

Support for COVID-19 vaccine effectiveness studies in EMR countries:

evidence generation for immunization policymaking

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On behalf of EMR COVID-19 Vaccine Effectiveness study team

Regional capacity building sessions on
13 and 15 December 2021

Acknowledgments

EMR COVID-19 Vaccine Effectiveness study team

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EMR COVID-19 vaccine effectiveness study team

The regional team at the WHO EMRO is an interdisciplinary group of experts in:

- ❑ Epidemiology (and vaccine effectiveness studies)
- ❑ Medicine (vaccines and immunizations)
- ❑ Pharmacy
- ❑ Laboratory
- ❑ Public Health
- ❑ Health policy and economics
- ❑ Statistics

Overview

- ▶ Importance and purpose of COVID-19 vaccine effectiveness studies
- ▶ WHO EMRO support for countries interested to partake in the Regional COVID-19 vaccine effectiveness Study
- ▶ Progress and actions since Sep 2021
- ▶ Status update on COVID-19 vaccine effectiveness studies in the EMR

Importance of COVID-19 Vaccine Effectiveness Studies

- ▶ Evaluate the real-world performance of vaccines in comparison to *vaccine efficacy* from *clinical trials* which are determined under carefully controlled conditions of RCTs
- ▶ Address gaps in evidence from clinical trials, including:
 - vaccine effectiveness for outcomes of interest (e.g., severe disease, death, transmission, etc.)
 - vaccine effectiveness in subpopulations (e.g., elderly, immunocompromised)
 - vaccine effectiveness against SARS-CoV-2 variants of concern
 - Duration of protection from vaccines
 - Provide input into impact models and post-authorization confirmation of effectiveness for conditionally approved products

The Purpose / Objective of Regional COVID-19 Vaccine Effectiveness Studies

- ▶ They are methodological complex
 - ▶ Hence susceptible to important biases if not conducted vigorously
 - ▶ Not recommended to be conducted in all countries
- ▶ Focus on variety of vaccines, producers and context is needed
 - ▶ Hence multi-country studies recommended
- ▶ Region-specific (pooled) vaccine effectiveness estimates help guide vaccine policies
 - ▶ Answering additional questions with more statistical powers
 - ▶ Reducing individual study risks of biases

WHO EMRO support for member countries interested to partake in the regional COVID-19 vaccine effectiveness study

- ✓ Guidance on assessing and selecting appropriate sites for study conduction
- ✓ Adaptation of generic WHO vaccine effectiveness protocols to institutional or national capacities
- ✓ Detailed technical comments on study proposal and relevant supporting documents
- ✓ Face-to-face consultation meetings with PIs to address technical issues or questions
- ✓ Guidance on data entry process using the study questionnaires and follow-up forms; either through the WHO/EMRO's centralized data entry platform (DEP) or the country's DEP of choice
- ✓ Direction for proper data collection, aggregation and statistical analysis to report study results

Regional Vaccine Effectiveness Technical Team Functions (since Sep 2021)

- ▶ Creation of a COVID-19 VE Dashboard for monitoring all proposals and studies taking place in the EMR
- ▶ Development of the Terms of Reference for participating EM countries, deciding upon
- ▶ Securing a Regional Ethical Clearance (in progress)
 - ▶ National ethical clearance is needed for each individual study
- ▶ Establishment a central Data Entry Platform for data entry
 - ▶ For aggregation and preliminary statistical analysis of collected data (REDCap) (in progress)
- ▶ Organizing the capacity-building sessions on COVID-19 VE Studies
 - ▶ To inform and support countries interested to participate in the Regional COVID-19 vaccine effectiveness Study

Categories of countries according to COVID-19 vaccine effectiveness proposal / study status in the EMR (as of 8 December 2021)

Countries interested in conducting COVID-19 VE study with WHO/EMRO's support

Expressed interest in or submitted proposal to WHO/EMRO:

Iran, Lebanon, Morocco, Oman, Palestine, and Tunisia

Submitted proposals in line with WHO protocol and currently under reviews by WHO/EMRO's VE technical team:

Jordan and Egypt

Proposal deemed eligible to participate in Regional COVID-19 VE study and in implementation phase:

Pakistan

Countries with COVID-19 VE studies independent of WHO/EMRO's support

Planned, ongoing, or completed COVID-19 VE studies in the EMR: Bahrain, Iran, Jordan, Kuwait, Lebanon, Qatar, Saudi Arabia and the UAE

Activity Report of Regional Vaccine Effectiveness Technical Team

Activity	Report
Internal meetings	<u>9 meetings</u> with the Regional vaccine effectiveness technical team members
Technical meetings	<u>11 meetings</u> with PIs from the following EM countries: Egypt, Jordan, Iran, Lebanon, Morocco, Oman, Pakistan, and Tunisia
COVID-19 Vaccine Effectiveness Proposals	Evaluated <u>7 proposals</u> from <u>6 EM countries</u> : Egypt, Jordan, Iran, Lebanon, Palestine and Pakistan
Comprehensive technical support	Provided extensive technical support to <u>3 countries</u> (Egypt, Jordan, and Pakistan) whose proposals were <i>in line with the WHO VE protocols</i> <ul style="list-style-type: none">➤ For each country:<ul style="list-style-type: none">✓ <u>three</u> rounds of proposal revisions✓ <u>two</u> technical meetings discussing data collection, aggregation and analysis

Dashboard for Regional COVID-19 Vaccine Effectiveness

► The Dashboard which is weekly updated includes the following information:

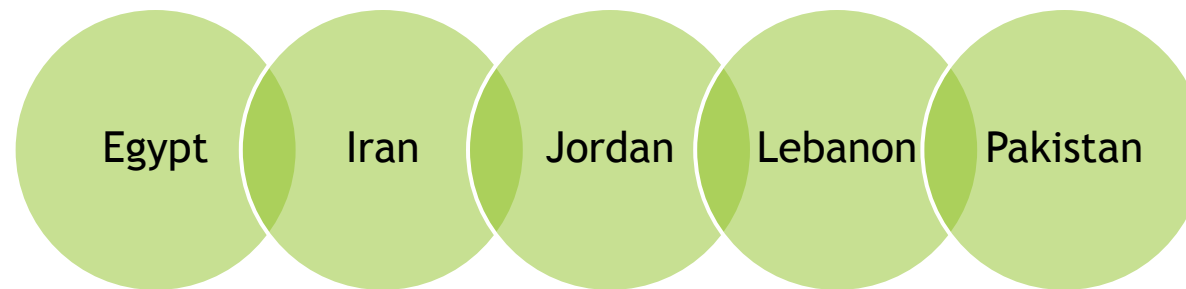
Institution & PI information	Ethical clearance	COVID-19 VE Proposal Shared	Study design / Methods	In line with WHO VE Protocol (HCWs or SARI)	WHO support requested (\$ or technical)	COVID-19 VE proposal development / study implementation	Revision rounds & dates	Consultation / technical meetings
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	A	B	C	D	E	F	G	H	I	J	K	L	M
	EM country	Institution	National ethical committee	PI (direct contact point w/ country and email)	COVID-19 VE Proposal shared	Study design	In line with w/ WHO protocols	WHO/EMRO support requested / offered	COVID-19 VE proposal / study phase and decision	Revision round	Last revision date	First F2F Consultation w/ VE technical team	Second F2F Consultation w/ VE technical team
1	Egypt	Academic Med Cntr Al Azhar University	Yes	Dr. Zeinab NABIL SAID zeinabnabil@azhar.edu.eg	Yes	Cohort study among HCWs (mix retrospective + prospective)	Yes	Both technical & financial	Proposal development	Third-round of revisions by VE technical team	15-Nov-21	4-Oct-21	9-Dec-21
2	Iran	MoH & Shahrood University of Medical Sciences (SUMS)	NA	---	Yes	Cohort (sero survey)	No	Both technical & financial	Revised and not included	First-round of revisions by VE technical team	6-Sep-21	NA	NA
3	Iran	Kerman University of Medical Sciences (KUMS)	NA	Dr. Ali MIRZAZADEH ali.mirzazadeh@ucsf.edu	Yes	Cohort or nested case-control study	No	Both technical & financial	---	Second-round of revisions by VE technical team	16-Nov-21	NA	NA
4	Jordan	MoH	Yes	Dr. Fatima ZERRIOUH THNEIBAT toom832016@gmail.com	Yes	Case-control (TND SARI)	Yes	Both technical & financial	Proposal development	Second-round of revisions by VE technical team	21-Nov-21	13-Oct-21	9-Dec-21
5	Lebanon	MoPH	Yes	Dr. Moubadda ASSI assimo@who.int	Yes	Cohort study among HCWs (retrospective)	Partial / exception made	Technical support	Study implementation - not included in regional CVE study	Fourth-round of revisions by VE technical team	2-Nov-21	30-Sep-21	NA
6	Morocco	MoH	NA	---	No	NA	NA	NA	Initial plannings	NA	NA	NA	NA
7	Oman	MoH	NA	Dr. Warda AL AMRI alamri.warda@gmail.com	No	NA	NA	NA	Initial plannings	NA	NA	6-Oct-21	NA
8	Pakistan	Khyber Pakhtunkhwa Medical University (KMU)	Yes	Dr. Sheraz FAZID (PI) sherazvs@gmail.com	Yes	Cohort study among HCWs (prospective)	Yes	Both technical & financial	Proposal development	Third-round of revisions by VE technical team	14-Nov-21	21-Oct-21	9-Dec-21
9	Palestine (oPt)	MoH/PNIPH	NA	---	Yes	Cross-section household serosurvey (befor / after study)	No	Both technical & financial	Revised and not included	Other	NA	NA	NA
10	Tunisia	MoH	Yes	---	No	Cross-section household serosurvey (before/after vaccination) or Case-control SARI TND	NA	NA	Initial plannings	NA	NA	11-Oct-21	NA
11													
12													
13	Initial Interest	Proposal under revision	Eligible for Regional Study	Not in line with WHO VE Protocol	Unknown								

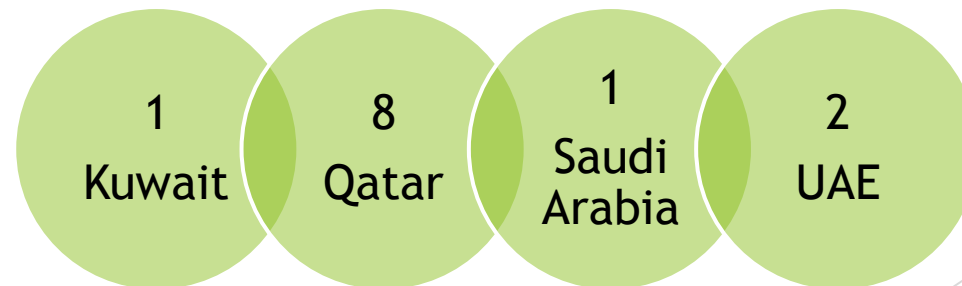
List of planned, ongoing and completed COVID-19 VE studies in the EMR (reference: view-hub.org)

As of 12 December 2021, there were 17 studies in the Region independent of WHO/EMRO's support, of which:

- 5 studies are being planned or ongoing:



- 12 studies were completed with published results:



Thank you