



# Defining Value in Health Care Resource Utilization: Articulating the Role of the Patient

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This paper was commissioned by The John Hartford Foundation to inform a multi-stakeholder meeting held on May 12, 2015 aimed to explore how researchers and stakeholders can partner together to reduce unnecessary care. Sixty-six participants representing patients, researchers, health systems, purchasers, policymakers and practitioners gathered to discuss the current evidence base and identify future research priorities. The meeting was hosted by AcademyHealth in partnership with the ABIM Foundation, the Veterans Affairs Health Services Research and Development Branch (HSR&D), Kaiser Permanente, and the Hartford Foundation. The paper was written by Shannon Brownlee, M.Sc. from the Lown Institute and Amy Berman, B.S., R.N. from The John A. Hartford Foundation.

What is value? The answer is becoming more and more relevant to health care policy, research, and practice redesign efforts as the United States confronts rising costs in the face of only modest improvements in population health. With increasing rates of obesity and chronic disease and a doubling of the number of older adults over the next two decades, projections show that health care resource utilization will continue to grow.<sup>1</sup> At the same time, the waste of resources on unnecessary or potentially unwanted services is a major concern.<sup>2,3</sup>

Not surprisingly, policymakers and payers have begun to focus on identifying “low-value” services—those that offer little or no benefit to patients—with the goal of restructuring incentives and penalties to reduce the use of such services and rein in costs. Earlier this year, the secretary of the U.S. Department of Health and Human Services set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and to 90 percent by 2018.<sup>4</sup> This historic shift from volume-based payments to rewarding value comes amid growing recognition that patients and their families can and should play a role in care decisions. When patients and families are directly engaged in their care and more aware of cost and potential benefits and risks, they become better stewards of health care resources.<sup>5</sup>

As the population ages, health care utilization shifts broadly from acute episodic care of a young and generally healthy population to the management of older adults with several chronic diseases. As individuals grow older and approach the end of life, their care goals often shift and focus first and foremost on independence, followed by pain and symptom relief; eventually, length of life becomes less important than quality of life.<sup>6</sup>

We argue in this paper that, while there is no greater value than care and outcomes concordant with a patient’s goals and values, significant barriers hamper consumers’ ability to make value-based decisions and impede payers’ and policymakers’ efforts to assign value in the context of what matters to patients and their families.<sup>7</sup> For most care, even extremely costly services such as most surgeries, cancer therapies, and end-of-life care, research on the patient

perspective has been limited and lackluster, failing to test adequately how patients and families balance health care decisions against the range of real-world constraints such as personal finances, impact on work, time with family, and overall effect on quality of life. The perspectives of patients, families, and the public are often absent from the national conversation about value in health care policy and practice redesign. Consequently, few if any mechanisms are in place to incorporate those perspectives into the conversation. As a result, most decisions about value are the province of experts, payers, or the “the market.”

To understand the role of patients and the public in relation to value-based care and payments, we first need to understand the term *value* and its unique meaning from the perspective of payers, providers, and patients. Even though many policymakers, health care analysts, and researchers assume a common definition of the term, there can be no absolute measure of value devoid of the patient’s and public’s perspective. Thus, if health care and insurance reform is tied to base payments on value, it must reflect the context of evidence, an understanding of patient goals, and public input.

In making the case that value is inextricably linked to the patient’s and the public’s perspective, we considered four overarching questions:

1. How does value differ for patients, payers (government and private), and the public as a whole?
2. When evidence points to a minimal chance of benefit and patients want a treatment, does the treatment have value? In other words, are there low-value treatments that should nevertheless be considered coverable? And can value exist where evidence does not?
3. Who is the ultimate arbiter of value when payers, policymakers, or providers disagree with patients?
4. What are the barriers to assessing value within the context of evidence-based, patient goal-directed care?

In this paper, we suggest some concrete goals for ensuring that future efforts to assign value to specific treatments and tests reflect the *values* of patients, their families, and the public. Our recommendations are grounded in three fundamental principles:

- First, value should be based on high-quality medical evidence. When evidence is poor or lacking, the value placed on a service may be provisional, or, in some cases, the test or treatment may be deemed experimental. Every effort should be made to collect data from patients who receive the test or treatment, and, whenever possible, studies should be initiated to gauge the test's or treatment's efficacy.
- Second, evidence alone is not sufficient to assign value. Regulatory bodies and payers must routinely and actively seek patients' and the public's perspectives, including their values and preferences, with regard to tests and treatments. In parallel, regulatory bodies and payers must identify public attitudes toward trade-offs between paying for health care versus paying for other goods.
- Third, if we are to engage patients and the public in efforts to reduce unwanted or unnecessary health care resource utilization, research needs to reflect the outcomes of greatest importance to patients. Even in an era of so-called "patient-centered care," researchers and clinicians often focus on measures of mortality or disease-free progression, devoting less attention to measures of impact on function, employment, pain, quality of life, and out-of-pocket spending, all of which may be equally if not more important to patients.

### Different Strokes: What You Value Depends on Where You Sit

In a 2009 paper published in the *New England Journal of Medicine*,<sup>8</sup> Harvard Business School professor Michael E. Porter introduced the term "value-based health care" and offered a clear and simple definition: *health outcomes for dollars spent*. In the intervening years, Porter's term has come into widespread use in health services research and public policy discussions about reform of the health care delivery system. Yet, different stakeholders define the term in different ways.

Today, the definition of value has largely evolved into a Porter-esque formula, *quality or outcomes over cost*. Unfortunately, as the term is applied, it does not always measure outcomes that matter to patients; as a result, the definitions of both quality and cost shift, depending in part on who uses the term. Thus, value for private insurers and health plans reflects profitability, marketability, consumer demand, the "medical loss ratio," and the prices of services that a plan covers, offers, or allows within a highly regulated and competi-

tive environment. For government payers, value should align with Porter's original intent: population health outcomes over dollars spent, assuming that government's goal is to improve the lives of its citizens. The public's definition of value should align with that of government: health outcomes over cost, including out-of-pocket costs. Unfortunately, surveys and focus group studies suggest that the American public has little understanding of either quality or outcomes, and many associate the term value with "cheap."<sup>9</sup> Value is what the public wants from K-Mart, not from health care.

For both the public and government, the definition of value should be framed by trade-offs. When we spend 18 percent of GDP on health care, for example, less money is available to hire more or better teachers or to offer social supports to the needy; clearly, expenditures in both sectors can potentially contribute to the health of individuals and the nation.<sup>10</sup> Whether discussed among policymakers or in the popular press, the trade-offs between paying for health care and the social determinants of health have barely begun to penetrate the debates about health care spending. In addition, families face other possible trade-offs: paying for an expensive treatment versus a child's college tuition, remaining current on mortgage payments, purchasing other medication or food, and even maintaining financial solvency. For too many families, the cost of care leads to personal bankruptcy.

For individual patients, the definition of value is deeply personal and depends on a person's situation along life's trajectory, how the individual views the potential benefits and harms of treatment options, the individual's understanding of his or her health status, and what the individual most wants to preserve.<sup>11</sup> For an 85-year-old in frail health, the value of a blood pressure medication with minor but palpable side effects may be far lower than it might be for a 45-year-old with young children. Other trade-offs might include the time spent in pursuing treatment versus its impact on one's family, ability to work (and maintain health insurance), and the quality and quantity of life. The 85-year-old might reasonably choose to refuse a potentially life-extending treatment, such as surgery or chemotherapy, because of the risk of imminent death, the possibility of a significantly diminished quality of life, or long hours spent away from family.

### The Role of Evidence in Determining Value

Despite the above complexities, much of the discussion of value has focused almost exclusively on clinical evidence. It is legitimate to argue that ineffective services are by definition of low or no value and that insurers should not cover them.<sup>12</sup> No insurer covers mammary artery myocardial implantation, an ineffective and outmoded treatment for ischemic heart disease used widely in the 1940s—and nobody would argue that such treatment should be covered, no

matter how low the price. Conversely, a service can be considered potentially high-value if it has been shown to be effective for all patients who need it—and at a low price (for example, insulin for Type I diabetes).

Ms. Berman, who is an author of this paper and lives with stage IV (metastatic) cancer, experienced an example of evidence-based, high-value care. In late 2014, she suffered unremitting pain in the middle of her back, the result of the cancer's spread to a new area of her rib cage. The recommended treatment for pain associated with bone metastases is a palliative course of radiation, for which the standard course has been 10 to 20 sessions of radiation. Recently, a study of more than 16,000 patients showed that a different radiation protocol provides more immediate relief at significantly lower cost.<sup>13,14</sup> A recommendation from the *Choosing Wisely* campaign,<sup>15</sup> led by the American Board of Internal Medicine Foundation and endorsed by the American Society of Clinical Oncology (ASCO) and the American Society of Radiation Oncologists (ASTRO), suggests that single-fraction radiation therapy—one course of treatment—is as effective as several sessions. For Ms. Berman, single-fraction treatment provided relief from pain with no ill effects and little disruption of her life—and at a low cost compared to the cost of the standard course.

Had Ms. Berman opted for the standard 10 to 20 doses of radiation—despite the overwhelming evidence and professional society endorsements to the contrary—she would have risked suffering dry, burned, peeling skin; redness, swelling, and pain in the affected area; weakness; and loss of appetite and energy. She would have missed work for 10 to 20 days. Any pain relief would have occurred not at the end of treatment but rather after recuperation from the treatment's side effects. She would have been burdened by a significant copayment for each treatment. Surprisingly, most patients in Ms. Berman's situation receive the standard treatment.

### The Gray Zone

From the perspective of payers, patients, and the public, the comparative value of the above two treatments for pain associated with bone metastases should be obvious. Unfortunately, medicine frequently does not offer such a clear trade-offs, making it difficult to assign an absolute value to a treatment on the basis solely of evidence. Another cancer treatment—bevacizumab (trade name: Avastin)—provides another example. After two randomized controlled trials (AVADO<sup>16</sup> and RIBBON-1<sup>17</sup>) conducted by the manufacturer found that Avastin was ineffective for breast cancer, the U.S. Food and Drug Administration (FDA) pulled the drug's authorization for that indication. (The drug remains on the market because it has been found to be effective for other cancers, such as lung and ovarian.) Observational data<sup>18</sup> and post hoc analysis of the

AVADO and RIBBON-1 trials suggested that some patients enjoyed an improved quality of life on the medication, at which point bloggers<sup>19</sup> and the *Wall Street Journal* accused the Obama Administration and FDA officials of rationing a beneficial treatment. Against this backdrop, Medicare decided to continue paying for Avastin.

### Who Should Decide?

To many policymakers, the results of randomized controlled trials of drugs showing little or no benefit in terms of length of life or disease-free progression translate into a low-value drug and therefore a service that should not be covered by insurance. But the randomized controlled trials did not measure the quality-of-life indicators described by pro-Avastin patients; thus, it is possible that, for some patients, the treatment offers benefits despite its side effects. To many patients and members of the public, even a slim chance that Avastin might improve patients' quality of life is reason enough for insurance coverage. (As one indication of how informed and rational people can arrive at different conclusions about the value of a given intervention, the authors of this paper disagree on whether insurance should cover Avastin.)

Such disagreements over evidence frequently raise the specter of rationing. A patient typically trusts his or her doctor to determine what is in the patient's best interest and assumes that the doctor's recommendations are based on sound science.<sup>20</sup> In addition, a patient often routinely overestimates the potential benefits of many treatments and underestimates harms.<sup>21</sup> Thus, it is not surprising that the public is often quick to bring charges of rationing when a treatment or test recommended by a doctor or touted in the press for its benefits is deemed ineffective by a government entity such as the U.S. Preventative Services Task Force or FDA, especially when the treatment is expensive. Manufacturers and providers may fan the fears of rationing if they stand to gain financially from a given treatment or test, and then there are the ideologues who wield political power in directing the health care debate.<sup>22</sup>

For many other treatments, a lack of evidence further complicates discussions of value. Only a minority of treatments has been shown to be clearly beneficial to all patients who need and want them and thus may be considered high-value based on the evidence. Single-fraction radiation for pain associated with bone metastases is one such treatment. Similarly, only a fraction of treatments has been shown to be clearly ineffective and therefore of low or no value. Most treatments lie in a more nebulous gray zone, where the evidence is equivocal or lacking; where reasonable alternative treatments might be less expensive or safer; or, as in the case of Avastin, where patients and policymakers disagree about the evidence.

Even when high-quality clinical evidence exists, few clinical trials make clear *which* patients are most likely to benefit and which patients may be harmed by a given treatment. Most trials are underpowered for harm. Moreover, the follow-up that occurs after approval of a drug or device is often inadequate, leaving many unanswered questions about safety among large populations of patients undergoing treatment.<sup>23</sup> In addition, outcomes that matter to patients are often not included in the endpoints that are either measured or reported.<sup>24</sup> A recent analysis by Chandra and Skinner suggests that much of our current spending is attributable to treatments in the gray zone.<sup>25</sup> Thus, any discussion of value must acknowledge the uncertainty surrounding many treatments. At the level of the individual, a patient and his or her clinicians also struggle to gauge the value of the treatment *for that patient*.<sup>26</sup>

### Price Matters

The other half of the value equation is price, and Avastin's is hefty—as much as \$100,000 a year per breast cancer patient. Given the drug's limited effectiveness, the outcomes-over-cost equation suggests that its value is low. But what if the price tag were lower, say \$10,000 per year or even \$1,000? At what price would the potential but unproven health outcomes tip the value equation in Avastin's favor in the eyes of policymakers and payers?

For many treatments and tests, the price often seems to bear little or no relationship to the benefit offered, particularly in the United States, where prices of everything from an indwelling catheter to an hour of a doctor's time are the highest in the world. One obvious means for payers to extract greater value from medical services is to negotiate lower prices for products and services that offer moderate or poor benefit to patients. Many payers are improving the value equation for themselves by asking patients to pay a larger percentage of the bill in a tiered-benefit package, a strategy that raises the possibility of an increasingly Hobbesian health care system in which those with means will have full access to needed care while everyone else must fend for him- or herself.

### Other Barriers to Evidence-Based, Patient Goal-Directed, Value-Based Care

The lack of patient-oriented evidence and the mismatch between price and effectiveness are just two of many barriers that complicate efforts to determine value. Both clinicians and patients also need better guidelines. A 2009 paper published in the *Journal of the American Medical Association* found that rigorous (Class A) scientific evidence backs up only 11 percent of the 2,700 clinical guidelines issued by the American Heart Association and American College of Cardiology for treating cardiac patients.<sup>27</sup> Most cardiac guidelines, and indeed the guidelines issued in the vast majority of specialties, are grounded less in science than in expert opinion, and

expert opinion, in turn, is routinely biased by financial conflicts of interest among guideline committee members.<sup>28</sup>

Another barrier to determining value is the American public's aversion to discussions of cost-effectiveness. The term is practically forbidden in Washington, even as “Congress rings[sic] its hands in despair over the millions of American families priced out by the ever-rising cost of health care, and over the bigger chunk of the federal budget taken up by Medicare and Medicaid,” as economist Uwe Reinhart stated recently in the *New York Times*.<sup>29</sup> In part, providers and manufacturers may be somewhat to blame for refusing to face the fact that care must be paid for and that resources are not infinite<sup>30</sup>; after all, for them, a dollar saved through cost-control efforts is a dollar left unearned by the health care industry.<sup>31</sup> During the Clinton Administration, manufacturers successfully opposed efforts to include cost-effectiveness in decisions about coverage<sup>32</sup>; manufacturers prevailed again during the debate over the Affordable Care Act (ACA) and formation of the federally funded Patient-Centered Outcomes Research Institute (PCORI). Today, many stakeholders point to threats of rationing whenever policymakers or payers want to use cost-effectiveness as a means to contain costs.<sup>33</sup>

Manufacturers' marketing campaigns and physician insensitivity to cost also stymie value-based care. For example, manufacturers heavily market brand-name indacaterol inhalers for chronic obstructive pulmonary disease (COPD), at about \$7.00 a dose. Not surprisingly, most patients use a brand-name product rather than generic formoterol inhalers, which cost \$0.37 a dose and are just as effective; such a switch would save COPD patients and payers millions of dollars a year.<sup>34</sup>

### Keeping Patients in the Dark

For patients, the single most important barrier to assigning value to a possible treatment is the failure of health care providers and manufacturers to ensure that patients have the information they need to make informed choices. Even though policymakers have started paying increased attention to the concept of shared decision making<sup>35</sup>—which, by definition, must involve informing patients—patients and the public still remain woefully in the dark about most medical decisions.<sup>36</sup> In a recent study in the *New England Journal of Medicine*, 69 percent of patients with metastatic lung cancer and 81 percent of patients with metastatic colon cancer believed that their chemotherapy was curative rather than palliative.<sup>37</sup> Many patients, when faced with an elective decision, do not even know that they have a choice and instead assume (incorrectly) that their doctor knows which treatment is appropriate for them.<sup>38</sup> Even the information presented in consumer-facing medication package inserts does not reflect the patient experiences, symptoms, and side effects of greatest interest to patients.<sup>39</sup>



The gaping hole in patients' and the public's knowledge of the limits of medicine spills over into discussions about value. For any patient, the value placed on a particular treatment necessarily involves a balance between potential benefit and harm versus how possible outcomes intersect with the patient's goals, fears, and life circumstances. A value-based decision is unachievable if the patient is not sufficiently informed and his or her preferences remain ignored. Similarly, for the public, gauging the value of a treatment must involve a realistic weighing of patient and population outcomes and the additional consideration of societal values and trade-offs. We currently have few mechanisms in place for soliciting public deliberation of and input into decisions about value.

In summary, there are 10 principal barriers to achieving value-based care:

1. The public thinks that more is better when it comes to medicine and that a doctor would not recommend a bad or ineffective treatment.
2. The public dislikes considerations of cost-effectiveness.
3. Patients overestimate potential benefits and underestimate harms.
4. The evidence base for many treatments is insufficient to permit an evidence-based decision about value.
5. Conflict of interest biases many clinical guidelines.
6. Marketing drives many clinical decisions.
7. Prices have little relationship to outcomes.
8. There is little transparency around public trade-offs and opportunity costs.
9. Patients are not a party to deliberations about value.
10. Few mechanisms are in place to permit a public debate about value.

## Recommendations

For patients and the public at large to support the reduction of unwanted or unnecessary care, mechanisms must support patients' efforts to make value-based decisions. Recommendations for such mechanisms fall into three discrete areas (below), all aimed at ensuring that optimal health care utilization accounts for patients' and the public's perspective and engagement.

### 1. At the point of care (care that matters)

- Routine incorporation of patient' health care goals into care management
- Care and treatment with patient goals
- Shared decision making as routine practice
- Use of validated or certified decision-making tools
- Routine conversations with patients around end-of-life care
- Advance care planning

### 2. Public deliberation around value (transparency and measures that matter)

- Transparent information about level of evidence
- Integrated patient representation in the development of patient-reported outcome measures (PRO) and the design of Comparative Effectiveness Research (CER)—not a separate group convened to give “experts” input but rather full integration on committees and efforts related to value<sup>40</sup>
- Transparent information about efficacy and harms
- Public deliberation as a regular part of health care cost control<sup>41</sup>

### 3. Government and private payers (paying for what matters)

- Transparency around how value is determined
- Routine inclusion of informed patients and the public in plan-level decision processes
- Funding of cost-effectiveness research

## Conclusion

The amount of overuse and other waste in the U.S. health care system suggests that the nation can spend considerably less than it spends today for the same or better outcomes. Value-based insurance offers an attractive path to reducing much of today's wasted spending by curbing unnecessary, ineffective, or unwanted services. But current methods for determining value do not adequately integrate patients and the public into the process, both at the point of care, when patients are confronted with treatment choices and need to be informed, and in other settings. The public should be involved in designing clinical and cost-effectiveness research and making decisions about needed trade-offs that result when value is assigned to medical services. Regulators and payers should actively seek public input into coverage decisions. Finally, the perspectives of aging citizens and patients should be solicited; after all, it is they who assume much of the burden of unwanted, unnecessary, or low-value care.

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