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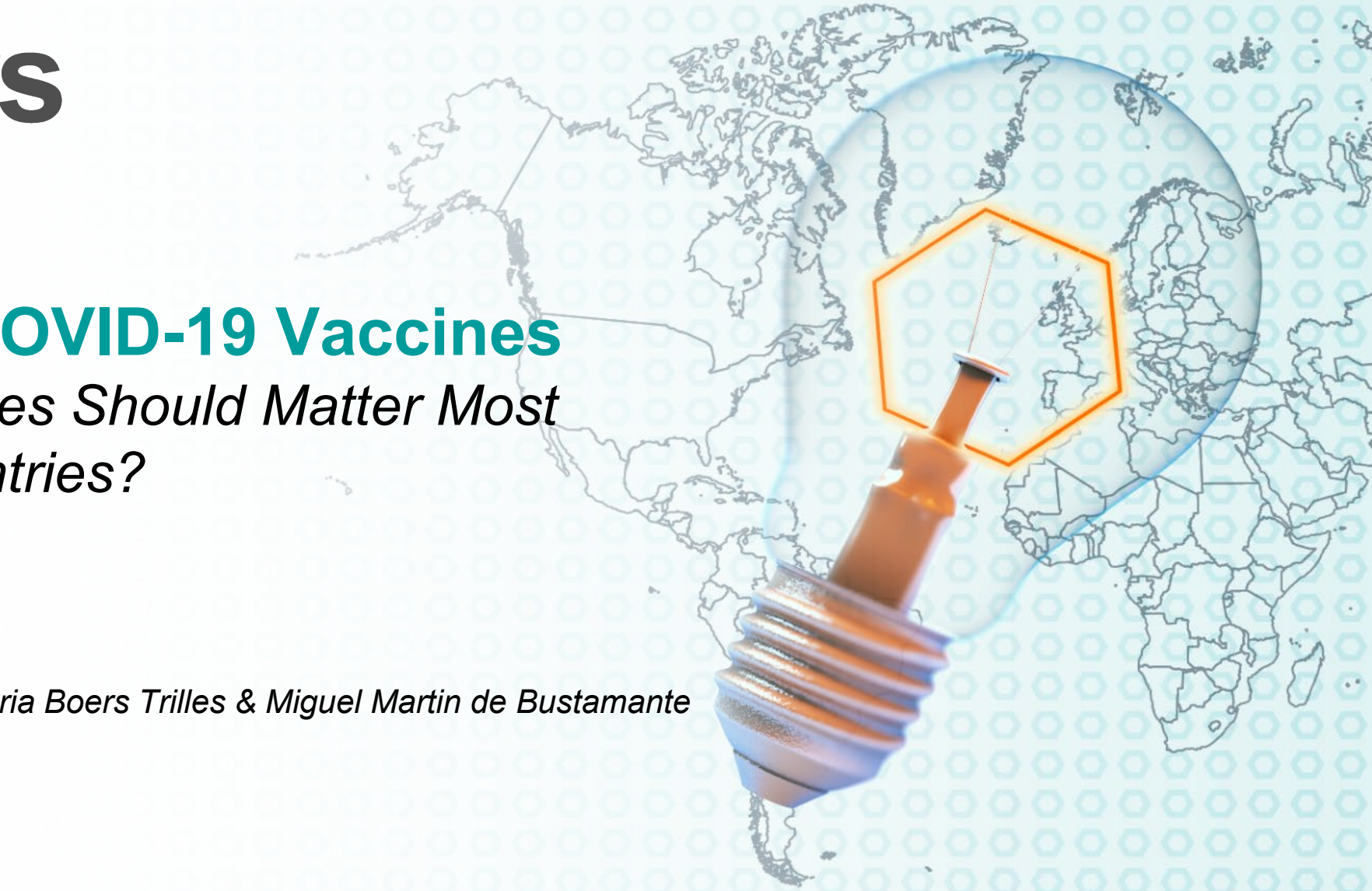

Race to Secure COVID-19 Vaccines

What Vaccine Attributes Should Matter Most in Latin America Countries?

VIRTUAL ISPOR 2021

Diego Guarin, Manuel Espinoza, Valeria Boers Trilles & Miguel Martin de Bustamante

MAY 19, 2021

NEW YORK CITY
SAN FRANCISCO
LONDON

Agenda

5 MIN.	20 MIN.	5 MIN.	20 MIN.	10 MIN.
OPENING & INTRODUCTIONS	COVID-19 VACCINE EVALUATION FRAMEWORK	AUDIENCE POLL	EVALUATION FRAMEWORK RESULTS	Q&A / CLOSING

Agenda

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Speakers

Diego Guarin
Co-Chair Value and Access to Innovation Working Group

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Manuel Espinoza
Associate Professor and Chief of the HTA Unit

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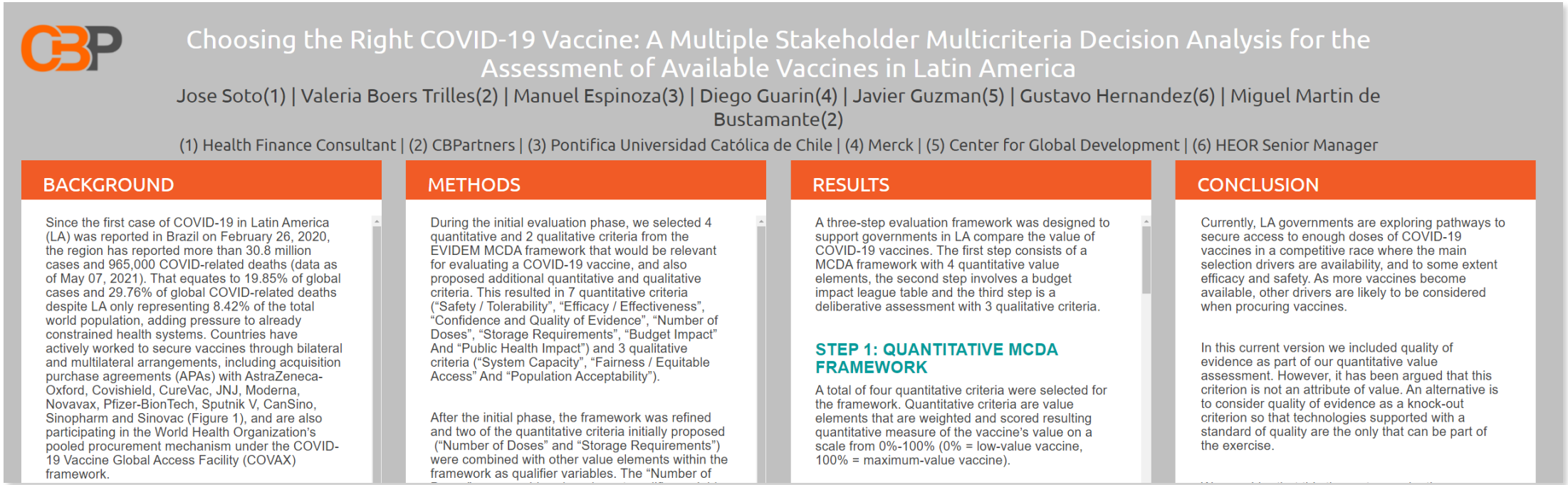
This presentation was prepared by panelists' in their personal capacity. The opinions expressed are based on individual perspectives and not the companies that they represent.

Acknowledgements



Choosing the Right COVID-19 Vaccine: A Multiple Stakeholder Multicriteria Decision Analysis for the Assessment of Available Vaccines in Latin America

Jose Soto(1) | Valeria Boers Trilles(2) | Manuel Espinoza(3) | Diego Guarin(4) | Javier Guzman(5) | Gustavo Hernandez(6) | Miguel Martin de Bustamante(2)

(1) Health Finance Consultant | (2) CBPartners | (3) Pontifica Universidad Católica de Chile | (4) Merck | (5) Center for Global Development | (6) HEOR Senior Manager

BACKGROUND

Since the first case of COVID-19 in Latin America (LA) was reported in Brazil on February 26, 2020, the region has reported more than 30.8 million cases and 965,000 COVID-related deaths (data as of May 07, 2021). That equates to 19.85% of global cases and 29.76% of global COVID-related deaths despite LA only representing 8.42% of the total world population, adding pressure to already constrained health systems. Countries have actively worked to secure vaccines through bilateral and multilateral arrangements, including acquisition purchase agreements (APAs) with AstraZeneca-Oxford, Covishield, CureVac, JNJ, Moderna, Novavax, Pfizer-BionTech, Sputnik V, CanSino, Sinopharm and Sinovac (Figure 1), and are also participating in the World Health Organization's pooled procurement mechanism under the COVID-19 Vaccine Global Access Facility (COVAX) framework.

METHODS

During the initial evaluation phase, we selected 4 quantitative and 2 qualitative criteria from the EVIDEM MCDA framework that would be relevant for evaluating a COVID-19 vaccine, and also proposed additional quantitative and qualitative criteria. This resulted in 7 quantitative criteria ("Safety / Tolerability", "Efficacy / Effectiveness", "Confidence and Quality of Evidence", "Number of Doses", "Storage Requirements", "Budget Impact" And "Public Health Impact") and 3 qualitative criteria ("System Capacity", "Fairness / Equitable Access" And "Population Acceptability").

After the initial phase, the framework was refined and two of the quantitative criteria initially proposed ("Number of Doses" and "Storage Requirements") were combined with other value elements within the framework as qualifier variables. The "Number of

RESULTS

A three-step evaluation framework was designed to support governments in LA compare the value of COVID-19 vaccines. The first step consists of a MCDA framework with 4 quantitative value elements, the second step involves a budget impact league table and the third step is a deliberative assessment with 3 qualitative criteria.

STEP 1: QUANTITATIVE MCDA FRAMEWORK

A total of four quantitative criteria were selected for the framework. Quantitative criteria are value elements that are weighted and scored resulting quantitative measure of the vaccine's value on a scale from 0%-100% (0% = low-value vaccine, 100% = maximum-value vaccine).

CONCLUSION

Currently, LA governments are exploring pathways to secure access to enough doses of COVID-19 vaccines in a competitive race where the main selection drivers are availability, and to some extent efficacy and safety. As more vaccines become available, other drivers are likely to be considered when procuring vaccines.

In this current version we included quality of evidence as part of our quantitative value assessment. However, it has been argued that this criterion is not an attribute of value. An alternative is to consider quality of evidence as a knock-out criterion so that technologies supported with a standard of quality are the only that can be part of the exercise.

SCAN TO SEE POSTER

Jose Soto – Health Finance Consultant, Mallorca

Valeria Boers Trilles – Associate Principal, CBPartners

Manuel Espinoza – Associate Professor, Pontifica Universidad Catolica

Diego Guarin – Co-Chair Value and Access to Innovation Working Group, Fifarma

Javier Guzman – Director Global Health Policy, Center for Global Development

Gustavo Hernandez – Senior Manager, HEOR & Epidemiology Emerging Markets Vaccines

Miguel Martin de Bustamante – Principal, CBPartners

Workshop Objectives

OBJECTIVES

Walk through the **MCDA framework** designed to compare the value of COVID-19 vaccines from the perspective of LA countries

Assign weights to the **quantitative criteria** of the MCDA framework using live polling

Evaluate three **hypothetical COVID-19 vaccines** representing relevant vaccine (e.g., mRNA, inactivated) using the MCDA framework

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COVID-19 Vaccine Evaluation Framework

1	2	3
MCDA	**ECONOMIC ASSESSMENT**	**DELIBERATION**
CONFIDENCE & QUALITY OF EVIDENCE	LEAGUE TABLE	SYSTEM CAPACITY
EFFICACY / EFFECTIVENESS		FAIRNESS / EQUITABLE ACCESS
SAFETY / TOLERABILITY		POPULATION ACCEPTABILITY
PUBLIC HEALTH		

*Three-step evaluation framework consisting of an **MCDA framework with 7 elements of value** and a **league table***

Confidence & Quality of Evidence

CONFIDENCE & QUALITY OF EVIDENCE

DEFINITION

Robustness of the evidence package associated with a vaccine

GRADING STRUCTURE

INDICATOR #1 – QUALITY OF EVIDENCE BASED ON GRADE

NEGATIVE (SCORE = 1)	NEUTRAL (SCORE = 2)	POSITIVE (SCORE = 3)
GRADE SCORE LOW & VERY LOW	GRADE SCORE MODERATE	GRADE SCORE HIGH

Efficacy / Effectiveness

EFFICACY / EFFECTIVENESS

DEFINITION

How well the vaccine performs against different health outcomes including death, severe COVID-19 cases that result in ICU, COVID-19 cases that result in hospitalization, new variants, and duration of protection

GRADING STRUCTURE

INDICATOR #1 – EFFICACY

ILLUSTRATIVE

	WEIGHT	EFFICACY	WEIGHTED SUM
DEATHS	0.5	95%	47.5%
ICU	0.3	85%	25.5%
HOSPITALIZATION	0.2	75%	15%
SCORE			0.88

INDICATOR #2 – EFFICACY ADJUSTMENT FACTOR

	SCORE
EFFICACY AGAINST NEW STRAINS	+1
DURATION OF PROTECTION >6 MO.	+1

NEGATIVE (SCORE = 1)	NEUTRAL (SCORE = 2)	POSITIVE (SCORE =3)
<2.88	2.88	>2.88

Safety / Tolerability

SAFETY / TOLERABILITY

DEFINITION

Real-world safety and tolerability associated with a vaccine

GRADING STRUCTURE

INDICATOR #1 – REAL WORLD AE RATES REPORTED BY WHO-UMC

NEGATIVE (SCORE = 1)	NEUTRAL (SCORE = 2)	POSITIVE (SCORE = 3)
GRADE 4 AE REPORTED	GRADE 3 AE REPORTED	ONLY GRADE 1 & 2 AE REPORTED

Public Health Impact

PUBLIC HEALTH IMPACT

DEFINITION

The product volume (number of vaccine doses) needed to achieve sustained immunity for one person was used as a proxy to measure a vaccine's public health impact

GRADING STRUCTURE

INDICATOR #1 – PRODUCT VOLUME

$$\text{PRODUCT VOLUME} = \frac{\text{NUMBER OF DOSES}}{\text{VACCINE EFFICACY}} = \text{XX}$$

NEGATIVE (SCORE = 1)	NEUTRAL (SCORE = 2)	POSITIVE (SCORE = 3)
>2.5	1.67 – 2.5	≤1.67

League Table

LEAGUE TABLE

INPUTS	OUTPUTS
COUNTRY POPULATION SIZE	**PROCUREMENT COSTS** (# DOSES x PRICE PER DOSE)
CURRENT COVID-19 COVERAGE	
COVERAGE GAP TO HERD IMMUNITY	
REQUIRED NUMBER OF VACCINE DOSES	**TOTAL COSTS** ((# DOSES x PRICE PER DOSE) + ADDITIONAL PROCUREMENT COSTS)
VACCINE PRICE PER DOSE	
VACCINE DELIVERY COSTS	
COLD-CHAIN INVESTMENT REQUIREMENTS	**VALUE FOR MONEY** TOTAL COST / MCDA SCORE

Fairness / Equitable Access

FAIRNESS / EQUITABLE ACCESS

DEFINITION

Degree to which a given vaccine can be made available to the entire population

GRADING STRUCTURE

INDICATOR #1 – POPULATION GROUPS

	SCORE
APPROVED FOR ≥18 ONLY	0.6
APPROVED FOR ≥18 & <18	1.0

INDICATOR #2 – STORAGE REQUIREMENTS

	SCORE
REFRIGERATOR (2°C to 8°C)	+0.1
NORMAL FREEZER (2°C to -20°C)	0
ULTRA-COLD FREEZER (-20°C)	-0.1

NEGATIVE	NEUTRAL	POSITIVE
<0.7	0.7	>0.7

System Capacity

SYSTEM CAPACITY

DEFINITION

Ability of the healthcare system to administer the required number of vaccinations to fully immunize 70% of the population against COVID-19

GRADING STRUCTURE

INDICATOR #1 – COVID-19 VACCINATION COEFF.

$$\frac{\text{(70\% - \% POPULATION ALREADY VACCINATED) x POPULATION x DOSES}}{\text{2019 NIP ADMINISTERED DOSES}} = \text{SCORE}$$

SCORE = XX

INDICATOR #2 – STORAGE REQUIREMENTS

	SCORE
REFRIGERATOR (2°C to 8°C)	-0.5
NORMAL FREEZER (2°C to -20°C)	0
ULTRA-COLD FREEZER (-20°C)	+0.5

NEGATIVE	NEUTRAL	POSITIVE
≥2	0.75 – 1.99	<0.75

Population Acceptability

POPULATION ACCEPTABILITY

DEFINITION

% of the population that would be willing to receive a given COVID-19 vaccine

GRADING STRUCTURE

INDICATOR #1 – POPULATION SURVEY

0% ⟷ 100%

No willingness to receive the vaccine

High willingness to receive the vaccine

INDICATOR #2 – INTERNATIONAL VALIDATION

	SCORE
WHO PREQUALIFICATION	+5%
FDA / EMA APPROVAL	+5%
OTHER SRA APPROVAL	+5%

NEGATIVE	NEUTRAL	POSITIVE
<70%	70% - 89.99%	≥90%

Agenda

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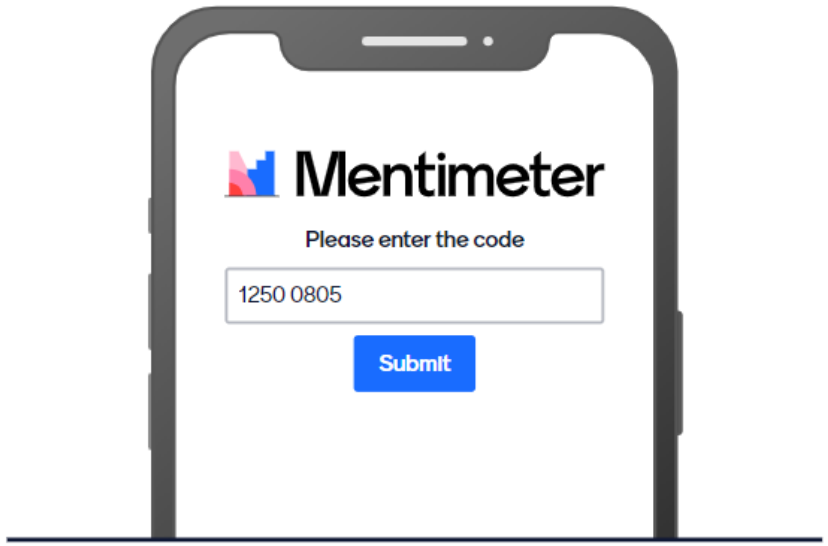

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Agenda

5 MIN.	20 MIN.	5 MIN.	20 MIN.	10 MIN.
OPENING & INTRODUCTIONS	COVID-19 VACCINE EVALUATION FRAMEWORK	AUDIENCE POLL	**EVALUATION FRAMEWORK RESULTS**	Q&A / CLOSING

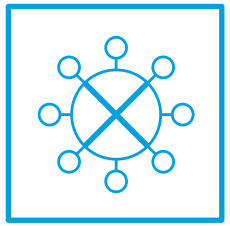
Evaluation Framework Results Comparison

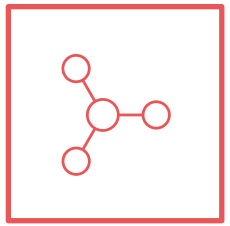
To **illustrate the applicability** of the evaluation framework developed to compare the value of COVID-19 vaccines we will leverage a **fictional country** and the **hypothetical profiles** of four COVID-19 vaccines that a reflective of real-world vaccine candidates

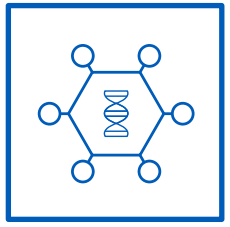
Then, we will compare the **results** of the **MCDA** and **league table** using the **different criteria weights** assigned by the **expert panel*** that developed the framework and the **audience attending this workshop**

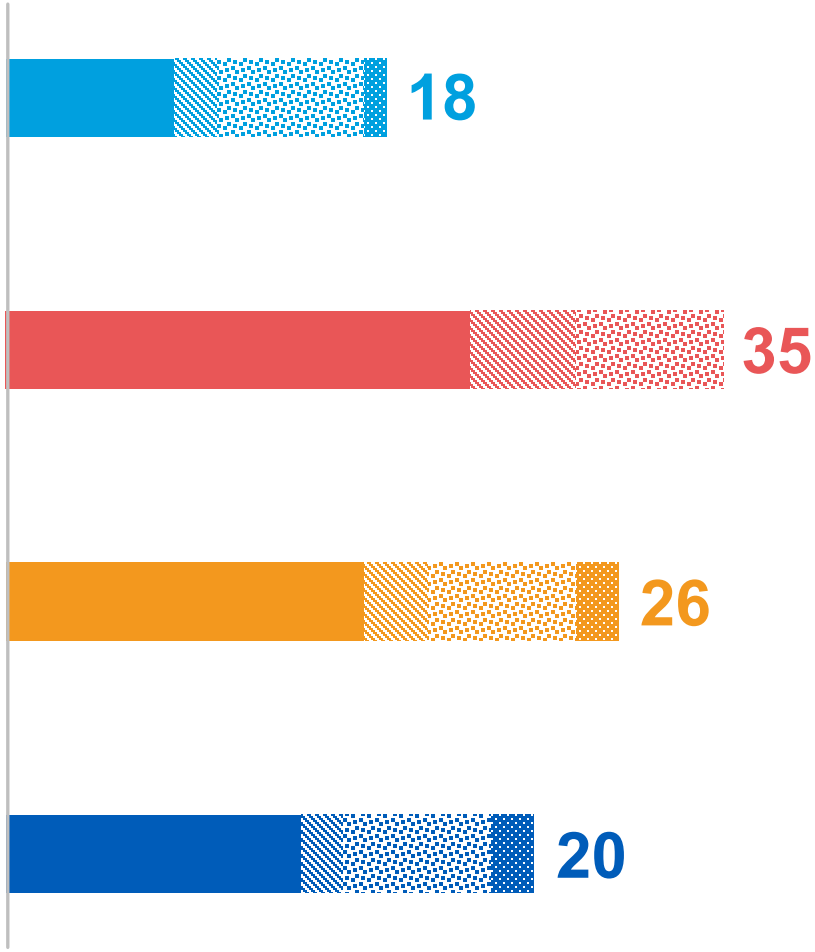
There are four types of COVID-19 vaccines

VACCINE TYPE	DEFINITION	# VACCINE CANDIDATES
WHOLE VIRUS	*Vaccines that use **live-attenuated or inactivated viruses** to trigger an immune response*	18
PROTEIN SUBUNIT	*Vaccines that use **proteins** of the virus to trigger an immune response*	35
NUCLEIC ACID	*Vaccines that use **genetically engineered mRNA** to trigger an immune response*	26
VIRAL VECTOR	*Vaccines that use a **weakened live virus** (like adenovirus) to **deliver genetic material** from the COVID-19 virus, triggering an immune response*	20









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SOURCE: WHO COVID-19 Candidate Vaccine Landscape & Tracker (data as of May 11, 2021)

PHASE 1 & 1/2 | PHASE 2 & 2/3 | PHASE 3 | PHASE 4

Hypothetical COVID-19 Vaccine Profiles (1 of 2)

	WHOLE VIRUS	PROTEIN SUBUNIT	NUCLEIC ACID	VIRAL VECTOR
PREVENTION OF SYMPTOMATIC COVID-19	50%	90%	95%	65%
PREVENTION OF HOSPITALIZATION	85%	100%	100%	90%
PREVENTION OF ICU	90%	100%	100%	95%
PREVENTION OF COVID-19 DEATH	80%	100%	100%	100%
DURATION OF EFFICACY >6 MO.	✗	✗	✓	✗
SUSTAINED EFFICACY VS. VARIANTS	✗	✗	✓	✓
GRADE 3 AE HAVE BEEN REPORTED	✓	✓	✓	✓
GRADE 4 AE HAVE BEEN REPORTED	✗	✗	✗	✓
GRADE ANALYSIS OF EVIDENCE	MODERATE	MODERATE	HIGH	HIGH

MO.: Month; **ICU:** Intensive Care Unit; **AE**: Adverse Events

Hypothetical COVID-19 Vaccine Profiles (2 of 2)

	WHOLE VIRUS	PROTEIN SUBUNIT	NUCLEIC ACID	VIRAL VECTOR
DOSES REQUIRED	2	2	2	1
AUTHORIZED POPULATION GROUPS	18+	18+	12+	18+
STORAGE REQUIREMENTS	2°C to 8°C	2°C to 8°C	-60°C to -70°C	2°C to 8°C
WHO PREQUALIFICATION	✓	✗	✓	✓
FDA / EMA APPROVAL	✗	✗	✓	✓
APPROVAL BY ANOTHER SRA	✗	✗	✓	✓
PRICE PER DOSE	$29.75	$16	$19.5	$10

WHO: World Health Organization; **FDA**: Food and Drug Administration; **EMA**: European Medicines Agency; **SRA**: Strict Regulatory Authority

Hypothetical Country Profile

LATANDIA

COUNTRY PROFILE	
POPULATION	51.4 M
2021 GDP	$ 296 B
CURRENT COVID-19 VACCINE COVERAGE	0%
COVERAGE GAP TO HERD IMMUNITY	70%
2019 NIP VACCINE DOSES	24 M

VACCINE ACCEPTABILITY SURVEY RESULTS	
WHOLE VIRUS	45%
PROTEIN SUBUNIT	65%
NUCLEIC ACID	75%
VIRAL VECTOR	55%

GDP: Gross Domestic Product; **NIP:** National Immunization Program; **M:** Million; **B:** Billion | DISCLAIMER: Latandia and all data presented on the slide is fictional country created for the purposes of doing a simulation of the MCDA framework

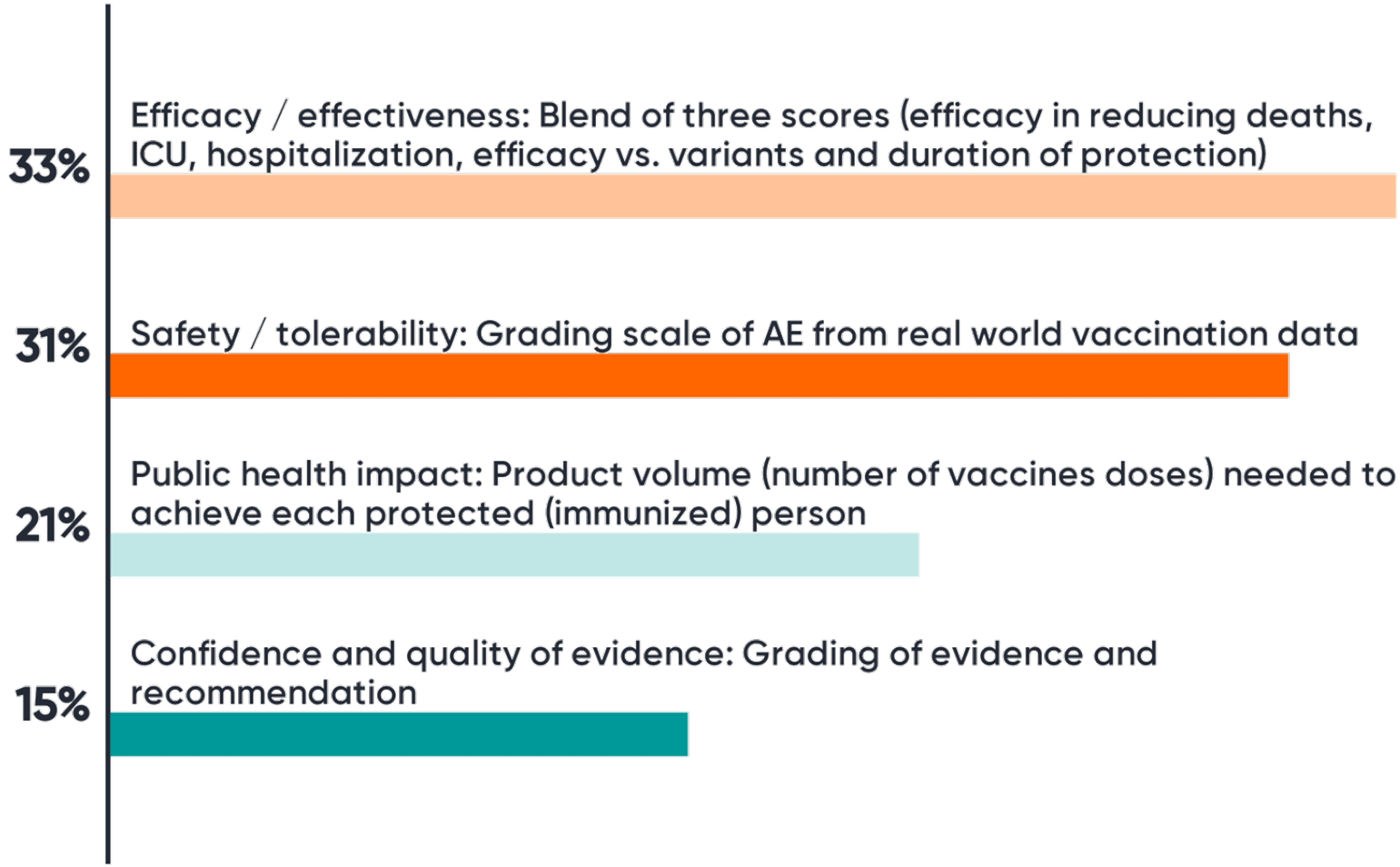
Scoring of MCDA Criteria

		WHOLE VIRUS	PROTEIN SUBUNIT	NUCLEIC ACID	VIRAL VECTOR
QUANTITATIVE	CONFIDENCE & QUALITY OF EVIDENCE	2	2	3	3
	EFFICACY	1	1	3	1
	SAFETY	2	2	2	1
	PUBLIC HEALTH	1	2	2	3
QUALITATIVE	FAIRNESS	NEUTRAL	NEUTRAL	POSITIVE	NEUTRAL
	SYSTEM CAPACITY	NEGATIVE	NEGATIVE	NEGATIVE	NEUTRAL
	POPULATION ACCEPTABILITY	NEGATIVE	NEGATIVE	POSITIVE	NEUTRAL

Hypothetical vaccines were **scored** across the **MCDA qualitative** and **quantitative** criteria using the **grading structure** presented in the first section of the presentation

Quantitative Criteria Weighting via Direct Point Allocation

QUANTITATIVE CRITERIA WEIGHTING BY EXPERT PANEL*



* Expert panel consisted of six experts representing different stakeholder perspectives (e.g., pharma, academia, policy, etc.)

Weighting of Quantitative Criteria

	WHOLE VIRUS			PROTEIN SUBUNIT			NUCLEIC ACID			VIRAL VECTOR		
	S	W*	SxW	S	W*	SxW	S	W*	SxW	S	W*	SxW
CONFIDENCE & QUALITY OF EVIDENCE	2	15%	**0.30**	2	15%	**0.30**	3	15%	**0.45**	3	15%	**0.45**
EFFICACY / EFFECTIVENESS	1	33%	**0.33**	1	33%	**0.33**	3	33%	**0.99**	1	33%	**0.33**
SAFETY / TOLERABILITY	2	31%	**0.62**	2	31%	**0.62**	2	31%	**0.62**	1	31%	**0.31**
PUBLIC HEALTH IMPACT	1	21%	**0.21**	2	21%	**0.42**	2	21%	**0.42**	3	21%	**0.63**
TOTAL SCORE	**48.6%** (1.46)			**55.6%** (1.67)			**82.6%** (2.48)			**57.3%** (1.72)		

TOTAL SCORE WAS CONVERTED FROM A **1-3 SCALE** TO A **0-100 SCALE** TO EASE INTERPRETATION OF RESULTS

S: Category Score; **W:** Category Weight; **SxW:** Score Multiplied by Weight | *Criteria weights were assigned through direct point allocation by an expert panel that consisted of six experts representing different stakeholder perspectives

League Table Introduction

	COST ($ M)	QALY	VALUE FOR MONEY (COST / QALY)	RANKING
A	50	6,000	$8,000	2
B	42	7,000	$6,000	1
C	35	5,000	$7,000	3

Source: Thokala, P. orcid.org/0000-0003-4122-2366, Ochalek, J., Leech, A.A. et al. (1 more author) (2018) Cost-effectiveness thresholds: the past, the present and the future. Pharmacoeconomics, 36 (5). pp. 509-522. ISSN 1170-7690

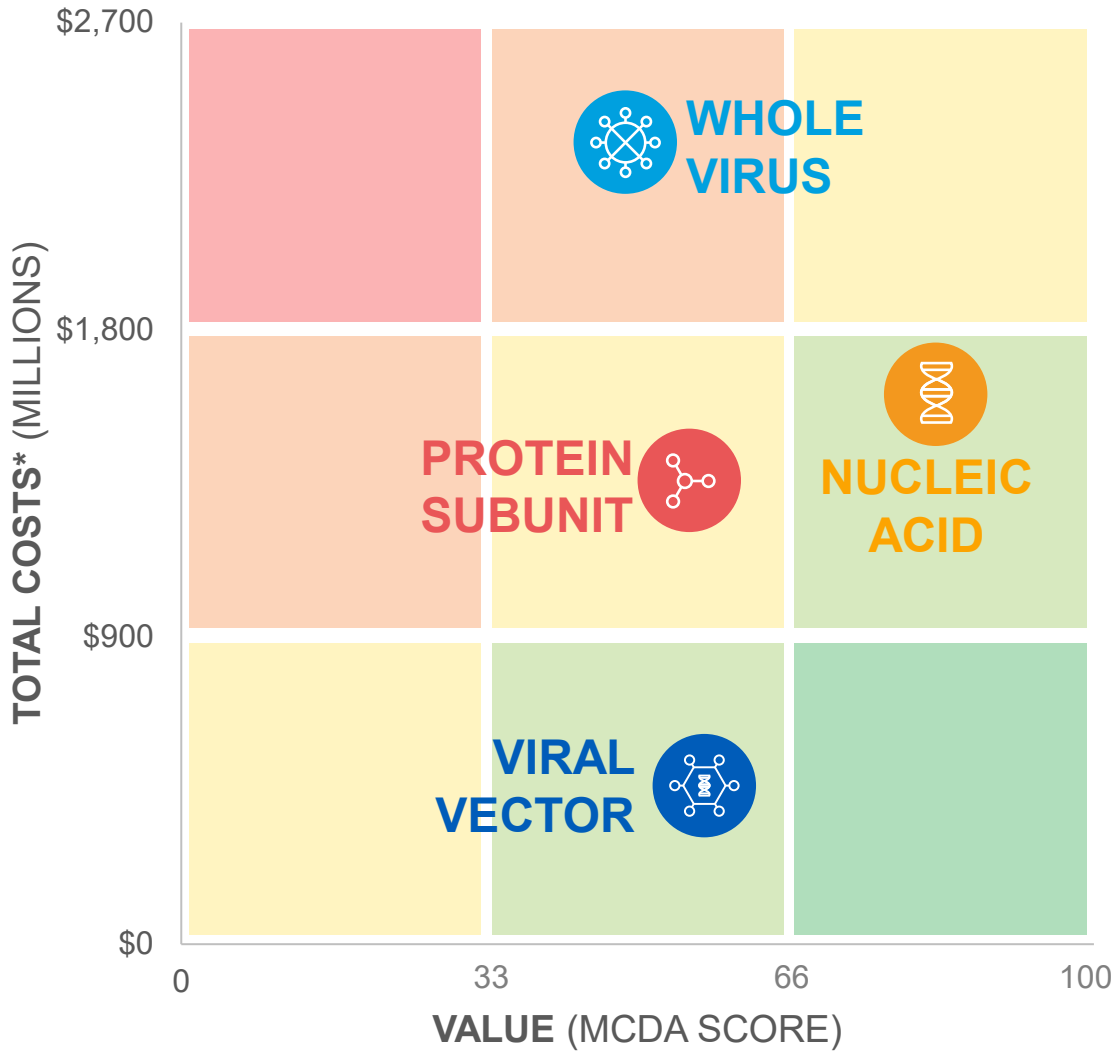
League Table Results

	PRICE PER DOSE	# DOSES TO HERD IMMUNITY	PROCUREMENT COST (PRICE x DOSE x POP.)	TOTAL COSTS ((PRICE x DOSE) + ADDITIONAL COSTS*)	VALUE FOR MONEY
VIRAL VECTOR	$10	36 M	$360 M	$464 M	**$8.1**
WHOLE VIRUS	$19.5	72 M	$1,403 M	$1,611 M	**$19.5**
PROTEIN SUBUNIT	$16	72 M	$1,151 M	$1,359 M	**$24.4**
NUCLEIC ACID	$29.75	72 M	$2,140 M	$2,349 M	**$48.3**

HIGHEST TO LOWEST VALUE FOR MONEY

*Procurement costs and program costs additional to procurement (e.g., cold chain investment, distribution, storage, etc.)

Deliberation



QUALITATIVE CRITERIA

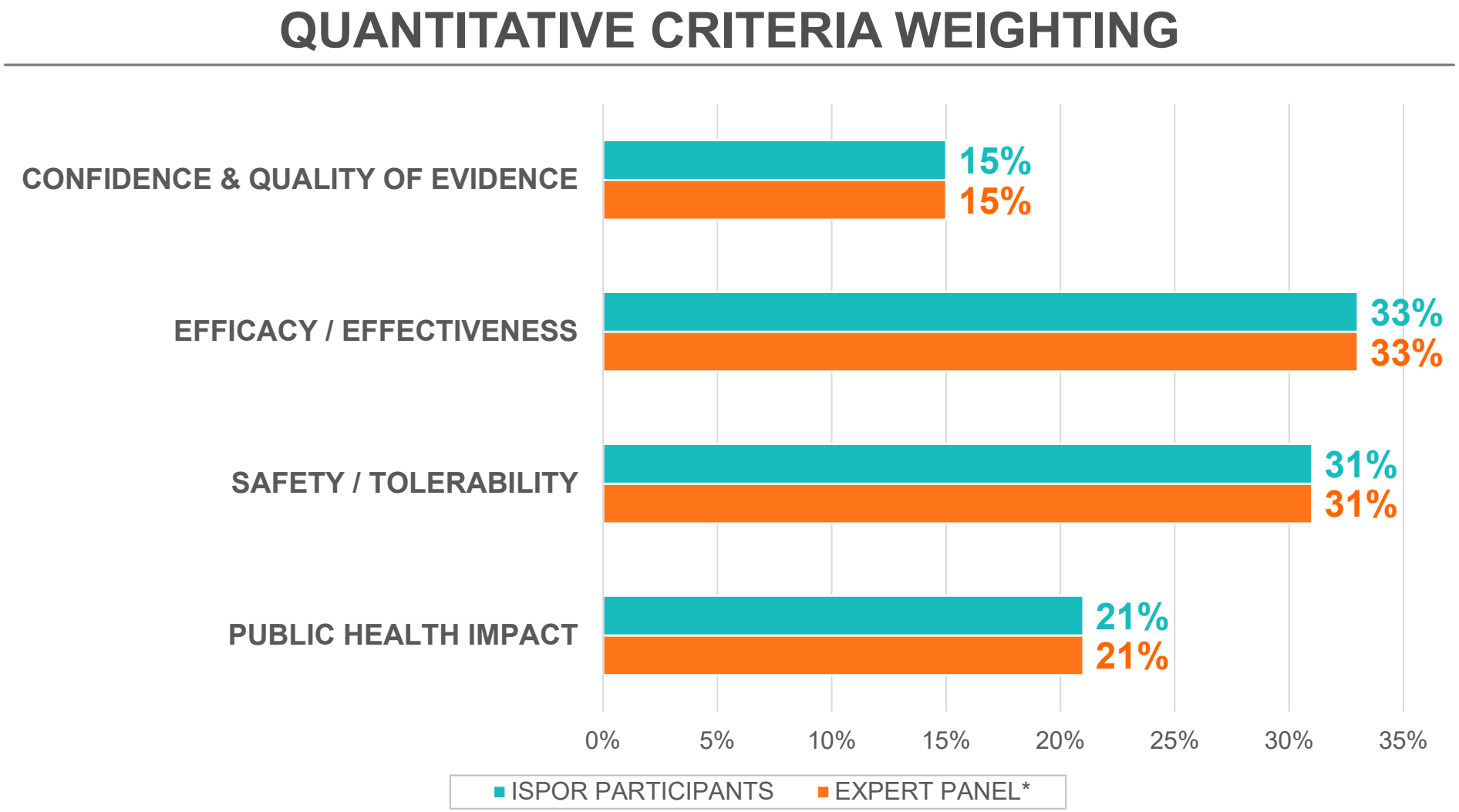
	FAIRNESS	SYSTEM CAPACITY	POP. ACCEPTA-BILITY
VIRAL VECTOR	NEUTRAL	NEUTRAL	NEUTRAL
NUCLEIC ACID	POSITIVE	NEGATIVE	POSITIVE
PROTEIN SUBUNIT	NEUTRAL	NEGATIVE	NEGATIVE
WHOLE VIRUS	NEUTRAL	NEGATIVE	NEGATIVE

HIGHEST TO LOWEST VALUE FOR MONEY

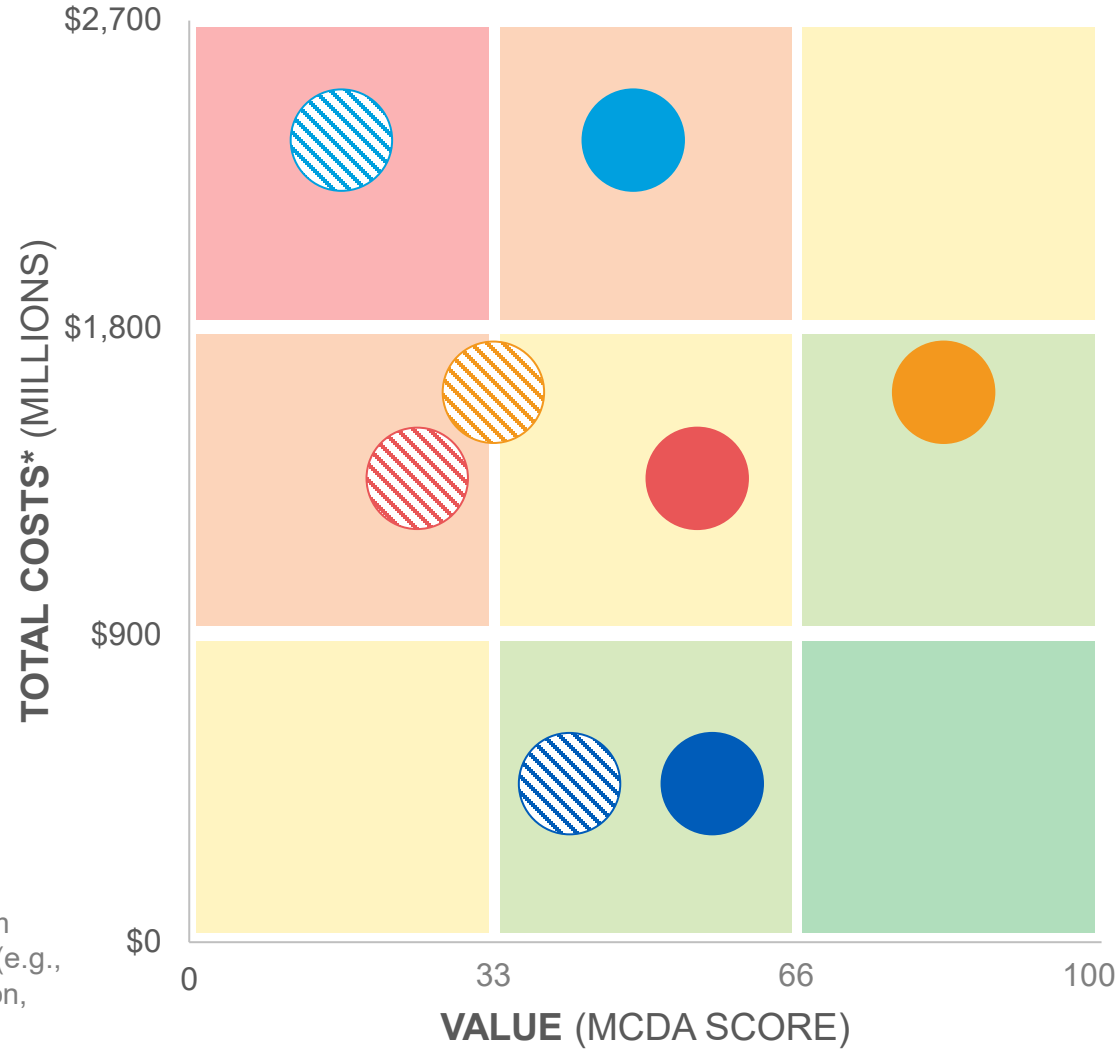
*Procurement costs and program costs additional to procurement (e.g., cold chain investment, distribution, storage, etc.)

LOW VALUE & HIGH COST — HIGH VALUE & LOW COST

Expert Panel vs. ISPOR Participants Results Comparison: **Quantitative Criteria Weights**



Expert Panel vs. ISPOR Participants Results Comparison:
COVID-19 Vaccine Value vs. Total Costs



WHOLE VIRUS
PROTEIN SUBUNIT
VIRAL VECTOR
NUCLEIC ACID

ISPOR PARTICIPANT RESULTS (PATTERN FILL)
EXPERT PANEL RESULTS (SOLID FILL)

*Procurement costs and program costs additional to procurement (e.g., cold chain investment, distribution, storage, etc.)

LOW VALUE & HIGH COST — HIGH VALUE & LOW COST

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Conclusion

CONCLUSION

- In this current version we included quality of evidence as part of our quantitative value assessment. However, it has been argued that this criterion is not an attribute of value. An alternative is to consider quality of evidence as a knock-out criterion so that technologies supported with a standard of quality are the only that can be part of the exercise.

- We consider that this three-step evaluation framework consisting of an MCDA framework with 7 elements of value and a budget impact league table holds large potential to support governments in LA in assessing the value of COVID-19 vaccines in a context of multiple trade-offs and heterogeneous stakeholder perspectives.

Local knowledge, global thinking.

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Appendix – Grading of Hypothetical COVID-19 Vaccines

CATEGORY	INDICATOR	WHOLE VIRUS	PROTEIN SUBUNIT	NUCLEIC ACID	VIRAL VECTOR
CONFIDENCE AND QUALITY OF EVIDENCE	GRADE	MODERATE	MODERATE	HIGH	HIGH
EFFICACY	EFFICACY BLEND	0.84	1.00	1.00	0.97
	EFFICACY ADJUSTMENT	0	0	2	1
	TOTAL	0.84	1.00	3.00	1.97
SAFETY	AE	GRADE 3	GRADE 3	GRADE 3	GRADE 4
PUBLIC HEALTH	PRODUCT VOLUME	4.00	2.22	2.11	1.54
FAIRNESS	POPULATION	0.6	0.6	1	0.6
	STORAGE	0.1	0.1	-0.1	0.1
	TOTAL	0.7	0.7	0.9	0.7
SYSTEM CAPACITY	COVID-19 COEFF.	3.00	3.00	3.00	1.50
	STORAGE	-0.5	-0.5	0.5	-0.5
	TOTAL	2.50	2.50	3.50	1.00
POPULATION ACCEPTABILITY	SURVEY	45%	65%	75%	55%
	INTERNATIONAL VALIDATION	5%	0%	15%	15%
	TOTAL	50%	65%	90%	70%