

COVID-19 VACCINE ACCEPTANCE AMONG
PREGNANT WOMEN IN HOSPITAL UNIVERSITI
SAINS MALAYSIA

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by

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LIST OF ABBREVIATIONS

X ²	-	Chi-square Statistic
ATT	-	Anti-tetanus toxoid
CAN	-	Cognitive-Affective-Normative
CI	-	Confidence Interval
COPD	-	Chronic Obstructive Pulmonary Disease
COVID-19	-	Corona Virus Diseases 2019
DCA	-	Drug Control Authority
EUA	-	Emergency Use Authorization
FDA	-	Food and Drug Administration
GDP	-	Gross Domestic Product
KKM	-	Kementarian Kesihatan Malaysia
MERS	-	Middle East Respiratory Syndrome
O&G	-	Obstetrics and Gynaecology
PE	-	Preeclampsia
SARS- CoV-2	-	Severe Acute Respiratory Syndrome Coronavirus 2
SD	-	Standard Deviation
SPSS	-	Statistical Package for Social Science
TAM	-	Technology Acceptance Model
TBP	-	Theory of Planned Behavior
TRA	-	Theory of Reasoned Action
UTAUT	-	Unified Theory of Acceptance and Use of Technology
WHO	-	World Health Organisation

PENERIMAAN VAKSIN COVID-19 DALAM KALANGAN WANITA HAMIL DI HOSPITAL UNIVERSITI SAINS MALAYSIA

ABSTRAK

Setelah dua tahun memasuki pandemik koronavirus COVID-19, usaha global untuk membangunkan dan menyampaikan vaksin yang berkesan telah menghasilkan beberapa pilihan yang selamat dan berkesan. Kajian keratan rentas telah dijalankan untuk menentukan kadar penerimaan vaksin COVID-19 di Hospital USM di kalangan Wanita hamil. Ia dijalankan di Klinik Obstetrik dan Ginekologi, Hospital USM. Persampelan rawak mudah digunakan dalam kajian dan soal selidik telah diadaptasi daripada Goncu Ayhan, 2021. Sebab-sebab penolakan vaksin COVID-19 juga telah diperiksa. Korelasi antara kadar penerimaan vaksin COVID-19 dan faktor sosiodemografi telah diuji menggunakan ujian Chi-Square Pearson.

Seramai 254 responden terlibat dalam kajian ini. Majoritinya adalah 198 (78.0%) responden berumur 20-35 tahun, 246 (96.9%) responden Melayu, 180 (70.9%) wanita hamil dengan pendidikan kolej/universiti, dan 110 (43.3%) pegawai kerajaan. 68 (26.8%) majoriti pendapatan isi rumah peserta adalah antara RM1000 hingga RM1999 dan RM4000-RM4999, dan kebanyakannya adalah multigravida (2-3 kehamilan) dengan majoriti 148 (58.3%) berlaku antara 31 dan 40 minggu kehamilan. Kajian ini hanya melibatkan 58 (22.8%) wanita hamil yang mempunyai komorbiditi semasa kehamilan mereka.

Keputusan menunjukkan bahawa 174 (68.5%) mempunyai penerimaan sederhana manakala 42 (16.5%) menunjukkan penerimaan yang tinggi. Sementara itu, hanya 38

(15%) menunjukkan penerimaan rendah terhadap vaksin COVID-19. Seterusnya, tiga sebab utama mereka menolak vaksin ialah; kekurangan data mengenai keselamatan vaksin COVID-19 dalam kalangan wanita hamil di mana mereka percaya bahawa jika mereka sakit, kedua-dua ibu dan bayi tidak akan mengalami sebarang kesan negatif, dan vaksin akan membahayakan bayi. Terdapat korelasi yang signifikan antara umur ($P=0.001$), tahap pendidikan ($P=0.000$), kerjaya ($P=0.000$), pendapatan isi rumah ($P=0.000$), gravida ($P=0.007$), dan pariti ($P=0.010$) dengan kadar penerimaan vaksin COVID-19. Tiada korelasi yang signifikan antara etnik, umur kehamilan atau komorbiditi dengan kadar penerimaan vaksin COVID-19 ($P>0.05$). Kesimpulannya, kadar penerimaan vaksin COVID-19 dalam kalangan wanita hamil perlu ditingkatkan bagi mengurangkan risiko komplikasi lebih teruk jika dijangkiti penyakit COVID-19.

COVID-19 VACCINE ACCEPTANCE AMONG PREGNANT WOMEN IN HOSPITAL UNIVERSITI SAINS MALAYSIA

ABSTRACT

Two years into the COVID-19 coronavirus pandemic, the global effort to develop and deliver an effective vaccine yielded several safe and effective choices. A cross-sectional study has been conducted to determine the COVID-19 vaccine acceptance rate in Hospital USM among pregnant women. It took place in the Obstetrics and Gynaecology Clinic, Hospital USM. A simple random sampling was used in the study, and the questionnaire was adapted from Goncu Ayhan, 2021. The reasons for refusing the COVID-19 vaccine have also been examined. Pearson's Chi-Square test tested the correlation between the COVID-19 vaccine acceptance rate and sociodemographic factors.

A total of 254 respondents were involved in this study. The majority being 198 (78.0%) respondents aged 20-35, 246 (96.9%) Malays respondents, 180 (70.9%) pregnant women with college/university education, and 110 (43.3%) government official. The 68 (26.8%) majority of participants' household incomes ranged from RM1000 to RM1999 and RM4000-RM4999, and most of them were multigravida (2-3 pregnancy), with the majority of 148 (58.3%) occurring between 31 and 40 weeks of gestation. This study included only 58 (22.8%) pregnant women who had comorbidities during their pregnancy.

The result shows that 174 (68.5%) had moderate acceptance while 42 (16.5%) showed high acceptance. Meanwhile, only 38 (15%) indicate low acceptance of the

COVID-19 vaccine. Next, the three main reasons for them to refuse the vaccine were the lack of data on the safety of the COVID-19 vaccination in pregnant women, where they believed that if they are sick, both mother and baby will not encounter any negative effects, and the vaccine will harm the baby. There was a significant correlation between age ($P=0.001$), educational level ($P=0.000$), career ($P=0.000$), household income ($P=0.000$), gravida ($P=0.007$), and parity ($P=0.010$) with the COVID-19 vaccine acceptance rates. There was no significant correlation between ethnicity, gestational age, or comorbidities with the acceptance rate of the COVID-19 vaccine ($P>0.05$). In conclusion, the acceptance rate of the COVID-19 vaccine among pregnant women needs to be increased to reduce the risk of worse complications if contracting the COVID-19 disease.

CHAPTER 1

INTRODUCTION

This dissertation represents a detailed explanation of the study conducted entitled COVID-19 vaccine acceptance among pregnant women in Hospital Universiti Sains Malaysia (USM). This chapter discussed the background of the study, problem statement, research objectives, research questions, research hypotheses, conceptual and operational definitions, as well as the significance of the study.

1.1 Background of the study

COVID-19 was detected in Wuhan, China, on December 31, 2019. The World Health Organization (WHO) alerted one cluster of unknown etiology of pneumonia (Chan et al., 2020; WHO, 2020a). Initially, the cluster was linked to Wuhan's seafood wholesale market, although the following 41 cases had reported not being related to the market (Cucinotta & Vanelli, 2020). Later, COVID-19 or Coronavirus disease 2019 increased the infections and death rates worldwide (Pelegrín-Borondo et al., 2021). COVID-19, caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS- CoV-2), can be rapidly transmitted by close contact with an infected person and through the nasal route (Al-Zalfawi et al., 2021; Riou & Althaus, 2020). As of October 15, 2021, 239,437,517 COVID-19 confirmed cases, including 4,879,235 deaths, had been recorded globally (WHO, 2021b). As in Malaysia's latest update on October 15, 2021, daily recorded was 7,420 cases, making the total cases in this country 2,377,033 (Kementerian Kesihatan Malaysia (KKM), 2021b).

Before the vaccines or any effective treatment existed to control the spread of the virus, all the nations in the world struggled with lockdowns and quarantine, social distancing, mandatory times use of facemasks, and travel restrictions (Lin et al., 2020). Vaccine development and deployment are the most promising ways in the crisis. As soon as the SARS-CoV-2 was known as the causative agent and the first genome sequence was published, a few research centers and pharmaceutical companies began to produce the COVID-19 vaccine (Harapan et al., 2020; Hoque et al., 2020). Luckily, on December 11, 2020, the U.S. FDA (Food and Drug Administration) issued to individuals 16 years old and above an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, and first in the world, the EUA allowed the vaccine to be dispensed in the U.S. (Dooling et al., 2020; Tanne, 2020). Next, other countries got along once the issue had been approved, while the other vaccine candidates were followed as prospects (Cascini et al., 2021).

Malaysia's COVID-19 immunization programme started in February 2021, and with initially given to the frontliners. According to a recent survey by the Ministry of Health, about 85% of Malaysian are willing to get the vaccines (WHO, 2021a). Besides, Malaysia has booked 14 million doses of Sinovac, and Indonesia has received three million doses from more than 125 million public. The Philippines has ordered 25 million doses of the same vaccine (Baraniuk, 2021). Since the number of COVID-19 is rising in Malaysia, taking vaccines, including other public health measures, is the best choice to aid in protecting oneself and reducing the infection rate (WHO, 2021a). Several vaccines used in Malaysia, such as Pfizer, AstraZeneca, and other vaccines that had also been approved, are used by the National Pharmaceutical Regulatory Agency (WHO, 2021a). However, we can see that Malaysia still has not hit the whole population to be vaccinated.

According to the Ministry of Health Malaysia, as the date of October 28, 2021, Malaysia reached 74.0% of the vaccinated population, was 49,581,855 total administered. The highest-ranking state was Klang Valley which was 88.0%. The lowest ranking was Sabah, which only 56.8%, as shown below:

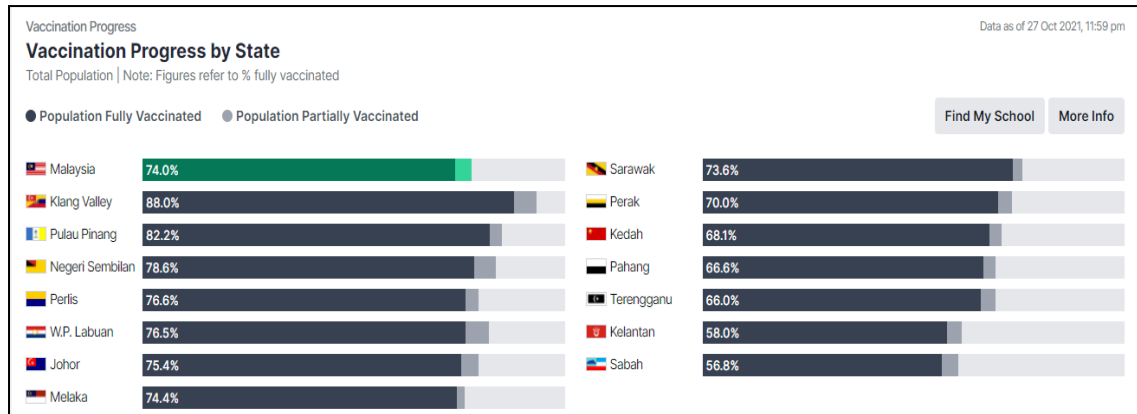


Figure 1.1: Vaccination Progress by State (Ministry of Health Malaysia, 2021)

The epidemic may be stopped if herd immunity is achieved within the population, which can be gained by vaccination or community infection (Hoque et al., 2020). Each individual has a risk of becoming infected, especially those in an immunocompromised state with a higher chance of getting COVID-19 than other general populations like pregnant mothers (Liu et al., 2020; Zhao et al., 2020). Many reports recently showed worried outcomes such as neonatal pneumonia, preterm birth, postpartum infections to the mother, and COVID-19 vertical transmission to the fetus happened in pregnancy (Gatta et al., 2020; Mascio et al., 2020; Rodrigues et al., 2020; Yang et al., 2020). A study in Malaysia conducted to assess the knowledge on COVID-19 among pregnant women showed that 95% of them demonstrated enough knowledge of COVID-19 (Syed Anwar Aly et al., 2021) but not about the COVID-19 vaccinations.

COVID-19 may impact the health of mothers and newborns by altering immunological responses at the maternal-fetal interface (Liu et al., 2020). Since the pregnant women had a higher risk of contracting the severe infection, they already formed a vulnerable group because the changes were unique in pregnancy (Docherty et al., 2020). A vaccine's success is determined by its efficiency and acceptability (Goncu Ayhan et al., 2021). Therefore, this study clarified and identified the COVID-19 vaccine acceptance among pregnant mothers in the Obstetrics and Gynaecology (O&G) clinic in the Hospital USM. The researcher chose pregnant women as the respondents due to the high interest in the population, and USM is where the researcher studied.

1.2 Problem Statement

Not everyone will get vaccines simultaneously since there is the insufficient manufacturing capacity to meet global needs in 2021. Hence, the countries should follow the recommendations from WHO, which prioritize health workers as the frontliners and those with a higher risk of death from COVID-19, such as the elderly or people with morbidities problems (United Nations International Children's Emergency Fund (UNICEF), 2021). Pregnant women are potentially vulnerable to the Covid-19 virus due to the ongoing to learn the safety and side effects of COVID-19 vaccination during pregnancy. Still, there are no apparent advantages of vaccination for pregnant mothers (UNICEF, 2021). COVID-19 vaccination is an effective and safe approach to controlling the pandemic and decreasing associated morbidity and mortality (Mose & Yeshaneh, 2021). Pregnant women with good knowledge of COVID-19 and all the preventive measures are six times more likely to take the vaccines than poor knowledge in Mose & Yeshaneh (2021). This shows the maternal understanding of the severity of the virus to

both mother and fetus. Thus, to reduce the effect of the pandemic, they decided to take vaccination of COVID-19 (Mose & Yeshaneh, 2021).

Moreover, the hypotheses (Syed Anwar Aly et al., 2021) about the knowledge of COVID-19 will be affected by the women's education level, and adequate knowledge will lead to a good perception of the clinical care received. It has been proved that 95% of urban and educated women respondents have enough knowledge and more interest to combat the outbreak (Syed Anwar Aly et al., 2021). Nevertheless, a study to determine knowledge, acceptance, and perception of the COVID-19 vaccine among 1,406 Malaysian residents showed a total of 62.0%, 872 respondents had poor knowledge regarding the COVID-19 vaccine (Mohamed et al., 2021). Meanwhile, 64.5% of respondents indicated the acceptance of being vaccinated. The majority agreed if the government makes the vaccination accessible to high-risk groups (Mohamed et al., 2021). About 30% perceived they were susceptible to getting a severe infection, and 55% of respondents perceived being able to spread the virus to others. Also, 75% of them did not agree with the statement that infection can occur from the COVID- 19 vaccines (Mohamed et al., 2021).

Based on the result, we can conclude that most Malaysians still had poor knowledge about COVID-19 vaccines. A review of a study conducted during the COVID-19 pandemic by (Puspitasari et al., 2020) demonstrated that knowledge would directly influence attitudes and behaviors. To the best knowledge, there is still less study conducted in Malaysia to assess the COVID-19 vaccine acceptance among pregnant mothers. Most Malaysians were more likely to be vaccinated if female, had a higher education level, and had a lower age group (Mohamed et al., 2021). Hence, the study's main objective was to determine COVID-19 vaccine acceptance among pregnant women

in the O&G clinic at Hospital USM. With such information, this finding can help the Ministry of Health plan new future efforts to enhance the uptake of vaccines and eventually aid in achieving herd immunity against COVID-19.

1.3 Research Question

To guide the research study and inform the research, the following research questions were formulated:

- i. What are the acceptance rates of the COVID-19 vaccine among pregnant women in Hospital USM?
- ii. What are the reasons for refusing the COVID-19 vaccine among pregnant women in Hospital USM?
- iii. Is there any correlation between COVID-19 vaccine acceptance and sociodemographic factors?

1.4 Research Objectives

1.4.1 General Objectives

This study aims to assess the COVID-19 vaccine acceptance among pregnant women in Hospital USM.

1.4.2 Specific Objectives

The specific objectives for this study were:

- i. To determine the acceptance rates of COVID-19 vaccine among pregnant women in Hospital USM.

- ii. To determine the reasons for refusing the COVID-19 vaccine among pregnant women in Hospital USM.
- iii. To examine any correlation between COVID-19 vaccine acceptance and sociodemographic factors.

1.5 Hypotheses

H₀: There is no significant correlation between COVID-19 vaccine acceptance and sociodemographic factors.

H_A: There is a significant correlation between COVID-19 vaccine acceptance and sociodemographic factors.

1.6 Conceptual and Operational definitions

Table 1.1 Definition for the operational terms used in the dissertation

Terms	Conceptual	Operational
COVID-19	A novel coronavirus disease 2019, caused by SARS-CoV-2, is considered relative to severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome (MERS) (Sohrabi et al., 2020).	The acceptance of COVID-19 vaccines being asked in Part B in the instrument, which is the acceptance rates of COVID-19 vaccine of pregnant women to fight against COVID-19.

Vaccine	An effective way to protect the body from harmful diseases and make the immune system stronger is by using the body's natural defense to build resistance to specific infections (WHO, 2020b).	This study was regarding the acceptance of pregnant women to receive the COVID-19 vaccines during their pregnancy.
Acceptance	A concept opposed to the term refuse refers to a positive decision to employ an invention (Taherdoost, 2018).	In this study, the acceptance rates of the COVID-19 vaccine and the reasons for refusing them were assessed among pregnant women in the questionnaire using a 2-Likert scale question either yes or no.
Pregnant Women	Women that are having a baby or babies developing inside their womb (Cambridge Dictionary, 2021).	Pregnant women who visit the O&G clinic in Hospital USM had been the respondents for this study.

1.7 Significance of the study

Until now, Malaysia has still struggled to reduce the infection of COVID-19. This battle to fight COVID-19 is still ongoing worldwide. Also, to help the outbreak management among pregnant women, an urgent is needed to explain the awareness of COVID-19 at the critical moment (Ibrahim Mohamed et al., 2020). However, the vertical transmission has not yet been confirmed (Chen et al., 2020; Saccone et al., 2020). The women must feel fear and anxiety related to the infection, which later makes the demand to abort or use operative deliveries (Guan et al., 2020; Saccone et al., 2020). Furthermore, as primary health care providers, nurses supposedly provide health education for pregnant women's needs during antenatal visits.

In addition, the study focuses more on pregnant women, specifically in the Hospital USM. This is due to the less study conducted on the COVID-19 and obstetrics population. So, this study suggested that further health education intervention must be more effective, mainly targeting specific demographic groups such as pregnant women. The physiology of the women changed during pregnancy, making them vulnerable groups. COVID-19 vaccine may be the only way to prevent the poor outcome of the pregnancy. Finally, it will be significant to the obstetrics department in Hospital USM since we provide a new finding on the acceptance of COVID-19 vaccines from the maternal. Since this study also finds the reasons for pregnant women to refuse the vaccine, then a lot of benefits will be obtained if the negative thought can be changed. It also would facilitate modifying the policies and guidelines to successfully prevent COVID-19 due to the increasing uptake of obstetric vaccination population in Malaysia.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter will represent the literature review regarding the knowledge of pregnant women about the COVID-19 vaccines and their attitude towards this type of vaccination. It will also review the previous studies based on the COVID-19 Vaccinations. Lastly, the descriptions of the theoretical framework chosen will be presented in this chapter.

2.2 COVID-19 disease

Corona Virus Diseases 2019 (COVID-19) has magnificent colossal mortality and morbidity burdens among the general population worldwide (Nersesjan et al., 2020). Globally, evidence shows that until November 5, 2021, there were 5,027,183 deaths due to COVID-19 (WHO, 2021c). The higher risk of dying involves several diseases such as lung cancer, asthma, hypertension, Chronic Obstructive Pulmonary Disease (COPD), Alzheimer's, Ischemic Heart Disease, diabetes, and depression (M. J. Hashim et al., 2020). Also, there were six other sociodemographic factors for high-risk mortality: age over 65 years, unemployment, population density, urbanization, sociodemographic index, and Gross Domestic Product (GDP) per capita (Hashim, M. J. et al., 2020). Thus, enormous efforts were needed for governments to support the scientific community and pharmaceutical industry to develop efficacious and safe vaccines to fight this COVID-19 pandemic (Conte et al., 2020). The efforts were fulfilled by the approval of a few types

of vaccines. Malaysia has received the Pfizer COVID-19 vaccine and begun the immunization programs (J. H. Hashim et al., 2021).

2.3 Effects of COVID-19 on high-risk people

Like other viruses, the COVID-19 virus affected high-risk people, including older people above 65, immunocompromised people, children, and pregnant women (Brenner, 2021). The most vulnerable group with a greater risk of developing COVID- 19 is pregnant women. It was associated with poor outcomes such as preterm birth, cesarean delivery, preeclampsia (PE), ventilation, and death (Huntley et al., 2020; Mascio et al., 2020). On a global scale, reserving the restricted COVID-19 vaccines for the high-risk people and completing the immunization programs on time for these groups could reduce COVID-19 deaths before the herd immunity population is achieved (Brenner, 2021).

2.4 Clinical Manifestation of COVID-19

There are a few signs and symptoms that may be seen in COVID-19 patients. The most common symptoms are fever, cough, fatigue, or myalgia, while the distinctive signs include headache, hemoptysis (nosebleed), sputum production, and diarrhea (Huang et al., 2020). In other studies (Elibol, 2021), otolaryngological symptoms are more frequent in ages 18 to 30 than in different age groups. Although it was rare, symptoms such as tinnitus, sudden hearing loss, hoarseness, and gingivitis could still be seen in COVID-19 patients, and the result showed that females had a higher frequency of those symptoms than males (Elibol, 2021). Besides, the study (Huang et al., 2020) led to pneumonia. As this study conducted the pregnant women, the complications of getting COVID-19 should be ascertained. Most of them remain asymptomatic after being positive for COVID-19 or

having mild symptoms and then recovering without undergoing the delivery procedure (Wu & McGoogan, 2020).

Many will develop critical illness and could have prolonged and challenging disease courses (Huntley et al., 2020). Several systematic reviews regarding pregnancy and COVID-19 have been found. Commonly, the reported symptoms that pregnant women who experienced COVID-19 were cough, fever, fatigue, dyspnoea, diarrhea, myalgia, and sore throat (Yang et al., 2020). To conclude, most patients had cesarean delivery because of the indications. At the same time, other cases like stillbirth, preterm death, fetal distress, neonatal death, low birth weight, and neonatal asphyxia were reported as the complications of contracting COVID-19 (Gatta et al., 2020; Mascio et al., 2020; Yang et al., 2020).

2.5 Prevention and Treatment of COVID-19

The primary measure to minimize the transmission of COVID-19 in the community is by isolating the infected people as the Chinese Health Authorities take immediate action by making the suspected people quarantined (Wang et al., 2020). In Malaysia, the government asserted a standard precaution that must be abiding. For example, frequently hand wash with soap and water or using alcohol-based hand sanitizer, a social distancing of 2 meters, wear a mask in a crowded place, avoid touching eyes, mouth, and nose if the hand is soiled, also avoid handshaking (Elengoe, 2020; Singh Gill et al., 2020). Besides that, Malaysia also went into total nationwide lockdown from June 1, 2021, until June 14, 2021, when the cases hit a new record (Teoh Shannon, 2021). This is important to control the issues in a country.

As for treatment, until now, there is still no specific antiviral therapy confirmed by the WHO against COVID-19 (Adhikari et al., 2020; Singh et al., 2020). Nevertheless, some medicines can potentially treat COVID-19, such as Remdesivir, Chloroquine, and Hydroxychloroquine (Elengoe, 2020). For the patient who has symptoms of COVID-19, the appropriate treatment should be delivered, and supportive care, including oxygen therapy, fluid management, and antibiotics for secondary bacterial infections, are recommended (Huang et al., 2020). Since COVID-19 vaccines have been approved, they will prevent this virus (Abbasi, 2020; Tanne, 2020; Zieneldien et al., 2021).

2.6 COVID-19 vaccines

Previous studies have recognized a lot of information regarding COVID-19 vaccines, such as the types, the common adverse effects people can get from COVID-19 vaccines, and the rules and guidelines for pregnant women to take these vaccines. In this subtitle, these three points will be discussed in detail.

2.6.1 Types of Vaccines Used in Malaysia

The Pfizer-BioNTech vaccine is the first to have obtained conditional approval from the Drug Control Authority (DCA) and NPRA on January 8, 2021 (KKM, 2021a). Malaysia has gained access to 66.7 million doses as the supply of COVID-19 vaccine through the COVAX Facility and get initial purchases from five manufacturers of COVID-19 vaccine (KKM, 2021a). Until now, Malaysia has approved seven types of COVID-19 vaccines: Moderna mRNA-1273, Pfizer/BioNTech BNT162b2, CanSino Ad5-nCoV, and Janssen (Johnson & Johnson) Ad26.COV2.S, Oxford/AstraZeneca AZD1222, Sinopharm (Beijing) BBIBP-CorV (Vero Cells), and Sinovac CoronaVac

(McGill, 2021; Ministry of Health (MOH), 2021a). However, the vaccine's type will be administered randomly to individuals.

2.6.2 Side effects of COVID-19 Vaccines

The reported incidence in Malaysia of anaphylaxis due to vaccination is similar to developed countries (Elnaem et al., 2021). Widespread side effects such as injection site pain, muscle pain, fatigue, and fever have occurred in all the vaccines (Zare et al., 2021). The latest case report form (Eslam et al., 2021) described a new case of tinnitus in a 55-year-old female as a possible side effect after the first shot of Pfizer-BioNTech, an mRNA vaccine. (Dashraath et al., 2020) stated that it is possible to transfer maternally generated antibodies across the placenta without transferring the virus vector to the fetus. Unfortunately, pregnant women have historically been excluded from pharmaceutical research due to well-intentioned but occasionally erroneous worries about fetal safety (Dashraath et al., 2020).

2.6.3 Guideline for Pregnant Women to take the vaccines

According to the recent paper utilizing the V-safe after vaccination health checker, there are still no safety signals connected to mRNA COVID-19 vaccination (MOH, 2021b; Shimabukuro et al., 2021). No safety signals were associated with mRNA COVID-19 vaccinations, according to a recent paper employing the V-safe after vaccination health checker. This is consistent with the Malaysia Ministry of Health's recommendation of the Pfizer vaccination for pregnant and lactating moms. All the data documented adverse effects were rare, moderate, temporary, and manageable (MOH, 2021b).

The guidelines should include maternal and fetal safety monitoring, documenting problems, and offspring follow-up after delivery (Dashraath et al., 2020). Avoiding COVID-19 vaccination during the critical phase of the first trimesters is advisable out of caution due to protect before the vulnerable late second and third trimesters (Ministry of Health (MOH), 2021b). Therefore, it is recommended that the first dose of the vaccine be given during that time, while the second dosage can be given after thirty-three weeks, depending on the vaccine's timetable (MOH, 2021b). If there were simultaneous other vaccines in pregnancy, such as anti-tetanus toxoid (ATT), the first recommendation was to wait a minimum of 4 days before receiving the COVID-19 vaccine (MOH, 2021b).

2.7 The acceptance rate of COVID-19 Vaccines among pregnant women

Malaysia still had no study conducted regarding the COVID-19 acceptability among pregnant women. Understanding the barriers to vaccination acceptance and the factors that influence vaccine acceptability will help speed up vaccine delivery in the obstetrics population in Malaysia. A few studies are carried out regarding the COVID-19 vaccine acceptance among pregnant women in other countries. A survey from 16 countries showed the approval was generally higher in India, the Philippines, and all sample countries in Latin America but lowest in the United States, Australia, and Russia (Skjefte et al., 2021). If effectiveness of 90% was obtained, 52.0% (n = 2747) of pregnant women expected to get the COVID-19 vaccine throughout their pregnancy (Skjefte et al., 2021).

The responses differed significantly by nation (range: 28.8– 84.4%) (Skjefte et al., 2021). The outcome of the acceptance must have differed for each country. Thus, the study (Skjefte et al., 2021) shows COVID-19 vaccination was well- received by pregnant

women in Mexico and India, but not so much in the United States, Australia, or Russia, and the difference in the acceptance must be affected by other factors influencing someone to receive the vaccine. Contrarily, Stuckelberger et al. (2021), in a trial study in Switzerland (29.7%) among pregnant and breastfeeding women, and in Geoghegan et al. (2021) investigations among pregnant women in Ireland found the lowest vaccination acceptance rates among pregnant women (38%). Seven out of nine studies noted that more than 50% of pregnant women accepted the vaccines (Januszek et al., 2021).

This current study imitated a study from Ankara, Turkey, entitled COVID- 19 vaccine acceptance in pregnant women and participated by 300 pregnant women respondents (Goncu Ayhan et al., 2021). The study's outcome appeared to be only 37% (n=111) of the pregnant women who intended to get the COVID-19 vaccine if the vaccines were recommended in their pregnancy (Goncu Ayhan et al., 2021). It was totally in contrast with the study in Durban, South Africa which 63.3% of 346 pregnant women reported accepting the COVID-19 vaccine once it became available (Hoque et al., 2020). The past study of COVID-19 vaccine acceptability was decomposed by region and study type. The research from China (77.4%) by Tao et al. (2021), Qatar (75%) by Mohan et al. (2021), and Italy (74.5%) by Mappa et al. (2021) showed the greatest vaccine acceptance rate among pregnant women (2021).

Besides, pregnant women were reported to have the lowest rate of acceptance of the COVID-19 vaccine (44.3%; $P<0.001$) compared to nonpregnant (76.2%; $P<0.001$) and breastfeeding (55.2%; $P<0.001$) in Sutton et al. (2021). Another study by Levy et al. (2021) indicated 58.3% (95% CI, 54.5-62.2), of which 381 from 653 pregnant women would take COVID-19 during their pregnancy. Of the more significant respondents of pregnant women who were 1392 in China, 77.4% (95% CI, 75.1-79.5) would willingly

get the COVID-19 vaccine (Tao et al., 2021). Therefore, this study is conducted to fill the gap in which the outcome of pregnant women in Malaysia will be known since there is no such study conducted in Malaysia.

2.8 Reason for refusing COVID-19 Vaccines among pregnant women

There were many factors regarding the pregnant women would refuse the COVID-19 vaccine. This may be numerous reasons behind the refusal, according to the individuals. A study in Indonesia among the public population, including 1359 people, showed that 93.3% (n=1268) of them agreed to be vaccinated if only for the 95% COVID-19 vaccine effectiveness. Still, the number reduced to 67.0% (n=911) if the vaccine was only 50% effective (Harapan et al., 2020). It was relatable that the effectiveness of the COVID-19 vaccine might affect the acceptance of pregnant women being vaccinated.

Furthermore, Marzo et al. (2021) analysed that 1282 Malaysian considered that 95.5% of them had thought that the COVID-19 vaccine would be an effective way to control and prevent the virus. The study also explained that vaccine convenience (95.7%) and the doctor's recommendation (97.3%) were the important factors that influenced the COVID-19 vaccination decision (Marzo et al., 2021). Both general population studies represent the random individuals' thoughts and perceptions of the COVID-19 vaccine. Thus, this study is conducted to determine why the specific population, pregnant women, refuses to receive those vaccines.

It is crucial to keep in mind that no study has yet demonstrated the COVID-19 vaccine's safety for unborn and newborn recipients while considering the risks and benefits of vaccinations (Oliver et al., 2020). This issue may become one of the worrying matters for the mothers to take the vaccines in the first place. However, a recent

prospective cohort study (Gray et al., 2021) recognized that all umbilical cord blood and breastmilk samples were present with the vaccine-generated antibodies. In addition, with the vaccine booster, the SARS-CoV-2 specific IgG, not IgA, was increased in the maternal blood and breastmilk (Gray et al., 2021). So, pregnant women should not be worried that the vaccine may not be effective during the pregnancy. Even so, a balanced and precise assessment of the COVID-19 risk in pregnancy should be provided to pregnant women and counseled about the direct and indirect benefits of the COVID-19 vaccine while acknowledging the limited safety data (Kalafat et al., 2021).

According to a study by Goncu Ayhan et al. (2021), there were three main reasons for pregnant women who experiences low-risk pregnancy refuse the vaccine. First, they think the COVID-19 vaccine could harm their health. Next, they also believed that the vaccine is ineffective, and some of them have family members who are hesitant about the COVID-19 vaccine ($P < 0.05\%$). To conclude, this study was conducted to find out the exact reason for pregnant women who refuse the vaccine.

2.9 Factors associated with COVID-19 vaccine acceptance

To increase the uptake of the COVID-19 vaccination among pregnant women, the associated factors must be ascertained. In this study, the socio-demographic data will be observed to discover the relationship that could impact pregnant women's vaccination decisions. The socio-demographic data include age, ethnicity, education level, career, household income, gravida, parity, gestational age, and co-morbidity. A study by Pairat & Phaloprakarn (2022) revealed no significant relationship between socioeconomic status, education, occupation, monthly income, and public health insurance coverage with the acceptance of the COVID-19 vaccine in Thailand.

Pregnant women expressed higher acceptance to take the COVID-19 vaccine in their first trimester ($P<0.05$) compared to in the second and the third trimesters (Goncu Ayhan et al., 2021). In the study of the general population in Saudi Arabia, the respondents aged 45 years and above, married, and had postgraduate education or higher (68.8%) had a significant association with the COVID-19 vaccine acceptance (Al-Mohaithef & Padhi, 2020).

A study in Malaysia reported that the factors influencing might differ due to the different places and cultures (Marzo et al., 2021). In the study, those less than 24 years of Malay, living in urban areas, had tertiary education, students, single, and had family income between RM4,850-RM10,959 and >RM10,960 were all significantly associated with vaccine acceptance COVID-19 vaccination (Marzo et al., 2021). Additionally, the acceptance rate of COVID-19 vaccine among 1392 pregnant women in five provinces of mainland China had associated with young age (aOR = 1.87, 95% CI: 1.20–2.93), late pregnancy (aOR = 1.49, 95% CI: 1.03–2.16) and high knowledge of COVID-19 (AOR = 1.05, 95% CI: 1.01–1.10) (Tao et al., 2021).

Related to the coverage and safety during pregnancy, a cohort study from (Blakeway et al., 2021) with 1328 respondents resulted in a decreased vaccine intake in a young woman ($P<0.001$) while there was increased uptake in pre-pregnancy diabetes mellitus women ($P=0.008$). The result also showed that 1188 pregnant women did get the COVID-19 vaccine before giving birth, and 140 received at least one dose, which 85.7% of those vaccinated received in the third trimester, yet only 14.3% obtained in the second trimester (Blakeway et al., 2021).

2.10 Theoretical/Conceptual Framework of the Study

The Cognitive-Affective-Normative (CAN) model was chosen as the theoretical framework for this study. This model was developed to justify adopting a new product or service (Pelegrín-Borondo et al., 2016). The CAN model was created from a few models, which were the Theory of Planned Behavior (TBP) (Ajzen, 1991), Technology Acceptance Model (TAM) (Venkatesh & Davis, 2000), Theory of Reasoned Action (TRA) (Dillard & Pfau, 2002) and Unified Theory of Acceptance and Use of Technology (UTAUT) models (Venkatesh et al., 2003).

Pelegrín-Borondo et al. (2021) stated that cognitive (performance expectation, effort expectancy), affective (good emotions, negative emotions, anxiety), and normative (social influence) variables are all addressed in theory. The model is well-suited to the current research purpose, which is to investigate the variables that influence the vaccination acceptability of the COVID-19 vaccine. The model provided here is a modified version of the CAN model that includes vaccination efficacy as a cognitive variable, vaccine fear and COVID-19 fear as emotional variables, and social influence as a normative variable (Pelegrín-Borondo et al., 2021).

First, the perceived efficacy of the COVID-19 vaccination influence people's decision to use it. In the context of vaccine acceptance, fear of the disease has been demonstrated to have a distinct impact than fear of the vaccination (Anraad et al., 2020a; Nguyen et al., 2020). Similarly, fear of vaccination side effects has been found to be a significant disincentive to becoming vaccinated (Anraad et al., 2020b; Otieno et al., 2020), with fear of both short-term and long-term adverse effects impacting behavior in distinct ways (Borena et al., 2016).

Second, the fear of COVID-19 positively impacts people's willingness to receive the vaccination. The third point of this model is people's willingness to utilize the COVID-19 vaccination is limited by concerns about the vaccine's negative consequences. The previous study has shown the significance of the opinions of individuals to be influential in vaccine acceptance (Al-Mohaithef & Padhi, 2020; Fu et al., 2017; Sarathchandra et al., 2018). Hence, doctors and healthcare organizations' recommendations are predicted to significantly influence people's willingness to become vaccinated, particularly in the case of COVID-19 (Pelegín-Borondo et al., 2021).

This is due to novel viruses, and the only knowledge and possible vaccinations accessible are from doctors, biologists, healthcare institutions, government agencies, and the scientific community. The fourth and last point of this CAN model is a tremendous social influence has a beneficial impact on people's intentions to take the COVID-19 vaccination. Figure 2.1 shows the adapted CAN model used in the research of COVID-19 vaccine acceptance.

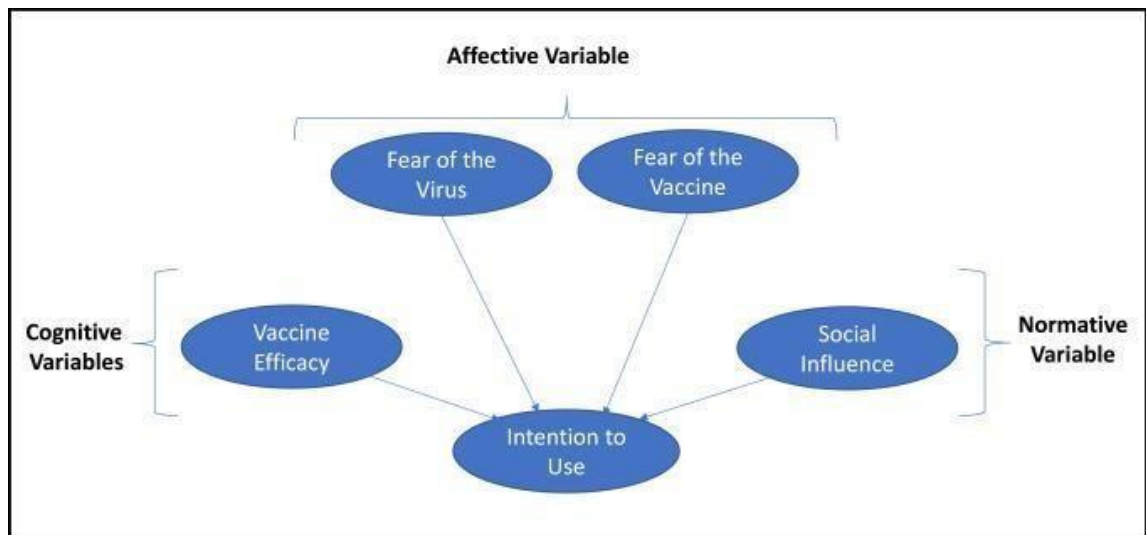


Figure 2.1: COVID-19 Vaccine Acceptance Model (adapted CAN model)

(Pelegrín-Borondo et al., 2021)

Since this study assesses the acceptance of the COVID-19 vaccine among pregnant women, the conceptual framework will adopt the CAN model. However, some modification was done to the original model. The study also identified the correlation between COVID-19 vaccine acceptance and sociodemographic characteristics, leading to the vaccine's intention. The CAN model explained important cognitive, affective, and normative variables. Thus, the conceptual framework adapts this model to show how pregnant women intend to be vaccinated. The first cognitive variable plays a considerable role in the COVID-19 vaccine efficacy. Pregnant women would be emotional and fearful, especially with the physiological changes in their bodies. They must be worried about the vaccine's effectiveness, which may benefit their fetus or vice versa.

Next, for the affective variables, the pregnant women, to be sure, must be afraid of both COVID-19 disease and the vaccine. It would be harmful and life-threatening if they had COVID-19 during the pregnancy. The virus may also affect the fetus and lead to poor pregnancy outcomes such as preterm labor and stillbirth. Indeed, if they choose to take the COVID-19, they must fear if the vaccine may harm the baby or not. The recommendation for pregnant mothers to take this vaccine is still up to date since they include the vulnerable group and high risk. The third variable is normative, and social influence greatly affected this. Pregnant women may be discouraged by their family and friends from taking the COVID-19 vaccine. This is more worrying when the thought of the beloved people is being agreed upon and followed. Therefore, the study focused on the acceptance rates and why pregnant women refuse the COVID-19 vaccine. Figure 2.2 shows the conceptual framework for this study.

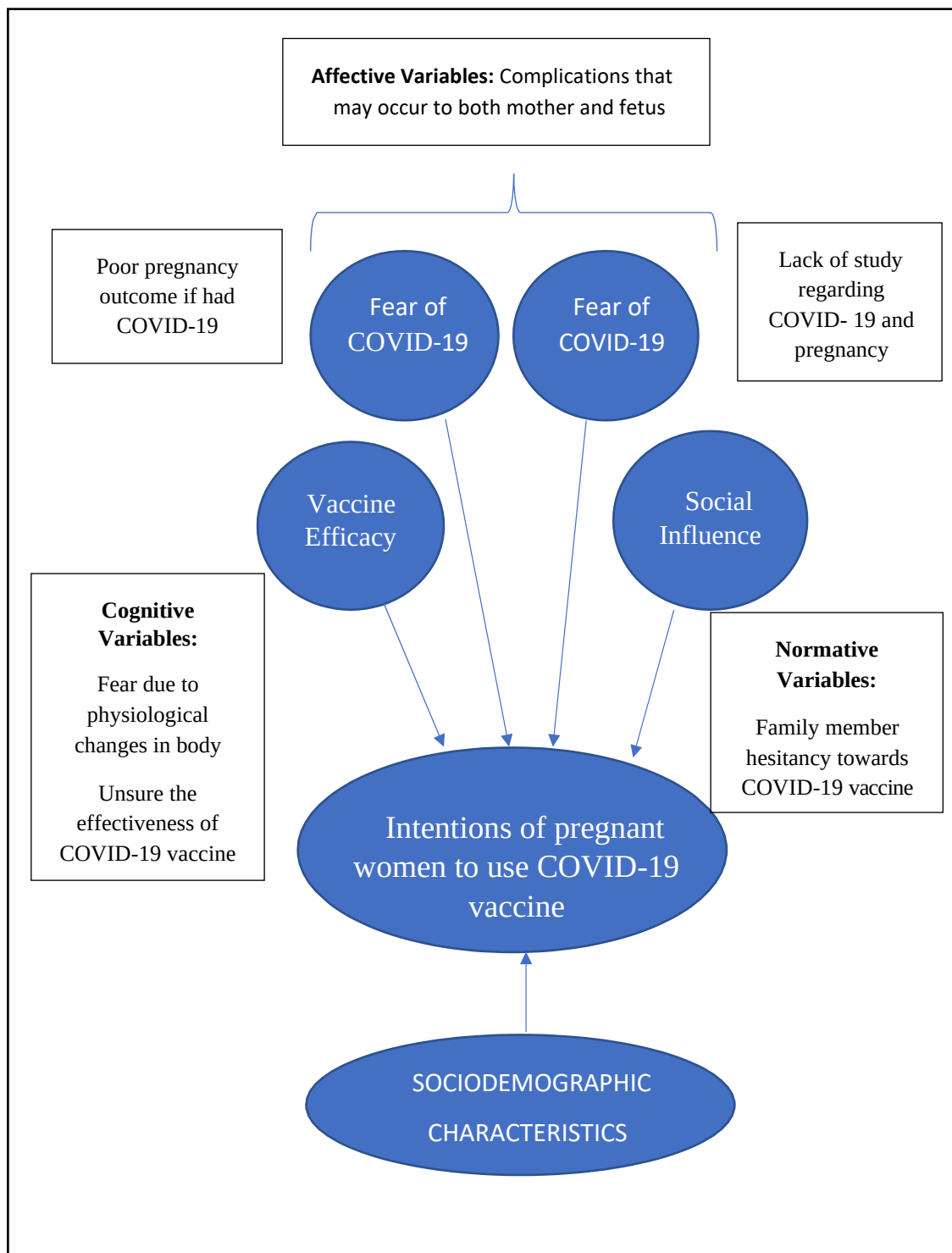


Figure 2.2: COVID-19 Vaccine Acceptance Model (adapted CAN model)

Adaption from (Pelegrín-Borondo et al., 2021)