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High Intention to Vaccinate Against Tuberculosis During Pregnancy and Lactation: Understanding Vaccine-specific Maternal Immunization Acceptance in Amhara, Ethiopia

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Abstract

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Author contributions: EMQ, LMC, SO, AG and JNC conceptualized the study and wrote the protocol. MLB and LAE collected data. EMQ, LMC, JNC and RK performed and reviewed the analyses. EMQ and LMC wrote the initial draft of the manuscript. All authors helped interpret the findings and reviewed, edited, and approved the final version of the manuscript.

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Introduction: Tuberculosis (TB) disease during pregnancy results in adverse maternal and infant outcomes. Development of a TB vaccine with potential for administration during pregnancy or lactation is a priority identified by the World Health Organization. We assessed acceptability of vaccines currently administered during pregnancy (tetanus, diphtheria (Td) and COVID-19) and willingness to receive a new TB vaccine during pregnancy and/or lactation among Ethiopian women.

Methods: From January to February 2022, we conducted surveys among pregnant women receiving antenatal care at 20 hospitals in Amhara, Ethiopia. We evaluated uptake of available vaccines (Td), acceptance of new and future vaccines (COVID-19 and TB) during pregnancy and lactation, and knowledge, attitudes, and beliefs associated with vaccine-specific acceptance.

Results: Among 200 participants, we found high intention to receive a TB vaccine during pregnancy (90%) and lactation (92%), and low COVID-19 vaccine acceptance during pregnancy (40%) and lactation (47%). Most participants believed TB vaccination would protect their child from disease (82.5%) and had societal benefits (81.5%), while few women perceived COVID-19 vaccine to offer protection (35.5%) have societal benefits (42.5%). Intention to receive TB vaccination during pregnancy was associated with the belief that a future maternal TB vaccine would prevent TB among infants (adjusted PR 1.37, 95% CI 1.10, 1.70). Most participants reported high acceptability of educational interventions to increase uptake of maternal immunization.

Discussion: We found high intention to receive a new TB vaccine during pregnancy and lactation among Ethiopian women. Our findings support vaccine-specific educational interventions to strengthen maternal immunization programs in Ethiopia.

Keywords

vaccination during pregnancy; lactation; tuberculosis; COVID-19; tetanus; maternal child health

INTRODUCTION

Maternal immunization is a safe and effective tool for reducing maternal and perinatal morbidity and mortality from infectious diseases, including tetanus, pertussis, influenza, and COVID-19.(1–4) However, the benefits of immunization to pregnant mothers for emerging infectious pathogens have been significantly delayed given the exclusion or late inclusion of pregnant women in clinical trials evaluating new vaccine candidates. For example, an inactivated influenza vaccine was licensed for the general population in 1945(5) but was not recommended for use during pregnancy until 1960(6) despite high risk of influenza-related severe disease and hospitalization among pregnant women.(7) Additionally, higher morbidity and mortality among pregnant women(8) and their infants was observed early in the COVID-19 pandemic,(1) yet pregnant women were included late in preclicensure trials, and lack of safety data led to low global uptake among pregnant and lactating women compared to the general population.(9) A maternal vaccine for Zika virus infection has not yet been licensed(10) despite a 2015–2016 outbreak leading to congenital defects in infants, leaving the public health community unprepared should another outbreak occur.(11) In addition, uptake of maternal immunization for vaccines known to be safe in pregnancy

has been limited in many low- and middle-income countries (LMICs).(12) Context-specific facilitators and barriers to maternal vaccine acceptance are needed to design effective interventions to improve uptake of currently available vaccines and enable expansion of maternal vaccination programs as new vaccines become available.(13)

While the adverse effects of perinatal infections such as influenza, Zika, and COVID-19 have been more visible, the ongoing chronic tuberculosis (TB) pandemic and its effect on maternal and fetal outcomes is under-recognized. It is estimated that TB affects over 200,000 women of childbearing age annually, though the precise global burden of TB among pregnant and postpartum women has not been quantified.(14) TB during pregnancy is associated with unfavorable maternal-infant outcomes including higher risk for maternal morbidity (odds ratio (OR) 2.8, 95% confidence interval (CI) 1.7, 4.6), preterm birth (OR 1.7, 95% CI 1.2, 2.4), low infant birth weight (OR 1.7, 95% CI 1.2, 2.4), and perinatal death (OR 4.2, 95% CI 1.5, 11.8).(15–17) Women experience two-fold higher risk of progression to active TB disease in the first 3–6 months postpartum.(18–20) Maternal TB during pregnancy or postpartum is associated with high rates of infant *Mycobacterium tuberculosis* infection (19, 21) and an eight-fold higher risk of child mortality among household contacts. (17, 22) With few options to prevent and treat TB during pregnancy and lactation,(23) the World Health Organization (WHO) has identified the development of a TB vaccine that can be administered during pregnancy and lactation as a priority.(24) Ideally, women of childbearing potential would receive a TB vaccine prior to pregnancy; however, adolescents and adult populations have had historically poor vaccine uptake of new vaccines given limited contact points with the healthcare system. Antenatal care and hospitalization for childbirth provide opportunities for immunization, and women should have the option to receive a new TB vaccine during pregnancy or lactation if not previously immunized.(24) Depending on the time to immunogenicity and durability of immunity for new candidate TB vaccines, immunization during pregnancy could prevent maternal progression to TB disease during the postpartum period thereby lowering infant TB exposure, and/or prevent maternal TB and related poor birth outcomes in subsequent pregnancies.(24)

Ethiopia's national guidelines recommend that pregnant women receive tetanus and diphtheria (Td) vaccination,(25) which has reduced maternal and neonatal tetanus cases nationally by 30%.(2) Despite this progress, maternal tetanus vaccination coverage in the Amhara region has been low, with only 35.7% of women receiving two or more tetanus-containing vaccines during pregnancy.(13) The rollout of COVID-19 vaccination in Ethiopia was expanded in November 2021 to include pregnant women, yet subsequent uptake among pregnant women was around 15% (95% CI 11.7%, 17.3%).(26),(27) Ethiopia has a high incidence of TB at 132 per 100,000 persons (in 2020) and ranks 12th among the top 30 high TB burden countries.(28) We designed this study to assess facilitators and challenges to uptake of Td vaccination, acceptance of COVID-19 vaccine, and intention to vaccinate against TB during pregnancy and lactation in Amhara, Ethiopia. This study was designed to identify opportunities to optimize current maternal immunization efforts and pave the way for expansion of the maternal immunization pipeline in Ethiopia and similar healthcare systems for high-impact pathogens such as TB.

METHODS

Study Design and Setting

We conducted a cross-sectional survey (see Survey, Supplemental Digital Content 1) among 200 pregnant women receiving antenatal care (ANC) at 17 primary healthcare centers and 3 referral hospitals in the Amhara region of Ethiopia. Healthcare facilities were in urban and rural regional zones of Amhara, including Bahir Dar City, West Gojjam, and South Gondar. Participants were recruited by convenience sampling and were eligible if they were pregnant (during all trimesters), age ≥ 18 years, and able to provide informed consent. Surveys were administered by trained interviewers in Amharic and responses were recorded into a Kobo Toolbox database using mobile tablets. Surveys were conducted between January 1, 2022, and February 28, 2022, after the rollout of COVID-19 vaccination in Ethiopia; however, COVID-19 vaccines were not yet offered to pregnant women at the ANC facilities where surveys were conducted.

Cross-Sectional Survey

We collected sociodemographic information, obstetric history, vaccination experience, and sources of vaccine information using close-ended questions. Vaccine acceptance and associated knowledge, attitudes, and beliefs were ascertained using questions with five-point Likert scaled responses. Specific questions regarding participants' reasoning for intention to receive a TB vaccine and COVID-19 vaccine acceptance were evaluated. The content of this survey was adapted from tools previously developed to assess maternal immunization acceptance in Kenya(29) and by the WHO's Strategic Advisory Group of Experts on vaccine hesitancy.(30)

Statistical Analysis

Sociodemographic data and survey responses were summarized using descriptive statistics. We used counts and percentages for categorical variables and median and interquartile ranges (IQR) for continuous variables since they were not normally distributed. Rates of Td vaccine uptake, intention to vaccinate against TB and COVID-19 acceptability in pregnancy were calculated. Since our outcome was not rare, we used binomial logistic regression to model prevalence ratios (PR) and estimate predictors of uptake, acceptance, or intention to vaccinate. We used Poisson regression with robust variance estimates for models which did not converge. Maternal age and geographic residence (rural or urban), determined *a priori*, were adjusted for in the multivariate models.(27, 31–34) Maternal education level was also evaluated as a covariate; however, given the lack of impact (10% change from the unadjusted model) on confounding assessment, it was not included in the final model.

Ordinal qualitative scales were recoded for analysis. We defined vaccine acceptance as both 'strongly agree' and 'agree.' Hesitancy was defined as 'strongly disagree,' 'disagree,' and 'neither agree nor disagree.' A sample size of 200 participants produces a two-sided 95% CI of 14.3%. If 50% of survey respondents reported vaccine acceptance, we estimated the true acceptance rate in the population would be between 42.9% and 57.1%.

Ethics Statement

This study was approved by the Research and Technology Transfer Directorate of Amhara Public Health Institute, Amhara National Regional State Health Bureau (NoH/R/T/T/D/5/7, November 2, 2021) and the Institutional Ethical Review Board of Emory University (STUDY 00001790, May 17, 2021).

RESULTS

Study Characteristics

Among 200 participants, median age was 27 years (IQR 24–30). Most participants resided in urban areas (80.5%, n=161) and had some formal education (76.5%, n=153). The median annual income was 72,000 Ethiopian birr (IQR 48,000–100,000, approximately \$1,356.04 USD, IQR \$904.03 – \$1,883.39 USD).(35) Most participants (46.0%, n=92) had 2–3 prior pregnancies; 35.5% (n=71) had 0–1 prior pregnancies, and 8.5% (n=37) had ≥ 4 prior pregnancies. The median pregnancy duration at the time of the survey was 6 months (IQR 3–9 months). One-quarter of participants had a history of prior miscarriage (25%, n=50). 80.5% (n=161) of participants reported receiving a vaccine during the current pregnancy. Of the 161 women who reported having received a vaccine in their current pregnancy, half identified the vaccine as Td (50.9%, n=82). Most participants did not report ever having a negative experience when receiving a vaccine (89.5%, n=179). Approximately 9 of 10 women reported uptake of a tetanus-containing vaccination in their current or prior pregnancy (88.5%, n=177). (see Table, Supplemental Digital Content 2)

Td Vaccine Uptake

A high proportion of participants reported receiving a Td vaccine during their current [80.5% (n=161)] or a prior pregnancy [88.5% (n=177)]. Maternal Td vaccine uptake was associated with a higher level of education (adjusted prevalence ratio (aPR) 1.24, 95% CI 1.09, 1.41), prior negative experience with a vaccine (aPR 1.17, 95% CI 1.09, 1.26), and receipt of counseling on vaccines in pregnancy (aPR 1.13, 95% CI 1.01, 1.27). (see Tables, Supplemental Digital Content 3–4)

COVID-19 Vaccine Acceptance

Acceptance of a COVID-19 vaccination in pregnancy was 39.5% (n=79) with 5.0% (n=10) who strongly agreed they would receive a COVID-19 vaccine during pregnancy and 34.5% (n=69) who agreed. Acceptance of the COVID-19 vaccine while lactating was 47% (n=94) with 5.5% (11) strongly agreeing and 41.5% (n=83) agreeing (see Table, Supplemental Digital Content 5). The prevalence of COVID-19 vaccine acceptance in pregnancy was lower among those who lived in an urban compared to a rural area (aPR 0.62, 95% CI 0.44, 0.88). Additionally, those with a higher level of education had a lower likelihood of COVID-19 vaccine acceptance compared to those with no formal education (aPR 0.56, 95% CI 0.34, 0.93). The prevalence of COVID-19 vaccine acceptance during pregnancy increased for each additional living child (aPR 1.18, 95% CI 1.05, 1.32). (see Tables, Supplemental Digital Content 3–4)

Intention to Vaccinate Against TB

Intention to vaccinate against TB during pregnancy was 90.0% (n=180) with 13.5% of participants (n=27) who strongly agreed and 76.5% of participants (n=153) who agreed they intended to receive a vaccine for TB in pregnancy if one was shown to be safe and effective in pregnancy. Reported intention to receive a TB vaccination while lactating was 92.0% (n=184) with 13.0% (n=26) strongly agreeing and 79.0% (n=158) agreeing they would receive a TB vaccine while lactating if one was shown to be safe and effective (see Table, Supplemental Digital Content 5). Intention to participate in a research study to evaluate a future new vaccine for TB during pregnancy or lactation was 67.0% (n=134) and 66.0% (n=132) of participants, respectively.

COVID-19 and TB Knowledge, Attitudes and Beliefs

A higher proportion of women reported knowledge that pregnancy increased the risk of TB for themselves and their unborn children (78.0%) compared to COVID-19 (46.5%). More women also believed a future TB vaccine would protect their unborn child from TB disease (82.5%) compared to COVID-19 (35.5%) (see Figure, Supplemental Digital Content 6). The attitude that receiving the COVID-19 vaccination is a societal responsibility was strongly associated with COVID-19 vaccine acceptance in pregnancy (aPR 4.48, 95% CI 2.86, 7.01). Agreement with the knowledge 'pregnant women and their infants are at increased risk of severe disease from COVID-19' was highly associated with maternal vaccine acceptance (aPR 2.58, 95% CI 1.74, 3.82) as was belief that 'the COVID-19 vaccine will protect my unborn child from COVID-19 disease' (aPR 3.31, 95% CI 2.29, 4.77). Participants who agreed with the following attitudes and beliefs were less likely to accept a COVID-19 vaccine in pregnancy: 'there may be serious side effects from the COVID-19 vaccine' (aPR 0.19, 95% CI 0.10, 0.35), 'COVID-19 vaccine may harm my unborn child' (aPR 0.19, 95% CI 0.10, 0.35), and 'there is not enough data on maternal COVID-19 vaccine safety and efficacy in pregnancy and the postpartum period' (aPR 0.51, 95% CI 0.37, 0.69). (see Figure, Supplemental Digital Content 7, and Table, Supplemental Digital Content 8) Intention to receive a TB vaccination in pregnancy was associated with the belief that a TB vaccine would protect a woman's unborn child from TB disease (aPR 1.37, 95% CI 1.10, 1.70). Belief that the TB vaccine may harm their child was associated with decreased maternal intention to receive a TB vaccination (aPR 0.76, 95% CI 0.61, 0.94). (see Figure, Supplemental Digital Content 7, and Table, Supplemental Digital Content 8)

Drivers and Challenges to Maternal Vaccination

Factors pregnant women identified as facilitators of vaccination uptake during pregnancy included a healthcare provider's recommendation (69.0%, n=138) the belief that vaccines prevent diseases (38.5%, n=79), diseases are dangerous for their baby (18.0%, n=36), vaccines are beneficial to the baby in the womb (17.0%, n=34), vaccines are effective (14.5%, n=29), and whether a friend, relative or neighbor recommended vaccines (11.0%, n=22). When asked who is most influential in the decision to receive a vaccine during pregnancy, respondents most frequently reported themselves (66.0%, n=132). This was followed by doctor, nurse, or other health care providers (46.5%, n=93), husbands (35.0%, n=70), health extension workers (13.5%, n=27), and friends (12.0%, n=24).

Immunization Intervention

Interventions to increase maternal vaccination uptake were found to be very acceptable to pregnant participants attending ANC. Of 200 participants, 65.5% (n=131) reported they had received educational information on vaccines during pregnancy. Nearly all (97.0%, n=194) stated they would attend an educational session on vaccines during pregnancy, they would consider receipt of educational information on vaccines during pregnancy useful (98.0%, n=196), and they would be more likely to receive a vaccine during pregnancy if they felt well-educated about it 98.5% (n=197). (see Figure, Supplemental Digital Content 9)

DISCUSSION

To our knowledge, this is the first published study to assess acceptability of a future vaccine for TB during pregnancy and lactation. Most women (~90%) intended to receive a TB vaccine while pregnant or lactating, while few women (~40%) were willing to receive a COVID-19 vaccine during pregnancy or lactation. We found reasons cited for receipt of a vaccine during pregnancy centered on the knowledge that vaccines can prevent diseases that may be harmful to a woman's baby, knowledge of the safety of vaccines in pregnancy, and belief in vaccines' importance. Participants reported higher perception of TB disease severity compared with COVID-19, consistent with the relative disease burden in Ethiopia. In 2022, TB was ranked as the 5th leading cause of death in Ethiopia (575 deaths per week) compared to COVID-19's ranking as 115th (2 deaths per week).(36, 37) Higher vaccine acceptance in an outbreak setting has been observed.(38) In addition, given high rates of Bacille Calmette Guerin (BCG) vaccination at birth in Ethiopia, overall national BCG vaccination coverage in Ethiopia was estimated at 79% in 2019,(39) participants' prior receipt of BCG or experience vaccinating their children and baseline knowledge of TB may have influenced their willingness to receive a new TB vaccine.(40) While most women in our study were willing to receive a new TB vaccine during pregnancy or lactation, potential barriers to implementation remain. Misinformation around COVID vaccine safety and efficacy was a significant global barrier to vaccine uptake in pregnancy and lactation.(41) Proactive development of tailored vaccine risk communication interventions and identification of trusted messengers to prevent misinformation prior to and during the rollout of new TB vaccines will be critical.(42–45) In addition, identification of health system factors that contribute to discordance between intention to vaccinate and actual receipt of vaccination will be important.(45) Vaseduvan et al. found that while most Tanzanian women surveyed during their 3rd trimester of pregnancy intended to vaccinate their children, 72% of their children under 2 years had missing or delayed receipt of vaccines, influenced by unexpected health system barriers such as vaccine stock-outs or transportation difficulties.(46, 47) While assessing acceptability of a theoretical vaccine has limitations, understanding potential barriers to vaccine uptake can inform strategic public health messaging prior to vaccine rollout.(48–50)

We found maternal Td uptake in pregnancy was associated with higher maternal education and prior receipt of counseling on vaccines, consistent with other studies in Ethiopia.(34, 51) In contrast, COVID-19 vaccine hesitancy was associated with higher maternal education. In 2022, Abebe et al. found that attaining a higher level of education (college or university

degree), was a barrier to COVID-19 vaccine uptake among pregnant women (adjusted odds ratio (aOR) 0.43, 95% CI 0.12, 0.69).(27) Higher education may be associated with access to more information, including misinformation, which has been shown to have a negative impact on COVID-19 vaccine uptake.(42) In other LMICs, COVID-19 vaccine hesitancy in adult populations was found to be slightly higher in those who had attained a higher education (44%, 95% CI 40.2%–46.8%) compared with those who had attained a secondary education (40.9%, 95% CI 38.3%–44.0%) or no or primary education (37.8%, 95% CI 32.5%–41.6%).(52) We also found that living in an urban versus a rural area was associated with COVID-19 vaccine hesitancy. In contrast to our findings, Taye et al. found that urban residence was associated with higher COVID-19 vaccine acceptance among pregnant women in Central Gondar, Ethiopia [aOR 2.03 (95% CI 1.09, 3.77)].(31) In a recent socioeconomic survey, both school enrollment and literacy were found to be higher in urban versus rural locations in Ethiopia.(53) Thus, those living in an urban environment may have attained a higher level of education, had more access to information including misinformation, and may also have higher rates of COVID-19 vaccine hesitancy. The discrepancy in our findings compared to Taye et al. could have been impacted by timing; their study was completed prior to ours and misinformation increased as the pandemic progressed.(42) Our finding that a prior negative experience with a vaccine was associated with Td vaccine uptake suggest confounding by indication, given that prior receipt of a vaccine is necessary to have had a negative experience with vaccination.

We found high acceptability of educational interventions to enhance maternal immunization uptake. To date, there are few intervention trials to target maternal immunization in LMICs, including Ethiopia. Data from upper-middle- and high-income countries have shown the potential for successful interventions to increase maternal vaccination as they relate to provider-to-patient engagement, talking points, educational brochures, posters, lapel buttons, and tablets loaded with patient-centered tutorials.(54, 55) As our study found that health providers were a trusted source for vaccine information, implementing interventions targeted at improving health workers' knowledge of vaccination and communication skills surrounding immunization could be a successful means to increase maternal vaccination uptake in community campaigns. Our findings and other prior published studies in Amhara suggest educational interventions should address knowledge, attitudes, and beliefs surrounding COVID-19 and TB disease impact in pregnancy and maternal vaccine safety and effectiveness in pregnancy. (27, 31–33) Our study was limited by convenience sampling, which was used to recruit women and may have introduced self-selection or voluntary response bias that could impact the generalizability of our results. Participant responses may also have been influenced by social desirability bias as surveys were conducted at healthcare facilities. Recall bias may have influenced maternal reporting. As our study was only conducted in the Amhara region, the findings may not be generalized to other regions of Ethiopia. We collected data from primary and referral hospitals to optimize participant availability, but this population may not be representative of more rural populations. Differing knowledge of TB and COVID-19 likely impacted our findings, and future studies should evaluate how disease knowledge impacts vaccine acceptance. Finally, direct comparison of maternal acceptability of COVID-19 vaccination and a theoretical TB vaccine

may have limited value; assessment of post-licensure acceptability of TB vaccine candidates among pregnant and lactating women will be needed.

CONCLUSIONS

We found that most women were willing to receive a TB vaccine, while few were willing to receive a COVID-19 vaccine during pregnancy and lactation. Vaccine-specific knowledge, attitudes, and beliefs were associated with vaccine acceptance. Our findings suggest the importance of evaluating and implementing vaccine-specific, patient-targeted educational interventions and healthcare provider training to strengthen acceptance and uptake of maternal vaccination in pregnancy and lactation. Stakeholders can use such platforms to better plan for the rollout of new maternal vaccines targeting pathogens with a high impact on pregnant women and infants, including TB.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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