# Qualitative Analysis Of Covid-19 Vaccine Reactogenicity In Banjarmasin City, South Kalimantan During The Pandemic

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***Abstract.***

*The World Health Organization (WHO) officially recognized COVID-19 as a pandemic. By March 29, 2020, global cases had reached 634,835 with 33,106 fatalities. In Indonesia, there were 1,528 confirmed infections and 136 deaths. According to Indonesia's Presidential Regulation No. 99 of 2020, the government is expediting the acquisition of COVID-19 vaccines and the vaccination program to combat the pandemic. COVID-19 has spread extensively across nearly all provinces in Indonesia. The government remains committed to gradually delivering safe, high-quality, and effective vaccines. Despite these efforts, many people remain hesitant about vaccination due to concerns over side effects and vaccine safety. This study aims to qualitatively analyze the reactogenicity of COVID-19 vaccines. Using a descriptive observational qualitative design, informants were selected through purposive sampling. Reported side effects include drowsiness, injection site pain, increased appetite, fever around 38-39°C, weakness, recurrence of asthma, chest tightness, cough, and runny nose. The most common reactions observed were fever up to 39°C (18.51%) and vomiting (11.11%).*

***Keywords:*** *COVID-19 vaccine; reactogenicity and adverse events following immunization (AEFI).*

## I. INTRODUCTION

Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is a new type of coronavirus that has never been found in humans before. At least two types of coronaviruses are known to cause severe illness, such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Common signs and symptoms of COVID-19 infection include acute respiratory symptoms such as fever, cough, and shortness of breath. The average incubation period for this virus is 5-6 days, with the longest incubation period being 14 days. Severe COVID-19 can lead to kidney failure, pneumonia, acute respiratory syndrome, and even death [1]. The World Health Organisation declared COVID-19 a pandemic. As of March 29, 2020, there were 634,835 cases and 33,106 deaths worldwide. Meanwhile, in Indonesia, 1,528 cases of COVID-19 have been confirmed with 136 deaths. In Indonesia itself, the first case of COVID-19 was reported on March 2, 2020. The spread of COVID-19 in Indonesia is widespread, affecting almost all provinces. The number of patients infected with COVID-19 is also continuing to increase. Over the next few months, the Indonesian nation will face major problems due to COVID-19 if not handled appropriately. The government continues to strive to make safe, high-quality, and effective COVID-19 vaccines available in stages [2]. The COVID-19 vaccine is expected to be the determining factor in overcoming this pandemic, with countries around the world also making similar efforts.

Vaccination is the act of administering a vaccine to a person, where the vaccine contains one or more antigens. The goal is that if the individual is exposed to the same antigen, the immune system formed will destroy that antigen [3]. The COVID-19 vaccination program is a focus for the World Health Organisation (WHO) and the entire world. Tedros Adhanom Ghebreyesus, as WHO Director-General, emphasised the importance of political commitment from every national leader for the equitable distribution of the COVID-19 vaccine [4]. The Indonesian government is participating in efforts to reduce the incidence of COVID-19. Dr. Reisa Brotoasmoro, spokesperson for the COVID-19 Task Force, stated that vaccines are a preventive measure to protect the public from COVID-19 by building immunity [5]. Presidential Regulation No. 99 of

2020 states that in order to combat the Coronavirus Disease 2019 (COVID-19) pandemic, the government is accelerating the procurement of COVID-19 vaccines and the implementation of COVID-19 vaccinations. COVID-19 vaccinations aim to reduce the transmission of the COVID-19 virus, as well as reduce morbidity and mortality rates. From an economic perspective, prevention efforts through the provision of vaccination plans will be more cost-effective than treatment efforts [6].The effectiveness, safety, and halal status of the COVID-19 vaccine are being studied in clinical trials by the government, the Indonesian Ulema Council, and various related institutions. This is a step taken by the government to ensure that the COVID-19 vaccine that will be provided is safe and halal to prevent COVID-19. However, there are still many doubts among the public about getting vaccinated due to concerns about reactogenicity or side effects and vaccine safety.

In addition, there are also a number of opinions, including about the dangers of this new vaccine, especially regarding long-term side effects that are not yet evidence-based and seem rushed [7]. Another opinion is the doubt that arises from information about the effectiveness rate, which is only around 50-60 percent, while trials and clinical trials are still ongoing. The halal status of the vaccine is also a factor behind the public's intention to use the vaccine [8]. The Indonesian Ulema Council (MUI) Fatwa Commission, based on MUI Fatwa No. 2 of 2021, has announced that the AstraZeneca vaccine contains porcine trypsin. Although it has declared that the AstraZeneca Covid-19 vaccine is haram, the MUI ultimately stated that the vaccine can still be used. The MUI cited five reasons for permitting the use of the AstraZeneca COVID-19 vaccine [9]. This MUI fatwa is based on, among other things, the urgent need due to the emergency situation, expert testimony regarding the danger (fatal risk) if COVID-19 vaccination is not carried out immediately, and the insufficient availability of halal and pure COVID-19 vaccines to achieve herd immunity. Additionally, there is a government guarantee of safety in its use, while the government lacks the flexibility to choose the type of COVID-19 vaccine due to the limited availability of vaccines [10]. Based on the above, it is necessary to conduct direct research on vaccine reactogenicity to provide additional information sources to encourage the public to weigh the risks and benefits of vaccination.

## II. METHODS

The design of this qualitative and quantitative analysis research is descriptive observational, using purposive sampling to determine the informants in this study. In this study, the researcher did not intervene or treat the research subjects, but only provided interview forms to the respondents. Data collection was conducted through in-depth interviews with respondents, as follows:

a. The researcher obtained ethical clearance No. 510/KEPK-FKULM/EC/XI/2022.
b. Informants filled out an informed consent form.
c. The researcher asked several questions presented in the interview guidelines according to the characteristics of the selected informants.
d. The researcher wrote down and recorded the interview results.
e. The researcher conducted triangulation through observation at the Banjarmasin City Health Office.
f. The researcher summarized the interview results from all informants.
g. The researcher processed the data.

*Sample*

The samples in this study were Adverse Events Following Immunization (AEFI) data from the Banjarmasin City Health Office and 11 informants who met the inclusion and exclusion criteria.

Inclusion Criteria

a. Vaccine recipients must have received at least one booster (having received vaccines 1, 2, and 3), comprising 4 patients who have received the Sinovac, AstraZeneca, Moderna, or Pfizer vaccines.
b. Head of Disease Control and Eradication (P2P) at the Banjarmasin City Health Office.
c. Community Health Center pharmacists who are among the top 3 in providing COVID-19 vaccinations to the community in Banjarmasin City.
d. Community Health Center immunization coordinators who are among the top 3 in providing COVID-19 vaccinations to the community in Banjarmasin City.

Exclusion Criteria Informants who are unwilling to participate in the study until completion

## III. RESULT AND DISCUSSION

Reactogenicity or Adverse Events Following Immunization (AEFI) are all medical events that occur after immunization, which are of concern and suspected to be related to immunization. Theoretically, reactions that occur are usually local or systemic effects. Local effects that often occur are pain, redness, soreness, cellulitis, and swelling at the injection site. Meanwhile, systemic effects that appear after vaccination are fever, muscle pain throughout the body (myalgia), joint pain (arthralgia), weakness, nausea, vomiting, and headache [11]. Data on vaccine side effects can provide additional information to encourage people to consider the risks and benefits of vaccination [12]. One reason for public hesitancy to get vaccinated is concern about side effects and vaccine safety [13]. The COVID-19 vaccine has the potential to cause reactogenicity. Reactogenicity generally manifests as muscle aches, fever, nausea, and is normal after receiving the vaccine. This is a sign that the vaccine is working and the body is building antibodies to fight viruses that may infect it in the future. Side effects usually last for about 3 days and will disappear on their own.

Reactogenicity can occur with different signs or conditions in each person, ranging from mild symptoms to severe reactions, depending on the individual's body response [14]. Severe reactogenicity is rare and is generally caused by the immune system's response to the vaccine, leading to severe allergic reactions to vaccine ingredients, decreased platelet count, seizures, and hypotension [15]. All symptoms of severe reactogenicity can be managed and resolved completely without any long-term effects. The risk of reactogenicity is still lower than the risk of contracting a serious disease, which is undoubtedly more life-threatening [16]. Based on observations from interviews regarding the reactogenicity experienced by vaccine recipients at the Banjarmasin City Health Center, the community stated the following:

“The first vaccine injection didn't feel anything, but 1 hour after that, I felt sleepy for 1-2 days. The second vaccine injection felt really painful when touched, like I had a craving for food and felt hungry” (Informant 8, female, 33 years old).

“After the vaccine, I felt feverish with a temperature of almost 39°C and felt weak for 1 day” (Informant 9, male, 22 years old).

“I had a fever for 2-3 days that didn't go down, reaching 39°C, and felt a lot of pain at the injection site, but I didn't feel sleepy” (Informant 10, female, 25 years old).

“The effects after the vaccine, because I have a history of asthma, were shortness of breath, weakness, and pain. I felt tightness in my chest, high fever, and a cough and runny nose for two days. There were no other side effects” (Informant 11, female, 26 years old).

Based on this study, the effects felt by the community are drowsiness, pain at the injection site, increased appetite, fever ±38-39°C, weakness, drowsiness, asthma recurrence, chest tightness, coughing, and colds. The statements from the community are also supported by observational data showing the percentage of adverse reactions from January 2021 to October 31, 2022, as shown in the following table:

**Table 1.** Reactogenicity Effects

| No. | Reactogenicity Effects | Percentage (%) |
|---|---|---|
| 1 | Swelling at the injection site | 1,35 |
| 2 | Bleeding | 2,78 |
| 3 | Redness at the injection site | 1,35 |
| 4 | Spread redness | 1,35 |
| 5 | Body Itching | 2,78 |
| 6 | Cough and Cold | 1,35 |
| 7 | Drowsiness | 2,78 |
| 8 | Nausea | 1,35 |
| 9 | Vomiting | 11,11 |
| 10 | Asthma (Comorbid) | 1,35 |
| 11 | Headache & Dizziness | 14,84 |
| 12 | Local rash (itching of the eyes, skin, lips) | 2,78 |

| | | |
|---|---|---|
| 13 | Weakness/lethargy | 1,35 |
| 14 | Diarrhea | 2,78 |
| 15 | Fever ≤ 39 | 18,51 |
| 16 | bdominal pain or heartburn | 1,35 |
| 17 | Chest pain | 1,35 |
| 18 | Chills/Shivering | 1,35 |

*Source: Banjarmasin City Health Department*

However, the data only includes reports from the community that were recorded because they reported to the immunization coordinator and based on interviews with the community, they also experienced similar effects that were never reported to health workers because these effects were temporary, lasting 2 to 3 days. The results of this qualitative analysis align with a previous study Gonen et al [17]. Which specifically examined the AstraZeneca vaccine. The study found that 229 (89.4%) respondents experienced side effects, while 27 (10.6%) did not. Of the 256 people vaccinated with AstraZeneca, 69 (27%) experienced local side effects at the injection site and 229 (89.4%) experienced systemic reactions. The most common symptoms experienced by vaccine respondents were fever, which was experienced by 92 (35.9%) people, followed by chills, which were reported by 90 (35.1%) people, headaches, which were complained of by 86 (33.6%) people, and pain at the injection site. Muscle pain was reported by 69 (27.0%) respondents, osteoarticular pain was reported by 42 (16.4%) people, nausea was experienced by 39 (15.2%), and fatigue by 28 (10.9%).

Swelling at the injection site was reported by 22 (8.6%) people, redness at the injection site was reported by 10 (3.9%) people, coughing was reported by 5 (2%) people, vomiting by 5 (2%) people, diarrhea was reported by 4 people (1.6%), shortness of breath by 2 people (0.8%), abdominal pain was experienced by three people (1.2%) experienced abdominal pain, and two people (0.8%) experienced swollen lymph nodes [18].In order to implement the vaccination program to achieve herd immunity, the government continues to strive to provide safe, high-quality, and effective COVID-19 vaccines in stages [19] . Herd immunity is a situation where most of the population is protected/immune to a particular disease, thereby creating an indirect effect, namely the protection of vulnerable groups who are not targeted for vaccination. This condition can only be achieved with high and equitable vaccination coverage [20].The results of monitoring health workers involved in vaccine administration can be seen in the following interview results: "Some reported reactions after vaccination, such as fever with chills, coughing, and a runny nose, similar to COVID-19 symptoms. The most common adverse reactions were fever with chills, similar to upper respiratory tract infection symptoms, and pain after vaccination. If there is pain at the injection site, it can be treated immediately with a cold compress. (Informant 5, female, 35 years old) According to other health workers involved in disseminating information about the effects of vaccines, which has been communicated directly and indirectly to the public, this is supported by the following statement:

"Yes, we always make banners, for example, about the types of vaccines, such as Sinovac or whatever, and the effects that will be felt. for a long time, because in the observation stage there is indeed a lead time, a waiting period before we input the data and so on. We usually ask them to read it first. The information is general and not specific to any type of vaccine because the effects are more or less the same. The strongest is indeed Moderna, but it also depends on each person's body response. There was a patient whom I gave the vaccine to indirectly and I accidentally asked them, Coincidentally, the patients who received Pfizer, AstraZeneca, and Moderna generally complained of severe pain and so on, while others said they felt nothing and even asked if they needed another shot, “Have I been vaccinated or not?” (Informant 1, female, 41 years old)

“Yes, but before vaccination, we educate the public about the side effects of vaccines so that they are aware of other side effects, such as pain after vaccination, which is normal, as well as fever.” (Informant 3, male, 40 years old)

Health workers can advise vaccine recipients to drink more fluids, wear comfortable clothing, apply compresses or take a warm bath, and take paracetamol according to the recommended dosage. To anticipate serious Adverse Events Following Immunization (AEFI), recipients are asked to remain at the vaccination

site for 30 minutes after vaccination, and health workers must remain at the site for at least 30 minutes after the last recipient has been vaccinated, for example, in the case of patients with comorbidities such as hypertension or other chronic diseases [21]. Health workers are advised that if a vaccine recipient experiences a Post-Vaccination Adverse Event, they should remain calm and follow the instructions provided by the health facility staff where the vaccination took place. After vaccination, participants will receive a sheet of paper containing contact information that they can call if they experience a Post-Vaccination Adverse Event. In addition, all participants who have been vaccinated will also be monitored and supervised by health workers who will inquire about the daily condition of the vaccination participants [22].

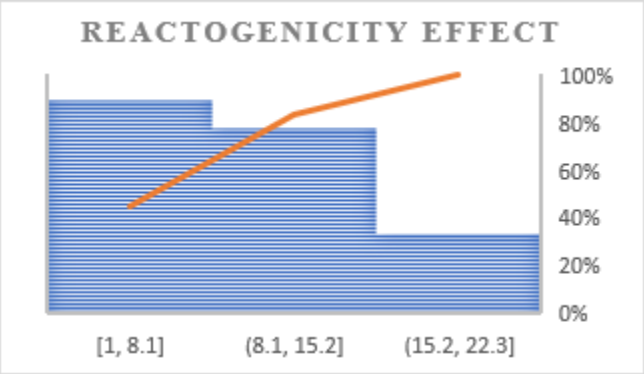


**Fig 1.** Reactogenicity effect

## IV. CONCLUSION

Based on this study, the effects experienced by the community were drowsiness, pain at the injection site, increased appetite, fever of ±38-39°C, weakness, drowsiness, asthma recurrence, chest tightness, coughing, and colds. The highest percentage of observations were fever ≤39°C (18.51%) and vomiting (11.11%).

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## REFERENCES

[1] Yu SHI1, Gang WANG1, Xiao-peng CAI1, Jing-wen DENG1, Lin ZHENG2, Hai-hong ZHU1, Min ZHENG†‡1, Bo YANG†‡2 ZC. AnOverviewOfCOVID-19. 2020;21(5):343–60.

[2] Nur Syahadati Retno Panenggak, Nur Shanti Retno Pembayun, Erta, Hapsari Shinta Citra Puspita Dewi, Nurhasan. Efek Samping Dan Reaktogenisitas Vaksin Covid-19: Survei Penerima Vaksin. ***Jurnal Ilmiah Indonesia*** p–ISSN: 2541-0849 e-ISSN : 2548-1398 Vol. 6, Special Issue No. 2, Desember 2021 Google Scholar

[3] Zhao J, Zhao S, Ou J, Zhang J, Lan W, Guan W, et al. COVID-19: Coronavirus Vaccine Development Updates. Front Immunol. 2020;11(December):1–19.

[4] Germas Kemenkes RI. Question ( Faq ) Pelaksanaan Vaksinasi Covid-. Kesmas [Internet]. 2021;2(1):1–16. Available from: kesmas.kemkes.go.id

[5] Kemenkes RI. Keputusan Menteri Kesehatan Republik Indonesia Nomor HK.01.07/Menkes/4638/2021 Tentang Petunjuk Teknis Pelaksanaan Vaksinasi Dalam Rangka Penanggulangan Pandemi Corona Virus Disease 2019 (Covid-19).***JurnalrespirologiOrg***

[6] Presiden Republik Indonesia. Peraturan Presiden Republik Indonesia Nomor 99 Tahun 2020 tentang Pengadaan Vaksin dan Pelaksanaan Vaksinasi Dalam Rangka Penanggulangan Pandemi Corona Virus Disease 2019 (COVID-19).Peratur Pres [Internet]. 2020;2019(039471):1–13. Available from: https://peraturan.bpk.go.id/Home/Details/147944/perpres-no-99-tahun-2020

[7] Sharma O, Sultan AA, Ding H, Triggle CR. A Review of the Progress and Challenges of Developing a Vaccine for COVID-19. Front Immunol. 2020;11(December 2019):1–17.

[8] Rifka Alkhilyatul Ma'rifat, I Made Suraharta IIJ. No Title 済無No Title No Title No Title. 2024;2:306–12.

[9] Majelis_Ulama_Indonesia. Fatwa Majelis Ulama Indonesia Nomor 02 Tahun 2021 Tentang Produk Vaksin Covid-19 dari Sinovac Life Sciences Co. Ltd. China dan PT. Bio Farma (Persero). Majelis Ulama Indones. 2022;1–8.

[10] Ghiasi N, Valizadeh R, Arabsorkhi M, Hoseyni TS, Esfandiari K, Sadighpour T, et al. Efficacy and side effects of Sputnik V, Sinopharm and AstraZeneca vaccines to stop COVID-19; a review and discussion. Immunopathol Persa [Internet]. 2021;7(2):e31–e31. Available from: https://doi.org/10.34172/ipp.2021.31

[11] Awanis AT, Amal S, Frianto D. Perbedaan Tingkat Kepercayaan Mahasiswa Farmasi Dan Nonfarmasi Terhadap Penerimaan Vaksin Covid-19. ***J Buana Farma***. 2021;1(3):1–5.

[12] Azarpanah H, Farhadloo M, Vahidov R, Pilote L. Vaccine hesitancy: evidence from an adverse events following immunization database, and the role of cognitive biases. BMC Public Health. 2021;21(1):1–13.

[13] Nossier SA. Vaccine hesitancy: the greatest threat to COVID-19 vaccination programs. ***J Egypt Public Health Assoc.*** 2021;96(1):18–20.

[14] Barrett ADT, Titball RW, MacAry PA, Rupp RE, von Messling V, Walker DH, et al. The rapid progress in COVID vaccine development and implementation. npj Vaccines. 2022;7(1):19–20.

[15] San Francisco Ramos A, Liu Sanchez C, Bovill Rose T, Smith D, Thorn N, Galiza E, et al. Comparing reactogenicity of COVID-19 vaccine boosters: a systematic review and meta-analysis. Expert Rev Vaccines [Internet]. 2024;23(1):266–82. Available from: https://doi.org/10.1080/14760584.2024.2315089

[16] Sutton N, San Francisco Ramos A, Beales E, Smith D, Ikram S, Galiza E, et al. Comparing reactogenicity of COVID-19 vaccines: a systematic review and meta-analysis. Expert Rev Vaccines [Internet]. 2022;21(9):1301–18. Available from: https://doi.org/10.1080/14760584.2022.2098719

[17] Gonen T, Barda N, Asraf K, Joseph G, Weiss-Ottolenghi Y, Doolman R, et al. Immunogenicity and Reactogenicity of Coadministration of COVID-19 and Influenza Vaccines. ***JAMA Netw Open***. 2023;6(9):E2332813.

[18] Matsumura T, Takano T, Takahashi Y. Immune responses related to the immunogenicity and reactogenicity of COVID-19 mRNA vaccines. Int Immunol. 2023;35(5):213–20.

[19] Ning Z. E cacy and safety of COVID- inactivated vaccine : A.

[20] Mahallawi WH, Mumena WA. Reactogenicity and Immunogenicity of the Pfizer and AstraZeneca COVID-19 Vaccines. Front Immunol. 2021;12(December):1–9.

[21] Sultana A, Shahriar S, Tahsin MR, Mim SR, Fatema KR, Saha A, et al. A retrospective cross-sectional study assessing self-reported adverse events following immunization (AEFI) of the COVID-19 vaccine in Bangladesh. Vaccines. 2021;9(10):1–10.

[22] Bhandari B, Rayamajhi G, Lamichhane P, Shenoy AK. Adverse Events following Immunization with COVID-19 Vaccines: A Narrative Review. Biomed Res Int. 2022;2022(5).