

# THE BARRIERS AND FACILITATORS OF UNDERTAKING FLU VACCINATION IN PREGNANT WOMEN IN THE UNITED KINGDOM: A QUALITATIVE SYSTEMATIC REVIEW

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**Abstract:** Pregnant women are classified as one of the groups who have a high risk of flu complications. the flu vaccination uptake in pregnant women in the United Kingdom is still low and a slight decrease reported which was from 45.2% in 2018-2019 to 43.7% in 2019-2020. This systematic review aims to explore the factors which influence pregnant women undertaking or refusing flu vaccination. Six electronic databases were included, such as MEDLINE, CINAHL, PsycInfo, EMBASE, PubMed, Scopus, and grey literature. This systematic review selected full texts English language and the studies from 2009 to 2019. Data were assessed using CASP checklists, extracted, and synthesised. The results of the review are the views of pregnant women from the multicultural community from many different countries aged 18-48 based on 4 included studies. The themes were grouped using thematic analysis and produced 7 new analytic themes. The barriers are acceptability; service provision; lack of information; communication and interaction. The facilitators are benefits for the babies and the vulnerable environment. One theme that acted as a barrier and facilitator is the influence of others, such as family, friends and community. Reducing the barriers will lead to an increasing in flu vaccination uptake in pregnant women, therefore, the improvement of health care services and providing greater information regarding flu vaccination are needed. The facilitators should be used as ways to inform pregnant women about the benefits and risks.

**Keywords:** barriers, facilitators, flu vaccination, pregnant women, United Kingdom

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## Introduction

Influenza or better known as flu is an infectious disease caused by viruses, and there are several types, namely types A, B, and C (CDC 2019a). The National Childbirth Trust (NCT 2018) states pregnant women are classified as one of the groups who have a high risk of flu complications such as bronchitis which can develop into pneumonia and ear or blood infections which can lead to septic shock and meningitis. Moreover, the impact not only can affect pregnant women but also on the infants that they are carrying, such as low birth weight or born prematurely and possibly preterm birth, stillbirth or death are complications to the infants (Nunes et al. 2016 and NHS 2019).

Vaccination is an effective way to prevent influenza (CDC 2019b). According to McMillan et al. (2015), flu vaccination is safe because there is no association between influenza vaccination and the increasing risk of fetal death, congenital malformation or spontaneous abortion. The only contraindication to flu vaccination is the occurrence of severe egg protein allergy and age-appropriate flu vaccine is recommended (CDC 2019b). The allergic reaction that can occur, such as hives,

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angioedema, asthma and anaphylaxis (Grohskopf et al. 2019; Kellerman; Rakel 2019). For patients who have egg protein allergy is recommended to have whether Inactivated Influenza Vaccine (IIV), Recombinant Influenza Vaccine (RIV4), or Live Attenuated Influenza Vaccine (LAIV4) vaccine (Kellerman and Rakel 2019). However, for pregnant women is not allowed to get LAIV4 vaccine because of the plausible risk for disease attributable to the vaccine virus (Grohskopf et al. 2019). According to the Advisory Committee on Immunization Practices (2019) recommendation, LAIV4 vaccine is approved for use in non-pregnant individuals, 2 years through 49 years of age only without specific medical conditions. Therefore, IIV and RIV4 vaccination are recommended for pregnant women with an egg protein allergy. Additionally, vaccine administration should be supervised by a health care provider who can recognize and manage severe allergic reactions (Roshental and Buchum 2017).

On the other hand, Poehling et al. (2011) state that flu vaccination reduces the risk of influenza-attributable hospitalization during six months among infants when infants are most vulnerable. Serum Immunoglobulin G (IgG) and Immunoglobulin A (IgA) antibodies in influenza vaccines are transferred through transplacental before birth, also via breastmilk after birth (Puck et al. 1980; Englund 2003). Therefore, aside from the effects of pregnant women itself, flu vaccination has protection to infants against influenza. Pregnant women are suggested to get vaccinated before the winter or rainy season because influenza often occurs when winter comes (NHS 2019). The World Health Organization (WHO 2012) recommends that pregnant women take inactivated flu vaccines at any stage in trimester I, II or III in reducing maternal morbidity and mortality due to respiratory diseases.

In the United Kingdom, the flu vaccination uptake in pregnant women during the 2017-2018 influenza season is still quite low, which is below 50%, which was only 45.2% in 2018 to 2019. Furthermore, Public Health England (PHE 2020a) reported a slight decrease in flu vaccination uptake in pregnant women in the United Kingdom from 45.2% in 2018 to 2019 to 43.7% from 2019 to 2020. Meanwhile, the vaccine uptake ambitions also increase from at least 55% in 2019–2020 to at least 75% in 2020-2021 because of the COVID-19 pandemic to reduce the risk of cross-infection (PHE 2020b). In the United Kingdom, flu was also the cause of maternal death in 1 in 11 pregnant women between 2009 and 2012 which included the influenza pandemic reported by the national maternal death report, called Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) (PHE 2014). The maternal deaths happened after the flu vaccination was introduced and recommended, unfortunately, none of the pregnant women was known to take the flu vaccination. Therefore, it is essential to meet the high higher coverage of flu vaccination in order to reduce the risk of influenza in the United Kingdom.

Some systematic reviews are conducted to evaluate the incidence of outcomes of flu in pregnant women, examine the effectiveness of flu vaccination in pregnant women and the effects on their infants, also the cost-effectiveness of flu vaccination (D'Angiolella et al. 2018; Giles et al. 2019; Jeong et al. 2019; Katz et al. 2017; Nunes et al. 2016). The incidence of outcomes associated with influenza virus infection in pregnant women was collected in the systematic review by Katz et al. (2017) which was quite challenging to assess pregnancy as a risk factor for severe flu illness because of lack of laboratory confirmation, lack of population denominators or used ecological study methods.

However, high-quality studies reported the incidence of outcomes associated with influenza virus infection in pregnancy, such as influenza-attributable hospitalizations and deaths (Katz et al. 2017).

The other systematic reviews that were conducted by Giles et al. (2019) and Nunes et al. (2016) examined that flu vaccination in pregnancy was associated with a decreased risk of preterm birth and low birth weight. Besides preterm birth and low birth weight, a systematic review by Jeong et al. (2019) added the effect of flu vaccination to decrease the risk of small for gestational age, congenital malformation and fetal death. These effects of flu vaccination for pregnant women also influenced the flu vaccination uptake. Also, the flu vaccination is cost-saving or cost-effective intervention compared to a no vaccination strategy against flu as a result of a systematic review that was conducted by D'Angiolella et al. (2018).

Most studies of the views of flu vaccination in pregnant women were presented in the quantitative systematic review, such as Yuen and Tarrant (2014) which were examined the cross-sectional and intervention studies about knowledge and attitudes of pregnant women concerning the uptake of flu vaccination. However, qualitative synthesis is viewed as an essential role in evidence-based health research to answer questions that cannot be addressed by quantitative data (Munn et al. 2014). Accordingly, this systematic review focuses on what are the factors for pregnant women who are not taking flu vaccination through the qualitative systematic review, which includes the views in depth based on the findings. Also, reviewing the barriers and facilitators of flu vaccination uptake is vital to inform and guide strategies to promote flu vaccination uptake in pregnant women in the United Kingdom. The main purpose of this systematic review is to explore the factors which influence pregnant women undertaking or refusing flu vaccination in order to reduce the risk of influenza in pregnant women in the United Kingdom through investigating, synthesising, discussing and giving recommendation the strategies to reduce barriers, increase the effectiveness of facilitators and increase the uptake of flu vaccination in pregnant women in the United Kingdom.

## **Materials and Methods**

Six electronic databases were included in the database sources, such as Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Literature (CINAHL), Psychological Information (PsycInfo), Excerpta Medica dataBASE (EMBASE), PubMed and Scopus. The grey literature was considerably to seek in order to identify the potential sources from general search engines, such as Google, Google Scholar, Bradford Index and Open Grey. This systematic review was selected full texts English language as a requirement, and there was a restriction on publication year, which is the studies in 2009–2019.

A search strategy was designed based on the PICOS (Population, Intervention, Comparator, Outcome and Study Design) to search by search syntax. The Medical Subject Headings (MeSH) terms were selected to avoid missing out on important studies and combined with words such as “pregnant women” OR pregnancy OR pregnan\* OR maternity OR maternal OR matern\* as the reflection of the population and “influenza vaccination” OR “flu vaccination” OR “influenza vaccin\*” OR “flu vaccin\*” OR “flu shot” OR “flu shot\*” as the reflection of the intervention. The terms “qualitative stud\*” OR qualitative OR interview OR interview\* OR “qualitative research” were also added to search honing in on qualitative studies. This systematic review is focused on the studies which were conducted in the United Kingdom as one of inclusion criteria of the study. Therefore, the term of the

location is added, such as England OR "United Kingdom" OR britain OR british OR "great britain" OR UK.

The relevance of the studies was assessed according to the to the inclusion and exclusion criteria. These inclusion and exclusion criteria were used as a guide to separate search results based on the focus of this systematic review. The inclusion criteria are as follows: (1) Pregnant women in any ages with or without the risk factors of influenza complication (2) Flu vaccination in pregnant women, including seasonal flu vaccination. Also, flu vaccines for pregnant women, including IIV or RIV4 which is recommended for pregnant women who have an egg protein allergy (3) Pregnant women who have done the flu vaccination and have not done the flu vaccination (4) The studies which are conducted in the United Kingdom (5) The studies which address barriers and facilitators (6) Qualitative primary studies, including qualitative data from mix method studies. Meanwhile, the exclusion criteria are as follows: (1) Non-pregnant women. (2) Other kinds of vaccination for pregnant women. (3) The studies which address other aspects which are not including barriers and facilitators. (4) Quantitative primary studies from all methodological approaches.

The quality risk of bias of the qualitative primary studies in this systematic review was assessed by utilising the Critical Appraisal Skills Programme (CASP) checklist for the systematic review. Data was considered to extract in this systematic review with data extraction tool by dividing into two types of data, such as descriptive and analytical data. Best fit framework synthesis was used as an appropriate method to synthesise the results after the data extraction to examine the barriers and facilitators of undertaking flu vaccination in pregnant women. Additionally, thematic analysis was used as a tool to describe in-depth, provide new analytical theme(s) and increase transparency in analysing the qualitative data).

## **Results and Discussion**

In total, the number of citations identified was 3525 citations from all the databases, including grey literature. PRISMA Flow Diagram was used to help making a note the number of findings (Fig. 1 PRISMA Flow Diagram of the Search Strategy).

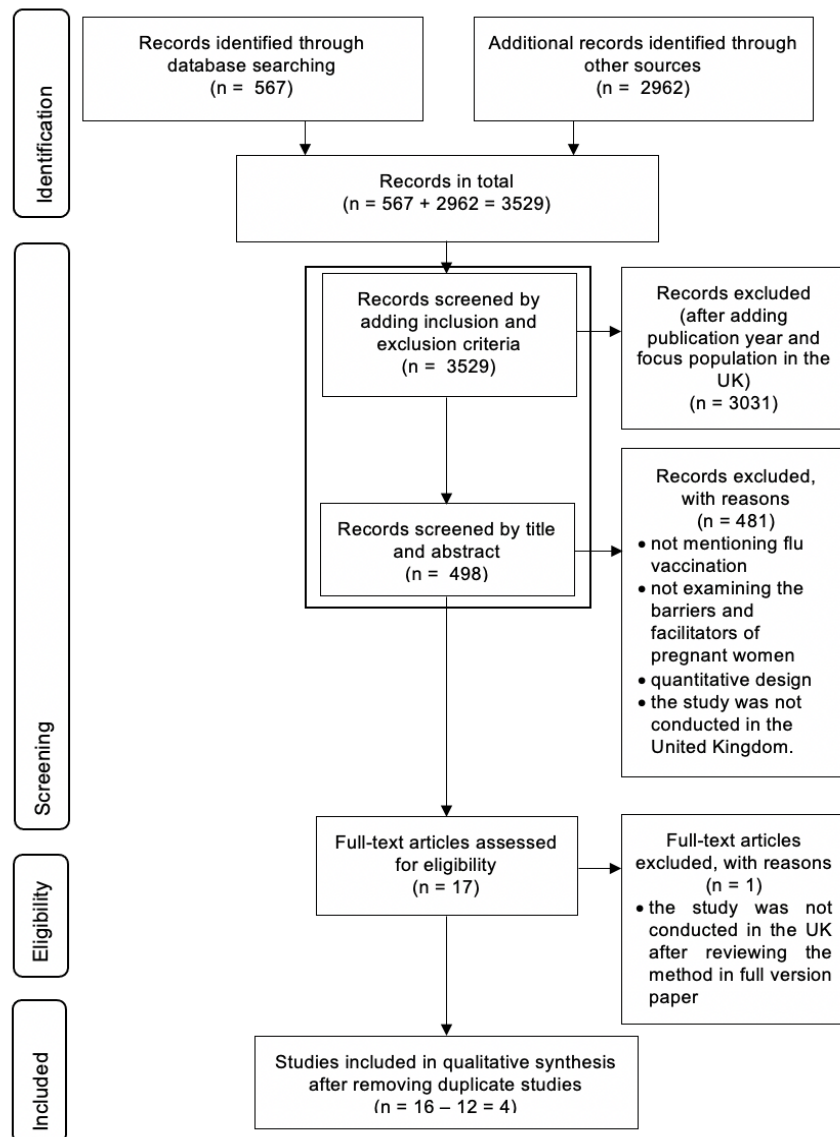


Figure 1: PRISMA Flow Diagram of the Search Strategy

Table 1 shows the overview of database and 16 citations were included in total before removing the duplicate studies. The reason for removing the duplicate studies at the end is to look at each database that contributed to this systematic review. Scopus (n=4) and grey literature (n=4) had the greatest number of citations that were included in this systematic review following by PubMed (n=3), MEDLINE (n=3), CINAHL (n=1) and, PsycInfo (n=1). There were no papers selected from EMBASE. After removing the duplicate studies, 4 studies were included after reviewing title, abstract and full version based on inclusion and exclusion criteria.

Table 1: Overview of Database Search

Database	Number of Citations Identified*	Number of citations excluded by inclusion and exclusion criteria**	Number of citations selected for the title and abstract review	Number of citations selected for full version paper review	Number of included citations
Databases					
MEDLINE	116	106	10	4	3
CINAHL	69	65	4	1	1
PsycInfo	15	14	1	1	1
EMBASE	131	81	50	0	0
PubMed	100	87	13	3	3
Scopus	136	126	10	4	4
Total Studies from Databases	567	479	88	13	12
Grey Literature					
Google	656	411	245	1	1
Google Scholar	56	11	45	0	0
Bradford Index	2244	2127	117	3	3
Open Grey	6	3	3	0	0
Total Studies from Grey Literature	2962	2552	410	4	4
Total	3529	3031	498	17	16
Total after removing the duplicate studies					4

Note:

\*number of citations identified based on the search strategy

\*\* number of citations excluded by inclusion and exclusion criteria, such as adding the publication year (2009 – 2019) and the United Kingdom’s pregnant women as the focus population of the systematic review

The results of the review are the views of pregnant women from the multicultural community, as shown in Table 2, from many different countries in aged 18-48 based on 4 included studies. Included studies were undertaken in the United Kingdom, such as one study in London, Lincolnshire and Berkshire (Bell et al. 2019), one study in Belfast, Northern Ireland (Maisa et al. 2018), one study in Lothian, Scotland (Sim et al. 2011) and one study in Hackney, a borough in north-east London (Wilson et al. 2019). All the studies were qualitative study which means there is no study with mix method in the methodological. The total of sample is 93 pregnant women in the United Kingdom of included studies. Sample sizes ranged from 10 to 40. There were a wide range of ethnicity, such as Polish, Romanian, Scottish, British, British Caribbean, Japanese, German, Nigerian, Caribbean, Chinese, Australian, South Africa, Somalian, Orthodox Jewish, Pakistani, Brazilian, Turkish, Norwegian, Italian and Lithuanian.

Table 2: Study and Participants Characteristic

Study	Sample Size*	Data Collection	Data Analysis	Age range	Ethnicity	The status of vaccination
Sim et al. 2011	10	Interviews	Deductive and inductive analysis	20-34	Polish (n=5) and Scottish (n=5)	Vaccinated (n=4) and unvaccinated (n=6)
Maisa et al. 2018	16	Interviews and focus group discussion	Thematic analysis and inductive analysis	18-44	not specified	Vaccinated (n=8) and unvaccinated (n=7)
Bell et al. 2019	27	Interviews	Thematic analysis	not specified	Polish (n=19) and Romanian (n=8)	not specified
Wilson et al. 2019	40	Interviews and video-recording	Deductive and inductive analysis	18-48	British (n=16), British Caribbean (n=4), Japanese (n=1), German (n=2), Nigerian (n=2), Caribbean (n=1), Chinese (n=2), Australian (n=1), South Africa (n=1), Somalian (n=1), Orthodox Jewish (n=2), Pakistani (n=1), Brazilian (n=1), Turkish (n=2), Norwegian (n=1), Italian (n=1), Lithuanian (n=1)	Vaccinated (n=14), unvaccinated (n=21), N/A (n=5)

Note:

\*sample size of pregnant women in the study

The qualitative synthesis used Best fit Framework Synthesis that has provided the data systematically into new themes with the description. Themes of each included study were collected with the description of the theme and separated into barrier or facilitator or factor that acted as barrier and

facilitator. A new framework was produced from 7 new analytical themes using thematic analysis. 4 themes were considered to be barriers, such as acceptability; service provision; lack of information; communication and interaction. Two were the facilitators, such as benefits for the babies and vulnerable environment. One theme was acted as barrier and facilitator, such as influence of others.

### ***The Barriers of Undertaking Flu Vaccination***

#### *Acceptability*

All the studies contributed to the acceptability theme that affected the acceptance of flu vaccination in pregnant women. Some pregnant women were uncertainty and worried about the side effects of vaccination (Sim et al. 2011; Maisa et al. 2018; Bell et al. 2019; Wilson et al. 2019). However, the specific side effects of flu vaccination that were experienced by the pregnant women were not addressed specifically in the 4 included studies. According to the CDC (2019b), the side effects of flu vaccination are fatigue, nausea, muscle aches, fever, fainting, headache, soreness, redness and/or swelling from the shot. The health care practitioners should inform the side effects of flu vaccination specifically in the beginning and noted to give the information that there are IIV and RIV4 vaccination for pregnant women who have egg protein allergy instead of explaining after the vaccination. Also, the greater awareness of the effect of flu itself needs to be prioritised to increase uptake of flu vaccination in pregnant women.

On the other hand, the unexpected finding related to the Measles, Mumps and Rubella (MMR) vaccination controversy in the 1990's and the autism scare which caused vaccine anxieties also appeared in some studies that affected the flu vaccination uptake (Sim et al. 2011; Maisa et al. 2018; Bell et al. 2019). Aside from the concern about the side effects in pregnant women, pregnant women also concern about the potential effect on their unborn babies. This should be considered a further explanation for pregnant women from the health care practitioners to also convince about the safety of flu vaccination for both, the mothers and babies.

The perception of flu vaccination as an unnecessary and less severe vaccine than other vaccines in pregnant women was also reported that caused the common refusal of flu vaccination for migrant communities, such as Polish and Romanian (Bell et al. 2019). In the country like Poland and Romania, the flu vaccination is not funded and recommended for pregnant women, and this policy affected the decision making of pregnant women to take the flu vaccination in the United Kingdom (ECDC 2018). This also suggests that further exploration is needed for particular communities who did not take the flu vaccination and more effective promotion of the importance of flu vaccination in pregnant women in particular communities.

#### *Service Provision*

Pregnant women viewed that the process to take flu vaccination in the United Kingdom as a complicated process because of a lack understanding of how health care systems in the United Kingdom works (Maisa et al. 2018; Bell et al. 2019; Wilson et al. 2019). It also happened because some participants in the studies are migrants. A study by Bielecki et al. (2019) found the flu vaccination uptake in Scotland in 2018 was 25% among Polish compared to 70% among British. The



different procedures between the country of origin and the United Kingdom were linked to the perceptions and expectations of the health care system. Therefore, this highlights the need to communicate about the English health care system for those who are unfamiliar and conduct more exploration of the vaccination history of pregnant women during the antenatal care visit.

Some pregnant women reported experience a long waiting process in the health care centre (Wilson et al. 2019). Pregnant women also said that they had a lack of time to be vaccinated (Maisa et al. 2018; Wilson et al. 2019). Additionally, some of them did not receive the letter of appointment or vaccination reminders (Bell et al. 2019; Wilson et al. 2019). Pregnant women also reported the pressure of appointment, such as chaotic care environment (Wilson et al. 2019). This should be considered a further exploration to have a good appointment system a particular space in a good environment during the waiting time in the health care centre, especially in COVID-19 era while delivering the flu vaccination.

#### *Lack of Information*

Most pregnant women felt the health care practitioners did not spend enough time to explain about the flu vaccination and prefer to give leaflets or give the advice to check the information online (Maisa et al. 2018; Bell et al. 2019; Wilson et al. 2019). Misunderstanding and unexpected statements of flu vaccination appeared because the lack of information is provided. Meanwhile, the unexpected perception of vaccination is observed in Sim et al.'s (2011) study, in which pregnant women reported that only themselves are benefited from the vaccination, not the babies they carried. This highlights a need for advice from the health care practitioners directly to provide greater awareness and understanding of flu vaccination. In practice, if pregnant women had a better understanding of the benefits of flu vaccination, they would make a decision to undertake the flu vaccination.

#### *Communication and Interaction*

According to the participant characteristics of the studies, most of the ethnicity of the participants is originally from outside the United Kingdom. This affects the communication difficulty to understand the information about flu vaccination in pregnant women because English is not their mother language (Sim et al. 2011; Bell et al. 2019; Wilson et al. 2019). To address the issue of communication difficulty, the leaflets should be ensured to provide the information by providing the translation service or leaflets in any other languages based on the chosen language of the most ethnicity population who live in the particular area, and it needs to be further assessed to meet the need.

Pregnant women also reported difficulty of building trust and relationship with the health care practitioners (Maisa et al. 2018; Wilson et al. 2019). One of the pregnant women mentioned the reason for the issue, such as did not get the same health care practitioners during pregnancy (Maisa et al. 2018). Therefore, a lack of trust in the effectiveness of flu vaccination for pregnant women was also mentioned in relation to the lack of trust in health care practitioners (Maisa et al. 2018).

Pregnant women also need to make a decision whether to take the flu vaccination or not. For marginalised pregnant women, the recommendation from the health care practitioners is needed to emphasise that flu vaccination is important instead of only mentioned it (Maisa et al. 2018; Wilson et

al. 2019). The research by Vishram et al. (2018) found the reasons for lack of confidence in recommending vaccination to pregnant women could be lack of belief and knowledge. Therefore, training for health care practitioners is important to increase confidence in delivering information.

### ***The Facilitators of Undertaking Flu Vaccination***

#### *Benefits for the babies*

Some pregnant women were encouraged to take the flu vaccination because of the responsibility of the babies (Sim et al. 2011; Maisa et al. 2018). This highlights that pregnant woman were aware of their unborn babies health. Their concern on the unborn babies could be a critical motivation to undertake the flu vaccination. Some studies that were conducted also reporting the increasing of willingness to undertake flu vaccination in pregnant women if the vaccine is promoted for the baby's protection (Regan et al. 2016; Naidu et al. 2017).

#### *Vulnerable Environment*

The vulnerable environment or condition will encourage pregnant women to undertake the flu vaccination that can affect their selves and their babies. In the H1N1 influenza pandemic in 2009, the flu vaccination programme in the United Kingdom was prompted rapidly as the concern for those who have a greater risk, such as pregnant women (Mosby et al. 2011b). In this situation, pregnant women would encourage to improve their personalised understanding of immunity of the infection (Sim et al. 2011). Other vulnerable conditions, such as the increasing number of infections during the winter season, also affected the decision to take the flu vaccination (Sim et al. 2011). Therefore, this also highlights the alternative way to promote flu vaccination by giving some examples about the vulnerable environment or condition and how serious the flu is.

In COVID-19 era, flu vaccination programme in the United Kingdom is predicted more challenging because of the impact on the health care services, such as maintaining social distancing and the risk of cross-infection cases of COVID-19 (CDC 2020; PHE 2020b; Li et al. 2020). PHE (2020b) reported those the most at risk from flu are also most vulnerable to COVID-19 in 2020-2021, including pregnant women. Some researches state that influenza vaccination could contribute significantly to the control of COVID-19 and reduce the risk of cross-infection because of the hospitalisation (Fink et al. 2020; Li et al. 2020; Salem and El-Hennawy 2020). This might affect the decision of pregnant women to undertake flu vaccination, whether to take it or not.

### ***The Factor that Acted as Barrier and Facilitator of Undertaking Flu Vaccination***

#### *Influence of Others*

Health care practitioners have a positive influence on pregnant women to increase flu vaccination uptake. However, influence of others, such as family, friends, community, was reported to affect the

decision making of pregnant women to undertake the flu vaccination (Sim et al. 2011; Bell et al. 2019; Wilson et al. 2019).

This highlights that health care practitioners have a greater role in promoting flu vaccination in pregnant women, including doctors and midwives. The involvement of health care practitioners is the strategy for increasing uptake of vaccination in pregnant women, whether it is in the health care centre or outside (Bisset and Paterson 2018).

On the other hand, it was evident that some pregnant women seek to be vaccinated because of the recommendation from their friends or family members (Wilson et al. 2019). This highlights the importance of involving a wider public instead of pregnant women only to tackle the negative views towards the flu vaccination from friends or family members.

## **Conclusion**

This systematic review has a positive implication for practice to increase flu vaccination uptake in pregnant women through reducing barriers and using facilitators to increase the effectiveness. The greater awareness will lead to the flu vaccination uptake in pregnant women to reduce the risks of flu for both mothers and babies. The findings of the included studies show that pregnant women require information in detail and discussion about flu vaccination. The recommendation for practice is health care practitioner requires a guideline or a procedure to inform, recommend and discuss the flu vaccination to pregnant women, such as the side effects, the safety, the benefits of flu vaccination and the health care system in the United Kingdom for a particular community, for example, for migrants. The skills training is needed, which focuses on educational efforts, attitudes and confidence for health care practitioners to build trust in pregnant women (Stiggelbout et al. 2015). Health care services improvement is also essential to encourage pregnant women to undertake flu vaccination, such as appointment system, vaccination reminders and environment during waiting time. Other than that, the involvement of the broader public in promoting flu vaccination is essential to avoid the negative views from others, such as, partners, friends or family members of pregnant women. Importantly, the flu vaccination programme in COVID-19 era should consider maintaining social distancing, the guideline to promote the benefits of undertaking flu vaccination in COVID-19 era and manage the delivering of flu vaccination.

The theme of the facilitator is limited in this systematic review because the involvement of pregnant women who take the flu vaccination as participants in the studies is also less than pregnant women who did not take the flu vaccination. For future studies, it is recommended to identify more facilitators through conducting researches for pregnant women who take flu vaccination as participants in the study to take views about the flu vaccination and health care services. Additionally, poor quality of evidence has resulted in poor understanding and quality of the study, therefore, a stronger evidence base is needed for future studies. Some limitations were identified in this systematic review. First, the review focus in some areas of the United Kingdom only, such as Lothian in Scotland, Belfast in Northern Ireland, London, Lincolnshire and Berkshire, because the studies were also limited. Additionally, not all the studies' theme with narrative or verbatim quotes as evidence-based, which could be improved by contacting the authors. Therefore, a great of evidence might have been missed.

## Declaration of Interest Statement

The authors declare that they have no conflict of interests.

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