

# Eastern Mediterranean Regional COVID-19 Vaccine Effectiveness Network: Challenges and the Way Forward

Kamal Fahmy, MD

Medical Officer, Immunization and Vaccine Preventable Diseases

**WHO EMRO COVID-19 Vaccine Effectiveness Study;**

**Status Update and Important Considerations**

**17 November 2022**

# Overview

1. General challenges for designing and implementing COVID-19 VE studies
2. Country-specific challenges in the EM Regional COVID-19 VE Study
3. The way forward

# *General challenges*

The slide features a dark blue background. The title 'General challenges' is centered in a white, italicized serif font. Below the title, there are two horizontal blue bars. The first bar is a solid blue rectangle. The second bar is a 3D-style blue rectangle that overlaps the first one, extending further to the right and appearing to be slightly offset downwards.

# General challenges for conducting COVID-19 VE studies

- 1. Shifting landscape of COVID-19 epidemiology and vaccination:** emergent nature of the disease and continuous findings from clinical trials and observational studies → frequent updates to recommendations / guidance for COVID-19 studies, including VE
- 2. Complex vaccination schedules (programs):** considerable variability worldwide, across the region and within countries → different vaccine products authorized, including locally manufactured products, various dosing schedules, all of which have complicated estimating VE accurately
- 3. Justification of cost-benefit value for certain tests:** serology or anti-S and anti-N antibody testing, genetic sequencing of novel SARS-CoV-2 variants, etc.
- 4. Possibility to reliably use less expensive alternatives in resource-limited settings:** Use of Rapid Diagnostic Test (RDTs) instead of PCR tests for diagnosis of COVID-19 positive cases

# Common challenges for conducting *Regional* COVID-19 VE studies

1. **Standardizing study designs and methodologies** for participating countries in accordance with WHO guidelines (protocols)
2. **Inadequate access** to necessary *infrastructure* (e.g., the need for specific lab equipment, antibody and genetic sequencing test kits, absence of electronic medical record systems, etc.)
3. **Obtaining necessary approvals:** ethical and security clearance from respective authorities in each country to conduct a clinical study and share (transfer) disaggregated anonymized data within the Regional Data Entry Platform (**REDCap**)
4. **Lengthy administrative (bureaucratic) processes** for issuing individual contracts with participant countries in the VE Network while *staying on schedule*
5. **Secure funding:** internal and external financial support

# *Country-specific challenges*

The slide features a dark blue background. At the bottom, there are two horizontal blue bars. The first bar is a solid blue rectangle. The second bar is a blue rectangle that is slightly offset to the right and has a 3D effect, appearing to be layered on top of the first bar.

# Technical and operational challenges

1. **Missing data** due to various reasons (e.g., tracing / tracking study participants and collecting blood samples / NP swabs during the fasting month of Ramadan was difficult in a cohort study among HCWs)
2. **Reaching adequate (target) sample size** for certain studies (e.g., difficulty recruiting controls among HCWs in the cohort design, identifying cases in the SARI TND method, lack of some cases consent forms, loss of follow-up, etc.)
3. **Standardization and importation of existing electronic data** from national datasets (excel) into the Regional Data Entry Platform (REDCap): The case for retrospectively collected data and necessary to allow pooling results across countries for reporting Regional VE estimates
4. **Amendments / adjustments to the study design** post implementation; since this is an emergent disease, there are new vaccination guidelines and expanding target population (e.g., pediatric doses – it would be beneficial to investigate VE in this age group, however, inadequate sample sizes to account for stratified statistical analyses in sub-groups)
5. **Study interruption** due to unforeseen circumstances (e.g., natural disaster, inflation rates, etc.)

*The way forward*

The bottom of the slide features two horizontal blue bars. The first bar is a solid blue rectangle spanning most of the width. The second bar is a 3D-style blue rectangle that starts to the right of the first bar and extends to the right edge of the slide, appearing to be layered on top of the first bar.



## Technical support

- Adopting approaches from similar experiences in the past
- Adapting technical guidance specific to the needs and requests from investigators and countries in the Region

## Upcoming plans

- Visits to study sites
- Capacity-building programs

# Technical support

- **Adopting approaches** based on previous experiences from other viral respiratory diseases (e.g., influenza) and lessons learned from other global surveillance programs (e.g., FluNet or *influenza sentinel surveillance systems*) to address similar challenges encountered for COVID-19
- **Adapting our technical support** based on specific requests from PIs which are unique challenges they have encountered in their respective studies; tapping into the collective expertise of the *multidisciplinary Regional COVID-19 VE technical team* to provide customized technical support to each research team based on their unique *capacities and circumstances*

# Visits to study sites

- As part of the **Regional support** to the participating countries, site visits of participating research centers and hospitals were planned to be conducted by the Regional VE technical team and focal points in each country:
- The **aims of the visits** are to:
  - Ensure finalization of participants enrollment
  - Review the processes for samples collection, transfer and analysis, as well as data management
  - Optimize data transfer to the regional data platform
  - Plan for further support to facilitate the study until its completion
- Visits were **prioritized** with countries that had ongoing or prospective studies:
  - **Pakistan and Jordan:** certain site visits have been conducted
  - **Egypt and Iran:** arrangements to be made / underway

# Capacity-building programs for countries in the Region

November 2022

## Virtual workshop (two 2-hour sessions online over two days)

- Updated recommendations and guidelines for conducting COVID-19 VE studies
- Discussing new variants, booster doses, antibody testing, rapid diagnostic tests, etc.

April 2023

## In-person consultative meeting (2-day event in Cairo, Egypt)

- Experience sharing for lessons learnt and challenges encountered among PIs of participating countries in the EM Regional COVID-19 VE Study
- Feedback and guidance from technical support team

*Thank you!*

The bottom of the slide features two horizontal blue bars. The first bar is a solid blue rectangle spanning most of the width. The second bar is a slightly shorter blue rectangle positioned to the right of the first, creating a layered effect.