

Pharmacovigilance monitoring of COVID-19 vaccines in Niger

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Background

Between April 2021 and March 2022, a total of 2,180,972 people in Niger received a first dose of COVID-19 vaccine and 1,545,630 people were considered fully vaccinated (i.e. 15% of the eligible population). Vaccines available were Sinopharm, AstraZeneca, Janssen and Pfizer with all persons aged 18 and above eligible for vaccination with prioritization depending upon supply. From May 2021, the Ministry of Health (MoH) in collaboration with the WHO and Epicentre implemented activities to rapidly detect adverse events following immunization (AEFI).

Methodology

Active pharmacovigilance monitoring was conducted at 3 sites (United Nations Dispensary in Niamey, Hospital District Niamey I and an urban health clinic in Maradi). Any adult presenting for primary vaccination and consenting to participate was eligible for inclusion. At enrollment, information on vaccine administered, demographic data, and medical history were collected. Reactogenicity data (i.e. local and systemic reactions) were collected through the remote completion of a questionnaire every day for one week. Any other AEFI were collected through monthly calls up to 4 months after 1 dose and 2 months after 2 doses. Data were entered into a secured REDCap database with summary information transmitted weekly to the MoH and WHO.

Results

As of February 2022, 1229 individuals were included with 55% receiving a dose of the Janssen vaccine (n=678), 44% the two doses of AstraZeneca (n=540) and the remainder receiving Pfizer or Sinopharm. Reactogenicity was poorly documented during the week following vaccination, with 7% (n=91) of participants fully answering questionnaires. A total of 782 AEFIs including 7 serious events were documented through monthly calls. All adverse events were resolved except one (erythema multiform). The main AEs reported were fever (25%), headache (21%) and fatigue (16%).

Conclusion

This is the first implementation of active pharmacovigilance follow-up in Niger. Follow-up of vaccinees has provided important information on safety to the MoH.

Pharmacovigilance: The implementation of this activity at vaccination sites and the collection of data is an important step to ensure the safety of the population of Niger.

