DEVELOPMENT AND VALIDATION OF KNOWLEDGE AND ATTITUDE ON COVID-19 INFECTION AND VACCINATION TOWARD PREGNANCY QUESTIONNAIRE AND VALIDATION OF ADULT VACCINE HESITANCY SCALE (AVHS) AMONG PREGNANT WOMEN.

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DEVELOPMENT AND VALIDATION OF KNOWLEDGE AND ATTITUDE ON COVID-19 INFECTION AND VACCINATION TOWARD PREGNANCY QUESTIONNAIRE AND VALIDATION OF ADULT VACCINE HESITANCY SCALE (AVHS) AMONG PREGNANT WOMEN.

by

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LIST OF SYMBOLS

χ^2 Chi-square

LIST OF ABBREVIATIONS

AMOS	Analysis of a Moment Structure
aVHS	Adult Vaccine Hesitancy Scale
BRUSO	Brief, Relevant, Unambiguous, Specific, and Objective
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
COVID-19	Coronavirus Disease of 2019
CVI	Content Validity Index
df	Degree of freedom
DNA	Deoxyribonucleic acid
EFA	Exploratory Factor Analysis
FMSA	Malaysian Family Medicine Specialists Association
FRGS	Fundamental Research Grant Scheme
FVI	Face Validity Index
HRPZ (II)	Hospital Raja Perempuan Zainab II
HUSM	Hospital Universiti Sains Malaysia
I-CVI	Content validity of individual items
IPS	Institut Pengajian Siswazah
KA	Knowledge Attitude
KAP	Knowledge, Attitude Practice Theory
MCO	Movement Control Order
MERS	Middle East Respiratory Syndrome Coronavirus
PCA	Principal Component Axis
pKAC19	Pregnancy Knowledge Attitude COVID-19
PPE	Personal Protective Equipment
pVHS	Pregnancy Vaccine Hesitancy Scale
RMSEA	Root Mean Square Error of Approximation
SARS	Severe Acute Respiratory Syndrome Coronavirus
S-CVI/UA	Scale-level content validity index based on the universal agreement method
SPSS	Statistical Package for Social Science
SRMR	Standardized Root Mean Square Residual
TLI	Tucker–Lewis Index

VHM   Vaccine Hesitancy Model

B40   Household income under RM5000

M40   Household income in between RM5000 – RM10 000

T20   Household income RM10 000 and above

HBM   Health Belief Model

LIST OF APPENDICES

PEMBANGUNAN DAN PENGESAHAN SOAL SELIDIK PENGETAHUAN DAN SIKAP TERHADAP JANGKITAN DAN VAKSINASI COVID-19 TERHADAP KEHAMILAN DAN PENGESAHAN SKALA HESITANCY VAKSIN DEWASA (AVHS) DALAM KALANGAN WANITA HAMIL.

ABSTRAK

Kehamilan adalah salah satu risiko jangkitan COVID-19 yang teruk dan penerimaan vaksin COVID-19 dalam kalangan wanita hamil masih menjadi isu. Kajian ini bertujuan untuk menghasilkan dan mengesahkan soalan kaji selidik tentang pengetahuan dan sikap terhadap jangkitan dan vaksinasi COVID-19 di kalangan wanita hamil. Ia juga untuk mengesahkan *Pregnancy Vaccine Hesitancy Scale (pVHS)* untuk menilai keraguan vaksin dalam kalangan wanita hamil di Malaysia. Terdapat enam panel pakar yang terlibat dalam pengesahan kandungan item pengetahuan dan sikap selepas dikenal pasti. Kira-kira 10 wanita hamil terlibat dalam *face validity* diikuti ujian *reliability*: *Exploratory Factor Analysis (EFA)* melibatkan 200 wanita hamil yang hadir di Klinik Obstetrik dan Ginekologi, Hospital Universiti Sains Malaysia, Kelantan. *Confirmatory Factor Analysis (CFA)* melibatkan 300 wanita hamil daripada klinik Obstetrik dan Ginekologi, Hospital Raja Perempuan Zainab II (HRPZ), Kelantan. Semasa Fasa 1: Indeks Pengesahan Kandungan Peringkat Item (I-CVI) ialah 0.96 untuk pengetahuan dan 0.99 untuk sikap manakala 1.00 untuk keraguan vaksin COVID-19, menunjukkan perkaitan yang baik daripada 20 item untuk menilai pengetahuan dan 22 item digunakan untuk menilai sikap manakala 10 item digunakan. untuk menilai keraguan. Fasa 1: Indeks Kesahan Muka Peringkat Item (I-FVI) yang diperolehi ialah 0.99 untuk pengetahuan, 0.98 untuk sikap dan 0.99 untuk

soal selidik keraguan terhadap vaksin COVID-19 menunjukkan item tersebut jelas dan boleh difahami. Fasa 2: EFA telah dijalankan, dan semua item mendapat pemuatan factor yang bagus kecuali dua item dari domain keraguan terhadap vaksin COVID-19 yang telah dibuang dari set soalan. Fasa 2: CFA telah dilakukan selepas itu dengan baki item dalam soal selidik. Model yang dicadangkan sesuai dalam kesemua lima indeks model ($\chi2$ = 1079.584 (499) p <0.001; RMSEA = 0.062; CFI = 0.917; TLI =0.857) dengan pemuatan faktor berjulat dari 0.22 hingga 0.92. Item akhir yang tinggal menghasilkan soal selidik yang baru digabungkan dengan 3 domain iaitu pengetahuan (16 item), sikap (10 item) dan keraguan terhadap vaksin COVID-19 (8 item). Skor *Cronbach Alpha* masing-masing adalah 0.66, 0.81 dan 0.94 untuk pengetahuan, sikap dan keraguan. Soal selidik versi Bahasa Melayu yang baru digabungkan yang antara soalan pengetahuan dan sikap terhadap jangkitan dan vaksinasi COVID-19 dan *Pregnancy Vaccine Hesitancy Scale (pVHS)* didapati sah dan boleh dipercayai untuk menguji pengetahuan dan sikap terhadap jangkitan dan vaksinasi COVID-19 dalam kalangan wanita hamil di Malaysia.

DEVELOPMENT AND VALIDATION OF KNOWLEDGE AND ATTITUDE ON COVID-19 INFECTION AND VACCINATION TOWARD PREGNANCY QUESTIONNAIRE AND VALIDATION OF ADULT VACCINE HESITANCY SCALE (AVHS) AMONG PREGNANT WOMEN.

ABSTRACT

Pregnancy is one of the risks for severe COVID-19 infection and COVID-19 vaccination hesitancy among pregnant women is still an issue. This study aims to develop and validate the knowledge and attitude (pKAC19) to examine COVID-19 infection and vaccination among pregnant women. It also validates the Pregnancy Vaccine Hesitancy Scale (pVHS) to assess vaccine hesitancy among pregnant women in Malaysia. First phase involved the development of new Knowledge and Attitude (pKAC19) and the adaptation of the aVHS, second phase includes a cross-sectional study for internal validation of the new Knowledge and Attitude (pKAC19) to assess the knowledge and attitude on COVID-19 infection and vaccination toward pregnancy and vaccine hesitancy among pregnant women using EFA. Meanwhile, CFA data collection; a cross-sectional study was conducted to confirm Knowledge and Attitude (pKAC19) validation. During phase 1, face and content validity were performed; meanwhile, during phase 2, EFA and CFA were performed in two locations with larger sample sizes. Six expert panels were involved in content validity after the items for knowledge and attitude and COVID-19 vaccine hesitancy were evaluated. About ten pregnant women were involved in the face validity followed by reliability testing: Exploratory Factor Analysis (EFA) involving 200 pregnant women attending Obstetrics and Gynaecology Clinic, Hospital Universiti Sains Malaysia, Kelantan. Confirmatory Factor Analysis (CFA) involved 300 pregnant women from Obstetrics

and Gynaecology clinic, Hospital Raja Perempuan Zainab II (HRPZ), Kelantan. During Phase 1: Content Validity, the item-level content validity index (I-CVI) is 0.96 for knowledge and 0.99 for attitude while 1.00 for COVID-19 vaccine hesitancy, demonstrating good relevance of the 20 items to assess knowledge and the 22 items used to assess attitude while 10 items used to assess vaccine hesitancy. Phase 1: Face Validity index (I-FVI) obtained is 0.99 for knowledge, 0.98 for attitude and 0.99 for COVID-19 vaccine hesitancy questionnaires, indicating that the items were clear and comprehensible. Phase 2: EFA was conducted, and all items had good factor loadings; two items from COVID-19 vaccine hesitancy domain were removed due to low factor loadings where the cut-off point for factor loadings should be more than 0.3 (Samuels, 2017). Phase 2: CFA was performed afterwards with the remaining items in the questionnaire. The proposed model fit in all five model indices with ($\chi2$ = 1079.584 (499) p <0.001; RMSEA = 0.062; CFI = 0.917; TLI =0.857) with factor loading ranged from 0.22 to 0.92. The final remaining items produced a newly combined questionnaire with 3 domains which are knowledge (16 items), attitude (10 items) and COVID-19 vaccine hesitancy (8 items). The Cronbach alpha scores were 0.66, 0.81 and 0.94 for knowledge, attitude, and COVID-19 vaccine hesitancy, respectively. The newly combined Malay version questionnaire which included the newly developed Knowledge and Attitude (pKAC19) and adapted version of Adult Vaccine Hesitancy Scale (aVHS) which turned into Pregnancy Vaccine Hesitancy Scale (pVHS) is found valid and reliable to test the knowledge and attitude towards COVID-19 infection and vaccination and COVID-19 vaccine hesitancy among pregnant women in Malaysia.

CHAPTER 1

INTRODUCTION

1.1   Background of Study

1.1.1   What is COVID-19

Coronavirus disease (COVID-19) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Chin et al., 2022). Coronavirus is a family of viruses that attack the respiratory and intestinal organs and cause patients to have breathing difficulties, high fever, and severe body aches (Zeidler & Karpinski, 2020). This deadly virus could sometimes be distinguished as minor respiratory symptoms. Still, Severe Acute Respiratory Syndrome Coronavirus (SARS) and Middle East Respiratory Syndrome Coronavirus (MERS), which are also coronaviruses, can cause severe respiratory diseases (Zeidler & Karpinski, 2020). COVID-19's symptoms could appear in asymptomatic conditions to severe breathing difficulties, septic shock, organ failure and death (Guan et al., 2020). The mode of transmission for COVID-19 was primarily via respiratory droplets from one person to another when an infected person coughs or sneezes (Güner et al., 2020). The virus can land on one's mouth or nose and inhale into the lungs (Güner et al., 2020).Clinical symptoms caused by SARS-CoV-2 differ from non-symptomatic to even severe respiratory failures (Gralinski & Menachery, 2020), where affected patients have a fever, dry cough, and shortness of breath (Gralinski & Menachery, 2020).

1.1.2   COVID-19 Pandemic Outbreak

A pandemic is a condition with a large scale of infectious disease cases, causing increased morbidity and mortality while affecting the world's economy social and political growth (Madhav et al., 2017). Two years ago, coronavirus was first

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detected and infected 15 people in an exotic animal market in Wuhan, China, yet it was still unidentified and infamous among citizens at that moment (Wilkinson et al., 2022). It was known as pneumonia, caused by mysterious etiologic agents related to a market selling live animals in the capital (Bogoch et al., 2020). Since the coronavirus emergence in late 2019, several mutations, such as Alpha, Beta, Delta and Gamma, while the Omicron variant began to be identified in 2021 and continued to evolve (Shrestha et al., 2022).

In late January 2020, around a month after the first cases were detected, 12,540 confirmed cases, counting 306 deaths (World Health Organization, 2022). In the meantime, China was the first to enforce Movement Control Order (MCO) in Wuhan to ensure social distancing and lockdown (Hashim et al., 2021). Later, the lockdowns progressed to other cities in China. Since the first cases of COVID-19 were detected in Malaysia in late January 2019 (Tang, 2022), people travelled in and out of China. Other countries, including Malaysia, implemented the MCO with various terms (Hashim et al., 2021).MCO was a home confinement where everyone was obliged to stay home and avoid interacting with other people outside their houses (Tang, 2022). This means working at home, travelling within a certain distance, home-school through online teaching outdoor activities, shutting down businesses until further notice, and crowding the house all the time. Because of the lockdown and social distancing, the world was blown in several forms, including medical and non-medical drawbacks. Practically, by explicitly identifying the agent and what causes the disease, it was easier to provide information about the preventive measures, symptoms, and treatments. Its speedy spread caused limited hours for the medical team to provide the best treatment to completely overturn the tables (Boshra et al.,

2022). This lack of clinical information was unmatched by the expeditions; the infection caused many confirmed cases and deaths.

There are several steps in implementing preventive measures, such as physical hygiene, especially hands, personal protective equipment (PPE), social distancing, sanitising, self-test kits, and vaccination (Güner et al., 2020). Physical hygiene includes avoiding touching your face with bare and contaminated hands, frequently washing hands, adequate sanitising, and covering your mouth if coughing (Güner et al., 2020). Meanwhile, social distancing includes quarantine, avoiding crowded places, working at home, and home learning. Besides, PPE includes face masks, gloves, and face shields (Güner et al., 2020). Even so, sanitising includes frequently touched spaces in an area, such as a doorknob, which should be handled carefully so as not to harm anyone (Prajapati et al., 2022). On the other side, self-test kits or COVID-19 home antigen tests were still under development to produce the most accurate antigen detection since at earlier usage, RT-PCR, or molecular testing, in general, have been the primary determinants of viral genomic regions (Yüce et al., 2021). The following preventive measure is the vaccination program. Vaccination is a medical attempt to reach herd immunity (Hashim et al., 2021).

1.1.3   Global Impact of COVID-19 Pandemic

Globally, the COVID-19 pandemic has caused drawbacks in both medical and non-medical fields. In terms of medical, after the first cases were detected, 12,540 confirmed cases, counting 306 deaths (World Health Organization, 2022), while a total of 2.63% of the mortality rate for pregnant women due to COVID-19 infection occurred more among pregnant women with co-morbid severe illness (Tekin et al., 2022) which showed a massive number of mortality and morbidity worldwide. The

psychological state of the people being confined in their homes for some duration could be triggered by the fear of losing their loved ones, panic over the economy and risks of infection and sudden changes in the social environment (Al-Sejari & Al-Ma'seb, 2022). The changes in the psychological state have caused further severe mental health issues among the family members, thus abusing one another due to being stuck in their own house all the time (Al-Sejari & Al-Ma'seb, 2022). Conversely, domestic violence cases increased briskly during the COVID-19 lockdown. According to a Brazil study, there is a 17% increase in complaint calls for domestic violence and over the state, domestic violence has increased by 50% since the pandemic outbreak (Galvani G, 2020), while in the United States, more purchases of guns led by the stress and caused domestic violence cases (Campbell, 2020). Physical changes were also noticed when the pandemic lockdown first started. A study found that changes in body weight are due to switches in diet patterns, physical activities, and sleep quality (Chin et al., 2022). Another study claimed that the lockdown could cause unhealthy eating patterns such as more snacking, eating foods that suit their palate with undefined balanced nutrition, and alcohol consumption (Sidor & Rzymski, 2020). These findings show that the COVID-19 pandemic lockdown has caused disadvantages in terms of medicine.

Scoping through, these micro-sized viruses had challenged the world of medicine and compromised other industries (Boshra et al., 2022). This includes manufacturing sectors, transportation, food supply, and civil aviation. Tourism and cultural sectors, agriculture, reported by the International Labor Organization (ILO) in 2022. Unexceptionally, the global economy concluded that millions of people were pushed into poverty (Blake P & Wadhwa D, 2020). Blake and Wadhwa (2020) stated that according to the 2022 Poverty and Shared Prosperity Report, as lockdowns

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affected manufacturing, construction, and other services, those affected will be most likely to be transferred into the fields yet being underpaid, causing them to be trapped in poverty (Blake P & Wadhwa D, 2020). In Malaysia, the dramatic lifestyle changes affected their eating, sleeping, negative emotions, and physical activities (Zhang et al., 2020). Malaysia's economy was also severely affected due to the preventive measures taken by the government, which caused a precise reduction in the country's income and household income (Yusuf & Oyelakin, 2022).

1.1.4　COVID-19 and Risks of Infection

Some factors that influence the risks of COVID-19 infection are the length of time for exposure to disease, symptoms, wearing masks, ventilation, and social distancing (Buitrago-Garcia et al., 2022). According to the article, more prolonged exposure would increase the risk for infection and being around people with symptoms, not practising wearing masks, being poorly ventilated indoors and being close or touchy with another person (Buitrago-Garcia et al., 2022). In contrast, it is safer to avoid being in a crowd or close to anyone physically, avoid asymptomatic people, wear masks, and ensure the houses are well-ventilated to reduce the risks of COVID-19 infection (Buitrago-Garcia et al., 2022).

1.1.5　COVID-19 Infection in Pregnancy

As of 12 December 2022, the World Health Organization's COVID dashboard reported 651,918,402 confirmed cases and 6,656,601 deaths (WHO Coronavirus (COVID-19) Dashboard, 2022). While among 300,000 pregnant women, 12%-33% developed positive COVID-19 symptoms (Berghella & Hughes, 2022). According to the COVID-19 spectrum infection systematic review, pregnant women whom COVID-19 infects have risks of miscarriage, preterm birth, preeclampsia, might have to change to caesarean delivery, and potential prenatal deaths and NICU admission

compared to uninfected pregnant women (Di Mascio et al., 2020). However, Wilkinson (2022) found no comparable evidence of perinatal death rates and foetal growth issues between infected and non-infected pregnant women (Wilkinson et al., 2022). Meanwhile, a study by Wong (2022) stated that there was a slight possibility for newborns to be infected by COVID-19 through their mothers. Yet, in previous studies, some findings showed that the COVID-19 virus affects and causes other neonatal complications (Y. P. Wong et al., 2021). COVID-19's strain, the Delta Variant, was found to be transmissible and pile up in the respiratory system rapidly that despite a lower vaccination rate than other general populations, pregnant women are more receptive to COVID-19 infection (Rangchaikul & Venkataraman, 2021). Generally, these studies supported that COVID-19 infection could affect pregnant women and their babies at some level. Other than perinatal mortality, other impacts of COVID-19 infection included respiratory distress syndrome, hyperbilirubinemia, breastfeeding rates at discharge and the length of stay in neonatal care (Norman et al., 2021). Besides, some of the infected pregnant experienced severe symptoms that required them to be admitted to intensive care unit (ICU) and a number of the infected pregnant women transmitted the virus onto their newborns (Díaz-Corvillón et al., 2020). Furthermore, a study confirmed that more than 60 mothers with a history of being infected by COVID-19 had prematured birth caused by the infection where maternal anemia being used by the main predictor for prematurity birth associated with COVID-19 infection (Hrubaru et al., 2022). Those impacts reflect physical and health impacts towards pregnancy if a pregnant mother is infected by the COVID-19 virus. Impacts in social and financial are mostly related to each other. Past studies found that a pregnant woman being infected by COVID-19 is more fragile and vulnerable towards than a non-pregnant women's body (Wastnedge et al., 2021). This

is because during pandemic outbreak, the social inequalities became more gapped due to limited access to physical interaction and that altogether causing the severing economic condition to drive more women towards poverty (Wastnedge et al., 2021). In terms of emotional impact, pregnant would tend to become more anxious and stressful as the adrenal axis is detected to be more active once pregnant woman is infected (Wastnedge et al., 2021), it induced an upregulation of inflammatory pathways, exhibiting a robust correlation with neuropsychiatric disorders in subsequent offspring (Wastnedge et al., 2021). These experienced conditions and potential risks of developing more impacts have brought pregnant women as the group that needs attention, to provide prevention from being infected thus the pregnant women being chosen as the population for this study.

1.1.6   COVID-19 Vaccination

Vaccination is an effort to give someone a type of vaccine into one's body to prevent them from being infected by some disease (World Health Organization (WHO), 2023). Types of COVID-19 vaccines are varied, such as Comirnaty (BioNTech/Pfizer), Spikevax (Moderna), COVID-19 vaccine Janssen (Johnson & Johnson), and Vaxzevria (AstraZeneca) (Stöcker et al., 2023). To contain the COVID-19 infection, countries, including Malaysia, pledged commitment to WHO to start vaccine clinical trials in nine hospitals around the state (Hashim et al., 2021). Despite the concern about the speed of vaccine development, Malaysia spent billions to procure the vaccines and started vaccination programs in February 2021 (MOH, 2021). The first phase involved in the vaccination were frontliners, high-risk groups, and adults aged 18 and above (Hashim et al., 2021). Several types of COVID-19 vaccines are the mRNA, viral vector and protein subunits. Shortly, the mRNA vaccine contains the mRNA, which can alert our immune systems and provide protection from germs.

Meanwhile, the vector vaccines use a modified version of the different viruses other than the COVID-19 virus to let our system learn and protect in the future. Lastly, the protein subunit vaccine uses pieces of COVID-19 virus as spike protein to teach our immune system to respond better to the actual virus in the future. Since these vaccines do not contain a live virus, their ingredients would not cause infection from getting vaccinated. It does not interact with the consumer's DNA (*Myths and Facts about COVID-19 Vaccines*, 2023). Vaccination is a medical attempt to reach herd immunity (Hashim et al., 2021). Before it arrived in the state, the public was advised to practise strict preventive measures such as social distancing and their best hygiene (Hashim et al., 2021). The public needs to get vaccinated as a study found that the

vaccination rate within a population significantly influences the mortality and severity caused by the virus (Shrestha et al., 2022), thus why vaccination is crucial. According to Hashim et al. (2022), the priority of getting the COVID-19 vaccine was given to the frontliners during the initial phase, followed by the immunisation of the vulnerable and high-risk groups (older adults, pregnant women and those with comorbidities) (Hashim et al., 2021). After that, the vaccination programme continued its inoculation procedure with healthy adults aged 18 and above (Hashim et al., 2021). The vaccines can be consumed with healthcare worker's assistance and supervision at the vaccination centres around Malaysia. Furthermore, these COVID-19 vaccines can cause fever, headache, fatigue, pain around the injection area, muscle pain, nausea, chills, redness and swelling on the injection site (*Myths and Facts about COVID-19 Vaccines*, 2023). WHO claimed that COVID-19 vaccines are safe to use as most of them passed the third phase of a clinical trial, and the benefits of the vaccines outweigh the potential risks since no transmission of the virus by getting vaccinated (*Safety of COVID-19 Vaccines*, 2021). Regarding COVID-19 vaccine side effects, it was possible to feel pain, swelling and redness in the arm where one got injected (CDC, 2023). At the same time, they also experience headaches, tiredness, nausea, fever, chills, and muscle pain afterwards(CDC, 2023).

1.1.6(a)   Vaccination Hesitancy

Meanwhile, vaccination hesitancy is described as demonstrating a delay in substance acceptance or deliberately refusing to get vaccinated even though immunisation could lessen the mortality and morbidity rate caused by COVID-19 (Pires, 2022). Globally, the COVID-19 vaccine hesitancy rate was 75.2% as of June 2021, which was 3.5% higher than the year-earlier (Lazarus et al., 2022), while in Malaysia, the vaccination rate remained low as of the mid of 2022 due to noticeable

poor participation, especially from Sabah and Kelantan (Jafar et al., 2022). Furthermore, a meta-analysis study showed a global prevalence of COVID-19 vaccination hesitancy was 25% higher among unmarried individuals, women, unemployed, low educational people, and households of five or more (Fajar et al., 2022). According to Boshra et al. (2022), 42.3% of the public are hesitant before getting vaccinated, and the immunisation attempts have been influenced by hesitance, rejection, rumours, and suspicions (Boshra et al., 2022). In the meantime, a South Korean study recorded a considerable level of vaccine hesitancy among people, with a brisk increase throughout 2021 (Lee & You, 2022). This complements the finding from Limbu et al. (2022) where it was reported that South Korea was among the highest in vaccine hesitancy at 53.3% as well as France (60.6%), followed by China (56.4%), Bangladesh (46.2%), and the USA (43.5%) (Limbu et al., 2022). This high rate could be caused mainly by the concern about vaccine safety initiated by the rapid development of the vaccine itself (Machingaidze & Wiysonge, 2021).

1.1.7   Vaccination Hesitancy Issue among Pregnant Women

As of April 2020, there was no maternal death worldwide but higher morbidity rates among pregnant women especially when it comes to severe respiratory issues caused by COVID-19 infection (Hantoushzadeh et al., 2022). Hantoushzadeh et al (2020) then conducted a study in Iran and found that 7 of 9 infected pregnant women died while another 1 was critically ill from COVID-19 when the last one recovered (Hantoushzadeh et al., 2022). There was a recovered pregnant woman after being infected by COVID-19, yet there is a higher potential of maternal death among those being infected (Hantoushzadeh et al., 2020). Another study, conducted in South African found that pregnant women with comorbidities were at risk at death since COVID-19 infection have contributed to South African pregnant women's death (Basu et al., 2021). Aside from maternal death, stillbirth was very high among infected pregnant women (Basu et al., 2022). Another study conducted among pregnant women in United States found that there was no difference in terms of mortality, yet morbidity rates were higher compared non-pregnant women (Kisling & M Das, 2024). These prevalences from previous studies have shown that pregnant women are vulnerable to the infection and should be led to prevention from COVID-19 infection. One of the steps is vaccination program.

A systematic review examining COVID-19 vaccine hesitancy involving 25,147 participants found that 51% of pregnant women had higher vaccine hesitancy globally (Bhattacharya et al., 2022), while in Malaysia, it was found that the percentage of vaccine-hesitant among pregnant women was relatively low at 8.0% (Kalok et al., 2020). On the other hand, 71% of the public were unsure about the safety of COVID-19 to be consumed by pregnant women, and 16% of the rest would avoid giving the vaccine to pregnant women (Boshra et al., 2022). Compared to the general

population of women in Scotland, pregnant women had the lowest percentage of vaccine uptake, which has continuously declined since August 2021 (Stock et al., 2022). Moreover, Levy et al. (2021) found that the main concern about COVID-19 vaccination among pregnant women was the safety of the vaccines (Levy et al., 2021). The vaccine's safety also became the primary reason for a high frequency of vaccine hesitancy among pregnant women in another study. Regan et al. (2022) found a noticeable percentage of pregnant women who delayed vaccination and did not plan to get vaccinated, which was triggered by the vaccine's safety (Regan et al., 2022).

1.2 Problem statement/Originality of research

A total of 2.63% of the mortality rate for pregnant women due to COVID-19 infection occurred more among pregnant women with co-morbid severe illness (Fajar et al., 2022). After the new variant of COVID-19, the mortality rate increased five times more than before the delta wave (Tekin et al., 2022). Malaysia faced immense economic and health losses alongside other countries (Kumari et al., 2022), such as financial aid, mass vaccination, and strict movement control until more people are vaccinated to sustain more significant virus spread (Freeman et al., 2021). The WHO also concluded that coronavirus spread as a global threat (Marchildon J, 2019).

1.2.1 Understanding Issues of Knowledge and Attitude About COVID-19 Infection and Vaccination: The Roles in Improving Care and Outcome of Pregnancy

A Thailand study found that pregnant women's educational level is usually associated with the possibility of seeking more information regarding the proper actions for them to take to avoid COVID-19 infection (Gerdprasert S et al., 2021). A study found a strong link between COVID-19 infection and between COVID-19 infection and foetal and neonatal complications such as stillbirth and low birth weight (Zhu et al., 2020). In addition, another study suggested that more preventive measures should be delivered to less educated pregnant women (Kunno et al., 2022a).

Studies showed pregnant women with good knowledge are more likely to practise good infection preventive measures (Mose et al., 2022). Poor knowledge about how the virus spreads and transmits is associated with a high risk of infections and higher death. Pregnant women and their husbands with higher educational levels showed more positive attitudes towards battling COVID-19 disease than those from lower academic levels (Tasnim et al., 2022). It was found that half of the participants

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had poor knowledge associated with a higher likelihood of poor practices against the COVID-19 infection (Tasnim et al., 2022).

Furthermore, a Saudi Arabia study found noticeably similar results. The study claimed it was essential to have good knowledge as it would determine the attitude and practices against COVID-19 infection prevention (Alsafi et al., 2022a). The study emphasised how pregnant women were unaware that the virus cannot be transmitted via milk but transmittable via respiratory droplets during direct breastfeeding (Alsafi et al., 2022a). A previous study discovered that attitudes, norms, and perceived behaviour control are linked to the individual's intentions and health behaviour (McEachan et al., 2011). Therefore, assessing pregnant women's attitudes towards COVID-19 infection was essential since past research has shown a significant relationship between preventive measures and mood, especially during pregnancy (Yazdi et al., 202.2). Pregnant women being anxious and careful about their newborns would be the main reason for pregnant women to practice reasonable measures against COVID-19 infection (Yazdi et al., 2022). Moreover, using this study's definition of negative attitude led to reckless health behaviour, which indicates less proper preventive measures (Yazdi et al., 2022).

Nevertheless, as vaccination was seen as one of the alternatives to prevent viral transmission, it was necessary to have a broader population to get vaccinated. Vaccination is one of the most reliable alternative treatments that healthcare providers attempt to offer to fight against the infection of the harmful coronavirus, aside from anti-inflammatories or respiratory therapy (Niknam et al., 2022).

An earlier study in 2021 explained that vaccine hesitancy could develop due to trust and doubt and found that a noticeably moderate number of people involved were either ambivalent or admitted to being anti-vaccination for COVID-19 (Freeman

et al., 2021). More vaccine hesitancy in younger women later caused more complications, such as critical care admission and perinatal mortality (Stock et al., 2022). However, a study by Lee and You found that older people and college students were more likely to be hesitant about COVID-19 vaccination (Lee & You, 2022). Surprisingly, the Lee and You (2022) study complements the finding from another study where females and a person aged 50 or older are more vaccine-hesitant (Fajar et al., 2022). Yet, the study revealed that those with lower education than an undergraduate degree would prefer unvaccinated (Fajar et al., 2022). The investigation later added that the major contributing factor in ensuring vaccination hesitancy was long-term studies that are appropriately documented to act as proven evidence of the effectiveness and safety of the vaccine (Fajar et al., 2022).

With the brisk increase in viral transmission and the vast death toll, the WHO suggested the country needed to start finding ways to defeat the coronavirus thoroughly (Kumari et al., 2022). One of the steps was to promote mass vaccination to ensure herd immunity, and the development of various vaccinations directly helped. Notwithstanding the doubts about the vaccination, more people were vaccinated over time. The government was left to fight the anti-vaccine stigma and prepare an explanation of whether the vaccine would be the better option for high-risk groups (Boshra et al., 2022).

It was found in a study that the risks are higher for unvaccinated pregnant women than vaccinated pregnant women in terms of pregnancy complications such as critical care and perinatal mortality (Stock et al., 2022); the global vaccination hesitancy among pregnant women is still unknown, whereas there are still doubts on its effectiveness as much as the lack of awareness towards vaccination importance (Boshra et al., 2022).

1.2.2   Study Rationale

Higher COVID-19 morbidity and mortality were found in pregnant women compared to non-pregnant women (Tekin et al., 2022). Moreover, preventive measures and vaccination programs have been shown to reduce the risks and severity of infection (Mose et al., 2022). Good knowledge and attitude play a vital role in understanding the practice of preventive measures and accepting vaccination (Yazdi et al., 2022). Referring to the level of prevention, where knowledge, attitude and vaccine hesitancy act as the first phases of primordial prevention; the risk factor reduction by focusing on underlying conditions that perceived the disease by providing health education while vaccination acts as the primary prevention; limiting the risk exposure and prevent the disease from progressing (Kisling & M Das, 2024) Level of prevention: the primordial, primary, secondary and tertiary prevention, are the strategies to prevent the disease from spreading and causing worse effects on individuals (Kisling & M Das, 2024).

Therefore, assessing the current knowledge and attitude of COVID-19 infection and vaccination toward pregnancy among pregnant women is essential. To achieve that, there must be a validated questionnaire with good reliability. However, no validated knowledge and attitude (pKAC19) and vaccine hesitancy questionnaire among pregnant women fit the Malaysian context. This study developed a new knowledge and attitude (pKAC19). It investigated the validation and reliability of the newly developed questionnaire to assess knowledge and attitude toward COVID-19 infection and vaccination toward pregnancy (pKAC19). This study also modified and validated the Adult Vaccine Hesitancy Scale (aVHS) questionnaire into the Pregnancy Vaccine Hesitancy Scale (pVHS) to assess vaccine hesitancy among pregnant women.

1.3   Research questions

1) Is the new questionnaire valid to assess knowledge and attitude on COVID-19 infection and vaccination towards pregnancy among pregnant women?

2) Is the new questionnaire reliable to assess knowledge and attitude on COVID-19 infection and vaccination towards pregnancy among pregnant women?

3) Is the Pregnancy Vaccine Hesitancy Scale (pVHS) valid to assess vaccine hesitancy among pregnant women?

4) Is the Pregnancy Vaccine Hesitancy Scale (pVHS) reliable to assess vaccine hesitancy among pregnant women?

1.4   Research hypotheses.

1) The new questionnaire is valid to assess knowledge and attitudes on COVID-19 infection and vaccination towards pregnancy among pregnant women.

2) The new questionnaire is reliable to assess knowledge and attitudes on COVID-19 infection and vaccination towards pregnancy among pregnant women.

3) The Pregnancy Vaccine Hesitancy Scale (pVHS) is valid to assess COVID-19 vaccine hesitancy among pregnant women.

4) The Pregnancy Vaccine Hesitancy Scale (pVHS) is reliable in assessing COVID-19 vaccine hesitancy among pregnant women.

1.5   Research aims and objectives.

1) To determine the validity of the newly developed questionnaire in assessing knowledge and attitude on COVID-19 infection and vaccination towards pregnancy among pregnant women.

2) To determine the reliability of the newly developed questionnaire in assessing knowledge and attitude on COVID-19 infection and vaccination towards pregnancy among pregnant women.

3) To determine the validity of the Pregnancy Vaccine Hesitancy Scale (pVHS) in assessing COVID-19 vaccine hesitancy among pregnant women.

4) To determine the reliability of the Pregnancy Vaccine Hesitancy Scale (pVHS) in assessing COVID-19 vaccine hesitancy among pregnant women.

CHAPTER 2

LITERATURE REVIEW

2.1   Literature Review

2.1.1   Overview of studies related to COVID-19 infection among pregnant women in Malaysia.

COVID-19 is no longer news to Malaysians; its mutation and new variants keep evolving, engaging more interest fields, thus numerous research was conducted. That research focused on the breakthrough infection among healthcare staff (Yang et al., 2022), online KAP questionnaire for social media users (Al-Zalfawi et al., 2021) and Malaysia's parent's willingness to let their children get vaccinated (L. P. Wong et al., 2022).

Despite the long list of research, there are very few of them that focus solely on pregnant women. One of the research projects studied pregnant healthcare employees' vaccination, and another studied maternal vaccine hesitancy alone without further attempts at pregnant women's knowledge and attitude on COVID-19 infection and vaccination. While pregnant women are categorised as one of the at-risk populations for the virus infection, it is only necessary to pay extra attention to the group. Therefore, after an extensive review of past studies, we barely found four studies focusing on the population, yet most of the questionnaire's validations were not mentioned. It was then necessary to study and validate a reliable questionnaire to study the knowledge and attitude on COVID-19 infection and vaccination and COVID-19 vaccine hesitancy among pregnant women in Malaysia. Table 2.1 lists the COVID-19 infection studies among pregnant women in Malaysia.

Table 2.1   Summary of the study on COVID-19 infection among pregnant women in Malaysia.

Source	Sample	Study Method	Focus	Relevant Findings
Fahmy et al (2021) Location: Malaysia	Summaries the challenges to obstetric practice posed by the severe (COVID-19) pandemic	Narrative Review:	Obstetric challenges: COVID-19-positive pregnant women	Enforcement of strict SOPs in the community setting is essential to reduce cross-infection incidence and reassure patients to utilise available health facilities. Limitation: Study based on general obstetric challenges, no questionnaire.
Syed Anwar Aly et al (2021) Location: Malaysia	415 women	Cross-sectional study	Pregnancy and COVID-19 Pandemic Perception in Malaysia: A Cross-Sectional Study	One of the reasons for the high level of awareness and best practices regarding the prevention of CVID-19 among urban pregnancies in Malaysia was the high economic status of the women.

2.1.2   Overview of studies related to COVID-19 vaccination and vaccine hesitancy among pregnant women in Malaysia.

Several past studies discussed COVID-19 vaccination and the COVID-19 vaccine hesitancy among pregnant women in Malaysia is summarized in Table 2.2.

Table 2.2   Summary of the COVID-19 vaccination and vaccine hesitancy among pregnant women in Malaysia.

Source	Sample	Study Method	Focus	Relevant Findings
Kalok et al. (2023) Location: Klang Valley Malaysia	1272 pregnant women	A multi-centre study across four teaching hospitals.	Maternal COVID-19 vaccine hesitancy among Malaysian pregnant women	Low hesitancy is associated with low socio-economic status, good internet use and health professional advice. Limitation: Questionnaire only for vaccine hesitancy (tested for face validation yet no internal validation mentioned), no KAP
Arulappen et al, (2022) Location: Malaysia	121 pregnant healthcare personnel	A multicenter cohort studies.	Adverse Effects Evaluation After Messenger RNA COVID-19 Vaccination Among Pregnant Healthcare Employees	THE mRNA COVID-19 vaccine is safe for pregnant women: the findings did not show obvious safety warning signs. Limitation: No validation for the questionnaire mentioned in the study.

2.1.3 Pre-existing Questionnaire on Knowledge and Attitude about COVID-19 Infection among Pregnant Women

Previous studies used pre-existing questionnaires on knowledge and attitudes about COVID-19 infection among pregnant women is summarized in Table 2.3.

Table 2.3   Summarises instruments used to assess knowledge and attitude about COVID-19 infection among pregnant women.

Developer	Characteristics and concepts measured	Total items	Statistical method andlimitation
Al-Safi et al. (2022) Location: Arab Saudi	Online self-reported questionnaire Assess the levels of knowledge, attitude, and practice of infection among pregnant women. Subdivided into 4 sections: Demographic information (7 items) Knowledge of pregnant women regarding COVID-19 (19 items) Attitudes of the participants toward COVID-19 (5 items) Practices of pregnant women (7 items)	38 items	Validity: Not mentioned Reliability: Not mentioned Limitations The questionnaire was answered by Saudi Arabia's Western region residents only.
Kunno et al. (2022) Location: Thailand	Knowledge, Attitudes and Practices (KAP) questionnaire (Fan et al., 2018), (Kumari et al., 2021) Assess the levels of knowledge, attitude, and practice of infection among pregnant women. Subdivided into 4 sections: Socio-demographic information, clinical characteristics, participant's risk of contracting COVID-19 (15 items) Knowledge of pregnant women (13 items) Attitudes of the participants toward COVID-19 (17 items) Practices of pregnant women (11 items)	56 items	Validity: Not mentioned Reliability: Not mentioned Limitations based on the perceptions and experiences of a specific group. The questionnaire's reliability was not evaluated.
Javier and Garin (2022) Location: Philippines	Self-reported questionnaire Assess pregnant women's knowledge, attitudes, and practices regarding COVID-19 infection. Composed of 4 parts: Causes, Signs and symptoms Mode of transmission Management control	39 items	Validity: Not mentioned Reliability: Not mentioned Limitations

Table 2.3 Continued

Tasnim et al. (2022) Location: Bangladesh	WHO-guided Pre-tested Questionnaire Investigate pregnant women's knowledge, attitudes, and practices (KAP) to prevent COVID-19 and determine the factors associated with KAP. Composed of 5 divisions: Socio-demographic characteristics reproductive health-related characteristics knowledge-related characteristics attitude-related characteristics, practice-related characteristics source of information regarding COVID-19	6 items	Validity: Good internal consistency Reliability: Good internalp-p-values < 0.05 at 95% CI were considered statistically significant Limitations only a limited number of questions to assess knowledge, attitude, and practice.
Yazdi et al. (2022) Location: Iran	Self-administered researcher-made questionnaire. Investigate pregnant women's knowledge, attitudes, and practices (KAP) to prevent COVID-19 and determine the factors associated with KAP. Composed of 3 divisions: knowledge attitude practice	20 items	Validity: latent class (LC) analysis, 0.68 Limitations They need more initial fundamental knowledge of COVID-19 and attitudes through a self-reported questionnaire.
Naz et al. (2022) Location: Pakistan	A self-administered questionnaire, WHO recommendation. Assess pregnant women's knowledge, attitude, and practice during COVID-19. Subdivided into two sections: Demographic variables, clinical characteristics, participant's risk of contracting COVID-19 (7 items) 21-items scale: Knowledge of pregnant women regarding COVID-19 (12 items) Attitudes of the participants toward COVID-19 (3 items) Practices of pregnant women (6 items)	28 items	Validity: Not mentioned Reliability: Consistency ($\alpha = 0.93$) Limitations: Not mentioned

Table 2.3 Continued

	written self-answered questionnaire.	20	Validity: Not mentioned
Pairat et al.	Investigate factors for COVID-19 vaccine attitude.	items	Reliability: Not mentioned
(2022)	Composed of 3 divisions:		
Location: Thailand	Demographic (15 items)		Limitations
	Attitude on infection (1 item)		
	Vaccine hesitancy (4 items)		
	KAP Questionnaire	21	Validity: Not mentioned
Naqvi et al.	Assess the levels of knowledge regarding COVID-19 of pregnant women.	items	Reliability: Not mentioned
(2022)	Assess the levels of knowledge related to COVID-19.		
Location: Kenya, Zambia, the	Subdivided into:		Limitations
Democratic Republic of the Congo,	Identify COVID-19 symptoms (9 items)		No pilot-study.
Pakistan, India, Guatemala, and	Ways of transmission (4 items)		Evaluation of questionnaire done
Bangladesh.	Steps to prevent spread (6 items)		by staff members
	Knowledge of high-risk group (2 items)		Potential bias from the
			questioner's view.
	Knowledge, Attitude, and Practice of COVID-19 Prevention in Pregnancy	33	Validity: Validated but not
Kalpana et al.	Assess the levels of knowledge, attitude and practices related to COVID-19.	items	mentioned
(2022)	Subdivided into:		Reliability: Pilot study on 20
Location: South India	Sociodemographic characteristic and obstetric variables (17 items)		samples, result not mentioned
	Knowledge (8 items)		
	Attitudes (4 items)		Limitations: Not mentioned
	Preventive practices (4 items)		