Pfizer COVID-19 Vaccine Safety Monitoring and Surveillance in Ethiopia.

Adverse Events Following Immunizations (AEFIs) Reports of Pfizer-BioNTech Covid-19 Vaccine in Ethiopia for two round campaigns from Nov 15, to Nov 28,2021 and Feb14, to Feb 28,2022

July 2022

Addis Ababa, Ethiopia.

1. Introduction

Adverse Events Following Immunizations (AEFIs) are reported to Ethiopian Food and Drug Authority (EFDA) by health care providers and vaccine recipients. EFDA investigates and assesses all AEFI reports and conducts causality analysis where necessary and take appropriate actions accordingly.

This report provides a summary of adverse events following immunization (AEFIs) that are temporally associated (i.e., occur after receiving the vaccine) with receipt of Pfizer-BioNTech Covid-19 vaccine. It is important to note that AEFIs described in this report are defined as any untoward medical occurrences that followed immunization and do not necessarily have a causal relationship with the vaccine.

The Covid-19 vaccine on which surveillance is conducted is manufactured by Pfizer-BioN Tech (Pfizer vaccine) with batch number of 330068D, 33006BD, FL3201, FH8012 - FH8029, FJ8764, FH8029, FL3201 - FL3235, FC3201, FH8029, 3006FD, FL3189, PAA173696, PAA173393, PAA17369 with expiry dates of 16/12/2021, 17/12/2021, 20/12/2021, 28/2/2022, 28/6/2022 June -2022, February-2022, respectively.

During this active surveillance, 10,947 participants who received the first dose of Pfizer-BioN Tech Covid-19 vaccine were recruited after obtaining their consent. Vaccine recipients were observed for the first 30 minutes after vaccination at the vaccination site, followed by phone call every other day (on day 2, 4, 7) for the 1st week and then weekly (on week-2, week -3, and week-4) via telephone for the consecutive weeks in two round campaigns from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022.

Out of the 10,947 participants followed, a total of 3851 reported one or more AEFI and were considered for analysis. Thus, the total prevalence rate of AEFI in this surveillance is calculated to be 35.18 %. As there were incomplete data in each variable, missing values are excluded and percentages are based on the number of non-missing values (only the complete data is used to compute frequency and percentage).

1.1 Active surveillance participant by regions for Pfizer's Covid-19 vaccine

Active surveillance on Pfizer's Covid-19 vaccine was conducted in five regions (Harari, Oromia, Sidama, Southern Nations, Nationalities, and Peoples, and South West Ethiopia) and two city administrations (Addis Ababa and Dire Dawa). As described in Figure 1 below, majority of the data were collected from Addis Ababa (75.2%) followed by Oromia (6.4%) and Dire Dawa (5.5%).

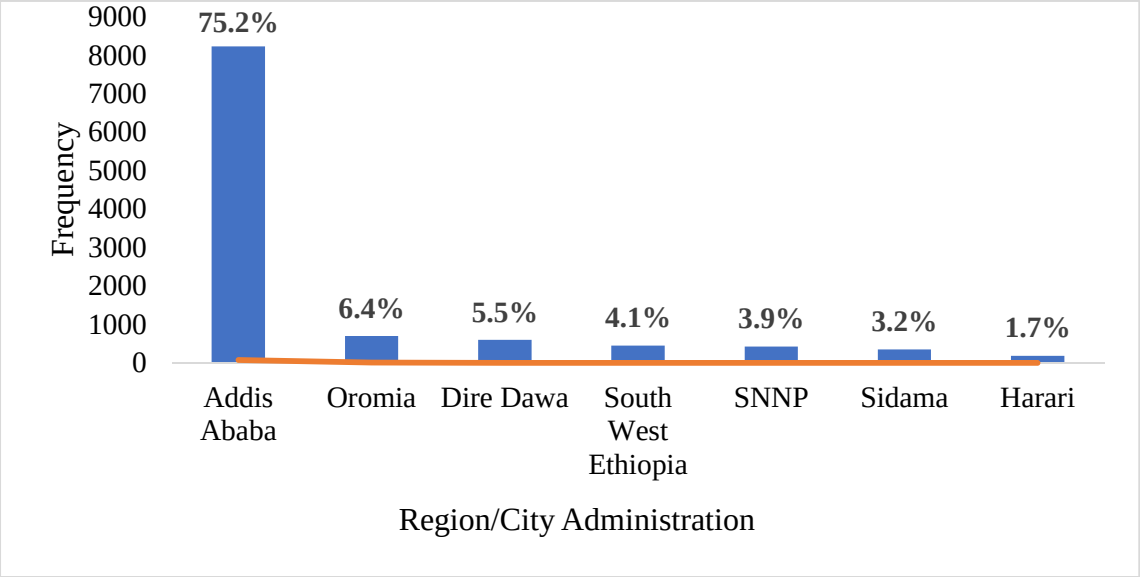

Figure 1: Active surveillance participant by regions for Pfizer Covid-19 vaccine in two round campaigns from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022, Ethiopia (N= 10,947).

1.2 Sociodemographic Characteristics of active surveillance participants for Pfizer's Covid-19 vaccine

From a total of 10,854 vaccine recipients, the median (±SD) age of the participants was 16(10.5) years with a range of 11 to 97. Out of the total, the most frequent age was **14 years (1694, 15.5%),** followed by 13 years (1439, 13.1 %), and then 30 (487, 4.3%) years. (See in Figure 2) (Missing Value = 93)

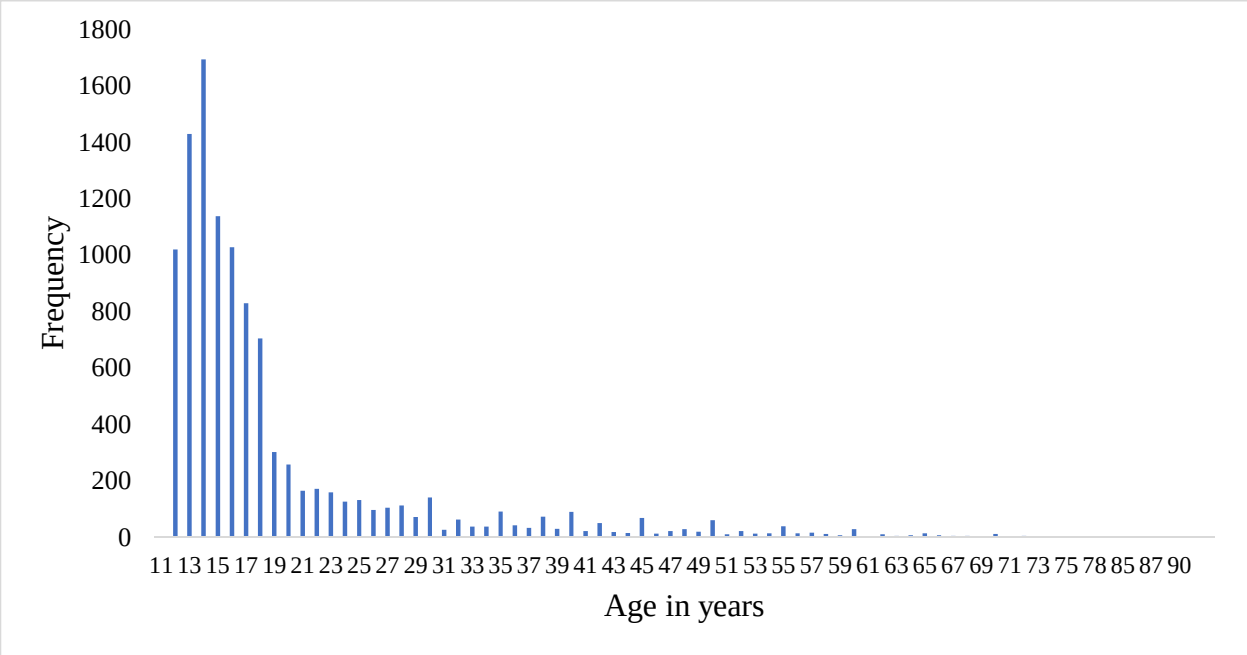

Figure 2: Age distribution of active surveillance participant from Nov 15 to Feb 28,2022, Ethiopia (N= 10,854).

From a total of 10, 885 participants (missing value = 62), more than half (56.6 %) were females and 43.4 % were males. Among the females, 77 (1.2%) were lactating and 8(0.1%) were pregnant women. (See in Figure 3)

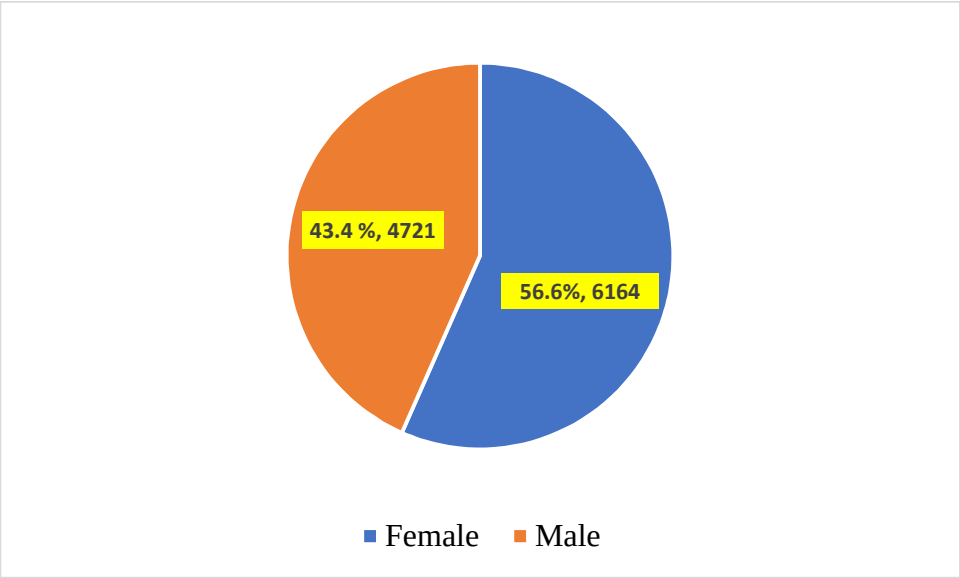

Figure 3: - Gender distribution of all vaccine recipients from Nov 15 to Feb 28,2022, Ethiopia (N=10885, Missing values=62).

1.3 Clinical characteristics of participants with AEFI and non-AEFI

At the start of the follow up, the active surveillance participants were asked about the medications they are using. Out a total of 10,924 vaccine recipients (missing value 23), only 94 participants (0.9%,) responded being on medication for their acute and chronic diseases. The most commonly used category of drugs by the 94 participants who reported using medications at the time of vaccination were anti-infectives, ART drugs, cardiovascular and antidiabetic drugs (Table 1).

Table 1: - Classes of drugs used by the participants at the vaccination time for the treatment of acute and chronic diseases from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022, Ethiopia (n=94).

Class of Drugs	Frequency	Percent (%)
ART Drugs	15	**16.0**
Antidiabetic Drugs	13	13.8
Cardiovascular Drugs	15	16.0
Anti-infective Drugs	19	20.2
CNS Drugs	3	3.2
GI Drugs	4	4.3
Respiratory Drugs	3	3.2
NSAIDS	3	3.2
Others	6	6.4
Unspecified	13	13.8
Total	94	100

1.4 Types of co-morbidities of all vaccine recipients

Out of a total 10,618 participants (missing value 329), only 69 (0.6%) of them had one or more comorbidity. Among the 69 participants who reported having one or more comorbid diseases, the majority 17 (24.6%) reported having hypertension followed by diabetes, HIV/AIDS and asthma/chronic lung diseases (See in Figure 4).

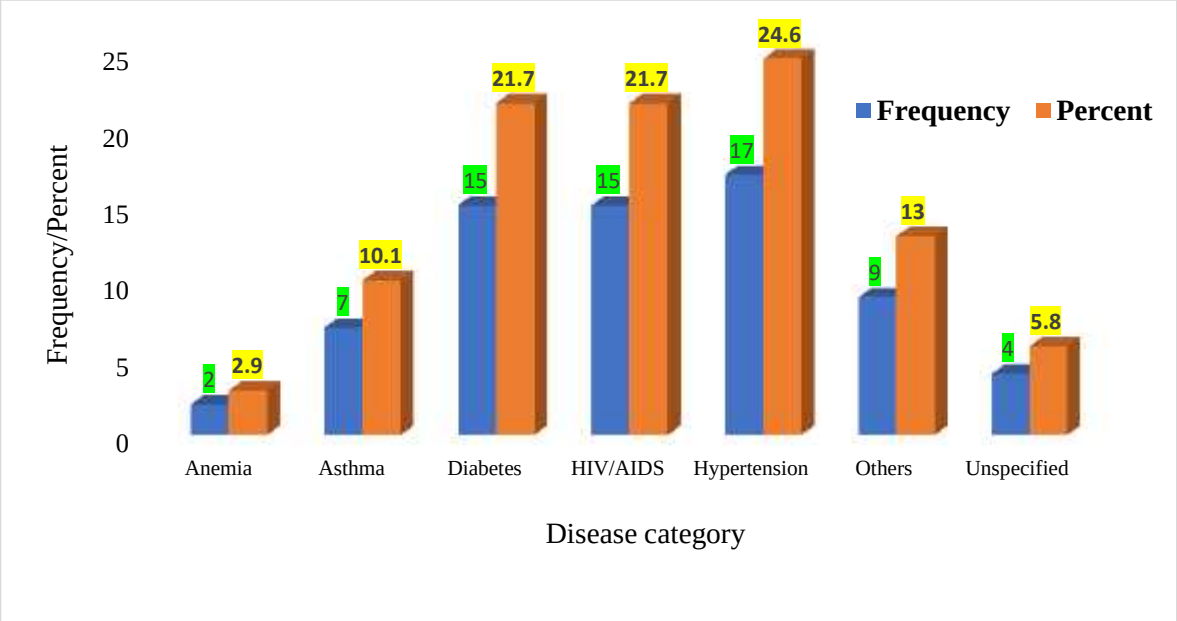

Figure 4: Types and frequency/percent of comorbidities reported by the participants from Nov 15 to Feb 28,2022, Ethiopia (n=69)

2. Active surveillance participants with AEFI for Pfizer-BioNTech Covid-19 vaccine

2.1 Sociodemographic characteristics of participants with AEFI by region

From a total of 10,947 participants, 35.18% (3851) of them encountered with one or more AEFIs. Pfizer covid-19 vaccine was distributed to different regions of Ethiopia to vaccinate individuals considered as age ≥12 years of population. Among the regions included in the active surveillance, the majority of the participants, who developed one or more AEFIs –were from Addis Ababa which accounted for (68.0%, 2,621), followed by Dire Dawa (9.2 %, 354), and then Oromia (7.0 %, 269) (See in Figure 5)

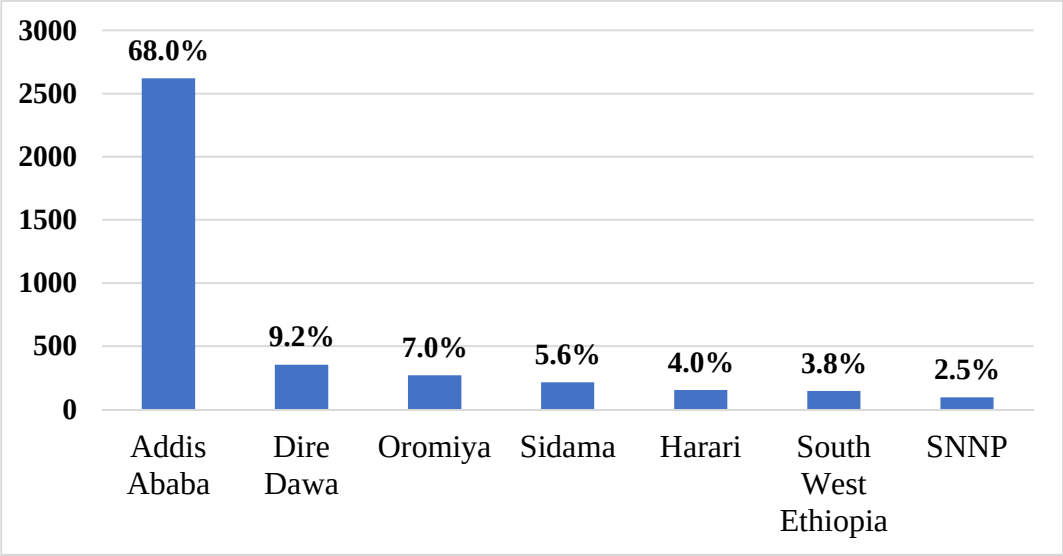

Figure5: Active surveillance participants for Pfizer vaccine, reported AEFI by region from Nov 15 to Feb 28,2022, Ethiopia (N= 3851).

2.2 Sociodemographic characteristics of participants with AEFI by city /towns

The occurrence of AEFI among the four city/towns was reported as follows. Addis Ababa accounts for two-third (67.9%, 2616), followed by Dire Dawa (9.1 %, 352), and then Hawassa (5.8%, 223). (Missing Value= 9) (See in Figure 6).

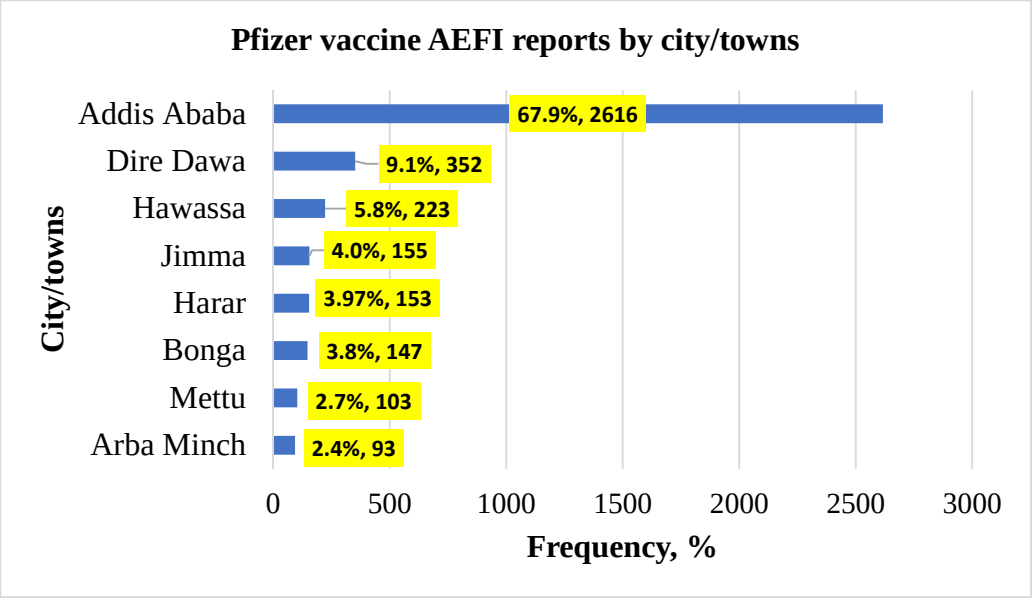

Figure 6. Pfizer vaccine AEFI reports by city/towns for participants with AEFI in two round campaigns from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022, Ethiopia (N= 3843).

Out the total participants who developed AEFI, 2151 (56.25%) were females and 1673(43.75%) were males. Among the females, 44 lactating and 2 pregnant women reported encountering one or more AEFI. The mean (±SD) age of participants with AEFI was 19.12(± 9.91) years with a range of 11 to 97. Age between 12 to 18 years were the most frequently encountered group of population with AEFI (Figure 7, Missing value =41). The height and weight of participants with AEFI were described in Table 2.

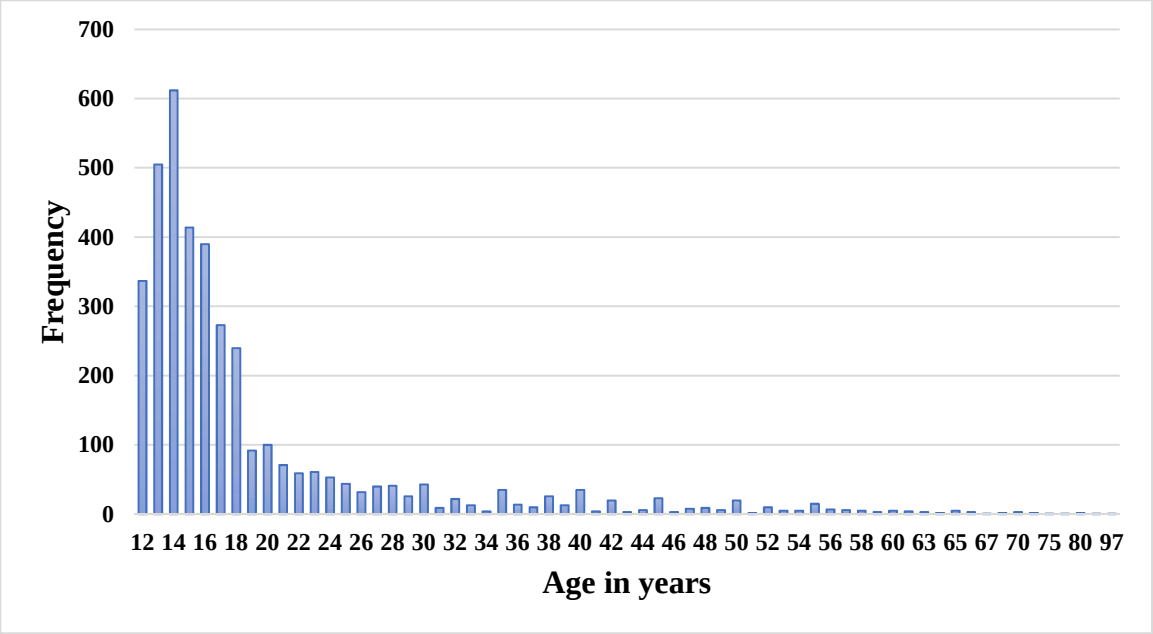

Figure 7. Age distribution of vaccine recipients with AEFI from Nov 15 to Feb 28,2022, Ethiopia (N= 3811)

Table2. Sociodemographic characteristics of vaccinee for Pfizer vaccine with AEFI from Nov 15 to Feb 28,2022, Ethiopia.

Characteristics	Variables	Frequency	Remark
Age in years	Mean (±SD), Range	19.12(± 9.91) years, 12-97	41 incomplete data
Gender	Male (%)	1673(43.75%)	27 incomplete data
	Female (%)	2161 (56.25 %)	
Height (cm)	Mean (±SD), Range	155cm (± 19.8) 120-190	3679 incomplete data
Weight (kg)	Mean (±SD), range	52.31 kg (±16.33) 23 - 90	3287 incomplete data

2.3 Clinical characteristics of participants with AEFI

2.3.1 Class of drugs taken by participant with AEFI for various disease at the time of vaccination.

Out of the total 3847 participants with AEFI, only 1.4% (55) of the participants reported taking one or more medication. Of them, antidiabetic drugs (9, 16.4%) and antiretroviral drugs (9, 16.4%) were the leading medication taking by the participants followed by antibiotics (7, 12,7%) and cardiovascular (7, 12.7%) (See Figure 8).

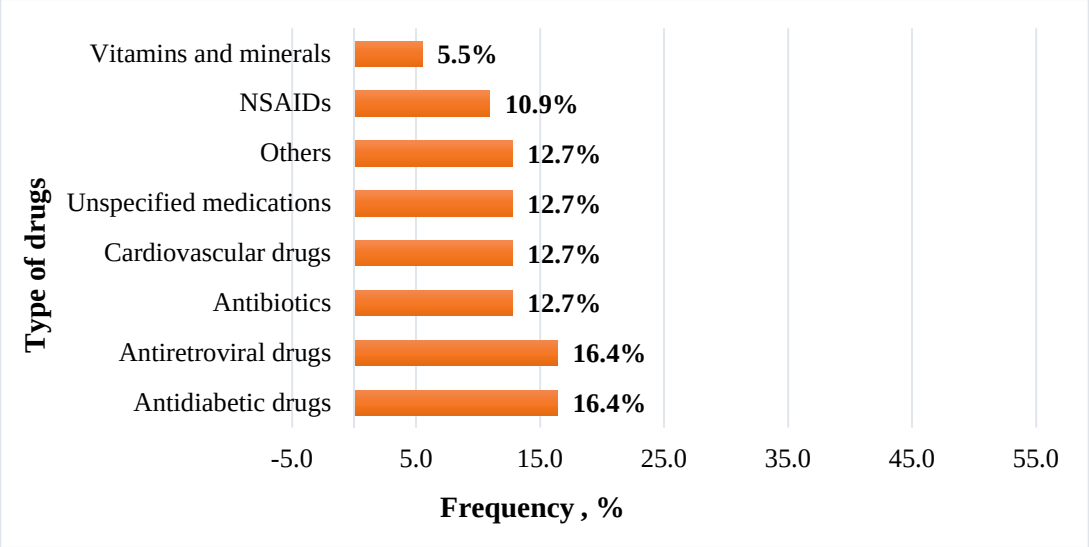

Figure 8. Class of drugs used by vaccine recipients with AEFI from Nov 15 to Feb 28,2022, Ethiopia (n=55)

Others includes anti-TB, Phenobarbitone, Omeprazole, Amitriptyline, antithyroid drugs.

2.3.2 Types of common comorbid disease of vaccine recipients with AEFI

In this surveillance, from 3658 (Missing Value 193) participants with AEFI, only (1.34%, 49) were having a co-morbid disease. Of which, diabetes mellitus accounts for 22.4 % (11), followed by HIV/AIDS 20.4% (10), and then hypertension 18.4 % (9). (See Figure 9)

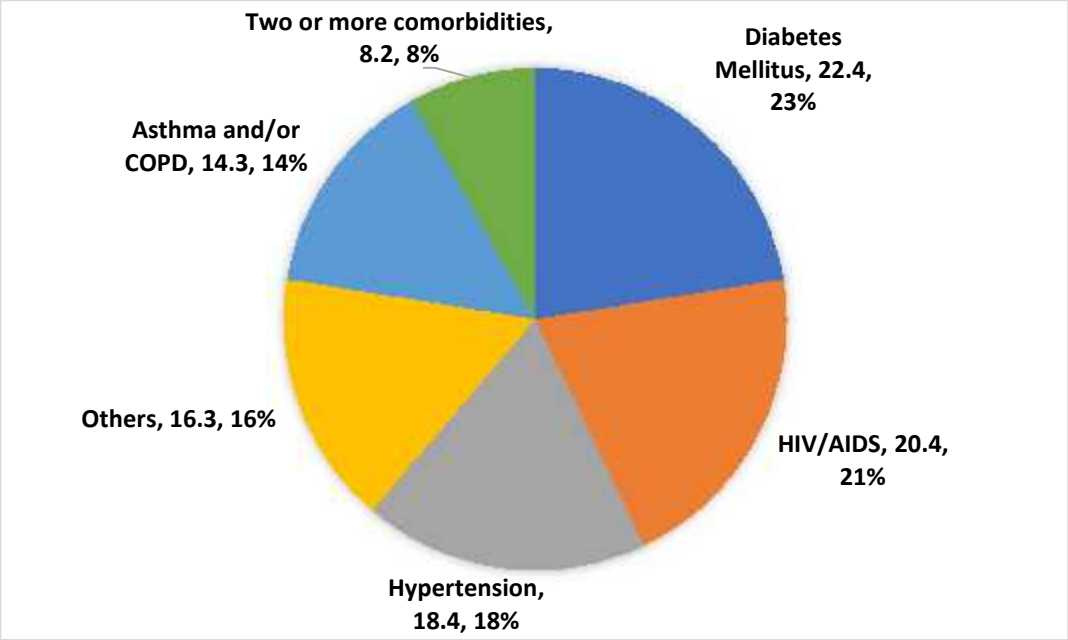

Figure 9. Type of common comorbidities of participants with AEFI in two round campaigns from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022, Ethiopia (n=49)

Key: Multiple comorbidities include diabetes and hypertension, hypertension and asthma, Others includes anemia, heart failure, epilepsy

In this surveillance, out of 3,666 (Missing value=156) participants with AEFI, 28(0.76%) reported history of allergy to……. Moreover, 42 (0.8%) reported about vaccine received within the past 6 months. (Table 3).

Table 3: Clinical characteristics of clients with AEFI in two round campaigns from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022, Ethiopia (N= 3851).

Characteristics	Response	Frequency (%)	Remark
Comorbidity (n=3658)	Yes	49(1.34%)	Missing value=193
	No	3,609(98.66%)	
On medications at the time of vaccination (N=3847)	Yes	55 (1.4%)	Missing value = 4
	No	3,793 (98.6%)	
Any known allergy (N= 3,666)	Yes	28 (0.76%)	Missing value=156
	No	3,638(99.24%)	
Any vaccine received within 6 months (n=3739)	Yes	17 (0.45%)	Missing value=114
	No	3719 (99.54%)	
Any substance use	Yes	6(0.15%)	Missing value =360
	No	3485(99.85%)	

2.3.3 Occurrence of AEFI within 30minutes of post vaccination

From a total of 3851 participants who experience AEFI, 83 (2.2 %) encountered one or more AEFIs within 30 minutes following vaccination. Out of 83 encountered AEFIs, injection site pain/redness/swelling / numbness 34(41.0%) was being the most common symptom, followed by headache 20(24.1%), and then one or more AEFIs 12 (14.5%) were experienced by the participants. Of which, the most commonly reported systemic symptoms within 30 minutes following immunization were headache (20.8%), nausea (6.0) and joint pain (4.8%). (Table 4).

Table 4: - Type and frequency of AEFI within 30minutes of vaccination from Nov 15 to Feb 28,2022, Ethiopia (N= 83).

Type of AEFIs encountered within 30 minutes	Frequency	Percent (%)
Injection site pain/redness/swelling	34	41.0
Headache	20	24.1
Fever	**3**	3.6
Dizziness	2	2.4
Arthralgia/Joint pain	**4**	4.8
Nausea	5	6.0
Two or more AEFIs	12	14.5
Others	3	3.6
Total	83	100

Key: *Injection site pain and headache, headache, fever, and injection site pain, headache and fever, headache and blurred vision were the most frequent two or more AEFIs.*

Others include chills, blurred vision, and fatigue

As most of the AEFIs encountered within 30 minutes were **mild and/or moderate, among 83** participants having an AEFI within 30 minutes, only 19 (22.9%) of them received medication to treat the AEFIs. Among those who received treatment for AEFIs that encountered within 30 minutes, 11 (57.9%) received paracetamol and the remaining two received diclofenac (26.3%) and ibuprofen (15.8%), respectively. The medications were given mainly for the treatment of headache, fever and to relieve injection site pain. Following the occurrence of AEFIs, the outcomes of the 19 participants who received treatments were categorized as recovering (8) and recovered fully (11) within a day.

2.3.4 AEFI encountered after 30 minutes

From a total of 3829 participants with AEFIs, 3603 (94.1%) reported as one or more AEFIs after 30 minutes of vaccination. Of 3603 participants with AEFI, injection site pain/redness/swelling (48.68%), headache (18.62%), two or more AEFIs (10.94%) and fever (8.08%) were the most frequently reported AEFIs after 30 minutes of vaccination (**Table 5**). Among the most commonly reported AEFIs, the majority 3689 (96.3%) occurred within the first 24 hours post-vaccination.

Table 5: Type and frequency of AEFI after 30minutes of vaccination from Nov 15 to Feb 28,2022, Ethiopia (n= 3603). Missing Value =226

Types of AEFIs encountered after 30 minutes	Frequency	Percent (%)
Injection site pain/redness/swelling	1754	48.68
Headache	671	18.62
Two or more AEFIs	394	10.94
Fever	291	8.08
Body weakness/ tiredness/fatigue	98	2.72
Arthralgia/ Joint pain	78	2.16
Chills	64	1.78
Myalgia /muscle weakness	58	1.61
Nausea and/or vomiting	41	1.14
Dizziness	39	1.08
Cough	23	0.64
Back pain	13	0.36
Flue like symptoms	12	0.33
Numbness	10	0.28
Sweating	10	0.28
Loss of appetite	8	0.22
Abdominal crampy pain	7	0.19
Itching	7	0.19
Others	25	0.69
Total	3603	100

Keys: - *Injection site pain and headache; headache and fever; injection site pain, headache and fever; injection site pain, headache, joint pain, blurred vision and nauseas/vomiting; injection site pain, chills, blurred vision and, loss of appetites were the most frequent two or more AEFIs Others include blurred vision (4), insomnia (3), burning sensation (2), diarrhea (4), chills (4), generalized body pain (1), breast tenderness (1), vertigo (2), and tonsilitis (2).*

Out of the 3603 participants who had AEFIs after 30 minutes, only 282 (7.8 %) has taken medications. Nearly two-third (67.7 %) of those who took medications used paracetamol. Diclofenac and ibuprofen were the 2nd and 3rd commonly used medications (**Table 6**).

Table 6: Types of medications used for AEFIs encountered after 30 minutes of vaccination with Pfizer Covid-19 vaccine from Nov 15 to Nov 28,2021 and Feb14, to Feb 28,2022, Ethiopia (n=282).

Name of drugs used	Frequency	Percent (%)
Paracetamol	191	67.7
Diclofenac	40	14.2
Ibuprofen	16	5.7
Tramadol	12	4.3
Antibiotics	9	3.2
Salbutamol	4	1.4
Unspecified	7	2.5
Others (glucose, chlorpheniramine)	3	1.1

Most the encountered AEFIs after 30 minutes were mild and/or moderate and occurred with the first week following immunization. Three-fourth (74.1%, 209) of participants who received treatments for AEFIs encountered after 30 minutes were fully recovered within a week (**Table 6)**

Table 6: Treatment outcome of AEFI after 30 minutes in those who received medications (n=282)

Participant status after AEFIs	Frequency	Percent (%)
Not recovered	5	1.8
Recovered fully	209	74.1

Recovering	68	24.1

At the end of the follow up period, all the participants (n= 282) who had AEFI and took treatment were fully recovered.

3. AEFIs reported as Serious

A total of 11 cases were reported as a serious AEFIs. Out of those, 7 cases were submitted to causality assessment and classified. Whereas, 2 cases (one alive and one death) not submitted to causality assessment because of incomplete investigation /clinical data and the remaining 2 cases were considered as non-serious AEFIs (disregarded as non-serious). The 7 serious AEFI clinical cases were hospitalization and then they are fully recovered. However, among two cases not submitted to causality assessment one was death. Four consistent and two coincidental and one indeterminate classification of causality assessment were reported for the 7 serious AEFI cases.

Summary

From the total of 10947 participants followed during active surveillance, 3851(35.18 %) experienced one or more AEFIs. To this effect, most of the AEFIs reported were mild and/or moderate. Among these, injection site pain/redness/swelling / numbness, headache, fever, body weakness/ tiredness/fatigue and arthralgia/ joint pain were the most frequently reported AEFIs. In addition, out of a total 11 serious AEFIs reported, 7 were hospitalization and then fully recovered, and one death reported.