

DESCRIPTION OF THE ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) PFIZER VACCINE IN THE COMMUNITY IN PUSKESMAS UMBUL HARJO I, YOGYAKARTA

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The Covid-19 pandemic which has an impact on the health system in all countries. The implementation of government policies as an effective effort to stop the transmission of COVID-19 is through vaccination. There is no vaccine that is 100% safe and without risk which also has adverse reactions known as Adverse Events Following Immunization (AEFI). The aim is to find out the description KIPI of the Pfizer vaccine in the community in the Puskesmas Umbul Harjo I, Yogyakarta City. This research was descriptive with a cross-sectional method, with a sample of 96 people who were taken by purposive sampling and data collection. by observation. Based on the results of this study, the proportion of AEFI cases of the Pfizer Covid-19 vaccine was divided into three categories, namely mild local AEFI, mild systemic AEFI and severe AEFI. Based on the number of respondents experiencing mild local AEFIs, there were 56 people (60.22%), respondents who experienced systemic AEFIs were 37 people (39.78%) but did not get data on respondents who were classified as having severe AEFIs. The conclusion of this study is the characteristics of the emergence of AEFI in respondents who received the Covid-19 vaccination based on age, sex, education, occupation and criteria of AEFI.

Keywords: Covid-19; Vaccinations Pfizer; Adverse Events Following Immunization (AEFI)

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1. Introduction

Coronavirus Disease 2019 (COVID-19) is an infectious disease which is currently still endemic in almost all parts of the world. This disease is caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) which is transmitted by respiratory air and droplets (Hafizzanovian dkk, 2021). This virus attacks everyone regardless of age or gender, and has been declared a global pandemic. The COVID-19 pandemic has had various impacts on sectors of life in society, causing large numbers of residents to become infected and even die (Moudy, Syakurah, & Artikel, 2020).

The number of COVID-19 cases continues to increase. The increase in the number of cases can be caused by the emergence of new virus variants, namely the delta and omicron variants. The delta and omicron variants are known to be more contagious than the previous alva variant (Arumsari, *et al*,

2021). This case of the omicron variant of COVID-19 was first discovered in South Africa, where the overall average number of confirmed cases reached 280 cases per day per week increasing to 800 cases per day per week (Anon, 2020).

In Indonesia, based on data as of January 24 2022 the number of confirmed cases of COVID-19 has reached 4,289,305 with active cases totaling 20,867. The recovery rate for COVID-19 has reached 4,124,411 cases, of which the total death rate is 144,227 cases (Simanjuntak dkk, 2022). In the Special Region of Yogyakarta, data for February 2022 show that a total of 162,039 positive cases of COVID-19. Of these, 152,106 cases were declared cured and 5,285 cases died. The highest number of positive cases was in Sleman Regency with 506 cases, Bantul Regency 241 cases, Yogyakarta City 211 cases, Kulon Progo Regency 89 cases, and Gunung Kidul Regency 18 cases (Susanto, 2022).

Various countries, including Indonesia, have developed guidelines for preventing and controlling the spread of COVID-19, namely by implementing health protocols including imposing physical distancing, using masks when sick or when in public places, washing hands regularly using water and soap or alcohol-based hand rubs, maintaining ethics of coughing and sneezing by covering the nose and mouth with a tissue or the inside of the upper arm not with the palm of the hand, avoiding touching the eyes, nose and mouth (facial triangle) with contaminated hands, and maintaining health and fitness so that the body's stamina remains healthy and the immune system can increase (Kementerian Kesehatan RI, 2020).

Some countries show success, but some show failure in the policy. Therefore, other effective interventions are needed to stop the transmission of COVID-19 through vaccination efforts (Zulfa, 2021). Vaccination is the administration of vaccines that can stimulate the formation of immunity (antibodies) in the human body. This vaccination is expected to reduce morbidity and mortality due to COVID-19. One of the things that need to be considered from this vaccination program is the Adverse Events Following Immunization (AEFI). AEFI is defined as any adverse medical event after vaccination which is not always related to the use of the vaccine. AEFIs can be in the form of unpleasant or unwanted signs such as pain at the injection site, dizziness, fever and lethargy (Kementerian Kesehatan, 2020; WHO, 2020).

Pfizer-BioNTech is a type of COVID-19 vaccine that has received emergency distribution approval in Indonesia from the Food and Drug Supervisory Agency (BPOM). This vaccine contains a genetic code called the spike protein which is an important part of the SARS-CoV-2 virus. After getting this vaccine, the body will make a copy of the spike protein and then the immune system will learn to recognize and fight the SARS-CoV-2 virus. The results of clinical trials involving around 44,000 people have confirmed that Pfizer is safe, effective and manufactured to very high quality standards (Kementerian Kesehatan RI, 2021; Australian Government 2021).

The results of the research by Hulu, Lubis, & Mahyuni (2022) showed that the incidence of AEFI in the Pfizer type COVID-19 vaccine was 62 people (64.6%), while as many as 34 people (35.4%) did not experience AEFI. The characteristics of AEFI vary from local reactions, systemic reactions, to other reactions. The local reactions that most complained

about were swelling accompanied by pain totaling 9 people (9.4%). Most systemic reactions, namely muscle pain, amounted to 7 people (7.3%). While other reactions that were felt a lot, namely numbness, amounted to 2 people (2.1%).

Based on the background above, this research was conducted with the aim of knowing the description of post-immunization adverse events (KIPI) of the Pfizer vaccine in the community in the working area of the Umbul Harjo I Health Center, Yogyakarta City.

2. Method

This research is a descriptive study using a cross-sectional method by means of observation to see the proportions and characteristics of post-immunization adverse events in consumers of the Pfizer COVID-19 vaccine. The research subjects were 93 people who had received the Covid-19 vaccination at the Umbuharjo I Health Center with the Pfizer vaccine type. This research was carried out directly after the respondents received the Covid-19 vaccination. The researcher got the contact number of the respondent who could be contacted then on the third day to monitor the incidence of AEFIs the researcher sent a questionnaire in the form of Googleform. This research was conducted from October to November 2022. The data collection technique used in this study was purposive sampling. This research obtained permission from the STIKES Guna Bangsa Yogyakarta Research Ethics Committee with No. 005/KEPK/VIII/2022.

3. Results and Discussion

The results of this study were analyzed with the aim of knowing the comparison of an event regarding how many parts of the sample experienced AEFI. In epidemiological studies, proportion analysis is used to compare events with the population at risk.

1. Characteristics of respondents

Based on the above it shows that the age frequency distribution is known that the majority of respondents by age are 21-30 years as many as 43 respondents (46.24%), the majority of respondents based on gender are women as many as 49 respondents (52.69%), the majority of respondents based on education were Bachelor (S1) as many as 43 respondents (46.24%), the majority of respondents based on work were students / students as many as 26 respondents (27.96%).

Tabel 1. Frequency distribution of the characteristics of the respondents

Characteristics	Frequency (n)	Percentage (%)
Usia		
< 21 tahun	10	10,75
21 – 30 tahun	43	46,24
31 – 40 tahun	18	19,35
41 – 50 tahun	9	9,68
51 – 60 tahun	8	8,60
61 – 70 tahun	5	5,38
Gender		
Male	44	47,31
Female	49	52,69
Education		
Elementary School	0	0
Junior High School	5	5,38
Senior High School	37	39,78
Associate's degree (DIII)	7	7,53
Bachelor (S1)	43	46,24
Masters (S2)	1	1,08
Occupation		
Student	26	27,96
Self-employed	24	25,81
Private sector employee	15	16,13
Government employees	6	6,45
Housewife	16	17,20
Doesn't work	6	6,45

Source: Primary data 2022

2. Frequency Distribution of Respondents Based on AEFI Classification

Table 2. Frequency Distribution of Respondents Based on AEFI Classification

Classification KIPI	Frequency (n)	Percentage (%)
Floaty local	56	60,22
Floaty Sistemik	37	39,78
Heavy	0	0

Source: Primary data 2022

From the table above, it shows that the distribution of the number of respondents who consumed the Pfizer COVID-19 vaccine was based on the classification of AEFI, with 56 respondents (60.22%) experiencing only mild local AEFI, 37 respondents (39, 22%) experiencing only mild systemic AEFI. 78%) and none of the respondents had severe AEFI classification.

3. Frequency Distribution of Respondents Based on local mild AEFI

From the table above, it shows that the distribution of respondents who received the Pfizer vaccination experienced local mild AEFI. In the distribution of AEFI with local mild, there were signs and symptoms experienced by respondents with swelling at the injection site, 46 people (32.86%), respondents who experienced pain at the injection site, 72 people (51.43%), respondents who

experienced redness and itchy skin, lips and eyes in 3 people (2.14%).

Table 3. Frequency Distribution of Respondents Based on Local Mild AEFI

Mild Local AEFI	Frequency (n)	Percentage (%)
Swelling in a vantage point	46	32,86
Pain at the injection site	72	51,43
Bleeding at the injection site	19	13,57
Redness and itching of the skin, lips and eyes	3	2,14

Source: Primary data 2022

Table 4. Frequency Distribution of Respondents Based on Mild Systemic AEFI

Sistemik Mild AEFI	Frequency (n)	Percentage (%)
High fever (chills, body temperature reaching over 39°C)	14	22,22
Headache	11	17,46
Muscle/joint pain all over the body	10	15,87
Weakness of the arm/leg muscles	7	11,11
Weakness and numbness all over the body	4	6,35
Easily tired	8	12,70
Faint	1	1,59
Cough and cold	3	4,76
Out of breath	3	4,76
liquid bowel movements/diarrhoea	1	1,59
Nauseous vomit	1	1,59

Source: Primary data 2022

From the table above, it shows that the distribution of mild systemic AEFI with several symptoms experienced by respondents including high fever (chills, body temperature reaching more than 39oC) of 14 people (22.22%), respondents who experienced headaches/headaches of 11 people (17.46%), respondents who experienced muscle/joint pain throughout the body were 10 people (15.87%), respondents who experienced arm/leg muscle weakness were 7 people (11.11%), respondents who experienced weakness and numbness all over the body 4 people (6.35%), respondents who experienced fatigue easily 8 people (12.70%), respondents who experienced fainting 1 person (1.59%), respondents who experienced coughs/colds 3 people (4.76%), 3 respondents experiencing shortness of breath (4.76), 1

respondent experiencing liquid bowel movements/diarrhea (1.59%), 1 respondent experiencing nausea/vomiting (1.59%).

This study uses consumers of the Pfizer type of COVID-19 vaccine as respondents. Respondents' assessment was carried out during the post-vaccine observation period after conducting interviews and observing symptoms based on minutes, hours and days. The short research time and limited number of samples were limitations in this study so that this study was only valid for samples measured during the research time at the Puskesmas Ulmbulharjo I, Yogyakarta.

The advantage in this study is the latest research regarding the proportions and characteristics of AEFI which has never been done before in the Pfizer type COVID-19 vaccine, the selection of all respondents meets the study sample criteria, further monitoring / observation is carried out for 3 days after immunization, the data taken is valid from respondent's statement.

Based on the results of research that has been conducted on 93 respondents, it was found that respondents who were immunized with the Pfizer type vaccine reported several symptoms in the mild local and systemic mild categories. These results are different from research conducted by Lidiana et al. (2021) on health workers in Surakarta with the results that the majority of respondents based on the incidence of AEFI after the COVID-19 vaccine were not there as many as 85 respondents (89.5%). Many factors can cause AEFI in consumers in the form of body resistance and body condition, other factors cannot be determined with certainty. The greater the coverage of vaccines, this results in the use of vaccines also increasing so that unwanted vaccination reactions also increase (Firdausy & Ghozali, 2018). AEFIs that occur in the community do not always have a causal relationship with vaccine use but can be influenced by procedural errors, co-incidence, anxiety reactions, the number of respondents or causal relationships that cannot be determined (Hulu et al., 2022). According to the researchers, when people experience AEFI, it is normal for AEFI to occur because this multifactorial cause is a new type of vaccine that needs further monitoring and evaluation in analyzing the effects that can be caused after immunization, the safety and effectiveness of protection from COVID-19 infection.

The local AEFI characteristics of the Pfizer type COVID-19 vaccine in this study were that the majority experienced symptoms of swelling at the injection site accompanied by local pain. This is in line with the results of research conducted by the majority of respondents who experienced Local AEFI experienced local pain symptoms as many as 243 people (42.5%) followed by symptoms of local redness and swelling at the injection site. In contrast

to the results of a study conducted by (Hulu et al., 2022), it was found that the majority of respondents experienced Local AEFI, with symptoms of swelling at the injection site in 15 people (17.4%). Local reactions that can occur after the COVID-19 vaccine are in the form of local pain reactions, redness, swelling at the injection site (Rusmiati, 2021). There are several reactions to injections and the method of injection carried out by vaccine workers in the field can affect this condition and the condition found by researchers in the field is that many consumers are afraid of being injected so that the muscles of the arms become stiff which can cause local pain.

The characteristics of the Systemic AEFI in the Pfizer type COVID-19 vaccine in this study were that the majority experienced muscle pain followed by fever and

weak. The results of this study are in line with research conducted by (Hulu, Lubis, 2022) which found that the majority of respondents experienced symptoms of muscle pain at the injection site, followed by fever on day 1 after the vaccine. The results of this study are different from research conducted by (Lidiana et al., 2021) which found that the majority of respondents experienced symptoms of dizziness as many as 65 people (11.4%) who were in the Systemic AEFI category in this study. Reporting from the (Kemenkes RI, 2021) reports that the most systemic side effects that arise from using the Pfizer type COVID-19 vaccine are fever, muscle aches, weakness, and headaches. Systemic side effects that can occur after the COVID-19 vaccine vaccination can include headaches, fatigue, chills and chills, diarrhea, fever, arthralgia, myalgia, and nausea. According to the researchers, differences in results can occur due to several things such as differences in the number of samples taken, environmental factors, work, and individual body conditions such as having a history of illness, dehydration and other factors that cannot be determined with certainty at the time of vaccination.

Characteristics of AEFI Other reactions to the Pfizer type COVID-19 vaccine in this study were experiencing numbness and symptoms of shortness of breath accompanied by Local AEFI, namely local redness. This is in line with research conducted by (Arumsari et al., 2021) which found an AEFI condition in the form of shortness of breath. In contrast to research conducted by (Kurniatillah et al., 2022) found symptoms of reduced eye function in other reactions to the AEFI to the Pfizer COVID-19 vaccine. In general, the effects that arise can vary which are usually mild and temporary, are not always present and are influenced by the condition of a person's body and AEFI. Other reactions vary greatly in some cases. Shortness of breath conditions need to be watched out for in monitoring anaphylactic reactions after immunization (Malfasari, 2021). Researchers found that consumers

who experienced post-immunization numbness had previously complained of these complaints before administering the vaccine and could also be influenced by the factor of old age and these complaints obtained is temporary. For consumers who experience shortness of breath, after being observed they have a history of controlled asthma and this occurs at night after immunization and is temporary so it cannot be determined whether the shortness of breath that occurs is an AEFI of the Pfizer COVID-19 vaccine or a recurrence from asthma.

In this study, it was found that consumers of the Pfizer type COVID-19 vaccine experienced a combination of the Local, Systemic and Other Reaction AEFI classifications. According to the researchers, an explanation for this cannot be determined with certainty and requires further and complete research because AEFI is influenced by many multifactors. When vaccinated, the body's immunity will recognize and respond to provide specific defenses against the infection. The body's response varies and can indicate the effect of the vaccine working in the body and does not mean that the vaccine will not work in the body if you do not experience AEFI.

According to Egitia & Rukmi (2020) most people in clinical trials only experienced mild side effects, and some of them had no side effects at all. Vaccination as protection from severe COVID-19 infection, regardless of having side effects after vaccination or not (Rahmatina, 2021). Side effects that can arise from using the Pfizer type COVID-19 vaccine can include local pain, redness, or swelling at the injection site, and/or fatigue, headache, muscle aches, chills, fever, or nausea all over the body. If these side effects occur, they will disappear within a few days. There are some serious side effects that can occur such as anaphylactic reactions, but they are (Yuniarti et al., 2022).

According to the researchers, an explanation of the various AEFIs that occur in society cannot be determined with certainty and requires further and complete research because AEFIs are influenced by multiple factors. When vaccinated, the body's immunity will recognize and respond to provide specific defenses against infection. The body's response varies and can indicate the effect of the vaccine working in the body and does not mean that the vaccine will not work in the body if you do not experience AEFI.

One form of the government's seriousness is to provide the best for the community so that the government only provides the COVID-19 vaccine that is proven safe and passes clinical trials that have received Emergency Use of Authorization (EUA) from BPOM (Ardiputra et al., 2020). No vaccine is 100% safe and without risk. According to Koesnoe (2021) the vaccines used in the COVID-19

vaccination program are still new vaccines, so active and passive surveillance is needed specifically to assess their safety. So that each type of COVID-19 vaccine has advantages and disadvantages, both in terms of safety and storage effectiveness (Makmun & Hazhiyah, 2020). In this study, the AEFIs that occurred were still in the mild and harmless category. numbness, and even experience a combination of the AEFI classification with the majority experiencing Local AEFI symptoms accompanied by Systemic AEFI.

4. Conclusions and suggestions

Based on the results of research on the proportion and characteristics of follow-up events post-immunization (KIPI) of the COVID-19 vaccine at the Umbulharjo I Health Center in 2022, the following conclusions can be drawn:

- a. AEFI Proportion Value of the Pfizer COVID-19 Vaccine in the community in the working area of the Umbulharjo I Health Center
- b. Demographic data on the characteristics of respondents to the Pfizer vaccination in the form of age, gender, education and occupation.
- c. The characteristics of AEFI of the respondents varied, some experienced Local AEFI with the majority of symptoms of swelling, pain and bleeding at the injection site, while the majority of AEFI experienced systemic symptoms of fever, local pain and arm muscle weakness.

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