Title Page

**Interventions to increase vaccination against COVID-19, influenza and pertussis during pregnancy: a systematic review and meta-analysis**

Short Title: Interventions to increase vaccination in pregnancy

Keywords: vaccine hesitancy, strategies, maternal immunisation, vaccine confidence, public policy, antenatal care, maternal health

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**Abstract**

**Background:** Pregnant women and their babies face significant risks from three vaccine-preventable diseases: COVID-19, influenza, and pertussis. However, despite these vaccines' proven safety and effectiveness, vaccine uptake during pregnancy remains low.

**Methods**: We conducted a systematic review (PROSPERO CRD42023399488; January 2012 – December 2022 following PRISMA guidelines) of interventions to increase COVID-19/influenza/pertussis vaccination in pregnancy. We searched nine databases, including grey literature. Two independent investigators extracted data; discrepancies were resolved by consensus. Meta-analyses were conducted using random-effects models to estimate pooled effect sizes. Heterogeneity was assessed using the I2 statistics.

**Results:** Out of 2681 articles, we identified 39 relevant studies (n=168,262 participants) across nine countries. Fifteen studies (39%) were randomised controlled trials (RCTs); the remainder were observational cohort, quality-improvement or cross-sectional studies. The quality of 18% (7/39) was strong. Pooled results of interventions to increase influenza vaccine uptake (18 effect estimates from 12 RCTs) showed the interventions were effective but had a small effect (Risk ratio = 1.07, 95%CI 1.03, 1.13). However, pooled results of interventions to increase pertussis vaccine uptake (10 effect estimates from six RCTs) showed no clear benefit (Risk ratio = 0.98, 95%CI 0.94, 1.03). There were no relevant RCTs for COVID-19. Interventions addressed the “three Ps”: patient-, provider- and policy-level strategies.

At patient level, clear recommendations from healthcare professionals backed by text reminders/written information were strongly associated with increased vaccine uptake, especially tailored face-to-face interventions, which addressed women’s concerns, dispelled myths and highlighted the benefits. Provider-level interventions included educating healthcare professionals about vaccines’ safety and effectiveness and reminders to offer vaccinations routinely. Policy-level interventions included financial incentives, mandatory vaccination data fields in electronic health records, and ensuring easy availability of vaccinations.

**Conclusions:** Interventions had a small effect on increasing influenza vaccination. Training healthcare providers to promote vaccinations during pregnancy is crucial, and could be enhanced by utilising mobile health technologies.

**Introduction**

Unvaccinated pregnant women face an elevated risk of severe illness, complications, and death from infection with the viral pathogens SARS-CoV-2 and influenza.1 2 3 4 5 6-9

Similarly, pertussis bacterial infection poses a considerable threat to infants, resulting in high rates of hospitalisation and mortality.10-12 Vaccination during pregnancy provides a high level of protection against these adverse outcomes.13-15 16 17 18 19 20 21 Most importantly, vaccination in pregnancy is safe 4 22 23 3 24 25 and is strongly recommended for all three vaccines: COVID-19, influenza, and pertussis.26 27

Historically the US Centers for Disease Control and Prevention (CDC) first recommended influenza vaccination for pregnant women in 1997, followed by Australia in 2009 and the UK in 2010. This is typically administered seasonally.28 29 Pertussis vaccination (usually at 16-32 weeks gestations for each pregnancy) was added to the CDC's maternal immunisation recommendations in 2010, with the UK following in 2012 and Australia in 2015.28 COVID-19 vaccination (effective against early pandemic strains) is offered seasonally to pregnant women.28 While the pertussis vaccine mainly aims to protect the infant by passive transfer of maternal antibodies, influenza and COVID-19 vaccines are designed primarily to protect the mother, indirectly benefiting the infant. This may necessitate tailored messaging for pregnant women.

Despite the well-established benefits, low vaccine uptake during pregnancy and high levels of vaccine hesitancy (delay in acceptance or refusal of safe vaccines despite availability of vaccine services) are reported across the world.30 31 32 3 24 33 34-44 Vaccine hesitancy is recognised as a top ten global health threat by the World Health Organization.45 This complex phenomenon manifests differently across time, regions, and sociodemographic factors.45 Lower vaccination rates during pregnancy are associated with younger age,3 24 33 lower socioeconomic status24 3 33, minority ethnicities, particularly Black and Latino populations,3 38 43 44 and migrant groups.34 46 47 48 49 Other barriers include concerns over vaccines’ long-term safety, side effects and efficacy, conflicting guidance from healthcare professionals, distrust of vaccines and healthcare providers, limited knowledge about vaccines, and practical challenges like inconvenient vaccination schedules and locations.37 39 45 50 51 The COVID-19 pandemic highlighted the importance of vaccination during pregnancy and revealed health disparities among different ethnic and socioeconomic groups.48 52 53 It is crucial to address these inequalities through effective interventions.

Previous systematic reviews showed that healthcare professionals' recommendations, vaccination reminders in antenatal records, and midwives administering vaccines might be effective;30 54-56 however, most interventions lack robust evaluation.30 45 54 57-61 A knowledge gap exists regarding effective interventions to enhance the uptake of all recommended vaccinations during pregnancy. In 2022-23, we conducted the first-ever systematic review of studies of interventions to increase vaccination in pregnancy against three vaccine-preventable diseases: COVID-19, influenza, and pertussis.

**Methods**

Search strategy and selection criteria

A systematic literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).62 The review protocol was registered on PROSPERO (International Prospective Register of Systematic Reviews; CRD42023399488). The primary outcome was pregnant women’s vaccination status and intention to vaccinate. We restricted the search to high-income countries with well-established vaccination programmes. Secondary outcomes were factors associated with vaccine acceptance or refusal (e.g., ethnicity, age, setting, vaccine type, and socioeconomic status).

We conducted a comprehensive search of relevant literature, encompassing both peer-reviewed and grey literature. A Boolean search strategy was applied across multiple databases for primary research reporting on interventions to increase vaccination (influenza, pertussis, COVID-19) in pregnancy between 1 January 2012 to 15 December 2022 (see appendix 1 for full search terms) with no language restrictions. We searched Embase, Web of Science, Oxford Academic Journals, PubMed NIH, Clinical Trials, China CDC, CDC reports, and the WHO COVID-19 global literature database for COVID-19 literature.63 Non-COVID-19 literature was searched using Embase, CINAHL, PsycINFO, and Medline. Supplementary grey literature was identified through a thorough examination of key institutional websites such as the Royal College of Obstetrics & Gynaecology and the UK Health Security Agency, as well as Google Scholar, manual searches and backwards and forwards citation checking.

Inclusion criteria were quantitative papers related to the outcome measures, including grey literature (e.g., government guidelines, preprints) reporting vaccination or intention to vaccinate in currently pregnant and recently post-partum women (within 12 weeks of childbirth). We included papers that presented primary data from Randomised Controlled Trials (RCTs), as well as observational studies (such as cross-sectional, case-control, quality improvement or cohort studies). In quasi-experimental studies such as quality improvement and audit, we allowed the control groups of either standard/usual care, historical control groups, or pre-and-post-intervention assessments. We excluded conference abstracts, systematic reviews, comments, editorials, literature reviews, and letters. We included countries in the World Bank's list of high-income countries.64

Data screening, extraction, and analysis

MSR carried out title and abstract screening and performed full-text screening, data extraction, and quality assessment. In line with PRISMA guidelines, all steps were duplicated by an independent second investigator (RM, CMA, SF or KR). Once the abstracts were regarded as relevant, the full paper was reviewed and scrutinised using strict inclusion/exclusion criteria. Any discrepancies were resolved by discussion between authors (MSR, RM).

Data extraction from each study was conducted according to predefined criteria. The extracted information included the first author, year of publication, study design, location (online, community, hospital), and date. The vaccine of interest (e.g., COVID-19, influenza, pertussis), sample and effect size, basic demographic characteristics of participants (ethnicity and age), gestational age, vaccination rate, and intent to vaccinate were also collected. For RCTs, we extracted Relative Risks (RRs) from intention-to-treat analysis. When RRs and CIs were not presented, we calculated them from available data in STATA.65 In cases of multiple comparisons within a single study, such as multiple vaccines and interventions, effect sizes were not combined. We used a random-effects meta-analysis with STATA (version 18)65 to calculate pooled log risk ratio estimates and associated 95% confidence intervals (95%CI), using a restricted maximum likelihood method (Raudenbush 2009).66 Results were back-transformed to risk ratios. Statistical heterogeneity was assessed using the I² and Chi² statistics. An I² value under 40% suggests statistical heterogeneity might not be important.67

Quality assessment was conducted independently by two reviewers (MSR, RM or PK) using the Effective Public Health Practice Project's (EPHPP) Quality Assessment Tool for Quantitative studies.68 69 Where decisions could not be reached, a third reviewer (PO) arbitrated. This tool was chosen because it allows for the assessment of both RCTs, and observational studies using a single framework and has demonstrated strong agreement among raters in systematic reviews. The EPHPP framework evaluates the quality of studies based on criteria such as selection bias, design, confounding, blinding, data collection, participant withdrawal and opt-out, intervention integrity, and analysis. Each paper was assigned a score of 'weak', 'moderate', or 'strong' based on its design and analysis.69 To ensure transparency, we did not exclude any study based on quality assessment.

**Results**

Overview of included studies

Figure 1 shows the PRISMA flow diagram.62 There was a total of 39 eligible studies (n=168,262 participants). A summary of the descriptive characteristics of these studies is shown in Table 1. Most studies were observational (e.g., cohort, quality improvement and cross-sectional n= 23/39, 59%), and the remaining were RCTs (15/39, 39%). The sample size of the studies ranged from 67 to 78898 participants (median 518). Most studies were conducted in the USA (24/39, 61.5%), followed by Australia and New Zealand (6/39, 15%) and the UK (3/39, 8%) (Supplementary Figure S1). The majority of studies were on influenza and pertussis (37/39, 95%) with only two focusing on COVID-19. Twenty four studies reported the ethnicity of participants. (The majority were white.)

The quality of seven studies (18%) was assessed as strong (Supplementary Figure S2). The remaining 32 had weaknesses such as inadequate study designs, insufficient consideration or control of confounding factors, and lack of clarity about the reliability or validity of data collection methods. Most RCTs (9/15, 60%) did not report any significant effect from the interventions.

Narrative summary of included studies by intervention types

The interventions were broadly categorised into patient-level, provider-level, policy-level and multimodal strategies (outlined below and summarised in Table 1 and Supplementary Figure S1). Most studies (18/39) were patient-level interventions such as providing pregnant women with information or verbal counselling, prompting through reminders and tailored messages. Provider-level interventions (5/39) included training healthcare professionals, and setting reminders for healthcare staff. Policy-level interventions (5/39) included funding community pharmacies to vaccinate pregnant women, implementing guidelines, and enforcing electronic alerts in medical records. Multimodal interventions (11/39) using a combination of two or three domains were common, highlighting the multipronged approach to vaccination. We provide intervention details and their effectiveness below.

1. Patient-level interventions (n=18)

Twelve out of eighteen studies reported positive effects of the interventions, seven of which were significant. Only five studies explicitly referenced a health behaviour change technique70 that underpinned their interventions.71-75

Three educational trials showed benefits. An RCT of pamphlets and statements of benefits of vaccination improved influenza vaccine uptake and perception of vaccine safety.75 Another RCT demonstrated improved vaccination uptake for influenza among participants given a leaflet and a one-to-one education session.76 A further trial showed that a patient educational video and iBook for pertussis information increased vaccination rates. Lack of recommendations from healthcare professionals and awareness were identified as reasons for not receiving the vaccine.71

Three trials using technology showed benefits, including a study in less affluent pregnant women. Interactive education and reminder text messages increased uptake of influenza vaccination.74 Text message reminders and influenza vaccine information increased vaccination rates in urban low-income women, especially in the early third trimester.77 Another RCT where participants were given access to a vaccine information website with interactive social media content, increased influenza vaccine uptake but not pertussis, compared to controls.78

However, four patient-level interventions did not show benefits. These included twice-weekly text messages recommending the influenza vaccine79; video case studies and interactive educational tutorials for patients based on affective and cognitive messaging80; an educational video developed by the CDC 81; modifying CDC information leaflets to lower literacy levels 82; and 12 weekly text messages about the importance of having the influenza vaccine.83

Four studies were on vaccination intention rather than vaccination receipt. An RCT of a smartphone app providing information and reminders about influenza showed increased vaccination intention.73 Educational presentations by experts accompanied by handouts decreased hesitancy and improved pregnant women’s knowledge of influenza and pertussis vaccinations.84 Written information and counselling by a physician increased willingness to receive vaccination against COVID-19.85 However, a cross-sectional study of message framing did not affect vaccine acceptability.86

1. Provider-level interventions (n=5)

Four out of five studies showed increased vaccination rates. A cohort study showed reminders to healthcare staff improved influenza vaccination rates regardless of age, race, education, primary language, or insurance.87 Similarly, supplementing usual care with brightly coloured reminder forms attached to antenatal clinic notes led to an increase in influenza vaccination rates.88 The CDC’s Quality Improvement (QI) Programme in obstetric clinics included twice weekly technical assistance meetings with designated immunisation champions, incentives for champions and staff, and adapted CDC QI tools. Post-intervention chart review showed increased influenza and pertussis vaccination rates in all clinics, with feedback, goal setting, and incentives improving provider motivation.89

Two studies compared two different interventions (rather than comparing them to no intervention. A QI project compared three hospitals' immunisation services led by nurses, midwives, and general practitioners (GPs). All three interventions resulted in improvements in vaccination rates. The biggest change was observed in the hospital, where standing orders were introduced. These are written protocols authorising a healthcare professional such as a midwife to administer vaccines without needing physician review or prescription. This led to vaccination rates increasing from 39% to 91%.90 Finally, a cohort study showed no difference in vaccination rates when vaccination was recommended by nurses versus physicians.91

1. Policy-level interventions (n=5)

Four out of five interventions increased vaccination uptake. A before and after study from New Zealand found that community pharmacy funding for administering maternal pertussis vaccination increased pertussis uptake, including in Maori women.92 A QI project suggested that implementing best-practice alerts in electronic prenatal records increased influenza vaccination rates.93 Similarly, an electronic medical record alert at 32 weeks of gestation resulted in a higher vaccination rate and a non-significant decline in neonatal pertussis incidence.94 Another QI project found that a mandatory vaccination field in electronic records doubled influenza vaccination rates between audit cycles.95 However, a cohort study introducing onsite COVID-19 vaccination at high-risk obstetric clinics, with around 70% of women from black and minority ethnic groups, found only a (non-significant) increase in COVID-19 vaccination rates from 3% to 10%, but the numbers were small.96

1. Multimodal Interventions (n=11)

Eight out of eleven multimodal studies reported higher vaccination rates, five of which were significant. An RCT of a practice-, provider-, and patient-focused package including talking points on coloured papers, vaccine champions, lapel buttons for staff, provider education, posters, brochures and iPad tutorials for patients, and maps to vaccination sites, showed a non-significant increase in influenza and pertussis vaccination rates, with provider recommendation being the most influential factor.97 A community awareness campaign in Stockport UK combined with a pharmacy programme and GP financial incentives resulted in higher influenza vaccine coverage in pregnant women in the intervention area. In this study, real-life case stories and staff support played important roles.98 In the USA, a combination of written information, CDC posters, clinician education, and electronic health record prompts both increased influenza vaccination rates and improved documentation.99 Another intervention combined maternity unit notifications, opportunistic immunisation, and after-hours vaccination options, which improved pertussis vaccine uptake. Lack of vaccination offer by GP was a major reason for non-vaccination.31 Updated vaccination guidelines and implementation strategies (e.g., medical record reminders, increased stocking of vaccines, feedback on vaccination rates) significantly increased pertussis and influenza vaccine coverage among non-Hispanic white women. 100 Implementation of the American College of Gynecologists’ guidelines and toolkit also increased pertussis vaccination rates.101

A US QI project which included staff education, reminders, and increased vaccine availability, increased pertussis vaccination rates.102 Similarly, in Australia, staff education, reminder messages, safety checklists, patient information brochures and increased vaccine supplies improved influenza vaccine coverage and reduced safety concerns, although lack of discussion by healthcare professionals remained a barrier to vaccination.103 In another study, national policies and professional statements promoting vaccination, patient information brochures, staff education, and improved vaccine supply increased influenza vaccination rates.104 Finally, two multimodal studies showed no difference in influenza and pertussis vaccination rates.105 106

Meta-analyses of RCTs

Overall, 14 RCTs reporting vaccination uptake during pregnancy were meta-analysed (n=86,424 participants). One RCT was excluded as it only reported vaccination intention.73 Most studies (11, 79%) were patient-level educational interventions (79%), and two studies were cluster RCTs. The Influenza vaccine uptake meta-analysis comprised eighteen effect estimates from twelve studies, while the Pertussis vaccine uptake meta-analysis included ten effect estimates from six studies. We did not identify any trials on COVID-19 vaccinations during pregnancy.

Figure 2 shows pooled results for interventions to increase influenza vaccination uptake among pregnant women. The forest plot indicated that the interventions are effective but have a very small effect (Risk ratio = 1.07, 95%CI 1.03, 1.13). Pregnant women offered the intervention were more likely to receive the influenza vaccination than pregnant women who were not offered the intervention. The Chi2 is not significant, and the I2 is low, suggesting heterogeneity may not be important.

Figure 3 shows pooled results indicating that interventions to increase Pertussis vaccination uptake among pregnant women were not effective in these studies (Risk ratio = 0.98, 95%CI 0.94, 1.03). The I2 = 0.01% and the Chi2 is not significant.

**Discussion**

Interventions from 12 RCTs promoting influenza vaccination among pregnant women significantly increased vaccination rates albeit with a small effect (Risk ratio = 1.07, 95%CI 1.03, 1.13).However, our meta-analysis of six RCTs suggests that interventions to increase pertussis vaccination in these studies were not effective. At patient level, clear, consistent, unambiguous recommendations from healthcare professionals backed by text reminders and written information increased vaccine uptake, especially tailored face-to-face interventions, which addressed women’s concerns, debunked myths and highlighted the benefits. Provider-level interventions included educating healthcare professionals about vaccines’ safety and effectiveness and reminders encouraging them to offer vaccinations routinely. Effective policy-level interventions included financial incentives for providers to vaccinate pregnant women, inserting mandatory vaccination data fields in electronic health records, ensuring easy availability of vaccinations across different healthcare facilities and the use of standing orders enabling midwives to give vaccinations.

A strength of this systematic review is that it is the first to examine all three currently recommended vaccinations in pregnancy. It offers a comprehensive overview of interventions across nine countries and includes studies with large sample sizes. It includes 24 studies which specifically reported on the percentage of participants from ethnic minority groups who often have lower vaccination rates despite being at higher risk.107 By incorporating both RCTs and observational studies, encompassing patient-level, provider-level, policy-level, and multimodal strategies, the utility of the findings is enhanced.

However, there are several limitations. Most studies focused on influenza and pertussis vaccination, which limits the applicability of the results to other vaccines, notably COVID-19. Nearly two thirds of studies were from the USA, potentially limiting generalisability to other countries and healthcare systems. Additionally, the heterogeneity of interventions and outcome measures within multimodal interventions makes it challenging to compare the effectiveness of different intervention components within and across studies. Only 18% of the studies were of strong quality. The review focused on high-income settings with established vaccination programmes and may not reflect the unique challenges of low- and middle-income contexts. Finally, four studies examined vaccination intentions rather than actual uptake.73 84-86 According to the Theory of Planned Behaviour, intentions are key determinants of behaviour.108 While a previous study found intent to be a reliable predictor of influenza vaccination, a recent COVID-19 study indicated that stated willingness did not consistently translate to actual vaccination.109 110

This study is comparable with previous systematic reviews, but these were smaller, mainly focused on pertussis or influenza, and were primarily narrative, excluding meta-analyses.111 55 112 54 113 The findings are consistent with existing evidence45 that it is crucial to increase pregnant women’s knowledge about vaccinations and to address concerns about safety and effectiveness.45 One-way sharing of information114 may not be as effective as interactive counselling from a healthcare professional.45 54 It is crucial that healthcare professionals are convinced of the benefits of vaccination (which is not always the case) and have good communication skills and up-to-date knowledge about vaccines.101 102 115 116 Previous studies suggest that most pregnant women consider healthcare professionals such as GPs and midwives to be reliable sources of information, and this could be effectively leveraged.107 Moreover, this study highlights policy changes that can facilitate vaccination, such as electronic alerts in healthcare records and incentives for healthcare providers.117 118

Several factors might have contributed to the null effects of interventions in the pertussis studies. These include contextual factors such as higher vaccine hesitancy 78 97 and unique challenges within obstetric care settings.105 Additionally, the absence of baseline equivalence – indicated by varying availability of pertussis vaccines across practices – and uncontrolled confounding factors, such as secular trends in immunisation, could have influenced the results.97 105 106 Moreover, certain study population characteristics not accounted for in the study design (e.g., providing written vaccine information for low literacy groups) may have influenced the outcomes.82 Possible contributors to the inefficacy of influenza vaccine interventions were inadequate behavioural change techniques, like single intervention exposure instead of repeated messaging needed for behaviour change,80 81 non-tailored messages not resonating with the target audience and flawed study procedures like late-season vaccination and lack of message receipt verification.83 97

Areas where action could be taken at the patient, provider and policy levels to improve maternal vaccination rates are summarised in Figure 4, based on the strength of evidence in each domain. Addressing misconceptions and promoting the benefits of vaccination among pregnant women and their families is crucial.98 73 Tailored approaches including written material, can enhance understanding and confidence in vaccination.73 99 74 71 75 106 79 Community outreach programmes can educate pregnant women and their families about the importance of vaccination, ensuring this information reaches diverse populations.31 100 116 119 91 Additionally, sharing success stories and personal testimonials from pregnant women who have received vaccines can increase confidence and motivation.98

At provider level, strong vaccination recommendations from healthcare professionals, especially using positively framed messaging, can increase vaccine uptake.80 96 116 119 98 81 97 99 104 Encouraging GPs, midwives and obstetricians to offer vaccinations during routine prenatal visits – with multiple opportunities for counselling – helps integrate vaccination into standard care, increasing accessibility and convenience for pregnant women and providing opportunities for discussions.84 80 103 88 76 Ongoing training ensures that healthcare providers stay up to date with the latest evidence.84 31 100 80 101 102 87 99 82 Finally, fostering collaboration among obstetricians, midwives, and other healthcare providers is essential to ensure clear and unambiguous messaging about vaccination during pregnancy.31

At the policy level, integrated collaborative healthcare approaches can enhance vaccination coverage and ensure consistent messaging across settings.31 Making vaccines readily available on-site in antenatal clinics, pharmacies, and community-based locations can improve accessibility.119 76 80 92 Leveraging mobile apps and technology can be an effective tool for vaccine promotion, reaching a wider audience and providing tailoring.73 78 80 104 106 Collecting data on factors influencing vaccine uptake and evaluating educational initiatives is essential for developing targeted interventions.84 99 83 89 102 105 106 Implementing vaccination reminders, best-practice alerts, and mandatory data field systems can help ensure that pregnant women receive vaccines in a timely manner.74 77 93-95 By reducing barriers (which may be different for different populations) uptake of maternal vaccines can be increased.89 120

Infectious diseases epidemiology and vaccine uptake are multifaceted and continuously shifting,114 121 (For example maternal vaccination against Respiratory Syncytial virus has been approved in the USA.) It is likely that in future multiple interventions will be needed which must be tailored to individual populations and may need to adapt as new technologies become available.120 Further research should focus on identifying the most effective components of interventions at the patient-, provider-, and policy levels and explore their long-term sustainability and cost-effectiveness. Continued research and collaboration between researchers and healthcare providers are vital to optimise vaccination rates, ultimately protecting the health of pregnant women and their babies.

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**Figure Legend**

Figure 1: PRISMA flow diagram of included and excluded studies

Figure 2. Forest plot of 12 studies (18 effect estimates) of interventions to increase influenza vaccination

Figure 3. Forest plot of six studies (10 effect estimates) of interventions to increase pertussis vaccination

Figure 4: Recommendations for increasing vaccination in pregnancy with the three Ps: Patient, Provider and Policy measures.

Table 1. Details of 39 included studies including quality assessment.

\*Intent to vaccinate. RCT = Randomised Controlled Trial. Tdap = Tetanus, Diphtheria and Pertussis vaccination. QI = Quality Improvement. At risk: eligible for influenza vaccine due to pre-existing medical condition, regardless of pregnancy.