Conflict of Interest Statement

- José Santiago is an employee and shareholder of Abbott
- Claudia Brabata is an employee of Medtronic and shareholder of Medtronic and Baxter and Chair of the Latin America Access Working Group at ADVAMED
- Diego F. Guarín is an employee and shareholder of Merck & Co., Inc and Co-Chair of FIFARMA Value and Access to Innovation Working Group
- Homero A. Monsanto is an employee and shareholder of Merck & Co., Inc. and President of the ISPOR Latin America Industry Committee

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ARE VALUE FRAMEWORKS IN LATIN AMERICA FIT FOR PURPOSE WHEN ASSESSING COVID-19 HEALTH TECHNOLOGIES?

Panelists:

Jose Santiago PhD, Director Scientific Affairs – Americas, Molecular Diagnostics, Abbott, USA (jose.santiago@abbott.com)

Claudia Brabata, MSc, Director Market Access & Public Affairs - Latin America, Medtronic, USA. (claudia.f.brabata@medtronic.com)

Diego F. Guarín, MD MPH MSc, Executive Director, Regional Market Access Latin America, Merck & Co., USA (diego.guarin@merck.com)

Moderator:

Homero A. Monsanto, PhD, Executive Director, Center for Observational and Real-world Evidence (CORE) Latin America, MSD (IA) LLC, Puerto Rico, USA (homero.monsanto@merck.com)

COVID-19 in Latin America

- The SARS-CoV-2 infection (COVID-19) has had profound **health, social and economic effects** across the world.

- As of April 12, 2021, five countries in Latin America (Brazil, Colombia, Argentina, Mexico, and Peru) were among the **top 20 countries in the world** in number of cases and deaths due to COVID-19 [*https://covid19.who.int/*]

- Health innovations to tackle the pandemic, ranging from vaccines and antivirals to clinical diagnostics and medical devices, are advancing at incredible speed adding pressure to provide **rapid and broad access** to these technologies for those who need them in order to manage the pandemic.

Overview of the Panel Presentation

- HTA Agencies in Latin America follow explicit value frameworks to assess health technologies. These frameworks have a **narrow definition of value**, mainly focused on health benefits (e.g. LYG, QALYs) and costs, disregarding other elements.

- COVID-19-related health technologies illustrate the **challenges of the current definition of value** and opportunities to discuss other elements that should be considered relevant.

- This panel will address **challenges** that will be faced by **decision makers** in the near term when **assessing the value of COVID-19-related health innovations** under the established value frameworks once the pandemic ends in three countries with established HTA agencies: Brazil, Colombia and Mexico.

- Representatives of the **clinical diagnostics, medical devices and biopharmaceutical sectors** will discuss these challenges, highlighting those value elements that should be considered.

Impact of COVID-19 on HTA across the LA Region

- Health Technology Assessment (HTA) is facing **unprecedented global challenges** in the wake of the COVID-19 pandemic, with **new pressures on health systems and decision makers** forcing HTA's traditional processes and roles to adapt to a new normal.

- Latin America is no exception, and stakeholders in the region are looking for **greater clarity around HTA's role in the pandemic and beyond** for clinical diagnostics, medical devices and biopharmaceuticals.

- On October 15, 2020, ISPOR hosted an invitation-only virtual **HTA roundtable** with the participation of **government policymakers, healthcare payers and HTA experts from Latin America** to discuss the topics pertinent to HTA and healthcare decision-making to make HTA more effective and harmonized for the region.

Source: HTA's Evolving Role through the COVID Pandemic and Beyond – Virtual ISPOR 52nd HTA Roundtable – Latin America (https://press.ispor.org/LatinAmerica/2021/02/htas-evolving-role-through-the-covid-pandemic-and-beyond-virtual-ispor-52nd-hta-roundtable-latin-america/)

What are the Key Challenges and Opportunities for Health Systems in Latin America as a Consequence of the pandemic?

Challenges

- Speed vs rigor
- Impact of treatment delays and equity in access
- Virtual care and online meetings
- Managing political and media influence
- Supply chain considerations
- Budget deficits
- HTA processes delayed
- Accelerated approvals and concerns with products going directly to price negotiations.

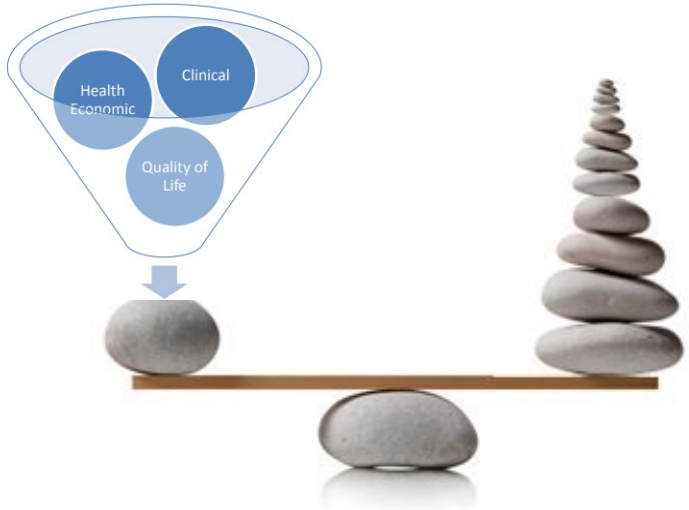
Opportunities

- Demonstrate the benefit of HTA
- Shift in priority to public health (real need vs technology driven demand)
- Opportunity for increased national, regional, and international collaboration
- Opportunity to expand the lifecycle approach to HTA
- Use of RWE

Source:HTA's Evolving Role through the COVID Pandemic and Beyond – Virtual ISPOR 52nd HTA Roundtable – Latin America (https://press.ispor.org/LatinAmerica/2021/02/htas-evolving-role-through-the-covid-pandemic-and-beyond-virtual-ispor-52nd-hta-roundtable-latin-america/)

What are Value Frameworks?

A defined process or methodology for determining a product or service relative value compared to another treatment and its cost or relative cost in relation to health economics, quality of life, and the clinical setting.



How are these frameworks evaluated?

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

Table 1 – Proposed taxonomy for evaluation of frameworks assessing the value of health care interventions.

Category	Component details
Purpose	Is the purpose defined and are the elements of the framework consistent with the purpose?
Conceptual approach, perspective, and preferences	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 breakthrough?
	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	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?
Conflicts of interest	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?

Source: Mandelblatt J et al, 2017_ Evaluating Frameworks That Provide Value Measures for Health Care Interventions. Value in Health 20 185-192 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5539503/)

How does LA Value Frameworks score?

- BRA — Comissão Nacional de Incorporação de Tecnologias (CONITEC)
- COL — Instituto de Evaluación Tecnológica de Salud (IETS)
- MEX — Consejo de Salubridad General (CSG)

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	Yes	Partial	Yes	Partial	No	Partial	Partial	Partial	Yes	Yes	Partial	Yes	Yes	Partial
IETS	Yes	Partial	Yes	Yes	No	No	Partial	Yes	Yes	Partial	Partial	Partial	Yes	No
CSG	Yes	Partial	Yes	Yes	No	No	Yes	Partial	Yes	No	No	Yes	No	No

Yes Partial No

Source: DEFINING VALUE IN LATIN AMERICA: THE GOOD, THE BAD AND THE UGLY. Presented at ISPOR Latin America Meeting, Bogota, Colombia. September 12-14, 2019
https://www.ispor.org/docs/default-source/latin2019/paper929532.pdf?sfvrsn=d21582be_0

What elements are not included within the current value frameworks that are relevant to be considered from the perspective of the clinical diagnostics, medical devices and biopharmaceutical industries?

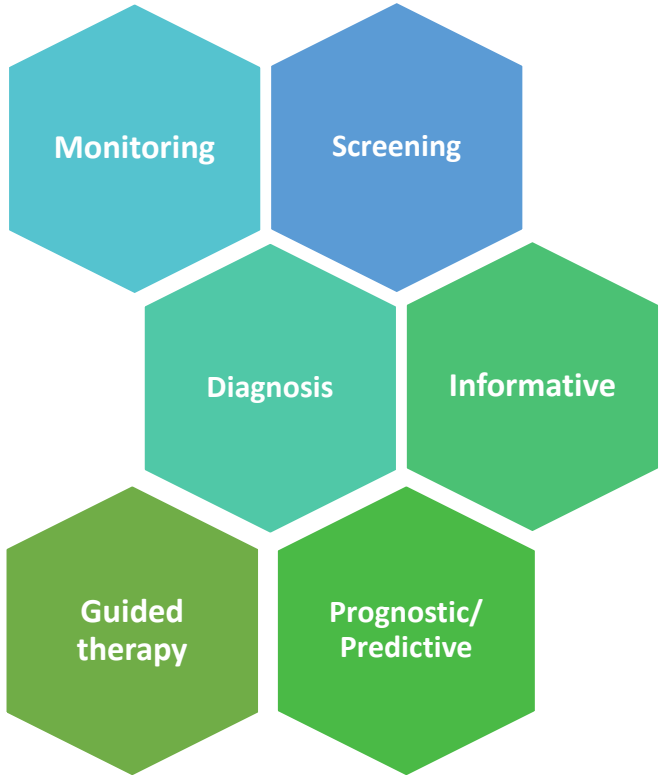
Value Framework in Clinical Diagnostics - TODAY

Elements included:

- Test performance & safety & effectiveness –
- Costs (Net) – (direct and indirect)
- Companion Dx follow more traditional HTA's

Elements partially or not-included:

- Value Frameworks tailored for Clinical Diagnostic Technologies
- Special Considerations for evaluating Organizational, Structure, Access and Applications of Diagnostic Technology



COVID LESSONS LEARNED:

- Different Dx Technologies even within the same clinical pathways have different "value"
- Balance Technical & Structural requirements

Value Framework in Medical Devices - TODAY

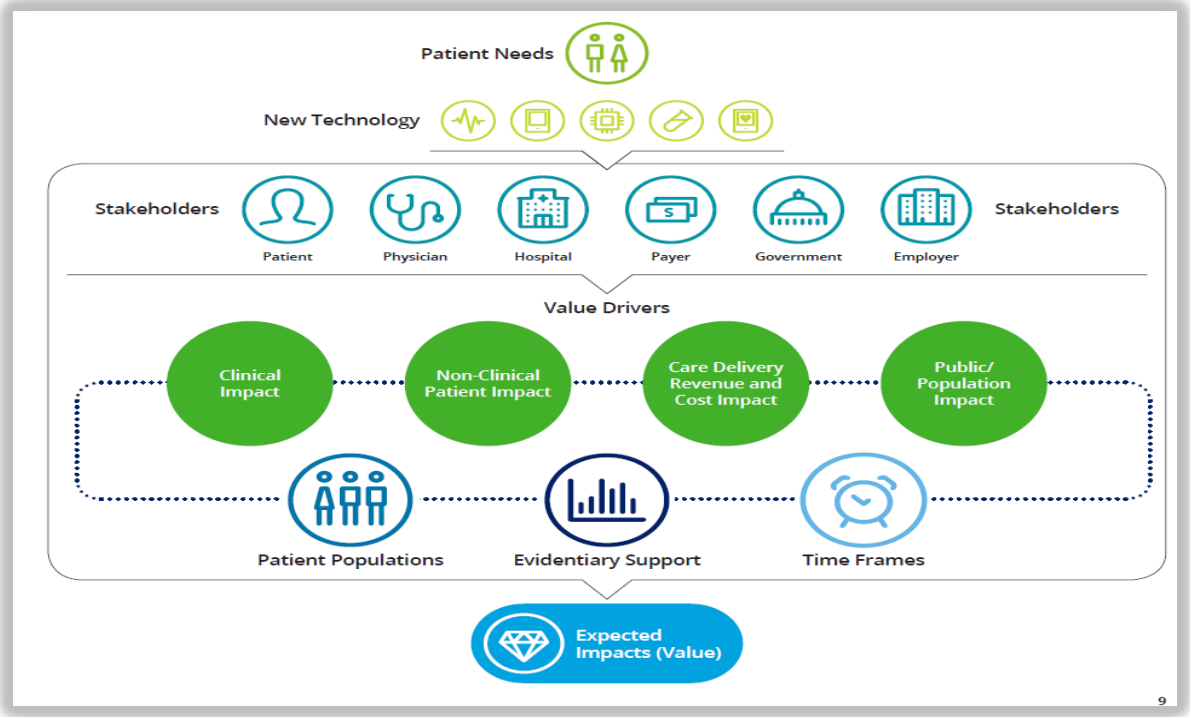
ADVAMED infographic
Value Framework for Medical Technologies [2]

<u>Elements included:</u>

- Payer perspective
- Core criteria: clinical impact – efficacy, effectiveness and safety- ; CE and budget impact

<u>Elements partially or not-included:</u>

- Dimensions for value with specifical characteristics to devices:
  - Impact to organizational aspects [1]
  - Learning curve required [1]
  - Non-clinical patient impact [2]
  - Data sources- evidence for MD
  - Digital Health



COVID LESSONS LEARNED:

- Limited healthcare installed capacity
  - Patient surge stressing the system
- Organizational services around hospital setting and presential support

(1) Pichon-Riviere A et al (2019). International Journal of Technology Assessment in Healthcare 35, 64-68
(2) ADVAMED & Deloite (2017). A Framework for Comprehension Assessment of Medical Technologies

Value Framework in Biopharma - TODAY

Elements included:

- Payer perspective
- Core criteria: efficacy, safety, Cost-effectiveness Analysis (LYG, QALY) and budget impact analysis

Elements partially or not-included:

Vaccines

- Impact of vaccination on economic growth, sustainability, efficiency of healthcare systems and disease eradication.
- Intangible gains provided by vaccination (e.g. school enrolment, attendance, and attainment), and community externalities (herd immunity, prevention of antibiotic resistance) among others

Medicines

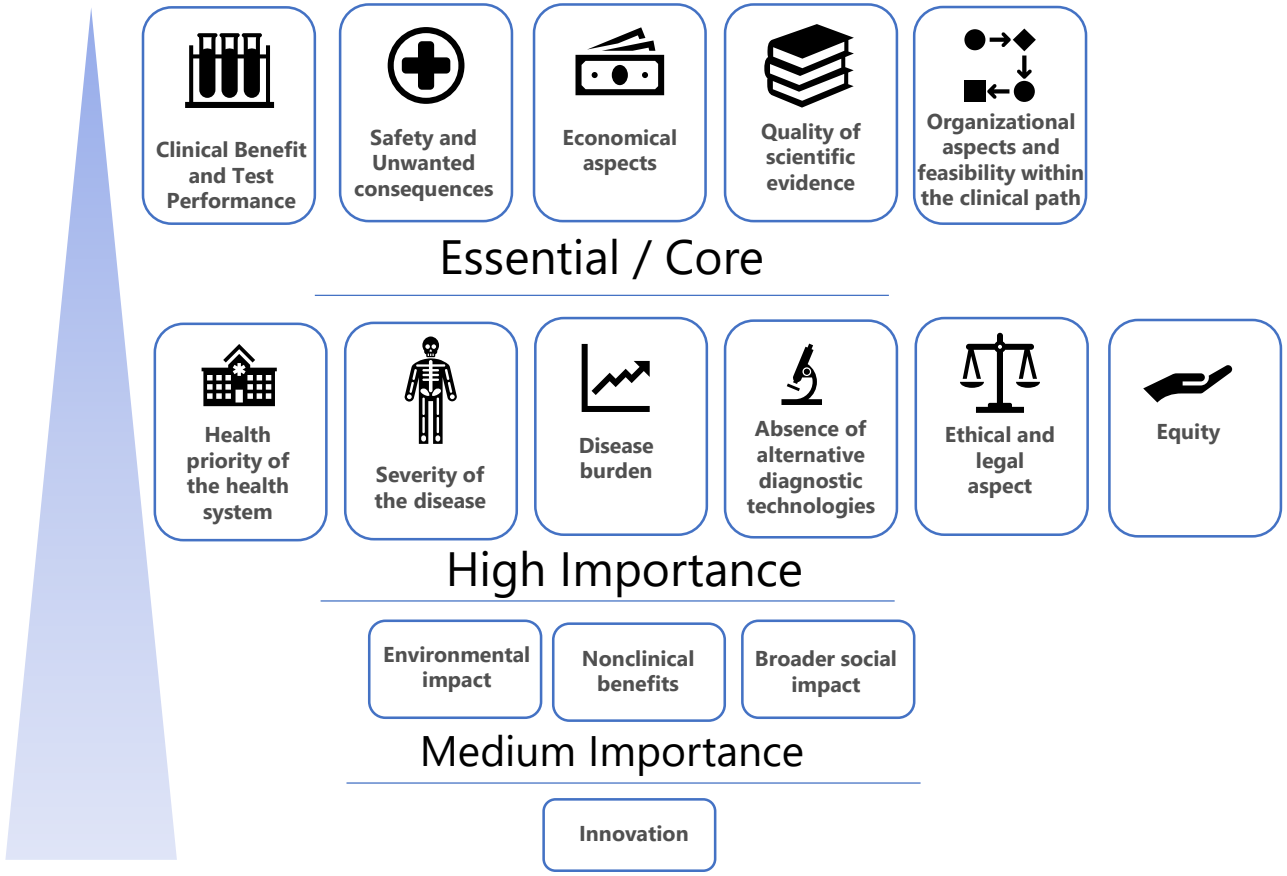
- Impact of antivirals in adherence, healthy aging (e.g. 4th 90), prophylaxis (e.g. PEP, PrEP) and disease eradication (e.g. HCV).

COVID LESSONS LEARNED:

- Current framework's narrow definition of value does not allow proper assessment of new technologies
- HTA agencies should introduce in their base case the societal perspective in their role as stewards of societal resources
- MCDA offers an approach to assess other value elements

What is the future of value assessment post-COVID-19 pandemic for clinical diagnostics, medical devices and biopharmaceutical products?

Value Frameworks in Clinical Diagnostics - FUTURE



- Ongoing efforts to structure systematic value frameworks for Diagnostics (Figure adapted from Augustovski F. et al.)
- Value Based Healthcare Models underscore the need for HTA value frameworks for diagnostic technologies.
- Value frameworks may differ depending on utility or test: Right Test, Right Time, Right Place
- Quantification, Transparency and Coordination with Manufacturers

1. Augustovski, F. et al. A Value Framework for the Assessment of Diagnostic Technologies: A Proposal Based on a Targeted Systematic Review and a Multistakeholder Deliberative Process in Latin America. Value in Health 2021; 24(4):486–496

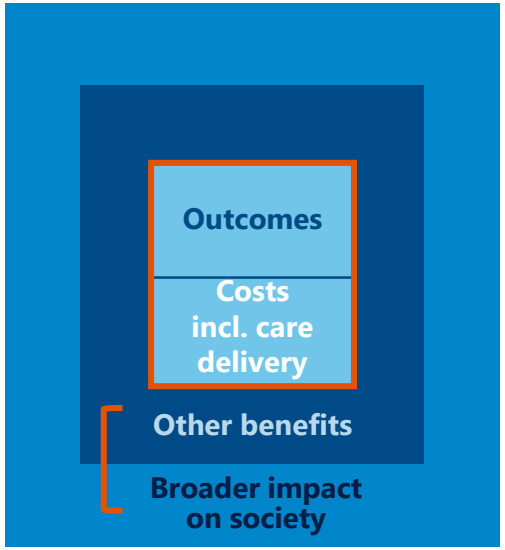
Value Framework in Medical Devices - FUTURE

- ✓ Technology adoption for **improving outcomes and resource use**. E.g: **Remote monitoring; Digital Health**

- ✓ **Organization aspects and non-clinical patient impact.**
- **Enabler for outpatient & home-care**
  - Deliver treatment decision or care nearer to home
  - Enable self-care
  - Enable treatment by a lower grade or less scarce type of staff
- **Learning curve and services**

  Necessary additional services, alongside the device (education, technical services, etc.) over time
  Telehealth for clinical and non-clinical services

- ✓ **MDs Life cycle** and continued upgrade
- ✓ **Long term effects & outcomes** [1]



COVID Lessons learned:

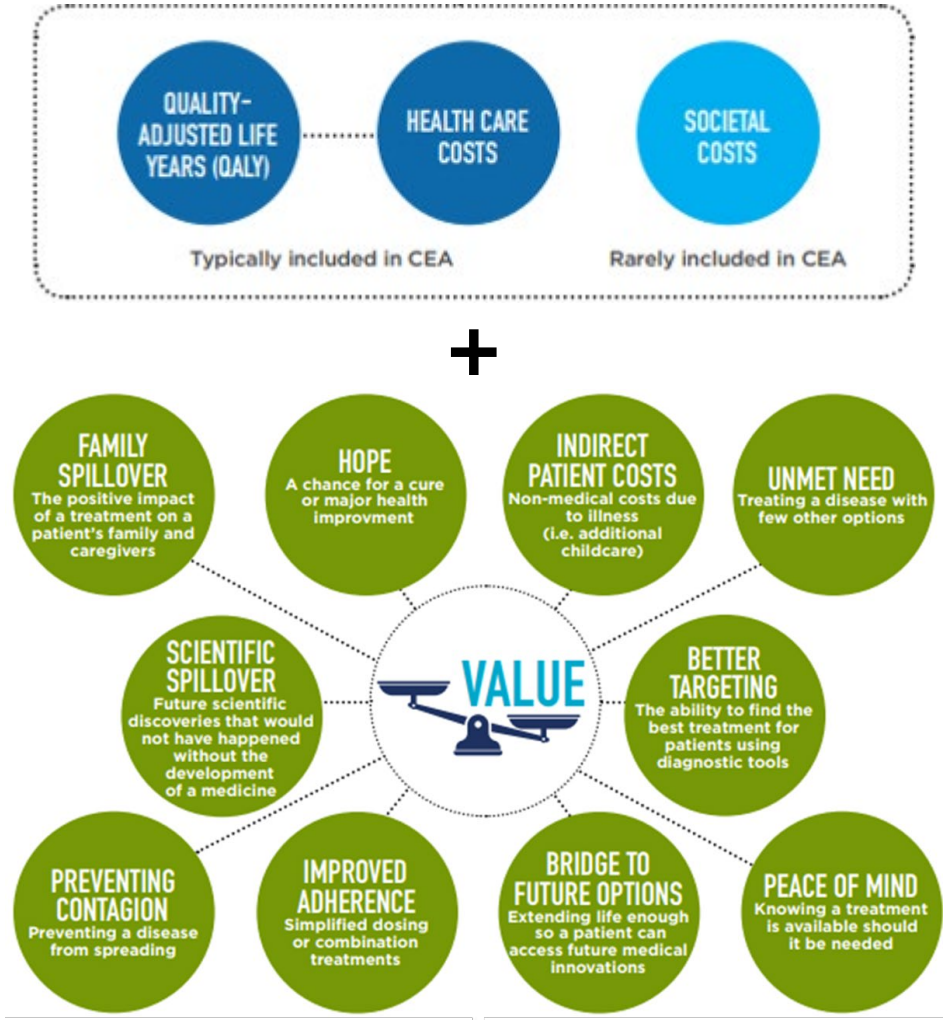
- VALUE AND NEED of technology to close the gap on healthcare infrastructure and to improve outcomes

- Services are crucial in the learning curve and life cycle. It is not only the medical device

Sources: (1) Sedrakyan C et al. BMJ 2016; 353:i2372

Value Framework in Biopharma - FUTURE

- COVID-19 has dramatically shifted priorities in Latin America, both in the delivery and funding of healthcare. However, there re still longer-term challenges related to the fragmentation of healthcare (financing, provision) and poorly aligned incentives.
- Current value frameworks are already not fit for purpose for new technologies limiting the analysis to a narrow set of elements. Expanding the elements considered leveraging approaches such as MCDA is paramount to cope with the wave of COVID-19 technologies coming.
- The challenge for HTA agencies is how to adapt their assessment methods given the pandemic context and levels of uncertainty and how to estimate the added benefit in relation to costs these therapies add to the system.



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Final Remarks

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Director Scientific Affairs – Americas, Molecular Diagnostics, Abbott, USA

Claudia Brabata, MSc
Director Market Access & Public Affairs - Latin America, Medtronic, USA.

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