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Original Research

Factors Influencing Adverse Events Following Immunization (AEFI) of the COVID-19 vaccine: A Case Study in Ubon Ratchathani Province, Thailand

Teeraporn Sadira Supapaan, Kittiyaporn Thongthai, Pongdanai Vinitchai, Wicharut Praken, Suttasinee Suwannakul, Prasittichai Poonphol, Sisira Donsamak, Tuanthon Boonlue, Nonglek Kunawaradisai, Wannisa Dongtai, Uraiwan Akanit, Sawaeng Watcharathanakij, Saksit Sripa, Patcharee Kanjanawat, Jakkrit Busapan, Chonladda Pitchayajittipong, Peerawat Jinatongthai

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Abstract

Background: The rapid development, approval, and distribution of these vaccines highlight the need to carefully assess their safety. One significant concern is the incidence of Adverse Events Following Immunization (AEFI). There are few reports on the factors influencing AEFI and differences in AEFI among different COVID-19 vaccine brands in Thailand. Exploration of the incidence and factors related to post-vaccination adverse reactions against SARS-CoV-2 in the population attending vaccination centers in Thailand is considered pivotal. **Objective:** To investigate the incidence and factors associated with adverse events following the administration of the COVID-19 vaccine in the Ubon Ratchathani province. **Methods:** We analyzed data from individuals who received COVID-19 vaccinations in Ubon Ratchathani province between June 1, 2021, and July 31, 2022. **Results:** The study examined data from 2,955,978 COVID-19 vaccines administered in Ubon Ratchathani province. Among these, 3.34% experienced an AEFI, further categorized into events occurring within 30 min (0.17%) and after 30 min (3.19%) of vaccination. The occurrences were higher in females compared to males. The age groups exhibited distinct AEFI rates, with children aged 5–17 years and adults aged 18–60 years facing a higher risk. Additionally, individuals with comorbidities are more likely to experience AEFI. The brand of the vaccine and the number of doses administered also influenced AEFI rates. This comprehensive analysis provides valuable insights into AEFI reports, vaccine brands, and associated risk factors, and offers crucial information for vaccine safety monitoring and management. **Conclusion:** This COVID-19 vaccine adverse events study revealed that higher odds of adverse events were associated with being female, younger, having comorbidities, brand of vaccines, or getting over two doses. These findings provide valuable real-world safety information regarding different COVID-19 vaccines, aiding healthcare professionals and policymakers in effectively monitoring and managing vaccine-related AEFI.

Keywords: factors; adverse events following immunization (AEFI); covid-19 vaccine; Thailand

Teeraporn Sadira SUPAPAAN. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. teeraporn.s@ubu.ac.th
Kittiyaporn THONGTHAI. Ubon Ratchathani Provincial Health Office, Ubon Ratchathani, Thailand. kittiyaporn34000@gmail.com
Pongdanai VINITCHAI. Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. pongdanai.vi.61@ubu.ac.th
Wicharut PRAKEN. Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. wicharut.pr.61@ubu.ac.th
Suttasinee SUWANNAKUL. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. suttasinee.s@ubu.ac.th
Prasittichai POONPHOL. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. prasittichai.p@ubu.ac.th
Sisira DONSAMAK. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. Sisira.d@ubu.ac.th
Tuanthon BOONLUE. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. tuanthon.b@ubu.ac.th
Nonglek KUNAWARADISAI. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. nonglek.k@ubu.ac.th
Wannisa DONGTAI. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. wannisa.d@ubu.ac.th
Uraiwan AKANIT. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. uraiwan.a@ubu.ac.th
Sawaeng WATCHARATHANAKIJ. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. sawaeng.w@ubu.ac.th
Saksit SRIPA. Division of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. Saksit.s@ubu.ac.th
Patcharee KANJANAWAT. Pharmacy department, Sunpasitthiprasong Hospital, Ubon Ratchathani, 34000, Thailand. patcharee_kan@yahoo.com
Jakkrit BUSAPAN. Ubon Ratchathani Hospital, Ubon Ratchathani University, Ubon Ratchathani, 34190, Thailand. jakkrit.b@ubu.ac.th

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Chonladda PITCHAYAJITTIPONG. Division of Pharmaceutical Chemistry and Pharmaceutical Technology, Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Ubon Ratchathani, Thailand. chonladda.p@ubu.ac.th
Peerawat JINATONGTHAI*. Division of Pharmacy Practice and UBU Pharmacy Clinical Outcome Research Group (UPCOR), Faculty of Pharmaceutical Sciences, Ubon Ratchathani University, Thailand. peerawat.j@ubu.ac.th

BACKGROUND

The coronavirus disease 2019 (COVID-19) pandemic, caused by the coronavirus SARS-CoV-2, has created an unprecedented global health crisis. Since its emergence in December 2019, the virus has rapidly spread worldwide, affecting millions and putting immense pressure on healthcare systems and economies.[1-3] To combat this crisis, COVID-19 vaccines have been developed, approved, and widely distributed at an accelerated pace.[4-6] Multiple vaccines have received emergency use authorization from health authorities, offering hope in the fight against the pandemic.[5-7]

The fast-tracked development and distribution of these vaccines highlight the need to carefully assess their safety.[5,6] One significant concern is the occurrence of Adverse Events Following Immunization (AEFI), as defined by the WHO, which refers to any medical event that occurs after immunization and is not necessarily causally linked to the vaccine.[8,9] This event could manifest as an undesirable or unexpected sign, an abnormal result in laboratory tests, a symptom, or even a medical condition. Monitoring and analyzing AEFI is crucial not only to protect public health but also to build trust in COVID-19 vaccines among the population.[10]

Various COVID-19 vaccine brands, developed based on diverse technological platforms such as mRNA, viral vectors, and inactivated viruses, have been rolled out in immunization programs worldwide.[4] Preliminary reports suggest a variance in the reactogenicity and AEFI across these vaccine brands.[11,12] Furthermore, intrinsic and extrinsic factors, including demographic attributes, pre-existing medical conditions, and vaccination protocols, might modulate AEFI incidence and severity.[13-15]

As of the latest data available from the WHO COVID-19 dashboard, a total of 13.59 billion COVID-19 vaccine doses have been administered globally. Additionally, approximately 67% of the total population has received a complete primary series of COVID-19 vaccines. These numbers reflect the significant progress made in the global vaccination effort to combat the pandemic.[16] With the worldwide effort to vaccinate against COVID-19, Thailand has been working actively to organize a well-planned vaccination campaign. the Ministry of Public Health of Thailand and the Center for COVID-19 Situation Administration (CCSA) have created guidelines to encourage people in Thailand to be vaccinated.[17,18] This is done to reduce the seriousness of the disease, slow its spread, and help build immunity among the Thai people. The COVID-19 vaccination program for healthcare workers began in 2021.

In Thailand, COVID-19 vaccines were given a green light for emergency use and included in the national vaccination plan of March 2021. Initially, the inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine, the chimpanzee adenovirus-vectored (ChAdOx1 nCoV-19) vaccine, and the Beijing Institute of Biological Products Co., Ltd. (BIBP)® COVID-19 vaccine were used. Later in 2021, vaccines such as the BioNTech (BNT) 162b2 mRNA COVID-19 vaccine and mRNA-1273 vaccine were used. Some people receive a combination of these vaccines as their primary and booster shots. Children and adolescents mainly received mRNA vaccines.[19,20] To make sure these vaccines are safe, Thailand set up a system to monitor for any problems after vaccination, known as AEFI surveillance.[20,21] Hospitals are required to quickly report any serious issues linked to COVID-19 vaccines, to the National AEFI Program (AEFI-DDC).[19,20] Additionally, they created a way for people who got vaccinated to report any issues using a mobile phone app called "Mo Phrom," which helps keep an eye on the vaccination program and gather information about side effects.[19,20]

Adverse events following the immunization against the Coronavirus disease 2019 in Thailand, as of August 23, 2023, recorded a total of 147,600,205 administered doses.[22] Common adverse reactions across all vaccine brands include fever, headache, dizziness, nausea, vomiting, and body aches, while severe adverse reactions include myocarditis/pericarditis, severe allergic reactions, and Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).[21-23] In monitoring the safety of the public post-vaccination, the Ministry of Public Health has arranged for an additional surveillance system on top of the existing passive AEFI Surveillance, focusing on patients with a history of receiving the COVID-19 vaccine and getting treated at healthcare facilities. This active surveillance system, utilizing the Mor Prom application, aims to comprehensively and intensively monitor adverse events following COVID-19 vaccination.[19,22] However, there have been few reports on factors influencing AEFI and differences in AEFI among different COVID-19 vaccine brands in Thailand.

The exploration of incidents and factors related to adverse reactions post-vaccination against SARS-CoV-2 in the population attending vaccination centers in Thailand is considered pivotal. It is envisaged that this study will provide crucial data for medical personnel and policymakers to harness the planning, development, and dissemination of appropriate information to various groups of recipients, such as the general public and the elderly. This information is anticipated to boost vaccine confidence, enlighten the public about vaccine safety, and prepare them for potential post-vaccination adverse reactions. Ubon Ratchathani is a large city in Thailand with a total population of 1,869,806. Therefore, this study aimed to explore the incidents and factors associated with the occurrence of adverse events following the COVID-19 vaccine administration in the Ubon Ratchathani province.

OBJECTIVE

To investigate the incidents and factors associated with the occurrence of adverse events following COVID-19 vaccine administration in the Ubon Ratchathani province.

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METHODS

Study population

The total number of COVID-19 vaccine doses administered and accessed services in Ubon Ratchathani Province were recorded in the database of the reporting systems of the Ministry of Public Health (MOPH) IC and the AEFI DDC Epidemiology Division of the Public Health Office of Ubon Ratchathani Province from June 1, 2021, to July 31, 2022.

Inclusion Criteria: The total number of COVID-19 vaccine doses administered and accessed services in Ubon Ratchathani Province, recorded in the database from June 1, 2021, to July 31, 2022. The exclusion Criteria: Incomplete basic information and vaccination details.

Ethical consideration:

This study was approved by the Research Ethics Committees of the Ubon Ratchathani Provincial Public Health Office (SSJ. UB 2565-191) and the Research Ethics Committee of the Ubon Ratchathani University (UBU-REC-113-2565).

Study design:

This retrospective cohort study was conducted by obtaining data from secondary sources, namely the reporting systems of the Ministry of Public Health (MOPH) IC and the AEFI Department of Disease Control Epidemiology Division in the Ubon Ratchathani Provincial Public Health Office. Data on adverse events following vaccination against the coronavirus 2019 in Ubon Ratchathani province were collected from June 1, 2021, to July 31, 2022.

Survey instrument

Database of the reporting systems of the Ministry of Public Health (MOPH) IC and AEFI DDC Epidemiology Division of the Public Health Office of Ubon Ratchathani Province, with details of the data including: 1. basic personal information, such as sex, age, and pre-existing diseases; 2. vaccine-related information, such as the date of vaccination, brand of vaccine, and number of doses received; and 3. Adverse reactions (minor to moderate) observed within the 30-min observation point. Adverse reactions were reported in the doctor-ready reporting system after 30 min of vaccination via the "Mor Prom" application. In this study, vaccines were blinded by assigning specific code names to ensure anonymity while maintaining clarity about the vaccine platforms. The code names were used as follows: INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

Data analysis

Descriptive statistics were used for demographic data. Sex, age group, brand of vaccine, number of vaccinations, and comorbidities were selected as adjusted variables for multivariable logistic regression. Predictors of the outcome variable were identified using independent variables with p-values <0.05 and an Adjusted Odds Ratio at 95% CI.

RESULTS

Of the 2,955,978 doses administered (from 1,404,562 individuals), 3.34% experienced any adverse events following immunization (AEFI). These AEFI events were further categorized into those occurring within 30 min (0.17%) and those occurring after 30 min (3.19%) of vaccination. Gender-wise, 47.55% were male, with AEFI rates of 35.19% within 30 min and 34.88% after 30 min, whereas 52.45% were female, with AEFI rates of 64.81% within 30 min and 65.12% after 30 min. Table 1 summarizes the AEFI reported among participants receiving the COVID-19 vaccine in Ubon Ratchathani province. The mean age of the participants was 41.94 years, with varying AEFI rates across age groups. Regarding comorbidity status, 8.86 % of participants with comorbidities experienced AEFI within 30 min after vaccination. Different vaccine brands were administered, each with varying AEFI rates, and participants received different vaccine doses, which affected the AEFI rates accordingly.

Table 1. Adverse Events Following Immunization (AEFI) reported among participants receiving the COVID-19 vaccination in Ubon Ratchathani province

Characteristics	Total doses 2,955,978 (100.00)	With AEFI		
		Any 98,767 (3.34)	Within 30 mins 4,914 (0.17)	After 30 mins 94,262 (3.19)
Gender				
• Male (%)	1,405,685 (47.55)	34,755 (35.19)	1,990 (40.50)	32,877 (34.88)
• Female (%)	1,550,293 (52.45)	64,012 (64.81)	2,924 (59.50)	61,385 (65.12)
Age (mean ± SD)	41.94 ± 19.77	35.43 ± 15.22	44.77 ± 17.23	34.94 ± 14.95
• 5-17 years (%)	433,760 (14.67)	8,391 (8.50)	390 (7.94)	8,055 (8.55)
• 18-60 years (%)	1,931,063 (65.33)	83,089 (84.13)	3,499 (71.20)	79,921 (84.79)
• ≥ 60 years (%)	591,155 (20.00)	7,287 (7.38)	1,025 (20.86)	6,286 (6.67)
Comorbidities				
• Yes (%)	263,995 (8.93)	8,750 (8.86)	705 (14.35)	8,078 (8.57)
• No (%)	2,691,983 (91.07)	90,017 (91.14)	4,209 (85.65)	86,184 (91.43)
Brand of vaccine*				
• INAC-1 (%)	639,889 (21.65)	15,558 (15.75)	2,210 (44.97)	13,482 (14.30)
• INAC-2 (%)	161,362 (5.46)	5,150 (5.21)	109 (2.22)	5,050 (5.36)
• VV-1 (%)	860,028 (29.09)	36,644 (37.10)	2,062 (41.96)	34,753 (36.87)
• mRNA-1 (%)	1,183,471 (40.04)	30,347 (30.73)	512 (10.42)	29,926 (31.75)
• mRNA-2 (%)	111,213 (3.76)	11,065 (11.20)	21 (0.43)	11,048 (11.72)

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Table 1. Adverse Events Following Immunization (AEFI) reported among participants receiving the COVID-19 vaccination in Ubon Ratchathani province

Characteristics	Total doses 2,955,978 (100.00)	With AEFI		
		Any 98,767 (3.34)	Within 30 mins 4,914 (0.17)	After 30 mins 94,262 (3.19)
• PS-1 (%)	15 (0.00)	3 (0.00)	0 (0.00)	3 (0.00)
Vaccine dose				
• 1st dose (%)	1,261,312 (42.67)	34,470 (34.90)	3,126 (63.61)	31,587 (33.51)
• 2nd dose (%)	1,183,237 (40.03)	41,652 (42.17)	1,697 (34.53)	40,100 (42.54)
• > 2 doses (%)	511,429 (17.30)	22,645 (22.93)	91 (1.85)	22,575 (23.95)
AEFI compared within brand at different visits				
Brand of vaccine at the first visit				
• INAC-1 (%)	618,163 (100.00)	14,332 (2.32)	2,033 (0.33)	12,416 (2.01)
• INAC-2 (%)	87,181 (100.00)	2,709 (3.11)	73 (0.08)	2,643 (3.03)
• VV-1 (%)	217,407 (100.00)	12,674 (5.83)	876 (0.40)	11,884 (5.47)
• mRNA-1 (%)	448,082 (100.00)	10,750 (2.40)	345 (0.08)	10,460 (2.33)
• mRNA-2 (%)	33,726 (100.00)	3,541 (10.50)	12 (0.04)	3,531 (10.47)
• PS-1 (%)	3 (100.00)	0 (0.00)	0 (0.00)	0 (0.00)
Total	1,404,562 (100.00)	44,006 (3.13)	3,339 (0.24)	40,934 (2.91)
Brand of vaccine at the second visit				
• INAC-1 (%)	21,653 (100.00)	1,226 (5.66)	117 (0.82)	1,066 (4.92)
• INAC-2 (%)	73,863 (100.00)	2,438 (3.30)	36 (0.05)	2,404 (3.25)
• VV-1 (%)	600,776 (100.00)	22,740 (3.79)	1,170 (0.19)	21,653 (3.60)
• mRNA-1 (%)	442,058 (100.00)	12,060 (2.73)	147 (0.03)	11,941 (2.70)
• mRNA-2 (%)	23,748 (100.00)	2,460 (10.36)	1 (0.004)	2,459 (10.35)
• PS-1 (%)	3 (100.00)	0 (0.00)	0 (0.00)	0 (0.00)
Total	1,162,101 (100.00)	40,924 (3.52)	1,531 (0.13)	39,523 (3.40)
Brand of vaccine at the third visit				
• INAC-1 (%)	72 (100.00)	0 (0.00)	0 (0.00)	0 (0.00)
• INAC-2 (%)	306 (100.00)	3 (0.98)	0 (5.21)	3 (0.98)
• VV-1 (%)	39,622 (100.00)	1,209 (3.05)	16 (0.04)	1,195 (3.02)
• mRNA-1 (%)	279,685 (100.00)	6,920 (2.47)	17 (0.01)	6,910 (2.47)
• mRNA-2 (%)	44,481 (100.00)	4,149 (9.33)	8 (0.02)	4,143 (9.31)
• PS-1 (%)	8 (100.00)	3 (37.50)	0 (0.00)	3 (37.50)
Total	364,174 (100.00)	12,284 (3.37)	41 (0.01)	12,254 (3.36)
Brand of vaccine at the forth visit and more				
INAC-1 (%)	1 (100.00)	0 (0.00)	0 (0.00)	0 (0.00)
INAC-2 (%)	12 (100.00)	0 (0.00)	0 (0.00)	0 (0.00)
VV-1 (%)	2,223 (100.00)	21 (0.94)	0 (0.00)	21 (0.94)
mRNA-1 (%)	13,646 (100.00)	617 (4.52)	3 (0.02)	615 (4.51)
mRNA-2 (%)	9,258 (100.00)	915 (9.88)	0 (0.00)	915 (9.88)
PS-1 (%)	1 (100.00)	0 (0.00)	0 (0.00)	0 (0.00)
Total	25,141 (100.00)	1,553 (6.18)	3 (0.01)	1,551 (6.17)
Brand of vaccine at all visits				
• INAC-1 (%)	639,889 (100.00)	15,558 (2.43)	2,210 (0.35)	13,482 (2.11)
• INAC-2 (%)	161,362 (100.00)	5,150 (3.19)	109 (0.07)	5,050 (3.13)
• VV-1 (%)	860,028 (100.00)	36,644 (4.26)	2,062 (0.24)	34,753 (4.04)
• mRNA-1 (%)	1,183,471 (100.00)	30,347 (2.56)	512 (0.04)	29,926 (2.53)
• mRNA-2 (%)	111,213 (100.00)	11,065 (9.95)	21 (0.02)	11,048 (9.93)
• PS-1 (%)	15 (100.00)	3 (20.00)	0 (0.00)	3 (20.00)
Total	2,955,978 (100.00)	98,767 (3.34)	4,914 (0.17)	94,262 (3.19)

*INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

Table 2 presents the number of vaccinations categorized according to age group. Participants aged 5-17 years received 226,755 (7.67%) first doses, primarily from INAC-1 vaccine (20.70%), and the mRNA-1 vaccine (12.61%). Regarding the number of vaccine doses administered to those aged 18-60 years, 792,455 (26.81%) received the first dose, with a diverse distribution of vaccines. Individuals aged 60 years and older received 242,102 first doses (8.19%), with the INAC-1 vaccine

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accounting for the largest proportion at 4.69%. In the second dose category, 186,347 (6.30%) participants aged 5-17 years were vaccinated, mostly with the mRNA-1 vaccine (6.28%). Participants aged 18–60 years received 765,057 (25.88%) second doses, with a predominant share of the VV-1 vaccine (15.79%). Lastly, participants aged ≥ 60 years received 231,833 (7.84%) second doses, again with the VV-1 vaccine (5.24%) being the dominant vaccine. For participants receiving over two doses, 20,658 (0.70%) were aged 5–17 years, 373,551 (12.64%) were aged 18–60 years, and 117,220 (3.97%) were aged ≥ 60 years. The mRNA-1 vaccine (3.18%) was the primary vaccine administered to this group. The total number of vaccinations for each age group is shown in Table 2.

Figure 1 presents the number of Adverse Events Following Immunization (AEFI) reports within 30 min of vaccination categorized by vaccine brands. The INAC-1 vaccine accounted for the highest number of AEFI reports at 2,436 (44.68%), followed by the VV-1 vaccine with 2,295 (42.09%) reports. The INAC-2 and mRNA-1 vaccines had 130 (2.38%) and 564 (10.34%) AEFI reports, respectively. The mRNA-2 vaccine had the lowest number of reports, at 27 (0.50%), whereas the PS-1 vaccine had no reported AEFI. The most commonly reported AEFI symptom was “Pain, swelling, or redness at injection site” with 669 (12.27%) reports, followed by “Effect on blood pressure” with 1,873 (34.35%) reports. Additional AEFI symptoms and their corresponding percentages are provided in table for reference. Table 3 illustrates the relationship between various characteristics and Adverse Events Following Immunization (AEFI) reports within 30 minutes of vaccination, classified by types of AEFI. For “Any AEFI,” the results showed that females had a 32% higher likelihood of experiencing AEFI compared to males (AOR 1.32, 95% CI 1.25, 1.40). Children in the 5-17 years age group were significantly more likely to report AEFI compared to those aged ≥ 60 years (AOR 3.32, 95% CI 2.72, 4.06). Additionally, individuals with comorbidities had a 38% higher likelihood of experiencing AEFI compared to those without comorbidities (AOR 1.38, 95% CI 1.01, 1.88). The brand of vaccine significantly influenced AEFI, with the mRNA-1 vaccine and the mRNA-2 vaccine having the lowest odds of AEFI (mRNA-1: AOR 0.10, 95% CI 0.08, 0.12; mRNA-2: AOR 0.13, 95% CI 0.08, 0.21) compared to the INAC-1 vaccine. For specific AEFI categories, similar associations were observed between sex, age, comorbidities, the brand of vaccine, and the likelihood of experiencing AEFI.

Figure 2 presents the number of AEFI reports that occurred 30 min after vaccination with various COVID-19 vaccines, categorized by specific adverse events. The overall count of any AEFI reports was 184,161, with the VV-1 vaccine accounting

Table 2. Number of vaccinations grouped by age

Vaccine*	Age group (%)			Total (%)
	5-17 years	18-60 years	≥ 60 years	
1st dose	**226,755 (7.67)**	**792,455 (26.81)**	**242,102 (8.19)**	**1,261,312 (42.67)**
• INAC-1	467 (0.02)	472,799 (15.99)	138,611 (4.69)	611,877 (20.70)
• INAC-2	206 (0.01)	65,611 (2.22)	15,272 (0.52)	81,089 (2.74)
• VV-1	301 (0.01)	132,987 (4.50)	46,135 (1.56)	179,423 (6.07)
• mRNA-1	225,678 (7.63)	108,170 (3.66)	38,868 (1.31)	372,716 (12.61)
• mRNA-2	103 (0.00)	12,886 (0.44)	3,216 (0.11)	16,205 (0.55)
• PS-1	0 (0.00)	2 (0.00)	0 (0.00)	2 (0.00)
2nd dose	**186,347 (6.30)**	**765,057 (25.88)**	**231,833 (7.84)**	**1,183,237 (40.03)**
• INAC-1	8 (0.00)	25,442 (0.86)	2,437 (0.08)	27,887 (0.94)
• INAC-2	165 (0.01)	64,902 (2.20)	14,800 (0.50)	79,867 (2.70)
• VV-1	308 (0.01)	466,825 (15.79)	154,949 (5.24)	622,082 (21.04)
• mRNA-1	185,771 (6.28)	194,985 (6.60)	56,876 (1.92)	437,632 (14.80)
• mRNA-2	95 (0.00)	12,902 (0.44)	2,771 (0.09)	15,768 (0.53)
• PS-1	0 (0.00)	1 (0.00)	0 (0.00)	1 (0.00)
>2 doses	**20,658 (0.70)**	**373,551 (12.64)**	**117,220 (3.97)**	**511,429 (17.30)**
• INAC-1	0 (0.00)	93 (0.00)	32 (0.00)	125 (0.00)
• INAC-2	5 (0.00)	336 (0.01)	65 (0.00)	406 (0.01)
• VV-1	30 (0.00)	48,722 (1.65)	9,771 (0.33)	58,523 (1.98)
• mRNA-1	20,433 (0.69)	258,639 (8.75)	94,051 (3.18)	373,123 (12.62)
• mRNA-2	190 (0.01)	65,750 (2.22)	13,300 (0.45)	79,240 (2.68)
• PS-1	0 (0.00)	11 (0.00)	1 (0.00)	12 (0.00)
Total	**433,760 (14.67)**	**1,931,063 (65.33)**	**591,155 (20.00)**	**2,955,978 (100.00)**

*INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

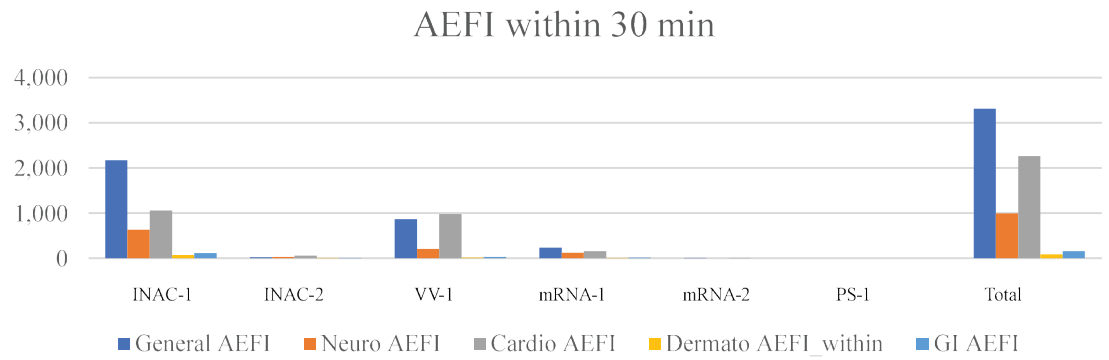

Figure 1. Adverse Events Following Immunization (AEFI) within 30 minutes by Vaccine Brands (Please see details in supplement Table S1)
(INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.)

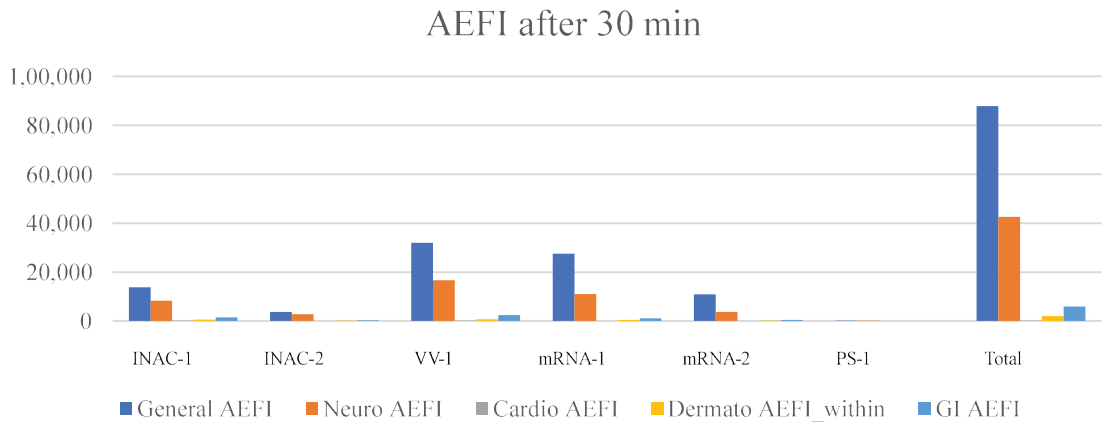

Figure 2. Adverse Events Following Immunization (AEFI) after 30 minutes by Vaccine Brands
(Please see details in supplement Table S2)
(INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.)

Table 3. Relationship of characteristics and AEFI report within 30 minutes of vaccination. (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)*	p-value
Any AEFI					
Gender					
• Male (%)	1,990 (40.50)	1,403,695 (47.57)	1	1	
• Female (%)	2,924 (59.50)	1,547,369 (52.43)	1.33 (1.26, 1.41)	1.32 (1.25, 1.40)	**<0.001**
Age	44.77 ± 17.23	41.94 ± 19.77			
• 5-17 years (%)	390 (7.94)	433,370 (14.69)	0.52 (0.46, 0.58)	3.32 (2.72, 4.06)	**<0.001**
• 18-60 years (%)	3,499 (71.20)	1,927,564 (65.32)	1.05 (0.97, 1.12)	0.99 (0.92, 1.07)	0.832
• ≥ 60 years (%)	1,025 (20.86)	590,130 (20.00)	1	1	
Comorbidities					
• Yes (%)	705 (14.35)	263,290 (8.92)	1.71 (1.58, 1.85)	1.38 (1.01, 1.88)	**0.043**
• No (%)	4,209 (85.65)	2,687,774 (91.08)	1	1	
Brand of vaccine**					
• INAC-1	2,210 (44.97)	637,679 (21.61)	1	1	
• INAC-2	109 (2.22)	161,253 (5.46)	0.20 (0.16, 0.24)	0.24 (0.19, 0.29)	**<0.001**
• VV-1	2,062 (41.96)	857,966 (29.07)	0.69 (0.65, 0.74)	0.98 (0.91, 1.07)	0.705

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Table 3. Relationship of characteristics and AEFI report within 30 minutes of vaccination. (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)*	p-value
• mRNA-1	512 (10.42)	1,182,959 (40.09)	0.12 (0.11, 0.14)	0.10 (0.08, 0.12)	**<0.001**
• mRNA-2	21 (0.43)	111,192 (3.77)	0.05 (0.04, 0.08)	0.13 (0.08, 0.21)	**<0.001**
• PS-1	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose	3,126 (63.61)	1,258,186 (42.63)	1	1	
• 2nd dose	1,697 (34.53)	1,181,540 (40.04)	0.58 (0.54, 0.61)	0.65 (0.60, 0.70)	**<0.001**
• > 2 doses	91 (1.85)	511,338 (17.33)	0.07 (0.06, 0.09)	0.24 (0.19, 0.30)	**<0.001**
General AEFI (injection site related infection, fatigue, fever, myalgia, difficult breathing)					
Gender					
• Male (%)	824 (40.39)	1,404,861 (47.56)	1	1	
• Female (%)	1,216 (59.61)	1,549,077 (52.44)	1.34 (1.23, 1.46)	1.32 (1.21, 1.45)	**<0.001**
Age	42.02 ± 16.94	41.94 ± 19.77			
• 5-17 years (%)	179 (8.77)	433,581 (14.68)	0.76 (0.64, 0.92)	5.30 (3.91, 7.17)	**<0.001**
• 18-60 years (%)	1,542 (75.59)	1,929,521 (65.32)	1.48 (1.31, 1.67)	1.43 (1.26, 1.62)	**<0.001**
• ≥ 60 years (%)	319 (15.64)	590,836 (20.00)	1	1	
Comorbidities					
• Yes (%)	282 (13.82)	263,713 (8.93)	1.64 (1.44, 1.86)	1.59 (0.95, 2.67)	0.08
• No (%)	1,758 (86.18)	2,690,225 (91.07)	1	1	
Brand of vaccine					
• INAC-1	898 (44.02)	638,991 (21.63)	1	1	
• INAC-2	22 (1.08)	161,340 (5.46)	0.10 (0.06, 0.15)	0.09 (0.06, 0.14)	**<0.001**
• VV-1	871 (42.70)	859,157 (29.09)	0.72 (0.66, 0.79)	0.71 (0.62, 0.81)	**<0.001**
• mRNA-1	236 (11.57)	1,183,235 (40.06)	0.14 (0.12, 0.16)	0.08 (0.06, 0.10)	**<0.001**
• mRNA-2	13 (0.64)	111,200 (3.76)	0.08 (0.05, 0.14)	0.13 (0.07, 0.23)	**<0.001**
• PS-1	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose	1,148 (56.27)	1,260,164 (42.66)	1	1	
• 2nd dose	835 (40.93)	1,182,402 (40.03)	0.78 (0.71, 0.85)	1.08 (0.96, 1.23)	0.211
• > 2 doses	57 (2.79)	511,372 (17.31)	0.12 (0.09, 0.16)	0.48 (0.35, 0.64)	**<0.001**
Neurological related AEFI (muscle weakness, drowsiness, headache, blurred vision, dizziness, numbness)					
Gender					
• Male (%)	192 (27.04)	1,405,493 (47.56)	1	1	
• Female (%)	518 (72.96)	1,549,775 (52.44)	2.45 (2.07, 2.89)	2.50 (2.11, 2.95)	**<0.001**
Age	36.76 ± 16.48	41.94 ± 19.77			
• 5-17 years (%)	101 (14.23)	433,659 (14.67)	2.42 (1.75, 3.34)	10.93 (6.56, 18.23)	**<0.001**
• 18-60 years (%)	552 (77.75)	1,930,511 (65.32)	2.97 (2.26, 3.89)	2.98 (2.25, 3.94)	**<0.001**
• ≥ 60 years (%)	57 (8.03)	591,098 (20.00)	1	1	
Comorbidities					
• Yes (%)	77 (10.85)	263,918 (8.93)	1.24 (0.98, 1.57)	1.17 (0.29, 4.79)	0.828
• No (%)	633 (89.15)	2,691,350 (91.07)	1	1	
Brand of vaccine					
• INAC-1	347 (48.87)	639,542 (21.64)	1	1	
• INAC-2	30 (4.23)	161,332 (5.46)	0.34 (0.24, 0.50)	0.47 (0.32, 0.68)	**<0.001**
• VV-1	211 (29.72)	859,817 (29.09)	0.45 (0.38, 0.54)	0.87 (0.70, 1.07)	0.19

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Table 3. Relationship of characteristics and AEFI report within 30 minutes of vaccination. (classified by types of AEFI)

Characteristics	**AEFI**	**without AEFI**	**COR (95%CI)**	**AOR (95%CI)***	**p-value**
• mRNA-1	122 (17.18)	1,183,349 (40.04)	0.19 (0.15, 0.23)	0.14 (0.09, 0.21)	**<0.001**
• mRNA-2	0 (0.00)	111,213 (3.76)	-	-	
• PS-1	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose	526 (74.08)	1,260,786 (42.66)	1	1	
• 2nd dose	172 (24.23)	1,183,065 (40.03)	0.35 (0.29, 0.41)	0.42 (0.34, 0.51)	**<0.001**
• > 2 doses	12 (1.69)	511,417 (17.31)	0.06 (0.03, 0.10)	0.19 (0.10, 0.35)	**<0.001**
Cardiovascular related AEFI (low or high blood pressure, abnormal heart rate, needed ECG monitoring)					
Gender					
• Male (%)	982 (45.55)	1,404,703 (47.56)	1	1	
• Female (%)	1,174 (54.45)	1,549,119 (52.44)	1.08 (1.00, 1.18)	1.07 (0.98, 1.17)	0.11
Age	50.02 ± 16.08	41.93 ± 19.77			
• 5-17 years (%)	114 (5.29)	433,646 (14.68)	0.24 (0.20, 0.29)	1.66 (1.18, 2.31)	**0.003**
• 18-60 years (%)	1,395 (64.70)	1,929,668 (65.33)	0.66 (0.60, 0.72)	0.60 (0.54, 0.66)	**<0.001**
• ≥ 60 years (%)	647 (30.01)	590,508 (19.99)	1	1	
Comorbidities					
• Yes (%)	345 (16.00)	263,650 (8.93)	1.94 (1.73, 2.18)	1.35 (0.91, 2.00)	0.137
• No (%)	1,811 (84.00)	2,690,172 (91.07)	1	1	
Brand of vaccine					
• INAC-1	952 (44.16)	638,937 (21.63)	1	1	
• INAC-2	57 (2.64)	161,305 (5.46)	0.24 (0.18, 0.31)	0.33 (0.25, 0.43)	**<0.001**
• VV-1	982 (45.55)	859,046 (29.08)	0.77 (0.70, 0.84)	1.33 (1.19, 1.49)	**<0.001**
• mRNA-1	157 (7.28)	1,183,314 (40.06)	0.09 (0.08, 0.11)	0.10 (0.08, 0.14)	**<0.001**
• mRNA-2	8 (0.37)	111,205 (3.76)	0.05 (0.02, 0.10)	0.17 (0.08, 0.34)	**<0.001**
• PS-1	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose	1,445 (67.02)	1,259,867 (42.65)	1	1	
• 2nd dose	688 (31.91)	1,182,549 (40.03)	0.51 (0.46, 0.56)	0.47 (0.42, 0.53)	**<0.001**
• > 2 doses	23 (1.07)	511,406 (17.31)	0.04 (0.03, 0.06)	0.12 (0.08, 0.18)	**<0.001**
Dermatological related AEFI (rash, petechiae)					
Gender					
• Male (%)	5 (15.15)	1,405,680 (47.55)	1	1	
• Female (%)	28 (84.85)	1,550,265 (52.45)	5.08 (1.96, 13.15)	5.18 (2.00, 13.43)	**0.001**
Age	41.27 ± 17.91	41.94 ± 19.77			
• 5-17 years (%)	433,759 (14.67)	years (0.00)	0.23 (0.03, 1.89)	1.04 (0.06, 17.35)	0.98
• 18-60 years (%)	1,931,037 (65.33)	years (0.00)	1.33 (0.55, 3.22)	1.41 (0.58, 3.45)	0.453
• ≥ 60 years (%)	591,149 (20.00)	years (0.00)	1	1	
Comorbidities					
• Yes (%)	2 (6.06)	263,993 (8.93)	0.66 (0.16, 2.75)	0.51 (0.12, 2.17)	0.364
• No (%)	31 (93.94)	2,691,952 (91.07)	1	1	
Brand of vaccine					
• INAC-1	15 (45.45)	639,874 (21.65)	1	1	
• INAC-2	1 (3.03)	161,361 (5.46)	0.26 (0.03, 2.00)	0.33 (0.04, 2.54)	0.285
• VV-1	15 (45.45)	860,013 (29.09)	0.74 (0.36, 1.52)	1.15 (0.44, 2.97)	0.78

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Table 3. Relationship of characteristics and AEFI report within 30 minutes of vaccination. (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)*	p-value
• mRNA-1	2 (6.06)	1,183,469 (40.04)	0.07 (0.02, 0.32)	0.15 (0.02, 1.17)	0.07
• mRNA-2	0 (0.00)	111,213 (3.76)	-	-	
• PS-1	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose	21 (63.64)	1,261,291 (42.67)	1	1	
• 2nd dose	12 (36.36)	1,183,225 (40.03)	0.61 (0.30, 1.24)	0.61 (0.24, 1.57)	0.304
• > 2 doses	0 (0.00)	511,429 (17.30)	-	-	
Gastrointestinal related AEFI (nausea, vomiting, diarrhea)					
Gender					
• Male (%)	17 (16.19)	1,405,668 (47.56)	1	1	
• Female (%)	88 (83.81)	1,550,205 (52.44)	4.69 (2.79, 7.89)	4.77 (2.84, 8.02)	**<0.001**
Age	37.78 ± 16.42	41.94 ± 19.77			
• 5-17 years (%)	11 (10.48)	433,749 (14.67)	1.50 (0.64, 3.53)	6.42 (1.65, 24.94)	**0.007**
• 18-60 years (%)	84 (80.00)	1,930,979 (65.33)	2.57 (1.33, 4.95)	2.44 (1.26, 4.74)	**0.008**
• ≥ 60 years (%)	10 (9.52)	591,145 (20.00)	1	1	
Comorbidities					
• Yes (%)	13 (12.38)	263,982 (8.93)	1.44 (0.81, 2.58)	1.15 (0.63, 2.07)	0.653
• No (%)	92 (87.62)	2,691,891 (91.07)	1	1	
Brand of vaccine					
• INAC-1	57 (54.29)	639,832 (21.65)	1	1	
• INAC-2	5 (4.76)	161,357 (5.46)	0.35 (0.14, 0.87)	0.51 (0.20, 1.28)	0.151
• VV-1	29 (27.62)	859,999 (29.09)	0.38 (0.24, 0.59)	0.81 (0.47, 1.40)	0.445
• mRNA-1	14 (13.33)	1,183,457 (40.04)	0.13 (0.07, 0.24)	0.14 (0.04, 0.44)	**0.001**
• mRNA-2	0 (0.00)	111,213 (3.76)	-	-	
• PS-1	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose	82 (78.10)	1,261,230 (42.67)	1	1	
• 2nd dose	22 (20.95)	1,183,215 (40.03)	0.29 (0.18, 0.46)	0.35 (0.20, 0.63)	**<0.001**
• > 2 doses	1 (0.95)	511,428 (17.30)	0.03 (0.00, 0.22)	0.10 (0.01, 0.78)	**0.028**

1 = Reference group; *Age group with comorbidities interaction was included as adjusted variables; **INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

for the highest percentage at 42.17%, followed by the mRNA-1 vaccine at 28.02%. Among specific adverse events, swelling, pain, and redness at the injection site were most commonly reported across all vaccines, with a total count of 28,157 (15.29%). Fever was another significant adverse event, with a total count of 39,592 (21.50%).

Table 4 illustrates the relationship between various demographic and vaccine-related characteristics and the occurrence of AEFI 30 min after vaccination, categorized by brands of AEFI. Among the a0uny AEFI, gender differences were evident, with females having a 71% increased likelihood of experiencing AEFI compared to males (AOR 1.71, 95% CI 1.68-1.73, p < 0.001). Age also played a significant role, with individuals aged 5-17 years having a 2.21-fold higher odds of AEFI compared to those over 60 years of age (AOR 2.21, 95% CI 2.13-2.29, p < 0.001). Comorbidities were associated with a higher likelihood of AEFI (AOR 2.10, 95% CI 1.90-2.32, p < 0.001). Furthermore, the brand of vaccine administered demonstrated varied AEFI risks, with the mRNA-2 vaccine exhibiting the highest odds (AOR 4.35, 95% CI 4.22-4.49, p < 0.001) compared to the INAC-1 vaccine as the reference group. The AOR for AEFI was significantly higher for those receiving over two doses at 1.14 (95% CI 1.12, 1.17) compared to those receiving the first dose (p < 0.001). The analysis, stratified by specific AEFI categories such as general, neurological, cardiovascular, dermatological, and gastrointestinal, revealed consistent trends in the risk factors across these categories.

Figure 3 shows the number of AEFI reports (both within and 30 min after vaccination) categorized by specific AEFI types and vaccine brands. In total, 189,451 AEFI reports were recorded, with the highest association with the VV-1 vaccine (42.17%), followed by the mRNA-1 vaccine (27.53%), the INAC-1 vaccine

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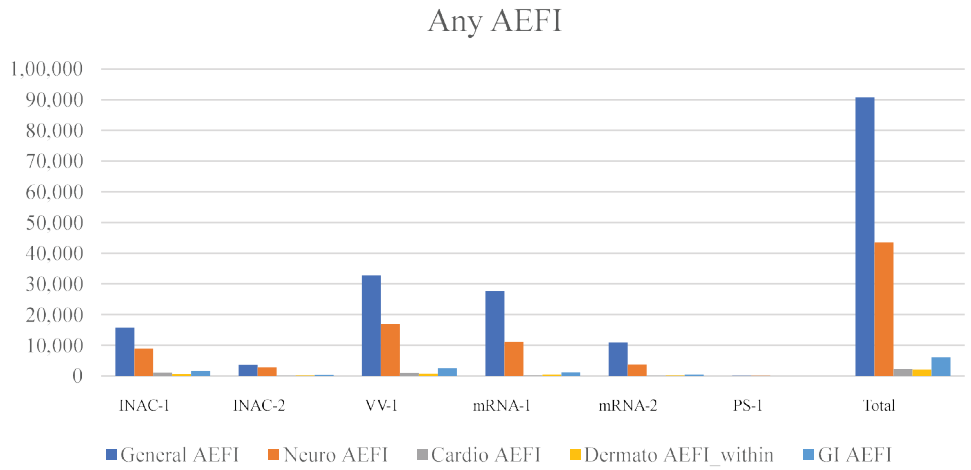

Figure 3. Any Adverse Events Following Immunization (AEFI) by Vaccine Brands
(INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.)

Table 4. Relationship of characteristics and AEFI report after 30 minutes of vaccination (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
Any AEFI					
Gender					
• Male (%)	32,877 (34.88)	1,372,808 (47.97)	1	1	
• Female (%)	61,385 (65.12)	1,488,908 (52.03)	1.72 (1.70, 1.75)	1.71 (1.68, 1.73)	**<0.001**
Age	34.94 ± 14.95	42.17 ± 19.87			
• 5-17 years (%)	8,055 (8.55)	425,705 (14.88)	1.76 (1.70, 1.82)	2.21 (2.13, 2.29)	**<0.001**
• 18-60 years (%)	79,921 (84.79)	1,851,142 (64.69)	4.02 (3.91, 4.12)	4.29 (4.17, 4.40)	**<0.001**
• ≥ 60 years (%)	6,286 (6.67)	584,869 (20.44)	1	1	
Comorbidities					
• Yes (%)	8,078 (8.57)	255,917 (8.94)	0.95 (0.93, 0.98)	2.10 (1.90, 2.32)	**<0.001**
• No (%)	86,184 (91.43)	2,605,799 (91.06)	1	1	
Brand of vaccine*					
• INAC-1 (%)	13,482 (14.30)	626,407 (21.89)	1	1	
• INAC-2 (%)	5,050 (5.36)	156,312 (5.46)	1.50 (1.45, 1.55)	1.45 (1.41, 1.50)	**<0.001**
• VV-1 (%)	34,753 (36.87)	825,275 (28.84)	1.96 (1.92, 2.00)	1.97 (1.93, 2.02)	**<0.001**
• mRNA-1 (%)	29,926 (31.75)	1,153,545 (40.31)	1.21 (1.18, 1.23)	1.34 (1.31, 1.38)	**<0.001**
• mRNA-2 (%)	11,048 (11.72)	100,165 (3.50)	5.12 (4.99, 5.26)	4.35 (4.22, 4.49)	**<0.001**
• PS-1 (%)	3 (0.00)	12 (0.00)	11.62 (3.28, 41.17)	8.40 (2.34, 30.18)	**0.001**
Vaccine dose					
• 1st dose (%)	31,587 (33.51)	1,229,725 (42.97)	1	1	
• 2nd dose (%)	40,100 (42.54)	1,143,137 (39.95)	1.37 (1.35, 1.39)	1.01 (1.00, 1.03)	0.106
• > 2 doses (%)	22,575 (23.95)	488,854 (17.08)	1.80 (1.77, 1.83)	1.14 (1.12, 1.17)	**<0.001**
General AEFI (injection site related infection, fatigue, fever, myalgia, difficult breathing)					
Gender					
• Male (%)	29,625 (35.30)	1,376,060 (47.91)	1	1	
• Female (%)	54,310 (64.70)	1,495,983 (52.09)	1.69 (1.66, 1.71)	1.67 (1.64, 1.69)	**<0.001**
Age	34.89 ± 15.01	42.15 ± 19.85			
• 5-17 years (%)	7,009 (8.35)	426,751 (14.86)	1.71 (1.65, 1.77)	2.09 (2.01, 2.17)	**<0.001**
• 18-60 years (%)	71,310 (84.96)	1,859,753 (64.75)	4.00 (3.89, 4.11)	4.28 (4.16, 4.41)	**<0.001**

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Table 4. Relationship of characteristics and AEFI report after 30 minutes of vaccination (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
• ≥ 60 years (%)	5,616 (6.69)	585,539 (20.39)	1	1	
Comorbidities					
• Yes (%)	7,142 (8.51)	256,853 (8.94)	0.95 (0.92, 0.97)	2.09 (1.88, 2.32)	**<0.001**
• No (%)	76,793 (91.49)	2,615,190 (91.06)	1	1	
Brand of vaccine					
• INAC-1 (%)	10,506 (12.52)	629,383 (21.91)	1	1	
• INAC-2 (%)	3,659 (4.36)	157,703 (5.49)	1.39 (1.34, 1.44)	1.34 (1.29, 1.40)	**<0.001**
• VV-1 (%)	32,008 (38.13)	828,020 (28.83)	2.32 (2.26, 2.37)	2.33 (2.27, 2.39)	**<0.001**
• mRNA-1 (%)	27,198 (32.40)	1,156,273 (40.26)	1.41 (1.38, 1.44)	1.59 (1.54, 1.63)	**<0.001**
• mRNA-2 (%)	10,561 (12.58)	100,652 (3.50)	6.29 (6.11, 6.46)	5.31 (5.14, 5.49)	**<0.001**
• PS-1 (%)	3 (0.00)	12 (0.00)	14.98 (4.23, 53.08)	10.80 (3.01, 38.80)	**<0.001**
Vaccine dose					
• 1st dose (%)	26,609 (31.70)	1,234,703 (42.99)	1	1	
• 2nd dose (%)	36,200 (43.13)	1,147,037 (39.94)	1.46 (1.44, 1.49)	1.02 (1.00, 1.04)	0.1
• > 2 doses (%)	21,126 (25.17)	490,303 (17.07)	2.00 (1.96, 2.04)	1.15 (1.13, 1.18)	**<0.001**
Neurological related AEFI (muscle weakness, drowsiness, headache, blurred vision, dizziness, numbness)					
Gender					
• Male (%)	12,475 (30.48)	1,393,210 (47.79)	1	1	
• Female (%)	28,453 (69.52)	1,521,840 (52.21)	2.09 (2.04, 2.13)	2.09 (2.05, 2.14)	**<0.001**
Age	33.75 ± 14.65	42.05 ± 19.81			
• 5-17 years (%)	3,475 (8.49)	430,285 (14.76)	2.36 (2.24, 2.50)	3.58 (3.37, 3.81)	**<0.001**
• 18-60 years (%)	35,439 (86.59)	1,895,624 (65.03)	5.47 (5.23, 5.72)	5.88 (5.61, 6.16)	**<0.001**
• ≥ 60 years (%)	2,014 (4.92)	589,141 (20.21)	1	1	
Comorbidities					
• Yes (%)	3,432 (8.39)	260,563 (8.94)	0.93 (0.90, 0.97)	2.17 (1.82, 2.58)	**<0.001**
• No (%)	37,496 (91.61)	2,654,487 (91.06)	1	1	
Brand of vaccine					
• INAC-1 (%)	6,906 (16.87)	632,983 (21.71)	1	1	
• INAC-2 (%)	2,790 (6.82)	158,572 (5.44)	1.61 (1.54, 1.69)	1.56 (1.49, 1.64)	**<0.001**
• VV-1 (%)	16,718 (40.85)	843,310 (28.93)	1.82 (1.77, 1.87)	1.85 (1.79, 1.92)	**<0.001**
• mRNA-1 (%)	10,897 (26.62)	1,172,574 (40.22)	0.85 (0.83, 0.88)	0.94 (0.91, 0.98)	**0.004**
• mRNA-2 (%)	3,616 (8.84)	107,597 (3.69)	3.08 (2.96, 3.21)	2.81 (2.67, 2.95)	**<0.001**
• PS-1 (%)	1 (0.00)	14 (0.00)	6.55 (0.86, 49.79)	4.99 (0.65, 38.33)	0.122
Vaccine dose					
• 1st dose (%)	14,914 (36.44)	1,246,398 (42.76)	1	1	
• 2nd dose (%)	18,436 (45.04)	1,164,801 (39.96)	1.32 (1.29, 1.35)	1.01 (0.99, 1.04)	0.3
• > 2 doses (%)	7,578 (18.52)	503,851 (17.28)	1.26 (1.22, 1.29)	1.00 (0.97, 1.04)	0.89
Cardiovascular related AEFI (low or high blood pressure, abnormal heart rate, needed ECG monitoring)					
Gender					
• Male (%)	4 (80.00)	1,405,681 (47.55)	1	1	
• Female (%)	1 (20.00)	1,550,292 (52.45)	0.23 (0.03, 2.03)	0.22 (0.03, 2.01)	0.182
Age	61.95 ± 15.34	41.94 ± 19.77			
• 5-17 years (%)	0 (0.00)	433,760 (14.67)	-	-	
• 18-60 years (%)	1 (20.00)	1,931,062 (65.33)	0.08 (0.01, 0.68)	0.09 (0.01, 0.78)	**0.029**

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Table 4. Relationship of characteristics and AEFI report after 30 minutes of vaccination (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
• ≥ 60 years (%)	4 (80.00)	591,151 (20.00)	1	1	
Comorbidities					
• Yes (%)	0 (0.00)	263,995 (8.93)	-	-	
• No (%)	5 (100.00)	2,691,978 (91.07)	1	1	
Brand of vaccine					
• INAC-1 (%)	1 (20.00)	639,888 (21.65)	1	1	
• INAC-2 (%)	0 (0.00)	161,362 (5.46)	-	-	
• VV-1 (%)	4 (80.00)	860,024 (29.09)	2.98 (0.33, 26.63)	0.59 (0.02, 22.79)	0.777
• mRNA-1 (%)	0 (0.00)	1,183,471 (40.04)	-	-	
• mRNA-2 (%)	0 (0.00)	111,213 (3.76)	-	-	
• PS-1 (%)	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose (%)	1 (20.00)	1,261,311 (42.67)	1	1	
• 2nd dose (%)	4 (80.00)	1,183,233 (40.03)	4.26 (0.48, 38.15)	7.15 (0.19, 274.29)	0.29
• > 2 doses (%)	0 (0.00)	511,429 (17.30)	-	-	
Dermatological related AEFI (rash, petechiae)					
Gender					
• Male (%)	537 (28.87)	1,405,148 (47.57)	1	1	
• Female (%)	1,323 (71.13)	1,548,970 (52.43)	2.23 (2.02, 2.47)	2.20 (1.99, 2.43)	**<0.001**
Age	38.67 ± 15.01	41.94 ± 19.77			
• 5-17 years (%)	99 (5.32)	433,661 (14.68)	0.75 (0.59, 0.96)	1.27 (0.97, 1.68)	0.087
• 18-60 years (%)	1,582 (85.05)	1,929,481 (65.31)	2.71 (2.32, 3.16)	2.68 (2.28, 3.14)	**<0.001**
• ≥ 60 years (%)	179 (9.62)	590,976 (20.01)	1	1	
Comorbidities					
• Yes (%)	228 (12.26)	263,767 (8.93)	1.42 (1.24, 1.64)	1.57 (0.80, 3.06)	0.189
• No (%)	1,632 (87.74)	2,690,351 (91.07)	1	1	
Brand of vaccine					
• INAC-1 (%)	453 (24.35)	639,436 (21.65)	1	1	
• INAC-2 (%)	132 (7.10)	161,230 (5.46)	1.16 (0.95, 1.40)	1.17 (0.95, 1.43)	0.133
• VV-1 (%)	704 (37.85)	859,324 (29.09)	1.16 (1.03, 1.30)	1.19 (1.02, 1.38)	**0.023**
• mRNA-1 (%)	421 (22.63)	1,183,050 (40.05)	0.50 (0.44, 0.57)	0.59 (0.49, 0.70)	**<0.001**
• mRNA-2 (%)	150 (8.06)	111,063 (3.76)	1.91 (1.58, 2.29)	1.61 (1.28, 2.02)	**<0.001**
• PS-1 (%)	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose (%)	768 (41.29)	1,260,544 (42.67)	1	1	
• 2nd dose (%)	744 (40.00)	1,182,493 (40.03)	1.03 (0.93, 1.14)	0.97 (0.85, 1.10)	0.619
• > 2 doses (%)	348 (18.71)	511,081 (17.30)	1.12 (0.98, 1.27)	1.15 (0.97, 1.37)	0.11
Gastrointestinal related AEFI (nausea, vomiting, diarrhea)					
Gender					
• Male (%)	1,291 (23.82)	1,404,394 (47.60)	1	1	
• Female (%)	4,129 (76.18)	1,546,164 (52.40)	2.91 (2.73, 3.09)	2.90 (2.72, 3.08)	**<0.001**
Age	35.28 ± 13.89	41.95 ± 19.78			
• 5-17 years (%)	301 (5.55)	433,459 (14.69)	1.18 (1.01, 1.38)	2.23 (1.87, 2.65)	**<0.001**
• 18-60 years (%)	4,772 (88.04)	1,926,291 (65.29)	4.22 (3.78, 4.70)	4.46 (3.98, 4.99)	**<0.001**

Table 4. Relationship of characteristics and AEFI report after 30 minutes of vaccination (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
• ≥ 60 years (%)	347 (6.40)	590,808 (20.02)	1	1	
Comorbidities					
• Yes (%)	549 (10.13)	263,446 (8.93)	1.15 (1.05, 1.26)	2.08 (1.36, 3.18)	**0.001**
• No (%)	4,871 (89.87)	2,687,112 (91.07)	1	1	
Brand of vaccine					
• INAC-1 (%)	1,085 (20.02)	638,804 (21.65)	1	1	
• INAC-2 (%)	330 (6.09)	161,032 (5.46)	1.21 (1.07, 1.36)	1.28 (1.12, 1.45)	**<0.001**
• VV-1 (%)	2,479 (45.74)	857,549 (29.06)	1.70 (1.58, 1.83)	1.95 (1.78, 2.12)	**<0.001**
• mRNA-1 (%)	1,118 (20.63)	1,182,353 (40.07)	0.56 (0.51, 0.61)	0.71 (0.63, 0.79)	**<0.001**
• mRNA-2 (%)	408 (7.53)	110,805 (3.76)	2.17 (1.93, 2.43)	2.05 (1.78, 2.35)	**<0.001**
• PS-1 (%)	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose (%)	2,153 (39.72)	1,259,159 (42.68)	1	1	
• 2nd dose (%)	2,342 (43.21)	1,180,895 (40.02)	1.16 (1.09, 1.23)	0.85 (0.79, 0.92)	**<0.001**
• > 2 doses (%)	925 (17.07)	510,504 (17.30)	1.06 (0.98, 1.14)	0.96 (0.87, 1.06)	0.458

1 = Reference group; *INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

(14.49%), the mRNA-2 vaccine (11.19%), the INAC-2 vaccine (4.63%), and the PS-1 vaccine (<0.01%). Among common AEFI categories, "Pain, swelling, and redness at the injection site" had the highest incidence (15.20%). "Fatigue" accounted for 9.10% of reports, "Muscle weakness" represented 2.17%, and "Fever" had 20.90% of reports.

Table 5 provides a comprehensive analysis of the relationship between various characteristics and AEFI reports (both within and after 30 min of vaccination) classified by the type of AEFI. The data show notable patterns: Females were 1.69 times more likely to report AEFI than males. The age group 18–60 years was at a higher risk, with an odds ratio of 3.81. Comorbidities substantially increased the risk (odds ratio 1.99). When examining vaccine brands, the mRNA-2 vaccine had the highest odds ratio (3.85), indicating a higher AEFI risk. The second dose was not significantly associated with an increased risk; however, receiving more than two doses increased the odds (1.11). The analysis was further subdivided into categories such as general AEFI, neurological-related AEFI, cardiovascular-related AEFI, dermatological-related AEFI, and gastrointestinal-related AEFI, which showed distinct patterns in terms of sex, age, comorbidities, vaccine brands, and dose.

Table 5. Relationship of characteristics and any AEFI report (both within and after 30 minutes of vaccination) (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
Any AEFI					
Gender					
• Male (%)	34,755 (35.19)	1,370,930 (47.98)	1	1	
• Female (%)	64,012 (64.81)	1,486,281 (52.02)	1.70 (1.68, 1.72)	1.69 (1.66, 1.71)	**<0.001**
Age	35.43 ± 15.22	42.16 ± 19.87			
• 5-17 years (%)	8,391 (8.50)	425,369 (14.89)	1.58 (1.53, 1.63)	2.05 (1.98, 2.12)	**<0.001**
• 18-60 years (%)	83,089 (84.13)	1,847,974 (64.68)	3.60 (3.52, 3.69)	3.81 (3.72, 3.91)	**<0.001**
• ≥ 60 years (%)	7,287 (7.38)	583,868 (20.43)	1	1	
Comorbidities					
• Yes (%)	8,750 (8.86)	255,245 (8.93)	0.99 (0.97, 1.01)	1.99 (1.81, 2.19)	**<0.001**
• No (%)	90,017 (91.14)	2,601,966 (91.07)	1	1	
Brand of vaccine*					
• INAC-1 (%)	15,558 (15.75)	624,331 (21.85)	1	1	
• INAC-2 (%)	5,150 (5.21)	156,212 (5.47)	1.32 (1.28, 1.37)	1.29 (1.25, 1.34)	**<0.001**

Table 5. Relationship of characteristics and any AEFI report (both within and after 30 minutes of vaccination) (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
• VV-1 (%)	36,644 (37.10)	823,384 (28.82)	1.79 (1.75, 1.82)	1.82 (1.78, 1.87)	**<0.001**
• mRNA-1 (%)	30,347 (30.73)	1,153,124 (40.36)	1.06 (1.04, 1.08)	1.18 (1.15, 1.21)	**<0.001**
• mRNA-2 (%)	11,065 (11.20)	100,148 (3.51)	4.43 (4.32, 4.55)	3.85 (3.74, 3.97)	**<0.001**
• PS-1 (%)	3 (0.00)	12 (0.00)	10.04 (2.83, 35.58)	7.48 (2.08, 26.84)	**0.002**
Vaccine dose					
• 1st dose (%)	34,470 (34.90)	1,226,842 (42.94)	1	1	
• 2nd dose (%)	41,652 (42.17)	1,141,585 (39.95)	1.30 (1.28, 1.32)	1.00 (0.98, 1.01)	0.725
• > 2 doses (%)	22,645 (22.93)	488,784 (17.11)	1.65 (1.62, 1.68)	1.11 (1.09, 1.14)	**<0.001**
General AEFI (injection site related infection, fatigue, fever, myalgia, difficult breathing)					
Gender					
• Male (%)	30,398 (35.43)	1,375,287 (47.92)	1	1	
• Female (%)	55,400 (64.57)	1,494,893 (52.08)	1.68 (1.65, 1.70)	1.66 (1.63, 1.68)	**<0.001**
Age	35.06 ± 15.10	42.15 ± 19.86			
• 5-17 years (%)	7,172 (8.36)	426,588 (14.86)	1.66 (1.60, 1.72)	2.06 (1.98, 2.14)	**<0.001**
• 18-60 years (%)	72,701 (84.74)	1,858,362 (64.75)	3.86 (3.76, 3.97)	4.13 (4.01, 4.24)	**<0.001**
• ≥ 60 years (%)	5,925 (6.91)	585,230 (20.39)	1	1	
Comorbidities					
• Yes (%)	7,411 (8.64)	256,584 (8.94)	0.96 (0.94, 0.99)	2.06 (1.85, 2.28)	**<0.001**
• No (%)	78,387 (91.36)	2,613,596 (91.06)	1	1	
Brand of vaccine					
• INAC-1 (%)	11,357 (13.24)	628,532 (21.90)	1	1	
• INAC-2 (%)	3,676 (4.28)	157,686 (5.49)	1.29 (1.24, 1.34)	1.25 (1.20, 1.30)	**<0.001**
• VV-1 (%)	32,792 (38.22)	827,236 (28.82)	2.19 (2.15, 2.24)	2.20 (2.15, 2.26)	**<0.001**
• mRNA-1 (%)	27,399 (31.93)	1,156,072 (40.28)	1.31 (1.28, 1.34)	1.47 (1.43, 1.51)	**<0.001**
• mRNA-2 (%)	10,571 (12.32)	100,642 (3.51)	5.81 (5.66, 5.97)	4.93 (4.77, 5.09)	**<0.001**
• PS-1 (%)	3 (0.00)	12 (0.00)	13.84 (3.90, 49.04)	10.05 (2.80, 36.07)	**<0.001**
Vaccine dose					
• 1st dose (%)	27,665 (32.24)	1,233,647 (42.98)	1	1	
• 2nd dose (%)	36,964 (43.08)	1,146,273 (39.94)	1.44 (1.42, 1.46)	1.02 (1.00, 1.04)	**0.048**
• > 2 doses (%)	21,169 (24.67)	490,260 (17.08)	1.93 (1.89, 1.96)	1.15 (1.12, 1.18)	**<0.001**
Neurological related AEFI (muscle weakness, drowsiness, headache, blurred vision, dizziness, numbness)					
Gender					
• Male (%)	12,651 (30.44)	1,393,034 (47.80)	1	1	
• Female (%)	28,903 (69.56)	1,521,390 (52.20)	2.09 (2.05, 2.14)	2.10 (2.05, 2.14)	**<0.001**
Age	33.80 ± 14.69	42.06 ± 19.81			
• 5-17 years (%)	3,566 (8.58)	430,194 (14.76)	2.36 (2.24, 2.49)	3.61 (3.39, 3.83)	**<0.001**
• 18-60 years (%)	35,921 (86.44)	1,895,142 (65.03)	5.40 (5.17, 5.65)	5.80 (5.54, 6.07)	**<0.001**
• ≥ 60 years (%)	2,067 (4.97)	589,088 (20.21)	1	1	
Comorbidities					
• Yes (%)	3,502 (8.43)	260,493 (8.94)	0.94 (0.91, 0.97)	2.14 (1.80, 2.55)	**<0.001**
• No (%)	38,052 (91.57)	2,653,931 (91.06)	1	1	
Brand of vaccine					
• INAC-1 (%)	7,216 (17.37)	632,673 (21.71)	1	1	
• INAC-2 (%)	2,818 (6.78)	158,544 (5.44)	1.56 (1.49, 1.63)	1.52 (1.45, 1.59)	**<0.001**

Table 5. Relationship of characteristics and any AEFI report (both within and after 30 minutes of vaccination) (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
• VV-1 (%)	16,899 (40.67)	843,129 (28.93)	1.76 (1.71, 1.81)	1.81 (1.75, 1.87)	**<0.001**
• mRNA-1 (%)	11,004 (26.48)	1,172,467 (40.23)	0.82 (0.80, 0.85)	0.91 (0.88, 0.95)	**<0.001**
• mRNA-2 (%)	3,616 (8.70)	107,597 (3.69)	2.95 (2.83, 3.07)	2.71 (2.58, 2.85)	**<0.001**
• PS-1 (%)	1 (0.00)	14 (0.00)	6.26 (0.82, 47.63)	4.83 (0.63, 37.05)	0.13
Vaccine dose					
• 1st dose (%)	15,382 (37.02)	1,245,930 (42.75)	1	1	
• 2nd dose (%)	18,585 (44.72)	1,164,652 (39.96)	1.29 (1.27, 1.32)	1.00 (0.98, 1.03)	0.893
• > 2 doses (%)	7,587 (18.26)	503,842 (17.29)	1.22 (1.19, 1.25)	0.99 (0.96, 1.03)	0.589
Cardiovascular related AEFI (low or high blood pressure, abnormal heart rate, needed ECG monitoring)					
Gender					
• Male (%)	986 (45.63)	1,404,699 (47.56)	1	1	
• Female (%)	1,175 (54.37)	1,549,118 (52.44)	1.08 (0.99, 1.18)	1.07 (0.98, 1.16)	0.128
Age	50.04 ± 16.08	41.93 ± 19.77			
• 5-17 years (%)	114 (5.28)	433,646 (14.68)	0.24 (0.20, 0.29)	1.65 (1.18, 2.30)	**0.003**
• 18-60 years (%)	1,396 (64.60)	1,929,667 (65.33)	0.66 (0.60, 0.72)	0.60 (0.54, 0.66)	**<0.001**
• ≥ 60 years (%)	651 (30.12)	590,504 (19.99)	1	1	
Comorbidities					
• Yes (%)	345 (15.96)	263,650 (8.93)	1.94 (1.73, 2.18)	1.34 (0.90, 1.98)	0.146
• No (%)	1,816 (84.04)	2,690,167 (91.07)	1	1	
Brand of vaccine					
• INAC-1 (%)	953 (44.10)	638,936 (21.63)	1	1	
• INAC-2 (%)	57 (2.64)	161,305 (5.46)	0.24 (0.18, 0.31)	0.33 (0.25, 0.43)	**<0.001**
• VV-1 (%)	986 (45.63)	859,042 (29.08)	0.77 (0.70, 0.84)	1.33 (1.19, 1.49)	**<0.001**
• mRNA-1 (%)	157 (7.27)	1,183,314 (40.06)	0.09 (0.08, 0.11)	0.10 (0.08, 0.14)	**<0.001**
• mRNA-2 (%)	8 (0.37)	111,205 (3.76)	0.05 (0.02, 0.10)	0.17 (0.08, 0.34)	**<0.001**
• PS-1 (%)	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose (%)	1,446 (66.91)	1,259,866 (42.65)	1	1	
• 2nd dose (%)	692 (32.02)	1,182,545 (40.03)	0.51 (0.47, 0.56)	0.47 (0.42, 0.53)	**<0.001**
• > 2 doses (%)	23 (1.06)	511,406 (17.31)	0.04 (0.03, 0.06)	0.12 (0.08, 0.18)	**<0.001**
Dermatological related AEFI (rash, petechiae)					
Gender					
• Male (%)	542 (28.69)	1,405,143 (47.57)	1	1	
• Female (%)	1,347 (71.31)	1,548,946 (52.43)	2.25 (2.04, 2.49)	2.22 (2.01, 2.46)	**<0.001**
Age	38.73 ± 15.07	41.94 ± 19.77			
• 5-17 years (%)	100 (5.29)	433,660 (14.68)	0.74 (0.58, 0.94)	1.25 (0.95, 1.65)	0.109
• 18-60 years (%)	1,604 (84.91)	1,929,459 (65.31)	2.66 (2.28, 3.09)	2.62 (2.24, 3.07)	**<0.001**
• ≥ 60 years (%)	185 (9.79)	590,970 (20.01)	1	1	
Comorbidities					
• Yes (%)	230 (12.18)	263,765 (8.93)	1.41 (1.23, 1.62)	1.51 (0.78, 2.96)	0.224
• No (%)	1,659 (87.82)	2,690,324 (91.07)	1	1	
Brand of vaccine					
• INAC-1 (%)	466 (24.67)	639,423 (21.65)	1	1	
• INAC-2 (%)	133 (7.04)	161,229 (5.46)	1.13 (0.93, 1.37)	1.15 (0.94, 1.40)	0.177

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Table 5. Relationship of characteristics and any AEFI report (both within and after 30 minutes of vaccination) (classified by types of AEFI)

Characteristics	AEFI	without AEFI	COR (95%CI)	AOR (95%CI)	p-value
• VV-1 (%)	717 (37.96)	859,311 (29.09)	1.14 (1.02, 1.29)	1.19 (1.02, 1.38)	**0.024**
• mRNA-1 (%)	423 (22.39)	1,183,048 (40.05)	0.49 (0.43, 0.56)	0.58 (0.48, 0.69)	**<0.001**
• mRNA-2 (%)	150 (7.94)	111,063 (3.76)	1.85 (1.54, 2.23)	1.58 (1.26, 1.99)	**<0.001**
• PS-1 (%)	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose (%)	787 (41.66)	1,260,525 (42.67)	1	1	
• 2nd dose (%)	754 (39.92)	1,182,483 (40.03)	1.02 (0.92, 1.13)	0.96 (0.84, 1.09)	0.521
• > 2 doses (%)	348 (18.42)	511,081 (17.30)	1.09 (0.96, 1.24)	1.13 (0.95, 1.35)	0.154
Gastrointestinal related AEFI (nausea, vomiting, diarrhea)					
Gender					
• Male (%)	1,306 (23.69)	1,404,379 (47.60)	1	1	
• Female (%)	4,207 (76.31)	1,546,086 (52.40)	2.93 (2.75, 3.11)	2.92 (2.74, 3.11)	**<0.001**
Age	35.33 ± 13.94	41.95 ± 19.78			
• 5-17 years (%)	311 (5.64)	433,449 (14.69)	1.19 (1.02, 1.38)	2.25 (1.90, 2.67)	**<0.001**
• 18-60 years (%)	4,845 (87.88)	1,926,218 (65.29)	4.16 (3.74, 4.64)	4.39 (3.92, 4.90)	**<0.001**
• ≥ 60 years (%)	357 (6.48)	590,798 (20.02)	1	1	
Comorbidities					
• Yes (%)	561 (10.18)	263,434 (8.93)	1.16 (1.06, 1.26)	2.02 (1.32, 3.08)	**0.001**
• No (%)	4,952 (89.82)	2,687,031 (91.07)	1	1	
Brand of vaccine					
• INAC-1 (%)	1,132 (20.53)	638,757 (21.65)	1	1	
• INAC-2 (%)	335 (6.08)	161,027 (5.46)	1.17 (1.04, 1.33)	1.25 (1.10, 1.42)	**<0.001**
• VV-1 (%)	2,507 (45.47)	857,521 (29.06)	1.65 (1.54, 1.77)	1.91 (1.75, 2.08)	**<0.001**
• mRNA-1 (%)	1,131 (20.52)	1,182,340 (40.07)	0.54 (0.50, 0.59)	0.69 (0.62, 0.77)	**<0.001**
• mRNA-2 (%)	408 (7.40)	110,805 (3.76)	2.08 (1.86, 2.33)	1.99 (1.74, 2.28)	**<0.001**
• PS-1 (%)	0 (0.00)	15 (0.00)	-	-	
Vaccine dose					
• 1st dose (%)	2,228 (40.41)	1,259,084 (42.67)	1	1	
• 2nd dose (%)	2,359 (42.79)	1,180,878 (40.02)	1.13 (1.07, 1.20)	0.84 (0.78, 0.90)	**<0.001**
• > 2 doses (%)	926 (16.80)	510,503 (17.30)	1.03 (0.95, 1.11)	0.94 (0.85, 1.04)	0.266

1 = Reference group; *INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

DISCUSSION

This study examined COVID-19 vaccination and adverse events in Ubon Ratchathani Province. In our study, out of 2,955,978 vaccine doses administered, 3.34% resulted in adverse events, with 0.17% occurring within 30 min and 3.19% after 30 min of vaccination. This aligns with Basavaraja CK et al.'s study, which reported a total AEFI rate of 3.48%.[24] However, there is a wide range of AEFI rates in other studies, ranging from 22.15% to 67.4%. [25-29]

In this study, it was discovered that gender disparities exist, with females having a 71% increased probability of experiencing adverse vaccine reactions, which is consistent with the global trend of women reporting up to 68% of adverse effects.[30-35] A gender-sensitive approach can enhance vaccine acceptance, coverage, and effectiveness, especially in COVID-19, taking into account women's unique physical, mental, and social factors.[31,36] Research and female-specific vaccine studies have led to positive outcomes, making it essential for national policies to prioritize tailored strategies for women, increasing awareness, improving vaccination experiences, willingness, and protection against COVID-19.[30,31,37-39]

Different age groups display different risks of AEFI, notably among children aged 5-17 years, underscoring the need for vaccination strategies tailored to specific age groups. This observation aligns with previous research highlighting a strong association between younger age and AEFI.[30] For instance, Kim et al. found that the younger the individual, the more frequent the AEFI occurrence.[40,41]

Participants with underlying health conditions had an elevated risk of experiencing AEFI after 30 min of vaccination, with a significant odds ratio of 2.09 ($p<0.001$), in line with prior research.[26,42] Those with any comorbidities were 2.08 times more likely to experience AEFI compared to those without comorbidities ($p<0.001$).[26] The occurrence of AEFI, including injection site reactions, headache, fatigue, and malaise, was significantly linked to comorbidities such as psychological, musculoskeletal, and endocrine disorders for both the first and second vaccine doses, with odds ratios of 1.23–1.77.[42] Special consideration is advised when vaccinating individuals with comorbidities or those on chronic medication.[26,42]

Although the specific vaccine brand had a significant impact on AEFI rates, the mRNA-1 and mRNA-2 vaccines had lower odds of AEFI within 30 min than the INAC-1 vaccine. However, the number of participants who experienced AEFI after 30 min was higher for the specific vaccine. Rahmat et al. investigated AEFI after COVID-19 mRNA vaccination was administered post-30 minutes. They reported a high AEFI rate of 87.5%, with predominantly mild to moderate reactions. These reactions mostly commenced within 1 d of vaccination and were short-lived, lasting approximately 30 min to 2.5 d.[43]

This emphasizes the importance of considering the vaccine brand in vaccination programs. However, compared to other studies, the AEFI rates varied among different vaccine brands. For instance, the mRNA COVID-19 vaccine (mRNA-1) had a rate of 10.42%, which was similar to Costa Rica's rate of 10.28% but higher than Italy's rate of 1.55%.[44] Another study by Beatty et al. found much higher AEFI rates, with 64.9% after one BNT162b2 or mRNA-1273 dose, and 80.3% after two doses of BNT162b2 or mRNA-1273 or one dose of JNJ-78436735.[30] Common adverse effects were included fatigue, muscle pain, headache, chills, injection site redness/swelling, joint pain, and fever.[25,30,43-46]

Examining AEFI in distinct categories emphasizes the frequency of symptoms such as swelling, pain, or redness at the injection site,[13,30,41,47] as well as alterations in blood pressure.[48,49] This underscores the significance of monitoring and addressing these specific adverse events. Transient blood pressure fluctuations post-vaccination may hypothetically pose a risk of neurovascular and cardiovascular adverse events[50-52], particularly in individuals with comorbid conditions.[49,53-55]

In this study, we noted an elevated likelihood of adverse events when individuals received over two doses (AOR 1.13, $p < 0.001$). However, findings from other studies have suggested that local and systemic reactogenicity events following the third dose were mild, and no new safety concerns were identified.[56] The most commonly reported local solicited adverse event was pain at the injection site, while fatigue was the predominant adverse event after receiving BNT162b2 or mRNA-1273 booster doses. It is worth highlighting that none of the serious adverse events reported after the fourth BNT162b2 dose were associated with the study vaccine.[57] In summary, the study vaccines effectively bolstered antibody and neutralizing responses without raising any safety concerns.[57,58]

However, it is important to acknowledge the limitations of this study. The data were retrospective and relied on reported AEFI cases, potentially leading to underreporting.[59,60] Additionally, the study did not investigate the long-term AEFI consequences, emphasizing the need for continuous real-time post-marketing surveillance to detect rare and lasting AEFIs.[45,61]

Our results are specific to the Ubon Ratchathani Province and may not fully represent broader populations, highlighting the importance of considering context when interpreting the results. Future research could investigate the long-term effects of AEFIs, including rare side effects [10,45], and include diverse populations and broader geographical areas to provide a more comprehensive understanding of vaccine safety.[62,63]

Further investigation is necessary to understand the significance of efficient procedures in national pharmacovigilance centers, particularly in monitoring COVID-19 vaccine safety in real-time during periods of high vaccination rates.[46,64-66] Recognizing the factors that influence AEFI is essential for effective immunization program planning.[13,19,44,67,68] Employing strategic communication is vital to bolster vaccine confidence, particularly among those who may be hesitant, and automated systems can streamline the handling of AEFI reports.[59,69,70] Additional research is required to study and enhance public health communication strategies aimed at increasing confidence in COVID-19 vaccine availability.[70-75]

CONCLUSIONS

This study found that being female, younger, having comorbidities, receiving specific vaccine brands, or getting over two doses were linked to increased odds of experiencing adverse events. These insights offer valuable information on the safety profiles of various COVID-19 vaccines in real-world scenarios and will assist healthcare professionals and policymakers in effectively monitoring and addressing vaccine-related adverse events.

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AUTHORS' CONTRIBUTIONS

Teeraporn Sadira Supapaan: Conceptualization, Methodology, Data Collection, Writing-Original Draft Preparation; Kittiyaporn Thongthai: Conceptualization, Methodology, Data Collection; Pongdanai Vinitchai: Methodology, Data Collection, Formal Analysis; Wicharut Praken: Methodology, Data Collection, Formal Analysis; Suttasinee Suwannakul: Conceptualization, Validation, Writing-Reviewing and Editing; Prasittichai Poonphol: Conceptualization, Validation, Writing-Reviewing and Editing; Sisira Donsamak: Conceptualization, Validation, Writing-Reviewing And Editing;Tuanthon Boonlue:

Conceptualization, Validation, Writing-Reviewing And Editing.

Nonglek Kunawaradisai: Conceptualization, Validation, Writing-Reviewing and Editing; Wannisa Dongtai: Validation, Writing-Reviewing and Editing; Uraiwan Akanit: Validation, Writing-Reviewing and Editing; Sawaeng Watcharathanakij: Methodology, Formal Analysis, Writing-Original Draft Preparation; Saksit Sripa: Conceptualization, Validation, Writing-Reviewing and Editing; Patcharee Kanjanawat: Conceptualization, Methodology, Writing-Reviewing and Editing; Jakrit Busapan: Conceptualization, Methodology, Writing-Reviewing and Editing; Chonladda Pitchayajittipong: Conceptualization, Methodology, Writing-Reviewing and Editing; Peerawat Jinatongthai: Methodology, Formal Analysis, Writing-Original Draft Preparation.

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Supplement

Table S1. Number of AEFI report within 30 minutes of vaccination. (Details of Figure 1)

AEFI	Number of AEFI report (percentage)						
	INAC-1* 2,436 (44.68)	**INAC-2 130 (2.38)**	**VV-1 2,295 (42.09)**	**mRNA-1 564 (10.34)**	**mRNA-2 27 (0.50)**	**PS-1 0 (0.00)**	**Overall 5,452 (100.00)**
Pain, swelling, or redness at injection site	197 (8.09)	6 (4.62)	349 (15.21)	106 (18.79)	11 (40.74)	0 (0.00)	669 (12.27)
Fatigue	23 (0.94)	2 (1.54)	17 (0.74)	10 (1.77)	1 (3.70)	0 (0.00)	53 (0.97)
Muscle weakness	11 (0.45)	1 (0.77)	6 (0.26)	1 (0.18)	0 (0.00)	0 (0.00)	19 (0.35)
Fever	1 (0.04)	0 (0.00)	8 (0.35)	0 (0.00)	0 (0.00)	0 (0.00)	9 (0.17)
Drowsiness	11 (0.45)	1 (0.77)	1 (0.04)	0 (0.00)	0 (0.00)	0 (0.00)	13 (0.24)
Headache	113 (4.64)	12 (9.23)	77 (3.36)	25 (4.43)	0 (0.00)	0 (0.00)	227 (4.16)
Myalgia	83 (3.41)	2 (1.54)	168 (7.32)	97 (17.20)	0 (0.00)	0 (0.00)	350 (6.42)
Joint pain	0 (0.00)	0 (0.00)	1 (0.04)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.02)
Blurred vision	7 (0.29)	2 (1.54)	3 (0.13)	0 (0.00)	0 (0.00)	0 (0.00)	12 (0.22)
Difficult breathing	12 (0.49)	3 (2.31)	7 (0.31)	7 (1.24)	0 (0.00)	0 (0.00)	29 (0.53)
Nausea	42 (1.72)	4 (3.08)	24 (1.05)	13 (2.30)	0 (0.00)	0 (0.00)	83 (1.52)
Vomiting	20 (0.82)	2 (1.54)	9 (0.39)	3 (0.53)	0 (0.00)	0 (0.00)	34 (0.62)
Diarrhea	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Petechiae	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Rash	15 (0.62)	1 (0.77)	15 (0.65)	2 (0.35)	0 (0.00)	0 (0.00)	33 (0.61)
Dizziness	134 (5.50)	8 (6.15)	75 (3.27)	85 (15.07)	0 (0.00)	0 (0.00)	302 (5.54)
Numbness	91 (3.74)	6 (4.62)	54 (2.35)	14 (2.48)	0 (0.00)	0 (0.00)	165 (3.03)
Effect on blood pressure	861 (35.34)	49 (37.69)	893 (38.91)	62 (10.99)	8 (29.63)	0 (0.00)	1,873 (34.35)
Effect on heart rate or rhythm	231 (9.48)	22 (16.92)	267 (11.63)	123 (21.81)	6 (22.22)	0 (0.00)	649 (11.90)
Others	584 (23.97)	9 (6.92)	321 (13.99)	16 (2.84)	1 (3.70)	0 (0.00)	931 (17.08)

*INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

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Table S2. Number of AEFI report after 30 minutes of vaccination. (Details of Figure 2)

AEFI	Number of AEFI report (percentage)						
	INAC-1 25,071 (13.61)	**INAC-2 8,640 (4.69)**	**VV-1 77,664 (42.17)**	**mRNA-1 51,610 (28.02)**	**mRNA-2 21,172 (11.50)**	**PS-1 4 (0.002)**	**Overall 184,161 (100.00)**
Pain, swelling, or redness at injection site	2,455 (9.79)	898 (10.39)	8,482 (10.92)	10,684 (20.70)	5,637 (26.62)	1 (25.00)	28,157 (15.29)
Fatigue	2,685 (10.71)	851 (9.85)	7,681 (9.89)	4,302 (8.34)	1,665 (7.86)	0 (0.00)	17,184 (9.33)
Muscle weakness	569 (2.27)	190 (2.20)	1,947 (2.51)	1,055 (2.04)	334 (1.58)	0 (0.00)	4,095 (2.22)
Fever	3,940 (15.72)	1,016 (11.76)	20,713 (26.67)	9,336 (18.09)	4,587 (21.67)	0 (0.00)	39,592 (21.50)
Drowsiness	3,509 (14.00)	1,650 (19.10)	5,151 (6.63)	4,232 (8.20)	1,086 (5.13)	0 (0.00)	15,628 (8.49)
Headache	3,763 (15.01)	1,303 (15.08)	12,368 (15.93)	6,566 (12.72)	2,458 (11.61)	1 (25.00)	26,459 (14.37)
Myalgia	4,539 (18.10)	1,508 (17.45)	13,673 (17.61)	11,552 (22.38)	4,068 (19.21)	2 (50.00)	35,342 (19.19)
Joint pain	374 (1.49)	133 (1.54)	1,614 (2.08)	611 (1.18)	267 (1.26)	0 (0.00)	2,999 (1.63)
Blurred vision	196 (0.78)	73 (0.84)	362 (0.47)	180 (0.35)	57 (0.27)	0 (0.00)	868 (0.47)
Difficult breathing	299 (1.19)	98 (1.13)	558 (0.72)	320 (0.62)	85 (0.40)	0 (0.00)	1,360 (0.74)
Nausea	599 (2.39)	194 (2.25)	1,504 (1.94)	643 (1.25)	275 (1.30)	0 (0.00)	3,215 (1.75)
Vomiting	214 (0.85)	73 (0.84)	618 (0.80)	197 (0.38)	69 (0.33)	0 (0.00)	1,171 (0.64)
Diarrhea	489 (1.95)	136 (1.57)	900 (1.16)	390 (0.76)	115 (0.54)	0 (0.00)	2,030 (1.10)
Petechiae	79 (0.32)	33 (0.38)	128 (0.16)	86 (0.17)	29 (0.14)	0 (0.00)	355 (0.19)
Rash	402 (1.60)	113 (1.31)	611 (0.79)	340 (0.66)	123 (0.58)	0 (0.00)	1,589 (0.86)
Dizziness	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Numbness	302 (1.20)	112 (1.30)	611 (0.79)	361 (0.70)	120 (0.57)	0 (0.00)	1,506 (0.82)
Effect on blood pressure	1 (0.00)	0 (0.00)	2 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	3 (0.00)
Effect on heart rate or rhythm	0 (0.00)	0 (0.00)	2 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	2 (0.00)
Others	656 (2.62)	259 (3.00)	739 (0.95)	755 (1.46)	197 (0.93)	0 (0.00)	2,606 (1.42)

*INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.

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Table S3. Number of any AEFI report (both within and after 30 minutes of vaccination). **(**Details of Figure 3)

AEFI	Number of AEFI report (percentage)						
	INAC-1 27,445 (14.49)	**INAC-2 8,764 (4.63)**	**VV-1 79,891 (42.17)**	**mRNA-1 52,151 (27.53)**	**mRNA-2 21,196 (11.19)**	**PS-1 4 (0.002)**	**Overall 189,451 (100.00)**
Pain, swelling, or redness at injection site	2,652 (9.66)	904 (10.31)	8,816 (11.04)	10,785 (20.68)	5,646 (26.64)	1 (25.00)	28,804 (15.20)
Fatigue	2,706 (9.86)	853 (9.73)	7,697 (9.63)	4,312 (8.27)	1,666 (7.86)	0 (0.00)	17,234 (9.10)
Muscle weakness	580 (2.11)	191 (2.18)	1,953 (2.44)	1,056 (2.02)	334 (1.58)	0 (0.00)	4,114 (2.17)
Fever	3,941 (14.36)	1,016 (11.59)	20,719 (25.93)	9,336 (17.90)	4,587 (21.64)	0 (0.00)	39,599 (20.90)
Drowsiness	3,519 (12.82)	1,651 (18.84)	5,151 (6.45)	4,232 (8.11)	1,086 (5.12)	0 (0.00)	15,639 (8.25)
Headache	3,865 (14.08)	1,314 (14.99)	12,435 (15.56)	6,589 (12.63)	2,458 (11.60)	1 (25.00)	26,662 (14.07)
Myalgia	4,620 (16.83)	1,510 (17.23)	13,837 (17.32)	11,644 (22.33)	4,068 (19.19)	2 (50.00)	35,681 (18.83)
Joint pain	374 (1.36)	133 (1.52)	1,615 (2.02)	611 (1.17)	267 (1.26)	0 (0.00)	3,000 (1.58)
Blurred vision	202 (0.74)	75 (0.86)	365 (0.46)	180 (0.35)	57 (0.27)	0 (0.00)	879 (0.46)
Difficult breathing	310 (1.13)	101 (1.15)	565 (0.71)	327 (0.63)	85 (0.40)	0 (0.00)	1,388 (0.73)
Nausea	634 (2.31)	198 (2.26)	1,527 (1.91)	656 (1.26)	275 (1.30)	0 (0.00)	3,290 (1.74)
Vomiting	232 (0.85)	75 (0.86)	627 (0.78)	200 (0.38)	69 (0.33)	0 (0.00)	1,203 (0.63)
Diarrhea	489 (1.78)	136 (1.55)	900 (1.13)	390 (0.75)	115 (0.54)	0 (0.00)	2,030 (1.07)
Petechiae	79 (0.29)	33 (0.38)	128 (0.16)	86 (0.16)	29 (0.14)	0 (0.00)	355 (0.19)
Rash	415 (1.51)	114 (1.30)	624 (0.78)	342 (0.66)	123 (0.58)	0 (0.00)	1,618 (0.85)
Dizziness	134 (0.49)	8 (0.09)	75 (0.09)	85 (0.16)	0 (0.00)	0 (0.00)	302 (0.16)
Numbness	389 (1.42)	118 (1.35)	664 (0.83)	375 (0.72)	120 (0.57)	0 (0.00)	1,666 (0.88)
Effect on blood pressure	862 (3.14)	49 (0.56)	895 (1.12)	62 (0.12)	8 (0.04)	0 (0.00)	1,876 (0.99)
Effect on heart rate or rhythm	231 (0.84)	22 (0.25)	269 (0.34)	123 (0.24)	6 (0.03)	0 (0.00)	651 (0.34)
Others	1,211 (4.41)	263 (3.00)	1,029 (1.29)	760 (1.46)	197 (0.93)	0 (0.00)	3,460 (1.83)

*INAC-1 for inactivated vaccine-1, INAC-2 for inactivated vaccine-2, VV-1 for viral vector vaccine-1, mRNA-1 for mRNA vaccine-1, mRNA-2 for mRNA vaccine-2, and PS-1 for protein subunit vaccine-1.