

DEFINING VALUE IN LATIN AMERICA: THE GOOD, THE BAD AND THE UGLY

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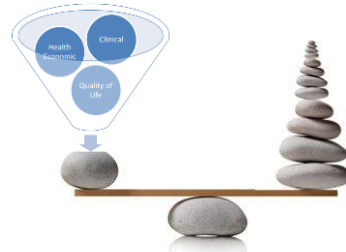
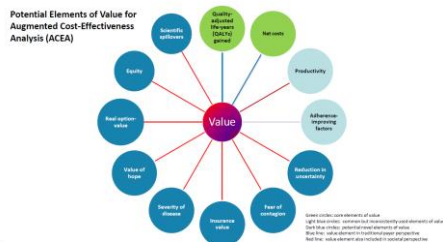
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Introduction

- **What are value frameworks?**
 - A defined process or methodology for determining a product's or service's relative value compared to another treatment and its cost or relative cost in relation to health economics, quality of life, and the clinical setting.



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What some organizations are thinking about value assessment frameworks...

Value frameworks can be useful decision-support tools but should not be viewed as providing a single, universally applicable answer to questions about a treatment's value

- PhRMA

The currently available frameworks, are widely diverse in their approaches. This inconsistency can lead to variable evaluations of treatments.

- ISPOR Value Assessment Frameworks Special Task Force

The purpose of the value framework is to form the backbone of rigorous, transparent evidence reports that, as a basis for broader stakeholder and public engagement, will help the United States evolve toward a health care system that provides sustainable access to high-value care for all patients.

- Institute for Clinical and Economic Review

Value assessment frameworks are a relatively new and emerging field... As these frameworks have the potential for considerable impact on patients, there is a need to understand whether these frameworks have been developed with adequate rigor.

- National Pharmaceutical Council

The task force is well aware that there are many elements that might be important to individual patients in assessing the relative value of their treatment options that are not taken into account in our model.

- ASCO Value in Cancer Care Task Force

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Methods

- ISPOR Industry Committee members performed a literature review, browsed Ministries of Health and HTA agencies websites, and surveyed ISPOR Latin America Industry Committee members to identify and select value assessment frameworks currently being used in Latin America.
- Once selected, 16 reviewers grouped in 7 teams assessed each framework's input, methodology and outputs using as a basis the evaluation taxonomy proposed by Mandelblatt J et al¹ using an evaluation grid.
- To ensure consistency in the application of each domain among reviewers, a working definition was developed.
- The evaluation grid was subject of peer review among members of the workgroup

¹ Mandelblatt J et al, 2017_ Evaluating Frameworks That Provide Value Measures for Health Care Interventions. Value in Health 20 185-192

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Evaluation Taxonomy

Mandelblatt J et al, 2017_ *Evaluating Frameworks That Provide Value Measures for Health Care Interventions. Value in Health* 20 185-192

Basic Components:

- 1) Define the **Purpose**
- 2) Detail the **Conceptual approach**, including perspectives, methods for obtaining preferences of decision makers (e.g. patients) and ability to incorporate multiple dimensions of value
- 3) **Inclusions and exclusions** of elements included in the framework, and whether the framework assumes clinical intervention or offers alternatives such as palliative care or watchful waiting
- 4) Evaluate **data sources** and their scientific validity
- 5) Assess the intervention's effect on **total costs** of treating a defined population
- 6) Analyze how **uncertainty** is incorporated
- 7) Illuminate possible **conflicts of interests** among those creating the framework

Category	Component details
Purpose Conceptual approach, perspective, and preferences	Is the purpose defined and are the elements of the framework consistent with the purpose? Is the value structure of the framework clear and transparent? If it requires assumptions, do they have general and clinical face validity? What perspective does the framework use (e.g., societal, patient, provider, payer)? Is the perspective made explicit or embedded in the framework? Does the framework include standard methods of measuring value, such as cost-effectiveness analysis? Does the framework consider multiple attributes of medical interventions such as individual preferences, equity and the distribution of health care benefits and costs, issues involving externalities (such as contagious diseases), and the value of scientific breakthroughs? If the framework includes multiple dimensions of value, are the weights for each component population-based or expert-provided, and are the methods for eliciting such weights both clearly stated and methodologically sound? Does the framework allow individual patient preferences? If so, are they elicited with methods known to be free of bias and to produce reliable results?
Intervention components and comparators	Does the framework include all components and consequences of the intervention, or merely a portion of those (e.g., drug acquisition costs)? Does the framework aggregate or disaggregate such things as toxicity or other side effects of intervention? Does the framework assume as a baseline that some intervention will be provided, or does it allow for "watchful waiting" or "palliative care" as an option?
Data sources	Are clinical and other data derived from expert opinion, population surveys, or other sources? Are the sources made clear, and is the process replicable?
Economics/costs	What is the effect of the intervention on the total cost of treating a defined population, including whether inclusion of the intervention will increase, decrease, or leave unchanged the total costs of care for that population?
Uncertainty and identification of important gaps Conflicts of interest	Is uncertainty in data about costs or effects considered in conclusions about value? Are there gaps in knowledge about aspects of care that could change the value rating? Does the sponsoring organization have a financial stake in the process, and if so, is this declared? Does the framework bias the results in favor of the sponsor's financial position?

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ISPOR Latin America Consortium Health Technology Producers (Industry)			
Value Frameworks Working Group			
Evaluation Grid			
No.	Question	Answer "Yes"; "No"; "Partially"	Comment
1	Is the purpose defined and are the elements of the framework consistent with the purpose?		
2	Is the value structure of the framework clear and transparent? If it requires assumptions, do they have general and clinical face validity?		
3	What perspective does the framework use (e.g., societal, patient, provider, payer)? Is the perspective made explicit or embedded in the framework?		
4	Does the framework include standard methods of measuring value, such as cost-effectiveness analysis?		
5	Does the framework consider multiple attributes of medical interventions such as individual preferences, equity and the distribution of health care benefits and costs, issues involving externalities (such as contagious diseases), and the value of scientific breakthroughs?		
6	If the framework includes multiple dimensions of value, are the weights for each component population-based or expert-provided, and are the methods for eliciting such weights both clearly stated and methodologically sound? Does the framework allow individual patient preferences? If so, are they elicited with methods known to be free of bias and to produce reliable results?		
7	Does the framework include all components and consequences of the intervention, or merely a portion of those (e.g., drug acquisition costs)?		
8	Does the framework aggregate or disaggregate such things as toxicity or other side effects of intervention?		
9	Does the framework assume as a baseline that some intervention will be provided, or does it allow for "watchful waiting" or "palliative care" as an option?		
10	Are clinical and other data derived from expert opinion, population surveys, or other sources? Are the sources made clear, and is the process replicable?		
11	What is the effect of the intervention on the total cost of treating a defined population, including whether inclusion of the intervention will increase, decrease, or leave unchanged the total costs of care for that population?		
12	Is uncertainty in data about costs or effects considered in conclusions about value? Are there gaps in knowledge about aspects of care that could change the value rating?		
13	Does the sponsoring organization have a financial stake in the process, and if so, is this declared?		
14	Does the framework bias the results in favor of the sponsor's financial position?		
		Name:	
		Date:	

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Value Frameworks Evaluated

- One developed by a regional entity, the Inter-American Development Bank
- Two country frameworks for price assessment (CMED-Brazil; IETS-Colombia)
- Four country frameworks to inform reimbursement (CONITEC-Brazil; Ricarte Soto-Chile; IETS-Colombia; CSG-Mexico).



Comissão Nacional de Incorporação de Tecnologias (CONITEC)



Câmara de Regulação do Mercado de Medicamentos (CMED)



Instituto de Evaluación Tecnológica de Salud (IETS)



New Drug Therapeutic Value Framework (Not yet implemented)



Ley Ricarte Soto



Consejo de Salubridad General



Interamerican Development Bank/DIME

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Results at a Glance

Framework	Purpose	Conceptual Approach					Interventions and Comparators			Data Sources	Economics/Costs	Uncertainty	Conflicts of Interest	
		Clear & transparent structure	Perspective	Std Method	Multiple attributes	Dimensions of value	All components	Aggregate vs disaggregate	Baseline vs horizontal scanning				Financial stake of sponsor	Bias in favor of sponsor's financial position?
CONITEC														
CMED														
IETS R														
IETS TV														
Ricarte Soto														
CSG														
IDB/Dime														
Overall														

Yes

Partial

No

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Results

- **Purpose:** Most of the frameworks examined have a clear definition of the purpose
- **Conceptual approach:** Most of the frameworks are fairly clear on the perspective of analysis and consider standard methods for measuring value. However, in most, the value structure of the framework is not completely clear and they fail to consider multiple attributes of medical interventions and multiple dimensions of value, including individual patient preferences and the societal perspective.
- **Interventions and comparators:** The majority of frameworks do not consider all components and consequences of the intervention beyond drug costs, but they consider toxicity and side effects as a disaggregated cost and assume that some intervention will be provided and will be evaluated against a base comparator. The majority also account for "watchful waiting".
- **Data sources:** The description of the evaluation of data sources and their scientific validity was inconsistent across frameworks. Some explicitly stated that RWE could be used but also there was a tendency to prefer RCT and data generated by academic institutions.

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Results

- **Economics/costs:** The value frameworks were also inconsistent in examining the effect of the intervention on the total cost of treating a defined population, focusing on direct medical costs and not taking into account indirect costs.
- **Uncertainty:** The issue of uncertainty in data about costs or effects in making conclusions about value was mentioned in all of the value frameworks but some do not completely detail how it would impact value rating and decision-making.
- **Conflicts of interest:** Possible conflicts of interest among those creating and applying the framework is not addressed, although most recognize the purpose of the framework in terms of their financial stake in the use of healthcare resources.

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Conclusions

- Value assessment frameworks are being adopted and implemented throughout the Latin America region, including seven examined in this work.
- Using the *Taxonomy for Evaluating Frameworks That Provide Value Measures for Health Care Interventions* proposed by Mandelblatt J *et al*, the results were mixed with regard to the components required in value frameworks.
- Among the strengths noted, most value frameworks examined have a clear purpose, establish the perspective of analysis, are fairly explicit on the intervention and comparators, and consider uncertainty.
- The value frameworks evaluated are limited in the consideration of the dimensions of value and attributes of the interventions, as well as in the use of data sources besides RCT and the inclusion of total costs beyond direct medical costs.
- Future work should address the real-life application of these frameworks and its impact on access to innovation and patient outcomes.

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