.e., physicians) are not aware of the actual total cost of the interventions they recommend, such as diagnostics, procedures or drugs.

+ **Healthcare is highly regulated:** While intended to be in the interest of the population and individuals, regulation can sometimes interfere with delivery of services and limit the ability of stakeholders to collaborate freely in the interest of improving service delivery and developing innovations.

+ **"End user" ability to assess value:** Consumers and patients receiving services are not always in the best position to assess the value of those services. They certainly assess their experience in the healthcare system; however they have little information to determine whether their clinical outcomes are consistent with those achieved in similar patients, or those that best clinical practices can deliver.

+ **Access to healthcare is perceived as a right:** Because many believe access to quality healthcare is a right, there is hesitancy to limit the quantity and quality of healthcare delivered. Discussions of access to healthcare raise the question of how much a life is worth, and thus, how much services and products are worth when they extend or improve life. Other countries have placed monetary value on the worth of a "quality adjusted life year," but the United States and its citizens seem unlikely to make such an assessment.

Few, if any, industries face the complexity and challenges related to assessing value that we see in healthcare. To identify ways in which HLC member organizations can further contribute to improving value in healthcare, we started by exploring how to best define value in healthcare.

Components of Value

Any discussion of value in healthcare must start with alignment on the objective of our healthcare system. At its core, the objective is to enable people to live long, healthy lives. Given this, it is important to frame our definition of value from the view of how it is delivered to improve the health of consumers and patients, while being sustainable from an economic perspective.

Across the stakeholders interviewed, there was general consensus that value in healthcare should be thought of in the classical definition of quality over cost (Figure 1).

Stakeholders were further aligned that *quality* should include both the humanistic and clinical aspects of patients' healthcare experiences. From a cost perspective, stakeholders were well aligned that total direct healthcare costs are most important to include. However, many noted that we must not lose sight of indirect costs such as lost productivity for patients and their caregivers, despite the fact that these costs can be difficult to measure, and that savings related to these costs are often not easily realizable other than at a significant population level.

Respondents noted that in the case of healthcare, in today's climate, it is imperative to simultaneously raise quality while lowering (or at least stabilizing) cost. It was not agreeable in the view of most HLC stakeholders to reduce healthcare quality in exchange for major cost reductions.

Figure 1: Value in Healthcare

Stakeholders shared their views on the types of humanistic and clinical measures that they believe must be taken into account when assessing value, some of which are summarized in Figure 2. Respondents focused on sharing their views on the high-level categories of quality, rather than seeking to align on the detailed measures, which are typically disease specific, and already well explored by organizations such as the Agency for Healthcare Research and Quality (AHRQ).

Humanistic Aspects	Clinical Aspects
+ Quality of life improvements, which may vary by individual + Service experience: respect for time, friendliness of support staff, accuracy of billing, etc. + Promptness and accessibility of care + Empathy demonstrated by providers + Ability to understand and effectively navigate the "system" + Maintenance of wellness or prevention of disease	+ Process-oriented measures: presurgery checklists, percentage of diabetics with eye exams conducted, etc. + Intermediate outcomes or leading indicators of health outcomes: HbA1c levels, cholesterol levels, blood pressure, BMI, etc. + Health outcomes: slowed disease progression, reduction in post-op infections, avoidance of hospitalization, avoidance of CV-related mortality, etc.

Figure 2: Humanistic and Clinical Aspects of Healthcare Quality

Stakeholders were varied in their views on the broad utility of detailed measures, such as those compiled by AHRQ, noting that perhaps too many metrics are process-oriented and not enough are outcome-oriented. Per the National Quality Measures Clearinghouse at the time of writing, there are 2,395 process measures and 715 patient-experience measures compared with only 654 outcome measures. Some respondents felt that the metrics used today provide only a glimpse into the overall quality delivered by a provider or an institution. Stakeholders were aligned that clinical quality metrics should be outcome-oriented when possible, while recognizing that some process-oriented metrics and intermediate outcomes can be important, insofar as they help predict true outcomes. An additional important but confounding factor is that outcome measures must be risk-adjusted for the individual or population being treated.

Additional Considerations Related to Defining and Assessing Value

We must also consider in our discussion of value how we address the needs of individuals relative to the population. For instance, in the case of rare diseases, orphan drug incentives are in place to support biopharmaceutical developments that treat only a few hundred patients. One could intellectually argue that such drugs, which in rare cases can cost more than $100,000 per patient, are not valuable to the population at large; however, our system must continue to consider the needs of the individual or minority in balance with the population at large.

Through our discussions, stakeholders identified an issue related to the time horizon over which value is measured. In concept, value in healthcare can be thought of over the full lifetime of a patient. An intervention in early life, such as the correction of a congenital heart defect, is immensely valuable in that it essentially enables the extension of life by decades. Interventions that reduce cardiovascular risk, such as hypertension medications or effective weight-loss programs, also deliver value that only becomes apparent through the avoidance of adverse outcomes in the distant future. In other cases, such as in acute surgery, procedures that reduce post-op infections or reduce hospital length-of-stay show nearly immediate value, with the benefit realized in days or weeks.

Multiple factors inhibit stakeholders from taking a long-term view. On the payer side, consumers can transition between payers on a regular basis as their employment changes, or as they choose new plans. Nongovernmental payers are not inherently incentivized to consider lifelong health, given that consumers age into Medicare at 65 years old. On the manufacturer side, most are publicly traded for-profit companies, and thus must concern themselves with market and shareholder dynamics that can impart a shorter-term view. Consumers are also often naturally limited in their long-term view as human behavior often prioritizes near-term needs, comforts or desires over long-term considerations. Thus, healthy behaviors that positively impact long-term health are far too uncommon.

Given that HLC stakeholders agreed in principle with the definition of value described above, and that there is general agreement that value in healthcare should be measured over a longer time period, it may be prudent to begin shifting payment and business models to align to this view over time, enabling all stakeholders to move toward a longer-term view of value.

Valuing Innovation in Healthcare

In the context of the value definition discussion, many HLC stakeholders raised the issue of how innovations and advancements in care are valued, and thus funded. As cost pressures continue to limit funds available to support innovation, we run the risk that needed innovations—whether drugs and devices, educational, or operational- or process-oriented—never see the light of day, nor have a chance to demonstrate how valuable they could be. In particular, innovations were highlighted as being difficult to appropriately value, given there is not always enough real-world data to assess how well they work and the impact they deliver, yet they have a known cost. Potential solutions were raised to create funding and evaluation mechanisms for innovations in the real-world setting, leading to a better determination of value, and thus pricing, after coming to market. Such ideas will be explored further in the "Opportunities to Improve Value in Healthcare" section of this report.

Sub-industry Perceptions of Value

"A conceptual answer about value in healthcare might be different than what drives day-to-day operations at each of our organizations." —Payer

While the overarching definition of value in healthcare is consistent across the sub-industries represented in HLC, there are differing perceptions and perspectives of value creation and delivery along the supply chain. Three themes were regularly uncovered during our interviews.

1) Stakeholders agree on a definition of value, but their priorities regarding value delivery differ.

Although HLC stakeholders agree that value is defined as quality over cost, each organization is subject to the business drivers of its own sub-industry.

Payers focus heavily on the cost containment aspect of the value equation, driven by their customers' needs. Some stakeholders believe that payers may not pay for incremental innovation unless it directly and clearly impacts overall cost. Additionally, commercial payers have a relatively short-term lens, given member churn and the coverage switch to Medicare at age 65; a few stakeholders believe the combination of these two factors contributes to a lesser focus on "humanistic" considerations in value creation and delivery.

On the other hand, **manufacturers** articulate the importance of product innovation as a driver of value more often than respondents in other sub-industries. For example, *"A patient with a serious condition may be 100% compliant with two injections per day, because otherwise they will die. But if there's a once-daily pill, they'd still prefer that, … I'd say there's extra value in the second option."* —Manufacturer

Cost as priority focus

"I don't think we're going to materially move the needle on value until we have providers compete on cost of care." —Payer

Product innovation as driver of value

"An antibiotic that could get someone out of the hospital quicker, with equal efficacy and safety, is a very powerful example of how innovation in the pharma industry can reduce costs and save money for the system." —Manufacturer

Providers are focused on quality of care more than cost of care and product innovation. Both acute and non-acute providers tend to operate under incentive models that emphasize revenue generation rather than cost containment. Providers' innovation efforts focus around process improvement and, in the case of academic centers, novel procedure development. *"Providers see value as providing more care to more people at high quality. … They may give credence to the affordability at the patient level, but they wouldn't consider it a success if their beds were empty."* —Payer

Consumer and employer priorities are more difficult to determine and characterize due to the heterogeneous nature of individuals' and businesses' values. *"Each individual has a different threshold for value. If you were to ask three different consumers what's more important to them—cost, quality or access—you will get three different answers."* —Payer

These types of differences in priorities underscore the general misalignment of incentives across stakeholders in healthcare, and provide context for the next theme that emerged.

2) Individual healthcare organizations are siloed in their sub-industries and have limited awareness or understanding of each other's goals.

For each HLC member organization to be successful, deep expertise and capability is required, whether in administration of a health plan, development of new medical devices or operation of an integrated delivery system. Potentially due to the focus required to be successful in their own businesses, we noted somewhat limited understanding of one another's goals. These gaps in understanding likely stem from the fact that current relationships between stakeholders are primarily formed through transactions or negotiations as opposed to partnerships—this leads to an incomplete understanding of one another's goals, needs and accomplishments.

Further, any given organization has a limited view of the healthcare journey of the patient. A hospital system's understanding of the patient's healthcare journey is likely limited to his or her admission into its care, and resulting discharge. However, the payer will likely have a broader view as it would have access to the various claims and transactions along the patient's journey. The payer would, however, likely be unaware of the patient's engagement in an adherence and community support program provided by a drug manufacturer to help avoid readmission.

3) Skepticism exists within the supply chain regarding one another's organizational intentions.

Differences in business models, priorities and incentives across the healthcare supply chain challenge alignment across sub-industries. Many respondents noted skepticism regarding other organizations' intentions and commented on each party's desire for control and pricing or negotiating power. Mistrust in some cases results in an overly skeptical view of the information and data shared across stakeholders.

A few questions about each other's intentions during the interviews:

What makes a new product truly innovative? Why is it coming to market at a high price?

"If you look at the prices for some approved medicines—rare diseases, oncology and hepatitis—it's going to be difficult to explain the value story. It's hard for people to appreciate R&D and other costs." —Manufacturer

Do risk-sharing agreements hold both parties accountable? How does each party perceive the stated metrics and outcomes?

"Who are the [collaborators] I can trust—not only telling me what they did, but being transparent about what the outcome really was." —Distributor

Who will benefit most from the data-sharing agreements? Who will own the results?

"There are issues with data ownership. Healthcare is largely an information business, so who is going to own the data when you're collaborating for RWE? And whose shareholders will benefit most?" —Manufacturer

During our interviews, viewpoints on a number of more granular value topics ranged in alignment. The table below outlines the value-related topics that were frequently mentioned; the first column describes value topics aligned across HLC stakeholders, while the last column shows value topics where respondents remain divided:

Most Aligned	Somewhat Aligned	Least Aligned
+ In today's value chain, manufacturers do not have a clear path for participating in value arrangements. + Providers are incentivized by an FFS system that can be seen as a barrier to cost reduction. + Nearly all manufacturers saw government regulations as barriers to demonstrating and … communicating their value. + All sub-industries are looking for better approaches to predict cost and outcomes.	+ While many agreed that the time horizon for measuring value needs to be lengthened, there is not a clear consensus on the appropriate duration. + Many respondents agreed that government intervention is not the best way to align incentives or improve value delivery, but some respondents felt government involvement could be beneficial.	+ Some stakeholders saw consumer involvement as a major contributor to value improvement. + A few respondents noted a gap in incentives between for-profit and nonprofit organizations.

Figure 3: Level of Alignment on Value-Related Topics Across HLC Executives

Improving Value in Healthcare

Our interviews with HLC stakeholders explored the existing barriers and opportunities that relate to improving value in healthcare. We have found the following simple framework helpful in synthesizing the insights shared by respondents.

Efforts to improve value in healthcare can be framed as follows:

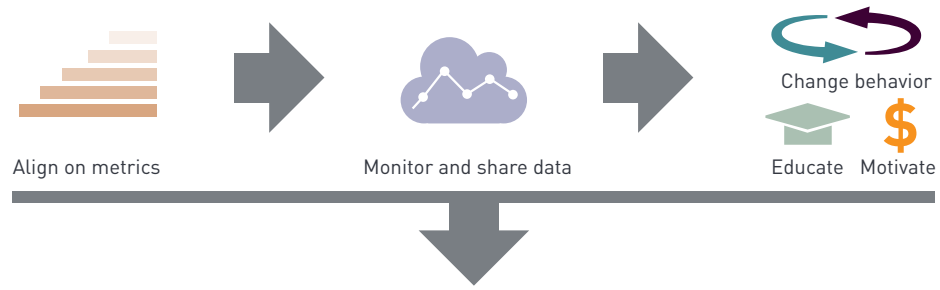


Figure 4: Value Improvement Categories

+ **Align on metrics:** What are we trying to achieve? What are the key quality and cost metrics for success? How will we measure each outcome, including humanistic ones? What are realistic and implementable metrics? How will we adjust for risk?

+ **Monitor and share data:** Are we achieving our goals and/or reaching our metrics? What data will help us measure our progress? How can we use cross-stakeholder information sharing to our advantage? How do we eliminate silos in understanding, visibility and data sharing? How can we drive real-time actions?

+ **Change behaviors:** How do we change stakeholder behavior to consistently achieve our goals? How do we educate providers to help them deliver higher-value care? How do we educate consumers, patients and caregivers to help them engage in their health and make better decisions? How do we motivate change through payment reform and other novel incentives?

It is important to note that collaborations in any one category can positively affect value creation and delivery; however, the greatest impact comes from tying all three categories together in solutions and/or pilot programs.

Additionally, these three categories can help HLC identify areas for value creation that apply across the healthcare sub-industries and collaborations today.

Barriers to Improving Value in Healthcare

To identify areas for value improvement in healthcare, it is necessary to recall the barriers that must be overcome. HLC member organizations frequently and consistently cited the following barriers to value improvement in the U.S. healthcare sector.

Each barrier is explained below, and Figure 5 illustrates how these barriers limit value improvements as they related to the framework shared in Figure 4.

1. **Misalignment of incentives:** Nearly every respondent quickly identified misalignment of incentives as a barrier to improving value in healthcare. In essence, one organization's costs are another's revenues, and thus efforts to reduce cost put pressure on the various business models within the system. Different organizations inherently value quality improvements over cost reductions, and vice versa, and thus misalignment of incentives is commonly encountered.

2. **Regulatory or policy challenges:** Most stakeholders noted regulatory or policy challenges related to demonstrating, and thus helping improve, value. For example, pharmaceutical manufacturers referenced "best price" regulations that make it nearly impossible to engage in risk-based contracts without running the risk of best-price calculations triggering a $0 price for their products in Medicaid. Providers referenced limitations in sharing patient information among one another to best deliver patient care, and manufacturers referenced anti-kickback and other regulations that limit how they engage and collaborate with payer and provider customers.

3. **Lack of data standards, interoperability and transparency:** Nearly every respondent addressed this barrier, which ultimately limits the ability to measure outcomes in a meaningful way across sites of care, over time and with all appropriate factors controlled.

4. **Trust issues between stakeholders:** As explored in "Sub-industry Perceptions of Value," trust issues limit the willingness to share information and collaborate in a way that would help identify ways to improve value, or address costs.

5. **Insufficient time horizon for appropriate measurement of value:** This barrier is explained in detail in the above section "Additional Considerations Related to Defining and Assessing Value." Manufacturers most often cited it in the context of innovations that increase short-term costs but provide long-term humanistic or quality outcomes (e.g., drugs that avoid future complications or transplantation; devices or implants that last for 15 years rather than 10 years).

6. **Lack of tools or ability for consumers, patients and caregivers to make more valuable healthcare decisions:** Consumers, patients and caregivers are increasingly expected to play a significant role in making healthcare decisions, whether related to cost management or treatment. Such engagement has the potential for many positive outcomes, however, respondents highlighted limitations. Information about insurance benefits, costs of various services and expected outcomes of various treatments can be challenging to understand and, in some cases, challenging to find. Further, patients are often compromised in their decision-making ability due to the cognitive and emotional impacts of their conditions.

Barriers	Value Improvement Category Impacted		
	Align on Metrics	Monitor and Share Data	Change Behaviors
1. Misalignment of incentives			x
2. Regulatory or policy challenges	x	x	x
3. Lack of data standards, interoperability and transparency	x	x	
4. Trust issues between stakeholders		x	x
5. Insufficient time horizon for appropriate measurement of value		x	x
6. Lack of tools or ability for consumers, patients and caregivers to make more valuable healthcare decisions		x	x

Figure 5: Barriers to Value Improvement in the U.S. Healthcare Sector

Some of these barriers are expanded upon with interviewee commentary in Figure 6, below.

1. Misalignment of incentives

"The model is flawed if I get paid when you walk through my door." —Provider

"People see healthcare as fixed pies from which all stakeholders are going to argue who gets the biggest share." —Manufacturer

"I can't fault dialysis centers for wanting to do the best possible job on the thing that they do. But they're not going to put money into the prevention of diabetes. … that'll put them out of business." —Payer

2. Regulatory or policy challenges

"If we can figure out best-price reporting and anti-kickback elements, risk-sharing arrangements hold value. A lot of us are willing to put money on the value that our product delivers and the economic impacts." —Manufacturer

"If we can incent people to get the flu shot, then we'd give them money. But Medicare won't allow us to do it." —Payer

3. Lack of data standards, interoperability and transparency

"The government has a huge database with Medicaid and Medicare. They can tell you a tremendous amount, but it's not all available." —Manufacturer

"Provider systems have invested in closed medical record systems to build walls around their care networks. They want to keep patients within their own referral network." —Manufacturer

4. Trust and skepticism issues between stakeholders

"There are some providers that … are looking to build higher walls and defend their fort. They want to avoid becoming a commodity, so they create an energy field of having a partnership with a payer so they don't have to figure out how to control costs and live on a smaller margin." —Payer

"Every large corporation is a separate entity. You have to find the appropriate border to get in. There is not enough of a clearinghouse to share opportunities and ideas." —Provider

"I don't blame anyone for it—if I were in their shoes, I'd be wary of what pharma is trying to achieve, too, but that's not what we're doing here." —Manufacturer

Figure 6: HLC Stakeholder Explanations of Barriers

As shown in Figure 5, barriers span multiple value improvement categories, providing HLC with numerous opportunities to take action. Not surprisingly, many of the collaboration ideas brought forth during interviews were directly tied to overcoming the barriers listed above.

Opportunities to Improve Value in Healthcare

When viewing the barriers discussed above from a new angle, they can shed light on the most promising opportunities for HLC and its member organizations to pursue to improve value in healthcare. Figure 7 outlines the opportunity areas that were discussed during stakeholder interviews and via HLC membership meetings, and highlights the value improvement categories those opportunities could address.

Opportunities	Value Improvement Category Impacted		
	Align on Metrics	Monitor and Share Data	Change Behaviors
A. Payment model pilots	x	x	x
B. Data interoperability standards	x	x	
C. Regulatory reforms		x	x
D. Value stream mapping—innovating the patient journey	x	x	x
E. Models to fund and evaluate innovation	x	x	
F. Episode-of-care pilots		x	x
G. Medication adherence programs		x	x
H. Creative consumer or patient incentives			x
I. Medical education improvements			x

Figure 7: Opportunities for HLC, by Value Improvement Category

Payment Model Pilots

Many respondents described variations of payment model pilots that can improve value in healthcare by more directly assessing and rewarding value by linking payment or price to quality delivered. Payer and provider organizations frequently discussed both government and commercial ACOs as an example of current models that are working to improve value in healthcare. While some have not yielded significant cost savings, they have typically shown strong quality measure improvements, thus increasing value.

Nearly half of the respondents referenced risk-sharing agreements as an opportunity for cross-sector collaboration to improve value. Such agreements were seen by payers and providers as attractive ways to engage manufacturers in payment model innovations, and manufacturers generally expressed interest in participation.

Opportunity Overview: Payment Model Pilots	
Barrier addressed	The majority of payment models that exist in healthcare today do not incentivize value improvement. Some programs, like accountable care organizations (ACOs), have recently been implemented to address this issue, but there are a number of other payment model changes that have yet to gain traction.
Objective	Design pilot programs between HLC stakeholders to test how new payment models, such as risk-sharing agreements, can improve value in healthcare delivery.
Core stakeholders involved	Payers, providers, distributors, manufacturers
Key actions	1) Construct the framework for a risk-sharing pilot program, including guidelines for measuring outcomes and resulting rewards or penalties for meeting or failing to meet those measures. 2) Establish a risk-sharing pilot program among HLC stakeholders. 3) If results are successful, encourage this type of collaboration across the private sector and share aligned-upon guiding principles.
Potential challenges	"Best price" considerations create drug manufacturer disincentive to participate, and stakeholders have encountered difficulty in aligning upon and measuring outcomes in these programs

Data Interoperability Standards

Nearly all of the HLC stakeholders interviewed agreed that a lack of data standardization, interoperability and transparency is an important barrier to improving value in healthcare.

Opportunity Overview: Data Interoperability Standards	
Barrier addressed	Stakeholders are not fully aligned on the data to capture that will enable assessment of value (quality and cost), nor on common data layouts and standards that would ease sharing of relevant data.
Objective	Develop an aligned set of standards for data collection, system interoperability and data exchange.
Core stakeholders involved	Providers, payers, manufacturers, distributors, technology or data providers
Key actions	1) Facilitate the formation of a working group on data interoperability standards to create guidelines that are endorsed and adopted across HLC member organizations (may require addition of new member organizations with appropriate systems expertise). 2) Engage non-HLC private-sector organizations to endorse and adopt standards. 3) If necessary, lobby HHS or CMS to adopt standards as part of policy.
Potential challenges	Implementation of systems for data interoperability, variation of metrics across therapy areas, and policy and legislative barriers to data-sharing agreements

Regulatory Reforms

In many cases, manufacturers would be willing to work closely with payers or providers in efforts to demonstrate the quality delivered by their products, by offering expertise, personnel and, in some cases, even no-charge products. Payers and providers would often rather evaluate products in their own populations or settings, rather than rely solely on manufacturer-conducted trials. However, anti-kickback statues and other regulations restrict manufacturers' ability to engage in these types of collaborations. In the current environment, one could view the manufacturer contributions described above as inducements, if they were not provided in the context of formal trials.

In practice, if a manufacturer agreed to refund a commercial payer the cost of a drug purchase because the patient did not achieve a particular outcome, the cost for that prescription would technically be $0. Based on conservative application of best-price rules, this would trigger Medicaid best price, and the manufacturer would be required to extend a net price of $0 for all Medicaid purchases.

The enactment of regulatory reforms would enhance the value delivered to the healthcare system by allowing manufacturers and payers or providers to collaborate in ways that are currently prevented by anti-kickback statutes.

Opportunity Overview: Regulatory Reforms	
Barrier addressed	Drug and device manufacturers find it difficult to engage in risk-sharing agreements, mainly due to challenges related to compliance concerns.
Objective	Implement two regulatory reforms that would improve manufacturers' ability to more meaningfully engage providers and payers to assess the value of their products, or to link price or payment to the value their products deliver.
Core stakeholders involved	Manufacturers, providers, payers
Key actions	1) Develop joint working guidelines for collaborations between manufacturers and other commercial entities. a. Consider leveraging the joint working guidelines aligned upon by the U.K.'s National Health Service and the Association of British Pharmaceutical Industry, which were developed when the U.K. healthcare industry sought to enhance collaboration with manufactures to improve value delivery. 2) Expand the applicability of waivers created by CMS and the Office of the Inspector General (OIG) to protect government ACOs and their constituent organizations from antitrust, fraud and other legal risks. 3) Engage HLC stakeholder organizations to endorse these reforms.
Potential challenges	Alleviating government concerns about loosening antitrust regulations for these arrangements; overcoming long time frame associated with regulatory or legislative changes

Value Stream Mapping—Innovating the Patient Journey

A few HLC members stressed that the siloed nature of each sub-industry leads to gaps in the understanding of the total experience of a patient's care. A robust value stream mapping approach would uncover a number of opportunities for HLC to act on, whether related to member collaborations or health policy improvements.

Opportunity Overview: Value Stream Mapping—Innovating the Patient Journey	
Barrier addressed	Traditional patient journey maps do not capture how the many different healthcare stakeholders interact and influence patient care; rather, patient journeys are often developed to represent the treatment process from the perspective of the organization that creates it.
Objective	Collaborate to co-develop a new type of patient journey—a value stream map that details the patient experience from a broader point of view and over a longer time horizon.
Core stakeholders involved	Payers, providers, manufacturers, distributors, data providers
Key actions	1) Develop methodology to illustrate the entire experience of care delivery as a value stream map (for select disease states, such as diabetes, heart failure or particular types of cancer). 2) Create a value stream map in collaboration with HLC stakeholders: + Map the patient experience across all aspects of their condition. + Analyze the time horizon for a specific condition, ranging from pre-diagnosis through chronic-care management. + Represent all stakeholders that impact the patient's care. + Identify elements that worsen or enhance the patient experience. + Identify gaps in health insurance coverage or gaps in payment. + Identify areas where misalignment of incentives results in suboptimal decision making. + Identify areas where hurdles (e.g., regulatory, data related) create measurement challenges or inhibit collaboration that could improve patient care. + Identify opportunities to improve provider and patient or caregiver education. + Identify where metrics, measurement and information sharing could enable behavior change. + Highlight areas in need of innovations.
Potential challenges	Distilling down the complexity of a disease state and variation in patient cohorts to produce a robust, functional value stream map

Models to Fund and Evaluate Innovation

Increasingly, stakeholders are finding it more difficult to successfully bring innovations to market, whether those innovations are incremental or more substantial. HLC and its member organizations could identify potential models to fund and evaluate new innovations in a way that focuses on improving overall value.

Opportunity Overview: Value Stream Mapping—Innovating the Patient Journey	
Barrier addressed	Traditional patient journey maps do not capture how the many different healthcare stakeholders interact and influence patient care; rather, patient journeys are often developed to represent the treatment process from the perspective of the organization that creates it.
Objective	Collaborate to codevelop a new type of patient journey—a value stream map that details the patient experience from a broader point of view and over a longer time horizon.
Core stakeholders involved	Payers, providers, manufacturers, distributors, data providers
Key actions	1) Develop partnerships between stakeholders and models to better assess the value of new products and processes in healthcare. a. Partnerships to assess the quality improvements delivered by a new drug or device, to then inform the market price and publish data to support appropriate use b. Collaborations to measure the value added by implementing clinical decision standardization methods c. Models to better capture innovations' value, such as a modified clinical trial programs, multiparty risk-sharing agreements at launch, etc. 2) Engage funders (government or private) in the partnership or model assessment process. 3) Create a working group to assess effectiveness and broader applicability of newly-constructed models.
Potential challenges	Agreement on metrics for quality, cost and other indicators of value; implementation of systems for capturing and sharing data; scalability and/or broad applicability of models and other methods developed in partnerships between individual organizations

Episode-of-Care Pilots

Pilot studies on episodic care were mentioned by a few individuals, primarily from manufacturer backgrounds. A key barrier to demonstrating value for manufacturers is the time horizon of value measurement, particularly for chronic disease drugs or medical devices like implants. In an episode-of-care pilot, manufacturers could be able to better demonstrate the value of their products if patient outcomes are viewed over the entire episode of care (even if this episode of care is defined in years, as opposed to weeks or months).

Opportunity Overview: Episode-of-Care Pilots	
Barrier addressed	Time horizons used to assess product value do not fully capture the value of interventions that have long-term impact on patient health.
Objective	Establish episode-of-care pilots to allow manufacturers and/or providers to better demonstrate the value of their products or care delivery.
Core stakeholders involved	Manufacturers, payers, providers
Key actions	1) Create episode-of-care pilot programs between manufacturers (whose products best demonstrate their value over longer time periods) and payers or providers, or between providers and payers. 2) Demonstrate results of measuring value over a longer time horizon. 3) If the pilots are successful, engage private-sector organizations in the adoption of new usage or reimbursement guidelines that reflect the true value of these interventions.
Potential challenges	Implementation of systems for data interoperability, willingness of all stakeholders to modify payment model for pilot

Medication Adherence Programs

During a recent HLC membership meeting, multiple member stakeholders highlighted ways they have attempted to improve adherence—pharmacist or physician engagement, patient education and patient financial incentives. Improving adherence to medication would likely generate positive value for the healthcare system—as quality is likely to increase, and costs are likely to be stable or improved, assuming increased drug costs are offset by escalations in care such as hospitalization.

HLC is uniquely positioned to enable a robust adherence program that engages key stakeholders—from payer to physician, pharmacist and drug manufacturer. Currently, most adherence programs are led by one stakeholder, without clear alignment and incentives for all stakeholders to support the patient in making positive behavior changes.

Opportunity Overview: Medication Adherence Programs	
Barrier addressed	Medication adherence is an important factor in producing quality outcomes, but patients often fail to adhere to their medication regimens.
Objective	Create collaborations across HLC stakeholders to improve medication adherence.
Core stakeholders involved	Manufacturers, payers, providers, distributors, technology or data providers
Key action	1) Develop medication adherence collaborations between HLC members. 2) Demonstrate results of medication adherence programs to private-sector and government organizations.
Potential challenges	Social and environmental factors that prevent patients from adhering to medication regimens; policy and legislative barriers that prevent stakeholders from using financial incentives to motivate patients

Creative Consumer or Patient Incentives

Currently, our health system tends to provide disincentives to discourage consumers and patients from making healthcare decisions that consume resources, even when those resources (such as preventive care, vaccinations, etc.) are highly cost-effective. Consumers and patients are exposed to penalties for not carrying health insurance and to increasing deductibles and copays for visiting their physician or filling their prescriptions.

An HLC member executive highlighted the impact of a positive patient incentive. Employees of the provider system were incentivized to take their prescribed medications. Co-pays were in place for medications, but were waived if patients adhere to their medications. Adherence to medications improved substantially within the employee base, reflecting the impact of positive incentives on achieving desired outcomes.

Other stakeholders mentioned potential incentives that, while they may seem unintuitive, would likely generate positive value. For example, paying patients a small incentive to come in for annual preventative care or vaccinations would likely help improve overall quality and reduce cost.

In recent years, companies and educators have sought to incent positive behavior through gamification. Similar opportunities likely exist in healthcare, to both educate patients to engage in good behaviors, and to incent them to adopt them.

Opportunity Overview: Creative Consumer or Patient Incentives	
Barrier addressed	Consumer and patient behavior can be a barrier to realizing valuable outcomes in healthcare, but such behaviors can be very hard to influence.
Objective	Identify ways to put in place novel consumer or patient incentives that drive positive behavior change, whether related to seeking care when appropriate, compliance with therapy, etc.
Core stakeholders involved	Manufacturers, payers, providers
Key actions	1) Hold cross-stakeholder brainstorming to identify potential methods to incent or drive behavior change (with collaboration of behavioral economists, technology providers or others with experience in driving consumer or patient behavior change). 2) Implement various pilot models to assess impact. 3) Develop guidelines for broader implementation based upon pilot outcomes. 4) If necessary, enact lobbying efforts to address any regulatory or policy hurdles to implementation.
Potential challenges	Human behavior dynamics or inertia; policy and legislative barriers that prevent stakeholders from using financial incentives to motivate patients

Medical Education Improvements

Today, medical education focuses mainly on developing physicians who make excellent clinical decisions. However, value, as discussed previously, is driven in part by patient experience, which can be a function of the empathy and support conveyed by the treating physician.

Opportunity Overview: Medical Education Improvements	
Barrier addressed	Medical education curricula place too little emphasis on delivering positive patient experiences.
Objective	Identify opportunities to enhance medical school curricula.
Core stakeholders involved	Providers, medical schools
Key action	1) Evaluate medical school curricula to identify improvement opportunities related to patient experience (and assess any such existing programs or classes). 2) Develop and pilot new programs or classes within HLC member organizations. 3) Evaluate pilot outcomes and, assuming success, establish guidelines for other medical schools to implement similar programs.
Potential challenges	Trade-offs within existing curricula; willingness of institutions to pilot new programs

Conclusion

Many opportunities exist to improve value in healthcare, whether via quality improvements or cost reductions. HLC is in a unique position to enable these opportunities—its membership can present a united, cross-sector position to influence regulators and other industry participants in a way that brings value to all stakeholders, or it can enable private-sector collaborations among its members to demonstrate the value of new approaches in healthcare.

HLC and its member organizations look forward to contributing their passion, ideas and resources to the National Dialogue for Healthcare Innovation, and in so doing, identifying and implementing ideas that positively impact the U.S. healthcare system.

About ZS

More than 3,000 ZS professionals in 21 offices worldwide draw on deep industry and domain expertise to deliver impact where it matters for clients across multiple industries. To learn more, visit www.zsassociates.com or follow us on Twitter (@ZSAssociates) and LinkedIn.

About the Healthcare Leadership Council:

The Healthcare Leadership Council (HLC) is a not-for-profit membership organization comprised of chief executives of the nation's leading healthcare companies and organizations. HLC is committed to advancing a consumer-centered healthcare system that values innovation and provides affordable, accessible, high-quality healthcare to all Americans.

For more information, please contact:

ZS Associates
+1 855.972.4769
inquiry@ zsassociates.com

www.zsassociates.com

02-15