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Commentary

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Introduction

Soon after the beginning of the COVID-19 pandemic (1), the World Health Organization (WHO), its global partners and Member States initiated a race towards the development and deployment of vaccines. In February 2020, WHO convened the first research meeting to discuss the new virus and ways to accelerate research priorities, including vaccine development (2). Public and private sectors joined hands in global cooperation for vaccine research and the efforts have paid off. Since June 2020, phase III randomized controlled trials of different vaccine candidates were underway around the world, including in several countries of the WHO Eastern Mediterranean Region (EMR). By November 2020, there were early reports of candidate vaccines' safety and efficacy, followed by peer-reviewed publications (3,4). Historically, this is unprecedented in the record time it has taken for effective vaccine development, and efforts are still ongoing. As of April 2021, there were at least 85 vaccines under clinical study, of which 28 had reached Phase III randomized controlled trials (5). Overall, multiple vaccine candidates have proven to be safe and effective (6–10).

In September 2020, WHO joined forces with Gavi the Vaccine Alliance and the Coalition for Epidemic Preparedness Innovations (CEPI) to create the COVAX Facility (11). COVAX aims to facilitate access to vaccines for all countries. Globally, 57 low- and middle-income countries are eligible for Gavi support. These, and an additional 35 middle-income countries, are eligible to access COVID-19 vaccines through the COVAX Advance Market Commitment (AMC). The AMC is a legally binding agreement for a fund amount to subsidize the purchase of a currently unavailable vaccine (12). Overall, 92 countries are eligible to this innovative financing mechanism that accelerates the global rollout of vaccines. High income and upper middle-income countries (World Bank country classifications by income level, 2020) can also access COVID-19 vaccines from the COVAX facility as Fully Self-Financing (FSF) participants (13). On 27 September 2020, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommended prioritizing initial vaccine use for the 20% of each country's population most vulnerable to severe disease and those at highest risk (14).

In December 2020, amid an increase in cases partly due to the emergence of variants of

concern (15,16), high-income countries started immunization programmes using vaccines procured through bilateral agreements. The COVAX Facility followed rapidly to allocate vaccines, starting with AMC countries (16). In January 2021, the WHO Director General pledged to introduce COVID-19 vaccines in all countries by the first 100 days of 2021 (i.e., by 12 April 2021), soon after World Health Day (7 April 2021). This article summarizes the regional efforts to fulfill this initial pledge towards the larger goal of vaccinating 20% of a country's population by the end of 2021.

Vaccine rollout and COVAX

The WHO Regional Office for the Eastern Mediterranean Region (EMRO) added a vaccine pillar to its COVID-19 Incident Management Support Team (IMST) (1), and reached out to the United Nations Children's Fund (UNICEF) and other partners to form a regional working group. EMRO supported countries through all steps of the COVAX allocation process, including (1) readiness assessment; (2) preparation of a National Deployment and Vaccination Plan (NDVP); (3) vaccine requests; (4) national emergency use authorization; (5) import license; and (6) indemnification and liability agreements. EMRO monitored country reports sent to WHO, purchase orders issued through COVAX, bilateral agreements officially announced, official internet sites of ministries of health, and press announcements. Progress was tracked at the global level for vaccines obtaining the necessary WHO emergency use listing; and at country level for the various steps of the allocation process and initiation of vaccination.

Vaccination coverage and monitoring of adverse events following immunization (AEFI)

A system was initiated to collect and report vaccine use data to WHO, monitor online sources of information (e.g., Our World in Data, Bloomberg), and centralize sources of information on vaccine coverage. A dashboard was created to visualize vaccine and regional data. Data were reviewed and analyzed on AEFI that had been reported through the Programme for international Drug Monitoring and the Uppsala Monitoring Centre. In addition, countries also shared adverse event data directly with WHO.

Results

All 22 EMR countries participated in COVAX, including 11 FSF countries and 11 AMC-supported countries, of which seven were Gavi eligible. A first wave of high-income EMR countries had initiated vaccinations from 14 December 2020 (Figure 1) and was followed by middle-income countries in January 2021. On 3 March 2021, Sudan received the first COVAX shipment in the Region; by 21 April 2021 all EMR countries had received vaccines and had started vaccination programmes. As of 21 April 2021, WHO has listed four vaccines (Comirnaty from Pfizer BioNtech, Covishield and Vaxzevria from AstraZeneca, and Janssen from Johnson and Johnson) for emergency use. By 28 February 2021, all EMR countries had been provided

with emergency use authorization for at least one COVID-19 vaccine. As of 21 April 2021, the 22 national regulatory authorities in the Region had also given emergency use authorization for a number of vaccines, including Covishield and Vaxzevria (n=22), Sputnik V (n=14), Comirnaty (n=11), Sinopharm, (n=11), Janssen (n=4), Coronavac (n=2), Convidicea (n=1) and Covaxin (n=1).

As of 21 April 2021, global monitoring sources indicated that 33.4 million doses had been administered in 21 countries in the Region (Figure 2). Meanwhile, only 21.4 million (64% of total administered) doses had been reported to WHO. The median ratio of doses administered by population was 5/100 population overall; the highest ratios were in the United Arab Emirates (98/100) and Morocco (24/100, Figure 3).

As of 21 April 2021, 12 393 cases of adverse effects were reported to the WHO global data base (Vigibase) of the WHO Programme for international Drug Monitoring, developed and maintained by the Uppsala Monitoring Centre (WHO Collaborating Centre); of these, 1.9% were serious. Females accounted for 55.2% of cases and the median age class was 45–64 years. The AstraZeneca vaccines accounted for the largest proportion of AEFI (74.3%, respectively). The majority of vaccine-related adverse effects were mild and related to general disorders and administration site conditions. The four most common adverse effects were headache (23.4%), fatigue (21.4%), asthenia (21.3%) and pyrexia (19.8%).

Discussion

All the EMR countries have managed to deploy vaccines and initiate vaccination programmes against COVID-19 at an unprecedented rate – by the 111th day of 2021. This achievement was made possible through a systematic approach that ensured solid national plans, predicted needs, engaged national regulatory authorities and strengthened logistics. All these interventions have the potential to strengthen immunization systems in the long term.

At least seven countries of the Region have participated in randomized clinical trials that have contributed to the development of COVID-19 vaccines. A number of studies are still ongoing and further efforts should be devoted to vaccine effectiveness studies and Phase IV randomized controlled trials (6). Such capacities not only enhance the knowledge needed for continuous response to the COVID-19 pandemic, but will also enhance the knowledge base for vaccine research in the Region beyond the COVID-19 response.

Vaccine deployment in the Region has reflected regional differences in capacities and

resources. High-income countries have vaccinated first, while middle-income countries followed rapidly, including bilateral agreements for the use of vaccines from China and Russia. The COVAX facility distributed its first vaccine in the Region approximately two months after the first EMR country started vaccination. This opened the way for deployment of the vaccine in low-income, Gavi-eligible countries that could not have afforded it otherwise, as well as in countries experiencing humanitarian emergencies.

Reported data pointed to a larger use of vaccine in countries of the Region with stronger health systems and substantial resources. However, Morocco – a middle-income country – constituted an exception after having administered doses to approximately 25% of the total population by 21 April 2021. Unfortunately, for most countries the data were not available for WHO to capture actual coverage by target groups. Information was often missing on the number of different high-risk and vulnerable population groups and on the characteristics of the vaccine recipients, e.g. age, sex, persons with comorbidities, professions, etc. In addition, vaccination coverage data among vulnerable population groups (e.g., refugees, migrants and people experiencing emergencies or humanitarian situations [7,8]) were not available in most countries. The COVAX allocation process based on equality within the context of heterogeneous epidemiological situations also represented a challenge in the Region.

Historically, vaccines have had high acceptance in the Region (9). However, the COVID-19 pandemic was characterized by the rise of ‘infodemics’ (10) and the spread of misinformation. Selected surveys in 13 EMR countries reported evidence of hesitancy to take COVID-19 vaccines (17–19); the highest being in Egypt, Iraq, Jordan and Tunisia, and the lowest in Afghanistan, Morocco and United Arab Emirates. Providing clear and consistent information, building trust and transparency around the vaccine’s development and distribution will improve uptake. Securing broader demand will be key to its long-term success, even if it is not critical in the initial phase of the deployment.

Adverse Events Following Immunization (AEFI) surveillance in the Region supports the hypothesis that COVID-19 vaccines are safe, even though large clinical trials had not captured a number of rare adverse events that were only detected through post-marketing surveillance (10). Thus, vaccine safety systems in the Region need to be further strengthened to monitor safety more closely, particularly in contexts where vaccinated persons are older or with pre-existing conditions.

Conclusions and recommendations

Unprecedented speed in vaccine development and deployment has led to the introduction of COVID-19 vaccines in all 22 EMR countries by 21 April 2021. In addition, the COVAX Facility

successfully secured access to low-income countries and countries in emergencies. Vaccination programmes often started well with health-care workers, but as of 21 April 2021, uptake still remained low and unequal across countries. Vaccine acceptance rates need to be monitored even though no major safety signals have been detected in the Region. Going forward, EMRO remains mobilized to building on this important start. Since no-one will be safe until everyone is safe, we need to increase coverage in an equitable manner across countries. Marginalized and underprivileged communities, including refugees, migrants and people living in humanitarian settings, are to be included in the national vaccination plan in accordance with SAGE recommendations. In addition, we need to build trust in populations to support community engagement, including strengthening our vaccine safety systems. These efforts should contribute to the achievement of the goal of ending the acute phase of the pandemic by the end of 2021, while establishing a platform for implementing a life-course approach to adult immunization – a priority of the Immunization Agenda 2030 (11).

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