Systematic Reviews

PROTOCOL

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Acceptance and uptake of vaccines against tetanus, influenza, pertussis, and COVID-19 among pregnant and postpartum women in low- and middle-income countries: a systematic review and meta-analysis protocol

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Abstract

Background Pregnant women, fetuses, and neonates are particularly vulnerable to vaccine-preventable diseases (VPDs). These VPDs are associated with high morbidity and mortality among expectant mothers and their fetuses and neonates. Vaccination during pregnancy can protect the expectant mother from VPDs to which she may be especially vulnerable while pregnant. In addition, the passive transfer of maternal neutralizing immunoglobulin G (IgG) and secretory immunoglobulin A (IgA) also protects the fetus against congenital infections and may further protect the neonate from infection during the first few months of life. Despite this, coverage of recommended maternal vaccines remains suboptimal globally, especially in resource-constrained settings. Determinants of vaccine acceptance and uptake are frequently understudied in low- and middle-income countries (LMICs) and among specific groups such as pregnant and postpartum women. This proposed systematic review will assess the acceptance and uptake of vaccines against tetanus, influenza, pertussis, and COVID-19 among pregnant and postpartum women in LMICs.

Methods A Boolean search strategy employing common and medical subject heading (MeSH) terms for tetanus, influenza, pertussis, and COVID-19 vaccines, as well as vaccine acceptance, hesitancy, together with uptake, pregnancy, and postpartum, will be used to search electronic databases for relevant literature published between 2009 and 2024. Only studies conducted in LMICs that investigated determinants of acceptance, hesitancy, and uptake of tetanus, influenza, pertussis, and COVID-19 vaccines among pregnant and postpartum women will be eligible for inclusion in the review. The quality and the risk of bias of all eligible full-text articles will be assessed using the Joanna Briggs Institute's (JBI) critical appraisal tools.

Discussion This protocol proposes a systematic review and meta-analysis that aims to assess the uptake of maternal vaccines and to systematically appraise and quantify determinants of the acceptance and uptake of recommended vaccines during pregnancy and postpartum in LMICs. A better understanding of these factors and how they influence maternal vaccine decision-making will enable public health practitioners as well as global and national policymakers

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to design more effective interventions as we look towards expanding the scope and reach of maternal immunization programs.

Keywords Maternal immunization, Vaccination in pregnancy, Postpartum, Vaccine acceptance, Vaccine uptake, Low- and middle-income countries

Introduction

Pregnant women, fetuses, and neonates are vulnerable to infectious diseases. This includes those that can be prevented by vaccination and are associated with high morbidity and mortality [1]. The maternal immune system undergoes significant changes during pregnancy to defend the mother and her unborn child against infections while preventing adverse immune reactions to the allogeneic fetus [2]. An essential condition for a healthy pregnancy is the mother's immune tolerance to the semi-allogeneic fetus [2–5]. The complex adaptive changes required to develop this tolerance increase the likelihood of a severe course of infectious disease, even in immunocompetent pregnant women. The fetus is susceptible to infections during pregnancy or birth [2–5]. Pregnant women often have the same ability as nonpregnant women to develop an immune response to natural illnesses and vaccines. However, as levels of the sex hormones, estrogen, and progesterone rise, the balance of pro-inflammatory and anti-inflammatory responses fluctuates throughout pregnancy. Along with these physiological and hormonal changes, pregnancy results in diminished pulmonary reserve and higher cardiac output, which may also reduce pathogen control and aggravate clinical symptoms [2–5]. As neonates transition from the protected intrauterine environment to the antigen-rich external world, they encounter many microbial challenges. Neonatal immune systems are still developing at this critical time, and they differ significantly from adult immune systems in many ways. Therefore, the administration of broad-spectrum passive innate immunity during infancy is essential for creating protective immunity while also preventing the negative effects of neonatal infections [6–8].

Many studies have indicated that pregnant women are more likely than nonpregnant women to develop severe disease and die from seasonal influenza [7, 9–12]. During the 2009 influenza A pandemic, pregnant women were 7.2% more likely to be hospitalized than nonpregnant women, and they also had a disproportionately higher risk of mortality [7, 9–12]. A recent prospective cohort research also revealed that pregnant women who were infected with influenza during pregnancy were more likely to have adverse pregnancy outcomes, such as late pregnancy loss and a reduction in their infants' birthweight when compared to women who were not infected [7, 9–12]. Additionally, acute lower respiratory infection (ALRI) caused by the influenza virus is a leading cause of death in children under the age of 5 [13, 14]. In 2018, influenza was linked to 15,300 inhospital deaths in children under the age of 5 worldwide [13, 14]. More than a third of inhospital deaths were in children under the age of 6 months, with the majority (82%) occurring in low-income and lower-middle-income nations (LMICs). When compared to older children in high-income countries (HICs), children under the age of 6 months had greater rates of influenza-related hospitalization and mortality [13, 14]. Infants can be protected early in infancy if their mothers are vaccinated [13, 14].

Bordetella pertussis is what causes the pertussis infection, also known as whooping cough, a highly contagious disease of the respiratory tract [15–17]. Despite decades of routine childhood vaccination, pertussis remains common globally and is difficult to contain [15–17]. While 60% of pertussis cases occur in adults and adolescents, infants under 2 months of age who are not yet old enough to receive the vaccine have the greatest incidence of the disease and the highest mortality rates [15–17]. According to the Global Burden of Disease Study's 2021 estimates, there were 7.2 million (95% UI 5.1–10.3 million) cases and 52,500 deaths (24,000–104,000) due to whooping cough (pertussis) globally in 2021 after accounting for COVID-19-associated changes in pertussis transmission [18]. Death rates were highest in children aged 1–5 months [18].

In addition to that, pregnant women are at a higher risk of severe disease and death from SARS-CoV-2 infection than nonpregnant women, according to data from several countries [19–22]. Furthermore, COVID-19 in pregnancy is linked to an increased risk of adverse pregnancy outcomes [19–22].

The World Health Organization (WHO) recommends that pregnant and postnatal women get vaccinated against tetanus influenza and pertussis [23–26]. In most LMICs, vaccination against tetanus during pregnancy has long been recommended. Recently, both pertussis and influenza vaccination programs for pregnant and postpartum women have been recommended in several HICs and LMICs [23–28]. Moreover, given the risks of COVID-19 disease during pregnancy and the growing body of evidence supporting the favorable safety profile of COVID-19 vaccines in pregnant and postpartum

women, the WHO recommends their use in pregnant and lactating women [29, 30].

The advantages of vaccination during pregnancy for infants were revealed for the first time in 1879 when it was discovered that babies born to mothers who had received the vaccinia virus vaccine during pregnancy were protected from smallpox during the early period of their life [14, 31, 32]. Neonatal vaccination is an alternate method for protecting young infants from infectious diseases. It may however be less likely to be effective in the first week of life as the ability of the infant to produce neutralizing antibodies may not yet have matured enough [14, 31, 32]. There are benefits to vaccinating pregnant women. Vaccination at this stage protects the expectant mother from diseases to which she may be especially vulnerable while pregnant and protects the growing fetus against congenital infections and other negative effects of maternal infections. Maternal immunization may be utilized to protect the infant from infection during the first few months of life through the placental transfer of neutralizing immunoglobulin G (IgG) antibodies and/or secretory immunoglobulin A (IgA) antibodies in breast milk [14]. Postpartum vaccination plays a role in protecting mothers from getting sick, and if they are breastfeeding, they will transfer vaccine-specific antibodies to the baby through breast milk. If mothers do not receive recommended vaccines before or during pregnancy, vaccination during postpartum turns out to be critically important [33].

Postpartum Tdap vaccination is recommended for mothers who were not vaccinated during pregnancy since it has been demonstrated to help protect newborns in their first few weeks of life [34]. The influenza vaccine is also recommended for postpartum women offering no risk to lactation [35].

Despite the above, most LMICs do not include maternal vaccination against influenza and pertussis in their routine immunization programs, and coverage of the influenza vaccine, for instance, is still low among pregnant women worldwide, particularly in resource-constrained settings in LMICs [36, 37]. According to the Maternal Immunization and Antenatal Care Situational Analysis (MIACSA) project conducted in LMICs, 59% of countries with available data had influenza vaccine included in their routine immunization schedule for pregnant women, but maternal influenza immunization was not offered on a routine basis in any of these countries. The MIACSA online survey further revealed that 25% of countries had introduced maternal influenza immunization, and 9% had introduced maternal pertussis immunization, with most of these countries located in Latin America [38]. However, comprehensive data on the acceptance and uptake of these vaccines, as well as COVID-19 vaccines, among postpartum women in LMICs remains limited.

This systematic review study seeks to investigate the prevalence or incidence of acceptance, intention to vaccinate, willingness, and uptake of all recommended vaccines during pregnancy and postpartum in low- and middle-income countries (LMICs). Secondly, the study aims to investigate the determinants of acceptance, intention to vaccinate, willingness, and uptake of these vaccines. Specifically, the systematic review and envisaged meta-analysis aims to assess the acceptance and uptake of vaccines against tetanus, influenza, pertussis, and COVID-19 in pregnant and postpartum women and systematically appraise and quantify determinants of the acceptance and uptake of these vaccines in these populations.

Methods

Vaccine uptake refers to the number of women vaccinated against any of the recommended vaccines during pregnancy or postpartum.

Vaccine acceptance is defined as the individual or group's decision to accept when presented with an opportunity to vaccinate [39]. It is also defined as willingness and intention to vaccinate [40].

Vaccine hesitancy is defined as a dynamic spectrum ranging from the complete refusal of all vaccines, the refusal of vaccines but hesitant about this decision, hesitating about some vaccines or only one of them, to hesitating but still taking vaccines [41].

Postpartum is defined as the weeks after birth up to 6 months when the physiologic changes related to pregnancy return to the nonpregnant state [42].

Pregnancy is defined as the period in which a fetus develops inside a woman's uterus [43].

Eligibility criteria

Inclusion criteria

These are studies that evaluated the prevalence of vaccination acceptability and uptake for COVID-19, pertussis, influenza, and tetanus among postpartum and pregnant women in low- and middle-income countries.

Exclusion criteria

These are studies conducted in HICs, studies conducted on nonpregnant or non-postpartum women, and studies that included vaccines other than tetanus, pertussis, influenza, or COVID-19.

Study design/characteristics

Observational studies including cross-sectional, case–control, and cohort studies that reported the prevalence or incidence of recommended vaccines' acceptance or

uptake among pregnant and postpartum women and explored the factors associated with acceptance and uptake of these vaccines will be considered for inclusion. Alternatively, the studies should include data that can be used to calculate these outcomes. In this review, we will only consider studies conducted in LMICs [44].

Population

This review will include pregnant and postpartum women in LMICs [44].

Intervention

It is vaccination against tetanus, pertussis, influenza, and Covid-19 during pregnancy or postpartum.

Comparators (controls)

- Pregnant or postpartum women who did not accept to receive or did not get vaccinated against tetanus pertussis influenza or COVID-19.
- Pregnant or postpartum women who were hesitant or refused to get vaccinated against tetanus pertussis influenza or COVID-19.

Outcomes

Primary outcomes

The incidence will be defined as events of acceptance or getting vaccinated against tetanus pertussis influenza or COVID-19 occurring over the total period participants are at risk. Prevalence will be defined as the proportion of all participants who agreed to get vaccinated or the proportion of participants who were vaccinated against tetanus pertussis influenza or COVID-19.

Secondary outcomes

It is prevalence ratio or odds ratio or incidence ratio for exploring the determinants of acceptance and uptake of vaccination against tetanus pertussis or influenza or Covid-19 among pregnant and postnatal women.

Search strategy methods for the identification of studies

A comprehensive and sensitive search strategy has been developed to identify relevant studies published between the 1st of January 2009 and the 15th of May 2024. Multiple electronic databases will be searched for all the relevant literature, namely MEDLINE through PubMed, Scopus, Web of Science (core collection), EBSCOhost (Academic Premier, Africa-Wide Information, CINAHL, Health Source Nursing Academic, MEDLINE, APA PsychArticles, and APA PsycINFO), WHOLLIS, WHO database, Google Scholar, and gray literature. We will use both key terms and Medical Subject Heading (MeSH) terms. The search strategy will be tailored for each database. Table 1 shows the search strategy developed and adapted for searches in PubMed.

Data management and study selection

Articles retrieved from databases will be exported to EndNote version 20 citation manager and will then be exported to Rayyan, a systematic review production tool for title/abstract screening, full-text screening, and data abstraction [45]. After deleting duplications, the authors I. A. and T. M. will screen the studies using titles and abstracts independently. In addition, publication date and country, type of vaccines, study setting, study design, methods, and population as well as study outcomes will be evaluated. Then, the authors I. A. and T. M. will independently read the full text of all potentially eligible studies for inclusion in this review to assess their eligibility. Discrepancies in the list of included studies between the two authors will be resolved through discussion and consensus, with the assistance of a third author.

Data collection process

Data will be extracted from text, tables, and figures and recorded in a standardized data extraction sheet designed for this review independently by two authors I. A. and T. M. The following data will be extracted from the included studies in this review:

Study characteristics: Publication date, period, design, and aims
Study population: Country, setting, and pregnant or postpartum participants
Type of vaccines: Tetanus pertussis or influenza or covid-19
Prevalence or incidence of acceptance or uptake of tetanus or pertussis influenza or COVID-19
The number of people vaccinated or who accepted to get vaccinated will form the nominator.
The number of participants studied will form the denominator.
Prevalence ratios, odds ratios, or risk ratios for determinants of acceptance or uptake of tetanus or pertussis influenza or COVID-19
Factors were associated with the acceptance and uptake of each vaccine.

Risk of *bias* in individual studies

Authors I. A. and T. M. will independently assess the risk of bias in the included studies using the Joanna Briggs Institute's critical appraisal checklists for observational studies for cross-sectional studies, case–control studies, and cohort studies as appropriate [46]. Conflicts

Table 1 Search strategy in PubMed

Query number	Search term
#1	Pregnant women [MeSH Terms] OR postpartum period [MeSH Terms] OR pregnancy [Title/Abstract] OR postpartum women [Title/Abstract]
#2	Vaccines [MeSH Terms] OR vaccination [Title/Abstract] OR immunization [Title/Abstract]
#3	Influenza, human [MeSH Terms] OR whooping cough [MeSH Terms] OR covid 19 [MeSH Terms] OR tetanus [MeSH Terms] OR influenza [Title/Abstract] OR influenza virus [Title/Abstract] OR pertussis [Title/Abstract] OR covid 19 [Title/Abstract] OR tetanus [Title/Abstract] OR coronavirus [Title/Abstract] OR sars cov2 [Title/Abstract]
#4	#2 AND #3
#5	Afghanistan OR Albania OR Algeria OR American Samoa OR Angola OR Armenia OR Azerbaijan OR Bangladesh OR Belarus OR Belarus OR Belorussia OR Belize OR Benin OR Bhutan OR Bolivia OR Bosnia OR Botswana OR Brazil OR Bulgaria OR Burma OR Burkina Faso OR Burundi OR Cabo Verde OR Cape Verde OR Cambodia OR Cameroon OR Central African Republic OR Chad OR China OR Colombia OR Comoros OR Comoros OR Comoro OR Congo OR Costa Rica OR Côte d'Ivoire OR Cuba OR Djibouti OR Dominica OR Dominican Republic OR Ecuador OR Egypt OR El Salvador OR Equatorial Guinea OR Eritrea OR Ethiopia OR Fiji OR Gabon OR Gambia OR Gaza OR Georgia OR Georgia Republic OR Ghana OR Grenada OR Grenadines OR Guatemala OR Guinea OR Guinea- Bissau OR Guyana OR Haiti OR Herzegovina OR Hercegovina OR Honduras OR India OR Indonesia OR Iran OR Iraq OR Ivory Coast OR Jamaica OR Jordan OR Kazakhstan OR Kenya OR Kiribati OR Democratic People's Republic of Korea OR Kosovo OR Kyrgyz OR Kirghizia OR Kirghiz OR Kyrgyzstan OR Lao PDR OR Laos OR Lebanon OR Lesotho OR Liberia OR Libya OR Macedonia OR Madagascar OR Malawi OR Malay OR Malaya OR Malaysia OR Maldives OR Mali OR Marshall Islands OR Mauritania OR Mauritius OR Mexico OR Micronesia OR Moldova OR Mongolia OR Montenegro OR Morocco OR Mozambique OR Myanmar OR Namibia OR Nepal OR Nicaragua OR Niger OR Nigeria OR Pakistan OR Palau OR Papua New Guinea OR Paraguay OR Peru OR Philippines OR Principe OR Romania OR Ruanda OR Rwanda OR Samoa OR Sao Tome OR Senegal OR Serbia OR Sierra Leone OR Solomon Islands OR Somalia OR South Africa OR South Sudan OR Sri Lanka OR St Lucia OR St Vincent OR Sudan OR Surinam OR Suriname OR Swaziland OR Syria OR Syrian Arab Republic OR Tajikistan OR Tadzhikistan OR Tajikistan OR Tadzhik OR Tanzania OR Thailand OR Timor OR Togo OR Tonga OR Tunisia OR Turkey OR Turkmen OR Turkmenistan OR Tuvalu OR Uganda OR Ukraine OR Uzbek OR Uzbekistan OR Vanuatu OR Venezuela OR Vietnam OR West Bank OR Yemen OR Zambia OR Zimbabwe
#6	#1 AND #4 AND #5
#7	Search: ((((("vaccine hesitancy"[Title/Abstract]) OR ("vaccine acceptance"[Title/Abstract])) OR ("vaccine intention"[Title/Abstract])) OR ("vaccine uptake"[Title/Abstract])) OR ("vaccine confidence"[Title/Abstract])
#8	#6 AND #7

while assessing the risk of bias between the two authors will be resolved through discussion and consensus, with the assistance of a third author. The JBI critical appraisal tool has 11 items to assess cohort studies, 10 items to assess case–control studies, and 8 items to assess cross-sectional studies [46]. Results of the study risk-of-bias assessment and data will be extracted into a standard sheet for data synthesis and statistical analysis.

Quality of evidence

To summarize the overall quality and assess the level of certainty of the evidence, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE approach) [47, 48] will be used for the meta-analysis pooling estimates data from all included studies. The following GRADE domain will be considered: risk of bias, imprecision, inconsistency, indirectness, and publication bias.

Data synthesis

Data will be analyzed, and all the statistical calculations were performed using STATA software version 18 (STATA Corporation, College Station, TX, USA). Heterogeneity among the included studies will be assessed by Cochran's Q χ^2 statistics and Higgins's (I^2 statistics) method [49]. The data will be pooled in a meta-analysis using a random effects model to combine the prevalence or incidence estimates. I^2 statistic estimates of 25%, 50%, and 75% would mean low, medium, and high heterogeneity, respectively [50]. Subgroup analysis will be conducted based on the population type of pregnant or postpartum women and by type of vaccine. Other variables that will be considered for subgroup analysis are risk-of-bias assessment and study design.

Forest plots will be used to summarize the pooled estimates allowing the visual examination of publication bias as well. The main characteristics of the included studies including study aim, population studied, types of vaccines, risk of bias, and main outcomes will be presented in tables.

The proposed systematic review will be conducted following standard methods and will be reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [51]. Findings in our systematic review will be presented using a PRISMA flow diagram to summarize the study selection process including reasons for exclusion, while tables will be used to summarize characteristics and outcomes from the included studies.

Results of the quality assessment of studies and level of evidence will be described narratively. Moreover, tables or graphs will be presented for the quality assessment

adding to the GRADE summary findings tables for the certainty of evidence.

Discussion

In LMICs, where the burden of vaccine-preventable diseases is highest, maternal vaccination is an effective way to reduce infection in neonates and infants [24, 52–54]. The Maternal Neonatal Tetanus Elimination program was the first maternal vaccination initiative to be put into action, and it serves as evidence suggesting the feasibility and potential of vaccination during pregnancy to reduce neonatal mortality, particularly in LMICs [24, 52–54]. Neonatal tetanus caused an estimated 787,000 infant fatalities in 1988, according to the WHO, with a global mortality rate of roughly 6.7 deaths per 1000 live births [24, 52–54]. In response, the WHO urged the eradication of maternal and neonatal tetanus and suggested that one of the four elements of the strategy be the routine vaccination of pregnant women with tetanus toxoid [24, 52–54]. As of March 2018, 45 of 59 countries have achieved elimination, with an estimated 96% reduction in tetanus-related neonatal deaths compared with the late 1980s [24, 52–54].

Vaccination during pregnancy and postpartum aims to reduce maternal and neonatal morbidity and mortality caused by infections. In settings where the disease burden is known, the WHO recommends the inactivated influenza vaccine, tetanus-toxoid-containing vaccines, and the combination tetanus, diphtheria, and acellular pertussis (Tdap) vaccine for pregnant women in order to lower maternal and newborn morbidity and death [2, 3, 55]. Pertussis vaccination was previously limited to childhood. Vaccination during pregnancy and postpartum contains great potential to reduce the global burden of morbidity and mortality among infants, with their unique position to access the infant's immune system through maternal antibodies' transfer before a childhood vaccine could be effective, especially when maternal vaccines are under development for respiratory syncytial virus (RSV) and group B streptococci, which are estimated to be major causes of neonatal morbidity and mortality worldwide [56–58].

Safe and effective maternal vaccines will only be effective if mothers choose to receive them. Maternal knowledge, attitudes, and beliefs about vaccines are important predictors of vaccine acceptance and uptake, but this issue is frequently understudied in low- and middle-income countries and among specific groups such as pregnant and postpartum women [52, 59]. By examining the factors that influence maternal vaccine decision-making, such as sociodemographic characteristics, cultural beliefs, perceived risks, and benefits, and confidence in healthcare providers, that will be quantified and critically evaluated. Adding to considering psychological and behavioral aspects, such as social influences from family, peers, and healthcare practitioners, this systematic review will provide a deeper understanding of how these factors collectively shape maternal decisions regarding vaccination, thereby offering insights into potential interventions and strategies to enhance vaccine uptake among pregnant and postpartum women. A better understanding of these factors and how they influence maternal decision-making will enable public health practitioners as well as global and national policymakers to design more effective interventions. Addressing determinants of maternal vaccination, such as mothers' knowledge, attitudes, and beliefs about vaccination during pregnancy and postpartum period, is critical to increasing global vaccination rates and reducing global vaccine-preventable maternal and neonatal morbidity [3, 56, 60].

Protocol registration

This protocol has been published in the PROSPERO International Prospective Register of Systematic Reviews (http://www.crd.york.ac.uk/PROSPERO), registration number CRD42023412893.

Abbreviations

VPDs	Vaccine-preventable diseases
LMICs	Low- and middle-income countries
IgG	Neutralizing immunoglobulin G
IgA	Secretory immunoglobulin A
MeSH	Medical Subject Heading
JBI	Joanna Briggs Institute
HICs	High-income countries
WHO	World Health Organization
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
Tdap	Tetanus, diphtheria, and acellular pertussis

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Authors' contributions

IA conceived the study. IA and SN developed the criteria and searched the literature. IA wrote the protocol. EAD, BK, and RM assisted in protocol design. EAD, BK, TM, and RM advised on protocol design and revised the manuscript. All authors read and approved the final manuscript.

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Declarations

Ethics approval and consent to participate

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Consent for publication

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Competing interests
The authors declare that they have no competing interests.

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