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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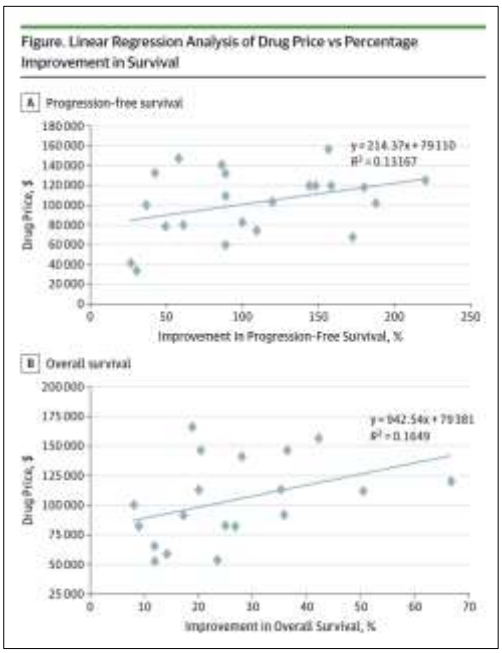
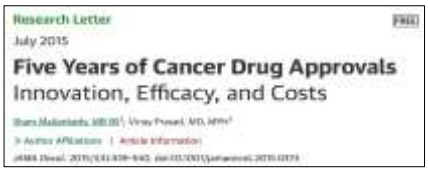
Agenda

- 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.?

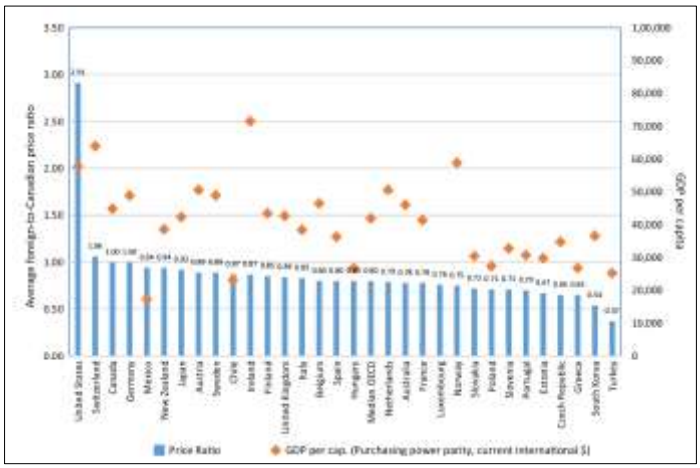
- Industry productivity is flat despite growing investments.
- Cost per new molecular entity is rising.
- Health systems are struggling to deal with high prices.
- Manufacturers are receiving declining returns—on average.
- Development is moving toward more specialized and orphan drugs.
- Scientific advances are affecting opportunities : gene and cell therapies, cures, combination treatments.
- Rewards (i.e., prices) are <u>not</u> 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.




Research Letter
July 2015
Five Years of Cancer Drug Approvals
Innovation, Efficacy, and Costs

- **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 **<u>appropriate approaches and methods</u>** 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

A Health Economics Approach to US Value Assessment Frameworks—Introduction: An ISPOR Special Task Force Report [1]
Peter J. Neumann, Richard J. Willke, Louis P. Garrison Jr

An Overview of Value, Perspective, and Decision Context—A Health Economics Approach: An ISPOR Special Task Force Report [2]
Louis P. Garrison Jr, Mark V. Pauly, Richard J. Willke, Peter J. Neumann

Defining Elements of Value in Health Care—A Health Economics Approach: An ISPOR Special Task Force Report [3]
Darius N. Lakdawalla, Jalpa A. Doshi, Louis P. Garrison Jr, Charles E. Phelps, Anriban Basu, Patricia M. Danzon

Objectives, Budgets, Thresholds, and Opportunity Costs—A Health Economics Approach: An ISPOR Special Task Force Report [4]
Patricia M. Danzon, Michael F. Drummond, Adrian Towse, Mark V. Pauly

Approaches to Aggregation and Decision Making—A Health Economics Approach: An ISPOR Special Task Force Report [5]
Charles E. Phelps, Darius N. Lakdawalla, Anriban Basu, Michael F. Drummond, Adrian Towse, Patricia M. Danzon

Review of Recent US Value Frameworks—A Health Economics Approach: An ISPOR Special Task Force Report [6]
Richard J. Willke, Peter J. Neumann, Louis P. Garrison Jr, Scott D. Ramsey

A Health Economics Approach to US Value Assessment Frameworks—Summary and Recommendations of the ISPOR Special Task Force Report [7]
Louis P. Garrison Jr, Peter J. Neumann, Richard J. Willke, Anriban Basu, Patricia M. Danzon, Jalpa A. Doshi, Michael F. Drummond, Darius N. Lakdawalla, Mark V. Pauly, Charles E. Phelps, Scott D. Ramsey, Adrian Towse, Milton C. Weinstein

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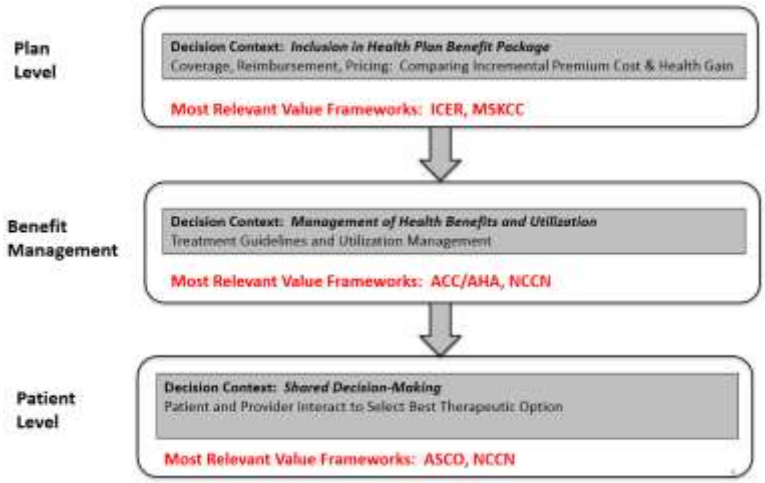
Frameworks Operate in Different Decision Contexts and Use Different Elements of Value

Element:	ACA/AHA	ASCO	ICER	MSKCC	NCCN
Clinical Benefit	✖	✖	✖	✖	✖
Toxicity/Safety	✖	✖	✖	✖	✖
Novelty				✖	
Rarity/Burden			✖	✖	
Affordability			✖		✖
Cost-Effectiveness	✖		✖		
Decision Contest:	***Treatment guidelines and pathways***	***Clinical Shared Decision Making***	***Coverage and Reimbursement***	***Shared Decision Making and Pricing***	***Treatment Guidelines and Shared Decision Making***

Decision Contexts and Value Frameworks



Source: STF Final Report, Section 2 (Garrison, Pauly, et al, Value Health, Feb. 2018)

Second-Panel Volume: Impact Inventory (October 2016)

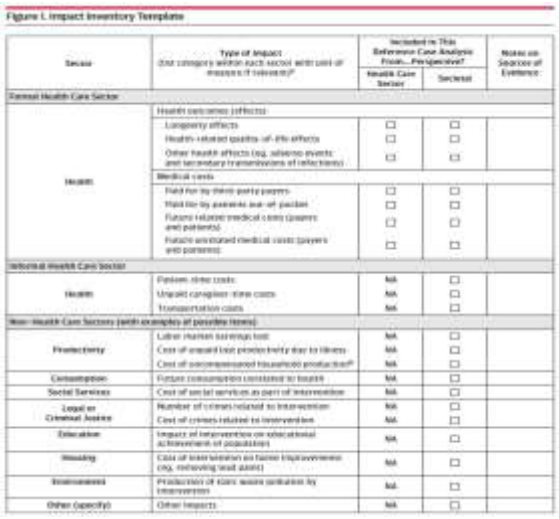


Figure 1. Impact Inventory Template

Sector	Type of Impact (list category within each sector with unit of measure if relevant)*	Included in This Reference Case Analysis From... Perspective?	
		Health Care Sector	Societal
Formal Health Care Sector			
Health	Health outcomes (effects):		
	Longevity effects	☐	☐
	Health-related quality-of-life effects	☐	☐
	Other health effects (eg, adverse events and secondary transmissions of infections)	☐	☐
	Medical costs:		
	Paid for by third-party payers	☐	☐
	Paid for by patients out-of-pocket	☐	☐
	Future-related medical costs (payers and patients)	☐	☐
	Future-unrelated medical costs (payers and patients)	☐	☐
Informal Health Care Sector			
Health	Patient time costs	NA	☐
	Unpaid caregiver time costs	NA	☐
	Transportation costs	NA	☐
Non-Health Care Sectors (with examples of possible items)			
Productivity	Labor market earnings lost	NA	☐
	Cost of unpaid lost productivity due to illness	NA	☐
	Cost of uncompensated household production*	NA	☐
Consumption	Future consumption unrelated to health	NA	☐
Social Services	Cost of social services as part of intervention	NA	☐
Legal or Criminal Justice	Number of crimes related to intervention	NA	☐
	Cost of crimes related to intervention	NA	☐
Education	Impact of intervention on educational achievement of population	NA	☐
Housing	Cost of intervention on home improvement (eg, removing lead paint)	NA	☐
Environment	Production of toxic waste pollution by intervention	NA	☐
Other (specify)	Other impacts	NA	☐

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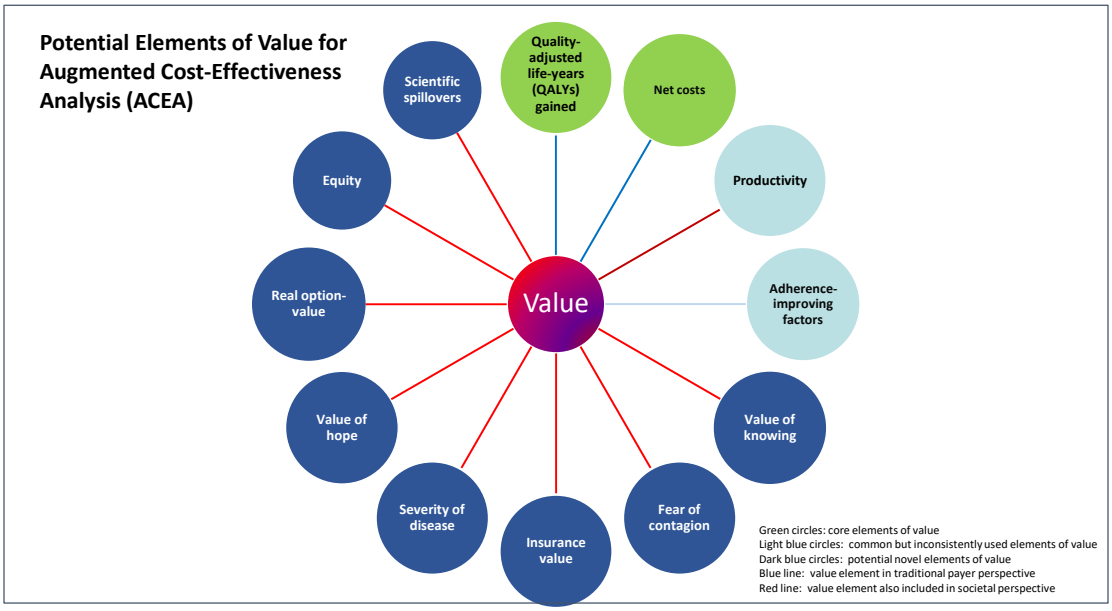

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Recommendation II: Base health plan coverage and reimbursement decisions on an evaluation of the incremental costs and benefits of healthcare technologies as is provided by cost-effectiveness analysis.

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**.

Source: STF Final Report Section 7 (Garrison, Neumann, et al, Value Health, Feb. 2018)

Figure 1: Countries included in the study

CPQ countries	Non-CPQ countries
Australia	France
Canada	Germany
England*	Italy
Scotland*	Spain
Sweden	United States

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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