The ICER value assessment framework
The current landscape

• Tremendous diversity in payer organizations and methods
• Lack of transparency, especially regarding role of costs in decision-making
• Inconsistency within and across payers
• Result
  – Uncertainty
  – Greater risk of conflicting understanding of “value”
  – Greater business risk for life science companies
  – Greater risk of fewer “high value” innovations

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The ICER value framework project

• Long range goals
  – Improve the reliability and consistency of value determinations by payers
  – Provide the basis for more transparent dialogue between manufacturers, payers, and other stakeholders over considerations of value

• The framework includes
  – Content
    • A list of elements to consider
  – Measurement options
    • Methods to measure or judge each element
  – Assessment process
    • Process by which to integrate measurements and other information in an assessment of overall value

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ICER value assessment policy development group

- **Insurers and Pharmacy Benefit Management Companies**
  - Aetna
  - Wellpoint
  - Kaiser Permanente
  - OmedaRx
  - Premera
  - America’s Health Insurance Plans (AHIP)

- **Patient Organizations**
  - FamiliesUSA

- **Physician Specialty Societies**
  - ASCO

- **Manufacturers**
  - Merck
  - Covidien
  - Lilly
  - GSK
  - Philips
  - Amgen
  - National Pharmaceutical Council (NPC)
  - Biotechnology Industry Organization

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What’s not in the value flowchart?

• Larger question: what is our goal?
  – Should we be aiming for static efficiency or not?
    • Is 18% of GDP the right amount of healthcare spending?

• What are the effects of using a value assessment framework to judge some but not all treatments on long-term allocation of resources in the health care system?

• What are the larger trade-offs associated with spending that supports (innovative) life science companies in the US economy?
A “value flowchart”

<table>
<thead>
<tr>
<th>Comparative Clinical Effectiveness</th>
<th>Incremental cost per outcomes achieved</th>
<th>Additional Benefits</th>
<th>Contextual Considerations regarding the illness and therapy</th>
<th>“Care Value”</th>
<th>Affordability</th>
<th>“Health System Value”</th>
</tr>
</thead>
</table>

Vote | Vote
Care value is a judgment comparing the average per-patient costs, clinical outcomes, and broader health effects of two alternative interventions or approaches to care.
Comparative clinical effectiveness is a judgment of the overall difference in clinical outcomes between two interventions (or between an intervention and placebo), tempered by the level of certainty possible given the strengths and weaknesses of the body of evidence.

- Magnitude of the comparative net health benefit
  - Measurement options
    - Disaggregated
      - Specific clinical outcomes, e.g. disease-specific mortality, serious adverse events
    - Aggregated: QALYs

- Level of certainty in the evidence on net health benefit

- Methods to integrate magnitude and level of certainty in comparative net health benefit
  - USPSTF
  - ICER matrix
Incremental cost per outcomes achieved is the average per-patient incremental cost of one intervention compared to another to achieve a desired “health gain,” such as an additional stroke prevented, case of cancer diagnosed, or gain of a year of life.

Relative measure
- Cost per a single desired clinical outcome
- Cost per aggregated health measure
  - cost per QALY
    - WHO thresholds
  - Controversial in the US but the best way to compare incremental costs across different health care interventions
Additional Benefits

• **Additional benefits** refers to any significant benefits offered by the intervention to caregivers, the delivery system, or other patients in the health care system that would not have been captured in the available “clinical” evidence.

  – Are there benefits of treatment that extend beyond patient-specific health improvement?
    • Reduction in care needed from friends and family, earlier ability to return to work
  
  – Will the treatment expand the population that will benefit from treatment?
    • Allows sicker patients or those with comorbidities to be treated

  – Does the treatment reduce disparities in health care outcomes?

  – Does the treatment offer a new or different mechanism of action when significant variation of treatment effect suggests that many patients who do not achieve adequate outcomes on other treatments may benefit?
Contextual Considerations

- **Contextual considerations** can include ethical, legal, or other issues (but not cost) that influence the relative priority of illnesses and interventions.
  - Do other acceptable treatments exist?
  - Is there a particularly high burden/severity of illness?
  - Does the condition include high-priority populations (e.g. children)?
  - Will the intervention be introduced through coverage with evidence development or other ways to reduce key uncertainties about patient outcomes and costs?
Rarely, when the additional per-patient costs for a new care option are multiplied by the number of potential patients treated, the short-term budget impact of a new intervention of reasonable or even high care value could be so substantial that the intervention would be “unaffordable” unless the health system severely restricts its use, delays or cancels other valuable care programs, or undermines access to affordable health insurance for all patients by sharply increasing health care premiums.

Therefore, *health system value* is a judgment of the affordability of the short-term budget impact that would occur with a change to a new care option for all eligible patients, assuming the current price and payment structure.
Managing Affordability

• **But managing affordability** is an action step!

• An assessment of high care value but low health system value does not imply that the health system should not adopt the intervention. This judgment serves as a trigger for policy action.

• Policy makers should take action
  – Reallocation of resources from lower value services
  – Patient selection
  – Step therapy
  – Pricing
  – Financing

• “Policymakers need to take action and work together to align care value with health system value.”

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### Using the “value flowchart”

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**Vote**

**Vote**

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## High Care Value and High Health System Value:

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</tr>
</thead>
<tbody>
<tr>
<td><strong>Superior</strong></td>
<td>Below comparator; or below threshold (~$50-100K/QALY)?</td>
<td>Additional Benefits?</td>
<td>Contextual Considerations</td>
<td>High</td>
<td>Below threshold (0.5-1% PMPM)?</td>
<td>High</td>
</tr>
</tbody>
</table>
A test case: Harvoni vs. previous Rx (PR)

<table>
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<tr>
<th>Harvoni vs. previous triple therapy</th>
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<tr>
<td><strong>Comparative Clinical Effectiveness</strong></td>
</tr>
<tr>
<td>-------------------------------------</td>
</tr>
<tr>
<td>SVR 95% vs. 70%</td>
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What’s in the framework for the life science industry and for payers?

• For life science companies
  – Explicit acknowledgment of “additional benefits” beyond strict comparative clinical effectiveness
  – Definition of “high care value” admits expensive new treatments that add to health care costs
  – The cost-effectiveness paradigm is introduced without hard-wiring to a cost/QALY threshold approach
  – Moving payers away from 1-3 year budget impact as only metric for “value”
  – Signaling that affordability is not simply a question of price; there are other policy mechanisms that should be explored

• For payers
  – Attention to uncertainty of the evidence on comparative clinical effectiveness as a core concern
  – Clarification that additional benefits are a part of value but overshadowed by considerations of comparative clinical effectiveness
  – Affordability is considered as a core part of the conversation about value and not viewed as the sole responsibility of payers
Concluding Thoughts

• The conceptual view of value by payers in the US today is dominated by comparative clinical effectiveness and budget impact.

• The conceptual view of value by manufacturers in the US is dominated by (comparative) clinical effectiveness, additional benefits, and the intrinsic value of having multiple treatment options, with a nod to the perspectives inherent in cost-effectiveness analysis.

• “Best practice in formulary decisions” will result if
  – US payers become more transparent and consistent while focusing more on the balance of long-term benefits and costs in their conception of value and
  – If manufacturers begin to view affordability as a joint, immediate challenge.