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The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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Active COVID-19 safety surveillance in Africa: update & lessons learnt

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BACKGROUND- Pharmacovigilance (PV) systems in low and middle income countries (LMICs) are limited due to resource and expertise constraints. The disparities between PV systems globally were highlighted during the COVID-19 pandemic. Two demonstration projects were established in Africa to estimate the risk of predefined adverse events of special interest (AESIs) with acute onset and short period of increased risk following immunization of the COVID-19 vaccine using a self-controlled risk interval (SCRI) study design. Predefined AESIs included generalized convulsions, myocarditis, pericarditis, anaphylaxis, thrombocytopenia, thrombocytopenia syndrome (TTS), Guillain Barré syndrome (GBS), Miller Fisher Syndrome (MFS), Acute Disseminated encephalomyelitis (ADEM), encephalitis, and myelitis.

METHODS- Hospital-based sentinel active COVID-19 vaccine safety surveillance studies were established at facilities across nine African countries: (i) **A**ctive **C**OVID-19 **va**ccine **s**afety **s**urveillance (ACVaSS) in eight COVAX-92 Advanced Market Commitment (AMC-92) eligible countries including Ethiopia, Ghana, Kenya, Mali, Malawi, Mozambique, Nigeria and Eswatini and (ii) the South African COVID-19 vaccine safety surveillance study. Patients presenting to hospital with an acute illness suggestive of a predefined AESIs were screened for study participation, and eligible, consenting patients were enrolled between October 2021 (SA)/ April 2022 (ACVaSS) and March 2023. Data were collected from medical records, COVID-19 vaccination cards and registers, and from the patient and entered into a study-specific, centralised REDCap database, and were analysed using R software version 4.3.1. Brighton Collaboration case definitions were used. The ACVaSS study was funded by Gavi, The Vaccine initiative, and the South African study was funded by the Global Vaccine Data Network (GVDN). GVDN provided technical support to both studies.

RESULTS- A total of 60 511 patients were screened on hospital admission, of whom 12 756 were enrolled into the studies. Challenges encountered included delays in obtaining ethics approvals and establishing sites; limited laboratory- and imaging capacity and limited access to medical- and vaccination records.

CONCLUSIONS- These studies have demonstrated that establishment of sentinel active surveillance sites is feasible in LMICs, despite challenges encountered.