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Factors associated with effects of COVID-19 vaccine among adults in Malaysia

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***Abstract*---**Introduction: Globally, the needs for more focused research to understand the effects of COVID-19 vaccines among the population to verify the previous research and generate more reliable data. Therefore, this cross-sectional study was aimed to identify the

factors associated with the effects of COVID-19 vaccination among adults in Malaysia. Methods: Malaysian people aged 18 and up were enrolled in a cross-sectional online survey. For data collection, a Google form was used to design an online questionnaire which was distributed through social media and in person by the author. Results: A total of 446 responses were analyzed. 58% participants received Pfizer BioNTech Covid 19 vaccine followed by Sinovac (21%) and AstraZeneca (16%). The most reported effect was local reaction pain, swelling and redness at the site of injection with 54.3% of participants. It was seen more in Pfizer BioNTech (56.8%) and AstraZeneca (57.1%) recipients in comparison to Sinovac recipients (42.9%), but this difference was not significant (x^2=3.453; p-value=0.315). Tiredness/fatigue was the next most reported effect 51.3% by participants. The other more frequently reported effects were body pain (43.3%), muscle pain (41%), fever (41%) and headache (33%) respectively, which are significantly associated with the type of vaccine. Conclusion: In a nutshell, collaborations with healthcare service providers were needed to overcome these issues, while additional laboratories were assigned to enhance the capabilities of the Ministry of Health.

***Keywords*---**COVID-19, SARS CoV-2, vaccines, Sinovac, Pfizer, AstraZeneca, adverse effects, Vaccine safety, Malaysia.

Introduction

SARS-CoV-2 virus is the virus responsible for causing COVID-19 (Fisher & Heymann 2020). It has been there with us since December 2019 that emerged from China spreading rapidly throughout the world and later COVID-19 outbreak has been declared as pandemic by WHO (Wu et al. 2020) (Sohrabi et al. 2020). In Malaysia the 1st COVID-19 case was confirmed on 4th February 2020 (Elengoe 2020). The response to this global crisis was very quick, and within just one year of emergence of the disease, on 11th December 2021, the first vaccine approved for Emergency use authorization was declared (Elnaem et al. 2021) .This was followed by AstraZeneca, Moderna, Jansen, Sinopharm, Sinovac, Covishield and Covaxin that are approved for emergency use by WHO (Organization 2021). On 21st February, Malaysia received its first shipment of Pfizer BioNTech vaccines; and later AstraZeneca, Sinovac and CanSino vaccines were also deployed to be administered in Malaysia (Size et al. 2020; Star 2021a, 2021b)

The National COVID-19 immunization program in Malaysia started on 24th February 2021(Aa 2021). Even though at the time of preparing this article 76.1% of Malaysian population fully vaccinated against COVID 19 that accounts for more than 24,849,925 doses to date, only one study has been conducted to record the vaccine effects together with the population attitude and perceptions towards COVID-19, which generalizes the study to both vaccinated and unvaccinated population making the results unable to be fully generalized among the vaccinated population causing it to be less reliable in identifying the effects of the vaccines (Malaysia 2021) (Elnaem et al. 2021). Thus, creating a need for more

focused research to understand the effects of COVID-19 vaccines among the Malaysian population to verify the previous research and generate more reliable data. Data from Vaccine Adverse Event Reporting System (VAERS) in the U.S. and several other studies have identified injection-site pain as the most common local effects with fatigue and headache as the most common systemic effects associated with the COVID-19 vaccines. (Wu et al. 2021)

This study was aimed to identify the factors associated with the effects of COVID-19 vaccination among adults in Malaysia. The common effects reported in previous literature and clinical trials after administering COVID-19 vaccines were assessed in the vaccinated adult population of Malaysia, providing a basis for the increase in awareness about the effects associated with COVID-19 vaccination among general population since Malaysians, the knowledge about the COVID-19 was observed to be highly inadequate; and prepare everyone for better management of these effects (Mohamed et al. 2021).

1. Method

2.1 Study design:

A cross-sectional study was conducted to identify the effects of the COVID-19 vaccines among vaccinated adults aged 18 years and above in Malaysia. An online self-administered questionnaire was distributed through google form among the Malaysian population. A non-probability convenience sampling technique was used to assemble the sample. Invitations are sent via the link individually through social media platforms such as WhatsApp, Instagram, emails and Facebook to reach the targeted population for quality control and respondent sincerity. Participants were given informed consent prior to enrollment of the survey.

2.2 Study Instrument

The questionnaire was composed of two main sections which are sociodemographic profiles and the post-vaccine effects. Sociodemographic factors consisted of questions of age, gender, race, education, occupation, residency, marital status, and family monthly income. The additional questions were asked as part of sociodemographic to associate any other possible factors including smoking status, previous Covid-19 infection, chronic disorders, and the vaccine types approved by the Malaysian Government consisting of Pfizer, AstraZeneca, Sinovac and others. The assessment of the post-vaccine effects includes the symptoms such as body pain, headache, fever, etc.

A pilot study was conducted to assess the validity and reliability of the questionnaire. Cronbach's alpha test of internal consistency was used to assess the reliability. The questionnaire was valid and reliable as the overall Cronbach alpha value was 0.83 and Cronbach's Alpha -The Cronbach’s alpha is 0.671 for a similar study conducted in Saudi Arabia which is acceptable, when compared to this study’s value, it is observed that this study has pooled more reliable results, which was higher than the accepted value for internal consistency of 0.70.

2.3 Sample size

The sample size (n) was calculated via the Raosoft sample size calculator using 95% confidence level (95% CI) and a 5% margin of error with a population proportion of 50%. The target population size is 25.4 million that consists of both fully vaccinated and partially vaccinated adults in Malaysia (Health 2021; Mohamad Radhi 2021). By taking into consideration of 10% attrition rate, the minimal sample size required in this study was 424. The inclusion criteria included Malaysians of 18 years and older who have taken at least one dose of the Malaysian mandated vaccines, while the exclusion criteria excluded anyone under the age of 18, unvaccinated or rather vaccinated but not by any of the Malaysian mandated vaccines.

2.4 Statistical analysis

Statistical analysis of the data collected was conducted using Statistical Package for Social Sciences (SPSS Version 26.0) and Microsoft Excel 2020. The respondents' sociodemographic characteristics were assessed and summarized by performing descriptive analysis and frequency analysis. The Chi-square test is used to evaluate the significant association between sociodemographic variables and the types of vaccine.

2.5 Ethical Approval:

All the participants were provided with informed consent before commencement of the survey. The ethical approval was acquired from the Centre of Research and Development, Asia metropolitan University (No. HEC25022022FOM0001), which is in accordance to the Declaration of Helsinki.

Results

The total respondents consisted of 481 out of 455 agreed to participate in the study, of which 9 were not vaccinated, 6 (1.3%) were partially vaccinated and 440 (96.7%) were fully vaccinated individuals. Therefore, our final sample size was 446 since this met the inclusion criteria in our study. Among them, 58% received Pfizer BioNTech Covid 19 vaccine followed by Sinovac (21%) and AstraZeneca (16%) (Fig. 1). According to Figure.2, Pfizer vaccine recipients (49%) reported having symptoms for 1-3 days, 10% for 4-7 days, 35.9% for less than 1 day, and 4.2% for more than 7 days. AstraZeneca (60%) of participants had symptoms for 1-3 days, (2.8%) for 4-7 days, (34.2%) for less than 1 day, and (2.8%) for more than 7 days. Participants who received Sinovac reported symptoms for 1-3 days (44%), 4-7 days (7.2%), less than 1 day (40%), and more than 7 days (7.2%). Other vaccination types caused symptoms in 23% of individuals for 1-3 days, 14% for 4-7 days, 61.9% for less than one day, and none for more than seven days. When comparing the duration of the system for various types of vaccines, 60% of AstraZeneca's symptoms last for 1-3 days. Participants reporting symptoms from other vaccination types reported High on days 4-7 (14%), and less than one day (61.9%). Sinovac achieved a new high in less than a day (7.2%).

Figure 3 summarizes the unusual symptoms expressed by the participants after vaccination. 91% of the participants didn't experience any unusual effects. The most common unusual symptom reported by participants was chest pain with a total of 15 cases (3%) of which8 7.5% Pfizer, 7.1% AstraZeneca vaccine and 14.2% Sinovac vaccine. 4 cases (0.8%) reported Cold, numbness, and tingling in limbs, Chest pain together with Increased/decrease in blood pressure only seen in Pfizer. Nosebleed was reported by a total of 2 cases (0.4%) with 50% from Pfizer and Sinovac. Increase/decrease in blood pressure was shared in relatively the same number of cases (28.5%) in all vaccine types**.**

According to Figure.4, Headache (57.1%), fever (51.4%), muscle pain (45.7%) , joint pain (27.1%) , dizziness (24.3%) , runny nose (10.0%), and loss of taste (4.3%) were frequently noted in participants who received the AstraZeneca vaccine compared with other types of vaccine. Tiredness, fatigue (53.1%), body pain (46.1%), gastrointestinal symptoms such as nausea, vomiting, diarrhoea, abdominal pain (6.6%) were more common adverse effects associated with the Pfizer vaccine. Loss of appetite (11.3%), tenderness or swollen lymph nodes (11.3%) , coughing (10.5%) , tachycardia (10.9%), sore throat (9.4%), sweating (8.9%) , and loss of smell (3.9%) were more frequently noted in participants who received the Pfizer vaccine compared with other vaccine types. Only shortness of breath (9.4%), anxiety (14.6%), and rashes (8.3%) were seen in participants who received Sinovac. The percentage of participants who did not report any effects was 22.9% for those who received the Sinovac vaccine, 16.1% who received the Pfizer vaccine, and 10.0% who had the AstraZeneca vaccine.

The Sociodemographic characteristics of the participants is depicted in Table 1. Participants aged 20-29 years consisting of almost half of the participants (49.3%). Females formed 57% of total number of participants. About half of the participants (49.1) had tertiary level of education with around 80% employed full-time or part-time. There were 37.4% Indian participants followed by 36.5% Malay participants and then Chinese and other races. Most 88.3% were non-smokers and only 11.4% were infected with COVID-19 infection before vaccination. Only 15.5% suffered from Chronic diseases with Diabetes mellitus and Obesity being the most prevalent.

The most reported effect was local reaction pain, swelling and redness at the site of injection with 54.3% of participants. It was seen more in Pfizer BioNTech (56.8%) and AstraZeneca (57.1%) recipients in comparison to Sinovac recipients (42.9%), but this difference was not significant (p-value 0.315). Tiredness/fatigue was the next most reported effect 51.3% by participants. The other more frequently reported effects were body pain (43.3%), muscle pain (41%), fever (41%) and headache (33%) respectively, which are significantly associated with the type of vaccine (Table 1).

The study's Chi-Square analysis has observed that most side effects have had high significance values that are notable enough to not show any evidence against the null hypothesis, except for the following categorized side effects in our statistical data, namely: "Body pain", "Headache", "Fever", "Muscle pain", and "Tachycardia". These five side effects have displayed minor significance in the results which means they favored greater evidence towards the null hypothesis,

primarily because the recipients of Pfizer BioNTech and Sinovac vaccines didn't suffer from these affects as much as recipients AstraZeneca and "other" vaccines, this variance in responses led to a somewhat uniform contradiction, which lead to our df value to be considerably high, yielding a low P value ratio, which meant the aforementioned side effects did in fact fail to reject the null hypothesis, due to the expected value being greater than the critical value in the chi-square statistical analysis for these five side effects. An outlier to the distribution in "Table 2" is the "Sore or dry throat" side effect category where the P value is greater than the significance level, thus the data favors the alternative hypothesis to the side effect's significance.

MySejahtera is a mobile application developed by the Government of Malaysia and supervised by the Ministry of Health Malaysia, primarily to assist contact tracing and public awareness of Covid-19. The vaccination status of individuals was later added to the application. The data collected shows that 59% of the participants under-reported their symptoms to the Ministry of Health Malaysia. The percentage of participants who did not report any effects was 22.9% for those who received the Sinovac vaccine, 15.8% who received the Pfizer vaccine, and 10.0% who had the AstraZeneca vaccine (Table 1).

Discussion

Since the start of the Coronavirus pandemic in January 2020 the Malaysian government has taken preventive steps to control SARS-CoV 2 transmission in the hopes of developing a safe and effective vaccine as quickly as possible (Aum Shah 2020). Despite the vaccine's availability to the Malaysian community, there is a wide range of people's ability to take it (Ss Deroo 2020). This is likely due to the fact that these vaccines were produced in a short period of time and mostly due to concerns about severe post-vaccination adverse effects(Mm Ahamad 2021). The study shows vaccines have recorded 60 % to 80 % of side effects among those people who received Oxford-AstraZeneca or Pfizer BioNTech, as well as Sinovac in Malaysia, with the percentage varying depending on the individual's age, vaccine type, and dose (Jx Li 2016).

According to a systematic review conducted, the most common local adverse reaction was pain or tenderness at the injection site, and the most common systemic adverse reaction was fatigue, fever, or bodily pain, which coincides with the results in our study with addition of muscle pain to the above list of effects.(Xing et al. 2021). In our study, body pain was significantly associated with the types of vaccine; where by 41.4% of those who received AstraZeneca got body pain when 45.6% body pain in Pfizer, 33.3% in Sinovac and 66.7% of body pain was occurred in other types of vaccines ($p<0.05$). Other than body pain; headache (41.4% AstraZeneca, 34.7% Pfizer, 19.8% Sinovac, 49.9% other vaccines), muscle pain (45.7% AstraZeneca, 43.2% Pfizer, 28.1% Sinovac,57.1% other vaccines) and fever (51.4% AstraZeneca, 43.6% Pfizer, 21.9% Sinovac, 61.9% other vaccines) was also observed to be significantly associated with the types of vaccine ($p<0.05$). These differences could be due to the kind of vaccine type and their mechanism of action.

Our study mainly included three vaccines, Pfizer, AstraZeneca and Sinovac. Pfizer is RNA based vaccine; AstraZeneca is non replicating viral vector vaccine whereas Sinovac is inactivated viral vaccine (Al-Jighefee et al. 2021). Meta analysis shows that collective rates of local and systemic reactions were significantly lower among inactivated vaccines (23.7%, 21.0%) compared to RNA vaccines (89.4%, 83.3%), non-replicating vector vaccines (55.9%, 66.3%) (Wu et al. 2020). This explains the highest frequency of no effects (22.9%) in Sinovac compared to Pfizer (15.8%) and AstraZeneca (10%) in our study.

Although all COVID-19 vaccines caused similar post-vaccination side effects, the frequencies of some side effects were also significantly associated with vaccine type. The following are the side effects that are significantly associated with types of vaccines injection site pain and swelling ($p = 0.00$); chills ($p = 0.02$); sore or dry throat, clogged nose, and runny nose ($p = 0.02$); sleepiness and laziness ($p = 0.00$) (Aa 2021).

We must review the cases of unusual symptoms after vaccination as they may be associated with the chronic diseases and as we did not observe the severity as recorded by other similar studies (Ronald N Kostoff 2020). The unusual symptoms expressed by the participants after vaccination in a study conducted to evaluate the safety of vaccines reported 2 participants with swelling and severe allergic reaction of their eyelids to the Pfizer vaccine, lasting up to 3 days. 6 participants (4 got Pfizer and 2 got AstraZeneca vaccine) were taken to hospital with severe hypotension, generalized body pains, shortness of breath, and fever of more than 39°C. one participant noticed Weakness and numbness in the injected hand that continued for 13 days after Sinopharm vaccination. Pfizer vaccination reported in 2 incidences of severe chest pain lasting 6 days, 4 cases of acute hypertension (with blood pressure exceeded 210/105 mm Hg) lasting 5 days and 1 case of acute hyperglycaemia, (FBS > 170 mg/dL) for 2 days were reported by Pfizer vaccine. 1 AstraZeneca recipient experienced severe chest pain for up to 6 days and one case experienced intermittent nasal bleeding for 2 days (Al Khames Aga et al. 2021).

Limitation

The study's approach and design were constructed to minimize limitations, however, the survey was done months after vaccines were administered in Malaysia, so we only kept the responses of those who we believed were fully aware of their responses (Plüddemann et al. 2018). Furthermore, since questionnaire was administered in English only and it might have an impact in pooling more responses for those who had limitation in English language.

Conclusion

The result of the study is to emphasize the effects of covid-19 vaccination among adults in Malaysia. To overcome these issues a provisional hospital was set up and collaborations with healthcare service providers were granted, while additional laboratories were assigned to enhance the capabilities of the Ministry of Health.

The need for continued access to research and learning has never been more important. We recognise our role in this and are working with global organizations, such as the World Health Organization and the initiative from the White House Office of Science and Technology to make all relevant global research, and data, immediately available. We also continue to work directly with teachers, lecturers, librarians, students and institutions to support their work.

Acknowledgement

We would like to extend our heartfelt thanks to the participants of this study. We also would like to thanks to Centre of Research and Development, Asia Metropolitan University for approval of our research ethic application.

Conflict Of Interest

There is no conflict of interest.

9. Funding

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11. Appendix

Figure 1. Types of vaccine received by all participants (N=446)

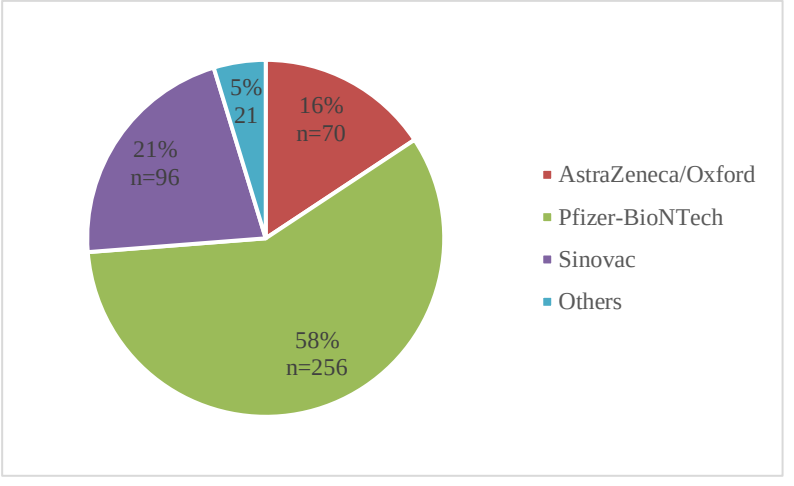

Figure 2. Duration of symptoms based on the type of vaccines

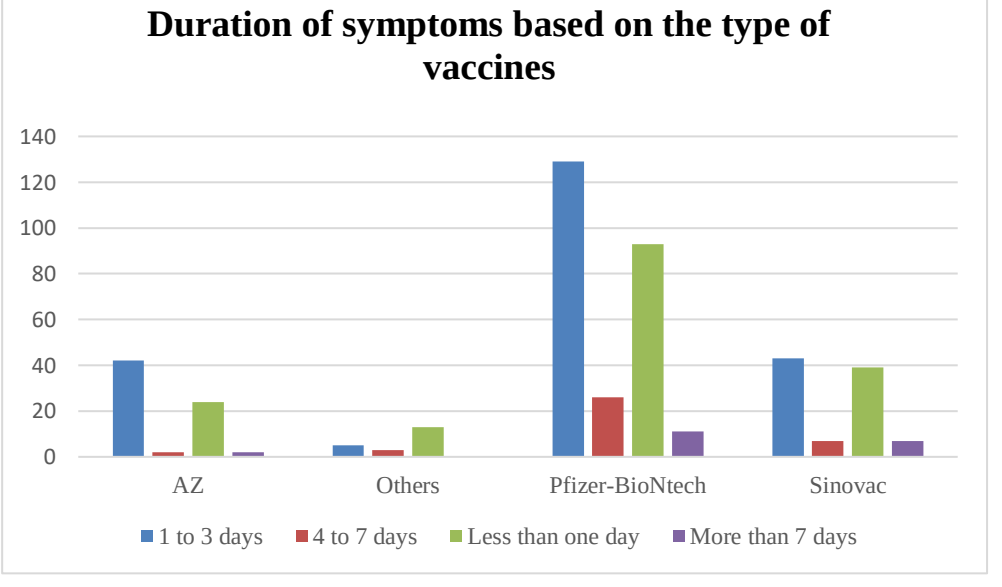

Figure 3. Experiencing unusual symptoms based on the type of vaccines

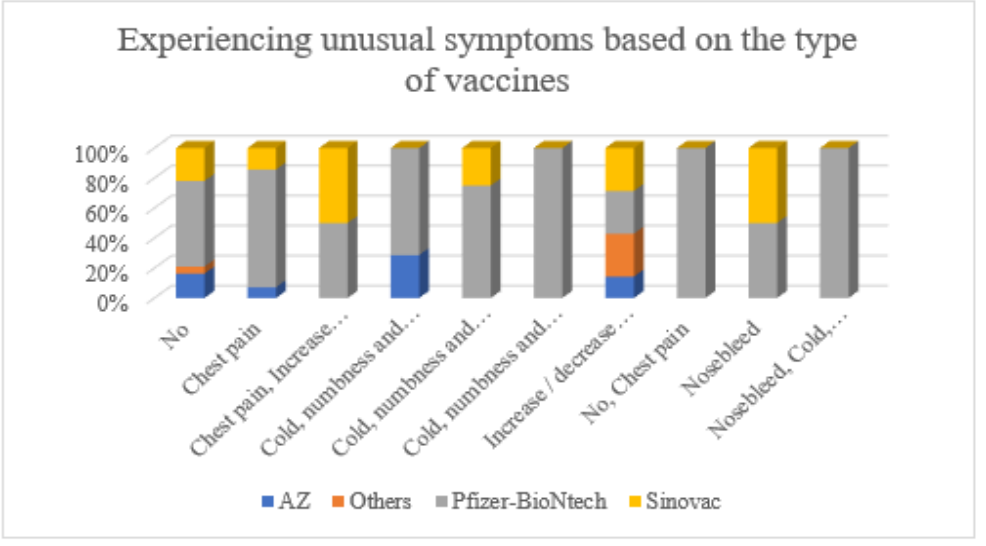

Figure 4. Effects reported by all participants based on type of vaccine (N=446)

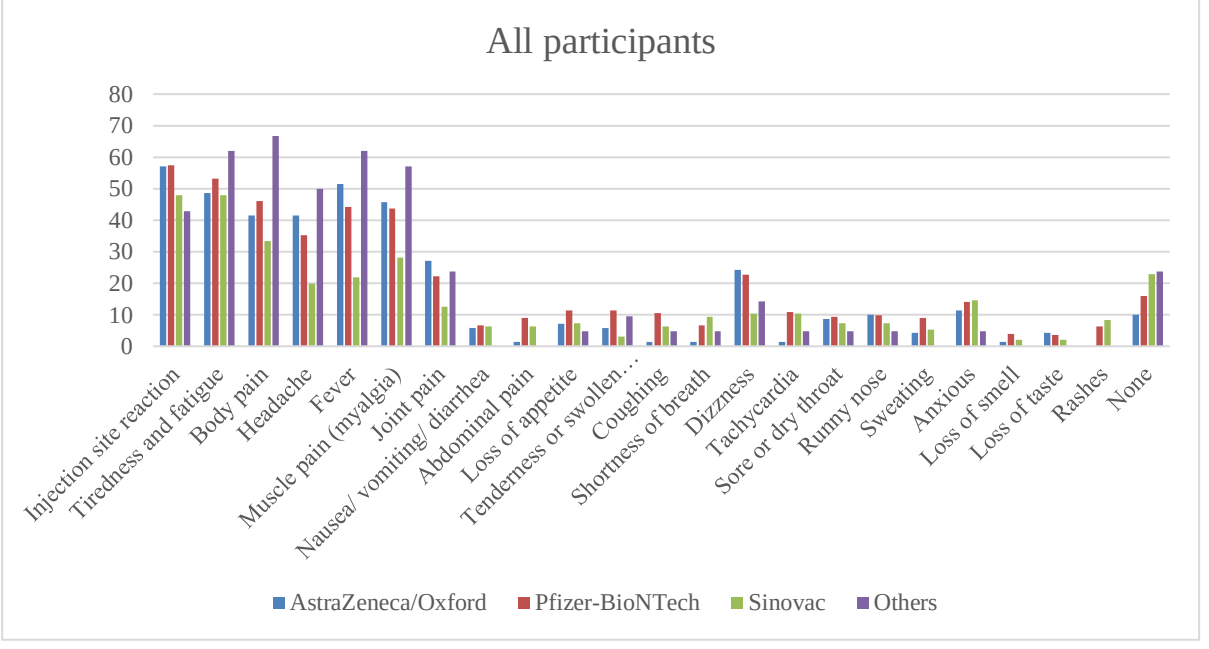

Table 1. Sociodemographic characteristics of the participants according to the type of vaccines received (N=446)

Participants Characteristics	AstraZeneca	Pfizer-BioNtech	Sinovac	Others	Total
Vaccination status					
1st dose	1	2	1	2	6
2nd dose	69	257	95	19	440
Age					
18 - 20 years	9	35	8	4	56
20 - 29 years	39	115	49	17	220
30 - 39 years	11	52	19	0	82
40 - 49 years	7	31	10	0	48
50 - 59 years	4	20	8	0	32
60 years and above	0	6	2	0	8
Residence					
Rural	13	84	26	7	130
Urban	57	175	70	14	316
Gender					
Female	35	156	57	6	254
Male	35	103	39	15	192
Marital status					
Divorced	0	5	5	1	11
Married	18	98	33	0	149
Single	51	152	57	20	280
Widowed	1	4	1	0	6
Race					
Chinese	10	42	29	0	81
Indian	31	90	30	16	167
Malay	22	103	34	4	163
Others	7	24	3	1	35
Family income					
Between RM 4850 - RM 10960	34	113	43	10	200
Less than RM 4849	23	111	46	5	185
More than RM 10960	13	35	7	6	61
Educational status					
No formal education	0	7	3	0	10
Post-secondary	21	76	34	5	136
Primary	0	9	5	0	14
Secondary	10	46	9	2	67

Tertiary	39	121	45	14	219
Employment status					
Employed (Full time)	25	119	36	1	181
Employed (Part time)	7	15	10	0	32
Others	2	1	0	0	3
Retired	1	11	3	0	15
Students	32	92	36	19	179
Unemployed/Home maker	3	21	11	1	36
Have you been infected with COVID-19 before vaccination?					
Yes	6	26	16	3	51
No					
Smoking status					
Smoker	5	33	13	1	52
Non smoker	65	226	83	20	394

Table 2. Measurement of associations between effects and the types of vaccine by using Chi- square test (N=446)

Variables		Type of vaccine				x^2 (df)	p-value
		AZ n(%)	Pfizer n(%)	Sinovac n(%)	Others n(%)		
1. Injection site reaction							
	Yes	40(57.1%)	147(56.8%)	46(47.9%)	9(42.9%)	3.543(3)	0.315
	No	30(42.9%)	112(43.2%)	50(52.1%)	12(57.1%)		
2. Tiredness and fatigue							
	Yes	34(48.6%)	136(52.5%)	46(47.9%)	13(61.9%)	1.745(3)	0.627
	No	36(51.4%)	123(47.5%)	50(52.1%)	8(38.1%)		
3. Body pain							
	Yes	29(41.4%)	118(45.6%)	32(33.3%)	14(66.7%)	9.194(3)	**0.027**
	No	41(58.6%)	141(54.4%)	64(66.7%)	7(33.3%)		
4. Headache							
	Yes	29(41.4%)	90(34.7%)	19(19.8%)	9(49.9%)	11.112(3)	**0.011**
	No	41(58.6%)	169(65.3%)	77(80.2%)	12(57.1%)		
5. Fever							
	Yes	36(51.4%)	113(43.6%)	21(21.9%)	13(61.9%)	22.191(3)	**0.000**
	No	34(48.6%)	146(56.4%)	75(78.1%)	8(38.1%)		
6. Muscle pain (myalgia)							
	Yes	32(45.7%)	112(43.2%)	27(28.1%)	12(57.1%)	10.020(3)	**0.018**
	No	38(54.3%)	147(56.8%)	69(71.9%)	9(42.9%)		
7. Joint pain							
	Yes	19(27.1%)	57(22.0%)	12(12.5%)	5(23.8%)	6.057(3)	0.109
	No	51(72.9%)	202(78.0%)	84(87.5%)	16(76.2%)		
8. Nausea/ vomiting/ diarrhoea							
	Yes	4(5.7%)	17(6.6%)	6(6.3%)	0(0.0%)	1.492(3)	0.684
	No	66(94.3%)	242(93.4%)	90(93.8%)	21(100%)		
9. Abdominal pain							
	Yes	1(1.4%)	23(8.9%)	6(6.3%)	0(0.0%)	6.596(3)	0.086
	No	69(98.6%)	236(91.1%)	90(93.8%)	21(100%)		
10. Loss of appetite							
	Yes	5(7.1%)	29(11.2%)	7(7.3%)	1(4.8%)	2.428(3)	0.488
	No	65(92.9%)	230(88.8%)	89(92.7%)	20(95.2%)		
11. Tenderness/ swollen lymphnodes							
	Yes	4(5.7%)	29(11.2%)	3(3.1%)	2(9.5%)	6.700(3)	0.082
	No	66(94.3%)	230(88.8%)	93(96.9%)	19(90.5%)		
12. Coughing							
	Yes	1(1.4%)	27(10.4%)	6(6.3%)	1(4.8%)	6.982(3)	0.072
	No	69(98.6%)	232(89.6%)	90(93.8%)	20(95.2%)		
13. Shortness of breath							
	Yes	1(1.4%)	17(6.6%)	9(9.6%)	1(4.8%)	4.481(3)	0.214
	No	69(98.6%)	242(93.4%)	87(90.6%)	20(95.2%)		
14. Dizzness							
	Yes	17(24.3%)	58(22.4%)	10(10.4%)	3(14.3%)	7.728(3)	**0.052**
	No	53(75.7%)	201(77.6%)	86(89.6%)	18(85.7%)		
15. Tachycardia							
	Yes	1(1.4%)	28(10.8%)	10(10.4%)	1(4.8%)	6.653(3)	0.083
	No	69(98.6%)	231(89.2%)	86(98.6%)	20(95.2%)		

16. Sore or dry throat						
	Yes	6(8.6%)	24(9.3%)	7(7.3%)	1(4.8%)	0.752(3)	0.861
	No	64(91.4%)	235(90.7%)	89(92.7%)	20(95.2%)		
17. Runny nose						
	Yes	7(10%)	25(9.7%)	7(7.3%)	1(4.8%)	1.025(3)	0.795
	No	63(90%)	234(90.3%)	89(92.7%)	20(95.2%)		
18. Sweating						
	Yes	3(4.3%)	23(8.9%)	5(5.2%)	0(0.0%)	4.279(3)	0.233
	No	67(95.7%)	236(91.1%)	91(94.8%)	21(100%)		
19. Anxious						
	Yes	8(11.4%)	36(13.9%)	14(14.6%)	1(4.8%)	1.764(3)	0.623
	No	62(88.6%)	223(86.1%)	82(85.4%)	20(95.2%)		
20. Loss of smell						
	Yes	1(1.4%)	10(3.9%)	2(2.1%)	0(0.0%)	2.231(3)	0.526
	No	69(98.6%)	249(96.1%)	94(97.9%)	21(100%)		
21. Loss of taste						
	Yes	3(4.3%)	9(3.5%)	2(2.1%)	0(0.0%)	1.431(3)	0.698
	No	67(95.7%)	250(96.5%)	94(97.9%)	21(100%)		
22. Rashes						
	Yes	0(0.0%)	16(6.2%)	8(8.3%)	0(0.0%)	7.141(3)	0.068
	No	70(100%)	243(93.8%)	88(91.7%)	21(100%)		
23. None						
	Yes	7(10%)	41(15.8%)	22(22.9%)	5(23.8%)	5.793(3)	0.122
	No	63(90%)	218(84.2%)	74(77.1%)	16(76.2%)		