A Tale of Two Ratios: Assessing Value from the Perspectives of Cost-Effectiveness and Affordability

Dan Ollendorf, PhD
Chief Scientific Officer
Institute for Clinical and Economic Review
April 12, 2016
Disclosure

I have no actual or potential conflict of interest in relation to this topic or presentation.
Pricing of new (or old) pharmaceuticals: current US context

Published on FiercePharma (http://www.fiercepharma.com)

Pfizer CEO: Drug-pricing snafu isn't pharma's fault. It's insurers and their poor coverage

October 15, 2015 | By Tracy Staton

Pfizer (SPFE) CEO Ian Read says he's met the drug-cost enemy, and it isn't pharma. The firestorm over U.S. drug pricing isn't a problem for drugmakers to solve, Read told Forbes in an interview. It's an insurance problem.

The public debate about rising drug prices--be they increases for existing meds or 6-figure cancer-treatment costs--overlooks the financial benefits of drug treatment, Read contends. In his Forbes interview, Read cites cost-benefit analyses showing that Lipitor and other statin meds cost $305 billion between 1987 and 2008, but they generated $1.3 trillion in economic benefits, by preventing heart attacks and strokes, and their costs to the healthcare system.

Oncologists' complaints about the rising cost of cancer treatment are similarly misplaced, Read figures. Some high-profile cancer doctors have been vocal about
Value framework efforts: many and varied

- International: CADTH/CDR, NICE, PBAC, etc.
- General
  - Premera Blue Cross
  - ACC/AHA
  - ICER
- Oncology
  - ASCO
  - Memorial-Sloan Kettering DrugAbacus®
  - NCCN
The ICER Value Framework

• The “problems” the value framework was intended to address
  – Poor reliability and consistency of value determinations by payers
  – Need for a more explicit and transparent way for HTA groups and payers to analyze and judge value
    • Tension between long-term and short-term perspectives

• The goal
  – A common language and mental model of the components of value across life science companies, payers, and other stakeholders

• A distinct goal for ICER
  – Underpin public HTA programs in California, the Midwest, and New England that deliberate and vote on effectiveness and value
A Value Assessment Flowchart

| Comparative Clinical Effectiveness | Incremental cost per clinical outcomes achieved | Other benefits or disadvantages | Contextual Considerations | “Care Value”
|-----------------------------------|-----------------------------------------------|--------------------------------|--------------------------|-----------------------------
| High                              | Intermediate                               | Low                            | High                     | Discussed and voted upon during public meetings |

<table>
<thead>
<tr>
<th>“Care Value”</th>
<th>Potential Short-Term Health System Budget Impact</th>
<th>Provisional “Health System Value”</th>
<th>Mechanisms to Maximize Health System Value</th>
<th>Achieved “Health System Value”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussed and voted upon during public meetings</td>
<td>Discussed and voted upon during public meetings</td>
<td>Discussed during public meetings; included in final ICER reports</td>
<td>Not evaluated by ICER or voted upon by public panels</td>
<td></td>
</tr>
</tbody>
</table>
Comparative Clinical Effectiveness reflects a joint judgment of the magnitude of the comparative net health benefit and the level of certainty in the evidence on net health benefit.

ICER reports use the ICER EBM matrix (www.cercollaborative.org) to describe the scientific staff’s judgment of comparative clinical effectiveness.
Incremental Cost per Outcomes Achieved

- Incremental Cost per Outcomes Achieved
  - Cost per aggregated health measure (QALY)
  - ICER uses commonly cited cost/QALY thresholds in its guidance to its public appraisal committees

- Associated with high care value
  - <$100,000/QALY
- Associated with intermediate care value
  - $100-150K/QALY
- Associated with low care value
  - >$150,000/QALY

1-3x GDP Per capita
Other Benefits or Disadvantages

- Benefits or disadvantages offered by the intervention to the individual patient, caregivers, the delivery system, other patients, or the public that would not have been considered as part of the evidence on comparative clinical effectiveness.
  - Methods of administration that improve or diminish patient acceptability and adherence
  - A public health benefit, e.g. reducing new infections
  - Treatment outcomes that reduce disparities across various patient groups

To be judged not by ICER but by one of its independent public appraisal committees
Contextual Considerations

• Contextual considerations include ethical, legal, or other issues that influence the relative priority of illnesses and interventions.

• Specific issues to be considered:
  – Is this a condition of notably high severity for which other acceptable treatments do not exist?
  – Are other, equally or potentially more effective treatments nearing introduction into practice?
  – Would other societal values accord substantially more or less priority to providing access to this treatment for this patient population?

• To be judged not by ICER but by one of its independent public appraisal committees
# A Value Assessment Flowchart

<table>
<thead>
<tr>
<th>Comparative Clinical Effectiveness</th>
<th>Incremental cost per clinical outcomes achieved</th>
<th>Other benefits or disadvantages</th>
<th>Contextual Considerations</th>
<th>“Care Value”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Discussed and voted upon during public meetings</td>
</tr>
<tr>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>Intermediate</td>
<td></td>
<td></td>
<td></td>
<td>Intermediate</td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>“Care Value”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discusses and voted upon during public meetings</td>
</tr>
<tr>
<td>High</td>
</tr>
<tr>
<td>Intermediate</td>
</tr>
<tr>
<td>Low</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential Short-Term Health System Budget Impact</th>
<th>Provisional “Health System Value”</th>
<th>Mechanisms to Maximize Health System Value</th>
<th>Achieved “Health System Value”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussed and voted upon during public meetings</td>
<td>Discussed during public meetings; included in final ICER reports</td>
<td>Not evaluated by ICER or voted upon by public panels</td>
<td></td>
</tr>
<tr>
<td>High Intermediate Low</td>
<td>High Intermediate Low</td>
<td>High Intermediate Low</td>
<td>Not evaluated by ICER or voted upon by public panels</td>
</tr>
</tbody>
</table>

---

Copyright ICER 2016
Potential Budget Impact of Unmanaged Utilization

- **Estimated net change in total** health care costs over an initial 5-year time-frame

- Calculations based on broad assumptions regarding the *unmanaged* uptake of new interventions, i.e. without estimating potential payer or provider group actions that might modulate uptake

- New interventions assigned to one of 4 uptake patterns – very high, high, intermediate, and low – based on consideration of 6 Rx/condition/market criteria
  - Magnitude of improvement in clinical safety and/or effectiveness
  - Patient-level burden of illness
  - Patient preference (ease of administration)
  - Proportion of eligible patients currently being treated
  - Primary care vs. specialty clinician prescribing/use
  - Presence or emergence of competing treatments of equal or superior effectiveness

Copyright ICER 2016
Potential Budget Impact Threshold

• How much potential budget impact is “too much”? 
• Theoretical basis of the potential budget impact threshold:
  – The amount of net cost increase per individual new intervention that would contribute to growth in overall health care spending greater than the anticipated growth in national GDP + 1%
  – A potential budget impact for an individual drug estimated to contribute significantly to cost growth above this threshold serves as an “policy trigger” for greater scrutiny and for efforts to maximize health system value
### Summary of Potential Budget Impact Threshold Calculations

<table>
<thead>
<tr>
<th>Item</th>
<th>Parameter</th>
<th>Estimate (Drugs)</th>
<th>Estimate (Devices)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Growth in US GDP, 2015-2016 (est.) +1%</td>
<td>3.75%</td>
<td>3.75%</td>
<td>World Bank, 2015</td>
</tr>
<tr>
<td>2</td>
<td>Total health care spending ($)</td>
<td>$3.08 trillion</td>
<td>$3.08 trillion</td>
<td>CMS NHE, 2014</td>
</tr>
<tr>
<td>3</td>
<td>Contribution of drug/device spending to total health care spending (%)</td>
<td>13.3%</td>
<td>6.0%</td>
<td>CMS NHE, Altarum Institute, 2014</td>
</tr>
<tr>
<td>4</td>
<td>Contribution of drug spending to total health care spending ($) (Row 2 x Row 3)</td>
<td>$410 billion</td>
<td>$185 billion</td>
<td>Calculation</td>
</tr>
<tr>
<td>5</td>
<td>Annual threshold for net health care cost growth for ALL new drugs (Row 1 x Row 4)</td>
<td>$15.4 billion</td>
<td>$6.9 billion</td>
<td>Calculation</td>
</tr>
<tr>
<td>6</td>
<td>Average annual number of new molecular entity or device approvals, 2013-2014</td>
<td>34</td>
<td>23</td>
<td>FDA, 2014</td>
</tr>
<tr>
<td>7</td>
<td>Annual threshold for average cost growth per individual new molecular entity (Row 5 ÷ Row 6)</td>
<td>$452 million</td>
<td>$301 million</td>
<td>Calculation</td>
</tr>
<tr>
<td>8</td>
<td>Annual threshold for estimated potential budget impact for each individual new molecular entity (doubling of Row 7)</td>
<td><strong>$904 million</strong></td>
<td><strong>$603 million</strong></td>
<td>Calculation</td>
</tr>
</tbody>
</table>
What if Potential Budget Impact causes Provisional Health System Value to be Judged “Low”?

- Maximizing health system value is an action step, ideally supported by enhanced early dialogue among manufacturers, payers, and other stakeholders.
  - Seek savings in other areas to optimize the entire portfolio of services
  - Change the payment mechanism (longer terms) and/or price (lower)
  - Prioritize Rx populations to reduce immediate cost impact
  - Share the costs with government or other funders

- The policy actions taken will determine the “achieved” health system value

Copyright ICER 2016
From Value Assessment to ICER “Value-Based Price Benchmarks”

• The ICER value-based price benchmark represents the price at which patients in the population being considered could be treated with reasonable long-term value at the individual patient level and with added short-term costs that would not outstrip growth in the national economy.

• ICER value-based price benchmark is price(s) to achieve $100-$150k/QALY (care value range), limited by $904 million per year budget impact threshold if applicable.
From Value Assessment to ICER “Value-Based Price Benchmarks”

### Praluent or Repatha

<table>
<thead>
<tr>
<th>Population</th>
<th>Care Value Price: $100K/QALY</th>
<th>Care Value Price: $150K/QALY</th>
<th>Max Price at Potential Budget Impact Threshold</th>
<th>Draft Value-Based Price Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>FH (n=453,443)</td>
<td>$5,700</td>
<td>$8,000</td>
<td>$10,278</td>
<td>$5,700-$8,000</td>
</tr>
<tr>
<td>CVD statin-intolerant (n=364,948)</td>
<td>$5,800</td>
<td>$8,300</td>
<td>$12,896</td>
<td>$5,800-$8,300</td>
</tr>
<tr>
<td>CVD not at LDL target (n=1,817,788)</td>
<td>$5,300</td>
<td>$7,600</td>
<td>$2,976</td>
<td>$2,976</td>
</tr>
<tr>
<td><strong>TOTAL (n=2,636,179)</strong></td>
<td><strong>$5,404</strong></td>
<td><strong>$7,735</strong></td>
<td><strong>$2,177</strong></td>
<td><strong>$2,177</strong></td>
</tr>
</tbody>
</table>

### Entresto

<table>
<thead>
<tr>
<th>Population</th>
<th>Price to Achieve $100K/QALY</th>
<th>Price to Achieve $150K/QALY</th>
<th>Max Price at Potential Budget Impact Threshold</th>
<th>Draft Value-Based Price Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entresto (n=1,669,235)</td>
<td><strong>$9,480/year</strong></td>
<td><strong>$14,472/year</strong></td>
<td><strong>$4,168/year</strong></td>
<td><strong>$4,168/year</strong></td>
</tr>
</tbody>
</table>

40-85% discount

9% discount
More Recently…

- Mepolizumab (Nucala®) for severe eosinophilic asthma
  - Significant reduction in exacerbation and oral steroid use in population with high unmet need
  - At current price, cost-effectiveness estimated at ~$400,000/QALY gained
  - Budget impact threshold not tripped, but price would require 60-75% discount to approach 100-150k/QALY range
Feedback to Date

- ICER framework not sufficiently vetted
- Need for clear participation from acknowledged clinical experts
- Incorporate patient perspective, especially for costs
- Need for additional transparency and willingness to meet with researchers/manufacturers during report preparation
- Some assumptions overly sympathetic to industry:
  - Adding “+1%” to GDP growth
  - Doubling share of budget impact for new innovative agents
  - Allowing all cost growth to be driven by new drugs (in US, cost growth for existing drugs an equal if not greater problem)
Process Modifications

- Formal outreach to all key stakeholders during scoping
- Posting of evidence review protocol / model specs / model technical monograph
- Release of preliminary model findings to mfrs
- Opportunities for public comment on scope and initial draft report
- Invitation for mfrs/clinical experts to make clarifying comments at public meeting
Summary

• Value framework created in recognition that prices of new, high-impact drugs/devices may be disconnected from perceptions of value from multiple perspectives
• ICER feels that explicit consideration of health-system affordability must also now be part of the conversation
• Methods discussions ongoing; public meeting to discuss possible revisions slated for fall 2016
Q&A

www.icer-review.org
http://ctaf.org/
http://www.icer-review.org/midwestcepac/
http://cepac.icer-review.org/

Personal contact: dollendorf@icer-review.org