Do Novel Value Measures Have a Place in European HTA?:
A U.S. Health Economist Perspective

ISPOR-EU panel presentation,
Monday Nov 12, 2018, 3.45-4.45pm
[Breakout Session #2 (IP6)]
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Agenda

• What is motivating the interest in value frameworks?
• Emergence of recent U.S. value assessment frameworks and formation of ISPOR Special Task Force
• Overview of U.S. value assessment frameworks
• Defining value in conventional cost-effectiveness analysis
• Augmented cost-effectiveness analysis (ACEA)
• Recommendation II of the ISPOR Special Task Force
• Translation to EU markets
What motivated value frameworks in the U.S.?

- Industry productivity is flat despite growing investments.
- Cost per new molecular entity is rising.
- Health systems are struggling to deal with high prices.
- Manufacturers are receiving declining returns—on average.
- Development is moving toward more specialized and orphan drugs.
- Scientific advances are affecting opportunities: gene and cell therapies, cures, combination treatments.
- Rewards (i.e., prices) are **not** strongly correlated with health gains delivered.
- U.S. prices are rising relative to other countries.
- All of this has led to greater interest in “value frameworks” in the U.S.

• Low correlation between oncology drug price and survival benefit.
Average Foreign-to-Canadian Price Ratios for Patented Drugs by Country, 2016

Source: Danzon, *PharmacoEconomics*, 2018

Key U.S. Value Frameworks to date
Overall Objective of Special Task Force

The Special Task Force (STF) will produce a scientific policy white paper that reviews relevant perspectives and appropriate approaches and methods to support the construction and use of high-quality health care value frameworks that will enable more efficient health sector decision-making in the US.

ISPOR Initiative on US Value Assessment Frameworks
STF Final Report. Feb. 2018
**What is (Economic) “Value”?**

- From an economic perspective:
  - Value is what someone is (actually) willing to pay or forgo to obtain something (opportunity cost)

- **Implications:**
  - Value varies *across individuals, across indications* for the same medicine, and *dynamically over time.*
  
  - Value is *difficult to measure in health care* because of insurance

  - In principle, we would ask a plan member about their willingness to pay the *incremental insurance premium (or taxes).* In practice, the amount is *too small to be estimated reliably.*

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**Frameworks Operate in Different Decision Contexts and Use Different Elements of Value**

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<th>Coverage and Reimbursement</th>
<th>Shared Decision Making and Pricing</th>
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Decision Contexts and Value Frameworks

![Diagram showing decision contexts and value frameworks](image)


Second-Panel Volume: Impact Inventory (October 2016)
Recommendation II: Base health plan coverage and reimbursement decisions on an evaluation of the incremental costs and benefits of healthcare technologies as is provided by cost-effectiveness analysis.

1. Cost-per-QALY analyses have strengths and limitations.

2. Frameworks that focus on coverage/reimbursement should consider cost per QALY, as a starting point.

3. Consider elements not normally included in CEAs (e.g., severity of illness, equity, risk protection) but more research needed.

Budget Constraints and Thresholds: Effect of Adding Novel Elements

• It does change the threshold
  • League table approach
  • Cost allocated per QALY falls

• Which margin?
  • Annual vs. lifetime
  • Health vs. non-health
  • Generational: deficit financing
Implications of U.S. Value Frameworks for EU Systems?

- EU HTA assessment will remain a complex and highly variable endeavor across member states.
  - Clinical data are critical in all HTA processes.

- Likely to strengthen support for cost-per-QALY approaches, in part by going beyond the QALY
- Will support importance of augmented CEA as a tool as part of a deliberative process.
- Will support current and growing interest in MCDA as part of deliberative process. Use QALY as key or “anchor” attribute.

Thanks!

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