Shaping local health policies during health emergencies: insights from WHO COVID-19 vaccine effectiveness study in the Eastern Mediterranean Region

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At the 73rd World Health Assembly on 19 May 2020, WHO Member States were encouraged to collaborate in advancing research and knowledge-sharing, particularly on vaccines, diagnostics and therapeutics, with funding by the private sector and governments across various domains, as a necessary measure to contain and halt the COVID-19 pandemic (*1*). Subsequently, global partnerships between public, private and philanthropic entities were established to expedite the development and deployment of COVID-19 vaccines (*2*). Early vaccine products received emergency use authorisation solely based on safety and efficacy findings from randomized controlled trials (RCTs) (*3*), because long-term safety and effectiveness observational studies are complex and resource-intensive (*4*), and there was an urgent need for data and evidence to support decisions and response to the pandemic. The constantly evolving nature of the pandemic, emergence of new viral variants, differences in vaccine access and distribution among countries, and dosing schedules for the different vaccines further complicated the analysis and interpretation of vaccine study results.

At that time, there were very few vaccine effectiveness studies in the Eastern Mediterranean Region (EMR) and there was limited or no data on specific vaccine products approved for use in EMR countries (*5,6*). Because EMR countries had primarily channelled their resources towards managing the pandemic's clinical impact, Member States requested WHO support in conducting vaccine effectiveness research to generate local evidence that could better inform COVID-19 vaccination policies at national level (*7*). Consequently, the leadership of the Incident Management Support Team at the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) initiated a rapid and comprehensive evidence generation response aimed to provide technical, operational and financial support for implementing such study in the EMR (*8*).

The regional COVID-19 vaccine effectiveness study commenced in September 2021 with the establishment of an ad-hoc multidisciplinary committee and technical team, consisting of WHO country representatives, clinicians, laboratory scientists, epidemiologists, bio/statisticians, public health practitioners, health policy experts, and contracted consultants. The technical team subsequently created a COVID-19 vaccine effectiveness dashboard and set up a central data entry platform (REDCap) to lay a solid foundation for sustainable vaccine effectiveness networking in the EMR (*9*).

Four EMR countries – Egypt, Islamic Republic of Iran, Jordan, Pakistan – were selected to participate in the study, which used the WHO protocol, design and methodology for evaluating COVID-19 vaccine effectiveness. The 2 main methods adopted were longitudinal study among a cohort of healthcare workers (HCWs Cohort) and test-negative case-control design (TND) for severe acute respiratory infection (SARI) cases.

Islamic Republic of Iran and Jordan adopted the TND for SARI method, while Egypt and Pakistan used the HCWs Cohort method. All studies were prospective, except in Islamic Republic of Iran where retrospective data were also included. The studies collected data from May 2021 to June 2023. The Iranian study involved 19 314 individuals in 8 provinces and 159 hospitals, Jordan's study included 1873 participants across 4 provinces and 4 hospitals, Egypt's cohort study included 1235 participants across 3 provinces and 5 hospitals, while Pakistan had 1472 participants in 1 province and 3 hospitals. The vaccines used for the studies were BBIBP-CorV (Covilo®, Sinopharm/BIBP), PiCoVacc (Coronavac®, Sinovac Biotech), AZD1222 (Vaxzevria®, AstraZeneca-Oxford), Gam-Covid-Vac (Sputnik V®, Gamaleya Institute), and (Comirnaty®, 61 Pfizer/BioNTech), along with a few additional domestically manufactured and authorized vaccines in Islamic Republic of Iran.

For the vaccine effectiveness study, WHO provided technical support to countries for the design,

conceptualization and vetting of technical proposals (*10*,*11*) through regular meetings, field visits and guidance on methodologies, data collection, management, and analysis. WHO convened several country-specific and region-wide forums to inform researchers about updates to the evaluation guidelines and enhance evidence-informed policymaking (*12*). Upon completion of the studies, WHO/EMRO organized an in-person technical consultative meeting for EMR stakeholders, including clinicians, researchers, regulators, and policymakers, to exchange ideas and share lessons.

WHO provided operational support to the 4 selected countries through direct communication with the national health authorities to streamline ethical clearance procedures, contracts development, funds allocation and disbursement, and timely procurement of necessary supplies for the research (e.g. test kits and laboratory equipment) despite global shortages.

The studies were concluded in December 2023 with lessons and recommendations for similar collaborative endeavours in the future. One critical takeaway was the importance of engaging diverse stakeholders from different countries, including the ministries of health, as well as academic, research and medical institutions in such research studies in the future because such inclusive approach could help reduce bureaucracy within participating countries and enhance administrative efficiency.

Although using a centralized electronic data entry platform such as REDCap was essential for efficient data management across the countries (ensuring transparency and quality assurance in data sharing), it is crucial to consider the resources needed for granting access and training each country's research team to use the platform. The skills of country-level research teams and their familiarity with the software and platforms should be accounted for during the preparatory phases.

The WHO protocols provide a flexible framework that is adaptable to specific country settings, but there were challenges due to variations in data collection, analysis and results presentation by the countries. This posed a barrier to the pooling of estimates and interpretation of results for large-scale (multinational) policymaking. More specific guidance is needed within the WHO protocols to address such variations and increase the ability to generate more robust datasets and standardized analyses.

Stakeholders have emphasized the need for sustainable capacity-building support by WHO to Member States' researchers and institutions. The focus should be on design, implementation, data analysis, and interpretation of results to effectively inform health policies.

Active involvement as well as timely and effective communication are vital when WHO is providing support to Member States during health emergencies. The results of this study have been published and it will inform COVID-19 immunization policies at the national and regional levels in the EMR (*13*).

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