Current Landscape: Value Assessment Frameworks

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Background

There are many aspects to the U.S. health care system, as well as many different stakeholder viewpoints on how to address current challenges as our system shifts from one driven by the volume of health care services to one focused on the value of health care that is provided. As part of this shift, there is an increased interest in understanding how to measure value. Given this backdrop, along with ongoing concerns about the rising costs of health care in general, and of drugs in particular, some stakeholders have developed frameworks as a way to measure value.

Value assessment frameworks are a relatively new and emerging field. Yet without other ways to clearly measure health care value, these value frameworks will likely be influential in determining what therapies are chosen by patients and their doctors, as well as if those therapies will be covered and reimbursed and made more broadly available to patients. As these frameworks have the potential for considerable impact on patients, there is a need to understand whether these frameworks have been developed with adequate rigor. By comparing and contrasting these frameworks, we can lay the groundwork for a dialogue about what elements should be included in a value framework, how those elements should be measured, and how a value assessment should be conducted and utilized.

Methodology

For this analysis, we focused on the five primary U.S. value assessment frameworks, which were reviewed at a high level by Neumann and Cohen.[1] These frameworks include:

- The American College of Cardiology and the American Heart Association (ACC-AHA) Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures, which aims "to include cost-effectiveness/value assessments and recommendations in practice guidelines and performance measures."[2]

- The Conceptual Framework to Assess the Value of Cancer Treatment Options, developed by the American Society of Clinical Oncology (ASCO) with the goal of providing a "standardized approach to assist physicians and patients in assessing the value of a new drug treatment for cancer as compared with one or several prevailing standards of care."[3]

- The Institute for Clinical and Economic Review (ICER) Value Framework, intended for insurers with the "specific aim… to develop a conceptual framework that identifies the relevant domains of value and describes options for measuring these domains and for integrating them into an overall assessment of value."[4]

[1] Neumann PJ, Cohen JT. Measuring the Value of Prescription Drugs. *N Engl J Med*. 2015 Dec;373:2595-2597.
[2] Anderson JL, Heidenreich PA, et al. ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures. *JACC*. 2014 Jun;63(21):2304-22.
[3] Schnipper LE, Davidson NE, et al. American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options. *J Clin Oncol*. 2015 Aug;33(23):2563-77.
[4] Institute for Clinical and Economic Review. Value assessment project, a framework to guide payer assessment of the value of medical services. ICER website. http://www.icer-review.org/impact-and-outcomes/value-assessment-project/. Published September 2015. Accessed March 4, 2016.

- Memorial Sloan Kettering Cancer Center's DrugAbacus, created by Dr. Peter B. Bach as "a first draft of a tool that could be used to determine appropriate prices for cancer drugs based on what experts tend to list as possible components of a drug's value."[5]

- The National Comprehensive Cancer Network (NCCN) Evidence Blocks, which are "intended as a visual representation of five key measures that provide important information about specific recommendations contained within the NCCN Clinical Practice Guidelines in Oncology…The goal is to provide the health care provider and the patient information to make informed choices when selecting systemic therapies based upon measures related to treatment, supporting data, and cost."[6]

Neumann and Cohen provided an informative comparison of the frameworks at a high level; this paper builds on their work by carrying the assessment further and providing specific detailed observations. It delves deeper into the rather disparate frameworks by comparing and contrasting key characteristics such as their intended purposes, development processes, methods, and the elements of value (benefits and costs).

Six broad categories were identified for analysis: the framework development process, measures of benefit, measures of cost, methodology, evidence, and the framework assessment process. Within each category we identified key components for evaluation and created table shells populated with those key components.

Each framework was initially assessed internally to fill in the table shells. The draft tables were then sent to each of the five organizations, and representatives from all five reviewed the tables to fill in missing information and make corrections. The tables in this paper reflect their updates.

Overview of Frameworks and Intended Purposes

The five value assessment frameworks have varying purposes, generally reflecting the interests and expertise of the developing organizations (Table 1). As professional societies with physician members, ACC-AHA, ASCO, and NCCN designed their frameworks to assist with shared decision-making between patients and physicians. ICER and DrugAbacus are intended for broader audiences—payers, policy makers, physicians and patients—although these two frameworks are generally perceived as payer tools. ASCO, NCCN, and DrugAbacus all have an oncologic focus; ACC-AHA has a cardiovascular one, and ICER has no limitations on the types of treatments that could be assessed. The frameworks are generally focused on drugs or drug regimens, although ICER also is being used to evaluate other medical services, and ACC-AHA and NCCN could be extended to other treatments beyond drugs.

[5] Memorial Sloan Kettering Cancer Center. DrugAbacus FAQs. DrugAbacus website. http://www.drugabacus.org/faqs. Accessed March 4, 2016.
[6] National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology (NCCN Guidelines®) with NCCN Evidence Blocks™. NCCN website. http://www.nccn.org/evidenceblocks/. Accessed March 4, 2016.

Table 1: Overview of Value Assessment Frameworks

	ACC-AHA	ASCO	DrugAbacus	ICER	NCCN
Target Audience	Physician/ patient	Physician/ patient	Payers, policy makers, physician/ patient	Payers, policy makers, physician/ patient	Physician/ patient
Services Addressed	Treatments, primarily drugs	Drug regimens	Drugs	Primarily drugs, has been extended to devices and delivery system programs	Treatment regimens, primarily drugs
Conditions Addressed	Cardiovascular	Oncologic	Oncologic	All conditions, particular focus on new drugs anticipated to be high impact	Oncologic
What is the "Value" Output?	Level of value assessment (high, medium, low, uncertain, not assessed)	Numerical net health benefit score (-20 to 130); drug regimen cost	Value-based price	Value-based price benchmark; assessments of care value and provisional health system value (high/ intermediate/ low)	Score (1-5) for each of 5 evidence blocks: efficacy, safety, quality of evidence, consistency of evidence, affordability
Evaluations to Date	1 guideline includes concept but makes no assessment	10 examples using draft framework	Tool includes 54 drugs approved from 2001-15	Assessments on 3 drugs and 1 device; 7 drug topics and 2 non-drug topics anticipated for 2016	Several guidelines include evidence blocks
Selection Process for Future Evaluations	As guidelines are updated, value assessments will be added	Undetermined at this time	Will eventually include other cancer drugs and other indications	Selected by ICER and advisory boards of CEPAC/CTAF, informed by horizon scan and payer input	As clinical practice guidelines are updated, evidence blocks will be added

The format and output varies greatly among these frameworks:

- ACC-AHA assigns one of five value levels to a treatment—high, medium, low, uncertain, not assessed.
- ASCO calculates a "net health benefit score" (ranging from -20 to 130) and separately reports cost.

- ICER estimates a range of prices representing both different cost-effectiveness levels and a "budget threshold" price; it also reports panel votes on "care value" (high, intermediate, low) and "provisional health system value" (high, intermediate, low).

- DrugAbacus calculates a "value-based price" that represents the user's weighted preferences and estimated monthly costs.

- NCCN presents five-by-five visual "evidence blocks" representing efficacy, safety, quality of evidence, consistency of evidence, and affordability, with the blocks filled in according to scores from 1-5, with 5 being the best.

Value assessments from ACC-AHA and NCCN will be included in guidelines issued by the organizations, while ICER's assessments are issued as public reports. DrugAbacus is an online tool through which the user generates a preference-weighted value assessment. ASCO will ultimately use its framework to populate a tool for shared decision-making.

Development of Frameworks

Development details are only publicly available for a few of the frameworks (Table 2). The ASCO framework was developed by the "ASCO Value in Cancer Care Task Force," composed of physicians. They sought input from an advisory committee that included oncologists, patient advocates, payers and the biopharmaceutical industry, and followed that input with a public comment period. The ICER framework was developed by ICER staff, who also sought input from an advisory committee, consisting of payers, patient organizations, physician organizations and biopharmaceutical manufacturers. The NCCN framework was developed by NCCN staff in consultation with disease specialist clinicians. Per NCCN regulatory requirements, development was restricted to NCCN members, but they accept public comments on the framework on an ongoing basis. Details are unknown for DrugAbacus and ACC-AHA, but the latter is still under development.

Most frameworks were not formally user tested. NCCN is beta testing its framework; ICER had several payers utilize its framework and provide feedback; and ASCO has plans to user test its framework after its software tool has been developed.

Table 2: Development of Framework

	ACC-AHA	ASCO	DrugAbacus	ICER	NCCN
Who Developed It?	Writing committee (primarily physicians); still underway	ASCO Value in Cancer Care Task Force (physicians)	Peter Bach/ Real Endpoints	ICER	NCCN staff in consultation with disease specialist clinicians
How Inclusive Was Development?	Unknown	Advisory committee including oncologists, patient advocates, payers, and biopharmaceutical industry provided input	Unknown	Advisory committee of payers, patient organizations, physician organizations, and biopharmaceutical industry provided input	Restricted to NCCN members per NCCN regulatory requirements
Was There a Public Comment Period?	Unknown	Yes	Unknown	No	NCCN accepts comments on an ongoing basis
Was It User Tested?	Unknown	Not yet; software tool will be user tested prior to release	Unknown	Payers used the framework and provided feedback	Beta testing underway
How Often Will the Framework Be Updated?	Unknown	To be determined	Unknown	Annually	Continuously as needed

Elements of Frameworks

In this section we consider four general framework elements: benefits, costs, methodology, and evidence. Each framework incorporates these elements in different ways.

A. FRAMEWORK COMPONENTS OF VALUE: BENEFITS

Benefits are a primary component for a measurement of value. However, benefits can be defined and measured in many different ways (Table 3). The various frameworks each include some measure of efficacy/effectiveness and safety, but they differ in how they are measured and incorporated. For both ACC-AHA and ICER, these measures will vary by condition or treatment.

Table 3: Benefits

	ACC-AHA	ASCO	DrugAbacus	ICER	NCCN
How Is Efficacy/ Effectiveness Measured?	No examples yet; likely to vary by treatment	Improvement in overall survival/ progression-free survival/ response rate (hierarchical); bonus for palliation of symptoms/ treatment free interval	Improvement in overall survival or surrogate	Varies by condition	Average of panel members' assessment of effectiveness in prolonging life, arresting disease progression, or reducing symptoms
How Is Safety/Risk Measured?	No examples yet; likely to vary by treatment	Relative frequency of grade 3-5 toxicities	Frequency and severity of side effects (grade 3 or 4) relative to side effects that would otherwise be experienced	Varies by condition	Average of panel members' assessment of likelihood of/ severity of side effects (5-point scale)
Inclusion of Patient-Centric Metrics (e.g., Quality of Life)	No	No	No	Qualitatively	No
Inclusion of Indirect Benefits (e.g., productivity)	No	No	No	Qualitatively	No
Inclusion of Unmet Need	Qualitatively	No	Yes	Qualitatively	No
Inclusion of Burden of Illness	No	No	Yes	Qualitatively	No
Credit for Innovation	No	No	Yes	Qualitatively	No
Inclusion of Development Costs	No	No	Yes	No	No
Time Horizon for Clinical Measurement	Unknown	Dependent on endpoint assessed in relevant clinical trials	Treatment duration	Varies by condition, generally long-term or lifetime	Varies with disease site

Although ASCO, DrugAbacus, and NCCN share an oncologic focus, their efficacy/effectiveness measures are somewhat different. ASCO uses a hierarchy for measure selection, beginning with improvement in overall survival (OS), followed by improvement in progression-free survival (PFS, if OS not available) or response rate (if OS and PFS not available). ASCO awards bonus points for palliation of symptoms and treatment-free intervals. DrugAbacus measures improvement in overall survival or a surrogate measure if overall survival data is not available. NCCN uses the average of panel members' assessment of effectiveness in prolonging life, arresting disease progression, or reducing symptoms (see the section, "Using Frameworks for a Value Assessment," for more information about the panel members).

The oncologic frameworks also measure safety somewhat differently. ASCO uses the relative frequency of grade 3 through 5 toxicities. DrugAbacus considers the frequency and severity of grade 3 or 4 side effects, relative to side effects that would otherwise be experienced. NCCN averages panel members' assessment of the likelihood or severity of side effects.

While patients care about how well a treatment works and what side effects they are likely to experience, they also care about factors such as their quality of life and ability to work productively. Some patients will value unmet need—a treatment for a condition that previously had none. Some will value reduced caregiver burden. High burden of illness is another factor for consideration. Only ICER includes all of these additional factors; however, they are included in a qualitative rather than quantitative way. ACC-AHA does include unmet need as a value factor, albeit in a qualitative manner. DrugAbacus includes both unmet need and burden of illness, and incorporates both quantitatively. DrugAbacus goes one step further and also includes quantitative credit for innovation and development costs. ICER also recognizes innovation, albeit in a qualitative manner.

In addition, patients care about the time horizon of benefits, ideally measuring benefit over the course of their entire life. The time horizon varies for the various frameworks, and even within a given framework it depends on such parameters as the disease site (e.g., breast cancer, colon cancer) or clinical trial endpoint. ICER takes the longest view and assesses lifetime benefit when the evidence allows it.

B. FRAMEWORK COMPONENTS OF VALUE: COST

Cost can be incorporated in a framework and measured in a variety of ways (Table 4). ASCO and NCCN keep cost as a separate factor in their assessments. ACC-AHA and ICER use cost as part of a cost-effectiveness (CE) analysis to calculate the cost in dollars to gain an additional quality-adjusted life-year. DrugAbacus reports cost as a comparator for a user-generated value assessment. ICER takes it one step further and uses cost to calculate a national budget impact estimate.

Table 4: Costs

	ACC-AHA	ASCO	DrugAbacus	ICER	NCCN
How Is Cost Included?	As part of a CE analysis	Reported separately	As a comparator for user-generated value assessment	As part of a CE analysis; to estimate national budget impact	Reported separately
How Is Cost Measured?	N/A; drawn from relevant health economic literature	Drug acquisition cost; patient co-pay	Actual cost to Medicare	Publicly available "list price" for interventions; Medicare fee schedules for other costs	Average of panel members' assessment of overall cost (1-5 scale)
Are Medical Cost Offsets Included?	Depends upon available literature	No	No	Yes, may vary by evaluation	No

The way costs are measured and which costs are measured also varies considerably. DrugAbacus uses actual cost to Medicare to estimate the monthly cost of a drug. ASCO uses drug acquisition cost and (separately) plans to use patient co-pay to estimate the cost of the entire drug regimen (including anti-cancer therapy and required supportive care). NCCN includes a view of the total cost of the full episode of care, based on the average of panel members' assessment of overall cost. ICER measures treatment cost using a publicly available "list price" and accounts for medical cost offsets using the Medicare fee schedule. ACC-AHA uses existing health economic literature in its assessments, so any cost estimates are specific to the literature from which they were drawn, as is any inclusion of cost offsets.

As noted above, ICER calculates a national budget impact. ICER posits that new drug expenditure growth should not exceed [two times GDP+1%], or 7.5%. Applying this percentage to $409.7 billion (ICER's estimate of national drug expenditures) results in $30.7 billion available for new drug expenditures. ICER divides this by the two-year running average of new drug approvals (34, for 2013-2014), resulting in a threshold of $904 million per drug. To evaluate a new treatment, ICER estimates the treatment adoption rate for an unmanaged population (e.g., no utilization management controls such as step therapy or prior authorization) over a five-year period and an estimate for replaced drug costs due to adoption of the new treatment. These parameters are used to determine a "benchmark price" at which the $904 million threshold is breached.

C. FRAMEWORK METHODOLOGY

Most of the frameworks have created new (and untested) methodologies for assessing value (Table 5). The exception is ACC-AHA, which is still developing its methodology, but intends to use established and accepted methods along with existing health economic literature.

The process of identifying the range of potential results, known as a sensitivity analysis, is missing from all frameworks. DrugAbacus incorporates weights into its methodology; the users customize the assessment to represent their personal preferences by choosing weights for, or giving varying levels of importance to, each of the factors in the framework. ASCO intends to include weights in the tool it is developing to allow for a similar type of preference customization by the user. The NCCN framework includes scores for five different factors; users can choose to give preference to specific factors in their decision-making, implicitly including a customization of sorts. ACC-AHA and ICER do not include customization.

Table 5: Methodology

	ACC-AHA	ASCO	DrugAbacus	ICER	NCCN
Use of Accepted Methodology	Yet to be developed, but intention is accepted methods	New methods	New methods	Combination of accepted and new methods	New methods
Ability for User to Customize Assessment	No	No; will be present in final tool	Yes	No	User can give preference to certain blocks in decision-making
Incorporation of Sensitivity Analysis	No	No	No	No	No

D. FRAMEWORK EVIDENCE

Frameworks vary in the type of evidence they include in a value assessment (Table 6). DrugAbacus uses clinical trials from Food and Drug Administration approval for a product's first indication. ASCO also uses pivotal trials used to support regulatory approval or prospective randomized trials. ICER uses clinical trials for assessments done prior to product launch; presumably post-launch assessments could incorporate real-world data. ICER also accepts manufacturer-submitted data. ACC-AHA conducts a literature review for relevant health economic studies. NCCN uses a broad range of evidence including meta-analyses, randomized and non-randomized trials, case reports, and clinical experience. NCCN accepts externally submitted data and will consider non-published evidence from external sources.

Table 6: Evidence

	ACC-AHA	ASCO	DrugAbacus	ICER	NCCN
What Types of Evidence Are Used?	Health economic studies from literature review	Prospective randomized trial or pivotal trial used to support regulatory approval	Clinical trials from FDA approval for 1st indication	Clinical trials; could be broader for post-approval assessments	Meta-analyses, RCTs, non-randomized trials, case reports, clinical experience
Is Non-published Evidence Allowed?	No	No	No	No	Yes
Can Manufacturer Submit Evidence?	No	No	No	Yes	Yes, process published on NCCN website

Frameworks have varying approaches to how quality, certainty and consistency of evidence are evaluated. DrugAbacus and ASCO rely on a single clinical trial, typically used in regulatory approval, and do no formal evaluation. ACC-AHA plans to use an approved tool, such as QHES (Quality of Health Economic Studies),[7] for its evaluation. ICER uses its evidence-based medicine (EBM) matrix to evaluate its evidence. NCCN relies on panel members' assessment of the quantity, quality and consistency of evidence.

Using Frameworks for a Value Assessment

After development is complete, a framework is used to make an assessment of value. Few of the frameworks have reached this point. The ACC-AHA framework has not yet been used to assess value. The ASCO framework was used for several "example" assessments, but the framework has not been finalized and the software tool that will produce the assessments has not yet been built. DrugAbacus is designed for online user-conducted value assessments; beyond that there is no formal assessment.

NCCN's assessment process begins with notice that guidelines are being developed and/or updated. External parties may submit evidence, but only NCCN panel members are involved with the actual assessment. Panel members are listed on the NCCN website and in the corresponding guideline.[8] Each panel member uses the available evidence and his or her own experience to arrive at a numerical assessment (1-5) for each of the evidence blocks; the final score for each block is the average of the panel members' assessments. Evidence blocks are released as part of NCCN guidelines. NCCN anticipates regular updates to its assessments.

[7] Ofman JJ, Sullivan SD, et al. Examining the Value and Quality of Health Economic Analyses: Implications of Utilizing the QHES. *J Manag Care Pharm*. 2003 Jan-Feb;9(1):53-61.
[8] National Comprehensive Cancer Network. Identification and disclosure of relationships with external entities. NCCN website. http://www.nccn.org/disclosures/guidelinepanellisting.aspx/. Accessed March 4, 2016.

ICER conducts a horizon scan and gathers payer input to identify potential treatments for assessment. Assessment treatments are selected by the ICER advisory boards for their three core programs, the California Technology Assessment Forum (CTAF),[9] the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC),[10] and the New England Comparative Effectiveness Public Advisory Council (New England CEPAC)[11] and are announced publicly. ICER reaches out to the manufacturer(s) involved in the assessment to obtain input prior to releasing a scoping document for public comment. The report is drafted by ICER staff and shared with the manufacturer(s) for input prior to public release. The draft report is posted for public comment, along with draft voting questions; this posting is announced via press release. The draft report is revised and released with the final voting questions and a response to the public comments. The assessment panel votes on "care value" and "provisional health system value" at a public meeting. ICER identifies panel members on its website and in the meeting summaries and posts videos from the meeting, including the panel votes. After the meeting the final report is prepared and announced via press release. It is unknown how often assessments will be updated.

Discussion

Value assessment tools can be one of many important inputs to complex decisions related to treatments. They have the potential for considerable impact on patients either through their use by patients and their doctors as a shared decision-making tool or by payers to make coverage and reimbursement decisions. Given this potential impact, it is important to think critically about the implications of how these frameworks are constructed and applied. A critical reflection on the above raises several areas of concern.

A. UNTESTED METHODS

Value assessments are an evolving area. While some of the underlying methodologies in these frameworks are based on established and accepted standards, most involve new methodologies that have not been fully tested or validated. Conducting assessments is a complex and sophisticated undertaking, as evidenced by the sheer volume of guiding principles and practices for health technology assessments. Using new and untested methodology calls into question whether the results of a value assessment are truly meaningful and credible.

B. CONFUSING OUTPUT

The output from all of these frameworks may be challenging for the user to interpret and apply because they utilize different scores with different meanings. Users must consider whether to make a decision based on, for example, estimated monthly treatment costs relative to preference-weighted costs, average scores ranging from one to five, or a "net" point system ranging from zero to 130.

[9] California Technology Assessment Forum. Advisory board. California Technology Assessment Forum website. http://ctaf.org/content/advisory-board/. Accessed March 4, 2016.
[10] Institute for Clinical and Economic Review. Midwest CEPAC. ICER website. http://www.icer-review.org/midwestcepac/. Accessed March 4, 2016.
[11] New England Comparative Effectiveness Public Advisory Council. ICER review advisory board. CEPAC website. http://cepac.icer-review.org/about-cepac2/advisory-board/. Accessed March 4, 2016.

The challenge of confusing output is illustrated in the case of bortezomib for the treatment of multiple myeloma, which was assessed using the ASCO, NCCN, and DrugAbabus frameworks.

- ASCO calculates a net health benefit (NHB) score for the regimen of [bortezomib + melphalan + prednisone] relative to the regimen of [melphalan + prednisone] in one of its assessment examples. The bortezomib regimen results in a 31% improvement in overall survival (32 points), a 24% increase in grade 3-5 toxicities (0 points), and a 50% improvement in treatment-free interval (15 bonus points), for a total NHB of 47 points (out of a maximum of 130). Monthly costs for the two regimens are reported as $7,043 vs. $279 (drug acquisition costs, not patient co-pay).

- NCCN includes both regimens in the multiple myeloma guidelines under "primary therapy for non-transplant candidates." The [bortezomib + melphalan + prednisone] regimen scores 4 for efficacy, 3 for safety, 4 for quality of evidence, 4 for consistency of evidence, and 3 for affordability (scale of 1-5, with 5 being the best). The [melphalan + prednisone] regimen scores 3, 4, 4, 4, and 4 for the same measures.

- DrugAbacus includes bortezomib in its online tool (but not melphalan or prednisone). Actual monthly cost (as paid by Medicare) is reported as $4,364. The user can choose values for the worth of a life-year, toxicity discount, and multipliers for development cost, rarity, and population burden. Varying these values results in a "value-based price" ranging from $841 to $262,197.

Without clear guidance about how to use the above information and what it means, it could be difficult for physicians or patients trying to make treatment decisions to actually use these value assessments as part of their decision-making process.

C. LACK OF PATIENT-CENTEREDNESS

The patient is at the epicenter of health value, yet a broad range of the factors that patients care about are not included in many of the frameworks. A comprehensive measure of patient-centered value would incorporate factors beyond effectiveness and side effects, such as quality of life, work productivity, caregiver burden, unmet need, and burden of illness. Different patients will value these factors in different ways, so including a way for patients to give more weight to the factors they value most will result in a more meaningful value assessment for individual patients. Additionally, individual patients will respond to treatments differently—the average effectiveness and side effect response only represents the average patient. Including sensitivity analyses to capture the range of responses is also important for a patient-centered value assessment.

Including relevant cost information is another important factor for a patient-centered value assessment. Patients care about the cost to them personally. Cost to the insurer or a "list price" that doesn't reflect what any stakeholder actually pays is not relevant for a patient-centered value assessment.

D. SUB-OPTIMAL INPUTS

Even a perfectly designed value assessment framework will be derailed if the evidence that feeds into the assessment framework is sub-optimal. Many of the assessments do not use the full range of available evidence, limiting their evidence base to clinical trials, and sometimes only a single clinical trial.

E. LACK OF A SYSTEM-WIDE PERSPECTIVE

A system-wide perspective on value is missing from the frameworks. The focus is generally on drugs rather than on the broad range of treatments and health care services. Care management involves many interrelated health care services, including physician visits, treatments such as drugs or surgeries, and hospital care. Value assessments should include consideration of all of these interrelated services, and value assessments should be conducted for a broad range of these services. Moving to value-based health care requires a comprehensive focus on all health care components, rather than on one segment of health care.

Next Steps

These are just a few areas of concern in this new and evolving area. They serve to highlight the considerable need for good practices to guide meaningful value assessments that are centered on the patient. All health care stakeholders have the same goal: delivering high value to patients. Being able to assess that value—in a manner that is truly patient-centric and meaningful—will serve us well as we strive to achieve that goal.

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