Report on Janssen (Johnson & Johnson) COVID-19 Vaccine Active Surveillance in Ethiopia from August 21, 2021 to June 20, 2022.

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Contents

Abstract

Introduction: Although the Janssen (J&J) coronavirus disease 2019 (COVID-19) vaccines have been granted emergency approval in many nations including Ethiopia, its safety has never been studied in Ethiopian population.

Objective: The aim of this study was to assess the safety of Janssen (J & J) COVID-19 vaccine through evaluating incidence, types and seriousness of AEFIs in Ethiopia over 9 months (August 21, 2021 to June 20, 2022).

Method: This was a prospective observational study conducted between August 21, 2021 to June 20, 2022. A total of 10,262 participants age ≥18 who came to get vaccinated with Janssen (J&J) COVID-19 vaccine were recruited after obtaining their consent. On the date of vaccination, sociodemographic data and information on comorbidities were collected from participants. Moreover, the participants were observed at the site of vaccination for 30 minutes following vaccine administration to identify any immediate AEFIs. Details about any AEFI occurring within thirty days of follow up period post-vaccination were then collected via telephone-based interviews on day 2, 4 and 7 for the 1st week and then weekly on week-2, 3- and 4 by trained data collectors from the vaccination area.

Results: This study involved 10,262 participants of which 6187(60%) were males. The median age of the participants was 37 (range=18-98) years. Seven-hundred ninety-one (8%) of the participants were taking one or more medications for the management chronic disorders. Cardiovascular (31.6%), anti-diabetics (29.32%) and anti-retroviral drugs (7.85%) were the top three most commonly used class of drugs. Hypertension (35.2%), diabetes (30.7%) and HIV/AIDS (12.6%) were the top 3 comorbidities reported by the 768 (7.5%) participants who reported having one or more comorbid conditions at the beginning of the study.

The overall prevalence of AEFIs was 44.51% and 97 (2.1%) participants reported encountering one or more immediate AEFIs within 30 minutes of vaccination. Injection site pain /redness/ swelling /numbness (53.6%), headache (18.4%), fever (9.6%) and nausea/vomiting (6.4%) were the three most common AEFIs reported within 30 minutes of vaccination. Of the total of 4568 who reported one or more AEFIs, 4430 (97%) participants reported facing one or more AEFIs after 30 minutes of taking the vaccine. Injection site pain/ redness/ swelling/ numbness (25.30%), headache (23.71%), fever (13.58%), arthralgia/joint pain (8.96%) and fatigue (6.57%)

were the top five types of AEFIs reported by the participants. Most of the AEFIs were reported as non-serious (mild and/or moderate) and self-resolve within a week of vaccination. However, 15 AEFI cases were reported as serious of which 7 were death and 7 were hospitalizations.

Conclusion

The overall incidence of AEFIs after vaccination with Janssen COVID-19 vaccine was 44.51% and injection site reactions, headache, fever, joint pain and fatigue are the most frequently reported AEFIs. Moreover, seven fatal cases were reported after vaccination which creates a concern about the safety of this vaccine.

Key Words: Janssen COVID-19 vaccine, types of AEFIs, prevalence of AEFI, serious AEFIs

1. Introduction

The COVID-19 pandemic is the most extreme combined health and economic crisis in the last century. It represents the most significant health challenge that the world has confronted in over 70 years of WHO's existence. The global toll of COVID-19 has been massive. By the end of 2021 there were reports of more than 282 million cumulative confirmed cases and 5.4 million deaths, with these numbers almost certainly a major underestimation of the true extent of cases and deaths.[1] The COVID-19 vaccines are one of the critical components of the response to the pandemic globally. The efficacy and safety of the COVID-19 vaccines given emergency use authorization were not fully documented. Thus, continuous safety monitoring is necessary to estimate risk of severe but rare adverse events (AEs) as the consequence of these AEs may be more substantial.[2]

The Ethiopian Food and Drug Authority (EFDA) issued an Emergency Use Authorization (EUA) for Janssen (Ad.26.COV2. S; Janssen Biologics B.V. and Janssen Pharmaceutical NV (Belgium)) COVID-19 vaccine in May 2021.[3] The Janssen (Johnson & Johnson) COVID-19 vaccine contains a piece of a modified virus called the vector virus. It uses a replication-incompetent human adenoviral type 26 vector platform and is administered as a single intramuscular dose to individuals ≥18 years. All currently available information has been provided by the vaccine manufacturers during clinical trials. The number of individuals exposed to vaccines during clinical trials is limited and their profiles do not represent the broader spectrum of individuals who will be the actual vaccine recipients when the vaccine is commercialized.[4,5]

Concerns about excessive risk of thrombosis (TTS) after the Janssen vaccine resulted in a 10-day suspension (April 13 to April 23) of its administration in April 2021.[2, 6] The excessive reporting risk of Guillain–Barré syndrome (GBS) afer Janssen vaccine was also reported by several studies.[6-8] Moreover, European Medicine Agency (EMA) ordered listing of GBS as a very rare side effect of Jcovden (previously COVID-19 Vaccine Janssen) and inclusion of a warning in the product information to raise awareness among healthcare professionals and people taking the vaccine.[9]

In July 2021, after review of an updated benefit-risk assessment accounting for risks of GBS and TTS, the US Advisory Committee on Immunization Practices (ACIP) concluded that benefits of vaccination with Janssen COVID-19 vaccine outweighed risks. Through ongoing safety surveillance and review of reports from the Vaccine Adverse Event Reporting System (VAERS), additional cases of TTS after receipt of Janssen COVID-19 vaccine, including deaths, were identified in the US. Then after, on December 16, 2021, after an emergency meeting to review updated data on TTS and an updated benefit-risk assessment, ACIP made a recommendation for preferential use of mRNA COVID-19 vaccines over the Janssen COVID-19 vaccine, including both primary and booster doses administered to prevent COVID-19, for all persons aged ≥18 years. The Janssen COVID-19 vaccine may be considered in some situations, including for persons with

a contraindication to receipt of mRNA COVID-19 vaccines, for whom ensuring a second dose might be difficult or in settings such as college campuses or drive through vaccination sites where simple storage requirements are important [9,10]. Thus, monitoring for common and rare adverse events after receipt of the Janssen COVID-19 vaccine, is must be continuing. Ongoing monitoring for rare and common adverse events after vaccination is important for evaluating the balance between risks and benefits for each authorized COVID-19 vaccine, including the Janssen COVID-19 vaccine[9].

Thus, active safety surveillance was conducted by EFDA on Janssen (J & J) COVID-19 Vaccine recipients to determine the incidence, type and nature of adverse events in Ethiopian population. The COVID-19 vaccine on which active surveillance was conducted is the Janssen (J & J) COVID-19 Vaccine manufactured by the Janssen Pharmaceuticals with batch numbers of 209C21A, XE437, XE498, XE559, ACB6050, ACB5522, ACB8111, ACB3781, ACB8119, ACB8108, ACB8115, ACB8112, ACC0303, ACC1437, ACC5104, ACC1442, ACC5104, ACC1442, XE609, XE606, 214C21A, 215C2A, 1822795, 1822800, 1822801, 1822805, 1873277, 1875728, 1875729, 1875730, 1875731, 1875732, 1875733, 1875734, 1875735 and 1875736.

This report provides a summary of AEFIs that are temporally associated with receipt of Janssen (J & J) COVID-19 Vaccine in Ethiopia. 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.

2. Objective

The main objective of this study was to assess the safety of Janssen (J & J) COVID-19 vaccine through evaluating incidence, types and seriousness of AEFIs in Ethiopia over 9 months (August 21, 2021 to June 20, 2022).

3. Methodology

3.1. Subjects and Settings

This active surveillance was conducted at purposively selected health facilities from seven regions of Ethiopia (Afar, Amhara, Harari, Oromia, Sidama, Southern Nations, Nationalities and Peoples and South West Ethiopia) and two city administrations (Addis Ababa and Dire Dawa). The WHO recommendation for identifying uncommon rare adverse events of drug/vaccine, requires recruitment of at least 10,000 vaccine recipients (95% chance with the incident rate of 1:3000). Thus, this study included 10,262 individuals aged ≥ 18 years who received Janssen (J&J) COVID-19 vaccine at selected health facilities after getting their consent. People diagnosed with mental disorders that could potentially impair their ability to interact with investigators were excluded from the study. A structured questionnaire (covid-19 vaccine active safety follow up forms) was used to collect the data.

3.2. Study Flow

A team of health professionals prospectively collected the AEFIs of Janssen COVID-19 vaccine through direct observation at vaccination site for 30 minutes after vaccination and by way of phone calls on day 2, 4 and 7 for the 1st week and then weekly on week-2, 3- and 4. The number of data collectors totaled 138 (74 nurses, 60 pharmacists, 3 health officers and a physician). Data collectors were trained on vaccine safety and how to collect data via phone calls, which included questions about types, nature, date, duration and outcomes of AEFIs. Participants were asked whether they encountered any of AEFIs or not. Moreover, on the date of vaccination,

sociodemographic data and information on comorbidities were collected from participants. Data collection process was supervised by a team of clinical trial and pharmacovigilance experts from the Product Safety Directorate of EFDA. Vaccinated individuals were also able to passively report AEFIs to EFDA; however, to avoid data bias, only serious AEFIs from passive reporting were included in the data analysis. The outcomes of the study were prevalence of AEFI, incidence of AEFIs, types and seriousness of AEFIs.

3.3. Data Analysis

The collected data were entered into pre-prepared Microsoft Excel spreadsheet template, pre-processed and cleaned, then then exported to SPSS version 25, coded for analysis and analyzed. Data are presented as count with proportions for categorical variables and using an appropriate measure of central tendency and dispersion for continuous variables. As there were some incomplete data in some variables, missing values are excluded and only the complete data is used to compute frequency and percentage.

4. Results and Discussion

4.1.Active Surveillance Participants by Region/City Administration

The study was conducted in 7 regions (Afar, Amhara, Harari, Oromia, Sidama, Southern Nations, Nationalities and Peoples and South West Ethiopia) and two city administrations (Addis Ababa and Dire Dawa) of Ethiopia. As described in Table 1, majority of the active surveillance participants were from Addis Ababa (3283, 32%) followed by Amhara (1699, 16.6%) and Oromia (1497, 14.6%).

Table 1. Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants by Regions/City Administration (N=10262).

Region/City Administration	Frequency	Percent
Addis Ababa	3283	32
Afar	532	5.2
Amhara	1699	16.6
Dire Dawa	1007	9.8
Harari	100	1
Oromia	1497	14.6
Sidama	1104	10.8
SNNP	202	2
South West Ethiopia	838	8.2
Total	**10262**	**100**

The main reason for high number of participants from Addis Ababa is that many health facilities were conveniently selected from Addis Ababa due to ease of access for supportive supervision and better spontaneous reporting culture as a result of awareness on the importance of reporting adverse events. Similarly, many health facilities were also selected from Dire Dawa proportionally based on previous performance on other active surveillance conducted and better AEFI reporting culture.

4.2. Sociodemographic Characteristics of Active Surveillance Participants

4.2.1. Age Distribution of Study Participants

The median age at vaccination of all study participants was 37 (range=18-98) years. As presented in Table 2, the majority (2761, 26.9%) of the participants were in the age group of 20-

29 years (IQR=21) followed by 30-39 years (2580, 25.1%). Similarly, the median age at vaccination of a total of 4525 active surveillance participants who reported experiencing one or more adverse events was 37 (range=18- 87) years. Moreover, majority (2761, 26.9%) of the active surveillance participants who had one or more AEFIs post vaccination with Janssen (J&J) COVID-19 Vaccine were in the age group of 20-29 years (IQR 21).

Table 2. Age distribution of Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants (total and participants with AEFIs).

Age Groups	**Total Participants (N=10155)**		**Participants with AEFI (N=4525)**	
	Frequency	**Percent**	**Frequency**	**Percent**
10-19	343	3.3	149	3.3
20-29	**2761**	**26.9**	**1240**	**27.1**
30-39	2580	25.1	1207	26.4
40-49	2134	20.8	942	20.6
50-59	1377	13.4	579	12.7
60-69	693	6.8	311	6.8
70 and above	267	2.6	97	2.1
Total*	**10155**	**99**	**4525**	**99.1**
Missing values (**Unknown**)	107	1	43	0.9
Total	**10262**	**100**	**4568**	**100**

*Active surveillance participants with complete data on which frequency and percentage is calculated.

Most the study participants (7475, 72.8%) were in the age group of 20-49 years. Similarly, majority of the study participants (3389, 74.1%) who reported encountering one more AEFIs after Janssen COVID-19 vaccine were in the age range of 20-49 years. Individuals in this age group are known to have higher immune responses and reactogenicity to vaccines.

4.2.2. Sex Distribution of Study Participants

More than half (6187, 60%) of the total participants were males. Among the 4055 (40%) female study participants, 2 were lactating and 2 were pregnant (Figure 1). Likewise, majority (2732, 59.8%) of the study participants who reported encountering one or more AEFIs were males. As

presented in Figure 2, among the females who reported having one or more adverse events, 2 were lactating and 2 were pregnant.

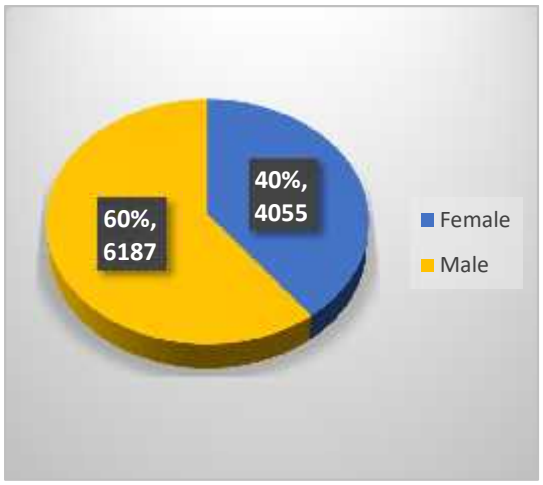

Figure 1. Sex distribution of Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants (N=10242).

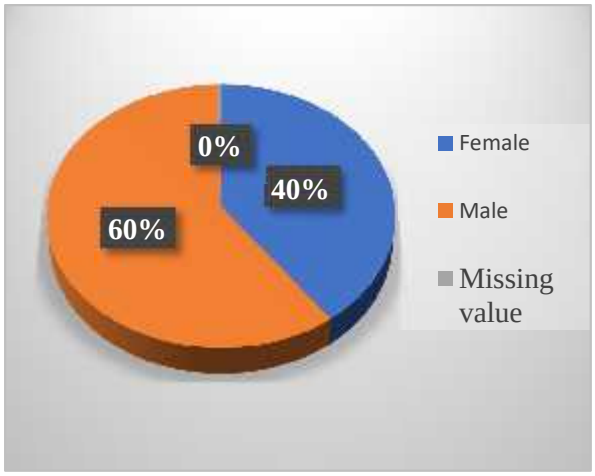

Figure 2. Age distribution of Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants who had one or more AEFIs post vaccination (N=4556).

4.3. Clinical Characteristics of Active Surveillance Participants

4.3.1. Class of Medications Used by Active Surveillance Participants

At the commencement of the active surveillance, participants were asked about any medications they are taking. From a total of 10,262 active surveillance participants, 791 (8%) replied that they are taking one or more medications for the management of chronic disorders. The most commonly used class of drugs were cardiovascular drugs (31.6%), anti-diabetics (29.32%) and anti-retroviral drugs (7.85%) (Table 3). Among the cardiovascular drugs, antihypertensive were the most commonly used medications.

Similarly, as described in Table 3, from a total of 4568 active surveillance participants who reported experiencing one or more AEFIs post vaccination, 414 (9.1%) were using one or more

medications. The most commonly used medications by this group of study participants were antidiabetics (26.95), cardiovascular drugs (26.21), and antiretroviral drugs (7.62%).

As can be seen from Table 3, the number of participants who are using medications are much less than the number of medications used. This is because many participants are using at least two medications.

Table 3. Classes of medications used by Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants (total and participants with AEFI).

Class of drugs	All Study Participants (N=791)		Participants with AEFI (N=414)	
	Frequency	**Percent**	**Frequency**	**Percent**
Cardiovascular drugs	**346**	**31.6**	**141**	**26.21**
Antidiabetic drugs	**321**	**29.32**	**145**	**26.95**
Unspecified	112	10.23	123	22.86
Anti-retroviral drugs	**86**	**7.85**	**41**	**7.62**
Respiratory drugs	**58**	**5.3**	**30**	**5.58**
Analgesics, Steroidal and Non-Steroidal Anti-Inflammatory Drugs	43	3.93	12	2.23
CNS drugs	35	3.2	12	2.23
Anti-hyperlipidemic drugs	33	3.01	15	2.79
Ant-infectives (antibacterial and antifungals)	25	2.28	7	1.31
Thyroid and anti-thyroid drugs	11	1	7	1.3
Vitamins and/or minerals	9	0.82	4	0.74
Anticancer drugs	6	0.55	1	0.19
Gastrointestinal drugs	5	0.46	-	-
Hormonal contraceptives	4	0.37	-	-
Total*	**1094**	**100**	**538**	**100**

Note: N=Number of participants who reported using one or more medications; *Total number of medications used by the participants.

4.3.2. Comorbid Conditions Reported by Active Surveillance Participants

Moreover, at the beginning of the active surveillance, participants were also asked about their comorbid conditions. From a total of 10,262 active surveillance participants, 768 (7.5%) replied that they have one or more comorbid conditions. Hypertension (35.2%), diabetes (30.7%) and

HIV/AIDS (12.6%) being the top three comorbidities reported by the active surveillance participants (Table 4).

Likewise, from a total of 4568 active surveillance participants who reported experiencing one or more AEFIs post vaccination, 398 (8.7%) reported having one or more comorbidities. Hypertension (33%), diabetes (28.7%) and HIV/AIDS (11.9%) were the top three comorbidities reported by the active surveillance participants with one or more AEFIs (Table 4).

Table 4. Types and frequency/percent of comorbidities reported by Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants (total and participants with AEFI).

Comorbidities	All Study Participants (N=768)		Participants with AEFI (N=398)	
	Frequency	Percent	Frequency	Percent
Hypertension	**316**	**35.23**	**154**	**33.2**
Diabetes	**275**	**30.7**	**133**	**28.7**
HIV/AIDS	**113**	**12.6**	**55**	**11.9**
Asthma and/or chronic obstructive lung disease	75	8.36	51	11
Cardiac problem	31	3.46	19	4.1
Dyslipidemia	21	2.34	12	2.6
Thyroid disorder	12	1.3	7	1.5
Epilepsy	10	1.1	6	1.3
Mental Problem	9	1	4	0.9
Cancer	7	0.7	2	0.4
Unspecified	5	0.6	5	1.1
Chronic kidney disease	4	0.4	2	0.4
Sinusitis	4	0.4	4	0.9
Neuropathy	3	0.3	3	0.6
Gouty arthritis	2	0.2	1	0.2
Hepatitis B	2	0.22	2	0.4
Rheumatoid arthritis	2	0.22		
Tuberculosis	2	0.2	1	0.2
Gastrointestinal disorders	1	0.11	1	0.2
Insomnia	1	0.1	1	0.2
Thrombocytosis	1	0.11		

Varicose vein	1	0.1	1	0.2
Total*	897	100	1	0.2

4.4. History of Vaccination, Allergy and Substance Abuse

Additionally, participants were also asked if they have any known allergies, history of vaccination within the past 6 months and history of any substance abuse. Of the 10,262 participants, only 65 (0.63%), 24 (0.2%) and 88(0.9) had known allergy, get vaccinated within the past 6 months and had history of substance abuse, respectively (Table 5).

Table 5. History of allergy, vaccination within 6 months and any substance abuse by Janssen (J&J) COVID-19 Vaccine Active Surveillance Participants (N=10,262).

Questions	Yes	No
Do you have any known allergies?	65	10197
Have you received any vaccines within 6 months?	24	10238
Do you have history of any substance abuse	88	10174

4.5. Adverse Events Following Immunization

4.5.1. Prevalence and Types of AEFI Reported Active Surveillance Participants

From the total of 10,262 active surveillance participants, 4568 (44.51%) reported experiencing at least one AEFI following vaccination with the Janssen (J&J) COVID-19 Vaccine. This makes the overall prevalence of AEFIs 44.51%. Some of the AEFIs encountered were immediate adverse events observed within 30 minutes following vaccination. Most of the AEFIs were reported as non-serious and a few were reported as serious. AEFI reports are classified as serious if any of the following are reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly, or birth defect.[4]

4.5.2. Type and Rate of AEFIs within 30 minutes of Vaccination

From a total of 4568 participants who reported experiencing AEFIs, 97 (2.1%) reported having one or more AEFIs within 30 minutes following vaccination. Among the 97 participants who had AEFIs within 30 minutes, 22 (22.7%) reported facing at least two AEFIs. Injection site

pain/redness/swelling/numbness (53.6%), headache (18.4%), fever (9.6%) and nausea/vomiting (6.4%) were the most frequently reported immediate AEFIs (Table 6).

Table 6. Types and rates of AEFIs encountered within 30 minutes post vaccination (N=97).

Type of AEFI	Frequency	Percent
Injection site pain/redness/swelling /numbness	**67**	**53.6**
Headache	**23**	**18.4**
Fever	**12**	**9.6**
Nausea/vomiting	**8**	**6.4**
Arthralgia/joint pain	**2**	**1.6**
Chills	2	1.6
Fatigue	2	1.6
Myalgia/muscle pain	2	1.6
Sweating	2	1.6
Syncope	2	1.6
Bitter taste	1	0.8
Not specified	1	0.8
Shortness of breath	1	0.8
Total*	125	100

Note: N=Number of participants who reported encountering one or more AEFIs; *Total number of AEFIs reported by the participants within 30 minutes.

When asked about how they managed the AEFIs encountered within 30 minutes following vaccination, 16 (16.5%) out of the 97 participants who had AEFIs with 30 minutes replied that they took medications after they went home. Among the 16 active surveillance participants who took medications mainly for the relief of pain/headache, the majority 14 (87.5%) took analgesics (12 paracetamol, diclofenac and ibuprofen) and the rest 2 (12.5%) didn't specify their medications. After taking the medications, 12 (75%) of the 16 participants who took medications for the management of AEFIs that occurred within 30 minutes of vaccination reported that their AEFIs were resolved within 24 hours.

4.5.3. Types and rates of AEFI after 30 minutes post vaccination

From a total of 4568 study participants who reported experiencing one or more AEFIs, 4430 (97%) participants reported facing one or more AEFIs after 30 minutes of taking the vaccine.

Among the 4430 participants who had AEFIs, 2242 (50.61%) reported facing at least two types of AEFIs. As shown in Table 7, injection site pain/redness/swelling/numbness (25.30%), headache (23.71%), fever (13.58%), arthralgia/joint pain (8.96%) and fatigue (6.57%) were the top five types of AEFIs reported by the study participants.

Table 7. Types and rates of AEFIs encountered after 30 minutes post vaccination with (N=4430).

Type of AEFI	Frequency	Percent
Injection site pain /redness/ swelling /numbness	**1988**	**25.3**
Headache	**1863**	**23.71**
Fever	**1067**	**13.58**
Arthralgia/joint pain	**704**	**8.96**
Fatigue	**516**	**6.57**
Chills	444	5.65
Myalgia/muscle pain	296	3.77
Backpain	258	3.28
Nausea/vomiting	149	1.9
Dizziness/confusion/depression	89	1.13
Loss of appetite	76	0.97
Sweating	70	0.89
Difficulty in sleeping/insomnia/nightmare	63	0.8
Abdominal crampy pain and/or epigastric pain	49	0.62
Cough	48	0.61
Flue like symptoms	26	0.33
Diarrhea	21	0.27
Convulsion	19	0.24
Generalized boy pain/discomfort/burning sensation	17	0.22
Allergic reaction/itching/skin rash	14	0.18
Bitter taste/tastelessness	14	0.18
Blurred vision/eye pain	13	0.17
Chest pain	10	0.13
Pain/numbness in lower extremities (right and/or left leg)	10	0.13
Delirium and/or speech disorder	7	0.09
Dryness of mouth /feeling thirsty	4	0.05
Neck pain/stiffness	4	0.05
Vertigo	4	0.05
Ear edema	3	0.04
Nasal bleeding/pain/loss of smell	3	0.04
Burning during urination/urine color change	2	0.03
Difficulty of swallowing/wound in the oral cavity	2	0.03
Loss of libido	2	0.03

Swelling of the left leg	2	0.03
Diaphoresis	1	0.01
Flunk pain	1	0.01
Total	7859	100.00

Note: N=Number of participants with AEFIs; *Total number of AEFIs reported by the participants after 30 minutes of vaccination.

Most of the AEFIs were reported as non-serious and self-resolve within a week of vaccination. However, 485 (10.95%) study participants out of a total of 4430 participants who reported facing one or more AEFIs after 30 minutes, reported taking at least one medication for the management of adverse events temporally associated with vaccination with Janssen COVID-19 Vaccine. Paracetamol (69%), diclofenac (10.5%) and ibuprofen (6.4%) were the three most frequently used medications. These medications were used mainly for the management headache/pain. Two participants with AEFI had severe lower leg pain for which heparin and warfarin was prescribed, respectively (Figure 4). At the end of the follow up period, all the participants who took medications for the management of AEFIs reported full recovery.

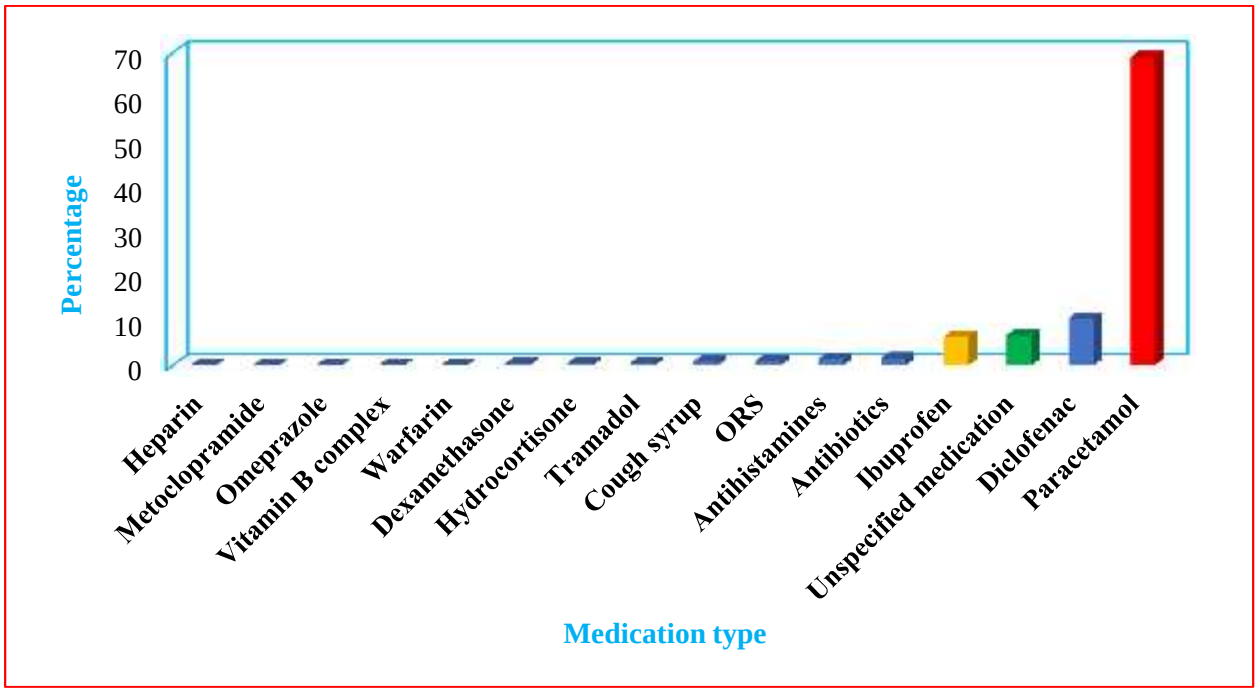

Figure 3. Medications used by active surveillance participants for the management of Suspected AEFIs encountered after 30 minutes of vaccine administration (N=485).

4.6. AEFIs Reported as Serious

A total of 15 AEFIs were reported as serious AEFIs of Janssen COVID-19 Vaccine. Among these 7 were death and 6 were hospitalization cases. The serious cases were carefully investigated by EFDA and presented to the National Safety Advisory Committee for causality assessment. The committee assessed the cases and classified the causal association using WHO's revised AEFI causality assessment tool as described in Table 8 below.

Table 9. Serious AEFIs reported after Janssen COVID-19 Vaccine, Clinical Outcomes and Causality Classification (N=15).

No.	Age (year)	Sex	Adverse Events Following Immunization	Reasons Serious	Clinical Outcomes	Causality Classification
1.	60	M	Leg swelling then diagnosed with DVT	Hospitalization	Recovered	Consistent
2.	56	M	Death	Death	Death	Indeterminate
3.	40	M	Hemorrhagic stroke	Hospitalization	Recovered	Coincidental
4.	58	M	Paraparesis (GBS)	Hospitalization	Recovered with sequalae	Consistent
5.	25	M	Facial deviation	Hospitalization	Recovered	Consistent
6.	30	F	Headache,nausea vomiting and body rash	Hospitalization	Recovered	Consistent
7.	59	F	Death	Death	Death	Consistent
8.	60	M	Body weakness	Hospitalization	Recovered	Unclassified
9.	30	F	Vaginal bleeding	Abortion	Abortion	Coincidental
10.	60	F	Death	Death	Death	Consistent
11.	36	M	Death	Death	Death	Coincidental
12.	28	F	Abortion	Abortion	Abortion	Coincidental
13.	18	M	Death	Death	Death	Consistent
14.	40	F	Death	Death	Death	Coincidental
15.	60	M	Death	Death	Death	Consistent

5. Conclusion and Recommendations

Even if majority of the encountered AEFIs were reported as non-serious and self-resolve within a week, causality assessment findings of the serious AEFIs revealed that 8 of the cases were categorized as vaccine product related reactions (4 death and 4 hospitalizations). This creates a safety concern with the use of this vaccine. Thus, the risk benefit balance of using this vaccine should be carefully evaluated and comparative safety evaluation of COVID-19 vaccines used in Ethiopia should made.

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