What is the Value of Value Frameworks in Making Healthcare Decisions?

Wednesday November 30, 2016
What is the Value of Value Frameworks in Making Healthcare Decisions?

Speakers:

• **Maureen Japha**, JD, Director Regulatory Policy, FasterCures and Legal Counsel, the Milken Institute
• **Clark Paramore**, MSPH, Head of Value Demonstration, bluebird bio
• **Michael S. Sherman**, MD, MBA, MS, CPE, FACPE, Senior Vice President & Chief Medical Officer, Harvard Pilgrim Health Care
• **Martin J. Zagari**, MD, Vice President, Global Health Economics, Amgen

Moderator:

• **Leora Schiff**, MS, MBA, Principal, Altius Strategy Consulting
Value Frameworks

A defined process or methodology for determining a product’s or service’s relative value compared to another treatment and its cost or relative cost:
US Value Frameworks

American College of Cardiologists and American Heart Association (ACC/AHA) Cost/Value Framework

American Society of Clinical Oncology (ASCO) Value of Cancer Care Framework

National Comprehensive Cancer Network (NCCN) Evidence Blocks™

Dr. Peter B. Bach, Memorial Sloan Kettering Cancer Center (MSKCC): DrugAbacus

Institute for Clinical and Economic Review Value-Based Price Benchmarks
Cost-Utility Analysis using WHO Thresholds:

**High Value:** ICER<$50,000 (1xGDP_{US})

**Intermediate Value:** ICER<$100,000 (2xGDP_{US})

**Low Value:** ICER>$150,000 (3xGDP_{US})

Depending on what is available in the published literature, drugs can also be classified as:

- **Uncertain Value**
- **Value Not Assessed**

**ABBREV:** ACC- American College of Cardiology; AHA- American Heart Association, ICER-incremental cost-effectiveness ratio; CT-clinical trial; RCT-randomized clinical trial; SOC-standard of care; WHO-World Health Organization

ASCO Value of Cancer Care Framework

Clinical Health Benefit + Toxicity + Bonus Points
(no max points specified) (-20 to 20 points) (max 60 points)

Net Health Benefit (NHB)

Patient Cost
- Patient’s monthly co-payment for the treatment regimen

Provider Cost
- Provider’s drug acquisition cost for the total course of regimen

Schnipper et al. Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received. JCO May 31, 2016, JCO682518.
# NCCN Evidence Blocks

*Expert panel rates five criteria on a scale of 1-5:*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy of Regimen/Agent</strong></td>
<td></td>
</tr>
<tr>
<td>5-Highly effective</td>
<td></td>
</tr>
<tr>
<td>4-Very effective</td>
<td></td>
</tr>
<tr>
<td>3-Moderately effective</td>
<td></td>
</tr>
<tr>
<td>2-Minimally effective</td>
<td></td>
</tr>
<tr>
<td>1-Palliative</td>
<td></td>
</tr>
<tr>
<td><strong>Safety of Regimen/Agent</strong></td>
<td></td>
</tr>
<tr>
<td>5-Usually no meaningful toxicity</td>
<td></td>
</tr>
<tr>
<td>4-Occasionally toxic</td>
<td></td>
</tr>
<tr>
<td>3-Mildly toxic</td>
<td></td>
</tr>
<tr>
<td>2-Moderately toxic</td>
<td></td>
</tr>
<tr>
<td>1-Highly toxic</td>
<td></td>
</tr>
<tr>
<td><strong>Quality of Evidence</strong></td>
<td></td>
</tr>
<tr>
<td>5-High quality</td>
<td></td>
</tr>
<tr>
<td>4-Good quality</td>
<td></td>
</tr>
<tr>
<td>3-Average quality</td>
<td></td>
</tr>
<tr>
<td>2-Low quality</td>
<td></td>
</tr>
<tr>
<td>1-Poor quality</td>
<td></td>
</tr>
<tr>
<td><strong>Consistency of Evidence</strong></td>
<td></td>
</tr>
<tr>
<td>5-Highly consistent</td>
<td></td>
</tr>
<tr>
<td>4-Mainly consistent</td>
<td></td>
</tr>
<tr>
<td>3-May be consistent</td>
<td></td>
</tr>
<tr>
<td>2-Inconsistent</td>
<td></td>
</tr>
<tr>
<td>1-Anecdotal evidence only</td>
<td></td>
</tr>
<tr>
<td><strong>Affordability of Regimen/Agent</strong></td>
<td></td>
</tr>
<tr>
<td>(includes drug cost, supportive care, infusions, toxicity monitoring, management of toxicity)</td>
<td></td>
</tr>
<tr>
<td>5-Very inexpensive</td>
<td></td>
</tr>
<tr>
<td>4-Inexpensive</td>
<td></td>
</tr>
<tr>
<td>3-Moderately expensive</td>
<td></td>
</tr>
<tr>
<td>2-Expensive</td>
<td></td>
</tr>
<tr>
<td>1-Very expensive</td>
<td></td>
</tr>
</tbody>
</table>

**Example of ratings:** [4,3,5,4,2]
DrugAbacus users are able to change the weights for eight domains:

<table>
<thead>
<tr>
<th>Component</th>
<th>Weights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price for a year of life</td>
<td>$12,000 to $300,000</td>
</tr>
<tr>
<td>Toxicity discount</td>
<td>0% to 30% in 5% increments</td>
</tr>
<tr>
<td>Novelty multiplier (premium)</td>
<td>1.0 to 3.0 in 0.5 increments</td>
</tr>
<tr>
<td>Rarity multiplier (premium)</td>
<td>1.0 to 3.0 in 0.5 increments</td>
</tr>
<tr>
<td>Population Burden of Disease (premium for large population burdens)</td>
<td>1.0 to 3.0 in 0.5 increments</td>
</tr>
<tr>
<td>Cost of development (premium for expensive R&amp;D)</td>
<td>1.0 to 3.0 in 0.5 increments</td>
</tr>
<tr>
<td>Prognosis (premium for treatment of aggressive disease)</td>
<td>1.0 to 3.0 in 0.5 increments</td>
</tr>
<tr>
<td>Unmet need (premium for diseases with few/no treatment options)</td>
<td>1.0 to 3.0 in 0.5 increments</td>
</tr>
</tbody>
</table>

- The DrugAbacus includes domain values for 52 cancer drugs approved between 2001 and 2015.
- The values for eight domains were determined by the DrugAbacus researchers; these values are not shown.
- While weights can be modified, domain values cannot.
- Actual drug prices used for comparison are estimated monthly prices for chemotherapy drugs based on allowable Medicare charges.
ICER Value-Based Price Benchmark

Step 1: CE Analysis
- Cost-effectiveness (CE) analysis compared to existing standard of care
- Based on ICER thresholds of $100,000 and $150,000 per QALY

Step 2: BI Analysis
- Budget impact (BI) model to determine cost impact of product
- Threshold for allowed budget impact based on GDP+1/number of new molecular entities approved by FDA; currently set at $904 M.

Step 3: Drug Price
- Calculation of “Care Value Range” = drug prices that satisfy the two ICER thresholds
- Calculation of “Health System Value*” = max drug price that satisfies the budget impact threshold

Step 4: “Fair” Price
- “Value-based price benchmark” is the “the care value price range that would achieve cost-effectiveness ratios between $100,000 and $150,000 per QALY gained, limited, if the results require, by the price at which the $904 million budgetary impact threshold would be exceeded.”*

* ICER refers to “Health System Value” in a 2015 presentation “Evaluating the value of new drugs”; however, in the reports this is referred to as “Max Price at Potential Budget Impact Threshold “.
*ICER. PCSK9 Inhibitors for Treatment of High Cholesterol: Effectiveness, Value, and Value-Based Price Benchmarks, Final Report, November 24, 2015.
# Summary Comparison of the Five Value Frameworks

<table>
<thead>
<tr>
<th>Organization</th>
<th>Indications</th>
<th>Targeted audience</th>
<th>Health economic perspective</th>
<th>HRQoL included</th>
<th>Considers levels of clinical evidence</th>
<th>Unique considerations</th>
<th>Methodology</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>Oncology</td>
<td>Physicians</td>
<td>Payer</td>
<td>Yes</td>
<td>Yes</td>
<td>Quality of health economic studies (QHES)</td>
<td>Cost-utility</td>
<td>ICER in terms of Cost/QALY</td>
</tr>
<tr>
<td>Oncology</td>
<td>Oncology</td>
<td>Physicians • Patients</td>
<td>• Patient • Provider</td>
<td>No</td>
<td>Yes</td>
<td>“Tail of the curve” benefits for sub-populations</td>
<td>Pricing formula multiplying six weighted domains</td>
<td>NHB Score Patient co-payment Regimen cost</td>
</tr>
<tr>
<td>Oncology</td>
<td>Oncology</td>
<td>Physicians • Patients</td>
<td>Unclear if patient and/or provider</td>
<td>No</td>
<td>Yes</td>
<td>• Rarity • Novelty • R&amp;D costs</td>
<td>Ratings by expert panel based on clinical evidence and knowledge of costs</td>
<td>DrugAbacus calculated price</td>
</tr>
<tr>
<td>Oncology</td>
<td>Oncology</td>
<td>Physicians • Patients</td>
<td>Payer</td>
<td>No</td>
<td>Yes</td>
<td>Consistency of clinical evidence</td>
<td>Cost-utility</td>
<td>Evidence Block™ 5 x 5 matrix</td>
</tr>
<tr>
<td>Any indications</td>
<td>All stakeholders</td>
<td>Physicians • Patients</td>
<td>Payer</td>
<td>Yes</td>
<td>Yes</td>
<td>Budget impact</td>
<td>Cost-utility • Budget impact • Calculation of prices meeting thresholds</td>
<td>Value-based price benchmark</td>
</tr>
</tbody>
</table>

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Assessing Value from the Patient Perspective

Maureen Japha, Director Regulatory Policy
FasterCures, a DC-based center of the Milken Institute, is driven by a singular goal – to save lives by speeding up and improving the medical research system.
“Partnering with Patients on Value, Coverage, and Reimbursement” workshop

- Held June 11, 2015
- Brought together **more than 100** patients, payers, biopharmaceutical companies, foundations and providers
- Facilitated **greater understanding** of one another’s needs and perspectives
- Fostered **more effective partnerships**
- Explored themes such as **paying for value** and **looking beyond regulatory evidence**
P4C Workshop: Partnering with patients on value, coverage and reimbursement (Nov. 2015)

**Audience:** primarily patients, patient advocates and pharmaceutical and medical device manufacturers

**Discussion uncovered 3 key gaps and challenges** in existing value frameworks:

1. Patient voice is largely lacking
2. Patient value considerations need to be thoroughly understood and assessed
3. All major stakeholders need to be involved in development of a new framework
U.S. Value Assessment Activity Has Increased in Recent Years

- Payers and providers have been assessing the value of drugs and technologies for many years.
- Over the past decade, rising health-care costs, price concerns and an aging population have increased the focus on value in health care.
- In recent years, activities related to value assessment of new drugs and technologies have increased in the U.S.

**Comparative-Effectiveness Research**
- Patient-Centered Outcomes Research Institute (PCORI)

**Value Frameworks**
- American Society of Clinical Oncology
- European Society for Medical Oncology
- National Comprehensive Cancer Network
- Memorial Sloan Kettering
- Institute for Clinical and Economic Review’s Emerging Therapy Assessment and Pricing Program

**Principles for Value Assessment**
- National Health Council
- National Pharmaceutical Council
- Pharmaceutical Research and Manufacturers of America
The Patient Perspective Value Framework (PPVF) Initiative

Before the PPVF Initiative
Early 2015

• In 2015, several value frameworks based on traditional concepts of value emerged

What We’ve Done
Nov 2015 – Nov 2016

• Receive public input on five draft PPVF domains at 2015 P4C Conference
• Review patient preferences literature and patient group comments to existing frameworks
• Develop PPVF draft criteria and measures based on research
• Refine PPVF draft concepts with Steering Committee

Mid-Term Next Steps
Nov 2016 – June 2017

• Seek broad public input on draft concepts
• Expand research with patients
• Develop PPVF Version 1.0

Long-term Next Steps
March 2017 and beyond

• Build applications of PPVF Version 1.0 in partnership with interested stakeholders
The Patient-Perspective Value Framework Initiative

THE PPVF INITIATIVE IS GUIDED BY A MULTI-STAKEHOLDER STEERING COMMITTEE

- Aetna
- American Heart Association/American Stroke Association
- America's Health Insurance Plans
- Amgen
- Astellas Pharma US
- Better Medicare Alliance
- Biogen
- Bristol-Myers Squibb
- Cancer Support Community
- CVS Health
- Edwards Lifesciences
- *FasterCures*
- Gilead Sciences
- GlaxoSmithKline
- Johnson & Johnson
- Leukemia & Lymphoma Society
- Michael J Fox Foundation
- National Health Council
- National Multiple Sclerosis Society
- Partnership to Improve Patient Care
- Patient-Centered Outcomes Research Institute
- Pharmaceutical Research and Manufacturers of America
- Sanofi
The PPVF has five broad domains, which contribute different types of information to the framework.
The PPVF Focuses on Considerations that Matter to Patients

Within each domain there are a set of technical criteria:

- Patient Preferences
  - Values
  - Needs
  - Goals/Expectations
  - Financial Tradeoffs
The PPVF Focuses on Considerations that Matter to Patients

WITHIN EACH DOMAIN THERE ARE A SET OF TECHNICAL CRITERIA

- Quality of life
- Complexity of regimen
- Efficacy & effectiveness
- Side Effects/Complications
The PPVF Focuses on Considerations that Matter to Patients

WITHIN EACH DOMAIN THERE ARE A SET OF TECHNICAL CRITERIA

- Patient & Family Financial Considerations
  - Medical out-of-pocket (OOP) costs
  - Non-medical costs
  - Future costs of care
The PPVF Focuses on Considerations that Matter to Patients

WITHIN EACH DOMAIN THERE ARE A SET OF TECHNICAL CRITERIA

Quality & Applicability of Evidence
- Quality of evidence
- Consistency of evidence
- Differences in treatment effects
The PPVF Focuses on Considerations that Matter to Patients

Within each domain there are a set of technical criteria

Usability & Transparency
- Transparent approach
- Meaningful information
- Accessible format
- Usefulness
The PPVF’s Measures, Data Sources and Methods

Link to Draft PPVF Methodology Report:
http://avale.re/2eisa9s
The PPVF’s Future Applications
The PPVF’s Future Applications
The PPVF’s Future Applications
The PPVF’s Future Applications

**Shared Decision Making**
The PPVF will be applied as a shared decision making tool to support conversations between patients and clinicians.

**Apply to Existing Frameworks**
The PPVF will be applied to existing value frameworks to reframe the value assessment from the patient perspective.

**Support Public Health Care Programs**
The PPVF will be applied to support public health care programs, including through shared decision making applications and others.

**Condition-Specific Public Analysis**
The PPVF will be applied as a standalone population-level value assessment that produces public analyses of the value of different healthcare options for a particular condition.

**Applications to Inform Future Versions of PPVF**
Each PPVF application will be used to inform other applications and future versions of the PPVF.
The Patient-Perspective Value Framework (PPVF) Initiative

**PATIENT PREFERENCES**
The Patient Preferences domain assesses a patient’s personal goals and preferences. It functions as a lens through which the PPVF views the Patient-Centered Outcomes, Patient & Family Financial Considerations, and Quality & Applicability of Evidence associated with different healthcare options.

**QUALITY & APPLICABILITY OF EVIDENCE**
The Quality & Applicability of Evidence domain assesses the strength and consistency of the evidence, as well as the degree to which the evidence applies to the individual patient. This domain impacts the Patient-Centered Outcomes and Patient & Family Financial Considerations domains.

**PATIENT-CENTERED OUTCOMES**
The Patient-Centered Outcomes domain uses a set of measures and data sources to assess the clinical, functional and quality of life benefits and drawbacks of different healthcare options to the patient.

**PATIENT & FAMILY FINANCIAL CONSIDERATIONS**
The Patient & Family Financial Considerations domain uses measures and data sources—including insurance benefit design and patient-reported data—to calculate the medical and non-medical costs of different healthcare options to the patient and family.

**USABILITY & TRANSPARENCY**
The Usability & Transparency domain is a foundation for the framework. This domain assesses the usability of the framework to its intended audience and the transparency of the framework’s approach. This domain determines how the weighted assessments of the other domains are communicated through a particular application.
THANK YOU!

mjapha@fastercures.org
Upcoming MassBio Forums

Dec 7: The Intersection of Environmental Health & Safety and Manufacturing; SEF


MassBio Annual Holiday Networking Party

December 7, 5:00 PM - 8:00 PM
Hyatt Regency Hotel, Cambridge