

Current major event

COVID-19 vaccine effectiveness studies: why and how?

The COVID-19 pandemic continues to pose a threat to societies worldwide. Efforts to develop and roll out vaccines against the disease have been unprecedented. However, their effectiveness at field level needs to be estimated as this information is important in identifying the potential impact of emergence of variants, country context and vaccination strategies.

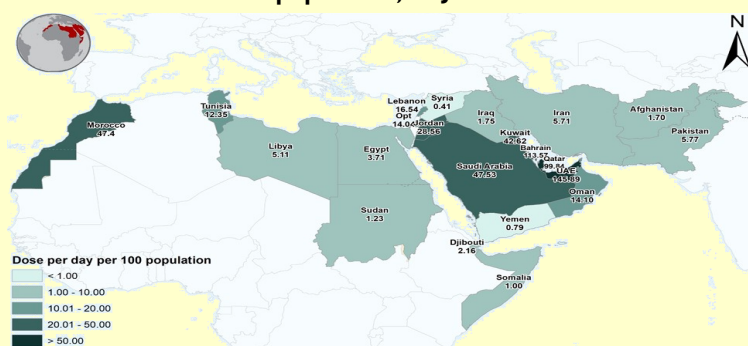
Editorial note

The WHO Regional Office for the Eastern Mediterranean supported countries through vaccine deployment, including readiness assessment, the preparation of National Deployment and Vaccination Plans, vaccine requests, national emergency use authorization, import license, and indemnification and liability agreements. Currently, six WHO approved vaccines are available in the Region: Pfizer/BioNtech, Oxford/AstraZeneca, Moderna, Janssen, Sinopharm and Sinovac. As of 21 June 2021, a total of 84.1 million doses were administered across all 22 countries, with the average ratio of doses given per 100 population being 11.2% (*see map*).

Vaccine effectiveness (VE) studies are needed to address many questions about the performance of vaccines under real-world conditions, which may vary from their published efficacy values. These studies are important for evaluating impact of conditions such as transportation and storage, timing and completeness of the dosing schedule, and vaccine co-administration, while addressing gaps in evidence from the clinical trials such as duration of protection, variants of concern and sub-populations at risk. They also provide updates to regulatory and policy-making bodies on post-authorization confirmation of VE for these conditionally-approved products.

There are several designs or methodologies to evaluate VE, however WHO recommends at this time to start small and build on already existing platforms such as the Unity Studies, which have two generic protocols for adaptation. One is the cohort study to measure COVID-19 VE among health workers (HWs). This is recommended to be a prospective longitudinal one-year

COVID-19 vaccine deployment in EMR: Vaccination doses administered per 100 population, 21 June 2021



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be an agreement.

Data source: (<https://www.bloomberg.com/geographies/covid-vaccine-tracker-global-distribution/>)
Map production: Health Emergency Information and Risk Assessment (HIMA) Unit
World Health Organization



Generic protocols of the WHO Unity Studies for assessing vaccine effectiveness

Cohort study to measure COVID-19 vaccine effectiveness among health workers in the WHO European Region: guidance document:

<https://apps.who.int/iris/handle/10665/340217>

Estimating COVID-19 vaccine effectiveness against severe acute respiratory infections (SARI) hospitalizations associated with laboratory-confirmed SARS-CoV-2: an evaluation using the test-negative design:

<https://www.who.int/publications/i/item/WHO-EURO-2021-2481-42237-58308>

study of the hospital-based HWs. All HWs eligible to be vaccinated with the COVID-19 vaccine can be enrolled in the study. The primary outcome should be SARS-CoV-2 laboratory confirmation by Rt-PCR in any participant, regardless of symptoms.

The other recommended study design is for VE against hospitalization due to severe acute respiratory infections (SARI). This protocol is based on the existing surveillance system for influenza, and uses the test-negative design. Cases are SARI patients who tested positive for SARS-CoV-2, and controls are SARI patients who tested negative for SARS-CoV-2. A respiratory specimen should be collected from these patients within 48 hours of admission to the hospital. The follow-up period should be six months or longer.

While VE studies are important to inform global, regional and national policies, they are challenging and time-consuming, and not every country needs to do them. WHO is assisting countries in their decision-making process on whether to pursue such studies, and is providing technical and financial support to those who do.

Update on outbreaks

in the Eastern Mediterranean Region

COVID-19 in 22 EMR countries

Current public health events of concern [cumulative N° of cases (deaths), CFR %]

Coronavirus disease 2019 (COVID-19): 2019-2021

Afghanistan	[134 653 (5791), 4.3%]
Bahrain	[267 112 (1376), 0.5%]
Djibouti	[11 614 (155), 1.3%]
Egypt	[282 985 (16 383), 5.8%]
Iran (Islamic Republic of)	[3 355 786 (85 694), 2.6%]
Iraq	[1 421 746 (17515), 1.2%]
Jordan	[756 354 (9826), 1.3%]
Kuwait	[374 104 (2100), 0.6%]
Lebanon	[547 497 (7873), 1.4%]
Libya	[204 090 (3240), 1.6%]
Morocco	[541 405 (9360), 1.7%]
occupied Palestinian territory (oPt)	[343 948 (3848), 1.1%]
Oman	[283 985 (3405), 1.2%]
Pakistan	[973 284 (22 582), 2.3%]
Qatar	[223 272 (599), 0.3%]
Saudi Arabia	[500 083 (7963), 1.6%]
Somalia	[14 995 (775), 5.2%]
Sudan	[36 959 (2774), 7.5%]
Syrian Arab Republic	[25 776 (1897), 7.4%]
Tunisia	[497 613 (16 388), 3.3%]
United Arab Emirates	[648 702 (1860), 0.3%]
Yemen	[6941 (1366), 19.7%]