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The Role of Influenza Vaccination in Pregnant Women: Benefits and Risks – An Integrative Review

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ABSTRACT

Background. Influenza is one of the most common seasonal viral infections and poses a significant risk of complications, especially for pregnant women. Due to immunological and physiological changes, pregnant women are more susceptible to severe influenza and adverse pregnancy outcomes. Annual influenza vaccinations are an effective preventive measure;

however, vaccination rates remain low, despite recommendations from the World Health Organization (WHO).

Aim. The aim of this study was to review the literature on the efficacy and safety of influenza vaccinations in pregnant women and to assess their impact on maternal and fetal health.

Material and methods. A literature review (2019–2024) was conducted in PubMed, focusing on influenza vaccination in pregnancy. An integrative approach was used to assess the risk–benefit balance for maternal and fetal health.

Results. Research findings suggest that vaccination significantly reduces the risk of influenza infections in both mothers and their newborns, and lowers the incidence of pregnancy complications, such as preterm birth and low birth weight. No significant risks associated with congenital defects or other adverse health effects for the fetus have been identified.

Conclusions. The analysis highlights the positive balance between the benefits and risks of influenza vaccination during pregnancy, supporting the need for widespread recommendations in this high-risk group.

Keywords: pregnancy immunization, influenza vaccination, immunization education, benefits of vaccination, risks of vaccination

1. Introduction

In temperate regions, seasonal influenza epidemics occur annually (1,2). Complications from influenza contribute to up to 500,000 deaths worldwide each year (3).

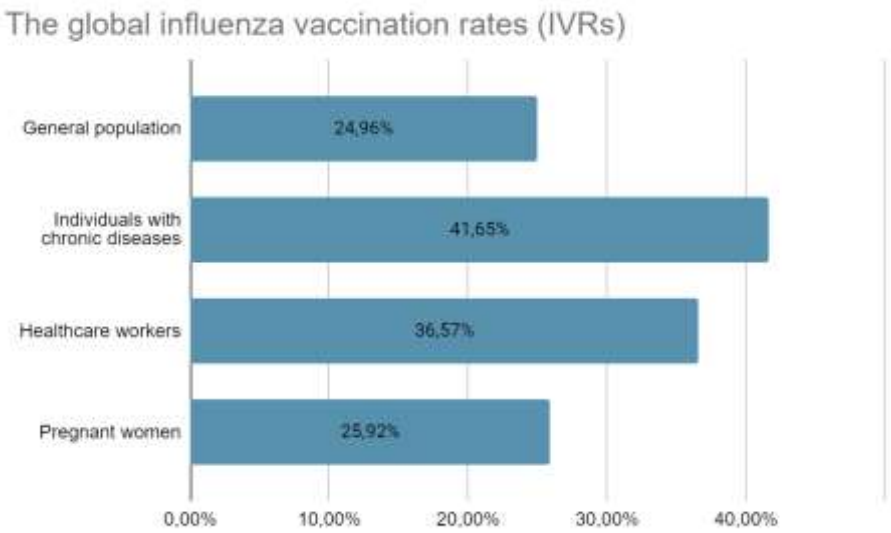
The evolution of influenza viruses is driven by two key processes: antigenic drift and antigenic shift (2,3). Antigenic drift is the gradual accumulation of mutations in the virus's genome, leading to its variation (2). This phenomenon explains the occurrence of seasonal influenza infections and the need for annual booster vaccinations (2). On the other hand, antigenic shift occurs when two different influenza viruses infect the same cell and exchange RNA segments, creating a new strain (2). Such a novel virus can cause severe illness and spread rapidly, potentially leading to a pandemic (2,3).

Annual influenza vaccinations can prevent the majority of infections (3). These vaccines provide protection against three or four virus strains (4). The trivalent vaccine protects against

two strains of influenza A (H1N1 and H3N2) and one strain of influenza B, while the quadrivalent vaccine includes an additional strain of influenza B (4). There are three main types of vaccines: inactivated (IIV), recombinant (RIV), and live attenuated (LAIV) (4). Recommendations for the use of specific vaccines may vary depending on age and specific risk groups (5). The World Health Organization (WHO) recommends prioritizing pregnant women (6,7). Other important risk groups include the elderly, children under five, residents of nursing homes, and individuals with comorbidities such as asthma, HIV/AIDS, or chronic heart and lung diseases (5,6). Vaccination is not recommended for individuals with contraindications (3). Developing a vaccine for a new influenza season takes 6–8 months, and during this time, the virus may change through antigenic drift, complicating effective protection (3).

C. Chen, in his study, reviewed 522 articles, showing that global influenza vaccination rates (IVR) are low. In the general population, the IVR was 24.96%, among individuals with chronic diseases it was 41.65%, and among healthcare workers, it was 36.57%. For pregnant women, the IVR was 25.92% (Figure 1). Higher-income countries had higher IVR than middle-income countries, and during the COVID-19 pandemic, IVR increased compared to previous seasons (8).

Figure 1. The global influenza vaccination rates (IVRs)



Source: Licata F, et al., 2023 cited Chen, 2022 (28)

The objective of this study is to evaluate global influenza vaccination rates and to compare vaccination coverage among different population groups. The study aims to address the following research problems: what is the level of influenza vaccination coverage worldwide and whether there are differences in vaccination rates between the general population and high-risk groups. It is hypothesized that global influenza vaccination rates remain insufficient and that vaccination coverage differs between population groups, with higher rates observed among high-risk groups than in the general population.

2. Research materials and methods

A literature search was conducted in the PubMed database in 2024. The search was limited to articles published within the last five years (2019–2024) to ensure the relevance of the data. The focus was on studies related to influenza vaccination in pregnant women. Keywords used included phrases such as “Pregnancy immunization,” “Influenza vaccination,” “Immunization education,” “Benefits of vaccination,” and “Risks of vaccination.”

The integrative review method was used in this work. The results of individual studies were analyzed qualitatively. The studies were grouped by main topics: the impact of influenza on pregnancy, the efficacy of influenza vaccination, and the risks and benefits of vaccination. Within each of these categories, data were synthesized descriptively, considering parameters such as the reduction in the risk of contracting influenza, a decrease in pregnancy complications, and the occurrence of potential side effects. Special attention was given to evaluating the balance between the benefits and risks in the context of maternal and fetal health. This analysis allowed for a balanced assessment of arguments for and against vaccination, considering various clinical scenarios. This methodological approach provided a comprehensive analysis of studies on influenza vaccination in pregnant women, enhancing the scientific value of the conclusions.

3. Research results

3.1. Impact of Influenza on Pregnancy:

Pregnant women are more susceptible to severe influenza infections and serious complications compared to non-pregnant women (5–7). This increased risk is due to physiological and immunological changes, such as increased heart rate, oxygen consumption, reduced lung capacity, and alterations in the immune system (6). These changes can lead to more severe influenza infections and an elevated risk of adverse pregnancy outcomes (6,9).

A study conducted in Bangkok, Lima, and Nagpur (2021) aimed to examine the impact of influenza and acute respiratory infections (ARI) on pregnancy outcomes in approximately 11,000 women. The women were recruited before the flu season and monitored throughout pregnancy. The primary outcomes measured were preterm birth and birth weight of full-term infants. Secondary outcomes included spontaneous miscarriages, stillbirths, and newborns classified as small for gestational age (SGA) (10).

Table 1. Impact of influenza and acute respiratory infections (ARI) on pregnancy outcomes

Assessed Outcomes:	Impact on Pregnancy:
Preterm Birth	aHR 1,4, 95% CI 0,9 to 2,0; p=0,096
Birth Weight of Full-Term Infants (g)	−55,3 g, 95% CI −109,3 to −1,4; p=0,045
Small for Gestational Age (SGA) Newborns	aHR 1,0, 95% CI 0,8 to 1,3; p=0,97
Late Pregnancy Loss	aHR 10,7, 95% CI 4,3 to 27,0; p<0,0001

The study found that influenza during pregnancy was not conclusively associated with preterm birth or small for gestational age (SGA) newborns. However, it was linked to lower birth weight in full-term infants and an increased risk of late pregnancy loss (Table 1) (10).

The Centers for Disease Control and Prevention (CDC), in collaboration with state health departments across several U.S. states, analyzed cases of H1N1 influenza among pregnant women during the 2009 pandemic. Data on treatment, hospitalization, and health complications were collected and linked to the birth records of their children. The aim was to evaluate the impact of H1N1 infection on neonatal outcomes. This project (Newsome, 2019) used a retrospective cohort model, comparing the outcomes of infants born to mothers with H1N1 infection to those of infants whose mothers reported no infection (11). The analysis included 531 live newborns delivered by women with H1N1 influenza in 2009 (490 singletons) and control groups, totaling 2,897 newborns (11).

Table 2. Impact of H1N1 infection on neonatal outcomes

Outcomes:	aRR (95%CI)
PTB a)	1,7 (1,3, 2,2)
PTB b)	1,4 (1,1, 1,9)
LBW a)	1,8 (1,2, 2,6)
LBW b)	1,2 (0,9, 1,7)
SGA a)	0,9 (0,6, 1,2)
SGA b)	1,0 (0,7, 1,4)
Low Apgar Score: a)	4,0 (2,1, 7,6)
Low Apgar Score: b)	2,3 (1,3, 3,9)

PTB = Preterm Birth, <37 weeks of gestation; LBW = Low Birth Weight, <2500 g; SGA = Small for Gestational Age, birth weight <10th percentile for gestational age; Low Apgar Score = 5-minute Apgar score ≤ 6; aRR = Adjusted RR = risk ratio adjusted for race/ethnicity and maternal age; a) - comparison within the same year; b) - comparison with the previous year (11).

The study revealed that infants born to women with H1N1 influenza in 2009 were more likely to be born preterm and had lower Apgar scores compared to those in the control groups (Table 2) (11).

These findings suggest that influenza can have a significant impact on both maternal and infant health, highlighting the importance of preventive measures such as vaccination. Given these risks, it is crucial to further analyze the benefits and potential risks of influenza vaccination in pregnant women to fully understand its effects on maternal health and pregnancy outcomes.

3.2. Effectiveness of Influenza Vaccination:

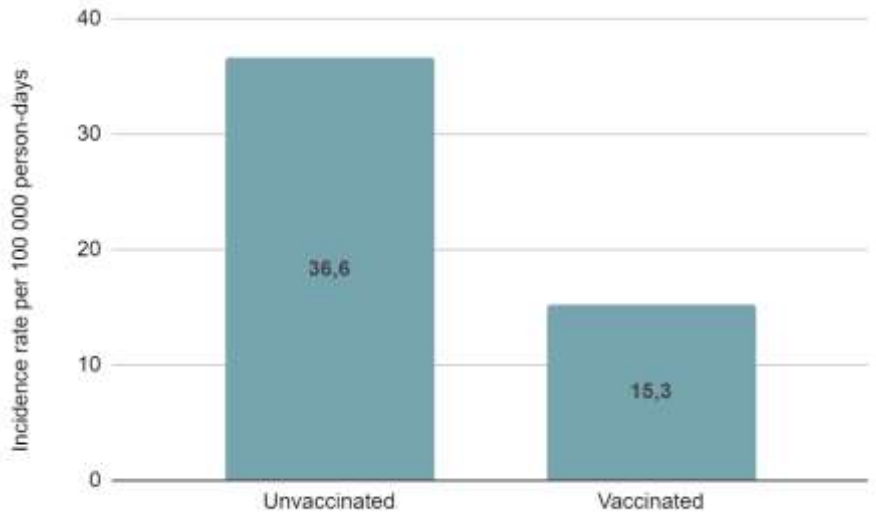
Since 2005, the World Health Organization (WHO) has recommended influenza vaccination for all pregnant women during the flu season (7). In many countries, inactivated (IIV) and recombinant (RIV) vaccines are recommended for women (5), while live attenuated influenza vaccines (LAIV) and other live vaccines are contraindicated due to the risk of viral transmission to the fetus (4–6). Maternal antibodies produced after vaccination cross the placenta, providing infants with protection until six months of age, which is significant since

infants at this age cannot yet be vaccinated (5). Later vaccination during pregnancy results in a stronger maternal immune response and better antibody transfer to the fetus, although antibodies may wane more quickly (9). Vaccination early in pregnancy protects the mother for most of the pregnancy but may lower antibody levels at delivery, reducing newborn protection (9).

A study conducted in Denmark from 2010 to 2017 assessed the effectiveness of influenza vaccination in pregnant women and their infants. The results (Mølgaard-Nielsen, 2019) showed that maternal vaccination reduced the risk of influenza infection in pregnant women by 63.9% (95% CI, 29.1 to 81.6) and lowered the risk of influenza in infants under six months of age by 56.8% (95% CI, 25.0 to 75.1). The study demonstrated significant vaccine effectiveness, protecting both mothers and their children from influenza (12).

In the PRIME study conducted in Peru, involving 1,896 pregnant women, it was found that 54.8% exhibited influenza-like symptoms, with 7% of those confirmed to have influenza via RT-PCR. The incidence of influenza (Owusu, 2023) among vaccinated women was 50% lower than that among unvaccinated women (15.3 vs. 36.6 per 100,000 person-days) (Figure 2). The vaccine effectiveness (VE) against influenza A and B was 22% (95% CI: −64.1% to 62.9%), and VE against influenza A/H1N1pdm09 was 15.9% (95% CI: −87.1% to 62.2%). When vaccination status was treated as a fixed variable, VE was 80% (95% CI: 59.7%–90.1%) (13).

Figure 2. Incidence of influenza among vaccinated and unvaccinated women, (%)



Both studies indicate that influenza vaccination is an effective health protection strategy for pregnant women and their infants. The results suggest that vaccination is an important preventive measure, helping to guard against serious complications related to influenza.

3.3. Risks and Benefits of Influenza Vaccination:

A cohort study (Sarna, 2022) conducted in Western Australia analyzed birth data from 2012 to 2016. It compared the risk of serious congenital anomalies in children of mothers vaccinated against influenza in the first trimester with the risk in unvaccinated mothers, accounting for confounders such as maternal age and socio-economic status. Multiple pregnancies, chromosomal abnormalities, and congenital infections were excluded from the analysis. Logistic regression and linear models were used to analyze the data, considering classification errors (14). The study included a cohort of 125,866 single births, of which 4,864 (3.9%) were diagnosed with severe structural defects. The most common were musculoskeletal defects (51.7%). The impact of seasonal influenza vaccination (IIV) during pregnancy on the risk of these anomalies was assessed. The results did not show a significant association between vaccination in the first trimester and serious congenital anomalies (PR 1.02, 95% CI: 0.84, 1.24), although a slight increase in the incidence of developmental dysplasia of the hip (DDH) was noted. However, after adjusting for multiple comparisons, this association was no longer significant (14).

In a study (Mehrabadi, 2021) conducted in Nova Scotia, data from 28,255 births were analyzed, of which 10,227 children were vaccinated. The study did not find a significant association between vaccination and asthma, cancers, or sensory impairments in children. Furthermore, no significant differences were observed in the incidence of infections or in the use of urgent medical services. The results of the trimester-specific analysis also did not differ significantly from the primary results. However, in a post hoc analysis, a certain association was found between vaccination in the third trimester and lower respiratory tract infections (adjusted IRR, 1.19 [95% CI, 1.01 to 1.40]) (15).

In a study (Ohfuji, 2020) conducted in 117 hospitals and clinics in Japan, participants provided data on vaccinations and pregnancy outcomes, such as miscarriages, stillbirths, preterm births, low birth weight, and congenital anomalies. The analysis of the data, using a logistic regression model, aimed to assess the relationship between vaccination and adverse birth outcomes, considering various variables (16). Among 20,420 recruited pregnant women, 12,838 responded to the questionnaire, with 10,330 women remaining after exclusions. Among them, 38% received the influenza vaccine during pregnancy (16). A total of 997 women (10%) reported adverse birth outcomes, such as miscarriage, stillbirth, preterm birth, or low birth weight. In the vaccinated group, women reported slightly fewer adverse outcomes (9%) compared to the unvaccinated group (10%), although the difference was not statistically significant ($p = 0.09$). In the multivariate analysis, vaccination during pregnancy had no

significant impact on birth outcomes (OR 0.90, 95% CI 0.76–1.07). However, it was noted that women vaccinated in the third trimester had a lower risk of adverse outcomes (OR 0.70; 95% CI 0.51–0.98), particularly low birth weight (6% vs. 8% in unvaccinated women) (16).

A double-blind, randomized, placebo-controlled clinical trial (Mølgaard-Nielsen, 2019) conducted in Soweto, South Africa, aimed to evaluate the efficacy of a trivalent inactivated influenza vaccine in pregnant women and its impact on fetal health. The study spanned two flu seasons (2011 and 2012) and focused on pregnant women aged 18 to 38 years, between 20 and 36 weeks of gestation. The study found no significant differences in fetal deaths between the vaccinated group and the placebo group, with 29 cases reported in each group. Regarding preterm birth, no significant differences were noted; in the vaccinated group, 12.5% of infants were born prematurely, compared to 11.5% in the placebo group. Similarly, no significant differences were observed in terms of low birth weight—both groups had rates of 12.5% and 11.5%, respectively. The average birth weight was slightly lower in the vaccinated group (3032 g) compared to the placebo group (3071 g), but this difference was not statistically significant (P = 0.094). However, the results indicated that the trivalent inactivated influenza vaccine during pregnancy significantly reduced the risk of laboratory-confirmed influenza infections in mothers and their infants. The study's conclusions suggest that IIV3 vaccination had no significant impact on fetal health outcomes (12).

A study (Shaikh, 2023) conducted at Yashwantrao Chavan Memorial Hospital (YCMH) in Pune included 558 pregnant women, of whom 47.5% (265 women) received the trivalent inactivated influenza vaccine. Vaccination during pregnancy was not associated with statistically significant differences in birth outcomes compared to the unvaccinated group. The analysis found no increased risk of stillbirth (0.53% among participants), congenital anomalies, or preterm birth (7.7% of preterm births in the entire sample). It was observed that women who were not vaccinated against influenza during pregnancy had a higher risk of giving birth to a child with very low birth weight (AOR 2.29, 95% CI; 1.03–5.58, p = 0.03). The average birth weight was 2693 g in the vaccinated group compared to 2579 g in the unvaccinated group. These results indicate that influenza vaccination during pregnancy is not associated with negative health outcomes for mothers and infants (17).

The prospective cohort study (Mohammed, 2020) STOP aimed to assess the impact of influenza vaccination during pregnancy on pregnancy and neonatal outcomes, such as preterm birth, preeclampsia, low birth weight (SGA), and the risk of hospitalization due to influenza-like illness. The final study cohort consisted of 1253 women. 48.1% of the women were vaccinated against influenza during pregnancy. Vaccinated women had a 39% lower risk of

hospitalization before delivery due to influenza-like illness compared to unvaccinated women (aHR 0.61; 95% CI 0.39–0.97). Influenza vaccination was not associated with a significantly increased risk of gestational hypertension (aHR 0.78), preeclampsia (aHR 0.84), or severe preeclampsia (aHR 0.65). No association was found with spontaneous miscarriage before 20 weeks of gestation (aHR 0.42). Maternal vaccination against influenza was shown to significantly reduce the risk of giving birth to a low birth weight child (aHR 0.38, 95% CI 0.16, 0.89), even after accounting for pertussis vaccination, and this effect was particularly strong during periods of high influenza activity. Vaccinated women had an average of 1.8 days longer gestation compared to unvaccinated women. In the analysis of preterm birth risk, influenza vaccination was not associated with a significant increase or decrease in the risk of this outcome (18).

Among 135,807 live births in Ontario, 31,295 (30%) children were born to women vaccinated against the pH1N1 influenza virus from 2009. Among 104,249 children included in the analysis (Walsh, 2019), the median follow-up period was five years. During this time, 14% of the children were diagnosed with asthma, at an average age of 1.8 years. The analysis revealed a small but statistically significant increase in asthma risk associated with the vaccine (aHR 1.05; 95% CI 1.02–1.09) and a decreased risk of gastrointestinal infections (aIRR 0.94; 95% CI 0.91–0.98). Other outcomes studied showed no significant associations with the vaccine (19).

E. AF Simões (2019) described a study involving 2,081 mothers, of whom 2,035 met the criteria for vaccination at least 14 days before delivery. In both the vaccinated (IIV3) and placebo groups, 29 fetal deaths were recorded. The average gestational length in the IIV3 group was 38.6 weeks, while in the placebo group, it was 38.9 weeks (P = 0.025), whereas birth weight differed insignificantly (3032 g vs. 3071 g, P = 0.094). No significant differences were found in fetal outcomes, such as preterm birth or fetal death. The study did not confirm significant benefits of the influenza vaccine regarding fetal outcomes (20).

Omer (2020) analyzed three randomized controlled trials conducted in Nepal, Mali, and South Africa in his study. The analysis included 10,002 women, of whom 5,017 received the influenza vaccine (IIV) and 4,985 were in the control group. The impact of vaccination on the health of infants and women was assessed. The overall efficacy of the vaccine in protecting infants against influenza was 35%, with efficacy being higher in the first two months of life (56%). However, efficacy declined to 46% during the first four months of life. The study found no significant differences in birth outcomes, such as low birth weight, preterm births, or stillbirths, except in Nepal, where vaccination was associated with a lower risk of low birth

weight (RR 0.85, 95% CI 0.74–0.96). The vaccine does not appear to negatively affect fetal development, and its effects are limited to protecting infants from influenza up to four months of age (21).

Table 3. Risks and benefits of influenza vaccination - summary of the analysed studies (14-21)

Study	Number of participants (vaccinated/unvaccinated)	Proven risk:	Proven benefits:
Sarna (2022)	125 866 (13 696/112 170)	-	No increased risk of serious congenitalanomalies was observed.
Mehrabadi (2021)	28 255 (10 227/18 028)	The association betweenvaccination in the thirdtrimester and lower respiratorytract infections (adjusted IRR, 1.19 [95% CI, 1.01 to 1.40]).	-
S. Ohfuji (2020)	10 330 (3 943/6 387)	-	Vaccinated women in the thirdtrimester had a lower risk of adverse birth outcomes (OR 0.70; 95% CI 0.51–0.98).
Mølgaard-Nielsen (2019)	350 888 (35 577/315 311)	-	Reduced risk of influenza infection in both mothers and infants.
Shaikh (2023)	558 (265/293)	-	Vaccinated women had a lower risk ofgiving

			birth to a child with very lowbirth weight.
Mohammed (2020)	1 253 (603/650	-	Vaccinated women had a lower risk ofhospitalization before delivery due toinfluenza-like illness (aHR 0.61; 95% CI 0.39–0.97). Vaccinated women had a lower risk ofgiving birth to a lowbirth weight child(aHR 0.38, 95% CI 0.16, 0.89).
Walsh (2019)	104 249 (31 295/72 954)	Increased risk of asthma in children associated withmaternal vaccination (aHR1.05; 95% CI 1.02–1.09).	Reduced risk of gastrointestinal infections in children after maternal vaccination (aIRR 0.94; 95% CI 0.91–0.98).
Simões (2019)	2 035 (1 025/1 010)	Vaccinated women had a shorter gestational length[Vaccinated women - 38.6 weeks, placebo group - 38.9 weeks (P = 0.025)].	
Omer (2020)	10 002 (5 017/4 985)	-	Protection of infants against influenzaup to 4 months of age (46%).

In a meta-analysis of studies conducted before 2019, Lu Q. Chun (2021) included 18 studies comprising a total of 679,992 pregnant women. The analysis compared 181,479 women vaccinated against influenza with 498,513 women who did not receive the vaccination (22).

Table 4. Meta-analysis summary (22)

Endpoints which were assessed	RR with 95% CI	P values
Premature/Preterm birth (< 37 weeks)	0.80 [0.69–0.92]	0.002
Very preterm birth (< 32 weeks)	0.70 [0.58–0.84]	0.0001
Low birth weight (< 2500 g)	0.71 [0.49–1.04]	0.08
Very low birth weight (< 1500 g)	0.69 [0.23–2.11]	0.52
Small for gestational age	0.93 [0.83–1.05]	0.26
Stillbirth	0.63 [0.38–1.03]	0.07
Major birth defects	0.67 [0.26–1.72]	0.41
Admission to NICU	0.94 [0.87–1.02]	0.13
Apgar score < 7 in 5 min	0.89 [0.78–1.02]	0.09

These results (Table 4) suggest that influenza A vaccination during pregnancy may help reduce the risk of preterm birth and does not increase the risk of other negative health outcomes for the fetus (22).

4. Discussion

Several key factors influencing vaccination hesitancy among pregnant women in Europe have been identified during review. Among the most significant are low perceived risk of influenza, concerns about vaccine safety, anti-vaccination attitudes, and lack of information and recommendations from healthcare providers (23). It has been found that Black and Latina pregnant women have lower vaccination rates compared to White women (24). Women often fear that the vaccine may harm both themselves and their unborn children, or they are uncertain about its efficacy. Access to reliable information and appropriate recommendations from healthcare providers has also been identified as a problem (23). Women who were vaccinated against influenza in previous pregnancies demonstrate higher acceptance of vaccination in the future (25).

In a study conducted in Singapore involving 500 pregnant women, it was found that only 10% of them were vaccinated against influenza during their current pregnancy. Although awareness of the vaccine's existence was high, most women were not well-informed about its recommendations, which contributed to the low vaccination rate. A key factor increasing willingness to vaccinate was a personal recommendation from a healthcare provider. Barriers included a lack of information about the vaccine and concerns about side effects (26).

The stance of healthcare providers regarding influenza vaccination for pregnant women is largely positive. Most obstetricians and gynecologists strongly recommend vaccination and consider it safe. However, there is a significant portion of doctors who have concerns about vaccine safety, which influences their decisions regarding recommending vaccinations, especially in the first trimester. These concerns are often related to a lack of current knowledge and patient anxieties. Therefore, educating healthcare providers about vaccine safety and effective communication strategies with patients may be crucial for increasing vaccination rates in this group (27,28).

Looking at the above analysis of the latest sources and studies regarding vaccination for pregnant women, it can be concluded that the vaccine does not pose a risk to the lives of the mother or child. Studies conducted on large samples do not show significant harm to the fetus or adverse birth outcomes. Furthermore, the vaccine often prevents low birth weight in infants and significantly reduces the risk of contracting influenza for both the mother and the child after birth. Avoiding illness and the stress associated with influenza is, in itself, a strong argument for vaccinating pregnant women. To increase vaccination rates among pregnant women, it is crucial to properly train doctors and other healthcare workers. It is important for information on vaccine safety to be widely available among obstetricians and gynecologists. This will enable them to educate their patients with greater confidence and peace of mind. Conveying information based on reliable scientific research will allow doctors to build trust among patients, which, in turn, may contribute to an increase in influenza vaccinations among pregnant women.

5. Conclusions

The conducted integrative review clearly indicates that influenza negatively affects pregnant women, increasing the risk of complications. Vaccination against influenza is an effective preventive measure that significantly reduces the risk of illness for both pregnant women and their newborns. Recent studies have not shown any significant side effects associated with influenza vaccination in pregnant women, confirming its safety. Therefore, this vaccination is recommended by numerous health organizations as a safe and effective method

for protecting the health of pregnant women and their children. Despite the positive results, it is worthwhile to conduct additional research to further explore the topic and eliminate any doubts. Further studies may contribute to a better understanding of the long-term effects of vaccination and its impact on different population groups.

Disclosure

The authors declare no conflict of interest.

Supplementary Materials

Not applicable.

Author Contributions

Conceptualization, KK, and MK; methodology, SK; software, SK; check, MK, AK and WK; formal analysis, KK; investigation, LK; resources, MK; data curation, SK; writing - rough preparation, LK, AK and WK; writing - review and editing, KK; visualization, MK; supervision, WK; project administration, KK; receiving funding, KK All authors have read and agreed with the published version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interest.

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