Covishield COVID-19 Vaccine Safety Monitoring and Surveillance Finding Report from March 22, 2021 to June 20, 2021 in Ethiopia.

Background

In response to SARS-CoV-2 (COVID-19) pandemic, vaccines were developed and deployed for use. EFDA conducted post-market adverse events monitoring on the authorized AstraZeneca's COVID-19 vaccine (Covishield). This report provides a summary of the type and extent of adverse events following immunization (AEFIs). AEFIs described in this report are defined as any untoward medical occurrences that are followed immunization and do not necessarily have a causal relationship with the vaccine.

Objective

To determine the occurrence and types of adverse events following the first dose of AstraZeneca's /Covishield/ COVID-19 vaccine from March 22, 2021 to June 20, 2021 in Ethiopia.

Methodology

Active surveillance was conducted on 11476 participants who received the first dose of Covishield COVID-19 vaccine after obtaining their consent. Participants were recruited from Addis Ababa, Amhara, Harari and Oromia Regional States. Participants were observed for the first 30 minutes after vaccination at the vaccination site. Then, the participants were followed-up daily for seven days and weekly via telephone for consecutive 3 months from March 22, 2021 to June 20, 2021. As there were incomplete data in each variable, intention-to-treat analysis is used to analyze the data along with SPSS version 25.

Results

Sociodemographic and Clinical Characteristics of Participants

Participants from Addis Ababa took the majority (91.1%) followed by Harari, Oromia and Amhara, 4.4 %, 2.7%, and 1.1% respectively. The mean (±SD) age of the participants was 46.61(±17.83) years. 45% were females, of which, there were 7 lactating and 8 pregnant women. Nearly one-third (3578, 31.4%) of the participants were taking one or more medications for their co-morbid condition.

Prevalence of AEFI

Out of 11476 participants 4970 (43.3%) reported one or more AEFIs. Most of the AEFIs were reported as non-serious.

Five lactating and 5 pregnant women reported AEFIs. One-fourth of the AEFIs were people on medication for their comorbidities.

AEFI within 30 minutes following vaccination

From a total of 4970 participants who experienced AEFI, 101 (2%) encountered one or more AEFIs within 30 minutes. For details check the table below:

Table 1. AEFI within 30minutes (N= 101).

AEFIs within 30 minutes	Frequency	Percent (%)
Blurred vision	4	4.0
Body weakness/ tiredness	**9**	**8.9**
Burning sensation	3	3.0
Dizziness	4	4.0
Fever	**8**	**7.9**
Headache	**22**	**21.8**
Injection site pain	**12**	**11.9**
Nausea	6	5.9
Two or more AEFIs	19	18.8
Others	14	13.9

Key: *Injection site pain and nausea as well as sweating and chills were most frequent in those with ≥2 AEFIs. Others include dizziness, palpitation and vertigo.*

As most of the AEFIs encountered were mild and/or

moderate, only 10 of the 101 participants received medications mainly for headache and to relieve pain.

AEFI after 30 minutes

From a total of 4970 participants who experienced AEFI, 4608 (92.7%) reported one or more AEFIs 30 min. after vaccination. Headache (31.3%), injection site pain /redness/ swelling/numbness (21.8%) chills, (14.9%), fever (12.2%) and arthralgia/joint pain (6.1%) were the most frequently reported AEFIs after 30 minutes of vaccination.

Most the AEFIs encountered after 30 minutes were mild and/or moderate and the majority of AEFIs (85.9%) were encountered within the first 24 hours' post-vaccination. Moreover, almost all (99.8%) of the AEFIs were reported within a week following vaccination. Out of the 4608 participants with AEFIs after 30 minutes, 22.7 % have taken medications; 75 % of them took paracetamol, ibuprofen and diclofenac being the 2nd and 3rd commonly used medications. Majority of those who received treatments for AEFIs encountered after 30 minutes were fully recovered within a week. At the end of the follow up period, almost all participants who had AEFI and took treatment were fully recovered.

AEFIs reported as Serious

A total of 29 cases were reported as serious AEFIs. Twenty-eight of these cases were carefully investigated by EFDA while one was not due to insufficient information. Of which, 10 were classified as non-serious, 8 were fully recovered and causality assessment was done on the remaining 10 serious AEFIs by the National Pharmaco-vigilance Advisory Committee. The causality assessment classified four cases as coincidental, one product related and five indeterminate.

Challenges

- Data collectors' and encoders knowledge gap in categorizing seriousness of cases
- Tight schedule between the initiation of vaccination versus the active surveillance
- Use of hard copies while soft copies would have been a short cut
- Shortage of human resources and logistics / transportation
- Inadequate cooperation of health facilities for professionals deployed by EFDA for investigation of cases

Recommendations

- Strengthening AEFI surveillance system
- Selecting and training proper data collectors and encoders
- Promoting/advocating of EFDA's mandate
- Improving coordination and communication with health facilities and stakeholders.

Summary

From the total of 11476 participants followed during active surveillance, 4970 (43.31 %) experienced one or

more AEFIs. Most of the AEFIs reported were mild and/or moderate and occurred within 24 hour following vaccination. Headache, injection site pain and fatigue/body weakness were the most frequently reported AEFIs. Moreover, out of a total 28 serious AEFIs reported, 10 were classified as non-serious, 8 were fully recovered and causality assessment was done on the remaining 10 serious AEFI cases.