# The Balance Between Affordability, Value and Access

BY MICHELE CLEARY

Ever-growing healthcare spending is at risk of crowding out much-needed investments in infrastructure, education, and public health sectors. As discussed in a recent issue of *Value & Outcomes Spotlight*, aging populations will continue to challenge healthcare budgets. A 2017 study in the *Journal of the American Medical Association* noted that aging accounted for an 11.6% increase in US healthcare spending between 1996 and 2013.[1] In addition to growing demand due to aging populations and the rising prevalence of chronic conditions,[2] health systems around the globe are confronted with the release of more sophisticated and higher-priced medical technologies and drugs. In 2017, biologic drugs represented 2% of all US prescriptions, but 37% of net drug spending.[3] These spending trends show no signs of slowing. The Centers for Medicare & Medicaid Services's National Health Expenditure Projections 2018-2027 Forecast Summary predicts that the health share of gross domestic product (GDP) in the United States is expected to increase from 17.8% in 2019 to 19.4% by 2027.[4]

Decision makers are struggling under budget limits, trying to ensure access to effective treatments while keeping such care affordable. The balancing act begins when evaluating the value of a new medical technology—whose perspective taken, what threshold level should define value, when should the medical budget expand to accommodate new technologies? Trade-offs between perceived value and the ability to afford a new therapy given budget constraints often drive access to new innovations. The interconnection of value and affordability at a system level and how this impacts access to medical technology and pharmaceuticals may be the most challenging problem faced today by this audience.

The 2018 ISPOR Summit examined value frameworks from a variety of perspectives. HEOR researchers often focus on defining the "value" of medical technologies from various viewpoints. However, we are seeing that the ability to pay for such new innovations depends a great deal on how the payer defines its budget and the trade-offs payers make in order to ensure or deny access to treatments of value deemed to be insufficient to displace an established therapy. These conflicts cannot be ignored in the value judgment. More research is focusing on how to determine "willingness to pay" from different viewpoints and how that can be turned into thresholds used to objectively evaluate and compare value often measured by cost-effectiveness methods.

This article talks with some thought leaders in this field, to hear their concerns and proposed ideas about how health systems may better address these conflicts. For this article, A. Mark Fendrick, MD; Chuck Phelps, PhD; Joshua Cohen, PhD; and Stephen Schondelmeyer, PharmD, PhD shared their thoughts on this debate.

**Concerns regarding the current value methods**

Faced with limited healthcare budgets, stakeholders are more comfortable with the view of value—if price for healthcare service or product is at or below a defined threshold, then we are getting value for money spent in our healthcare system. Yet many have voiced concerns regarding how value is determined, especially those surrounding quality-adjusted life year or QALY.

Stephen W. Schondelmeyer, professor of Pharmaceutical Economics in the College of Pharmacy at the University of Minnesota, shared his concerns with the QALY approach, namely where thresholds are set. He noted that the QALY threshold used by ICER now reaches $150,000—a value significantly greater than the US median income. He argued, "If we assume that a value of a QALY is twice the median income in society, that sets up a structural deficit for the US economy. We're going to continue to spend more and more on healthcare than we have in total resources, and healthcare will grow so much that it chokes out other things in our economy." While some survey research has been conducted to help identify society's willingness-to-pay for services, he noted that these survey respondents tended to be better educated, wealthier people, who may view a QALY as worth more than a generalizable population.

Some assumptions used in cost-effectiveness analyses (CEA) also concerned Schondelmeyer. He finds that CEA models assuming that all patients received optimal care artificially inflate the cost savings from a new treatment given that optimal care is often more intensive than the level of care received in a real-world practice environment. He argued that these differences become especially pronounced when treatment benefits are modeled over a long time-horizon.

Schondelmeyer finished by voicing his concerns over cost models based on initial prices. Given that the rate of inflation in drug prices often far outpaces the rates of wage increase, the cost-effectiveness of a new treatment versus the standard of care is artificially high in these models and is further compounded over a five- or ten-year time-horizon.

While Schondelmeyer believes in value assessment models, in determinant values, he argues that they must be based on assumptions that are realistic and they must acknowledge that there is a limit to the resources we could spend on healthcare, stating, "I don't think we have a system in America that establishes prices that are truly based on the net value that someone would actually pay and based on the quantity of resources available to pay for it."

**The problem with increasing the threshold**

Charles E. Phelps, former provost of the University of Rochester, added his concerns regarding QALY thresholds, but thresholds in relation to budgets (defined as the maximum level at which you're willing to pay for healthcare).[5] Phelps argued that cost-per-QALY thresholds cannot be set independent of the budget. "My view is the budget is the relevant story," said Phelps. "You have to figure out what you can buy within that. And that really is the operational cost per QALY that you're willing to pay for."

Specifically, Phelps found the practice of increasing the thresholds for specific services misguided. As an example, he cited the British Health Service practice of increasing the cutoff threshold for end-of-life care, rare diseases, and pediatric diseases. Instead of arbitrarily changing these thresholds, he argued that once the thresholds are set, health systems must be able to say "no" to those products or services exceeding that threshold.

Phelps spoke of institutionalized US Medicare policies that preclude the Centers for Medicare and Medicaid aServices (CMS) from adequately rejecting treatments that exceed defined thresholds. The Social Security Act states that Medicare shall pay for all treatments that are "necessary and reasonable." That is the only language that guides CMS in terms of what they shall allocate. Similar policies bind the US Food and Drug Administration, as cost cannot be considered as a condition for approval of drugs, devices, or other biological products—only safety and efficacy. But he stated that CMS could be empowered with the ability to consider value, to use cost-effectiveness criteria in deciding what to cover, with a simple one-line modification to the Social Security Act. However, no such amendments are currently considered. >

Phelps emphasized that these examples reveal an important concern surrounding thresholds and value. "That's telling you something's missing from the standard cost-effectiveness formulation. Instead of saying 'how do we measure that value,' they're saying, 'we're going to relax the threshold.' You either say this is more valuable, and I know why and here's by how much, or you say, I know that's more valuable, but I don't know how, so I'm going to relax my threshold. To me, that's a signal that the cost-effectiveness model is incomplete."

For this, he has been advocating multiple criteria decision analysis (MCDA).[6-8] MCDA provides an alternative to CEA. It formally incorporates additional dimensions of value beyond those normally used in CEA to help make the final decisions about new technologies. Phelps noted that MCDA has not yet gained much traction in either the United States or in Europe. However, he encouraged this audience to embrace these new approaches. "It's coming," Phelps said. "If you want to make it more realistic, work to help make it better. Don't jam your foot on the brakes, because it's coming down the train tracks."

**Differing views of value**

Joshua P. Cohen, an independent healthcare consultant, echoed some of the previously mentioned concerns surrounding the QALY thresholds, noting that the threshold is arbitrary. "If not empirically determined, it's not necessarily value-based," said Cohen. But beyond the thresholds, he emphasized that the consensus across a truly representative round table of stakeholders regarding the "terminology of value" is needed. "Not just patients, not just doctors. But payers, policymakers, drug makers." The 2018 ISPOR Summit reinforced the importance of input from a broad mix of stakeholders when assessing value.

Cohen discussed the issue of protected drug classes as a demonstration of what happens when broad representative consensus is not considered. Medicare currently requires health plan sponsors include all drugs in 6 protected drug classes in their formularies. These protected drug classes include antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treating transplant rejection, antiretrovirals, and antineoplastics.

But he points out that by being required to cover all drugs in those protected drug classes, plans are limited from negotiating over price. "That, of course, is not value-based." He noted that a drug company could simply set the price, and the insurer has no choice but to cover that drug, regardless of whether it is better than the standard of care. "And that to me is really skirting the whole issue of value and value-based pricing."

Cohen stated, "(Payers) should at least have been at the table when it comes to these protected drug classes to make sure that the monopoly price…because that's what it becomes when the drug industry can set the price really as it wishes, without any fear of competition. They should have been at the table to at least discuss ways in which they could still have some leverage."

He reinforced the value of gathering a broad mix of stakeholders in these decisions. "If we can do that, then we're really well on our way to value-based pricing, but I don't think we're there yet."

Nonetheless, Cohen still is committed to QALY measure, "The QALY measure itself I think is the best we have, there certainly are criticisms, but it's the best we have at this stage."

**Value-based insurance design**

A. Mark Fendrick, professor in the Department of Internal Medicine and Department of Health Management and Policy at the University of Michigan, summarized his long fight to bring more intelligence into how healthcare stakeholders spend their healthcare dollars. "There is very good news when you're talking about healthcare," Fendrick began. "Everyone agrees that there's enough money in the system. And just about everyone agrees that we are spending some of it—maybe a lot of it—in the wrong places."

Fendrick is the director of the Center for Value-Based Insurance Design (V-BID), which promotes the development, implementation, and evaluation of health benefit designs that balance cost and quality. V-BID is built on the principle of lowering financial barriers to essential, high-value clinical services. He cites V-BID benefit design initiatives to ensure consumers "not have the low-value things be low-price things, but instead have the low-cost things be high-value things."

**How can we afford high-value, high-price treatments?**

Fendrick notes that expanding coverage of cost-effective care (eg, disease management services for hypertension, HIV, or depression) is not sufficient. As policymakers now recognize, expanding coverage of cost-effective care does not reduce total costs. And purchasers were demanding a V-BID plan that was cost-neutral.

To expand coverage for most any new treatments, plans could either raise premiums on healthy people, increase cost-sharing included deductibles (which Fendrick calls a tax on the sick), or decrease access to low-value care. This is the approach Fendrick believes should be the focus of the current value debate—removing no-value or low-value care in the system. Says Fendrick, "The good news is there's a lot of no-value care in the system. The bad news is there's a lot of no-value care in the system."

**The reallocation message**

While researchers have long focused on the high-value quadrants, Fendrick argues that more attention should be focused on those services that are in the low-value quadrants, stating, "People love to talk about the dominant situations (eg, save lives, save dollars) that rarely/never happen. But there's a whole bunch of things in a don't help/cost money quadrant." These low-value quadrants can be massive, as shown in a 2010 study by the Institute of Medicine showing 30% of healthcare spending in the United States was wasted on low-value and potentially harmful health services.[9]

By cutting investment of healthcare dollars in these low-value quadrants, Fendrick argued that new (high-price) treatments could be covered. This reallocation method is the basis for his V-BID benefit design.

Fendrick pointed to the V-BID Ex (ex for exchanges) product, which lowers cost-sharing on 20 high-value services by raising

cost-sharing on low-value services, achieving dollar-for-dollar coverage. He highlighted, "Premiums did not go up, deductibles did not go up. Access to high-value services went up and paid for entirely by decreasing access to low-value care."

The V-BID approach could address a core concern voiced by Cohen—cost-sharing that hinders treatment adherence. As Cohen stated, "if you have something that's really valuable, say it's a diabetes medication and needs to be taken on a daily basis in order for it to have that value, then you need to reduce the copayments, preferably to zero." V-BID would help treatment adherence of these high-value therapies by minimizing cost-sharing on these high-value interventions.

V-BID's reallocation approach is rapidly gaining wide support. Fendrick announced that V-BID design had been received by numerous states. "We are hopeful by the 2021 plan year we'll actually see V-BID Ex-type prototype plans available to individuals on the individual marketplace, and hopefully that will spill over largely to more public and private payers." V-BID will be implemented in numerous Medicare demonstrations, in TriCare, and is now taking hold in the commercial marketplace. "There's more than enough money in the system. Who's against more of the good stuff and less of the bad stuff? I think that my goal is having providers and consumers aligned around value."

He stated that he hopes public and private purchasers will "follow the lead of hundreds of public and private payers across the country and take a hard look at their benefit designs and align cost-sharing with clinical value, not price. We have every reason to believe that V-BID implementation will continue to be slow and steady."

## ISPOR and affordibility, value, and access

Both Phelps and Fendrick see ISPOR members playing an important role in the value debate.

Said Fendrick, "The ISPOR members need to know that as we continue to get payments and benefit design to be driven by clinical value, the work of ISPOR members will become increasingly relevant and implemented in the real world." He continued by saying, "That is what they do. They determine relative value of services. And they should be more actively involved in this clinically driven payment reform and benefits design. They should continue to refine the methodology." ISPOR members realize that funds are not unlimited, he stated, and "they can apply their expert methods to the identification and reduction of care that we shouldn't be buying so that we might create headroom to be able to purchase more of the things that we know improve the health of individuals and populations."

He closed by saying, "People really like the reallocation message. Everyone agrees with more of the good stuff and less of the bad stuff. Who should be the arbiter? The arbiter of good stuff and bad stuff? Why not ISPOR?"

Phelps sees ISPOR researchers as key in the development of value assessment methods, stating. "I would welcome the participation of people in industry to improve these methods. They're not perfect. MCDA methods are far from perfect. They're very clunky and hard to use. And cost-effectiveness is incomplete." He noted that some in this space have warned against the premature use of some value assessment models. But Phelps encouraged the ISPOR audience to venture ahead with these new methodologies, using his previously published Wright Brothers analogy.

"The Wright Brothers' first flight went a distance less than the wingspan of a Boeing 737. They made 6 flights that day. By the time they'd finished their sixth flight, that distance increased by a factor of 7 or 8 through experimenting and tinkering. You can't make these things better without using them."

"If they had said we have to perfect this tool before we use it, we would still be taking the train."

### *References*


1. Dieleman JL, Squires E, Bui AL, et al. Factors associated with increases in US health care spending, 1996-2013. *JAMA*. 2017;318(17):1668-1678. doi:10.1001/jama.2017.15927.

2. 2019 Global Medical Trends Survey Report. Wills Tower Watson. https://www.willistowerswatson.com/en-ID/insights/2018/11/2019-global-medical-trends-survey-report. Accessed November 2, 2019.

3. Medicine Use and Spending in the U.S. IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022. Published April 18, 2019. Accessed November 2, 2019.

4. National Health Expenditure Projections 2018-2027. Forecast Summary. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf. Centers for Medicare & Medicaid Services. Accessed November 1, 2019.

5. Phelps CE, Madhavan G. Using multi-criteria approaches to assess the value of health care. *Value Health*. 2017; 20: 251-255.

6. Thokala P, Devlin N, Marsh K, et al. Multiple criteria decision analysis for health care decision making—an introduction: report 1 of the ISPOR MCDA Emerging Good Practices Task Force. *Value Health* 2016;19:1-13.

7. Marsh K, IJzerman M, Thokala P, et al. Multiple criteria decision analysis for health care decision making—emerging good practices: report 2 of the ISPOR MCDA Emerging Good Practices Task Force. *Value Health* 2016;19:125-37.

8. Institute of Medicine (US) Roundtable on Evidence-Based Medicine; Yong PL, Saunders RS, Olsen LA, eds. The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary. Washington (DC): National Academies Press (US); 2010. Appendix A, Workshop Discussion Background Paper. https://www.ncbi.nlm.nih. gov/books/NBK53915.

9. Phelps CE, Madhavan G. Valuing health: evolution, revolution, resistance, and reform. *Value Health*. 2019; 22(5):505-510.



**About the Author**

*Michele Cleary is an HEOR researcher and scientific writer with more than 15 years of experience in the healthcare field.*