Table 2 Challenges encountered during implementation of COVID-19 vaccine effectiveness studies in Eastern Mediterranean Region

General challenges
• Changing landscape of COVID-19 epidemiology and vaccination during study implementation
• Complex vaccination programmes (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, such as the use of rapid diagnostic test instead of PCR testing for diagnosis of COVID-19 positive cases
Specific challenges for individual countries
• Inadequate access to necessary infrastructures or supplies (e.g. absence of electronic medical record systems, the need for specific laboratory equipment, antibody and genetic sequencing test kits)
• Study interruption due to unforeseen circumstances (e.g. natural disaster)
• Missing data due to difficulty with tracing and tracking of study participants (e.g. collecting blood samples or nasopharyngeal swabs during the fasting month of Ramadan, particularly in the cohort study among healthcare workers)
• Inability to reach adequate (target) sample size for certain countries where vaccination coverage was higher (e.g. difficulty recruiting controls among healthcare workers in the cohort design or identifying cases in the test-negative designs in SARI surveillance sites, challenges of obtaining informed consent forms, loss to follow-up)
• Amendments and adjustments to the study design post-implementation; since this was an emergent disease, new vaccination guidelines became available during the implementation phases of the vaccine effectiveness studies (e.g. expansion of the target population to include pediatric age groups in certain countries)
Specific challenges across countries
• 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