Active Safety Surveillance of Janssen (Johnson & Johnson) COVID 19 Vaccine: A National Study from Ethiopia

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Introduction:

The Janssen (Johnson & Johnson=J&J) COVID-19 vaccine was granted emergency approval by the Ethiopian Food and Drug Authority (EFDA) in May 2021. As almost all the currently available information on safety of J&J COVID-19 Vaccine have been provided by the vaccine manufacturers during clinical trials, ongoing vaccine safety monitoring is important. Monitoring the safety of all health products (medicines, vaccines, medical devices) is one of the EFDA's key functions. Thus, this active surveillance was conducted to monitor the safety of J&J COVID-19 Vaccine in Ethiopian population.

Objective:

To assess safety of J&J COVID-19 vaccine through evaluating incidence, types and seriousness of adverse events following immunization (AEFIs).

Method:

Active surveillance was conducted between August 21, 2021 to June 20, 2022 at conveniently selected health facilities from seven regions and two city administrations of Ethiopia. A total of 10,262 adults vaccinated with J&J COVID-19 vaccine were recruited after obtaining their consent.

Sociodemographic data and information on comorbidities were collected from participants before vaccination. 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 day 2, 4 and 7 for the 1st week and then weekly on week-2, 3- and 4 by trained data collectors. Data collection process was supervised by experts from

the Product Safety Directorate of the EFDA.

Results:

The median age of the participants was 37(range=18-98) years. The overall incidence of AEFIs was 44.51%. 97(2.1%) participants reported encountering immediate AEFIs within 30 minutes of vaccination and injection site pain, headache, fever and nausea/vomiting were the most common immediate AEFIs reported.

Of the total 4568 participants who had AEFIs, 4430(97%) reported facing one or more AEFIs after 30 minutes of taking the vaccine. Injection site pain, headache, fever, joint pain and fatigue were the top three types of AEFIs reported. Most of the AEFIs were reported as non-serious.

However, 15 AEFI cases were reported as serious: 7 death, 6 hospitalizations and 2 spontaneous abortions.

The National Safety Advisory Committee reviewed and assessed serious adverse events reported after immunization with Janssen COVID-19 Vaccine and established whether or not they are associated with the use of the J&J COVID-19 vaccine. The National Pharmacovigilance Safety Advisory Committee classified 8 of the serious cases as a vaccine product-related events where immunization with the J&J COVID-19 Vaccine was associated with the occurrence of adverse events in the vaccine recipients.

Conclusion and Recommendations:

The overall incidence of AEFIs with J&J COVID-19 vaccine was 44.51%. Injection site pain, headache, fever, joint pain and fatigue are the most frequent AEFIs reported. As most of the AEFIs were non-serious, based on the available evidences and findings of this active surveillance, the benefits of the J&J COVID-19 vaccine in terms of preventing serious and severe Covid-19 infections and mortality greatly outweigh the rare risk of serious adverse events. However, EFDA is committed to monitor the safety of COVID-19 Vaccines through ongoing review and analysis of all reported adverse events and conducting active surveillances.