Overview of the EM Regional COVID-19 Vaccine Effectiveness Study & Establishment of the EM Regional COVID-19 Vaccine Effectiveness Network

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

12–13 November 2023 | Cairo, Egypt

Justification and reasons for launching the EM Regional COVID-19 vaccine effectiveness initiative by IMST

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1. Existing information was mostly reflective of data collected under controlled conditions of RCTs (vaccine efficacy) as opposed to real-world conditions (in the field)
2. Due to complexity, technical expertise / specialization required for proper design and implementation of observational studies (vaccine effectiveness), and interpretation of results
3. Few studies on COVID-19 VE studies from the EM Region
4. Most published COVID-19 vaccine effectiveness studies at the time were on mRNA-based (e.g., Pfizer and Moderna) and adenovector (.g., AstraZeneca) vaccines, while less research was available from inactivated vaccines (e.g., Sinopharm)
5. Unique vaccine products manufactured and authorized for use only in certain EM countries (Member States) with limited published information

WHO's approach for conducting the EM Regional COVID-19 Vaccine Effectiveness Study (Sep 2021 – Dec 2023)

1. **Enhancing processes and structures in the Region**
    i. Development of the COVID-19 vaccine effectiveness studies dashboard for EMR
    ii. Standardization of study design and data analysis
    iii. Issuance of regional ethical clearance
    iv. Development of the regional data entry platform (REDCap)
    v. Establishment of the multidisciplinary regional COVID-19 vaccine effectiveness technical team
2. **Building national technical capacities in countries**
    i. Regionwide workshops
    ii. Country-specific trainings

EM Regional COVID-19 Vaccine Effectiveness Dashboard

(countries seeking WHO-EMRO's technical and / or financial support)

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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

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	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	Third F2F Consultation w/ VE technical team
2	Egypt	Academic Med Center 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 revised and eligible for regional CVE study	Third-round of revisions by VE technical team	15-Nov-21	4-Oct-21	9-Dec-21	17-Apr-23
3	Iran	MoH & Shahrood University of Medical Sciences (SUMS)	NA	---	Yes	Cohort (sero survey)	No	Both technical & financial	Proposal revised and not eligible for regional CVE study	First-round of revisions by VE technical team	6-Sep-21	NA	NA	NA
4	Iran	Kerman University of Medical Sciences (KMU)	NA	Dr. Ali MIRZAZADEH ali.mirzazadeh@ucsf.edu	Yes	Cohort or nested case-control study	No	Both technical & financial	Proposal revised and not eligible for regional CVE study	Second-round of revisions by VE technical team	16-Nov-21	NA	NA	NA
5	Iran	Kermanshah University of Medical Sciences (KUMS)	Yes	Dr. Farid NAJAFI farid_n32@yahoo.com	Yes	Case-control (TND SARI)	Yes	Both technical & financial	Proposal revised and eligible for regional CVE study	Third-round of revisions by VE technical team	23-Apr-22	16-May-22	NA	TBD
6	Iran	Pasteur Institute of Iran	Yes	Dr. Ehsan Mostafavi	Yes	Seroepidemiology of anti-spike antibodies and retro evaluation of Covid-19 VE in Iranian HCWs	Partial	Both technical & financial	Proposal revised and not eligible for regional CVE study	Third round of revision by VE technical team	18-Aug-22	28-Jun-22	NA	NA
7	Jordan	MoH	Yes	Dr. Fatima ZERRIOUH THNEIBAT toom832016@gmail.com	Yes	Case-control (TND SARI)	Yes	Both technical & financial	Proposal revised and eligible for regional CVE study	Second-round of revisions by VE technical team	21-Nov-21	13-Oct-21	9-Dec-21	18-Apr-22
8	Lebanon	MoPH	Yes	Dr. Moubadda ASSI assimo@who.int	Yes	Cohort study among HCWs (retrospective)	Partial	Technical support	Proposal revised and not eligible for regional CVE study	Fourth-round of revisions by VE technical team	2-Nov-21	30-Sep-21	NA	NA
9	Morocco	MoH	NA	---	No	NA	NA	NA	Initial interest	NA	NA	NA	NA	NA
10	Oman	MoH	NA	Dr. Warda AL AMRI alamri.warda@gmail.com	No	NA	NA	NA	Initial interest	NA	NA	6-Oct-21	NA	NA
11	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 revised and eligible for regional CVE study	Third-round of revisions by VE technical team	14-Nov-21	21-Oct-21	9-Dec-21	NA
12	Palestine (oPt)	MoH/PNIPH	NA	---	Yes	Cross-section household serosurvey (befor / after study)	No	Both technical & financial	Proposal revised and not eligible for regional CVE study	Other	NA	NA	NA	NA
13	Tunisia	MoH	Yes	---	No	Cross-section household serosurvey (before/after vaccination) or Case-	NA	NA	Initial interest	NA	NA	11-Oct-21	NA	NA

COVID-19 Vaccine Effectiveness Dashboard –

(all planned / ongoing or published studies from the EMR: 34 studies as of 1 Nov 2023)

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The Dashboard is updated monthly from view-hub.org and includes the following information:

Country	Title	Author and Publication Year	Start and End Dates	Population	Outcomes	Vaccine Products	SARS-CoV-2 Variants	Results published / link to publication
Egypt	Effectiveness and safety of inactivated SARS-CoV2 vaccine (BBIBP-CorV) among healthcare workers: A seven-month follow-up study at fifteen hospitals	Ashmawy, 2022	1 May 2021 to 30 September 2021	Healthcare workers	Symptomatic disease, Any infection, Hospitalization	Beijing CNBG (BBIBP-CorV)	Delta (B.1.617.2)	11-Mar-22
Egypt	N/A (planned/ongoing study)		Expected start date:March 2021, Results expected:November 2021	Healthcare workers	Any infection			
Iran (Islamic Republic of)	N/A (planned/ongoing study)		Expected start date:Unknown, Results expected:Unknown	Adults	Hospitalization, Death			
Iran (Islamic Republic of)	Effectiveness of COVID-19 vaccines on hospitalization and death in Guilan, Iran: a test-negative case-control study	Heidarzadeh 2023	22 May 2021 to 21 December 2021	Adults, Children (Less than 18 y)	Hospitalization, Death, Other Outcome, ICU admission	Bharat (Covaxin), Gamaleya (Gam-Covid-Vac), AstraZeneca (Vaxzevria), Shi	Mixed VOC	23-Dec-22
Jordan	N/A (planned/ongoing study)		Expected start date:September 2021, Results expected:2022	Adults	Severe disease, Hospitalization			
Kuwait	Effectiveness of BNT162b2 and ChAdOx1 vaccines against symptomatic COVID-19 among Healthcare Workers in Kuwait: A retrospective cohort study	Alali, 2021	24 December 2020 to 15 June 2021	Healthcare workers	Any infection	AstraZeneca (Vaxzevria), Pfizer BioNTech (Comirnaty)	Alpha (B.1.1.7)	29-Jul-21
Kuwait	Effectiveness of BNT162b2 and ChAdOx1 Vaccines against Symptomatic COVID-19 among Healthcare Workers in Kuwait: A Retrospective Cohort Study	Alali 2021	24 December 2020 to 15 June 2020	Healthcare workers	Symptomatic disease	AstraZeneca (Vaxzevria), Pfizer BioNTech (Comirnaty)	Alpha (B.1.1.7)	7-Dec-21
Lebanon	Immunogenicity and Effectiveness of Primary and Booster Vaccine Combination Strategies during Periods of SARS-CoV-2 Delta and Omicron Variants	Moghnieh, 2022	1 August 2021 to 1 March 2022	Adults	Any infection	Gamaleya (Gam-Covid-Vac), Pfizer BioNTech (Comirnaty), Pfizer BioNTec	Delta (B.1.617.2), Omicron (B.1.	22-Sep-22
Lebanon	N/A (planned/ongoing study)		Expected start date:September 2021, Results expected:2022	Healthcare workers	Any infection			
Morocco	Long term effectiveness of inactivated vaccine BBIBP-CorV (Vero Cells) against COVID-19 associated severe and critical hospitalization in Morocco	Belayachi, 2022	2 February 2021 to 1 October 2021	Adults	Hospitalization	Beijing CNBG (BBIBP-CorV)	Mixed VOC and Non-VOC	27-Jan-22
Morocco	Real-world study of the effectiveness of BBIBP-CorV (Sinopharm) COVID-19 vaccine in the Kingdom of Morocco	Zhang, Yaowen	1 February 2021 to 30 June 2021	Adults	Hospitalization	Beijing CNBG (BBIBP-CorV)	Alpha (B.1.1.7)	27-May-22
Pakistan	N/A (planned/ongoing study)		Expected start date:Unknown, Results expected:Unknown	Healthcare workers	Any infection			
Qatar	Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants	Abu-Raddad 2021	1 February 2021 to 31 March 2021	Adults	Any infection, Severe disease	Pfizer BioNTech (Comirnaty)	Alpha (B.1.1.7), Beta (B.1.351)	8-Jul-21
Qatar	mRNA-1273 COVID-19 vaccine effectiveness against the B.1.1.7 and B.1.351 variants and severe COVID-19 disease in Qatar	Chemaitelly 2021	1 February 2021 to 10 May 2021	Adults	Any infection, Severe disease, Symptomatic disease, Asymptomatic infection	Moderna (Spikevax)	Alpha (B.1.1.7), Beta (B.1.351),	9-Jul-21
Qatar	Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar	Bertollini, 2021	18 February 2021 to 26 April 2021	Adults	Any infection	Pfizer BioNTech (Comirnaty) or Moderna (Spikevax)	Mixed VOC and Non-VOC	9-Jun-21
Qatar	SARS-CoV-2 vaccine effectiveness in preventing confirmed infection in pregnant women	Butt, 2021	20 December 2020 to 30 May 2021	Pregnant women	Any infection	Moderna (Spikevax), Pfizer BioNTech (Comirnaty)	Mixed VOC	7-Oct-21
Qatar	SARS-CoV-2 vaccine effectiveness in immunosuppressed kidney transplant recipients	Chemaitelly, 2021	1 February 2021 to 21 July 2021	Immunocompromised, Kidney transplant recipients	Any infection, Severe disease	Pfizer BioNTech (Comirnaty) or Moderna (Spikevax)	Mixed VOC	9-Aug-21
Qatar	BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the SARS-CoV-2 Delta variant in Qatar	Tang 2021	21 December 2020 to 7 September 2021	All ages	Any infection, Severe disease, Symptomatic disease, Asymptomatic infection	Moderna (Spikevax), Pfizer BioNTech (Comirnaty)	Delta (B.1.617.2), Beta (B.1.351)	2-Nov-21
Qatar	Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar	Chemaitelly 2021	1 January 2021 to 15 August 2021	Adults, Older adults	Any infection, Symptomatic disease, Asymptomatic infection, Severe disease	Pfizer BioNTech (Comirnaty)	Mixed VOC, Alpha (B.1.1.7), Bet	27-Aug-21
Qatar	Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar	Chemaitelly 2021	1 January 2021 to 5 September 2021	Older adults, 12+ years	Any infection, Symptomatic disease, Asymptomatic infection, Severe disease	Pfizer BioNTech (Comirnaty)	Mixed VOC, Alpha (B.1.1.7), Bet	6-Oct-21
Qatar	Waning of mRNA-1273 vaccine effectiveness against SARS-CoV-2 infection in Qatar	Abu-Raddad 2021	1 January 2021 to 5 December 2021	Adults	Any infection, Symptomatic disease, Asymptomatic infection, Hospitalization	Moderna (Spikevax)	Mixed VOC	16-Dec-21
Qatar	Effect of mRNA Vaccine Boosters against SARS-CoV-2 Omicron Infection in Qatar	Abu-Raddad, 2022	19 December 2021 to 22 January 2022	Adults	Symptomatic disease, Hospitalization	Moderna (Spikevax) - 1st booster dose, Pfizer BioNTech (Comirnaty) - 1s	Omicron (B.1.1.529), Delta (B.1.	12-May-22
Qatar	Duration of mRNA vaccine protection against SARS-CoV-2 Omicron BA.1 and BA.2 subvariants in Qatar	Chemaitelly,2022	23 December 2021 to 28 February 2022	Adults	Symptomatic disease, Any infection, Severe disease	Moderna (Spikevax), Pfizer BioNTech (Comirnaty), Moderna (Spikevax) - 1	Omicron (B.1.1.529)	2-Jun-22
Qatar	Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections	Altarawneh, 2022	23 December 2021 to 21 February 2022	All ages	Any infection, Symptomatic disease, Hospitalization	Moderna (Spikevax), Pfizer BioNTech (Comirnaty), Moderna (Spikevax) - 1	Omicron (B.1.1.529)	15-Jun-22
Qatar	Effectiveness of the BNT162b2 vaccine against SARS-CoV-2 infection among children and adolescents in Qatar	Chemaitelly 2022	1 February 2021 to 12 July 2022	Children (Less than 18 y)	Any infection	Pfizer BioNTech (Comirnaty)	Omicron (B.1.1.529), Mixed VO	26-Jul-22
Qatar	Long-term COVID-19 booster effectiveness by infection history and clinical vulnerability and immune imprinting	Chemaitelly, 2022	5 January 2021 to 12 October 2022	Adults, 12+ years, Children (Less than 18 y)	Any infection, Severe disease	Moderna (Spikevax) - 1st booster dose, Pfizer BioNTech (Comirnaty) - 1s	Omicron (B.1.1.529)	15-Nov-22
Qatar	COVID-19 primary series and booster vaccination and immune imprinting	Chemaitelly, 2022	19 December 2021 to 15 September 2022	Adults, 12+ years, Children (Less than 18 y)	Any infection	Pfizer BioNTech (Comirnaty) or Moderna (Spikevax), Pfizer BioNTech (Co	Omicron (B.1.1.529)	1-Nov-22
Qatar	Effectiveness of Messenger RNA Vaccines against SARS-CoV-2 Infection in Hemodialysis Patients: A Case-Control Study	Alkadi 2022	29 February 2020 to 3 January 2022	Adults, ESKD patients on chronic hemodialysis	Any infection	Moderna (Spikevax) - 1st booster dose, Pfizer BioNTech (Comirnaty) - 1s	Mixed VOC and Non-VOC	26-Dec-22
Qatar	Bivalent mRNA-1273.214 vaccine effectiveness in Qatar	Chemaitelly, 2023	18 October 2022 to 5 April 2023	All ages				19-Apr-23
Qatar	Effects of previous infection, vaccination, and hybrid immunity against symptomatic Alpha, Beta, and Delta infections	Altarawneh 2023	18 January 2021 to 18 December 2021	Individuals (all ages) (<10 years upto 75+years)	Other Outcome, Severe disease	Pfizer BioNTech (Comirnaty), Moderna (Spikevax) - 1st booster dose, Pfi	Beta (B.1.351), Delta (B.1.617.2)	22-Apr-23
Qatar	Population immunity of natural infection, primary-series vaccination, and booster vaccination in Qatar during the COVID-19 pandemic: An observational study	Qassim, 2023	1 July 2020 to 30 November 2022	Adults, Children (Less than 18 y)	Any infection, Severe disease	Pfizer BioNTech (Comirnaty) or Moderna (Spikevax), Pfizer BioNTech (Co	Omicron (B.1.1.529)	29-Apr-23
Qatar	N/A (planned/ongoing study)		Expected start date:December 2020, Results expected::	Adults, Older Adults, Children	Any infection, Asymptomatic infection, Symptomatic disease, Severe disease, Hospitalization, Death		Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), Omicron	
United Arab Emirates	Impact of the Sinopharm's BBIBP-CorV vaccine in preventing hospital admissions and death in infected vaccinees: Results from a retrospective study in the emirate of Abu Dhabi, United Arab Emirates (UAE)	AlHosani,2022	1 September 2020 to 1 May 2021	Adults	Hospitalization, ICU admission, Death	Beijing CNBG (BBIBP-CorV)	Mixed VOC	18-Mar-22
United Arab Emirates	Effectiveness of BBIBP-CorV vaccine against severe outcomes of COVID-19 in Abu Dhabi, United Arab Emirates	Al Kaabi, 2021	1 October 2020 to 31 July 2021	Adults	Hospitalization, Severe disease, Death	Beijing CNBG (BBIBP-CorV)	Non-VOC	9-Jun-22

Regional Data Entry Platform (REDCap)

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Project Title	Records	Fields	Instruments	Type	Status
Practice project	0	2	1 form	■	
EM Regional COVID-19 Vaccine Effectiveness Study: Test-Negative Design in SARI	0	153	13 forms	■	
EM Regional COVID-19 Vaccine Effectiveness Study: Cohort Study in HCWs	0	267	5 forms	■	
COVID-19 VE Study (Cohort Study in HCWs) - Egypt 2022 (WHO-EMRO)	1'257	234	5 forms	■	☑
COVID-19 VE Study (Cohort Study in HCWs) - Pakistan 2022 (WHO-EMRO)	1'707	279	5 forms	■	☑
COVID-19 VE Study (TND in SARI) - Jordan 2022 (WHO-EMRO)	1'874	155	12 forms	■	☑
COVID-19 VE Study (TND in SARI) - Iran 2022 (WHO-EMRO)	19'360	161	13 forms	■	

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Participating countries in the EM Regional COVID-19 Vaccine Effectiveness Study

National COVID-19 VE Studies		Study design and method	Sample size	Number of study sites	Dates / study duration
Countries and Investigative Institutes	**Egypt** Al-Azhar University	Prospective Cohort Study in Health Care Workers (HCWs)	1,250 participants	5 hospitals	From 08/2022-09/2023 (12 months)
	Iran Kermanshah University of Medical Sciences	Retrospective Test-Negative case-control Design (TND) in Severe Acute Respiratory Infections (SARI)	20,000 participants	8 cities / provinces	From 05/2021 – 03/2022 (10 months)
	Jordan Ministry of Health	Prospective Test-Negative case-control Design (TND) in Severe Acute Respiratory Infections (SARI)	2,000 participants	4 hospitals	From 05/2022-05/2023 (12 months)
	Pakistan Khyber Medical University	Prospective Cohort Study in Health Care Workers (HCWs)	1,600 participants	3 hospitals	From 11/2021-12/2022 (12 months)

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Capacity-building programs

Target audience	Capacity-building trainings and workshops	Date
Region-wide (open to all EM countries)	COVID-19 VE Studies using WHO protocol for Cohort study in HCWs (Day 1)	13 December 2021
	COVID-19 VE Studies using WHO protocol for TND in SARI (Day 2)	15 December 2021
Country-specific (Jordan)	Interactive capacity-building training on the use of REDCap for study design and data management using WHO protocol for TND in SARI	7 March 2022
Country-specific (Egypt and Pakistan)	Interactive capacity-building training on the use of REDCap for study design and data management using WHO protocol for Cohort study in HCWs	8 March 2022
Region-wide (open to all EM countries)	WHO-EMRO COVID-19 Vaccine Effectiveness Study; Status Update and Important Considerations (Day 1)	17 November 2022
	WHO-EMRO COVID-19 Vaccine Effectiveness Study; Status Update and Important Considerations (Day 2)	24 November 2022

Multidisciplinary Regional COVID-19 Vaccine Effectiveness Technical Team

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WHO-EMRO team members

❖ **Core team members**

- Mehrnaz Kheirandish, Kamal Fahmy and Zahra Karimian

❖ **Team leads**

- Arash Rashidian, RKM Pillar Lead & Director of SID
- Yvan Hutin, Vaccine Pillar Lead & Director of DCD

❖ **Supporting technical team**

- Abdinaser Abubakar
- Quamrul Hasan
- Mohammed Osama Mere
- Amal Barakat
- Eman Aly
- Hala Abou-El Naja
- Amir Aman
- Noore Alam

Support team

❖ **Epidemiology and statistical consultants**

❑ Epiconcept (former)

❑ MM Global Health (current)

- Carsten Mantel
- Manuela Runge
- Giulio Borghi
- Natalie Woodniack
- Thomas Cherian

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Objective 1: Quality assurance of national study results

1. Standardization of study designs (research methodologies) in technical proposals based on the WHO's two main protocols for COVID-19 Vaccine Effectiveness evaluation (cohort study in HCWs and TND in SARI)
2. Adaptation of the WHO's generic questionnaires while accounting for country-specific details / variations
3. Development of uniform code books for reporting study results / online data entry in Regional data entry platform (REDCap)
4. Obtaining necessary documents to secure Regional Ethical Clearance from EM-RERC in addition to institutional and national ethical clearance for each country's study

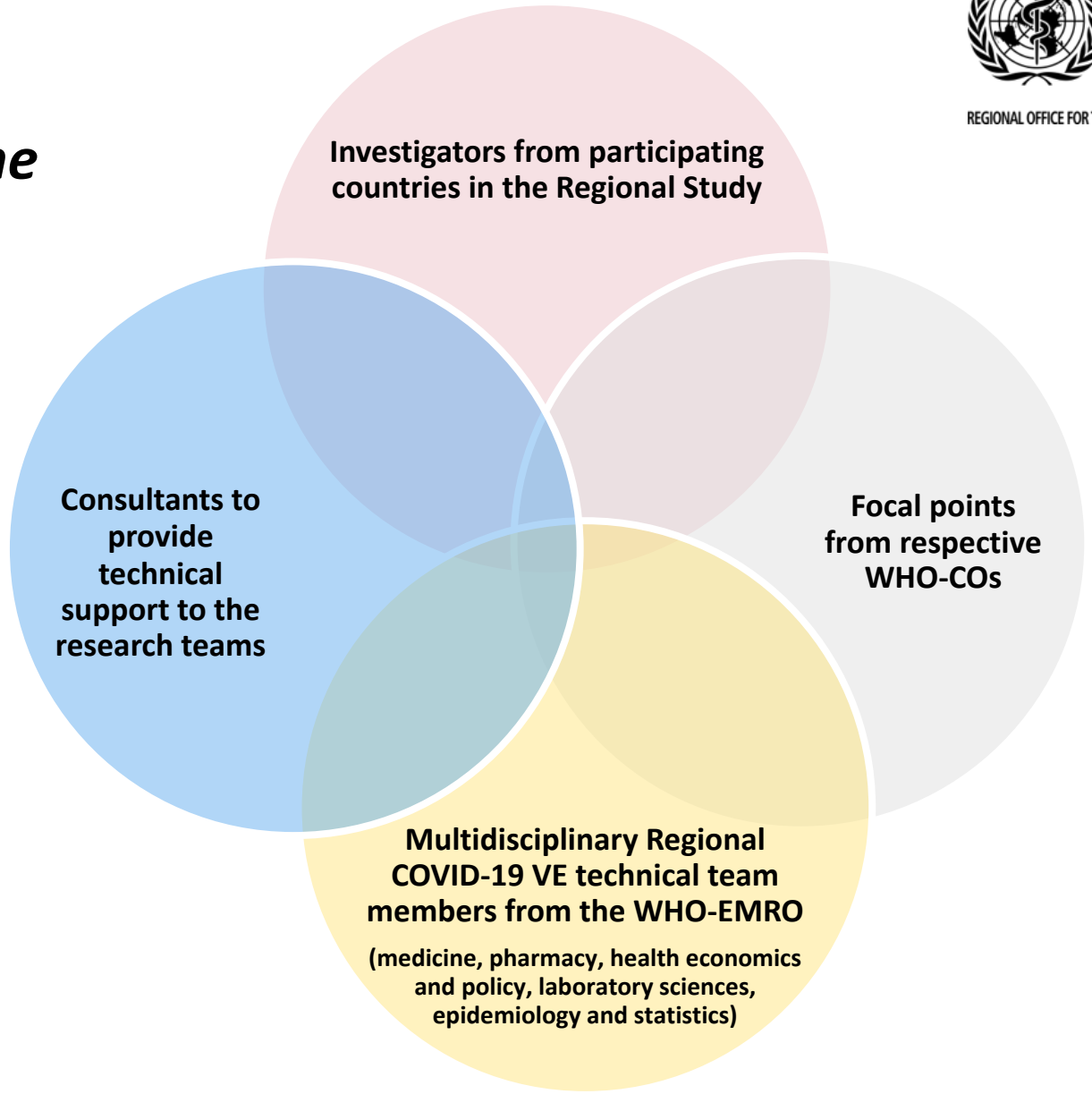
Objective 2: Facilitation of data sharing by countries with the WHO EMRO

1. Weekly evaluation of national datasets by epidemiology consultants through preparation of data cleaning / checking reports for each country's research team to immediately identify and report any missing or duplicate data
2. Monthly technical meetings with each country's investigators and focal contact points at the WHO-CO to address any questions
3. Planned site visits to collaborating study sites for a first-hand account of unique challenges encountered by each country's research team and to recommend appropriate solutions for overcoming them
4. Periodical data verification / validation checks by carrying out interim statistical analyses of national study results in REDCap to detect concerning trends and appropriately adjust for unexpected developments as early as possible

Objective 3: Expected outcomes from data use

1. Capacity building for conducting vaccine effectiveness research among member states
2. Statistical analysis of data from the Regional COVID-19 Vaccine Effectiveness Study to inform recommendations and policies in the decision-making process for COVID-19 immunization programs (both national and regional)
3. Establishment of the Regional COVID-19 Vaccine Effectiveness Network as a sustainable platform, such that it would facilitate conducting similar studies in the Region for the future

The ***Regional COVID-19 Vaccine Effectiveness Network*** comprises four groups:



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Relevant resources and references

- Evidence and Data to Policy (EDP) website
- Capacity-building programs for COVID-19 vaccine effectiveness studies
- Eastern Mediterranean Health Journal (EMHJ) special issue
- EM Regional COVID-19 Vaccine Effectiveness Study article: "Capacity-building for conducting COVID-19 vaccine effectiveness studies to enhance evidence-informed vaccination policymaking in the Eastern Mediterranean Region“
- The Evidence to Recommendation Process for National Immunization Technical Advisory Groups (NITAGs)

Challenges encountered during implementation of the Regional COVID-19 Vaccine Effectiveness Study

Different types of challenges encountered during implementation of the EM Regional COVID-19 Vaccine Effectiveness Study:

1. General challenges inherent to COVID-19 vaccine effectiveness studies
2. Specific challenges to conducting COVID-19 vaccine effectiveness studies encountered by countries (on a national scale)
3. Unique challenges to conducting a COVID-19 vaccine effectiveness study on a regional scale (multinational level)

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General challenges

- Changing landscape of COVID-19 epidemiology and vaccination during study implementation
- Complex vaccination programs (dosing schedules), mixing vaccine types, and variability of COVID-19 vaccine products authorized among countries (including locally manufactured products)
- Justification of the cost-benefit value for use of certain tests in the evaluation of vaccine effectiveness, such as serology or antibody testing, genetic sequencing for novel SARS-CoV-2 variants
- Possibility to reliably use less expensive alternatives in resource-limited settings (e.g.: use of RDT rapid diagnostic test instead of PCR for diagnosis of COVID-19 positive cases)
- Use of a new data platform (REDcap) which needed specific capacity building for its use

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Specific challenges for individual countries

- Inadequate access to necessary infrastructures or supplies
- Study interruption due to unforeseen circumstances
- Missing data due to difficulty with tracing and tracking of study participants
- Inability to reach adequate (target) sample size for certain countries where vaccination coverage was higher
- Amendments and adjustments to the study design post-implementation
- Data management and interoperability with standardized data platform

Challenges unique to the regional study

- Inability to standardize study designs and methodologies for the technical proposals / protocols among all participating counties in line with the WHO protocols
- Difficulty in importing existing electronic data from national datasets into the regional data entry platform, especially in the case for retrospectively collected data
- Difficulty in obtaining necessary authorizations and approvals, including institutional and national ethical clearance from respective health authorities in each country and sharing of disaggregated anonymized health data
- Difficulty in securing adequate funding to support individual studies despite the increasing inflation rates in certain countries

Future needs for implementation of evidence and guidance [1]

Country inputs for generating evidence will continue to be helpful / informative. Therefore, continued collection of implementation experiences will be essential, including:

1. Experience with various scheduling and combination of different products, as well as co-administration with other vaccines
2. Linking diseases reporting with vaccine histories and health outcomes data
3. Closer collaboration with RITAG and NITAG to ensure utilization of evidences in relation to use and introduction of new vaccines
4. Successful service delivery models and integration in PHC
5. Maintaining AEFI reporting systems (safety data) linked to regional and global databases
6. Financing sustainable vaccine supplies

1. International Vaccine Access Center (IVAC). COVID-19 Vaccine Policy in a Changing World: Contributions of Vaccine Effectiveness Studies (2023).

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Thank you

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

12–13 November 2023 | Cairo, Egypt