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# DETERMINANT OF POST COVID-19 VACCINATION (SINOVAC) ADVERSE EVENTS AMONG HEALTH CARE WORKERS IN PALEMBANG

**Mustika Fatimah[1]*, Dianita Ekawati[2], Rico Januar Sitorus[3], Supli Effendi Rahim[4], Alfredo Armando Parensyah[5]**

[1] Faculty of Health, Kader Bangsa University, Jl.Mayjend Ryacudu No.88, Palembang, 3000, South Sumatra, Indonesia; LKC Dompet Dhuafa Clinic, Medical Doctor, Palembang, South Sumatra, Indonesia.
[2]Center For Environmental Health And Disease Control Engineering, Infectious Disease Control Installation, Jl. Sultan Mahmud Badaruddin II KM 11 No.55, Palembang, 30961, South Sumatra, Indonesia.
[3]Faculty of Public Health, Sriwijaya University , Jl. Palembang-Prabumulih KM 32, Ogan Ilir, 30662, Indonesia.
[4]Kader Bangsa University, Post Graduate Studies, Jl.Mayjend Ryacudu No.88, Palembang, 3000, South Sumatra, Indonesia.
[5]Ar Rasyid Hospital, Medical Doctor, Jl. HM. Saleh KM.7 No.2 Palembang, 30961, South Sumatra, Indonesia.

## *ABSTRACT*

*The COVID-19 cases in Palembang are still increasing every day. This pandemic has forced the adaptation of the "New Normal" lifestyle, which will have an impact on communicable and non-communicable diseases. The Sinovac vaccine used in the COVID-19 vaccination program for Health Care Workers (HCW), which is a top priority, is still a new vaccine, so a survey of complaints and the determinant is important. This study aimed to survey complaints and the determinant of Post COVID-19 Vaccination (Sinovac) Adverse Events among HCW. A cross-sectional study was conducted in Palembang between June and August 2021 on 414 HCWs who received the COVID-19 vaccine injection. The instrument consisted of demographic characteristics, marital status, distance to health care facilities, Body Mass Index (BMI), diet, sleep quality, anxiety, and some medical histories. Overall, although many, all complaints were classified as mild. There was a significant relationship between age, anxiety, and history of food allergy with Post COVID-19 Vaccination Adverse Events (p-value = 0.003; 0.017; 0.050), and anxiety was the determinant of the adverse events (p-value < 0.05). However, there was a significant relationship between age, anxiety, and history of food allergy with Post COVID-19 Vaccination Adverse Events indicates that these factors need to be considered in determining the standard operational procedure for the next vaccination. While there was no significant relationship between obesity, diet, sleep quality, history of drug allergy, atopic disease, hypertension, and dyspepsia syndrome are expected to increase public knowledge and confidence so there will be no worries about receiving the vaccine.*

***Keywords:*** *determinant, health care workers, post vaccination adverse events*

## ABSTRAK

Kasus COVID-19 di Palembang masih terus bertambah setiap harinya. Pandemi ini memaksa adaptasi gaya hidup "*New Normal*" yang akan berdampak pada penyakit menular dan tidak menular. Vaksin Sinovac yang digunakan dalam program vaksinasi COVID-19 untuk tenaga kesehatan yang menjadi prioritas utama, masih merupakan vaksin baru, sehingga survei mengenai keluhan dan determinannya merupakan hal penting. Penelitian ini bertujuan untuk mengetahui keluhan dan determinan kejadian ikutan pasca vaksinasi COVID-19 (Sinovac) pada petugas kesehatan. Studi potong lintang ini dilakukan di Palembang antara Juni hingga Agustus 2021 terhadap 414 petugas kesehatan yang menerima suntikan vaksin COVID-19. Instrumen terdiri dari karakteristik demografi, status perkawinan, jarak ke fasilitas kesehatan, Indeks Massa Tubuh (IMT), diet, kualitas tidur, kecemasan, dan beberapa riwayat kesehatan. Secara keseluruhan, meski banyak, semua keluhan tergolong ringan. Ada hubungan yang bermakna antara usia, kecemasan, dan riwayat alergi makanan dengan Kejadian Ikutan Pasca Vaksinasi COVID-19 (*p value* = 0,003; 0,017; 0,050) dan kecemasan merupakan determinannya (*p value* = 0,009). Adanya hubungan yang bermakna antara usia, kecemasan, dan

*Correspondence Address: Mustika Fatimah, Faculty of Health, Kader Bangsa University, Jl.Mayjend Ryacudu No.88, Palembang, 3000, South Sumatra, Indonesia; LKC Dompet Dhuafa Clinic, Medical Doctor, Palembang, South Sumatra, Indonesia., e-mail: fatimahmustika271214@gmail.com*

riwayat alergi makanan dengan Kejadian Ikutan Pasca Vaksinasi COVID-19 menunjukkan bahwa faktor-faktor tersebut perlu dipertimbangkan dalam menentukan standar operasional prosedur vaksinasi selanjutnya. Sedangkan tidak adanya hubungan signifikan antara obesitas, pola makan, kualitas tidur, riwayat alergi obat, penyakit atopik, hipertensi dan sindrom dyspepsia. Diharapkan dapat meningkatkan pengetahuan dan kepercayaan masyarakat sehingga tidak ada kekhawatiran dalam menerima vaksin.

**Kata Kunci:** determinan, kejadian ikutan pasca vaksinasi Covid-19, tenaga kesehatan

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## Introduction

Coronavirus Disease 2019 (COVID-19) is a newly emerging disease that is endemic globally, affecting almost all countries in the world, and has infected more than 100 million people.[1] Indonesia has been part of the pandemic since the discovery of the first case on March 2, 2020, in Depok. The increase in cases per day has been higher since the end of August 2020, which reached more than 2000 cases per day.[2] This highly contagious disease has an impact on global demographics where there have been 2.9 million deaths as of April 2021, making it the worst global health crisis since the influenza pandemic in 1918.[3]

The COVID-19 pandemic has forced the development and adaptation of the "New Normal" lifestyle, which will have an impact on communicable and non-communicable diseases.[4] Based on metabolic research conducted by Louis J. Aronne, on average, patients aged 54 years (younger) with obesity were admitted to the ICU when exposed to COVID-19.[5] This is because obese patients tend to experience severe symptoms when exposed compared to normal-weight patients; in addition to the possibility of comorbid comorbidities, inflammation is often experienced by obese patients where fat cells can increase inflammatory signals that reduce the ability of the immune system to increase an effective response afterward.[6]

Dietary components and nutritional status are relatively related to vaccine response in healthy adults. Although nutritional deficiencies have little impact on vaccine response, overall diet is considered important. The association of disturbed sleep with a lower antibody response was found in a cross-sectional study by Burns et al. in 2002 and an experimental study on sleep restriction by Spiegel et al. in 2002, where healthy adults who normally sleep 7.5-8.5 hours are reduced by 4 hours every day-night for 6 nights, when they received the influenza virus vaccine, there was lower antibody production than normal people at 10 days after vaccination, and after 3-4 weeks of vaccination, their antibody levels did not last long.[6]

In the 2021 WHO guideline regarding Post Vaccination Adverse Events Due to Anxiety Due to Fear of Injections which we often see in various media. This feeling of anxiety or fear can react before or after the injection.[7] Gang Chen et al based on the Adverse Event Reporting System data after the COVID-19 Vaccination m-RNA vaccine on December 2020. Based on VAERS data, there

were 3908 complaints of Post Vaccination Adverse Events on December 2020. From the Post Vaccination Adverse Events reported, complaints were obtained, the most common disorders (48.80%), nervous system disorders (46.39%), and digestive system disorders (25.54%). A history of anxiety or depression was more common in subjects who experienced severe neurologic Post Vaccination Adverse Events than those who reported other types of Post Vaccination Adverse Events (18.37% vs. 7.85%, OR = 2.64, P < 0.017).[8]

Based on a retrospective cohort study conducted by Kimberley et al regarding acute allergic reactions to m-RNA vaccines, from 64,900 employees who received the first dose of vaccine (December 16 2020-February 12 2021) to February 18 2021, anaphylactic reactions experienced 0.025% sample: 7 cases Pfizer-BioNTech vaccine recipients and 9 cases of Moderna vaccine recipients where 63% had a history of allergies, and only 1% had a history of severe drug allergy and 5% had a history of severe food allergy.[9] Then based on a study conducted by Tom Shimabukuro and Narayan Nair regarding allergic reactions, including anaphylaxis after receiving the first dose of Pfizer-BioNTech vaccine on December 14-23, 2020, anaphylactic reactions occurred in 21 samples, and 81% of them had a history of drug and food allergies.[10] Then also based on a cohort study conducted by Kelley N Dages et al. regarding the risk of allergic reactions in patients with a history of atopy and COVID-19 vaccination where of 68 samples, 97% received the Pfizer-BioNTech vaccine, 47% had a history of drug allergies, 13% had a history of food allergies, and 91% had a history of atopic disease in the form of allergic rhinitis.[11]

Hypertension is one of the main cardiovascular comorbidities that can worsen and increase the risk of being treated for COVID-19 patients in the intensive care unit.[12] Based on a retrospective study of 487 COVID-19 patients in Zheijang, the prevalence of hypertension was higher in 49 severe cases compared to 438 mild cases (53.1% vs. 16.7%, p<0.0001).[4] This is related to the role of Angiotensin-Converting Enzyme 2 (ACE2). Another mechanism is dysregulation of the immune system resulting in a cytokine storm mediated by an unbalanced response from helper T cells.[12]

Covid-19 is indeed a disease that attacks the respiratory tract, but the SARS-CoV-2 virus can cause serious systemic reactions in major organs, including the digestive system. Patients with digestive system symptoms had a longer onset of symptoms (p<0.001) and produced a positive RT-PCR on the stool test (p=0.033).[13] In addition, Covid-19 also changes the gastrointestinal microbiome, where there is an increase in microorganisms that cause opportunistic infections and a reduction in beneficial commensal microorganisms. Recent research has also evaluated the long-term impact of Covid-19 in the form of dyspepsia syndrome.[14]

Vaccines are one of the efforts chosen with great hopes that they will become one of the main weapons in controlling COVID-19. There are currently around 100 vaccine candidates under development and the first clinical trials for a vaccine already started in March 2020. WHO

estimates that a new COVID-19 vaccine will be available in January 2021.[15] In Indonesia, based on Presidential Regulation Number 14 of 2021 and Regulation of the Minister of Health of the Republic of Indonesia Number 10 of 2021 concerning Vaccine Procurement and Vaccination Implementation in the context of Combating the Covid-19 Pandemic, vaccination is carried out immediately, so the safety of vaccination can be assessed from The occurrence of Post Vaccination Adverse Events is also at stake. The experience of health workers as a top priority in this vaccination program related to Post Vaccination Adverse Events can be used as an example for the general public, who will be the target of the next vaccination program.

Based on the above background, where research on the safety of the COVID-19 vaccine is still limited, researchers are interested in 1) seeing an overview of the safety of the COVID-19 vaccine in the form of Post Vaccination Adverse Events, 2) knowing the proportion of health care workers as a top priority in the Covid-19 vaccination program in Palembang who experience Post COVID-19 Vaccination (Sinovac) Adverse Events, 3) analyzing the determinant of Post COVID-19 Vaccination (Sinovac) Adverse Events such as age, gender, obesity, dietary factors, sleep quality, anxiety, or various medical history. *T*his study aimed to survey complaints and the determinant of Post COVID-19 Vaccination (Sinovac) Adverse Events among HCW

## Method

The study was conducted in Palembang between June and August 2021 through a cross-sectional study with a population of all Health Care Workers (HCW) in Palembang who received the first COVID-19 vaccine (Sinovac) injection. The minimum number of samples taken using the Lemeshow formula and accidental sampling technique was 414 HCW spread across health care facilities and registered as HCW through the distribution of questionnaires in Hard Copy and Google Forms. The exclusion criteria for this research were HCWs who were not in the place at the time of the study (due to leave or outside service).

Primary data were obtained from interviews with HCW using a Hard Copy questionnaire at various healthcare facilities (public health centers, clinics, and hospitals) in Palembang guided by data from the Palembang Public Health Office regarding healthcare facilities with the highest number of HCW and the highest vaccination coverage. In these health care facilities, 10-15 HCWs are selected by the Human Resources Department. HCW who are on-site fill out the questionnaire directly in hard copy form, while HCW who are working from home fill out the Google Form questionnaire.

This research questionnaire consists of two parts of questions, namely: Part A contains questions regarding age, gender, marital status, distance to health care facilities, classification of HCW, Body Mass Index (BMI), diet, sleep quality, anxiety, history of disease and Part B contains questions regarding Post COVID-19 Vaccination (Sinovac) Adverse Events reactions (local,

systemic, other reactions, or no complaints) (Supplementary Materials 1). Data on age, gender, marital status, distance to health care facilities, and classification of HCW, Body Mass Index (BMI), diet, sleep quality, anxiety, history of disease and Post COVID-19 Vaccination (Sinovac) Adverse Events are categorized.

Age (in years): 18-29, 30-39, 40-49, 50-65; >30 and ≤30; Gender: female and male; Marital status: not married yet and ever/already married; Distance to health care facilities: far >3km and near ≤3km; and Classification of HCW: Medical Personnel, Nursing Staff, Midwifery, Public Health Workers, Pharmacy Staff, Biomedical Engineering, Nutritionist, Environmental Health Workers, Medical Technicians, and Clinical Psychology Staff. Body Mass Index (BMI) (in kg/m2): underweight (<18,5), normal (18,5-24,9), overweight (25-29,9), and obesity (≥30); and Obesity: yes (obesity) or no (not obesity). Questions regarding diet refer to the General Guidelines for Balanced Nutrition (Less if score < mean/median or Enough if score ≥ mean/median) and have been tested for validity (Pearson Correlation score > 0.279) and reliability (Cronbach's Alpha value 0.665). Questions regarding sleep quality refer to the Pittsburgh Sleep Quality Index (PSQI) (Less if score < mean/median or Enough if score ≥ mean/median) and have been tested for validity (Pearson Correlation score > 0.279) and reliability (Cronbach's Alpha value 0.628). Questions regarding anxiety refer 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 regarding the history of diseases such as a history of drug allergies, food allergies, atopic diseases, hypertension, and dyspeptic syndromes such as the presence or absence of disease. If there are, the questions are continued in the form of complaints, allergies to what drugs and foods, and controlled diseases or not. Questions regarding Post Vaccination Adverse Events such as 1) there are and none, 2) the specific complaints: pain at the injection site, drowsiness, fever, myalgia, weakness, headache, swelling at the injection site, arthralgia, redness at the injection site, dizziness, vomiting, tingling hands, and allergies.

The correlation test between age, gender, marital status, distance to health care facilities, obesity, diet, sleep quality, anxiety, and history of disease with Post Vaccination Adverse Events uses the Chi-Square Test with a 95% confidence degree and a limit of significance. : 0.05, then multivariate analysis was performed using a logistic regression test.

This research was declared ethically worthy by the Health Research Ethics Commission, Faculty of Health, Universitas Kader Bangsa (No: 09/UKB.FKES/TU.KEPK/2021 on August 14, 2021) in accordance with the seven 2011 WHO standards (Supplementary Materials 2). Each respondent stated that he was willing and agreed to the informed consent before answering the research questions on the questionnaire given. All procedures conducted in the study were in

accordance with institutional, national, and international ethical standards and guidelines. Data were de-identified to protect the anonymity of respondents.

## Results

From the characteristics of Post COVID-19 Vaccination (Sinovac) Adverse Events, the number of HCW who experienced complaints was more (58.9%) (Table 1). The classification of complaints was systemic reactions (55.5%), followed by local reactions (42.0%), anxiety-related reactions (1.0%), and allergic reactions (0.2%). The most common complaints were pain at the injection site (37.9%), followed by drowsiness (32.3%), fever (7.0%), myalgia (5.3%), weakness (5.1%), headache (3.4%), swelling at the injection site (2.9%), arthralgia (2.4%), redness at the injection site (1.2%), dizziness (0.5%), vomiting (0.2%), tingling hands (0.2%), and allergies (0.2%) (Table 1).

**Table 1. Categories of Post Covid-19 Vaccination (Sinovac) Adverse Events**

| Categories | Frequency (n=414) | Percentage (%) |
|---|---|---|
| **Post Vaccination Adverse Events** | | |
| There are | 244 | 58.9 |
| None | 170 | 41.1 |
| **Complaints of Post Vaccination Adverse Events** | | |
| No complaints | 170 | 41.3 |
| Pain at the injection site | 157 | 37.9 |
| Sleepy | 134 | 32.3 |
| Fever | 29 | 7.0 |
| Myalgia (whole-body muscle pain) | 22 | 5.3 |
| Weak body | 21 | 5.1 |
| Headache | 14 | 3.4 |
| Swelling at the injection site | 12 | 2.9 |
| Arthralgia (whole-body joint pain) | 10 | 2.4 |
| Redness at the injection site | 5 | 1.2 |
| Dizziness | 2 | 0.5 |
| Vomiting | 1 | 0.2 |
| Hand tingling | 1 | 0.2 |
| Allergies: urticaria (hives) | 1 | 0.2 |

From the demographic characteristics, Post COVID-19 Vaccination (Sinovac) Adverse Events experienced the most at the age of 40-49 years old and >30 years old (65.5%, p value = 0.003; 61.5%, p value = 0.420), female (60.5%, p value = 0.205), unmarried HCW (61.7%, p value = 0.505), and the distance from home to the location where the vaccine was given was close (≤3 km) (64%, p value = 0.119) (Table 2 and 3).

From the distribution of the classification of HCW, HCW from the classification of Medical Personnel amounted to the most (30.0%), followed by respondents from Nursing Staff (28.0%), Midwifery (12.6%), Public Health Workers (9.7 %), Pharmacy Staff (8.0%), Biomedical Engineering (4.8%), Nutritionist (3.1%), Environmental Health Workers (2.4%), Medical Technicians (1.2%), and Clinical Psychology Staff (0.2%) (Table 2).

**Table 2. Distribution of HCW in Palembang**

| Categories | Frequency (n=414) | Percentage (%) |
|---|---|---|
| **Age in years** | | |
| 18-29 | 158 | 38.2 |
| 30-39 | 178 | 43.0 |
| 40-49 | 55 | 13.3 |
| 50-65 | 23 | 5.5 |
| **Age category in years** | | |
| >30 | 235 | 56.8 |
| ≤30 | 179 | 43.2 |
| **Gender** | | |
| Female | 344 | 83.1 |
| Male | 70 | 16.9 |
| **Marital Status** | | |
| Not married yet | 133 | 32.1 |
| Ever/Already married | 281 | 67.9 |
| **Distance to health care facilities** | | |
| Far >3km | 253 | 61.1 |
| Near ≤3km | 161 | 38.9 |
| **Classification of HCW** | | |
| Medical personnel | 124 | 30.0 |
| Nursing staff | 116 | 28.0 |
| Midwifery | 52 | 12.6 |
| Public health worker | 40 | 9.7 |
| Pharmacy staff | 33 | 8.0 |
| Biomedical engineering | 20 | 4.8 |
| Nutritionist | 13 | 3.1 |
| Environmental health worker | 10 | 2.4 |
| Medical technician | 5 | 1.2 |
| Clinical psychology staff | 1 | 0.2 |
| **Body Mass Index (BMI) in kg/m2** | | |
| Underweight (<18.5) | 24 | 5.8 |
| Normal (18.5-24.9) | 231 | 55.8 |
| Overweight (25-29.9) | 130 | 31.4 |
| Obesity (≥30) | 29 | 7.0 |
| **Obesity** | | |
| Yes | 29 | 7.0 |
| No | 385 | 93.0 |
| **Diet** | | |
| Less | 111 | 26.8 |
| Enough | 303 | 73.2 |
| **Sleep Quality** | | |
| Less | 126 | 30.4 |
| Enough | 288 | 69.6 |
| **Anxiety** | | |
| Yes | 99 | 23.9 |
| No | 315 | 76.1 |
| **History of Disease** | | |
| **Drug Allergy** | | |
| Yes | 30 | 7.2 |
| No | 384 | 92.8 |
| **Food Allergy** | | |
| Yes | 73 | 17.6 |
| No | 341 | 82.4 |
| **Atopic Disease** | | |
| Yes | 94 | 22.7 |
| No | 320 | 77.3 |
| **Hypertension** | | |
| Yes | 23 | 5.6 |
| No | 391 | 94.4 |
| **Dyspepsia Syndrome** | | |
| Yes | 150 | 36.2 |
| No | 264 | 63.8 |

From the characteristics of Body Mass Index (BMI), Post Covid-19 Vaccination (Sinovac) Adverse Events were experienced the most by respondents with BMI 18.5-24.9 (62.3%), followed by respondents with BMI 30 (62.1%, p-value = 0.333) (Table 2 and 3). Then for the characteristics of obesity, HCW who are classified as obese are only 7% and 62.1% of them experience Post Vaccination Adverse Events (p-value = 0.873) (Table 2 and 3).

**Table 3. Bivariate Analysis Results (Chi-Square Test)**

| Variables | Post Vaccination Adverse Events | | | | p-value | PR | 95% CI |
|---|---|---|---|---|---|---|---|
| | There are | | None | | | | |
| | n | % | n | % | | | |
| **Age in years** | | | | | | | |
| 18-29 | 99 | 62.7 | 59 | 37.3 | 0.003 | 1.899 | 1.140-2.940 |
| 30-39 | 103 | 57.9 | 75 | 42.1 | | | |
| 40-49 | 36 | 65.5 | 19 | 34.5 | | | |
| 50-65 | 6 | 26.1 | 17 | 73.9 | | | |
| **Age category in years** | | | | | | | |
| >30 | 134 | 61.5 | 101 | 38.5 | 0.420 | 0.832 | 0.560-1.237 |
| ≤30 | 110 | 57 | 69 | 43 | | | |
| **Gender** | | | | | | | |
| Female | 208 | 60.5 | 136 | 39.5 | 0.205 | 1.444 | 0.862-2.420 |
| Male | 36 | 51.4 | 34 | 48.6 | | | |
| **Marital Status** | | | | | | | |
| Not married yet | 82 | 61.7 | 51 | 38.3 | 0.505 | 1.181 | 0.774-1.801 |
| Ever/Already married | 162 | 57.7 | 119 | 42.3 | | | |
| **Distance to health care facilities** | | | | | | | |
| Far >3km | 141 | 55.7 | 112 | 44.3 | 0.119 | 0.709 | 0.472-1.064 |
| Near ≤3km | 103 | 64 | 58 | 36 | | | |
| **Body Mass Index (BMI) in kg/m$^2$** | | | | | | | |
| Underweight (<18,5) | 12 | 50.0 | 12 | 50.0 | 0.333 | 1.354 | 0.843-2.389 |
| Normal (18,5-24,9) | 144 | 62.3 | 87 | 37.7 | | | |
| Overweight (25-29,9) | 70 | 53.8 | 60 | 46.2 | | | |
| Obesity (≥30) | 18 | 62.1 | 11 | 37.9 | | | |
| **Obesity** | | | | | | | |
| Yes | 18 | 62.1 | 11 | 37.9 | 0.873 | 1.151 | 0.529-2.504 |
| No | 226 | 58.7 | 159 | 41.3 | | | |
| **Diet** | | | | | | | |
| Less | 67 | 60.4 | 44 | 39.6 | 0.808 | 1.084 | 0.696-1.689 |
| Enough | 177 | 58.4 | 126 | 41.6 | | | |
| **Sleep Quality** | | | | | | | |
| Less | 76 | 60.3 | 50 | 39.7 | 0.788 | 1.086 | 0.708-1.664 |
| Enough | 168 | 58.3 | 120 | 41.7 | | | |
| **Anxiety** | | | | | | | |
| Yes | 69 | 69.7 | 30 | 30.3 | 0.017 | 1.840 | 1.135-2.982 |
| No | 175 | 55.6 | 140 | 44.4 | | | |
| **History of Diseases** | | | | | | | |
| **Drug Allergy** | | | | | | | |
| Yes | 18 | 60.0 | 12 | 40.0 | 1.000 | 1.049 | 0.491-2.238 |
| No | 226 | 58.9 | 158 | 41.1 | | | |
| **Food Allergy** | | | | | | | |
| Yes | 51 | 69.9 | 22 | 30.1 | 0.050 | 1.778 | 1.032-3.062 |
| No | 193 | 56.6 | 148 | 43.4 | | | |
| **Atopic Disease** | | | | | | | |
| Yes | 62 | 66.0 | 32 | 34.0 | 0.146 | 1.469 | 0.909-2.376 |
| No | 182 | 56.9 | 138 | 43.1 | | | |
| **Hypertension** | | | | | | | |
| Yes | 13 | 56.5 | 10 | 43.5 | 0.981 | 0.900 | 0.385-2.104 |
| No | 231 | 59.1 | 160 | 40.9 | | | |
| **Dyspepsia Syndrome** | | | | | | | |
| Yes | 97 | 64.7 | 53 | 35.3 | 0.093 | 1.457 | 0.963-2.203 |
| No | 147 | 55.7 | 117 | 44.3 | | | |

From the characteristics of a history of drug allergy, food allergy, and atopic disease, among HCW who have a history of drug allergy (7.2%), food allergy (17.6%), and atopic disease (22.7%) who experienced Post COVID-19 Vaccination (Sinovac) Adverse Events were 60.0%, 69.9%, and 66.0%, respectively. From the results of statistical tests, a history of drug allergy and history of atopic disease did not have a significant relationship with Post Covid-19 Vaccination (Sinovac) Adverse Events (p-value = 1,000 and 0.146), but a history of food allergy was the opposite (p-value = 0.0050) (Table 2 and 3).

From the characteristics of a history of hypertension, only 5.6% of HCW had a history of hypertension and 56.5% of them experienced Post COVID-19 Vaccination (Sinovac) Adverse Events (p-value = 0.981) (Table 2 and 3). From the characteristics of a history of dyspepsia syndrome, 36.2% of HCW had a history of dyspepsia syndrome and 64.7% of them experienced Post COVID-19 Vaccination (Sinovac) Adverse Events (p-value = 0.093) (Table 2 and 3).

**Table 4. Variable Selection For Multivariate Models**

| Variables | p-value | PR (95% CI) |
|---|---|---|
| **Age** | | |
| > 30 years old | 0.364 | 0.832 |
| ≤ 30 years old | | |
| **Gender** | | |
| Female | 0.163 | 1.444 |
| Male | | |
| **Obesity** | | |
| Yes | 0.119 | 0.730 |
| No | | |
| **Diet** | | |
| Less | 0.722 | 1.084 |
| Enough | | |
| **Sleep Quality** | | |
| Less | 0.706 | 1.086 |
| Enough | | |
| **Anxiety** | | |
| Yes | 0.013 | 1.840 |
| No | | |
| **History of Drug Allergy** | | |
| Yes | 0.902 | 1.049 |
| No | | |
| **History of Food Allergy** | | |
| Yes | 0.038 | 1.778 |
| No | | |
| **History of Atopic Disease** | | |
| Yes | 0.117 | 1.469 |
| No | | |
| **History of Hypertension** | | |
| Yes | 0.809 | 0.900 |
| No | | |
| **History of Dyspepsia Syndrome** | | |
| Yes | 0.075 | 1.457 |
| No | | |

**Table 5. Final Model From Multivariate Analysis (Logistics Regression Test)**

| Variable | p-value | PR | 95% CI |
|---|---|---|---|
| Anxiety | 0.009 | 1.923 | 1.181-3.130 |

From the final model of the Logistics Regression Test, the only variable that has a significant relationship with Post COVID-19 Vaccination (Sinovac) Adverse Events is anxiety (p-value = 0.009) and the anxiety variable has the greatest effect on or is a risk factor for Post COVID-19 Vaccination (Sinovac) Adverse Events (PR value = 1,923), so there is a significant relationship between anxiety and Post COVID-19 Vaccination (Sinovac) Adverse Events in the multivariate analysis show that anxiety is a risk factor for Post COVID-19 Vaccination (Sinovac) Adverse Events (Table 4 and 5).

## Discussion

About age, gender, marital status, and distance to health care facilities, it is similar to the survey conducted by Dovy DJanas et al., where the sample with an age range of 31–35 years and 36–40 years, female, married and living in the city center (close to the hospital) amounted to 36.9%, 67.9%, 88.5%, and 70.7%.[16] About classification of HCW, in contrast to the survey conducted by Dovy DJanas et al., where the most samples were nurses (43.2%), general practitioners (13.7%) and specialists (5.8%), midwives (3.5%) and included non-resident staff medical (33.8%).[16] This is also different from the observational study conducted by Min Ji Park, Yoo Jin Choi, and Sangchun Choi on 4,703 health workers who received the first dose of vaccine injections of ChAdOx1 (AstracZeneca) (n = 4,458) and BNT162B2 (Pfizer-BionTech) (n = 245) between March 4 - April 2, 2021 at Level C Hospitals in Korea by analyzing age, gender, profession, date, and type of vaccination as well as clinical information where the sample is more nurses (41.4%), doctors (13.7%), dentist (0.4%), pharmacist/pharmacist assistant (1.4%), and others (43.1%).[17]

All reactions to Post Vaccination Adverse Events in this study are mild. This is in line with a double-blind, placebo-controlled study conducted by Yanjun Zhang et al., where the most reported symptom was pain at the injection site 17% in the 3 g group, 21% in the 6 g group, and 4% in the placebo group at day 0-14 and 13% in the 3 g group, 13% in the 6 g group, and 13% in the placebo group in the period 0-28 days after injection. Other local complaints in the form of redness, swelling at the injection site, as well as systemic complaints such as cough, fever, and allergic reactions, where cough complaints are different complaints. However, all reactions are relatively mild.[18] However, it is different from the survey conducted by Dovy DJanas et al., where the most complaints were myalgia (39.6%), followed by tiredness/drowsiness (35.8%), headache (22.1%), swelling (9.2%), cough (7.9%), tingling (6.9%), diarrhea (3.1%), redness (2.0%), fever

(1.5%), arthralgia (1.5%), nausea and vomiting (1.5%), shortness of breath (1.3%), swelling of the lymph nodes (0.5%), anaphylactic reactions (0.4%), and fainting (0.1%). Complaints of cough, diarrhea, shortness of breath, and swollen lymph nodes are different complaints. However, all reactions are relatively mild.[16]

The results of the analysis of the relationship between age and Post Vaccination Adverse Events differ from the initial observations made by Raul Pellinia et al. on age, gender, obesity, and hypertension in antibody response to the Covid-19 BNT162b2 (Pfizer–BioNTech) vaccine in 248 HCW at the IFO (Institute Fisioterapici Ospitalieri) where multivariate linear regression results are obtained; age has a relationship with differences in antibody responses after vaccination (p-value = 0.0001).[19] Likewise, the retrospective cohort study of Post Vaccination Adverse Events on the first dose of the ChAdOx1 nCoV-19 (AstracZeneca) vaccine at Kosin University Hospital 3-22 March 2021, conducted by Minji Jeon et al. observed Post Vaccination Adverse Events 7 days after vaccination using MVAERS (Mobile Vaccine Adverse Events Reporting System) where the severity and number of Post Vaccination Adverse Events were less in the older age group and age had a significant relationship with local and systemic reactions (p value<0.001).[20] It is also different from the results of the analysis of the relationship between sex and Post Vaccination Adverse Events with the initial observations made by Raul Pellinia et al on age, sex, obesity, and hypertension in antibody response to the Covid-19 BNT162b2 vaccine (Pfizer–BioNTech) in 248 health care workers at the IFO (Institute Fisioterapici Ospitalieri). From the results of multivariate linear regression, gender had a relationship with differences in antibody responses after vaccination (p-value = 0.038).[19]

The characteristics of Body Mass Index (BMI) are the same as the initial observations made by Raul Pellinia et al on age, sex, obesity, and hypertension in antibody response to the Covid-19 BNT162b2 (Pfizer–BioNTech) vaccine in 248 HCW at the Institute of Physiotherapy Ospitalieri (IFO), the characteristics of the sample with the most normal BMI (59.2%), followed by pre-obesity/overweight (22.5%), obesity (10.4%), and the sample with the least underweight are (7.6%) and from multivariate linear regression, BMI did not have a relationship with p-value = 0.078. Then from the characteristics of obesity, as well as the initial observation made by Raul Pellinia et al. that from multivariate linear regression, BMI did not have a relationship with p-value = 0.078.[19] Likewise with the report of W. Scoth Butsch et al regarding the effectiveness and safety of Pfizer, Moderna, and Johnson and Johnson vaccines in obese samples. Of the 43,000 samples (>16 years) who received the Pfizer vaccine, there was no significant difference in the obese or non-obese samples, as well as in the 30,351 samples (>18 years) receiving the Moderna vaccine and the 12,492 Jhonson and Johnson vaccines.[21] This is also in accordance with the Indonesian Association of Internal Medicine Specialists (PAPDI) guidelines regarding inclusion and exclusion criteria for COVID-19 vaccine recipients where obese patients are eligible to receive the vaccine.[22]

This is in accordance with the review by Analise A Madison et al in 2021 regarding psychological and behavioral factors on the efficacy of the COVID-19 vaccine where for more than 30 years several studies have been documented on the impact of psychological and behavioral factors on vaccine response. There is strong evidence that stress, depression, and poor health behaviors impact the immune system's response to vaccines and on the prevalence and severity of vaccine-related side effects. Dietary components and nutritional status are relatively related to vaccine response in healthy adults. Although nutritional deficiencies have little impact on vaccine response, overall diet is considered important. Likewise, sleep substantially affects immune function. People whose sleep is disturbed are at high risk of not only developing unresponsive vaccines but also developing severe disease. The association of disturbed sleep with a lower antibody response was found in a cross-sectional study by Burns et al in 2002 and an experimental study on sleep restriction by Spiegel et al in 2002. Healthy adults who normally sleep 7.5-8.5 hours are reduced by 4 hours every day and night for 6 nights, when they received the influenza virus vaccine, there was lower antibody production than normal people at 10 days after vaccination and after 3-4 weeks of vaccination, their antibody levels did not last long.[6]

The results of the analysis of anxiety and Post Vaccination Adverse Events are in accordance with the review by Analise A Madison et al in 2021 regarding psychological and behavioral factors on the efficacy of the COVID-19 vaccine where over 30 years, several studies have been documented on the impact of psychological factors on vaccine response. There is strong evidence that stress, depression, loneliness, and poor health behaviors impact the immune system's response to vaccines. Psychological factors also have an impact on the prevalence and severity of vaccine-related side effects. These findings are generalized to many vaccines and may be relevant to the COVID-19 vaccine, which aims at psychological and behavioral interventions to increase vaccine efficacy and reduce side effects of vaccination.[6] Likewise with the Indonesian Association of Internal Medicine Specialists (PAPDI) guidelines regarding the inclusion and exclusion criteria for Covid-19 vaccine recipients where patients with psychosomatic disorders including anxiety deserve to receive the vaccine but it is strongly recommended that communication, information and education are quite straightforward until the previous medical treatment.[22]

The results of characteristic of a history of drug allergy, food allergy, and atopic disease slightly different from the article written by Vanita Sampath et al on vaccines and allergic reactions with two reports of allergic reactions after receiving the BNT162b2 (Pfizer) mRNA vaccine in the UK on December 30 2020, MHRA (the Medicines and Healthcare products Regulatory Agency) updated the guidelines that individuals with history of allergies to vaccine components should not receive the vaccine but individuals with a history of other allergies such as drug and food allergies may receive the vaccine.[23] Likewise with the Indonesian Association of Internal Medicine Specialists (PAPDI) guidelines regarding inclusion and exclusion criteria for COVID-19 vaccine

recipients where patients with a history of drug allergies, food allergies, and atopic disease (allergic rhinitis, atopic dermatitis) are eligible to receive the vaccine.[22]

Based on a retrospective cohort study conducted by Kimberley et al regarding acute allergic reactions to m-RNA vaccines, from 64,900 employees who received the first dose of vaccine (December 16 2020-February 12 2021) to February 18 2021, anaphylactic reactions experienced 0.025% sample: 7 cases Pfizer-BioNTech vaccine recipients and 9 cases of Moderna vaccine recipients where 63% had a history of allergies and only 1% had a history of severe drug allergy and 5% had a history of severe food allergy.[9] Then based on a study conducted by Tom Shimabukuro and Narayan Nair regarding allergic reactions including anaphylaxis after receiving the first dose of Pfizer-BioNTech vaccine December 14-23, 2020, anaphylactic reactions occurred in 21 samples and 81% of them had a history of drug and food allergies.[10] Then based on a cohort study conducted by Kelley N Dages et al regarding the risk of allergic reactions in patients with a history of atopy and COVID-19 vaccination where of 68 samples, 97% received the Pfizer-BioNTech vaccine, 47% had a history of drug allergies, 13% had a history of food allergies, and 91% had a history of atopic disease in the form of allergic rhinitis.[11] Also according to an article by Vanita Sampath et al regarding vaccines and allergic reactions with two reports of allergic reactions after receiving the BNT162b2 (Pfizer) mRNA vaccine in the UK on December 30 2020, where analysis of anaphylaxis reported via VAERS in the US only occurred in 828 cases, likewise in a 2003 study of more than 8 million routine vaccinations found the risk of anaphylaxis of 0.65-1.53 cases per million doses, also in 2016, found an anaphylaxis ratio of 1.31 cases per million doses, 85% of cases anaphylaxis with a history of atopic disease.[23]

The characteristics of hypertension in this study are in line with the initial observations made by Raul Pellinia et al where the largest number of samples without a history of hypertension (87.5%) and from multivariate linear regression found that hypertension had no relationship with p-value = 0.52.[21] This is also in accordance with the Indonesian Association of Internal Medicine Specialists (PAPDI) guidelines regarding inclusion and exclusion criteria for COVID-19 vaccine recipients where patients with a history of hypertension (controlled hypertension) are eligible to receive the vaccine.[22] It can be concluded that people with hypertension and their hypertension is controlled at the time of receiving the vaccine injection, will not experience symptoms.

The characteristics of a history of dyspepsia syndrome is in accordance with the Indonesian Association of Internal Medicine Specialists (PAPDI) guidelines regarding inclusion and exclusion criteria for COVID-19 vaccine recipients where patients with gastrointestinal disorders as long as these disorders are not associated with autoimmune diseases are eligible to receive the vaccine.[22] However, based on an article written by Nicholas J Talley et al regarding the pathophysiology of functional dyspepsia associated with an increase in duodenal eosinophils stimulated by infection or allergy, inflammation will alter gastroduodenal function and cause

symptoms.[24] Also, based on a population-based survey conducted by Tadayuki Oshima et al regarding the impact of the Covid-19 pandemic on functional dyspepsia (FD) online in Japan as many as 5,157 subjects randomly from 26-27 May 2020 where psychological stress, which may occur after vaccination, can be a cause this disease, especially if there is a history/complaint of this disease before.[25]

## Conclusion

In conclusion, all complaints of Post COVID-19 Vaccination (Sinovac) Adverse Events are classified as mild. The proportion of HCW experiencing Post COVID-19 Vaccination (Sinovac) Adverse Events exceeds 50%. There was a significant relationship between age, anxiety, and history of food allergy with Post COVID-19 Vaccination (Sinovac). Adverse Events indicate that these factors need to be considered in determining the Standard Operational Procedure for the next vaccination. Steps that can be taken regarding anxiety is a risk factor for Post COVID-19 Vaccination (Sinovac) Adverse Events; considering that the results of this study indicate that complaints of Post COVID-19 Vaccination (Sinovac) Adverse Events are classified as mild, HCW who screen patients must first convey that complaints that may arise are mild and can be resolved immediately at home and provide additional education about factors that are not related to the onset of complaints that will calm the patient. While there was no significant relationship between obesity, diet, sleep quality, history of drug allergy, atopic disease, hypertension and dyspepsia syndrome with Post COVID-19 Vaccination (Sinovac) Adverse Events are expected to increase public knowledge and confidence so that in the end there will be no worries in receiving the vaccine.

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## Conflict of Interest

The authors have no conflicts of interest to declare for this study.

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