Payer Decision Making: Economic and Clinical Considerations

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Economics:
- Formal evaluations
- Informal evaluations
- Budgets and finance

Value frameworks:
- Perspectives
- Inclusion
- Merging clinical and economic considerations

Real World Data to Real World Evidence:
- where is this going and why
## Economics

### Economic evidence
- Cost
- Price elasticity
- Efficiency
- Value

### Economic evaluation
- CEA
- CBA
- Budget impact
- Net monetary impact
- Combinations
Pharmaceutical firms make decisions on what drugs to bring to market and what price to set.

PAYERS ARE:

- Price Takers
- Technology Takers

Reactive
- Attempt to limit expenses
- Skeptical of benefits
Decision

- Payers make coverage decisions **not** treatment decisions

- Yes, decisions on payment and under what conditions payment is made will impact decisions regarding treatment...
  - …however payers are not actively treating individual patients and are making decisions for a population...
  - …their job is to provide access/payment to treat the patient while spending the least amount of money to do this
CEA is rarely used

Data for MS drug policies. Presented at AMCP by James Chambers, PhD, MPharm, MSc
Assistant Professor, Tufts Medical Center
CEA is thought not to be acceptable

- Most payers do not explicitly use comparative effectiveness analysis or other sophisticated tools.
- Not generally accepted in the US for making healthcare decisions.

“In the modern American political system, for a policy option to successfully navigate the path from a bill to a law often requires widespread public appeal, or at least little public opposition. This study should offer a warning to the research community that, despite the cost-saving potential of CEA, it is likely to engender widespread opposition when put into practice in the United States—particularly if decisions are widely known by the public.”

And CEA will not manage the budget

- CEA allows for choosing the most cost-effective treatment
  - Biggest bang for the buck
- However the most cost-effective treatment could be the most expensive leading to a serious budget catastrophe
- At an individual level a given intervention may be more effective allowing for use of a less expensive alternative in some patients
If no CEA?

- Payers use a variety of mechanisms to achieve the desired result of successfully treating patients while restraining costs:
  - Qualitative decision making e.g. comparative effectiveness
  - Cost constraint procedures e.g. step edits
  - Benefit designs promoting lower cost alternatives
  - Build a dam: prior authorization
## Evaluating value: cost and clinical outcomes

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Clinical Utility vs. standard of care</th>
<th>Cost per patient</th>
<th>Managed care decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>![Up Arrow]</td>
<td>![Up Arrow]</td>
<td>?</td>
</tr>
<tr>
<td>B</td>
<td>![Up Arrow]</td>
<td>![Down Arrow]</td>
<td>YES</td>
</tr>
<tr>
<td>C</td>
<td>![Down Arrow]</td>
<td>![Up Arrow]</td>
<td>NO</td>
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<tr>
<td>D</td>
<td>![Right Arrow]</td>
<td>![Down Arrow]</td>
<td>YES</td>
</tr>
</tbody>
</table>
Working around CEA

Most US payers do not use Cost Effectiveness Analysis

- Politically unacceptable
- Opens up criticism that they are too focused on cost
- But creates a problem when evaluating new treatments that are have more clinical utility but are more costly than existing therapies
- Therefore, payers use work around approaches like Utilization Management
Cost constraint procedure

A = 80% effective, $$
B = 50% effective, $$

No Constraint

First treatment = A

Effective?

Yes

Result: 80% receive A, 10% B

No

Go to B

With Constraint

First treatment = B

Effective?

Yes

Result: 50% receive B, 40% A

No

Go to A

No
Dam building: prior authorization

Prior Authorization sets height of dam controlling the amount of flow
- Can be adjusted on an annual basis
- Will not stop all use
- Can be overwhelmed
Available Value-Assessment Tools

- ACC/AHA-Cost Value Methodology✔
- ASCO-Value Framework
- Drug Effectiveness Review Project (DERP, Oregon)
- DrugAbacus (Memorial Sloan Kettering)✔
- ICER Value Framework✔
- NCCN Evidence Blocks
- NCCN Resource Stratification
- Oregon State Health Evidence Review Commission Prioritization✔
- Premera-Value Based Drug Formulary✔

✔ =$/QALY used

Value assessment frameworks can provide a common language and allow us to move ahead with a rational discussion of costs and benefits.
Current use of value frameworks

- Value frameworks are another way of describing HTA.
- Not all of the frameworks in use incorporate a formal economic or cost-utility function.
- US payers each have their own approaches which may be less formal and less sophisticated than the proposed frameworks or HTA.
- No payers have endorsed ICER or other frameworks as a reference for coverage decision making (i.e. no standard).
Value of value frameworks

- Moving the discussion ahead
  - Common vocabulary
  - Introduce decision makers and the public to economic constructs and analysis in decision making

- Making data sources and tools explicit
  - Citing data sources
  - Describing processes

- Enhancing the science of decision making
  - We need to address the lack of uniformity in decision making by independent payers in the US
Payer decisions are highly variable

Tufts Medical Center, Private Payer Drug Coverage Database, March 2017
Future of value frameworks

1) Value frameworks are not going to go away
2) Methods and approaches may be internalized by payers
3) Nongovernment payers will not be transparent unless compelled to be so
4) Government payers will be transparent but will avoid CEA and related tools for some time
5) ICER and other nonpayer/nongovernment organizations will play a roll by engaging in a public discourse
6) This roll for these pseudo-HTA organizations will require them to be more inclusive of various stakeholders, and more transparent in methods and discussion
Where does data come from?

- Payer decision makers use a broad range of data
- We have already seen that they use cost but do not use formal economic tools like CEA (although that would be useful)
- Most commonly used data sources
  - Manufacturer data
  - Published studies, esp. RCT
Data sources for P&T Monographs

% of Citations in Monographs

- Manufacturer info: 42%
- Clinical Trials: 35%
- FDA Website: 16%
- Expert/Consensus: 10%
- Compendia: 7%
- Systematic reviews: 6%
- Published RWE studies: 5%
- Review articles: 3%
- Other/unknown: 10%
- Tech/Dossier/Model: 1%

Hurwitz JT et al. JMCP online March 2017.
RWE in practice

- Depends on your definition of RWE
- Only 5% of plans used published RWE trials
  - Not many trials available right now
  - Likely to become more common
- Many plans do look at their own data but it has limited use for making formulary or clinical policy decisions
- There are collaborations between plans and pharma to develop better evidence and use more observational data
  - Quality metrics
  - Utilization
- Many outcomes based contracts contain RWD collection elements