

Original Article

Immediate adverse events following immunization (AEFI) in drive-through COVID-19 vaccination campaign in Yogyakarta, Indonesia: A cross-sectional study

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Background & objectives: The COVID-19 pandemic has led to unprecedented global immunization efforts, with drive-through vaccination campaigns established to expedite and ensure safe coverage. However, research on immediate adverse events following immunization (AEFI) in these settings is limited. This study aims to evaluate the frequency and characteristics of immediate AEFI during drive-through COVID-19 vaccination campaigns in Yogyakarta, Indonesia, using the Sinovac/CoronaVac vaccine

Methods: This cross-sectional study utilized secondary data from the local vaccine registry managed by the Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, Indonesia, from July 27 to September 6, 2021. Participants included individuals aged over 11 yr without underlying medical conditions such as diabetes, hypertension, cancer, or asthma. Key characteristics recorded were age, gender, and AEFI.

Results: Out of 27,459 registrants, only 20,817 were eligible and received a dose. The median participant age was 20 yr (IQR 10); 47 per cent were male (9,712) and 53 per cent female (11,105). The highest vaccination day was September 6, 2021, with 3,883 doses (18%). Among the 79 participants who experienced AEFI [0.38%; 95% Confidence Interval (CI): 0.30-0.47], the median age was 19 yr (IQR 8); 41 per cent were male (34) and 59 per cent female (48). Systemic adverse events (92%) were more common than local events (6.3%), with dizziness (77.2%) being most prevalent.

Interpretation & conclusions: The findings of this study suggest that immediate AEFI occurred rarely in the drive-through vaccination setting, indicating that this method appears safe and efficient for COVID-19 vaccinations, particularly in the context of immediate AEFI. Most adverse events were mild, underscoring the importance of preparedness and close monitoring in drive-through vaccination campaign sites to ensure patient safety and enhance vaccine confidence.

Key words Adverse event - COVID-19 - drive-through vaccination - immediate AEFI - vaccination campaign - vaccination

Following multiple waves with various infection rates, the COVID-19 pandemic, has transitioned to an

endemic phase in some countries^{1,2}. Although public interest in this disease has decreased, its significance

should not be underestimated³. As the most promising preventive measure, COVID-19 vaccinations are being developed and distributed worldwide⁴. Mass vaccination programmes have helped control the virus, and 169 countries have recorded immunizations. From December 13, 2020, until April 7, 2021, 710 million doses of the first UK vaccine were given globally⁵. In the global pandemic response, vaccination became the main intervention.

Modeling studies in Latin American and Caribbean nations show that mass vaccination programmes have reduced COVID-19 severity and death⁶. A study estimates COVID-19 immunization averted 610,000 to 2.61 million mortalities in the first yr and a half of the deployment (January 2021–May 2022)⁷. Other factors that affect vaccine acceptance include safety and effectiveness confidence⁸.

The pandemic has required new and creative methods for delivering vaccines. This includes using technology such as blockchain to ensure effective distribution⁹. Ensuring equitable access to vaccines has been underscored as a key element in achieving widespread immunity and controlling the spread of the virus¹⁰. Additionally, addressing vaccine hesitancy through targeted interventions and communication strategies has been crucial in enhancing vaccination acceptance rates¹¹.

Mass vaccination is a strategy that involves quickly vaccinating a large number of people in a short period. It has played a crucial role in densely populated nations by fast increasing immunity levels and controlling the spread of infectious illnesses¹². The drive-through vaccination approach has emerged as an innovative alternative to traditional mass vaccination strategies. Instead of centralized locations, individuals can receive vaccines while staying in their vehicles, such as cars or motorcycles¹³. This approach has clear benefits, such as decreased physical interaction and enhanced vaccination rate, contributing to more effective and comfortable vaccination programmes¹³.

Mass vaccination campaigns rely on public trust in COVID-19 vaccine safety and efficacy. To enable COVID-19 immunization campaign success, vaccine hesitancy and confidence must be addressed¹⁴. Build public confidence and reduce the transmission of infectious agents like SARS-CoV-2 by achieving herd immunity through high vaccination rates¹⁵. Mass immunization programmes have reduced vulnerable populations, suppressed outbreaks, and prevented

disease outbreaks¹⁶. Simulation techniques have been used to optimize drive-through mass vaccination clinics, ensuring effective planning and design¹³. Utilizing artificial intelligence models and temporary facilities on a broad scale have significantly improved the efficiency and safety of mass vaccination campaigns¹³.

Adverse events following immunization (AEFI) monitoring and surveillance are critical to vaccine safety programmes to identify and control vaccination risks¹⁷. Public health authorities can improve vaccination risks and benefits and retain public trust by methodically assessing bad events¹⁸. To optimize vaccine distribution and ensure the well-being of vaccine recipients, it is crucial to have a comprehensive understanding of the frequency and features of AEFI, particularly in the context of new vaccination approaches such as drive-through clinics¹⁹.

Rapid COVID-19 vaccine implementation raised concerns AEFI, particularly about drive-through vaccination. Due to a lack of extensive safety data, several studies have been conducted to monitor health events following vaccination^{20,21}. These studies have found varying rates of AEFI among different vaccinations and demographic categories¹⁹. Research has indicated that younger people and those who have received their second dose of the vaccine are more likely to develop AEFI. This highlights the need for thorough monitoring and evaluation of vaccine safety^{19,22}.

Although there have been extensive studies on AEFI, studies should explicitly examine the immediate AEFI in the context of drive-through COVID-19 vaccination¹⁹. We hypothesize that the need for participants to stay in their vehicles, combined with the continuous injection process, might limit rest and increase the likelihood of immediate adverse effects compared to more traditional mass vaccination settings where participants remain stationary. Therefore, examining the frequency of immediate AEFI during drive-through COVID-19 vaccination is imperative to guarantee the safety and effectiveness of large-scale vaccination initiatives¹⁴.

Materials & Methods

Study design: This study was conducted as a cross-sectional analysis using secondary data from the local vaccine data registry. The data were gathered at mass vaccination sessions conducted by the Faculty of Medicine, Public Health, and Nursing, Universitas

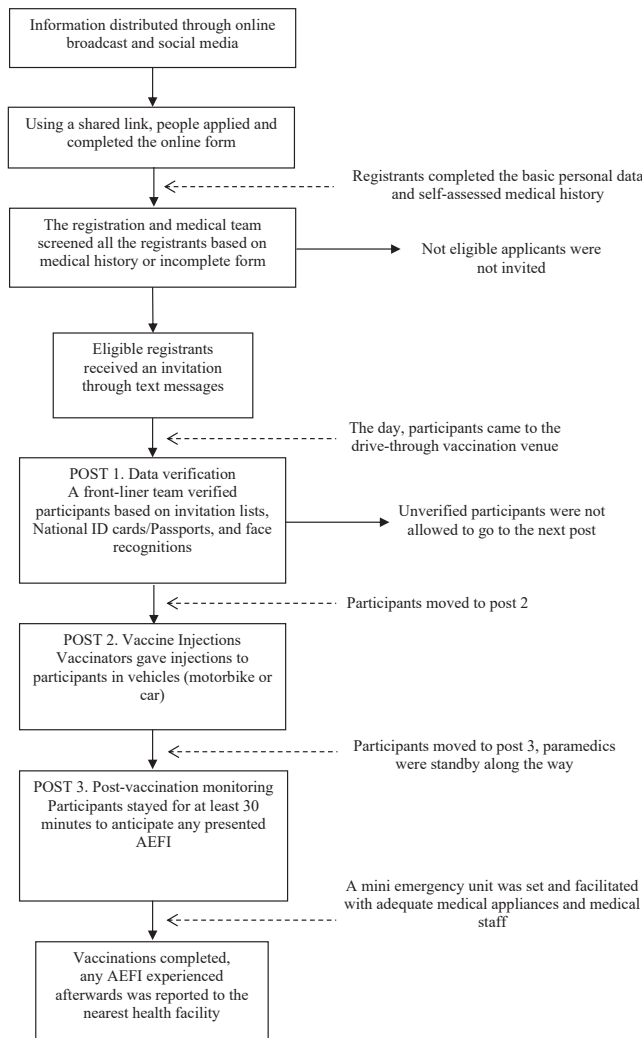


Fig. 1. The flow diagram of the drive through COVID-19 vaccination in Yogyakarta, Indonesia.

Gadjah Mada, Yogyakarta, Indonesia, from July 27 to September 6, 2021. The study was approved by the Medical and Health Research Ethics Committee (MHREC), Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada – Dr. Sardjito General Hospital.

Study site: The mass vaccination programme was conducted in Yogyakarta Province, Indonesia, where multiple drive-through COVID-19 vaccination sessions were organized to enhance regional vaccine coverage due to the elevated infection rates of the Delta variant. During the immunization process, individuals remained inside their vehicles (either motorcycles or cars) for registration, vaccination, and post-vaccination observation.

Study sample: This study included 11 yr or older individuals who participated in the drive-through vaccination events, and met the health standards stipulated by the government. These criteria included that willing participants should not have any comorbidities such as diabetes mellitus, hypertension, cancer, or asthma. Individuals with incomplete safety event records were not included in the analysis. All eligible participants were included without any explicit limitations on the sample process. The vaccine used in these events was Sinovac/Coronavac.

Procedure for receiving vaccination at the drive-through facility: Universitas Gadjah Mada, in partnership with local authorities, organized drive-through immunization events. Attendees enrolled on an internet platform a few days before the occasion and completed self-evaluation medical history documents. Individuals who satisfied the qualifying requirements were sent an invitation to participate in the immunization event. On the vaccination day, participants underwent a streamlined procedure consisting of three stages: data verification, vaccine injection, and post-vaccination observation. All of this was done without participants having to leave their vehicles. Participants were instructed to remain at the observation site for 30 min after receiving the vaccine. In case a hospital referral was needed, there were mini emergency units, emergency specialists, nurses, and ambulances accessible (Fig. 1).

Data collection and variables: The characteristics of each participant, including their vaccination information and any occurrences of safety-related incidents were documented. The variables obtained from the registry included age, gender, and AEFI. The study used the World Health Organization (WHO) reference to define AEFI as any medical event occurring after vaccination, whether it has a causal relationship with the vaccine or not²³. The AEFI types recorded in the registry included direct complaints from the vaccinees or assessments from the attending doctor in the observation space at the vaccination venue²⁴. Specifically for immediate AEFI, the time limit used refers to events occurring 15-30 min after injection²⁵. Medical interventions, including pharmaceutical therapy, supportive therapy (such as oxygenation), and referrals to hospitals, were the clinical responsibility of the emergency doctor on duty. The data collection process also documented the specific type of AEFI and the interventions administered, such as oxygen supply,

Table I. Summary of participants characteristics of the drive-through vaccination programme. This table summarizes the demographic characteristics and vaccination outcomes of participants involved in the drive-through COVID-19 vaccination campaign. The table highlights age distribution, gender breakdown, and the frequency of adverse events reported following immunization. The vaccination period, represented by different dates, captures the distribution of vaccine doses administered on each specific day

Study variable	No. of vaccinations, n (%); n=20,817
Age (yr), Median (IQR)	20 (10)
Gender	
Male	9,712 (47)
Female	11,105 (53)
Adverse event	
Yes	79 (0.38)
No	20,738 (99.62)
Vaccination date (DD/MM/YY)	
27/07/2021	775 (3.7)
28/07/2021	1,053 (5.1)
29/07/2021	954 (4.6)
31/07/2021	2,518 (12)
02/08/2021	1,955 (9.4)
07/08/2021	1,108 (5.3)
29/08/2021	2,791 (13)
01/09/2021	3,239 (16)
04/09/2021	2,591 (12)
06/09/2021	3,833 (18)

drugs, emergency procedures, or hospital referrals. The primary data source was the Faculty of Medicine, Public Health, and Nursing internal vaccination registrations at Universitas Gadjah Mada.

Statistical analysis: Participant characteristics, such as age, gender, and vaccination data, were summarized using descriptive statistics. Analysis was performed using RStudio, utilizing the Tidyverse package for data manipulation and visualization. Density plots were generated to visually represent the age distribution of participants who experienced adverse events and those who did not. A bar chart was employed to illustrate the distribution of several categories of adverse events.

Results

Characteristics of the participants: Among the 27,459 individuals who registered, only 20,817 met the criteria

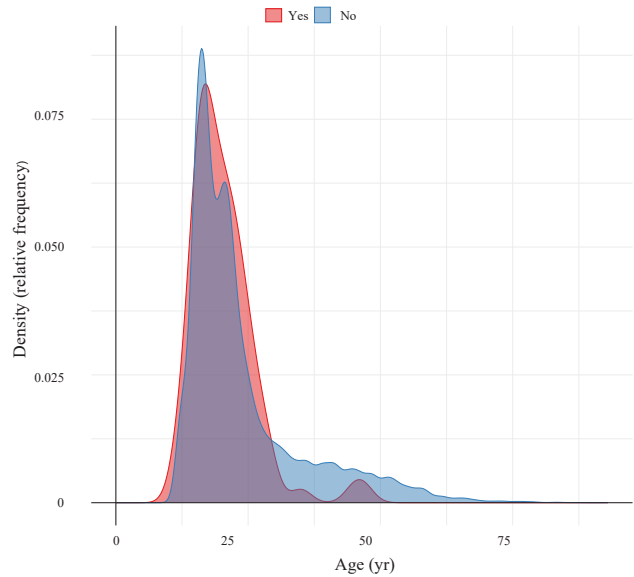


Fig. 2. Density plot of age by adverse event. This density plot shows the distribution of participant ages, separated into those who experienced adverse events and those who did not. The figure shows that younger participants (aged 15–25 yr) were more likely to report adverse events compared to older individuals.

and received a dose. Some registrants did not attend the vaccination event, while others were deemed ineligible during the self-assessment process for vaccination eligibility. The participants had a median age of 20 yr and an interquartile range (IQR) of 10 yr, suggesting that the population getting the immunization was relatively young (Table I). The gender breakdown was approximately equal, with 9,712 (47%) male participants and 11,105 (53%) female participants.

Immunization Period: The vaccination distribution during the study period shows fluctuations in the quantity of doses provided on various days. The most vaccinations occurred on September 6, 2021, with 3,833 doses provided, or 18 per cent of the total doses. The day with the lowest vaccination number was July 27, 2021, with 775 doses provided (3.7%). Figure 2 shows the age density plot of participants, divided into two groups based on the occurrence of immediate AEFI. The individuals who had adverse events are represented in red, while those who did not are in blue. The analysis reveals a more significant proportion of younger individuals, specifically those aged 15- 25 yr, suggesting that this demographic made up a substantial proportion of the vaccinated cohort. The density map indicates that the younger age groups experienced the highest adverse events, peaking around twenty cases, in overall. These findings suggest that younger

Table II. Participant characteristics with adverse events for drive-through vaccination programme. This table presents a detailed breakdown of participants who reported adverse events following immunization (AEFI). It includes demographic information, type of adverse events (systemic or local), medical treatment provided, and the vaccination period. Systemic adverse events, such as dizziness and nausea, were more common, with treatments like paracetamol and oxygen frequently administered

Study variable	No. of AEFI cases, n (%); n=79
Age (yr), Median (IQR)	19 (8)
Gender	
Male	29 (37)
Female	50 (63)
Local/systemic	
Systemic	73 (92)
Local	5 (6.3)
Systemic & local	1 (1.3)
Vaccination date (DD/MM/Yr)	
31/07/2021	11 (14)
02/08/2021	7 (8.9)
07/08/2021	5 (6.3)
18/08/2021	5 (6.3)
22/08/2021	7 (8.9)
25/08/2021	2 (2.5)
29/08/2021	4 (5.1)
30/08/2021	5 (6.3)
01/09/2021	4 (5.1)
04/09/2021	6 (7.6)
06/09/2021	5 (6.3)
31/07/2021	18 (23)
Medical treatment	44 (56)
Medicine	
Paracetamol 500 mg	19 (24.1)
Oxygen	14 (17.7)
Domperidone	13 (16.5)
Diphenhydramine	2 (2.5)
Multivitamin	1 (1.3)
CTM	1 (1.3)
Bandage	1 (1.3)
Complaints	
Dizziness	61 (77.2)
Nausea	22 (27.8)
Fatigue	13 (16.5)
Injection pain	5 (6.3)
Palpitation	3 (3.8)
Shortness of breath	2 (2.5)

Contd...

Study variable	No. of AEFI cases, n (%); n=79
Age (yr), Median (IQR)	19 (8)
Vomiting	2 (2.5)
Abdominal pain	2 (2.5)
Anxiety	2 (2.5)
Dyspnea	1 (1.3)
Itching at injection site	1 (1.3)
Bleeding	1 (1.3)
Fainting	1 (1.3)

persons were more likely to report immediate AEFIs than older groups. As individuals age, the frequency of participants reporting AEFIs declines substantially, with minimal adverse events recorded in people aged ≥ 50 yr.

The red and blue curves show a comparable distribution of ages among individuals who did and did not experience adverse events, with a minor tendency towards younger ages in the AEFI group. This pattern highlights the significance of regularly monitoring younger individuals who get vaccines for immediate AEFIs since they seem more susceptible than older individuals.

Adverse events following immunization in drive-through vaccination: Out of the 79 individuals who had adverse reactions after receiving the COVID-19 vaccine at a drive-through location, the median age was 19 yr. This indicates that younger people were more likely to report adverse reactions. The participants were distributed by gender: 29 males (37%) and 50 females (63%). This indicates that females had a higher occurrence of adverse events than males, as seen in Table II.

Table II displays the distribution of adverse events, indicating a higher event of systemic effects than local impacts. Seventy-three participants (92%) experienced systemic adverse events, while 5 (6.3%) experienced local adverse events. Dizziness was the most frequently reported adverse event, affecting 61 individuals (77.2%), followed by nausea in 22 participants (27.8%) and fatigue in 13 people (16.5%).

Adverse events distribution: Figure 3 visually illustrates the many types of adverse events that have been recorded. Dizziness was the most commonly reported side effect, followed by nausea and fatigue. Additional unfavorable occurrences documented included injection

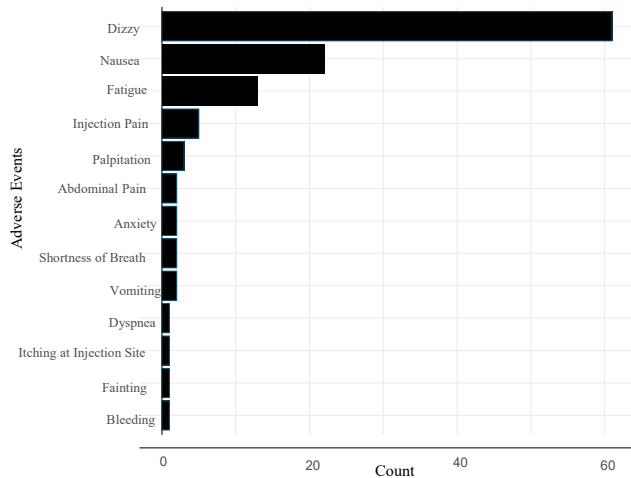


Fig. 3. Distribution of adverse events. This figure illustrates the distribution of adverse events reported during the drive-through COVID-19 vaccination campaign. The horizontal bars represent the frequency of each event.

pain, affecting 5 (6.3%) participants, palpitation in 3 (3.8%), participants, and shortness of breath also observed in 2 (2.5%) participants. Two (2.5%) reported experiencing shortness of breath, abdominal pain and anxiety. Infrequently reported adverse events included dyspnea, itching at the injection site, bleeding, and fainting, with each impacting one person (1.3%). All participants with immediate AEFI resolved at the vaccination site, with no need for further follow up.

Treatment modalities: Diverse treatments were administered to manage these adverse events effectively. Paracetamol 500 mg was given to 27 participants (33%) to relieve symptoms. Twenty-one participants (26%) received oxygen, whereas 26 (32%) were administered domperidone to manage nausea. Four people (4.9%) were given diphenhydramine for allergic responses, while two (2.4%) received CTM. One person (1.2%) received a multivitamin, while another participant (1.2%) was given a bandage to address bleeding.

Discussion

The study indicated that the median age of participants was 20 yr, suggesting that a wide range of community members participated in the immunization effort²⁶. Although there are difficulties in organizing mass immunizations, immediate AEFI was rare at 0.38 per cent 95 per cent CI (0.30-0.47), highlighting the overall safety of the drive-through vaccination approach²⁶.

One of the key factors driving vaccine acceptance is the public's confidence in the vaccine's safety. Studies have indicated that enhancing trust in the safety of vaccines can play a crucial role in reducing vaccine hesitancy²⁷. Addressing hesitance is vital for improving vaccine acceptance rates and increasing vaccination coverage²⁸. Furthermore, the research emphasizes the importance of ongoing surveillance and assessment of vaccine safety, particularly in innovative vaccination environments such as drive-through clinics.

As highlighted in studies on vaccine supply chain challenges and sustainable vaccination strategies, efforts to optimize vaccine distribution and logistics are essential for ensuring efficient and equitable vaccine delivery^{28,29}. Additionally, community-based interventions and mobile vaccine equity programme are vital in improving vaccine accessibility and equity, particularly marginalized populations^{30,31}

The successful implementation of drive-through vaccinations for tick-borne encephalitis in the Province of Belluno during the COVID-19 pandemic serves as a prime example of this approach¹³. Over 12,000 individuals were safely and efficiently vaccinated using the drive-through method, which was well-received by the community¹³. This approach allowed for mass immunization while maintaining social distancing, highlighting its effectiveness during a pandemic.

Drive-through vaccination sites also offer a convenient solution for individuals facing transportation barriers or limited access to healthcare facilities³². Innovative State-level vaccination campaigns, including both walk-through and drive-through clinics, have successfully provided accessible and efficient routes for vaccine administration, further enhancing vaccine coverage in underserved populations³³.

From this study, we can derive several lessons related to the barriers and enablers. The barriers to drive-in vaccination campaigns include the need for a large and free-flowing venue to accommodate vehicles, the requirement for an advanced medical emergency unit on-site, and the necessity of a larger team to facilitate the rapid movement of participants through the vaccination process. These logistical challenges are critical considerations in the planning and execution of such campaigns.

Enablers of these campaigns include high public enthusiasm, particularly among younger populations, a well-organized and experienced team in conducting mass vaccinations, and the commitment of local or

national authorities to maximize various methods for achieving rapid vaccine coverage.

This study's primary emphasis on immediate AEFI during drive-through COVID-19 immunization adds to the broader discussion on vaccine safety and monitoring³⁴. Through real-time evaluation of the frequency of adverse events, public health authorities can immediately respond to any safety issues and uphold public confidence in the vaccination programme³⁴. The low incidence of immediate AEFI in the drive-through setting underscores the feasibility and safety of this vaccination approach²⁵.

The studies on drive-through COVID-19 vaccination programme offers significant knowledge regarding the security, effectiveness, and community involvement in large-scale vaccination initiatives. Countries can address vaccine hesitancy, optimize logistics, and monitor adverse events to boost the success of vaccination programme and advance global health security.

The predominance of younger individuals reporting adverse events, as indicated by the age density plot, suggests a potential higher vaccine sensitivity in this demographic, highlighting the necessity for closer post-vaccination monitoring in younger age groups²⁰.

The study identified dizziness, nausea, and fatigue as the predominant side effects among participants, with dizziness being the most common at 77.2 per cent, followed by nausea at 27.8 per cent, and fatigue at 16.5 per cent²⁰. These findings differ from the results of a similar study conducted in Pakistan, where headache was the most reported systemic side effect with a prevalence of 18.7 per cent, making it more common than nausea and fatigue²¹. In contrast, nausea was reported by only 2.5 per cent of participants in the Pakistan study after receiving the second dose of the Sinovac vaccine, making it one of the least common side effects, whereas fatigue had a prevalence of 23.6 per cent, indicating it was more common than both nausea and headaches²¹. These variations may be due to differences in population characteristics, vaccine administration protocols, or environmental factors.

The study highlights the safety and preparedness of drive-through COVID-19 immunization programme in managing potential adverse events, as evidenced by the low occurrence of harmful incidents and the effective handling of reported reactions²⁰. To bolster public trust in vaccination efforts and ensure the success of mass immunization campaigns, it is crucial for vaccination teams to immediately and effectively handle any

adverse incidents that may occur. The study revealed notable fluctuations in the distribution of vaccinations during the study period, indicating distinct peaks likely associated with targeted public health initiatives or improved accessibility of vaccines²⁵. The significant volume of vaccinations provided on specific dates, such as September 6, 2021, indicates efficient organization and implementation of drive-through vaccination events, demonstrating the potential of such programme to adapt to increased demand or growing public health requirements²⁵.

The study found that females had more adverse outcomes than males, supporting earlier studies suggesting that females experience more vaccine reactogenicity³⁵. The significance of this gender inequality highlights the need for additional research into the fundamental biological or societal processes that contribute to this difference³⁵. Comprehending these parameters is essential for customizing immunization strategies and efficiently monitoring adverse effects.

The findings underscore the importance of drive-through vaccination as a feasible approach for widespread immunization, especially in times of pandemics, owing to its capacity to minimize physical interaction, mitigate the hazards of virus transmission, and effectively vaccinate large numbers of people³⁶. However, this study also acknowledges some challenges associated with the drive-through method, such as accurate data collection and managing adverse events in a non-clinical setting, highlighting the importance of meticulous planning and the presence of trained medical personnel to address emergencies³⁶.

The results indicating a more significant occurrence of adverse events among younger individuals are consistent with previous studies, underscoring the importance of specific communication and monitoring approaches for this population during vaccination campaigns³⁷. Public health authorities should consider these factors when designing and implementing vaccination programme to ensure the safety and well-being of all participants.

The study has several limitations. The reliance on self-reported data for AEFI measurement is a notable limitation, as these reports could not be independently verified. Additionally, the study was conducted in a single region (Yogyakarta) and within a specific vaccination period (first and second doses), which might not reflect safety issues associated with other vaccination periods. Moreover, the study focused solely on the Sinovac vaccine, which was available in

Indonesia at the time and had been proven safe; thus, the findings may not be generalizable to other vaccines.

In conclusion, the drive-through COVID-19 immunization programme in Yogyakarta Province successfully administered vaccines to many people while experiencing few harmful incidents. The infrequent occurrence of AEFI and the capacity to rapidly handle such incidents reinforce the ongoing utilization of drive-through vaccination as a crucial approach in the pandemic response. Future vaccination campaigns should utilize these findings by prioritizing comprehensive data collecting, efficient adverse event management, and tailored strategies for various demographic groups to optimize vaccine safety and effectiveness.

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Conflicts of Interest: None.

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