

# Overview and Trends in Value-Based Payment: A Health Economics Perspective

May 22, 2018

ISPOR International Conference  
Baltimore, Maryland, USA

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## ***Introduction***

Where we come from and where we move forward



## Setting the Stage—Outside and Parallel Trends

- What is value?
- Growth of HTA and ISPOR
- Trends in PBRsAs
- Pricing challenges and value frameworks

## What is “Value”?

- From an economic perspective:
  - Value is what someone is (actually) willing to pay or forgo to obtain something (opportunity cost)
- Implications:
  - Varies ***across individuals, across indications*** for the same medicine, and ***dynamically over time*** (as more evidence becomes available and competitors emerge).
  - 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.

# Defining Economic Value for Health Technology Assessment



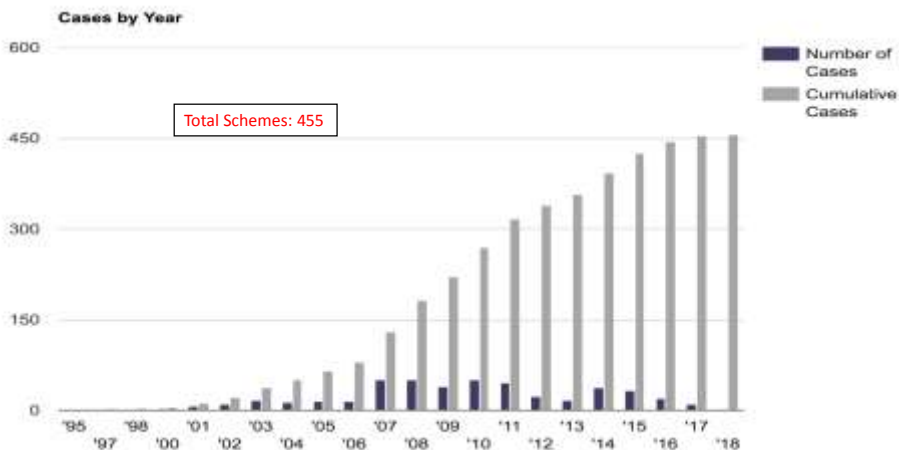
## What is “economic value”?

- “Value”= what fully informed patients would be willing to pay (WTP) for a new medicine based on:
  - 1) any cost-savings,
  - 2) life years gained (LYs),
  - 3) improvements in quality of life or morbidity

*(2+3) → Quality-adjusted life years (QALYs)  
Cost-per-QALY gained = “cost-utility analysis”*

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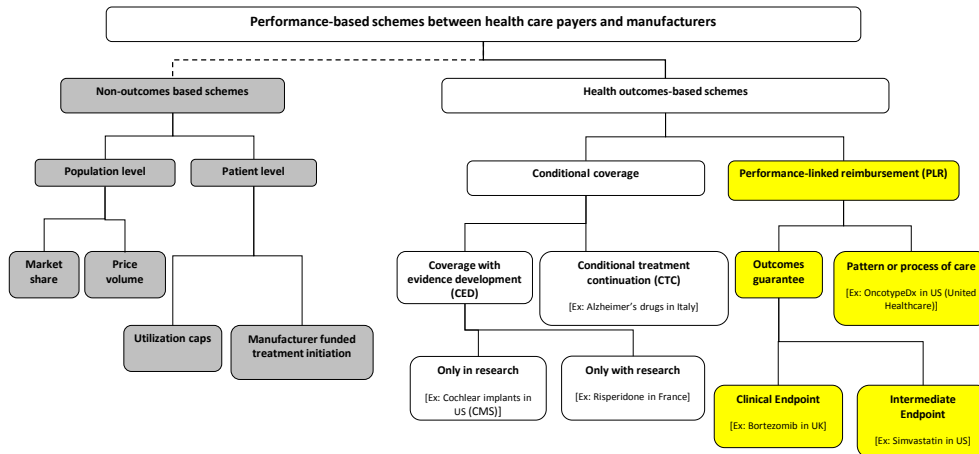
ISPOR TASK FORCE REPORTS

**Performance-Based Risk-Sharing Arrangements—Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force**

Louis P. Garrison Jr., PhD (co-chair)<sup>1,4</sup>, Adrian Towse, MA, MPhil (co-chair)<sup>2</sup>, Andrew Briggs, MSc, DPhil<sup>3</sup>, Gerard de Pauwourville, PhD<sup>5</sup>, Jens Grueger, PhD<sup>6</sup>, Penny E. Mohr, MA<sup>7</sup>, J.L. (Hans) Severens, PhD<sup>8</sup>, Paolo Siviero, BA<sup>9</sup>, Miguel Sleeper, ACMA<sup>3</sup>

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**PBRSA Taxonomy**



Source: Carlson et al., 2010

## Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects

Louis P. Garrison, Jr, PhD; Josh J. Carlson, PhD; Preeti S. Bajaj, PhD; Adrian Towse, MA, MPhil; Peter J. Neumann, ScD; Sean D. Sullivan, PhD; Kimberly Westrich, MA; and Robert W. Dubois, MD, PhD

### ABSTRACT

**Objective:** Risk-sharing agreements (RSAs) between drug manufacturers and payers link coverage and reimbursement to real-world performance or utilization of medical products. These arrangements have garnered considerable attention in recent years. However, greater use outside the United States raises questions as to why their use has been limited in the US private sector, and whether their use might increase in the evolving US healthcare system.

**Study Design:** To understand current trends, success factors, and challenges in the use of RSAs, we conducted a review of RSAs, interviews, and a survey to understand key stakeholders' experiences and expectations for RSAs in the US private sector.

**Methods:** Trends in the numbers of RSAs were assessed using a database of RSAs. We also conducted in-depth interviews with stakeholders from pharmaceutical companies, payer organizations, and industry experts in the United States and European Union. In addition, we administered an online survey with a broader audience to identify perceptions of the future of RSAs in the United States.

**Results:** Most manufacturers and payers expressed interest in RSAs and saw potential value in their use. Due to numerous barriers associated with outcomes-based agreements, stakeholders were more optimistic about financial-based RSAs. In the US private sector, however, there remains considerable interest—improved data systems and shifting incentives (via health reform and accountable care organizations) may generate more action.

**Conclusions:** In the US commercial payer markets, there is continued interest among some manufacturers and payers in outcomes-based RSAs. Despite continued discussion and activity, the number of new agreements is still small.

*Ann J Manag Care.* 2014;2(1):632-640

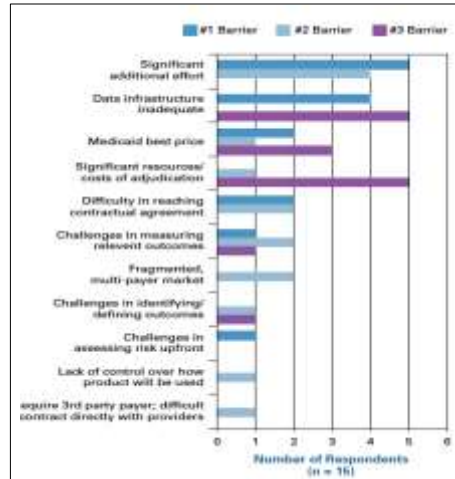
### Key findings:

- Lots of interest and talk by manufacturers
- Substantial implementation barriers
  - Need better data systems
  - Costs of negotiation
- More interest in financially-based RSAs
- Shift incentives? ACOs and government subsidies?

### ■ Figure 4. Potential Barriers to RSA Use in the United States

1. Significant additional effort required to establish/execute RSAs (eg, compared to traditional rebates/discounts)
2. Challenges in identifying/defining meaningful outcomes
3. Challenges in measuring relevant real-world outcomes
4. Data infrastructure inadequate for measuring/monitoring relevant outcomes
5. Difficulty in reaching contractual agreement (eg, on the selection of outcomes, patients, data collection methods)
6. Implications for federal (Medicaid) best price
7. Payer concerns about adverse patient selection
8. Fragmented multi-payer insurance market with and significant patient switching among plans
9. Challenges in assessing risk upfront due to uncertainties in real-world performance
10. Lack of control over how product will be used
11. Significant resources and/or costs associated with ongoing adjudication

■ **Figure 5. Survey Findings of Top Barriers to the Use of RSAs in the United States**



## Key U.S. Value Frameworks to date



# 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. Wilke, 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. Wilke, 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, Anirban 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, Anirban 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. Wilke, 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. Wilke, Anirban 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*

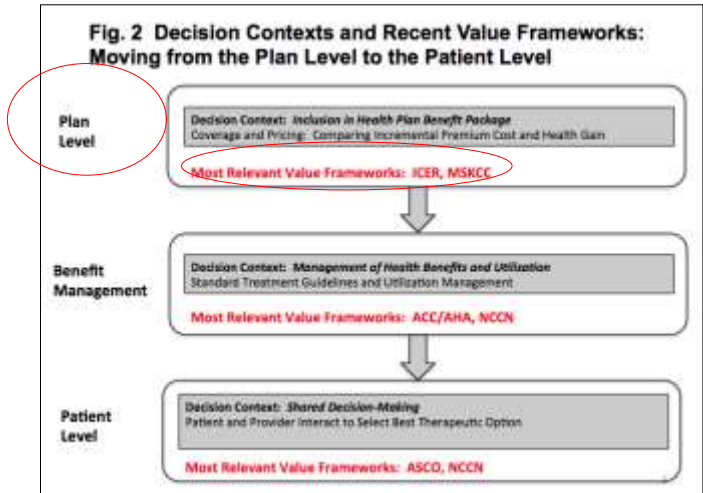


## Working Premise

“. . . it is critical to investigate these value frameworks **because of the signals they send to innovators**. Value-based approaches can encourage firms to produce more of what is being optimized in the frameworks, and discourage them from bringing to market products that do not produce good value. Ideally, that means society will benefit from medical products and healthcare technologies that **efficiently improve the health and welfare of the population** according to consistent and well-founded measures of value. Conversely, ill-conceived frameworks could produce long-lasting harms by encouraging innovators to develop treatments that fail to produce real value.”  
*[emphasis added]*

Source: STF Final Report [1], ViH, Feb. 2018

# Decision Contexts and Value Frameworks



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

## The Gospels

Resource allocation decisions: incremental cost per QALY gained





# Second-Panel Volume: Impact Inventory (October 2016)



Figure 1. Impact Inventory Template

Sector	Type of Impact (What category would each sector fit under if impacts fit together?)	Included in This Reference Case Analysis?		Notes on Source of Evidence
		Health Care Sector	Society	
<b>General Health Care Sector</b>				
Health	Health outcomes effects			
	Longevity effects	<input type="checkbox"/>	<input type="checkbox"/>	
	Health-related quality-of-life effects	<input type="checkbox"/>	<input type="checkbox"/>	
	Other health effects (eg, adverse events and secondary transmissions of infections)	<input type="checkbox"/>	<input type="checkbox"/>	
	Medical costs			
Health	Paid for by third party payers	<input type="checkbox"/>	<input type="checkbox"/>	
	Paid for by patients out-of-pocket	<input type="checkbox"/>	<input type="checkbox"/>	
	Future related medical costs (patients and payers)	<input type="checkbox"/>	<input type="checkbox"/>	
	Future unrelated medical costs (patients and payers)	<input type="checkbox"/>	<input type="checkbox"/>	
<b>General Health Care Sector</b>				
Health	Fixed-time costs	NA	<input type="checkbox"/>	
	Unpaid caregiver time costs	NA	<input type="checkbox"/>	
	Transportation costs	NA	<input type="checkbox"/>	
<b>Non-Health Care Sectors (with examples of possible impacts)</b>				
Pharmaceutical	Labour market savings lost	NA	<input type="checkbox"/>	
	Cost of unpaid time productivity due to illness	NA	<input type="checkbox"/>	
	Cost of administrative/healthcare production	NA	<input type="checkbox"/>	
Contamination	Future environmental contamination impacts	NA	<input type="checkbox"/>	
Social Services	Cost of care for services as part of intervention	NA	<input type="checkbox"/>	
Legal or Criminal Justice	Number of crimes related to intervention	NA	<input type="checkbox"/>	
	Cost of crimes related to intervention	NA	<input type="checkbox"/>	
Education	Impact of intervention on educational achievement of population	NA	<input type="checkbox"/>	
Residing	Cost of transportation and home improvement (eg, installing handrails)	NA	<input type="checkbox"/>	
Environment	Production of toxic waste pollution by intervention	NA	<input type="checkbox"/>	
Other (specify)	Other impacts	NA	<input type="checkbox"/>	

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## Recommendation I: Be explicit about decision context and perspective in value assessment frameworks.



1. No single value assessment framework captures everything.
1. For societal and health plan resource allocation decisions (coverage/ reimbursement), perspective should reflect those who pay for care (e.g., enrollees, employees, taxpayers).
2. Well-designed patient-level frameworks can help guide shared decision making for treatment choices

1. No single value assessment framework can simultaneously reflect multiple decision contexts and the perspectives of the patient, the health plan, or society as a whole. Thus, it is important for any framework to clearly articulate the value construct it represents and the perspective and decision context in which it is to be used, and to be well validated and reliable within that construct and context.

2. For societal and health plan resource allocation decisions, including coverage and reimbursement decisions, the perspective used should reflect, at a minimum, those who ultimately pay for care, including, for example, enrollees, employees, and taxpayers.

3. Well-designed patient-level frameworks can help guide shared decision making for treatment choices among the clinically appropriate options that have been approved for coverage so that patients and their providers can consider and weight factors most relevant to patient preferences and constraints.

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

## 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.



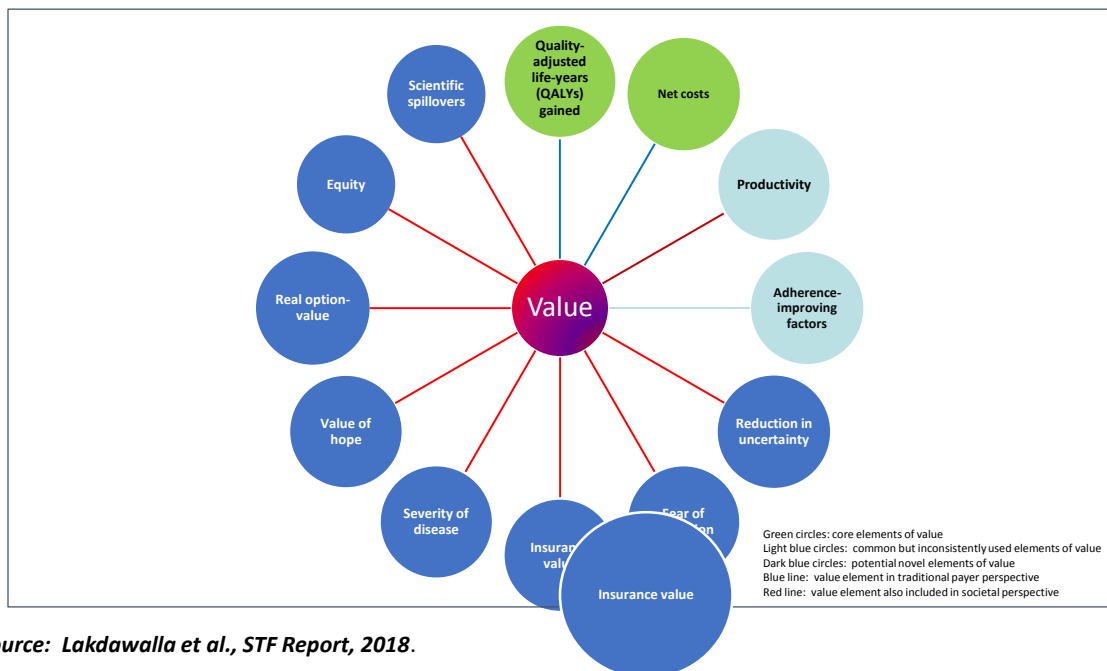
1. Cost-per-QALY analyses have strengths and limitations

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.

1. A central tenet in economics is to compare incremental costs and benefits in decision making. CEA and, in particular, cost-per-QALY analysis have many demonstrated strengths—and some recognized limitations; they are well established in health economics and used by decision makers in health systems worldwide.
2. Value assessment frameworks that focus on health plan coverage and reimbursement decisions should consider CEAs, as measured by cost per QALY, as a starting point to inform payer and policymaker deliberations. In many instances, the cost-per-QALY metric can serve well as the core component of these assessments.
3. Elements of costs and benefits not normally included in CEA that affect individual well-being (such as severity of illness, equity, and risk protection) may be relevant for some health plan decisions; more research is, however, needed on how best to measure and include them in decision making.

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



Source: Lakdawalla et al., STF Report, 2018.

# How to aggregate elements of value?

## 1. Monetization of elements in addition to cost per QALY

- Extended CEA—Risk protection and equity impact (used in global health)
- Augmented CEA—ECEA+other factors
- Net Monetary Benefit (NMB)—change in QALY x WTP threshold + Net cost

## 2. Multi-criteria Decision Analysis (MCDA)

- Analytical Hierarchy Process (AHP)
- Multi-attribute utility theory (MAUT)
- Deliberative processes

**Thanks!**

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