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Analysis of Factors Affecting Post Immunization Event (AEFI) of COVID-19 Vaccines in Indonesia: Online Survey

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ABSTRACT

Introduction: Cases of death and infection due to COVID-19 in Indonesia are the highest compared to other countries in Southeast Asia even though there are various types of Covid-19 vaccines in Indonesia. Although the Covid-19 vaccine has several benefits, there are side effects caused by vaccine administration (AEFI). Many studies have been conducted on AEFI of Covid-19 vaccine in the general public, but the number of studies that discuss special groups needs to be studied further.

Objective: This research aims to find out AEFI from more diverse community groups so that the results can be used as material for consideration in policy making.

Method: This type of research is a quantitative study with a research design using a cross-sectional study design and using the chi-square test. The sample amounted to 656 respondents who were taken using simple random sampling. Data collection was conducted in September 2023 based on a web survey through Google Forms. Questions regarding diet refer to the General Guidelines for Balanced Nutrition, sleep quality refers to the Pittsburgh Sleep Quality Index (PSQI), and anxiety refers to the Hamilton Rating Scale for Anxiety (HARS). Data will be processed using Stata 18 data processing application.

Result: There was no correlation between the factors studied and post-immunization adverse events (AEFI). However, history of atopic disease had an effect of 1.355 times greater than the dietary category which only had an effect of 0.725 times.

Conclusion: Factors associated with post-immunization adverse events (AEFI) such as socio-demographics, history of illness, diet and breakfast, history of allergic disease, history of atopic disease, history of anxiety, vaccine complaints, post-vaccine reactions did not have a significant association with AEFI.

Keywords: Post-Immunization Adverse Events (AEFI); Vaccine; Covid-19; Diet Category; History of Atopic Disease

INTRODUCTION

The death and infection cases due to COVID-19 in Indonesia are the highest compared to other countries in Southeast Asia (1). As of November 24, 2021, there were reported cases of 4,254,443 confirmed positive COVID-19 cases and 143,766 deaths (CFR: 3.4%). In order to break the chain of transmission and reduce the morbidity and mortality rates due to Covid-19, the government through the Ministry of Health of the Republic of Indonesia, has taken action to enhance COVID-19 mitigation efforts in Indonesia, referring to WHO guidelines on the novel Coronavirus by providing vaccination with 2 doses (0.5 mL) with a 14-18 days interval (2).

Vaccination is one of the most effective ways to protect and fight against the virus for vulnerable groups (3). Researchers have been striving to find vaccine formulations that can be used for Covid-19 prevention to boost group immunity (Herd Immunity). There are various types of Covid-19 vaccines, but in Indonesia, the Covid-19 vaccination program includes Sinovac, Biofarma, Moderna, Pfizer, Astra Zeneca, and Sinopharm (4). Although Covid-19 vaccines have several benefits, including stimulating the immune system, reducing transmission, reducing the severity of the virus, and achieving herd immunity, there are side effects caused by vaccine administration (AEFI). AEFI is an unwanted medical occurrence that happens after vaccination but not necessarily causally related to the vaccine. AEFI symptoms vary from mild discomfort to serious abnormalities threatening life.

Generally, AEFI due to Covid-19 vaccines manifest in various body reactions, ranging from local (swelling, pain, and redness at the injection site), systemic (fever, fatigue, and headache), to fatal reactions causing anaphylactic shock, thrombocytopenia thrombosis, and thromboembolism (5). One triggering factor of AEFI is the type of Covid-19 vaccine determining the pharmacokinetics and pharmacodynamics of the vaccine's metabolic reactions by the body. mRNA-based Covid-19 vaccines, such as Pfizer, have a higher likelihood of causing systemic and local reactions compared to inactive virus-based and viral vector vaccines (6). Additionally, AEFI due to Pfizer vaccine more frequently exhibits systemic and local reactions accompanied by joint and muscle pain during the first vaccine dose administration compared to the second dose (7).

News about AEFI often becomes a topic on social media. Feelings of anxiety or fear due to AEFI can occur before or after injection. Based on previous research conducted by Fatimah et al. (8) on healthcare workers experiencing post-vaccination adverse events after COVID-19 (Sinovac), it exceeded 50% of the total population of 414 healthcare workers. From several variables studied, there is a significant relationship between age, anxiety, and history of food allergies with post-COVID-19 vaccination (Sinovac) (8). Moreover, previous research also stated that a history of type 2 diabetes, hypertension, and heart disease is closely associated with more severe AEFI, as well as in patients with a history of anemia, hyperlipidemia, and kidney failure (9).

Previous research on AEFI of Covid-19 vaccines has been widely conducted but mostly discusses specific groups, such as healthcare workers. Therefore, researchers are interested in conducting research again on the general public to understand AEFI from more diverse groups, the results of which can be considered in policy making.

METHOD

This study employed a cross-sectional study design based on a web survey through Google Forms. Data collection was conducted in September 2023. The survey form was distributed to respondents through various platforms such as WhatsApp, Facebook, and Gmail. The questionnaire consisted of two parts: Part A contained questions about age, gender, marital status, distance to healthcare facilities, occupation, dietary patterns, sleep quality, anxiety, and medical history. Part B contained questions about Post-Vaccination Side Effects of COVID-19 (local systemic reactions, other reactions, or no complaints). Data on age, gender, marital status, distance to healthcare facilities, healthcare worker classification, dietary patterns, sleep quality, anxiety, medical history, and Adverse Events Following COVID-19 Vaccination (Sinovac) were categorized.

The instruments in this study were questionnaires adapted for gender (female and male); age (in years): 12-25, 26-45, 46-65 years; access to healthcare facilities: far >3km and near ≤3km; marital status: unmarried and ever/married; highest education: bachelor/more, diploma, high school, junior high school, elementary school; occupation: private, unemployed, civil servant; place of residence: rural and urban. Questions about dietary patterns referred to the General Guidelines for Balanced Nutrition (Less if score < mean/median or Adequate if score ≥ mean/median). Questions about sleep quality referred to the Pittsburgh Sleep Quality Index (PSQI) (Poor if score < mean/median or Adequate if score ≥ mean/median) and have been tested for validity (Pearson Correlation score > 0.279) and reliability (Cronbach's Alpha value 0.628). Questions about anxiety referred to the Hamilton Rating Scale for Anxiety (HARS) (Yes if score ≥ mean/median or No if score < mean/median) and have been tested for validity (Pearson Correlation score > 0.279) and reliability (Cronbach's Alpha value 0.922). Questions about medical history such as history of drug allergies, food allergies, atopic diseases, hypertension, and dyspepsia syndrome whether there is or not. If yes, the questions were followed by complaints, allergies to drugs and foods, and whether the disease was controlled or not. Questions about Adverse Events Following Vaccination such as 1) yes and no, 2) specific complaints: pain at the injection site, drowsiness, fever, myalgia, fatigue, headache, swelling at the injection site,

arthralgia, redness at the injection site, dizziness, vomiting, tingling hands, and allergies. The data was analyzed by using Stata 18.

RESULTS

Based on the univariate analysis results in table 1, it is known that in terms of respondents' age, the adult age group (26-45 years) has the highest category, accounting for 63.7% or 418 people. Male respondents accounted for 36.3% or 238 people, while females accounted for 63.7% or 418 people. The majority of respondents were married, accounting for 53.7% or 352 people. The highest level of education shows that bachelor's degree holders rank first, accounting for 57.62% or 378 people. Private employment (entrepreneurs and private employees) is the highest among others, with a percentage of 48.5% or 318 people. Most respondents reside in urban areas, accounting for 61.43% or 406 people.

Table 1. Socio-Demographic Characteristics of Respondents towards AEFI

Variable	n	%
Gender		
Women	418	36.3
Men	238	63.7
Age		
Adolescent (12-25 years)	187	28.5
Adult (26-45 years)	418	63.7
Elderly (46-65 years)	51	7.8
Health Facility Accesbility		
≤3km	393	59.9
>3km	263	40.1
Marital Status		
Married	352	53.7
Not Married	304	46.3
Education		
Bachelor	378	57.62
Diploma	119	18.14
Senior Highschool	124	18.90
Junior Highschool	18	2.75
Elementary School	17	2.59
Job		
Private sectors (Self-employed & Private Employee)	318	48.5
Unemployed (Housewive, Student & Retired)	171	26.1
Civil Servant	167	25.5
Residence		
Rural	250	38.57
Urban	406	61.43

Respondent medical history includes stroke, diabetes, and hypertension. There were 10 individuals (2.90%) with hypertension, 4 individuals (0.61%) with diabetes, and 1 individual (0.15%) with stroke. Meanwhile, other prevalent diseases among respondents were asthma (27.28%) and gastric ulcer (16.37%).

Table 2. Respondents Medical History towards AEFI

Medical History	N	%
Diabetes		
Yes	4	0.61
No	652	99.39
Stroke		

Yes	1	0.15
No	655	99.85
Hypertension		
Yes	19	2.90
No	637	97.10
Cancer		
Yes	0	0
No	0	0
Other Medical History		
Asthma	15	27.28
Gastritis	2	3.64
Cholesterol	1	1.81
Heart Disease	1	1.81
Indigestion	9	16.37
Gerd	1	1.81
Other Disease	26	47.28

Chi-square was used to identify factors associated with adverse events. The results of bivariate analysis considered several factors ranging from anxiety, vaccine duration, diet category, drug allergic reaction, history of atopic disease, hypertension, sleep quality, gender and married status with a significance p-value >0.05 contained in the analysis. Females had a risk of adverse events following immunization OR = 0.812; 95% CI (0.573 < OR < 1.149). Respondents with a history of atopic disease were at risk of adverse events following immunization (AEFI) OR = 1.534; 95% CI (0.880 < OR < 2.083). Meanwhile, respondents who experienced anxiety had a risk of AEFI OR = 1.241; 95% CI (0.855 < OR < 1.802) (Table 3). These results showed that there was no association between the factors studied and adverse events following immunization (AEFI).

Table 3. Factors Influencing AEFI

Variable	AEFI				Total		OR	95%CI	P-value
	Yes		No						
	N	%	N	%	n	%			
Anxiety									
Yes	148	30.2	342	69.8	490	100	1.241	0.855-1.802	0.256
No	58	34.9	108	65.1	166	100			
Vaccination Timeframe									
>1 Month	153	31	342	69	494	100	1.084	0.74-1.584	0.678
<1 Month	53	32.7	109	67.3	162	100			
Diet Category									
Good	138	34	268	66	406	100	0.726	0.513-1.026	0.069
Bad	68	27.2	182	72.8	250	100			
Drug Allergic Reaction (DAR)									
Yes	11	32.4	23	67.6	34	100			
No	195	31.4	427	68.6	622	100	0.955	0.456-1.998	0.902
History of Atopic Disease (HAD)									
Yes	40	37	68	63	108	100	1.354	0.880-2.083	0.167
No	166	30.3	382	69.7	548	100			
Hypertension									
Yes	12	31,6	26	68,4	618	100			
No	194	31.3	424	68.6	618	100	0.991	0.490-2.006	0.981
Sleep Quality									
Good	56	30.8	126	69.2	182	100	1.042	0.720-1.507	0.829
Bad	150	31.6	324	68.4	474	100			
Gender									
Women	138	33	280	67	418	100	0.812	0.573-1.149	0.238
Men	68	28.6	170	71.4	238	100			
Marital Status									
Married	111	31.5	241	68.5	352	100	0.987	0.709-1.374	0.938
Not Married	95	31.3	209	68.8	304	100			

Table 4 presents the results of multivariate analysis between diet category and history of atopic disease. Based on statistical tests, the p-value is 0.069 in the dietary category and 0.168 in the history of atopic disease, which means p>0.05, so it can be concluded that there is no relationship between dietary category and history of atopic disease with adverse events after immunization (AEFI). The risk of diet category for adverse events after immunization (AEFI) is significant with 95%CI of 0.725, while the history of atopic disease is 1.355.

Table 4. The Relationship between Diet Categories and History of Atopic Diseases towards AEFI

Factor	OR	95% CI	p-value
Diet Category	0.725	0.513 – 1.026	0.069
History of Atopic Disease	1.355	0.880 – 2.088	0.168

DISCUSSION

A total of 656 respondents voluntarily filled out the survey form. Adults immune systems have a higher frequency of AEFI cases. Immune system reactions caused by vaccination can result in side effects. Adults often have stronger immune systems, and they also tend to respond to vaccination more vigorously and experience more side effects (10). Gender also affects antibody response besides age (11). This study found no correlation between AEFI and gender. Gender is one of the most fundamental factors, although there is no correlation with variations in immune responses induced by vaccination. However, the underlying mechanisms of this variation remain unexplained and may be due to immune responses and vaccines administered (12). This study is in line with Ganesan et al (13) which found no significant relationship between gender and AEFI occurrence. The results of the study by Yulyani et al (10) found that women are more likely to experience AEFI than men in previous studies. Married individuals are more likely to experience depression because they have more responsibilities and time demands to take care of their families. Depression weakens a person's physical and lowers their immunity. Someone who has received the Covid 19 vaccination is more likely to experience an increase in AEFI occurrences when their immune system or immunity is lowered (14).

Individuals with uncontrolled underlying diseases such as diabetes or hypertension are advised not to receive the vaccine. This is because certain disorders impair a person's ability to produce antibodies (15). Elderly individuals or those with comorbidities are still allowed to receive vaccination with certain restrictions and prior screening, but no previous studies have found this (16). According to the Ministry of Health, vaccination administered in Indonesia is safe for the elderly and those with comorbidities. In addition to the fact that individuals with comorbidities can receive the Covid-19 vaccine after screening, other studies have shown that AEFI from vaccines is not related to comorbidities because individuals with comorbidities have different immune responses from each other (10).

Respondents who consumed ≤8 glasses of water accounted for 71.95%, and those who did not consume ≥4 teaspoons of sugar accounted for 76.68%. Meanwhile, respondents who consumed ≥1 teaspoon of salt accounted for 61.28%. This indicates that respondents who follow a diet by controlling water and tea consumption are more numerous than those who consume salt. However, there is no research supporting the relationship between diet and breakfast habits with AEFI. Respondents who have a habit of having breakfast have the highest percentage at 79.73%. Meanwhile, respondents who engage in physical activities like exercise are nearly the same with a difference of 11.28%.

Respondents with a history of drug or food allergies have a small percentage compared to respondents without allergies. The research results show that respondents without a history of allergies account for 94.81%, which is more than respondents with a history of allergies, accounting for only 5.19%. The statistical test result p-value = 0.902, which means there is no relationship between allergic history and the occurrence of AEFI. Other studies also indicate a significant difference in the proportion of side effects between groups with a history of allergies and those without a history of allergies (17). Previous research also found a significant difference in the proportion of side effects between age groups <43 years and age groups >43 years. However, there was no significant difference in the variable of allergic history (18).

The most common local reactions to vaccine complaints experienced by respondents are pain at the injection site (89.36%) and swelling at the injection site (7.93%). These findings are consistent with a safety study of the Sinovac vaccine conducted in China, which found that most post-immunization complaints were mild, and discomfort at the injection site was the most frequently reported complaint (19). Meanwhile, the most common systemic reactions experienced by respondents are drowsiness (52.33%) and fever (26.69%). Research by Lestari et al. (20) identified other common complaints, including fatigue after the first vaccination (32.1%) and after the second vaccination (23.7%), and hunger after the first vaccination (37.4%) and after the second vaccination (16%). Other studies have shown similar results, with fatigue being another common systemic effect following COVID-19 immunization (21). Additionally, another frequently experienced reaction is dizziness (64.77%). This is supported

by Lestari et al (20), as some respondents also reported complaints such as redness, swelling at the injection site, dizziness, fever >37.5°C, muscle pain (myalgia), joint pain (arthralgia), weakness, headache, nausea and vomiting, limb weakness, itching all over the body, and flu-like symptoms.

A total of 31.40% of respondents experienced post-vaccination complaints. The complaints reported by respondents are as follows: 8.2% experienced redness at the injection site, 60.7% experienced pain at the injection site, and the pain did not interfere with daily activities. 22.4% experienced swelling at the injection site, and the swelling did not interfere with daily activities. 47.1% experienced fatigue but it did not interfere with daily activities, 29.4% of respondents experienced headaches but it did not interfere with daily activities, and 15.3% of respondents experienced fever (22). Reports received by the National Adverse Event Following Immunization (AEFI) Commission include fatigue, pain at the injection site, redness, weakness, fever, nausea, and changes in appetite. Research conducted by Andini et al. (23) who stated that there was no relationship between anxiety and the incidence of AEFI in recipients of the 2nd dose of Sinovac vaccine at the Ma'rang Community Health Center, Pangkep Regency in 2021. AEFI for the Covid-19 vaccine can occur due to reactions related to vaccine components, defects in vaccine quality, errors procedures, anxiety due to fear of being injected, or accidental events or reactions (24).

The results of research on hypertension are consistent with initial findings by Raul Pellinia et al. (25) who found that multivariate linear regression did not show an association between hypertension with p-value = 0.52 and the majority of the sample (87.5%) had no history of hypertension. This is also in accordance with the recommendations of the Association of Indonesian Internal Medicine Specialists (PAPDI) for inclusion and exclusion criteria for the COVID-19 vaccine, which states that patients with a history of hypertension - as long as it is still under control - are eligible to receive the vaccine (26). It can be concluded that after receiving the vaccination injection, people with hypertension and controlled hypertension will not experience side effects.

The results regarding history of food allergies, drug allergies, and atopic diseases differ slightly from those reported in the article by Sampath et al (27) regarding vaccines and allergic reactions. In the UK, two reports of allergic reactions occurred following administration of the BNT162b2 (Pfizer) mRNA vaccine on 30 December 2020. The Medicines and Healthcare products Regulatory Agency (MHRA) revised its guidance, stating that the vaccination should not be given to people who have a history of allergies to vaccine components , but should be given to people who have a history of other allergies, such as drug or food allergies (27). Similar rules apply to recipients of the COVID-19 vaccine, as stated by the Association of Indonesian Internal Medicine Specialists (PAPDI). Patients with a history of drug allergies, food allergies, or atopic diseases (allergic rhinitis, atopic dermatitis) are eligible to receive the vaccine (26).

Relationship between diet category and history of atopic disease on AEFI

The results showed there was no relationship between diet category and history of atopic disease with AEFI. However, the variable that most influences AEFI is a history of atopic disease. Patients who have a history of atopic disease will get AEFI 1.355 times higher than patients who do not have a history of atopic disease. Meanwhile, the diet category has an influence 0.725 times higher compared to patients who do not diet. This is supported by research by Fatimah et al. (8) a history of atopic disease does not have a significant relationship with adverse events following Covid-19 (Sinovac) vaccination (p-value = 1.000 and 0.146).

CONCLUSION

Factors associated with adverse events following immunization (AEFI) such as socio-demographics, history of illness, diet and breakfast, history of allergic disease, history of atopic disease, history of anxiety, vaccine complaints, post-vaccine reactions did not have a significant association with AEFI. However, a history of atopic disease has an influence 1.355 times greater than the diet category which only has an influence 0.725 times. Future researchers are advised to research further regarding diet and breakfast so that the results can be more accurate.

SUGGESTION

This finding has implications in developing policies and intervention strategies aimed at knowing AEFI from a more diverse group of people so that the results can be taken into consideration in policy making. However, researchers have limitations in data analysis because there are some factors that have not been studied before. Future researchers are advised to further examine factors associated with AEFI, especially regarding diet and breakfast so that the results can be more accurate.

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