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Adverse events following Pfizer-BioNTec vaccine against COVID-19 in population more than 12 years of age, Nepal

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Abstract

Introduction: Pfizer-BioNTec vaccine was started in Nepal for the age group of more than 12 y. This study was conducted to find out the adverse event following immunization with Pfizer-BioNTech vaccine against COVID-19 at Patan Academy of Health Sciences (PAHS).

Method: This is a descriptive study conducted at PAHS from November to December 2021. The vaccine recipients were called over the phone after 72 h of receiving the vaccine to find out adverse events following immunization (AEFI). They were inquired about the list of pre-defined AEFI. Ethical approval was obtained.

Result: A total of 1377(27.4%) individuals among 5014 receiving the first dose and 983(71.4%) of 1377 receiving the second dose were enrolled in the study. Vaccine recipients who had minor AEFI in the first dose were 462(33.6%) and in the second dose were 205(20.9%). Reported AEFI in both first and second dose was pain 377(27.4%) and 97(9.9%) respectively, followed by fever in 65(4.8%) and 91(9.3%) respectively. There were no severe AEFI reported in both doses of vaccination. The AEFI started within 24 h and subsided within 72 h.

Conclusion: Minor AEFI of pain and fever was reported with the first and second dose of the Pfizer-BioNTech vaccine. There were no severe and serious AEFI reported in this study population.

Keywords: AEFI, COVID-19, Pfizer-BioNTech

Introduction

Nepal officially started the first phase of COVID-19 vaccination on 27 January 2021 with the COVISHIELD vaccine.¹ The COVISHIELD vaccine is an adenovirus vector vaccine in which a minor adverse event following immunization (AEFI) was reported in 85% and serious AEFI was reported in 0.05% with the first dose.² This was followed by Vero Cell, an inactivated vaccine.³ The AEFI reported was 19% after the first dose and 20.5% after the second dose.⁴ Third vaccine rolled out was the single-shot Janssen vaccine in July 2021 which is a viral vector vaccine.^{5,6} The systemic reaction following the vaccine was 61.5% in the age group between 18 to 59 y and 45.3% in the age group 60 y and above.⁷

Nepal started the Pfizer-BioNTec vaccine for the patient with chronic illness in the age group more than 12 y in the first phase followed by the healthy adolescent between 12-17 y from 14 November 2021.⁸ This is an mRNA vaccine and its systemic side effect has been reported to be minor and was observed in 88.7% of the recipient in the age group 18-55 y.⁹ Therefore, this study aims to find out the AEFI with Pfizer COVID-19 vaccine at Patan Academy of Health Sciences (PAHS), Lalitpur, Nepal.

Method

This is a descriptive study conducted at PAHS that was designated as a site for the Pfizer-BioNTec COVID-19 vaccine by the government of Nepal. The vaccination program for the first dose was started on 14 November 2021 till 23 November 2021 and the second dose after four weeks. Therefore, the duration of the study was from 14 November 2021 to 30 December 2021. The objective of the study was to find out the proportion of adverse events in vaccine recipients. All candidates coming for the vaccination between the given period (14-23 November 2021) for the first dose and after four weeks for the second dose who was listed in the register book for immunization at Patan Hospital, provided by

the health office of Nepal government were eligible for the study. Those who received the phone call and gave consent (in the case of a minor, consent was taken from guardians or parents) were included in the study while candidates with wrong phone numbers were excluded. Data for the second dose were collected by contacting only those individuals who were included in the first dose.

Working definitions were taken from WHO⁷ and CDC⁹, adverse event following immunization was considered when any untoward medical occurrence followed immunization and which did not necessarily have a causal relationship with the usage of the vaccine. Minor AEFI was considered to be occurring within a few hours of injection resolved after a short period and posed little danger. Local reaction was limited to a specific body part or region (pain, swelling, and redness at injection site) and systemic is related to the entire body (fever, malaise, muscle pain, headache chills, vomiting, diarrhea, fatigue, joint pain). AEFI was considered severe when it did not result in long-term problems and was rarely life-threatening (seizure, hypotonic response) but could be disabling. Serious AEFI was considered if it resulted in death and required inpatient hospitalization (anaphylaxis).

Pfizer-BioNTech is an mRNA vaccine manufactured by Pfizer Inc and BioNTech. It is administered in two doses intramuscularly 21 to 28 days apart.¹¹ Nepal Government planned to roll out a vaccine for all candidates above 12 y with a chronic illness e.g. Cardiac disease (Heart failure, Coronary Artery Disease, Cardiomyopathy), Chronic Kidney Disease, Malignancy, Chronic and Severe Pulmonary Disease, Solid Organ Transplant, Chronic Hypertension, Diabetes, and Immunosuppressive conditions. Contraindications for vaccination were a history of anaphylaxis, receiving monoclonal antibody or convalescent plasma in the last 90 d, and COVID-19 infection in the last one month.

The age group of 12-18 y and more than 18 y were taken as dependent variables and pain at the injection site, swelling, redness, fever, malaise, muscle pain, headache, chills, vomiting, diarrhea, fatigue, joint pain, seizure, anaphylaxis, need for hospitalization, self-medication was taken as independent variables.

Registration number, name, age, gender, phone number, and category of chronic illness of vaccinated individuals were collected from the registration book provided by Health Office, Nepal Government. Each vaccinated individual was called after 72 h. Upon receiving the call, the purpose of the call was explained and verbal consent was taken over the telephone. If the respondent informed about any health issues or AEFI, they were asked to visit the emergency department of PAHS. Visits to the emergency room and admission information were collected from the emergency department. The same process was repeated for data collection of the second dose. Ethical approval was taken from the IRC of PAHS (Approval letter number bss2111261580).

The collected data were entered in Microsoft Excel. After sorting and cleaning the data, it was exported into SPSS version 16.0 for analysis. Frequency and percentage were used to summarize the data. The Chi-square test was used for analysis, and a p-value of <0.05 was considered statistically significant.

Result

The total number of candidates who came for the first dose vaccine was 5014, and 1377(27.4%) were included in the study. Among the first dose respondent, 734(53.3%) were male and 643(46.7%) were female. There were 1224(88.9%) vaccine recipients in the age group of 12-18 y and 153(11.1%) in the age group of more than 18 y. Among 1377 vaccine recipients, 462(33.6%) had minor AEFI and no severe and serious AEFI were reported. The most common AEFI reported was pain at the injection site (377, 27.4%) followed by fever (65, 4.8%), Table 1.

Table 1. Incidence of Symptoms in first and second dose of Prizer-BioNTech COVID-19 vaccine in age group of 12-18 y and more than 18 y at Patan Academy of Health Sciences (PAHS), Lalitpur, Nepal

Variables	12-18 y			More than 18 y			Total in 1 st dose N(%)	Total in 2 nd dose N(%)
	1 st Dose N(%)	2 nd Dose N(%)	p value	1st Dose N(%)	2 nd Dose N(%)	p value		
Symptomatic	395(32)	186(20.9)	0	67(44)	19(20.4)	0	462(33.6)	205(20.9)
Pain	322(26)	89(10)	0	55(36)	8(8.6)	0	377(27.4)	97(9.9)
Fever	56(5)	81(9.1)	0	10(7)	10(10.8)	0.17	66(4.8)	91(9.3)
Headache	42(3)	26(2.9)	0.3	6(4)	0(0)	0.06	48(3.5)	26(2.6)
Muscle ache	23(2)	17(1.9)	0.5	9(6)	7(7.5)	0.3	32(2.3)	24(2.4)
Malaise	12(1)	13(1.5)	0.2	3(2)	0(0)	0.2	15(1.1)	13(1.3)
Swelling	7(1)	2(0.2)	0.19	1(1)	0(0)	0.62	8(0.6)	2(0.2)
Chills	4(0)	7(0.8)	0.12	1(1)	1(1.1)	0.61	5(0.4)	8(0.8)
Rigor	1(0)	3(0.3)	0.2	1(1)	0(0)	0.6	2(0.1)	3(0.3)
Joint pain	3(0)	1(0.1)	0.4	1(1)	1(1.1)	0.6	4(0.3)	2(0.2)
Fatigue	3(0)	3(0.3)	0.4	1(1)	0(0)	0.6	4(0.3)	3(0.3)
Vomiting	3(0)	4(0.4)	0.3	0(0)	0(0)		3(0.2)	4(0.4)
Diarrhoea	1(0)	1(0.1)	0.6	1(1)	0(0)	0.6	2(0.1)	1(0.1)
Redness	0(0)	1(0.1)	0.4	0(0)	2(2.2)	0.14	0(0)	3(0.3)
Skin rash	0(0)	0(0)		0(0)	1(1.1)	0.3	0(0)	1(0.1)
Itching	0(0)	0(0)		1(1)	0(0)	0.6	1(0.1)	0(0)

Out of all who had a symptom, the onset of symptoms for 430(93.1%) was within the first 24 h. Similarly, 269(58.2%) had symptoms

resolved in 24-48 h, Table 2. History of Covid-19 was documented in 99(7.2%) of the first dose vaccinated.

Out of 1377 first dose recipients, 983(71.4%) were included in the second dose. Of those who were included in the second dose, 889(90.5%) and 93(9.5%) were male and female respectively. The vaccine recipients in the age category of 12-18 y were 889(90.5%) and in the age category of more than 18 y were 93(9.5%). Of 983 respondents, 205(20.9%) had minor AEFI. There were no

severe and serious AEFI reported after vaccination. The pain at the injection site was the most common AEFI reported by 97(9.9%) individuals followed by the fever that was reported by 91(9.3%), Table 1. The onset of symptoms for all of those who had AEFIs was within the first 24 h for 200(97.6%). Similarly, most of the AEFIs resolved in 24-48 h for 87(42.4%), Table 2.

Table 2. Time to onset and resolve of symptoms, medication and hospitalization in first and second dose of Prizer-BioNTech vaccine in age group of 12-18 y and >18 y

Variables	12-18 y			> 18 y			Total in 1 st dose N(%)	Total in 2 nd dose N(%)	
	1 st dose N(%)	2 nd dose N(%)	p value	1 st dose N(%)	2 nd dose N(%)	p value			
Symptom started	<24 h	368(30)	181(20.4)	0	62(41)	19(20.4)	0	430(93.1)	200(97.6)
	24-48 h	25(2)	5(0.6)		5(3)	0(0)		30(6.5)	5(2.4)
	48-72 h	2(0)	0(0)		0(0)	0(0)		2(0.4)	0(0)
Symptom resolved	<24 h	98(8)	79(8.9)	0	12(8)	8(8.6)	0.02	110(23.8)	87(42.4)
	24-48 h	235(19)	63(7.1)		34(22)	7(7.5)		269(58.2)	70(34.1)
	48-72 h	60(5)	41(4.6)		20(13)	4(4.3)		80(17.3)	45(22)
	>72 h	2(0)	3(0.3)		1(1)	0(0)		3(0.6)	3(1.5)
Self-Medication	99(8)	89(10)	0.07	14(9)	12(12.9)	0.2	113(24.5)	101(49.3)	
Hospitalization	0(0)	0(0)		3(2)	0(0)	0.2	3(0.6)	0(0)	

Discussion

The minor AEFI reported with the first dose of Pfizer-BioNTec vaccine against COVID-19 was 462(33.6%) and that reported with the second dose was 205(20.9%). The report published by the CDC on AEFI of the Prizer-BioNTec vaccine suggests that 84.7% reported at least one local injection site reaction. By age group, 88.7% in the younger group (aged 18 to 55 y) and 79.7% in the older group (aged >55 y) reported at least one local reaction.⁹ This report took account of symptoms that occurred during the first seven days after vaccination compared to our study where we recorded symptoms that the vaccine recipient experienced in 72 h. Moreover, vaccine recipients were asked to complete diaries of their symptoms but in our study, recipients were interviewed at one point of time over the telephone. Though there is a chance of bias, since the call was made after 72 h, the chance of recall bias may be very low. Besides, our study has included vaccine recipients of less than 18 y as compared to a report published by CDC which took into

account recipients more than 18 y only. In our study, AEFI was more in the age group of more than 18 y with the first dose of vaccine 395(32%) versus 67(44%), however similar AEFI was seen with the second dose of vaccine 186(20.9%) and 19(20.4%).

A previous study published by PAHS was conducted on 3391 vaccine recipients getting their first dose of the COVISHIELD vaccine. This is a recombinant, replication-deficient chimpanzee adenovirus vector vaccine encoding the SARS COV-2 spike glycoprotein¹², a vaccine manufactured by Serum Institute of India Pvt Ltd which is similar to the COVID-19 Vaccine AstraZeneca.¹³ The AEFI noted with this vaccine was 3391(84.9%), severe Minor AEFI in 1(0.02%), and Serious AEFI in 2(0.05%).² This proportion is much greater than our study however, the vaccine was administered in the age group more than 18 y, so considering this age group only, the AEFI seen in this study is 67(44%). However, the sample size in the age group of more than 18 y was very low to conclude, besides the COVISHIELD

vaccine was given after the first wave while the Pfizer-BioNTech vaccine was given after the second wave, so there might be a contribution from the previous history of COVID-19 infection. Nevertheless, the overall data shows that there is less AEFI in the recipients of the Pfizer-BioNTech vaccine.

Another study was published from PAHS in 4574 vaccine recipients receiving the first dose and 941 receiving the second dose of Vero Cell vaccine against coronavirus disease 2019.¹⁴ A total of 868(19%) first dose vaccine recipients and 105(11.2%) second dose vaccine recipients reported AEFIs.⁴ This vaccine had the lowest rate of AEFI compared to the Pfizer and COVISHIELD vaccine rolled out at PAHS. In the study conducted by Singh et al¹⁵, the frequency of AEFIs was 0.04%, 0.06%, and 0.35% following administration of Pfizer-BioNTech, Moderna, and Johnson & Johnson's Janssen vaccines, respectively. The reported incidences were very low compared to our study, however, the data was taken from Vaccine Adverse Event Reporting System¹⁶ so there is a chance of varying degrees of reporting bias, particularly underreporting, especially for mild or common reportable events.¹⁵

There was no severe AEFI reported in our study population compared to the previous study population with the COVISHIELD vaccine that reported one anaphylaxis.² There are reported cases of Bell's palsy, Myocarditis/Pericarditis, Guillain-Barre syndrome, and transverse myelitis with Pfizer-BioNTech, Moderna, and Janssen vaccine.¹⁵ Thrombosis with thrombocytopenia syndrome was observed in Sputnik V, AstraZeneca, and Janssen vaccines these are all vector vaccines against SARS-COV2. We did not observe these adverse events as our follow-up was at 72 h.

In our study, pain at the injection site was the most common local AEFI in both doses and the frequency was more in the age group between 12-18 y in comparison to the age group of more than 18 y i.e. 322(26%) vs. 89(10%) in the first dose and 55(36%) vs.

8(8.6%) in the second dose. Various studies have reported pain at the injection site as the most common local reaction.^{2,4} Pain at the injection site was the most frequent local reaction following the Janssen vaccine reported by 58.6% in the age category of 18-59 y and 33.3% in age ≥ 60 y.⁷

Fever was the most common systemic reaction in both the first 65(4.8%) and second 91(9.3%) doses with the Pfizer-BioNTech vaccine in this study. Similar findings were observed with COVISHIELD vaccine², however, fatigue and headache were the most commonly reported systemic reactions in participants 18-59 y (12.8%), ≥ 60 y (3.1%) with Janssen vaccine⁷ and similar was the finding with Vero Cell vaccine.⁴

In the first dose, most of the symptoms started within the first 24 h 430(31.2%) and in the second dose also most of the symptoms 200(97.6%) started within 24 h following vaccination. Most of the symptoms with first and second-dose vaccines subsided within 24-48 h of symptom onset. Therefore, in the present context, vaccine recipients come with a symptom of COVID-19 post-vaccination putting clinicians in a dilemma whether it is due to the vaccine or COVID-19. This information will help us to decide as it is less likely for AEFI to start after 72 h. Any symptoms starting after 72 h cannot be accounted to AEFI. With the first dose of Vero Cell vaccine 821(94.6%) and the second dose of vaccine 102(97.1%) symptoms started within the first 24 h and most of the symptoms resolved within 24-48 h.⁴ Similar findings were observed with the COVISHIELD vaccine.²

The vaccine is one of the important public health tools which is very cost-effective as it not only prevents the disease but also prevents the spread of disease in the community.¹⁸ Therefore, this is the most effective approach available to fight against COVID-19. The benefit of the vaccine comes along with the adverse events therefore the surveillance programs from the national level are important for the safety of the vaccine.¹⁹

However, the benefit of the vaccine far outweighs the adverse events in reducing morbidity and mortality. A meta-analysis including 51 records assessing the effectiveness of the COVID-19 vaccine showed that the vaccine effectiveness of Pfizer-BioNTech was 91.2%, Moderna was 98.1% and Corona Vac was 65.7%.²⁰ Therefore, it is essential that everyone gets vaccinated against COVID-19.

Conclusion

Minor AEFI was reported in this study with the Pfizer-BioNTech vaccine. There were no severe and serious AEFI reported in this study population. Pain at the injection site followed by fever was the most common AEFI reported. The onset of most of the symptoms was within 24 h of vaccination and most of the symptoms subsided within 72 h of vaccination.

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Conflict of Interest

None

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None

Author Contribution

Concept, design, planning: RPD, SB, SA, PR, TS, MG, ST, BS, AS; Literature review: RPD, SB, SA, PR, TS, MG, ST, BS, AS; Data collection/analysis: RPD, SB, SA, PR, TS, MG, ST, BS, AS; Draft manuscript: RPD, SB, AS; Revision of draft: RPD, SA, PR, TS, MG, ST, BS; Final manuscript: RPD, SB, SA, PR, TS, MG, ST, BS, AS; Accountability of the work: RPD, SB, SA, PR, TS, MG, ST, BS, AS.

Reference

1. COVID-19 vaccination drive to commence from Wednesday in Nepal. The Himalayan Times [Internet]. 2021 Jan 24 [Cited 12 Nov 2021]. | [Weblink](#) |
2. Shrestha S, Devbhandari RP, Shrestha A, Aryal S, Rajbhandari P, Shakya B, et al. Adverse events following the first dose of ChAdOx1 nCoV-19 (COVISHIELD) vaccine in the first phase of vaccine roll out in Nepal. J PatanAcad Health Sci. 2021 Apr 29;8(1):9–17. | [DOI](#) | [Google Scholar](#) | [Full Text](#) |
3. Shah JN. The 'Vero Cell' COVID-19 vaccine rollout in Nepal: What we know about the Chinese vaccine development and access? J PatanAcad Health Sci. 2021 Apr 29;8(1):1–8. | [DOI](#) | [Google Scholar](#) | [Full Text](#) |
4. Aryal S, Devbhandari RP, Shrestha S, Shrestha A, Rajbhandari P, Shakya T, et al. Adverse events following Sinopharm (Vero Cell), the inactivated COVID-19. J PatanAcad Health Sci. 2021 Sep 28;8(2):18–24. | [DOI](#) | [Google Scholar](#) | [Full Text](#) |
5. Nepal begins inoculation of single-shot J&J vaccine starting today. The Himalayan Times [Internet]. 2021 Jul 19 [Cited 12 Nov 2021]. | [Weblink](#) |
6. Self WH, Tenforde MW, Rhoads JP, Gaglani M, Ginde AA, Douin DJ, et al. Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March–August 2021. MMWR Morb Mortal Wkly Rep. 2021 Sep 24;70(38):1337–43. | [DOI](#) | [PubMed](#) | [Google Scholar](#) | [Full Text](#) |
7. The Janssen COVID-19 Vaccine's Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events [Internet]. USA: Centre for disease control and prevention; 2021 Aug[Cited 12 Nov 2021]. | [Weblink](#) |
8. US-donate Prizervaccine to be administered from November 14. The Himalayan Times [Internet]. 2021 Oct 26[Cited 12 Nov 2021]. | [Weblink](#) |
9. Pfizer-BioNTech COVID-19 Vaccine Reactions & Adverse Events [Internet]. US: Centre for disease control and prevention. [Cited 12 Nov 2021]. | [Weblink](#) |
10. Pfizer BioNTec Notice [Internet]. 2021[Cited 12 Nov 2021]. | [Weblink](#) |
11. Pfizer-BioNTech COVID-19 Vaccine Overview and Safety (also known as COMIRNATY) [Internet]. Centre of disease control and prevention; 2021[Cited 12 Nov 2021]. | [Weblink](#) |
12. ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) [Internet]. India: Serum institute of India; 2021 [cited 2021 Mar]. | [Weblink](#) |

13. Fact sheet for vaccine recipient approved for restricted use in emergency situation of FACT (Recombinant) [Internet]. India: Serum institute of India; 2021 [cited 2021 Mar]. | [Weblink](#) |
14. COVID-19 Vaccine (Vero Cell), Inactivated (Sinopharm) [Internet]. WHO; May 2021[cited 25 Jan 2022]. | [Weblink](#) |
15. Singh A, Khillan R, Mishra Y, Khurana S. The safety profile of COVID-19 vaccinations in the United States. American journal of infection control. 2022 Jan 1;50(1):15-9. | [DOI](#) | [Google Scholar](#) | [Full Text](#) | [Weblink](#) |
16. VAERS data use guide [Internet]. US; November 2020 [cited 25 Jan 2022]. | [Weblink](#) |
17. Sobreira ML, Ramacciotti E, Paschôa AF, Matielo MF, Casella IB, Yazbek G, Soares RD, Bellen BV, Marques MA. Covid-19 vaccines and thromboembolic complications. Jornal Vascular Brasileiro. 2021 Dec 1;20. | [DOI](#) | [Google Scholar](#) | [Full Text](#) | [Weblink](#) |
18. Di Pasquale A, Bonanni P, Garçon N, Stanberry LR, El-Hodhod M, Da Silva FT. Vaccine safety evaluation: practical aspects in assessing benefits and risks. Vaccine. 2016 Dec 20;34(52):6672-80. | [DOI](#) | [Google Scholar](#) | [Weblink](#) |
19. Chandler RE. Optimizing safety surveillance for COVID-19 vaccines. Nature Reviews Immunology. 2020 Aug;20(8):451-2. | [DOI](#) | [Google Scholar](#) | [Full Text](#) | [Weblink](#) |
20. Zheng C, Shao W, Chen X, Zhang B, Wang G, Zhang W. Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis. International Journal of Infectious Diseases. 2022 Jan 1;114:252-60. | [DOI](#) | [Google Scholar](#) | [Weblink](#) |

Supplements

Proforma

Adverse events following Pfizer-BioNTec vaccine against COVID-19 in population more than 12 years, Nepal

Identification Number

Age in year: Sex: Male/Female Dose: First/ Second Chronic Illness: Yes/No

Chronic Illness Category:

1. Cardiac disease: Heart failure, Coronary Artery Disease, Cardiomyopathies
2. Chronic Kidney Disease
3. Cancer
4. Chronic and Severe Pulmonary Disease
5. Solid Organ Transplant
6. Chronic Hypertension and Diabetes
7. Immunosuppression condition

Adverse event following immunization- AEFI

1. Pain at the site of injection: Yes/No
2. Swelling at the site of injection: Yes/No
3. Redness at the site of injection: Yes/No
4. Fever: Yes/No
5. Malaise: Yes/No
6. Muscle pain: Yes/No
7. Headache: Yes/No
8. Chills: Yes/No
9. Vomiting: Yes/No
10. Diarrhea: Yes/No
11. Fatigue: Yes/No
12. Joint pain: Yes/No
13. Seizure: Yes/No
14. Hospitalization: Yes/No
15. Anaphylaxis (From ER record): Yes/No
16. Self medication: Yes/No