Research Article

Adverse Events Following Immunization (AEFI) of COVID-19 Vaccine: A Descriptive Survey in Malang City

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Abstract.
Vaccination is used to stop the transmission of COVID-19. However, it can stimulate Adverse Event Following Immunization (AEFI) symptoms, ranging from mild to severe. This study aims to identify the signs and symptoms of AEFI of the COVID-19 vaccine in the Malang City Community. The research design used is a descriptive survey. The sampling technique used was accidental sampling (n=275). The sample criteria were able and willing to fill out the questionnaire by accessing the google form from the researcher. Data were analysed using the Descriptive Statistical Analysis Test. The results of the study indicated that the number of respondents who experienced AEFI after receiving dose 1 vaccine was 97 people (35.2%), with symptoms including fever in 96 people (34.9%), swelling or redness at the injection site in 13 people (4.7%), pain in the injection site in 44 people (16.0%) and 1 person (0.4%) experienced other symptoms that required medical attention. After the second dose of the vaccine, 63 people (22.9%) had a fever, 11 people (4.0%) experienced swelling or redness at the injection site, 18 people (6.5%) experienced pain at the injection site, and 3 people (1.0 %) had other symptoms that required treatment. Signs and symptoms of AEFI of the COVID-19 vaccine most experienced by respondents after vaccine doses 1 and 2 were fever, pain at the injection site, and swelling or redness at the injection site, and there were no severe signs of AEFI were found in this study.

Keywords: AEFI, Covid-19 vaccine, signs, symptoms

1. INTRODUCTION

Coronavirus Disease 2019 or what is often referred to as Covid-19 is a virus that has taken the world by storm. Along with the rapid transmission of the Covid-19 disease accompanied by the addition of confirmed cases, the number of Covid-19 cases jumped sharply in several countries, especially in Indonesia. Therefore, on March 12, 2020, Covid-19 was declared a pandemic by the World Health Organization (WHO). A pandemic is a disease outbreak that can spread widely throughout the world, for example, occurs on several continents (1).

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Coronavirus Disease 2019 (COVID-19) is a new type of infection that has never been found in humans before. It was discovered in 2019. The virus that causes Covid-19 is called Sars CoV-2 (severe acute respiratory syndrome coronavirus 2). The virus is a zoonosis whose transmission can occur in animals and humans (2). The spread of the coronavirus can be transmitted from humans to other humans through splashes of saliva when someone coughs or sneezes (droplets). -1. The most common initial symptoms of Covid-19 include a dry cough and fever which can then resolve spontaneously or can get worse with difficulty breathing, chest tightness, and pneumonia. Symptoms of a person exposed to the Covid-19 virus will appear on average 5-6 days, but can also appear 14 days after being infected (3).

According to data from the World Health Organization (WHO) there are 123,419,065 confirmed cases of Covid, including the number of people who died as many as 2,734,374 from several countries in the world (4). The state of Indonesia itself has the number of confirmed Covid 19 cases as many as 1.47 million cases with the number of people who recovered 1.3 million and the number of people who died as many as 39,711 (5). In dealing with the spread of the Covid-19 virus, the Indonesian government must strive to overcome the pandemic by suppressing the rate of virus transmission by carrying out health protocols in a disciplined manner, such as using masks when doing activities outside the room or in crowded places, diligently washing hands with water and soap or hand sanitizer, and avoiding crowds with lots of people keep a distance of at least 1 meter and maintain endurance by consuming nutritious food, exercising regularly, getting enough rest (6).

One of the efforts to stop the transmission of Covid-19, the government also conducts a periodic vaccination program for all Indonesian people. It is hoped that giving this vaccine is the right solution to reduce the number of cases of Covid-19 transmission. Vaccine is a liquid or antigenic material made from live germs that are inserted into the body, the components of these germs have been designed to stimulate the body to form immunity or antibodies that are quickly able to recognize and can immediately fight the bacteria or viruses that causes the infection. So that if people who have been vaccinated are exposed, they will be able to avoid the transmission of the disease. This vaccine can also be used to reduce the possibility of severe symptoms and complications due to the Covid-19 virus (7).

There are several types of vaccines distributed in Indonesia, including the red and white vaccine, AstraZeneca, Moderna, Pfizer Inc, and BioNTech, Sinopharm, and Sino-vac (8). In Indonesia, it has started to carry out a periodic vaccination program for the entire community. The first stage is carried out by health workers and patients who are

treated for a period of time in a hospital, the second stage is frontline workers, such as firefighters, military/police, education workers (teachers, support staff, and childcare workers), and public service officers. others who have a high risk of being infected and transmitting Covid-19. People aged 65-74 years are at high risk for hospitalization, illness, and death from Covid-19. People aged 16-64 years with underlying medical conditions and an increased risk of serious, life-threatening complications from Covid-19 (9).

However, even though the Covid-19 vaccine has been successfully available, it cannot immediately stop the pandemic because there are pros and cons of giving the vaccine. Knowledge and attitude are interrelated components. The higher a person's knowledge will affect a person's attitude in his daily life. Public knowledge and understanding of the Covid-19 vaccine delivery strategy is very important for the government. This aims to overcome the obstacles that occur during the circulation of the Covid-19 vaccine (10). Lack of knowledge will cause people to refuse to give vaccines, which can have an impact on increasing the spread of Covid-19 and the occurrence of post-immunization follow-up (AEFI) adds to the sense of doubt in the community (1).

AEFI is a side effect or reaction on the body that is not wanted in someone that occurs after immunization if at the time of giving the vaccine there is a body response that shows symptoms of mild side effects up to a serious body reaction will be observed by the medical personnel on duty. This event can be a vaccine reaction or not. Clinical symptoms of AEFI can appear quickly or slowly and can occur with different signs or conditions. Ranging from symptoms of mild side effects to serious body reactions such as severe allergies to the composition of the vaccine. Mild symptoms of AEFI can be local or systemic which can cause pain, redness, and swelling in the infected area of the body after immunization. While the systemic response can cause body responses such as fever, headache, and weakness. The incidence of AEFI with mild symptoms occurs for a short time and can quickly improve. Symptoms of AEFI with severe conditions tend to be rare but can have serious consequences. So, to minimize the occurrence of AEFI it is necessary to observe for 15 minutes by the medical personnel on duty. This event may or may not be a vaccine reaction So to minimize the occurrence of AEFI it is necessary to observe for 15 minutes by the medical personnel on duty. This event may or may not be a vaccine reaction So to minimize the occurrence of AEFI, it is necessary to observe for 15 minutes by the medical personnel on duty. This event may or may not be a vaccine reaction (11). According to Public Health Ontario there are 6,359 reported AEFI counts in Ontario. There are 6,112 non-serious AEFI reports and 257 serious AEFI reports. According to the Covid-19 vaccine safety monitoring report in Hong Kong, 3,829 AEFI reports have been received. Based on the background described above,

researchers aims to identify the signs and symptoms of AEFI after the Covid-19 vaccine in the community in Malang City.

2. MATERIALS AND METHODS

This study uses a descriptive survey design to explain a complete picture of the phenomenon that is currently happening or being widely discussed, namely the signs and symptoms of post-immunization follow-up (AEFI) after the Covid-19 vaccine. The population in this study was the people of Malang City who had received the Covid-19 vaccine and had received the Covid-19 vaccine stage 1 and stage 2. The sample criteria in this study were respondents who were willing to fill out a questionnaire by accessing a google form from the researcher, and accidental sampling, the total number of respondents obtained is 275 people.

This research has been carried out on the community in Malang City from July 15 to August 30, 2021. In this study, the data collection process was carried out through an online questionnaire in the form of a google form, which contained several questions about respondents' demographic data, history of disease/comorbidities, types of vaccines received and the main question regarding the presence or absence of AEFI symptoms after receiving dose 1 vaccine. And dose 2, as well as what symptoms of AEFI are felt. Before the instrument is used in the study, validity and reliability tests have been carried out first. This test was carried out on 20 people in Malang Regency who had received the Covid-19 vaccine dose 1 and dose 2. The validity test of the Post-Immunization Adverse Events (AEFI) questionnaire was analysed using the "Product Moment Correlation" method using SPSS 22 (Software Statistical Product and Service Solutions). From the results of the analysis, it is known that all the calculated r values > from the r table value, which means that all question items on the questionnaire are declared eligible, namely > 0.444 so that the items are valid and can be continued as a data collection tool in the research conducted. In the reliability test of the Post-Immunization Adverse Events (AEFI) questionnaire, it was analysed using "Cronbach Alpha" through SPSS 22 (Software Statistical Product and Service Solutions). The results of the reliability test with Cronbach Alpha obtained that the Cronbach Alpha value met the requirements, namely > 0.600. It can be concluded that the Cronbach Alpha value obtained = 0.784 > r table = 0.444. It can be interpreted that the questionnaire items are reliable or reliable as a measuring tool for research data collection. In this study using descriptive statistical analysis test.

3. RESULTS

3.1. Respondent Demographic Data

The following is the demographic data of respondents including age, gender, education, occupation, history of congenital or comorbid diseases and types of vaccines received.

It is known from the results of table 1 that, from the total number of respondents aged 17- 25 years at most with a percentage (48.3%). The frequency of female gender (52.0%) is higher than that of male (48.0%). The frequency of the latest education level shows that the majority of respondents are with tertiary education as many as 233 respondents or 84.7%. While the frequency of work of most respondents is health workers with a percentage (31.2%). Meanwhile, the number of respondents who do not have a history of congenital or comorbid diseases is more than respondents who have a history of disease/comorbidities, which are 91.6%. The type of vaccine that was received the most by respondents in this study was Sinovac with a percentage (84.0%).

3.2. The Description of AEFI - Covid-19 Vaccine

The distribution of the frequency of respondents experiencing Adverse Events following Immunization (AEFI) after the Covid-19 vaccine, as presented in table 2 below.

Table 2 shows that the people in Malang City after receiving vaccine dose 1 obtained 120 people or 43.6% experienced AEFI while 155 people or 56.4% did not experience AEFI, then the condition of the respondents after receiving vaccine dose 2 obtained 76 people or 27.6% experienced AEFI and 199 people or 72.4% did not experience AEFI.

3.3. Description of the AEFI Symptoms

The distribution of the frequency of signs and symptoms of Post-Immunization Adverse Events (AEFI) after the Covid-19 vaccine in Malang City is explained in tables 3 and 4 below.

Table 3 above shows that people in Malang City after receiving vaccine dose 1 it is known that 96 people or 34.9% of respondents experienced fever, 13 people or 4.7% of respondents experienced swelling or redness at the injection site, 44 people or 16.0% of respondents experienced pain at the injection site. , 0 people or 0.0% of respondents experienced an allergic reaction, and 1 person, or 0.4% of respondents experienced symptoms that required medical attention.

TABLE 1: Demographic Characteristics of Respondents Recipient of Covid-19 Vaccine in Malang City.

Demographic Data	Amount	Percentage (%)
Age (year old)		
17-25	133	48.3
26-35	81	29.4
36-45	28	10.1
46-55	24	8.7
56-65	5	1.8
>65	4	1.4
Total	275	100.0
Gender		
Man	132	48.0
Women	143	52.0
Total	275	100.0
Level of education		
Elementary School	2	7
Junior High School	1	4
Senior High School	39	14.2
College	233	84.7
Total	275	100.0
Occupation		
Student	68	24.7
Teacher/Lecturer	24	8.7
Private sector	50	18.1
Government Employees	10	3.6
Health provider	86	31.2
Others	37	13.4
Total	275	100.0
Disease History/Comorbid		
Asthma	9	3.3
Diabetes mellitus	6	2.2
Hypertension	5	1.8
Lung TB	3	1.1
No comorbid disease	252	91.6
Total	275	100.0
Vaccine Type		
Sinovac	231	84.0
AstraZeneca	44	16.0
Total	275	100.0

The results of the description of respondents after receiving vaccine dose 2 according to table 4 above, it is known that 63 people or 22.9% of respondents had a fever, 11

TABLE 2: Description of Adverse Events following Immunization (AEFI) After the Covid-19 Vaccine in Malang City.

Number of AEFI	Frequency (n)	Percentage (%)
Vaccine Dose 1		
Experiencing AEFI	120	43.6
Not experiencing AEFI	155	56.4
Vaccine Dose 2		
Experiencing AEFI	76	27.6
Not experiencing AEFI	199	72.4
Total	275	100

TABLE 3: Table Description of the Frequency of Symptoms of AEFI Covid-19 Vaccine Dose 1 in the Community in Malang City.

Sign Symptoms AEFI	Frequency (n)	Percentage (%)
Fever	96	34.9
Swelling or redness at the injection site	13	4.7
Pain at the injection site	44	16.0
Allergic reaction	0	0.0
Symptoms that require treatment	1	0.4

TABLE 4: Description of the Frequency of Symptoms of AEFI Covid-19 Vaccine Dose 2 in the Community in Malang City.

Sign Symptoms AEFI	Frequency (n)	Percentage (%)
Fever	63	22.9
Swelling or redness at the injection site	11	4.0
Pain at the injection site	18	6.5
Allergic reaction	0	0.0
Symptoms that require treatment	3	1.0

people, or 4.0% of respondents experienced swelling or redness at the injection site, 18 people or 6.5% of respondents experienced pain at the injection site, 0 people or 0.0% of respondents experienced an allergic reaction, and 3 people or 1.0% of respondents experienced symptoms that required medical attention.

4. DISCUSSION

4.1. Characteristics of Respondents Who Received the Covid-19 Vaccine

Characteristics of respondents in this study describe the diversity of respondents based on age, gender, level of education and occupation. Based on data processing research that has been done in the city of Malang with the target respondents are in the age

range <20 -> 50 years. The results of the study were that the 17-25 year age group participated in this study the most (48.3%) compared to other age groups according to the Indonesian Ministry of Health (2009). In this study, respondents with the elderly age group (> 50 years) only (7.3%) compared to other age groups. Age difference is an important factor in a person's acceptance of health. Increasing age determines a person's level of maturity in thinking, this has to do with experience and knowledge during life which will ultimately affect the acceptance of an individual. Several studies reveal different results regarding age. Based on research by El-Elimat et al in Jordan, it was found that the adult age group, above 35 years, had a lower level of acceptance of the vaccine with a p-value = 0.001 compared to the younger age group (12). While Lazarus et al stated differently that older people, 25-64 years, tended to receive the vaccine than the younger age group / <25 years (13).

In this study, more female respondents participated (52.0%) than male respondents (48.0%). Gender has an impact on acceptance status, attitudes and overall vaccination outcomes. Women are less likely to receive the vaccine, but after vaccination women tend to develop a more durable protective antibody response than men. However, women also often experience side effects caused by vaccines (14). The results of this study stated that the most recent education level of respondents was at the undergraduate or tertiary level with a percentage (84.7%). In Paul et al's research, the level of education is one of the benchmarks for public acceptance of the COVID-19 vaccine, the cause of respondents' refusal is a lower level of education (15). The study illustrates that with higher education levels, public knowledge will increase so that vaccine acceptance will be higher. Research conducted by Febriyanti et al in the city of Surabaya stated that there was a significant relationship (p = 0.000) between knowledge and public willingness to receive the COVID-19 vaccine (16).

This study found that the occupation with the highest percentage was health workers (31.2%). Self-protection and the desire to protect family, friends, and patients have been driving health workers' decisions to get vaccinated. As health workers have more comprehensive knowledge about Covid-19, their relatively high awareness can lead them to protect themselves and not pass the virus on to their family members. This may make them more willing to receive vaccines compared to those working in the non-medical sector. In addition, our further analysis also shows that the perceived risk of health workers is higher compared to non-health workers (17). Next, it also found that respondents who did not have congenital or comorbid diseases were more than respondents who had comorbid diseases with a total of 252 respondents or 91.6%. Vaccines are given only to those who are healthy. There are several criteria

for individuals or groups who are not allowed to vaccinate against Covid-19. One of them is a respondent who has co-morbidities, therefore before the implementation of vaccination everyone will be checked for their body condition first. Those with comorbid disease must be under controlled conditions to obtain consent for vaccination from the treating physician. This is because people who have certain diseases do not have a good immune system to make antibodies (18).

A total of 230 respondents or 84% chose to receive the Sinovac vaccine. The Sinovac vaccine is currently undergoing phase three trials in various countries. Interim data from late-stage trials in Turkey and Indonesia show that the vaccine is 91.25% and 63.50% effective, respectively. Researchers in Brazil initially said in their clinical trials the effectiveness of the Sinovac vaccine was 78%, but after additional research data the figure was revised to 50.40% and declared in January 2021. The Sinovac vaccine has been unveiled for emergency use in at-risk groups in China since July 2020, and as of September 2020 Sinovac has been administered to 1,000 volunteers with less than 5% experiencing mild discomfort or fatigue (19).

From the distribution results above, the characteristics of respondents who received the Covid-19 vaccine played a very important role in the implementation of the vacci-nation program. This study is not in line with research by Arumsari et L., (2021) based on the results of research that the 25-31 year age group participated in this study the most with a percentage (48%) compared to other age groups. More than half of the respondents were female (77.7%) compared to male (22.3%) (20). In the research conducted by Rahayu & Mulyani (2020) the majority of respondents based on previous medical history were 86 respondents or 90.5%. In the research conducted, the majority of the respondents' jobs were nurses as many as 63 respondents or 66.3% (21).

4.2. Overview AEFI Frequency Description

Based on the results of research that has been carried out on 275 respondents, that people in Malang City after receiving vaccine dose 1 obtained 120 people or 43.6% experienced AEFI while 155 people or 56.4% did not experience AEFI, then the condition of respondents after receiving dose 2 vaccine obtained 76 people or 27.6% experienced AEFI and 199 people or 72.4% did not experience AEFI. This is in line with research conducted by Rahayu & Mulyani (2020) The majority of respondents who did not experience Post Immunization Adverse Events (AEFI) were 85 respondents or 89.5% (21). No vaccine is 100% safe and without risk. The vaccines used in the COVID-19 vaccination program are still new vaccines, so to assess their safety it is necessary to

carry out special designed active and passive surveillance (22). Each COVID-19 vaccine has advantages and disadvantages, both in effectiveness, safety and storage. The government is trying to provide the best for the community so that the government only provides Covid-19 vaccines that are proven safe and have passed clinical trials, and have received Emergency Use of Authorization (EUA) from BPOM (5).

4.3. Overview Description AEFI Symptoms

Based on the results of the study, it was found that the percentage of respondents who experienced Post Immunization Adverse Events (AEFI) after receiving vaccine dose 1 was known to 96 people or 34.9% of respondents experiencing fever, 13 people or 4.7% of respondents experiencing swelling or redness at the injection site, 44 people or 16.0% respondents experienced pain at the injection site and 1 person or 0.4% of respondents experienced symptoms that required medical attention.

The results of the questionnaire data analysis of respondents after receiving vaccine dose 2 revealed that 63 people or 22.9% of respondents had fever, 11 people or 4.0% of respondents experienced swelling or redness at the injection site, 18 people or 6.5% of respondents experienced pain at the injection site, respondents who experienced symptoms 3 people who need doctor's care or 1%. Vaccines are given to stimulate the body's antibody system so it is not easy to depend on the virus that causes the disease. When immunization takes place, a vaccine containing a weakened virus will be injected into the body, then the body will respond to the immune system in the same way as when the body was attacked by the disease, if the disease attacks the body, it will be ready to form a defense. Emergence of fever, pain at the injection site and redness is a positive response of the body to the injected vaccine. At that time, the body forms a new immune system with the vaccine which causes a response to an increase in body temperature or fever (11). The incidence of AEFI in Indonesia so far has symptoms of side effects that are still in the mild and harmless category. Reports received by the National Commission of Post-Vaccination Adverse Events (AEFI) include aches, pain at the injection site, redness, weakness, fever, nausea, changes in appetite (23). This is in line with research conducted by Arumsari et al., (2021) The majority of respondents based on the incidence of AEFI after the Covid-19 vaccine appeared, there was no fever 89.5%, diarrhea did not appear 97.9%, cough did not appear 97.9 %, did not appear shortness of breath as much as 97.9% and none (for those who did not appear symptoms) as much as 88.4% (20).

5. CONCLUSION

This research was carried out in the community in Malang City from July 15 to August 30, 2021, at which time the dominant types of vaccines circulating in the community were Sinovac and AstraZeneca. The results of this study indicate that most of the people who received the vaccine, both dose 1 and dose 2, did not experience AEFI, while those who experienced signs and symptoms of Post-Immunization Adverse Events (AEFI) after receiving the Covid-19 vaccine generally showed signs of mild symptoms. such as low-grade fever, pain, and redness at the injection site. This research can be used as a reference for people who will carry out vaccinations so that people do not worry about AEFI after the Covid-19 vaccine and support the vaccination program held by the government. The health team can provide correct information, especially nurses can provide correct education regarding the signs and symptoms of Post-Immunization Adverse Events (AEFI) after administering the Covid-19 vaccine.

Acknowledgments

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