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Increasing antepartum Tdap vaccine administration: A quality improvement initiative

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ABSTRACT

The Centers for Disease Control and Prevention (CDC) recommends antepartum Tdap vaccination for women with each pregnancy to protect themselves and their vulnerable infants through transplacental transfer of maternal antibodies. Our aim was to increase the rate of antepartum Tdap vaccine administration by 20%. Obstetricians were surveyed to identify their present approaches and barriers to antepartum Tdap vaccine administration to help guide the development of our intervention. Limited staff training, lack of vaccine on site, and cost were the most commonly identified barriers. Using these survey responses, existing literature, and brainstorming conversations with colleagues, an interdisciplinary workgroup then created a fishbone analysis and developed a 5-step intervention to address these barriers: (1) educate providers and patients on Tdap and pertussis; (2) increase Tdap availability to all pregnant women; (3) remind staff of the established Tdap standing order to facilitate administration; (4) encourage obstetricians to offer Tdap; (5) transfer documentation of Tdap administration from office to hospital. To monitor changes in the process over 15 months of pre- and post-intervention, data were collected from monthly chart audits and a two-phase control chart was created. The main outcome measure was proportion of eligible women who received Tdap during current pregnancy. In the pre-intervention period, 362 of 636 eligible women (56.9%) received Tdap during their current pregnancy; in the post-intervention period, 457 of 708 eligible women (64.5%) received Tdap during their current pregnancy. This absolute difference of 7.6% (64.5% vs. 56.9%, $p < 0.01$) represents a 13.4% relative increase (64.5%/56.9%) in the proportion of clinically eligible pregnant women who received Tdap. This represents a clinically and statistically significant increase in the rate of antepartum Tdap immunization. More research is needed to further understand obstetric barriers and maternal refusal of antepartum Tdap administration.

1. Introduction

Pertussis (i.e., "whooping cough") is a highly communicable, acute infectious respiratory disease that results in notable morbidity and mortality, especially among infants [1]. Infants less than one year of age have a higher incidence and greater risk of severe disease and death from pertussis. In 2017, the Centers for Disease Control and Prevention (CDC) reported the rate of pertussis among infants under six months was 64.5 per 100,000, and four out of the thirteen reported pertussis-related deaths were among infants less than one year of age [2].

Since 2012, the Advisory Committee on Immunization Practices (ACIP) of the CDC, American College of Obstetricians and Gynecologists (ACOG), and American Academy of Family Physicians (AAFP) have recommended antepartum vaccination against tetanus, diphtheria, and pertussis (Tdap) during *each* pregnancy, optimally at 27 through 36 weeks of gestation [3–5]. This recommendation was developed from evidence that showed antepartum Tdap vaccination protects the mother *and* her infant [6] through transplacental transfer of maternal antibodies.

A previous quality improvement (QI) initiative from our institution increased Tdap vaccination in the immediate *postpartum* period, indicating that QI methodology has the potential to help improve antepartum Tdap rates to meet the CDC recommendation [7]. The purpose of this project was to increase the rate of antepartum Tdap vaccine administration among eligible women who deliver in a high-volume, suburban, academic hospital through

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identification and alleviation of physician barriers to universal *antepartum* Tdap vaccination with *each* pregnancy. Despite the universal recommendation that all women should receive antepartum Tdap vaccination, the CDC reports that, on average, only 49% of women with a live birth received Tdap vaccination during pregnancy annually from 2015 through 2018 [8–10]. Although the baseline antepartum Tdap vaccination rate at our obstetric hospital already was above that national average, our aim was to further increase the relative rate of antepartum Tdap vaccine administration by 20%.

2. Material and methods

2.1. Setting

Our 73-bed, suburban, academic women's hospital serves the diverse New York communities of Queens and Long Island. The high delivery volume (>6500 deliveries per year) ensured appropriate pre- and post-intervention samples. This project was approved by the Northwell Health Institutional Review Board.

2.2. Securing leadership buy-in

Through introductory emails, we arranged individual in-person meetings with nursing staff, faculty, and community obstetricians to discuss our project aims and facilitate the formation of an interdisciplinary team with the following: the chief of Obstetrics-Gynecology, the Assistant Director of Hospital Pharmacy, the Chief Medical Informatics Officer of the hospital, and the Associate Executive Director of Quality Management. Gaining their support was crucial as it allowed for access to key personnel and advice on how to obtain resources.

2.3. Planning the intervention

Our interdisciplinary team met every week or two to ensure seamless implementation of the intervention, provide feedback on unanticipated challenges, explore areas for improvement, and adjust the intervention as necessary (Fig. 1). We also sent an online survey to all faculty and community-based obstetricians with privileges at our obstetric hospital in order to identify system barriers for Tdap administration to help guide the development of our intervention. This survey evaluated the percentage of obstetricians that routinely offered Tdap vaccine to their pregnant patients, how often patients agreed to be vaccinated when they were offered the vaccine, which trimester obstetricians offered the vaccine, and the barriers to vaccine administration encountered by obstetricians. Using these survey responses coupled with existing literature and brainstorming conversations with colleagues, the interdisciplinary team designed a five-step intervention to address the identified challenges and to ultimately increase rates of Tdap vaccine administration during pregnancy (Fig. 2).

2.4. The intervention

Step 1 of the intervention involved educating obstetricians and patients about the most recent CDC recommendations regarding antepartum Tdap vaccine administration. This was achieved both through in-person presentations at departmental meetings, which were attended by obstetric administration, leadership, and faculty and community-based obstetricians, as well as informative slides sent via email. The slides included educational materials for healthcare personnel, our project goals, CDC recommendations, patient educational resources from ACOG for distribution, and contact information for local urgent care centers and pharmacies that offer Tdap vaccine at discounted rates. Step 2 – to increase the availability of the Tdap vaccine to pregnant women – was achieved primarily through our partnership with the Hospital Pharmacy leadership, who ensured that the vaccine was always available at our hospital-based pharmacy and 23 system-affiliated urgent care center locations. In addition, we negotiated discounted rates for Tdap with hospital administration and supplied coupons to obstetricians' offices for distribution to pregnant patients. This coupon provided the Tdap vaccine at a discounted rate to patients with

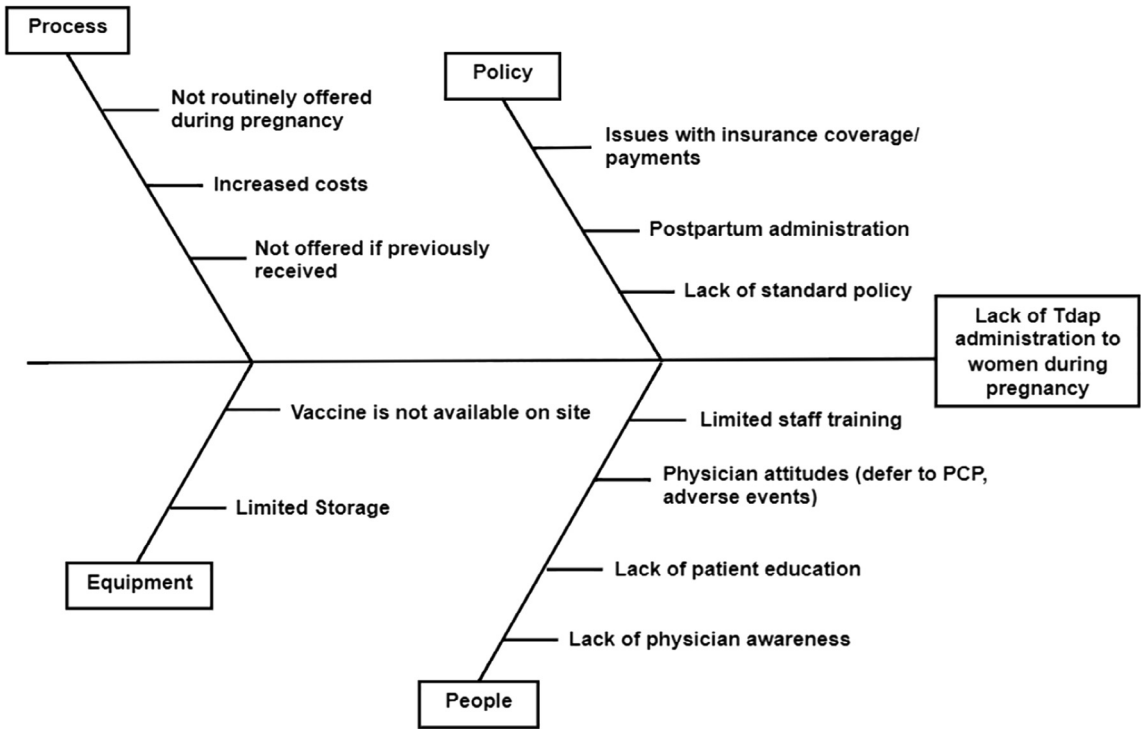

Fig. 1. Fishbone analysis identifying the causes of low antepartum Tdap vaccination rates, performed by the multidisciplinary focus group. PCP, primary care physician.

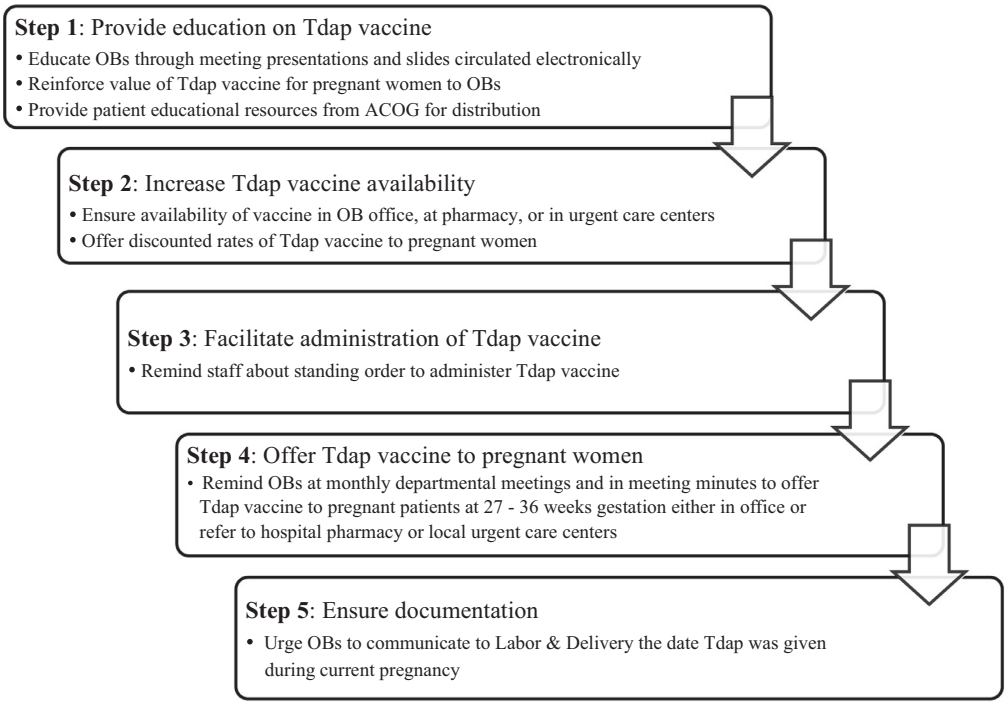

Fig. 2. Multi-step intervention created using the fishbone analysis.

limited or no insurance coverage. For Step 3, we reminded staff of a standing order (i.e., a prewritten order within our electronic medical record that could be activated for eligible patients without requiring a direct individual order from the patient's obstetrician) that was created in our previous postpartum QI study to facilitate administration of Tdap vaccine to pregnant women throughout the health system. For Step 4, the OB department leadership and administration verbally reminded obstetricians at departmental meetings to offer the vaccine to all of their pregnant patients at 27 through 36 weeks gestation, as recommended by the CDC. If the vaccine was unavailable in their office, obstetricians could direct their patients to the local, partnering pharmacies or urgent care centers. Lastly, for Step 5, obstetricians were again verbally reminded to transfer documentation of Tdap vaccine administration to Labor and Delivery with other prenatal data. Consistent implementation of this comprehensive 5-step intervention was anticipated to eliminate the majority of identified barriers and optimize rates of Tdap receipt. All interventions steps were implemented simultaneously.

2.5. Methods of evaluation

Our specific aim was to increase the rate of *antepartum* Tdap vaccine administration by 20% among eligible women. All pregnant women included in the chart audits were considered eligible to receive the vaccine if their deliveries were after 27 weeks and 0 days of gestation, if the Tdap vaccine was not contraindicated due to a history of allergic reaction to the vaccine, and if there was current documentation of Tdap vaccine receipt or refusal in the electronic medical record. Antepartum Tdap vaccine receipt or refusal was obtained through maternal report to labor and delivery staff and/or confirmed with documentation of timing provided by OB offices. If vaccine records from OB offices were not available, the maternal report, as documented in the electronic medical record, was accepted. Exclusion criteria included: no documentation of vaccine receipt or refusal in the electronic medical record, the indicated time of receipt was outside her current pregnancy, or the patient received the vaccine in the postpartum period of this pregnancy prior to discharge.

To establish the pre-intervention baseline, we conducted a retrospective chart review of 700 charts from August 2015 through February 2016. The first 25 charts available beginning on the 1st, 8th, 15th, and 22nd of each month were assessed, yielding a total of 100 charts per month. Post-intervention data were collected using the same methodology from March 2016 through October 2016. The selected charts were reviewed for eligibility for Tdap; only eligible women were included in the analysis.

2.6. Statistical analysis

To monitor the changes in the process over time, a two-phase control chart was created to plot the proportion of pregnant patients eligible for the vaccine and the proportion of eligible pregnant patients receiving the Tdap vaccine during pregnancy per month. The centerlines represent the overall average proportions for the baseline and post-intervention phases; the 3-sigma control limits were calculated based on the binomial distribution (p-chart). Overall rates of pre- and post-intervention Tdap vaccination receipt were calculated separately for the two study phases to estimate the impact of the intervention. Informal data were gathered regularly during workgroup and advisory committee meetings to contextualize the experience of implementing these changes. From the inception of the project, monthly summaries were created to document lessons learned, anticipated barriers, and unexpected challenges. The data were analyzed using JMP, Version 13 Pro (SAS Institute, Inc., Cary, NC). Chi square test was performed to quantitatively compare pre- and post-intervention data.

3. Results

3.1. Survey data

The initial electronic survey was distributed to all faculty and community-based obstetricians via email, and reminders were also

emailed twice more at monthly intervals. More than fifty obstetricians (approximately one third of those emailed the survey) replied, providing an adequate number of responses to achieve the specific intent of the survey – being useful for planning and designing our intervention.

Approximately three-quarters (77%) of responding obstetricians reported routinely offering Tdap vaccine to their pregnant patients. Barriers identified in preventing the administration of Tdap vaccine *during* pregnancy included increased costs (33%), not having vaccine on site (33%), limited staff trained in administration of vaccine (18%), and deferring to primary physician (16%). Surveyed physicians were able to identify more than one barrier and 40% included other barriers that were not explicitly listed in our survey. These included issues with storage, financial hurdles including insurance reimbursements, and patient reluctance (Fig. 3). Among the obstetricians who routinely offer Tdap vaccine during pregnancy, approximately one-third (37%) self-reported that fewer than 75% of their patients agreed to get vaccinated. These results confirmed the need to improve the rates of antepartum Tdap vaccine administration and were used to guide the development of our intervention.

3.2. Pre-intervention data

During the 7-month pre-intervention period, we audited 700 charts. There were 636 (90.8%) pregnant women who were clinically eligible for this study. Of these eligible women, 362 (56.9%) received Tdap vaccine during their current pregnancies while 274 (43.1%) did not.

There were 64 (9.1%) pregnant women who were excluded from our study. The most common reason for excluding a patient was due to missing data of Tdap vaccine receipt or refusal in her electronic medical record (58/64 or 91%). Women who delivered at less than 27 weeks gestation (4/64 or 6%) or had a contraindication to receive the Tdap vaccine (2/64 or 3%) were also ineligible for the study.

3.3. Post-intervention data

During the 8-month post-intervention period, we audited 800 charts. There were 708 (88.5%) pregnant women who were clinically eligible to receive antepartum Tdap vaccine and thus included in this study. Of these eligible women, 457 (64.5%) received the Tdap vaccine during their current pregnancy, while 251 (35.5%) did not.

There were 92 (11.5%) pregnant women excluded during this phase of the study. Similar to pre-intervention data, the most common reason for excluding a patient was lack of documentation of Tdap vaccine receipt or refusal in her electronic medical record (78/92 or 85%). Women who delivered at less than 27 weeks gestation (6/92 or 7%) or had a contraindication to receiving the Tdap vaccine (7/92 or 8%) were ineligible for the study.

We constructed a control chart to document changes in the rate of antepartum Tdap vaccination over time (Fig. 4). For both pre-

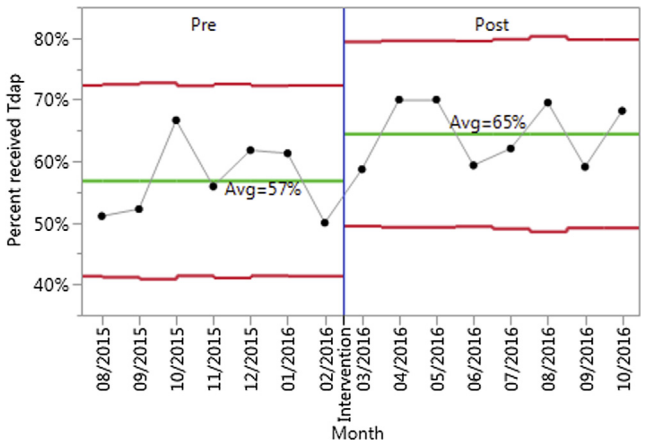

Fig. 4. A p control chart for the percentage of eligible antepartum women who received the Tdap vaccine pre-intervention and post-intervention.

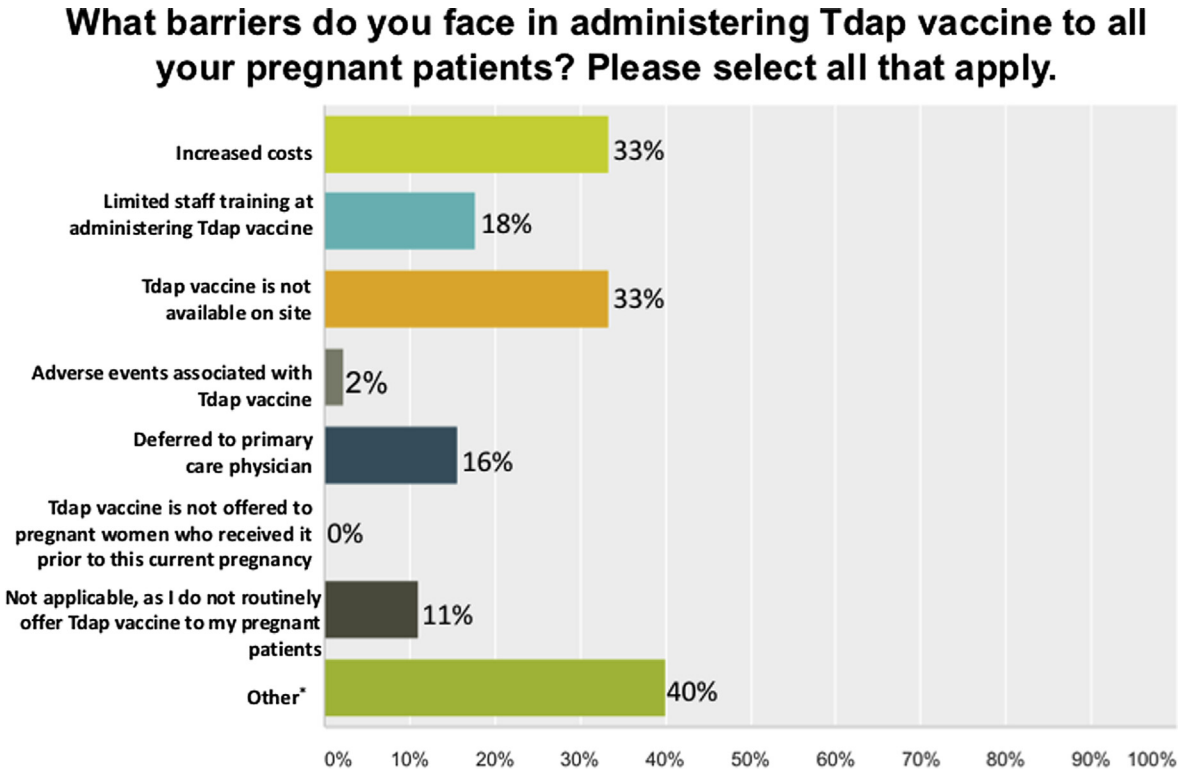

Fig. 3. Barriers to antepartum Tdap vaccine administration identified by surveyed obstetricians.

and post-intervention phases, all points were within their respective control limits (i.e., showed common-cause variation), which allows for a valid comparison of the overall proportions for the two periods. The uneven control limits are typical for a p-chart when the sample sizes for each point are not exactly equal. Overall, this absolute difference of 7.6% (post- minus pre-intervention percentage; 64.5% vs. 56.9%, $p < 0.01$) represents a 13.4% relative increase (64%/56.9%) in the proportion of clinically eligible pregnant women who received Tdap. Although this relative increase was lower than our aim, it represents a clinically and statistically significant positive change, as it would result in 495 more women receiving Tdap during pregnancy annually, if this 64% were extrapolated to the over 6500 deliveries that occur at our hospital.

4. Discussion

This study documented a statistically significant increase in the number of pregnant women that received Tdap vaccine during the 8-month post-intervention period compared with the pre-intervention period. Although this did not reach our aim of a 20% relative increase in the rate of antepartum Tdap vaccine administration, the difference is clinically important, as it would result in 495 more women receiving Tdap each year, protecting more infants against *Bordetella pertussis*, a notable cause of morbidity and mortality in this very young population. Furthermore, this positive increase improves our institution's compliance with national recommendations from organizations including the CDC, ACOG, and AAFP. Measures of compliance are gradually becoming more important in clinical medicine, and this QI initiative provides a framework to improve compliance.

Buy-in from hospital leadership was integral to our implementation, as were the pre-intervention survey responses from obstetricians that identified barriers to antepartum Tdap vaccine administration. These survey results, along with existing literature and brainstorming conversations with colleagues, directed development of our multi-step intervention using fishbone analysis and recommendations from our local experts in information systems, QI, clinical medicine, and pharmacy. Specifically, pharmacy staff helped to ensure the accessibility and affordability of Tdap vaccine at the hospital-based pharmacy and system-affiliated urgent care centers at a reduced cost; information systems staff confirmed the standing order in our electronic medical record; and obstetricians were provided instruction and education through departmental meetings and informative slides sent via email. Our progress was monitored via weekly meetings and monthly chart reviews.

Past studies have focused on increasing Tdap vaccination rates in postpartum women. For example, in a previous study from our institution, the rates of postpartum Tdap vaccination were increased by thirty-three percent [7]. While this current study and our previous one both used multi-step interventions, there were important differences. First, this study employed a pre-intervention survey to identify barriers to vaccination, while the previous study relied on expert opinion to guide intervention development. Further, the use of patient counseling by obstetricians during prenatal visits was a crucial part of our intervention, while patient counseling by labor and delivery nurses was previously performed. Previous studies in the literature have utilized interventions such as patient and staff education, creation of a vaccine registry, visual and electronic alerts and multidisciplinary participation to improve influenza vaccination rates in pediatric and obstetric patients [11,12]. Another published report focusing on family reminders, education, increased access to vaccines and coordination of care improved immunization rates that were sustained beyond 18 months [13].

This study has some limitations. It was conducted in a university-affiliated medical system in a suburban community, which may limit generalizability. Since only approximately one-third of obstetricians completed our pre-intervention survey, this may not have fully elucidated all obstetrician-identified barriers to Tdap vaccine administration. Increased response rates to our pre-intervention survey could provide more obstetrician perspectives, and address rates of buy-in from more obstetricians in the practice. In addition, our four-question survey was intentionally designed to be brief in order to maximize response rates. In doing so, however, some of our questions may have been perceived as vague, and more specific questions could potentially unveil additional barriers to vaccine administration. Moreover, our results are subject to recall bias since Tdap documentation was based in part on patient self-report. Further, our sample size was limited due to incomplete documentation, suggesting more emphasis needs to be directed towards clinical documentation to better clarify a less than ideal vaccination rate.

This QI initiative represents the second round of a PDSA cycle. Subsequent rounds would benefit from several additions. For instance, incomplete documentation could be addressed with required prompts built into the electronic medical record. Similarly, training medical staff, such as obstetric nurses and medical trainees, would increase opportunities for women to be offered Tdap during prenatal visits. It will be necessary to also implement an intervention directed towards maternal barriers to antepartum Tdap administration, as our study focused on obstetrician-identified barriers. Additionally, monitoring the clinical impact of our initiative by objectively studying rates of infants admitted with a pertussis-related illness is important. A significant decrease in pertussis disease rates would likely improve medical staff compliance and increase resource assignment by hospital leadership.

5. Conclusion

National organizations recommend antepartum Tdap vaccination to protect mothers and their young infants. In this study, we used QI methodology to significantly increase antepartum Tdap vaccine administration rates. Engaging providers, increasing access to care, and improving clinical documentation are modifiable factors that can improve vaccination rates. Ultimately, improving vaccination rates has the potential to prevent morbidity and mortality in young infants and improve compliance with national recommendations. Additional research is needed to better understand the attitudes of pregnant women who decline antepartum Tdap and of obstetricians uncomfortable with offering antepartum Tdap to their patients.

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Declaration of Competing Interest

All authors have indicated they have no potential conflicts of interest to disclose.

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