Active Surveillance of Adverse Events Following Immunization amongEthiopian Population with Pfizer-BioNTech Covid-19 vaccine

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Introduction:

Vaccines represent one of the greatest public health achievements for combating the COVID-19 pandemic. Although vaccines against SARS-CoV-2 have demonstrated excellent safety profiles in clinical trials, real-world surveillance of post-vaccination side effects is an impetus. TheEthiopian Food and Drug Authority (EFDA) is conducting intensive monitoring of COVID-19 vaccine safety using an active and passive surveillance to identify Adverse Events Following Immunizations (AEFIs). EFDA investigates and assesses serious AEFI reports and conducts causality analysis where necessary and take appropriate actions accordingly.

Objective:

The aim of this study was to investigate the incidence, type and seriousness of adverse event following the administration of the first dose of the Pfizer-BioNTech vaccine in Ethiopia.

Method:

A multicenter prospective cohort event monitoring study design was used to collect the data using active surveillance from five regions and two city administrations of Ethiopia. A total of 10,947 were in rolled with Pfizer vaccine obtaining their consent. Participants were observed at the site of vaccination for 30 minutes following immunization. Details about AEFIs occurring within 30 days of follow up period were collected via telephone calls on every other day (on day 2,4,7) for the first week and then weekly (on week-2, 3 and 4) by 4 trained data collectors. Data collection process was supervised by experts from the Product Safety Directorate of the EFDA and other exerts from EFDA Branch offices. The data was collected from selected 24 health facilities from November 15, 2021 to March 28,2022.

Result:

Out of a total 10,947 active surveillance participants, 3851 (35.18 %) vaccine recipients reported at least one AEFI symptom following COVID -19 vaccination. The mean (±SD) age of the participants was 16(10.5) years and more than half (56.6 %) of them were females. From the total, only 69 (0.6%) of them had one or more comorbidities. Of which, hypertension (17, 24.6%) and diabetes (15, 21.7%) were the most frequent comorbidities. From a total of 3851 participants with AEFI, the occurrence of AEFI before and after 30minutes of post vaccination were 83 (2.2 %) and 3603 (94.1%), respectively. Of which, injection site pain/redness/swelling (48.68%) and headache (18.62%), were the most frequently reported AEFIs after 30 minutes of vaccination. Out of a total participant who reported experiencing AEFI, a total of 4531 AEFI were reported. The rate of reports of AEFI was 1.26 per person. Injection site pain/redness/swelling (48.02 %), headache (17.15 %), fever (9.50%), body weakness/ tiredness/fatigue (3.14%) and arthralgia/joint pain (2.57 %) were the top five types of AEFIs reported by the active surveillance participants. Among serious AEFIs cases, 7 were requiring hospitalization and then fully recovered, whereas, one AEFI result in death. The National Pharmacovigilance Safety Advisory committee reviewed the serious cases and classify as follows, 4 cases were in consistent/product related, 2 cases were coincidental and one case was indeterminate (1) to Covid-19 vaccine.

Conclusion and recommendation

More than one-third the participants were experienced one or more AEFIs. Most AEFI were generally mild to moderate and frequently reported after 30 minutes of vaccination. Most of the AEFI encountered were in the age group of 12 to 18. Therefore, these AEFI are not a significant concern in recommending vaccination.