Evaluation of Vaccine Effectiveness for COVID-19 Vaccine in the American Region

Technical Consultive Meeting for the EM Regional COVID-19 Vaccine Effectiveness Studies

12-13 November 2023 | Cairo, Egypt

Francisco Nogareda PAHO/WHO



Current VE activities in PAHO Region

- 1. Evaluation of VE for COVID-19 vaccines using the sentinel surveillance network in the Region REVELAC-i
- 2. Estimation of VE for COVID-19 vaccines through research studies



Regional Network for Vaccine Effectiveness Evaluation in the American Region, (REVELAC-i)

- Regional network established in 2013
- Leverages the SARI sentinel surveillance system existing in countries
- Generates annual VE estimates for seasonal influenza Vaccines in the Southern Hemisphere
- September 2021, COVID-19 was integrated in REVELAC-i
- 2023: Five countries participated in the evaluation (486 hospitals/sentinel sites
- Intersectoral and inter-institutional network



Objectives REVELAC – COVID-19

- Estimate the effectiveness of COVID-19 and influenza vaccines in preventing SARI among patients with laboratory confirmed infection
- Specific VE estimates by:
 - Type of vaccine
 - Number of doses received
 - Age group
 - Genomic variant of SARS-CoV-2 and type/subtype influenza



Protocol available at: <u>https://www.paho.org/es/red-para-</u> evaluacion-efectividad-vacuna-latino-america-caribe-influenzarevelac-i

Methodology

- Multicentre case control study (*Test Negative Design*)
- Study population: SARI patients admitted at participating sentinel hospitals

WHO SARI case definition (Influenza and COVID-19)

A patient with acute respiratory infection with

- History of fever or a measured fever of \geq 38 °C,
- And cough
- And symptom onset within the last 10 days
- And who requires hospitalization



 $VE = (1 - aOR) \times 100$

Core variables

PATIENT



CLINICAL AND LABORATORY VACCINATION

- Country
- Hospital
- Age
- Sex
- Preexisting conditions

- Onset symptoms
- Admission date
- Date of specimen collection
- Result by RT-PCR

- Vaccination status for COVID-19 and influenza
- Type of vaccine
- Dates of vaccination (each dose)
- Source of information





Data collection and reporting

Nuevo registro

Pan American Health Organization		Sistema en línea para Vigilancia centinela de infección respiratoria aguda grave (IRAG) y enfermedad tipo influenza (ETI)				
Análisis situación	Ingreso	Denominadores	Import Lab CCSS	Reportes	Lista no importados	Monitoreo y Evaluación
Area: Seleccionar Región: Seleccionar	r	~				
Establecimiento de saluo	d: Todo(a	a)s	~			
No. identificación:				Cond. egreso:		~
Nombre:]	Apellido:		
De Fecha noti.:				Hasta Fecha no	ti.:]
ld registro:				Buscar		



Ethical review

- Observational study part of the routine M&E of the vaccination programs
- PAHOERC determined that the evaluation does not constitute research with human subjects and thus does not require full PAHOERC review
- However, countries can submit their protocols for national review and approval
- Ensures confidentiality and privacy of individuals



Pan American Health Organization Ethics Review Committee (PAHOERC)

Research Proposal Evaluation Form PAHOERC Ref. No: PAHOERC.0425.01

Unit:	FPL/IM
Title of Proposal:	Evaluation of the effectiveness of COVID-19 vaccines in Latin America and the Caribbean
Principal Investigator:	Francisco Nogareda; Alba Maria Ropero
Focal Point:	Francisco Nogareda; Alba Maria Ropero
Country(les):	Latin America & Caribbean Region

This proposal received preliminary ethics review from PAHOERC and on 21 September 2021 It was determined that it is <u>exempt from full PAHOERC review.</u>

The proposal does not constitute research with human subjects and thus does not require full PAHOERC review. However, investigators are responsible for ensuring that the project aligns with international guidelines for the ethical treatment of human subjects in research, and that it complies with any local or national-level regulations.



21-Sep-21

Maha Paz Ade, Member, PAHOERC

21-Sep-21

Note: Copy of this document approved and signed by PAHOERC must be attached to the documents used in the elaboration of contracts, letters of agreement, or legal PAHO documents relevant to the above project. 2109/2021

RESULTS COVID-19 2021-2022

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Vacunas autorizadas COVID-19*

Tipo de vacuna	Marca de vacuna	Chile	Costa Rica	Ecuador	Guatemala	Paraguay	Uruguay
Vector viral	AstraZeneca	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
	CanSino	\checkmark		\checkmark			
	Sputnik V	\checkmark		\checkmark	✓	\checkmark	
	J&J Janssen	\checkmark					
Virus inactvado	Covaxin					\checkmark	
	Sinovac	\checkmark		\checkmark		\checkmark	\checkmark
	Sinopharm	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			\checkmark		
mRNA	Moderna	\checkmark	\checkmark		\checkmark	\checkmark	
	Pfizer	\checkmark	\checkmark	\checkmark	✓	\checkmark	\checkmark
Subunidades proteicas	Medigen					\checkmark	
	TOTAL VACUNAS	7	3	5	4	8	3

*vacunas autorizadas hasta septiembre 2022 en los países participantes REVELAC-i



Vaccine Effectiveness of COVID-19 Vaccines for Primary Series by Brand, Age Group and Genomic Variant SARS-CoV-2



EV ajustada por país. edad, enfermedad preexistente, sexo y semana de inicio de síntomas

Vaccine Effectiveness of COVID-19 vaccines by time since last vaccination for Primary Series during Omicron variant period

Adults 18-64 year



RESULTS Influenza 2023 (Mid-term estimates August 2023)

Distribución de casos de influenza por subtipo, REVELAC-i, marzo-julio 2023 (n=2780)



SARI Admission Date

Pacientes IRAG, REVELAC-i 2023 (n=2,780)

n (%)		
88 (3.2%)		
918 (33.0%)		
1,158 (41.7%)		
167 (6.0%)		
449 (16.1%)		
1,262 (45.4%)		
388 (14.0%)		
1,130 (40.6%)		
900 (32.4%)		
815 (90.6%)		
5 (0.6%)		
668 (82.0%)		
142 (17.4%)		
85 (9.4%)		
1,880 (67.6%)		

Efectividad vacuna influenza por tipo y subtipo, REVELAC-i 2023

	Casas	Vaccinated cases	Non cases	Vaccinated Non	VE adjusted*
	Cases	vaccillateu cases	NOII Cases	cases	% (CI95%)
Influenza (any)					
Older adults	547	96	583	176	37.6% (13.1% 55.2%)
Children	214	19	1,048	286	70.2% (50.3%, 82.1%)
Individuals with comorbidities	139	23	249	64	38.0% (-10.8%, 65.3%)
All	900	138	1,880	526	51.9% (39.2%, 62.0%)
Influenza A					
Older adults	516	90	583	176	39.0% (14.7%, 56.3%)
Children	170	16	1,048	286	70.9% (50.3%, 83.0%)
Individuals with comorbidities	129	22	249	64	43.6% (-5.7%, 69.9%)
All	815	128	1,880	526	52.1% (38.9%, 62.5%)
Influenza A/H1N1					
Older adults	422	70	583	176	42.7% (18.5%, 59.8%)
Children	120	10	1,048	286	75.3% (52.1%, 87.3%)
Individuals with comorbidities	126	22	249	64	43.0% (-6.7%, 69.5%)
All	668	102	1,880	526	55.2% (41.8%, 65.5%)
Influenza A/H3N2					
Older adults	4	0	583	176	NC
Children	1	0	1,048	286	NC
Individuals with comorbidities	0	0	249	64	NC
All	5	0	1,880	526	NC
Influenza B					
Older adults	31	6	583	176	NR
Children	44	3	1,048	286	NC
Individuals with comorbidities	10	1	249	64	NC
All	85	10	1,880	526	46.2% (-7.9%, 73.2%)

*Adjusted VE by age in years, week of onset of symptoms and presence of at least one comorbidity accounting for country as a random effect

Efectividad vacuna influenza por tipo y subtipo, REVELAC-i 2023



Challenges

- Complex vaccination landscape
- Small sample size for some vaccines
- Matching vaccination registries and laboratory results with surveillance data collected at the sentinel sites
- Difficulty recruiting controls during the high incidence periods
- Omicron period: high vaccination coverage
- Comparison group





Network for the Evaluation of Vaccine Effectiveness in Latin America and the Caribbean - influenza, (REVELAC-i)



About Revelac-i

Generic protocol

About the influenza vaccine

https://www.paho.org/en/network-evaluation-vaccine-effectiveness-latin-america-and-caribbean-influenza-revelac-i

Articles

Effectiveness of COVID-19 vaccines against hospitalisation in Latin America during three pandemic waves, 2021–2022: a test-negative case-control design

Francisco Nogareda,^{a,*} Annette K. Regan,^{a,b,c} Paula Couto,^a Ashley L. Fowlkes,^d Radhika Gharpure,^d Sergio Loayza,^a Juliana Almeida Leite,^a Angel Rodríguez,^a Andrea Vicari,^a Eduardo Azziz-Baumgartner,^d and Daniel Salas,^a and the REVELAC-i Working Group^e

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The Lancet Regional Health – Americas. November 2023

https://www.sciencedirect.com/science/article/pii/S2667193X23002004







Morbidity and Mortality Weekly Report

Interim Effectiveness Estimates of 2023 Southern Hemisphere Influenza Vaccines in Preventing Influenza-Associated Hospitalizations — REVELAC-i Network, March–July 2023

Ashley L. Fowlkes, ScD^{1,*}; Francisco Nogareda, MPH^{2,*}; Annette Regan, PhD^{2,3}; Sergio Loayza, MD²; Jose Mendez Mancio²; Lindsey M. Duca, PhD¹; Paula Couto, MD²; Juliana Leite, PhD²; Angel Rodriguez, MD²; Daniel Salas, MD²; Eduardo Azziz-Baumgartner, MD¹; REVELAC–i Network

SARINET PLUS REVELAC-I VIII REUNIÓN REGIONAL

THANK YOU

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