12-2020

A System Intervention of Tetanus, Diphtheria, and Pertussis Vaccination for Pregnant Women in Primary Care

Tarshera Reyna
University of the Incarnate Word, tkreyna@student.uiwtx.edu

A SYSTEM INTERVENTION OF TETANUS, DIPHTHERIA, AND PERTUSSIS VACCINATION FOR PREGNANT WOMEN IN PRIMARY CARE

TARSHERA K. REYNA BSN, RN

DNP PROJECT ADVISOR

Karen L. Weis PhD, RNC-OB, FAAN
Professor, Ila Faye Miller School of Nursing and Health Professions

CLINICAL MENTOR

Yadira Anca MD, FACOG

Presented to the Faculty of the University of the Incarnate Word
in partial fulfillment of the requirements
for the degree of

DOCTOR OF NURSING PRACTICE

UNIVERSITY OF THE INCARNATE WORD

December 2020

ACKNOWLEDGEMENTS

First giving honor to God our Father, Christ our Redeemer, Holy Spirit our Comforter, to Humankind and our family.

I am blessed and thankful to have a loving and understanding family. To my husband (Concepcion Reyna), sons (Tony and Travaras), and granddaughter (Aryah Marie), who allow me to spend long days and nights on assignments, projects, study guides, researching, and preparing presentations. Thanks for sharing all the demanding chores around the house so that I could make this educational endeavor a success. This has been a journey, and journeys are never successful unless you have the right team in place. I am grateful to my parents for the encouraging words they instilled in me: "I can do all things through Christ that gives me strength." When I called them late at night, they always encouraged me and said, "You got this, your paper looks great, and I know you are going to nail it." To my siblings, my team, who has listened, critiqued, reviewed, and given me constructive feedback, even when I didn't want it. Thank you for the empowering honesty and loving kindness that you contributed.

To my friends who thought I had forgotten you, weekends are now for revising, reviewing, and repairing papers, projects, parenting, and pausing for a breath on this relentless pursuit. To all my professors, advisor (Dr. Karen Weis), mentors (Dr. Yadira Anca and Dr. Charlotte Matthews), Clinic manager (Rebecca Neu-Gyan), OB Clinic staff (Martha, Sarah, and Shandoa), and Ms. Mickey who did not hesitate when I called, texted, or emailed. Thanks for shining the light on my path to success through your thoughtfulness on calls, instructions, critiques, corrections, guidance, and patience that I received during my experience at *The*

ACKNOWLEDGMENTS—Continued

University of The Incarnate Word. I am elated that I can now see the light at the end of the tunnel.

(In Loving Memory of Eddie B. 4/12/2020)

Tarshera K. Reyna

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

LIST OF TABLES

Table Page

Abstract

The health care system in the United States has been described as having a deficit in care for women during pregnancy (IOM, 2019), and as a result there has been a resurgence over the last decade in diseases like pertussis, which is a severe respiratory infection that is particularly dangerous for infants less than 3 months of age (Tan & Gerbie, 2013). The primary objective of this project was to implement a Tdap vaccination program and increase the rates of Tdap vaccinations of obstetrical patients at a San Antonio clinic. The intervention included (a) establishing standing orders for the Tdap vaccination, (b) encouraging physician recommendation of the vaccination to every pregnant patient (with each pregnancy), and (c) providing educational materials on the safety and benefits of the Tdap vaccination. Between Feb. 3, 2020 and May 3, 2020, the clinic provided care to 338 obstetrical patients. All received a physician recommendation for the Tdap vaccination and were given further educational information at their initial prenatal appointment. Two-hundred and seven patients (59.2%) were eligible for vaccination (27-36 weeks' gestation) and received Tdap recommendations prior to vaccination (mean gestational age was 29 weeks). Ten women (5%) declined the Tdap vaccine after recommendation. Establishing an evidence-based process for Tdap vaccination ensured 100% of eligible patients were given recommendations and were offered the vaccination between 27 to 36 weeks of pregnancy. Ultimately, the combination of implementing standing orders within the host health center, securing a physician recommendation, and increasing patient and staff education influenced an increase in the Tdap vaccination in obstetrical patients.

Keywords: pregnant women, Tdap vaccinations, pertussis, passive immunity, whooping cough, immunization, maternal vaccination

A System Intervention of Tetanus, Diphtheria, and Pertussis Vaccination for Pregnant Women in Primary Care

In the middle of December 2019, a school in Houston, Texas, made the decision to close early for the winter break due to an outbreak of pertussis among its students and staff, despite the school's 100% vaccination policy (Ackerman, 2019). Even with high vaccination rates, Houston saw 30 cases of pertussis in 2019, including those affected at this school (Ackerman, 2019). Unfortunately, the trend of increasing pertussis rates is not isolated to Texas.

Pertussis, a severe acute respiratory infection that can lead to admission into an intensive care unit or even loss of life, particularly for infants less than 3 months of age, has seen a resurgence in the US in the past decade (Tan & Gerbie, 2013), despite it being largely preventable with the Tdap vaccination administered during pregnancy (Halperin et al., 2018). One study researching the presence of pertussis-related antibodies in pregnant women indicated that approximately 30-90% of reproductive age women have low-to-undetectable pertussis antibodies (Gonik et al., 2005). This creates a problem as infants are not only protected from the infection by the mother's own immunity while in utero, but this immunity can cover the infant until 2 months of age, or until they obtain their series of diphtheria, tetanus, and pertussis (DTap) vaccinations (Payakachat et al., 2015). Without a pertussis vaccination during pregnancy, an infant's pertussis antibodies are substantially decreased by 6 weeks of age and are almost undetectable at 4 months (Baxter et al., 2017).

In the search for solutions to the spread of pertussis and similar infections, agencies like the Centers for Disease Control (CDC) and the Prevention Advisory Committee on Immunization Practices recommended in 2011 that all pregnant women, as early as 20 weeks, should receive the Tdap vaccine (Baxter et al., 2017). In 2013, they further extended this

recommendation to advise the Tdap vaccine be given with each pregnancy, regardless of a previous Tdap vaccination (CDC, 2012). Due to concerns regarding the lack of vaccinations in reproductive women, as well as inequality within health care, the American College of Obstetricians and Gynecologists (ACOG) developed guidelines that recommended the administration of the Tdap vaccination between 27 and 36 weeks of gestation for all pregnant women, and vaccinations be included of close family members that may be in contact with a newborn (ACOG, 2017). An additional recommendation advises all pregnant women receive educational materials regarding the importance of the vaccine during pregnancy for both maternal and infant health (CDC, 2019).

The health care system in the United States has been described as having a deficit in care for women during pregnancy (IOM, 2019). Certainly, improving and encouraging vaccination coverage in pregnant women could significantly reduce the disease burden, as well as improve the standard of care for pregnant women and increase infant immunity.

Statement of the Problem

The American College of Obstetrics and Gynecology recommends that every pregnant woman receives all required vaccinations between 27 and 36 weeks gestation, including the Tdap vaccination (ACOG, 2017). However, in a 2017 Internet panel survey, 15.3% of recently pregnant women reported never receiving a Tdap vaccination (Kahn et al., 2018). These vaccinations create immunity and protection for infants until they are old enough to be vaccinated themselves by stimulating maternal anti-pertussis antibodies, which are transported from the mother to the infant via the placenta. Ideally, these vaccinations protect pregnant women from pertussis near the time of delivery, prevent the mother from transferring any infections to the newborn, and provide protection to the newborn from pertussis in the first few months of life (CDC, 2013). Pregnant women rely on the obstetrician to provide the necessary

continuity of care and to educate them on the relevant standards and guidelines so that they can make informed decisions regarding vaccinations. However, the reality is that not all pregnant women even receive a recommendation for the Tdap vaccination, despite the fact that women are more likely to receive the vaccination when it is recommended or offered by a doctor or other medical professional (CDC, 2018). Admittedly, there are multiple contributing factors to low Tdap immunization rates, requiring a multi-pronged approach.

Current Practice Assessment

Primary System Assessment

The host health system is a group of 15 federally qualified health centers, providing a variety of health care services in rural and underserved urban communities of Bexar, Kendall, and Hays counties in south-central Texas (Communicare Health Centers [CHC], 2019). The services offered include family medicine (primary care), dental care, pediatric care, women's health, senior care, behavioral health, a WIC program, vision care, integrated pediatrics, rheumatology, hepatitis care, sports medicine, minor surgery, and general surgery (CHC, 2019).

A practice assessment was performed within an OB/GYN practice, at Clinic P. Clinic P is located on the far west side of San Antonio, Texas, in a growing area of Bexar County in need of OB/GYN services. Clinic P's geographical location is a vital part of its accessibility to the public since it is on a major connection road between two of the city's busiest freeways. The area is newly developing, with many local and small businesses, including restaurants and shopping centers, a high school and a community college campus, a hospital, and two major grocery stores. The housing available in this area also varies, ranging from single-to-multi-family houses, apartments, and townhomes.

With the growing number of families in this developing area, the clinic's focus on providing family services reflects its mission of improving the health care of its surrounding community. Clinic P strives to serve women of childbearing age, including those who are uninsured and those who are insured with either private or public health insurance providers. The corporation's mission to help the underserved and uninsured with quality health care is a challenging, but worthwhile pursuit for improving and expanding the health of the population it serves (DeMarco, 2015). Both the clinic and the corporation's focus on family health is particularly important given that the mortality rates for Bexar County in 2015 were 6.3 deaths per 1,000 live births, an increase from the previous year (Texas Department of State Health Services, 2018).

In terms of demographics, the community surrounding the clinic is predominantly Hispanic, making up 67.4% and 61.7% of the population within the two zip codes that this FQHC serves (U.S. Census Bureau, 2017). Accordingly, both clinical staff and providers are fluently bilingual in both Spanish and English, which encourages a stronger community rapport, which in turn improves patient outcomes (Batalova & Zong, 2016).

The clinic's daily operations are carried out by a team of health care professionals who are on duty between the operating hours of 8:00 a.m. and 5:00 p.m., Monday through Friday; the clinic's sonographer and lab personnel have different service hours. The team of professionals includes two OB/GYN physicians, four medical assistants, one licensed vocational nurse who is employed to serve as the supervising nurse for both the pediatric and OB/GYN clinics, a practice manager who is also a registered nurse, and two additional front desk personnel. The practice manager describes the health care providers and staff at Clinic P as a cohesive team, with the

only identified staffing conflict being an issue with sharing one LVN position between both the pediatric and OB/GYN clinics.

The OB/GYN clinic consistently has availability for taking on new patients along with their existing patients. The patient visit history for the past year shows that 87.1% of the clinic's patients fall between 19 and 45 years of age, with the youngest patient being 11 and the oldest being 86. The majority of the clinic's patients are Hispanic, though the overall patient statistics reflect an ethnically diverse population. Reflecting its mission to bring health care to underserved populations, the clinic accepts all insurances in addition to accepting patients without insurance, providing an additional sliding-scale and income-based payment plan for patients who apply and qualify. Regarding the clinic's family services, they provide free pregnancy testing and vaccinations without a physician appointment, as well as obstetrical services from the point of pregnancy identification until birth. The clinic also has on-site WIC service representatives, which patients can access before or after an appointment. These services and considerations maximize the patient's ability to utilize qualifying programs that promote family development and increase health care outcomes.

Based on initial observations, the microsystem assessment, and a stated desire of the OB/GYN providers and host health system administrators, the focus of the intervention was the implementation of ACOG and CDC guidelines for the administration of the Tdap vaccine to all pregnant patients with each pregnancy. A secondary needs assessment follows to obtain baseline data and assess the organization's readiness for change.

Secondary Needs Assessment

The clinic's immunization tracking system provided a baseline, pre-intervention dataset. The retrospective electronic medical records (EMR) review found that only 133 of 330 (40%)

obstetrical (OB) patients were vaccinated with the Tdap vaccination in the past year. The low percentage rate of Tdap vaccination for this clinic is of great concern and prompted the primary aim of this project: to increase the clinic's Tdap vaccination by 50%, for a goal of 90% vaccination rate.

There are, however, significant systemic barriers to this goal. One primary barrier is the initial identification of a patient's need for a Tdap vaccination and the lack of a protocol to guide this process. The ACOG recommends that the Tdap vaccination be administered to each obstetric patient for each one of their pregnancies, but the clinic's EMR software does not currently flag the Tdap vaccine as an item of high importance. In comparison, there is a flag for the influenza vaccine in each patient's record. The development and subsequent implementation of a protocol is further hindered by a general lack of knowledge related to specific elements of the ACOG guidelines, as well as a disregard for the underlying research supporting the recommended vaccination timeline which ensures the highest level of antibodies for both the mother and unborn infant.

Contributing factors to the low Tdap immunization rate in Clinic P are similar to those facing other OB/GYN clinics, including issues related to the educational level and occupational status of the mother. The CDC study conducted by Kahn et al. (2018) found that among those surveyed, women with the lowest Tdap vaccination coverage during pregnancy were those with some college education (40.7%), while women with more than an undergraduate college degree had the highest coverage at 61.5%. Patients of various educational levels will analyze the information presented to them differently, and at Clinic P, there is currently no emphasis on patient education related to the importance of the Tdap vaccination during pregnancy, let alone any educational materials that target various patient educational levels. Clinicians, medical and

management staff all have a responsibility to improve the medical knowledge of patients, as the patients learn to navigate their own health care. Vaccination education empowers women to make informed decisions regarding disease prevention and allows for appropriate planning regarding their family's health care. In an era with an increasing anti-vaccine sentiment (Furuta et al., 2017), improving patient's education regarding vaccinations is of great importance for the general health of not only individuals, but for the greater community as well.

There were many project facilitators, including nurses, clinic managers, medical assistants, physicians, and information technology professionals. Approval for this project was determined by the chief medical officer, practice manager, IT supervisor, and the Health Insurance Portability and Accountability Act compliance officer.

The healthcare professionals in clinic P are engaged and enthusiastic about the planned intervention. There are project champions in both the DNP-student mentor and the DNP student. The OB/GYN providers recognize the need for the intervention and agree with the focused elements. They further recognize that efforts focused on the National Academy of Medicine (formally the Institute of Medicine) aims of providing patient-centered care also require thorough self-assessment and intervention for issues that impede quality healthcare delivery. With interventions that promote positive change, the clinic can empower patients to be active participants in both their own and their child's health outcomes.

Project Identification

The entire health care team assisted with the identification of Tdap vaccination strategies that would enhance the clinic's primary prevention methods aimed at decreasing the prevalence of infants affected by pertussis. The identified project objectives focused on improving the process of Tdap immunization administration in obstetric patients at clinic P. The primary

project aim was to improve the Tdap vaccination rates by adhering to ACOG's recommendation of 100% Tdap vaccination for all pregnant women with each pregnancy.

There was a need to reform current practices of the healthcare system at clinic P by implementing disciplined strategies to improve and implement the appropriate guidelines to protect the mother, baby, and community. Focusing on this issue was necessary to promote change and improve the quality of care to pregnant women. In accordance with ACOG guidelines, for Tdap immunization of pregnant women, the objectives of the intervention were:

1. Establish a clinic protocol for Tdap vaccination: Implement standing orders for Tdap vaccination within the host health system.
2. Educate and train all clinic staff and healthcare providers: Provide training to 100% of staff and providers on clinical protocol and ACOG recommendations as applied within the protocol.
3. Educate all obstetrical patients on the importance of Tdap vaccination at 2 timepoints: Provide educational materials and information regarding the benefits of Tdap vaccinations to 100% of the prenatal patients at 2 separate timepoints during their pregnancy (at the initial prenatal appointment, and prior to vaccination at 27-36 weeks gestation).
4. Initiate provider recommendations for Tdap vaccinations: All staff providers will recommend the vaccination to 100% of their pregnant patients during an obstetrical appointment in which the woman is between 27 to 36 weeks gestation.
5. Administer Tdap vaccinations: Administer the Tdap vaccination to 100% of all pregnant women, with each pregnancy, between 27 to 36 weeks gestation.

Summary and Strength of Evidence

Based on the evidence surrounding the benefits of the Tdap vaccination, ACOG recommended in their September 2017 Committee Opinion (Number 718), that all pregnant women receive the Tdap vaccination in the third trimester of each pregnancy. Despite ACOG recommendations for vaccination of Tdap to pregnant women in their third trimester, and with each pregnancy, the CDC surveillance report (2017) from 2002 to 2012 indicated an increase of 3,000 infant pertussis cases. To determine the available evidence related to Tdap vaccination in pregnancy and the passive immunity provided to the infant in utero, the following search terms "primary care," "pregnant women," "Tdap vaccinations," "pertussis," "passive immunity," "vaccine," "whooping cough," "immunization," and "maternal vaccination" guided the search for peer-reviewed articles written within the past 5 years.

O'Halloran et al. (2016) found that the Tdap vaccination administered during each pregnancy within the third trimester (optimally between the 27-36 weeks gestation), promoted adequate protection of the unborn child through an increase in antibodies and passive immunity from the mother. Their study also emphasized the importance of OB/GYN providers recommending and educating pregnant women on the importance of the immunization with each pregnancy, along with the routine use of health care reminder systems to promote the recommendations at the optimal point in pregnancy. In relation to the mother's passive immunity, Baxter et al. (2017) conducted a retrospective cohort study of infants between 2010 and 2015, evaluating the efficiency of the Tdap vaccination during pregnancy to provide protection to the newborn against pertussis until the infant reaches the age where they may receive their first dose of DTap. They found that the maternal Tdap vaccination protected the infant against pertussis up until the infant's first round of vaccinations. The findings also

validated the current ACOG recommendations for administering the Tdap vaccination with each pregnancy (Baxter et al., 2017).

Regarding the education of pregnant women about the Tdap vaccination, Kriss et al. (2019) performed a national Internet panel survey and study of pregnant women in the US to obtain initial data that would inform the development of appropriate educational strategies and materials regarding the Tdap vaccination. The primary objectives of this study were to evaluate the self-reported status of pregnant women (vaccinated or unvaccinated) in the United States, and to determine whether these answers were affected by race, ethnicity, or other factors that could affect a pregnant woman's ability to make an informed decision about receiving the Tdap vaccination (Kriss et al., 2019). The results of the study indicated that Hispanic women had higher Tdap vaccination rates than both white women and black women (53%, $p < .05$, compared with 38% and 36% respectively), and that both higher income and a geographical location within the western United States were also independently associated with Tdap vaccination during pregnancy (Kriss et al., 2019). The investigators further concluded that a health care provider's Tdap recommendation was the most common factor influencing a pregnant woman's decision and providing pregnant women with educational materials regarding the importance of the Tdap vaccination increases the likelihood of their receiving the Tdap vaccination (Kriss et al., 2019).

Payakachat et al. (2015) conducted a randomized prospective study to test the effectiveness of the Tdap vaccine information statement (VIS) in encouraging pregnant women to receive the Tdap vaccination at two different clinics. The average age of the women at entry into the study was 26.4 years, and they were approximately 26 weeks gestation. Of this sample, only 13% of the selected women had received the Tdap vaccination prior to the survey. Notably, the mean gestational age of the sample would indicate that many of the women were not yet

eligible for vaccination, which may have affected the results. Despite this unclear method, the authors found that by providing the surveyed women with a Tdap VIS (a patient information document produced by the CDC), they could increase the overall perception of the Tdap vaccine during each pregnancy and increase vaccination rates (Payakachat et. al, 2015).

There is a need for preventative screening in pregnant women and evidence-based methods to assist with prevention of pertussis. According to the ACOG recommendation, 100% of pregnant women should receive the Tdap vaccination to prevent pertussis and protect the lives of newborns. The CDC recommends that the VIS be given when a woman is notified of pregnancy, as well as before the administration of the Tdap vaccination to provide them with the information they need to make an informed decision regarding vaccination. Provider recommendations, patient educational materials, and professional development of health care providers and staff is essential for the uptake of maternal Tdap vaccination to provide passive immunity and protection to newborns against infection.

Project Intervention

The translation of evidence into practice requires a well thought out process that aligns to the needs of the healthcare team and their patient population. The evidence translation included these four steps outlined below.

Protocol Development and Training of Staff

The first step was to establish a protocol that included the healthcare team providing each pregnant women with a VIS at the patient's initial prenatal visit, and again at the recommended point of vaccination between 27 and 36 weeks gestation, so the mother is able to make an informed decision regarding the Tdap vaccination. Providing each patient with information about the vaccination with each pregnancy helps dispel some of the myths associated with

vaccinations, particularly during pregnancy. Each member of the healthcare team was encouraged to watch a special educational video regarding the importance of Tdap administration for pregnant women during the recommended gestational age. The video was short, lasting only 25-30 minutes, with content that aligned to the planned protocol and intervention. In addition, a survey regarding Tdap vaccination in pregnant women and providing education to the women within the clinic was given to all clinic staff. The survey, based on CDC guidelines, was 15 questions long, and the data obtained from the surveys was used to evaluate the staff's knowledge and understanding of the importance of the Tdap vaccination to determine whether the educational videos improved or otherwise impacted the intervention.

Education of Patients

The intervention included educating the patient on the Tdap vaccination with the use of the VIS produced by the CDC. The VIS was to be provided to each patient at the first prenatal appointment and again at the appointment in which the provider recommends the vaccination. The VIS provides the patient with information regarding the benefits of Tdap vaccination with each pregnancy and the need for family members in contact with the newborn to also receive the vaccination.

Recommendation From the Provider

The study conducted by Payakachat et. al (2015) described the benefits of educating mothers on the Tdap vaccination, with an emphasis on the increased vaccination rates in women whose physician specifically described the vaccine during their prenatal visit. To this end, the obstetrical healthcare providers were encouraged to recommend the Tdap vaccination at a prenatal appointment between 27 and 36 weeks gestation and ensure that each woman received educational materials that describe the benefits of the vaccination during pregnancy. The

recommendation is facilitated by establishing a rapport with pregnant patients during their very first prenatal visit. This relationship promotes and improves the continuity of care.

Vaccination Administration

The primary aim of the intervention was the administration of the Tdap vaccination. Each step of the intervention focused on the promotion of vaccination uptake through patient education and provider recommendation. Key to the entire intervention was the Tdap vaccination recommendation given by the provider to the pregnant woman at 27 to 36 weeks gestation. The clinic staff were then prepared to administer the vaccination to 100% of the women receiving the recommendation and meeting the gestational age guidelines.

The intervention was a quality improvement project that produced non-generalizable results. The evaluation of the intervention steps and outcomes was accomplished through chart reviews. The IRB review deemed the project to be non-regulated research/quality improvement.

Evaluation Plan

Project outcomes were collected throughout the intervention (February 3, 2020 – May 3, 2020). The outcomes, directly aligned to the project objectives, were (a) the presence of standing orders on each patient's chart for Tdap vaccination at 27 to 36 weeks gestation, (b) documentation within the patient record that the VIS was given at the initial prenatal appointment and again at an appointment between 27 to 36 weeks gestation, (c) a provider note indicating that Tdap vaccination was recommended at 27 to 36 weeks gestation, and (d) documentation of the Tdap vaccination being administered to patients between 27 to 36 weeks gestation or an indication as to why the vaccination was not administered within the patient record and NEXTGEN.

Each outcome variable was assessed for the percentage of change in protocol from the start of the intervention, and the results were compared to the clinic's vaccination rate from

2019, when only 40% of over 300 obstetric patients received their Tdap vaccination. The overall aim of the project was to increase the immunization rates from 40% to 90%. This aim was based on the ACOG recommendation that 100% of women should receive the Tdap vaccination with each pregnancy.

Results

During February 3, 2020 to May 3, 2020, 338 women presented for prenatal care. The women were predominantly Hispanic (60.9%), were on average, 9 weeks pregnant at their first appointment, and most were pregnant with their first or second child (70%), at a mean age of 29 years (Table 1).

Table 1

Summary of Demographic Characteristics

Characteristic	Total (n = 338)
Age [Years, Mean (*SD*)]	28.76 (6.37)
Husband's Age [Years, Mean (*SD*)]	30.25 (5.79)
Gestational Age [Weeks, Mean (*SD*)]	8.8 (4.23)
Race/Ethnicity	*n*(%)
Hispanic	206 (60.9)
White, Non-Hispanic	97 (28.7)
Black, Non-Hispanic	17 (5)
Others	13 (3.8)
Parity	*n*(%)
0	126 (37.3)
1	109 (32.2)
2	84 (24.9)
3 or more	19 (5.6)
Provider/Patient Break-down	*n*(%)
MD_1	218 (64.5)
MD_2	120 (35.5)

Implementing Protocol and Staff Education

A standardized protocol was developed with standing orders for vaccinations between 27 to 36 weeks. The clinic's healthcare team ensured all patient records for patients being seen between 27 to 36 weeks were flagged. All of the clinic staff were prompted to view a short educational video (25-30 minutes) on the importance of the Tdap vaccination and the various misconceptions surrounding vaccinations in our current culture. They were then provided a survey with 15 questions to gauge their knowledge of the topic. Four staff members (one LVN and three MAs) completed the training and survey questions. There were eight yes-or-no questions and seven fill-in-the-blanks questions (Appendix B). The survey was given twice at the beginning of the project with an average score of 80%, and at the end of the project the scores were 100%.

Patient Education

All obstetrical patients received educational materials and information regarding the importance and benefits of the Tdap vaccination at their initial prenatal appointment and again at an appointment prior to their gestational window of 27-36 weeks when the provider recommended the vaccination. The VIS was provided to 100% of the obstetrical patients at both timepoints.

Provider Vaccination Recommendation

All patients received an initial verbal recommendation from their provider at their first prenatal encounter. Each patient recommendation was documented within the EMR. Later in the intervention, 190 of the 338 OB patients (60.5%) received a second provider recommendation as they reached the gestational window of 27-36 weeks. One hundred and thirty-one women (38.8%) did not receive a second provider recommendation as they were too early in their

pregnancy to receive the vaccination during the intervention period. Seven women (2.1%) were too far along in their pregnancy to receive a recommendation (or a vaccination) (Table 2).

Table 2

Tdap Recommendation

Recommendation	Week's Gestation	Total (n = 338) n(%)
Initial prenatal visit		
	2-12 weeks	292 (86.4)
	13-20 weeks	41 (12.1)
	> 21 weeks	5 (1.5)
Prior to vaccination		
	27-36 weeks	207 (100)

Note: The numbers reflect all women who received prenatal care during the project period. Some women received the initial prenatal recommendation, but they are not able to receive the Tdap vaccination due to the window for vaccination of 27-36 weeks gestation.

Vaccination Administration

One hundred and ninety women received Tdap vaccinations during the period of the intervention. Of the 207 vaccine-eligible women, 10 women (5%) declined the Tdap vaccine after being provided a recommendation from their provider and educational materials on the safety and benefits of the vaccination. There were no correlations with declining the vaccination to age, ethnicity, or parity. Ultimately, 190 of the total women in the sample (56.2%) were administered the Tdap vaccination between 27 and 36 weeks gestation (Table 3).

One hundred and thirty-one of the 338 OB patients (40.8%) initiating prenatal care during the intervention were not eligible for vaccination as they fell outside of the 27 to 36 week

gestational range per ACOG guidelines. Seven women (2.1%) were missed and did not receive a Tdap vaccination.

Table 3

Tdap Vaccinations

Vaccination Stats	Week's Gestation	Total (n = 338) n(%)
Vaccination received		
	27-36 weeks	190 (56)
Vaccination not received		
	<27 weeks	131 (39)
Declined		10 (3)
Missed		7 (2)

Note: The numbers reflect all women who entered prenatal care during the project period. Some women received the initial prenatal recommendation, but they are not yet able to receive the Tdap vaccination due to the window for vaccination of 27-36 weeks gestation.

Discussion

This quality improvement project sought to implement a Tdap vaccination program and increase the rates of vaccinations of obstetrical patients at a San Antonio, Texas, clinic. The intervention included developing a clinic protocol and staff training, patient education, and instructions for provider recommendation, and resulted in 100% of OB patients receiving education and recommendations for the Tdap vaccination, as well as an overall increase in Tdap vaccination rates so that 190 of 207 vaccine-eligible women (95%) were administered the vaccination.

The clinic's current electronic medical record does not include a flag system to alert providers that OB patients are within the 27 to 36 weeks gestational window to receive the Tdap vaccination. Therefore, the MAs manually updated the daily brief (a run-down of each

patient appointment) the day before a patient's visit. Seven prenatal patients (2.1%) received the initial patient Tdap educational materials and an initial recommendation from their provider at their first prenatal visit, but they did not receive the Tdap vaccine during the recommended gestational age, prior to giving birth. It is possible that these seven women were overlooked due to human or system error and therefore did not receive the recommendation or the vaccination prior to delivery. Though the intervention step involving the implementation of the clinic protocol generally produced positive results (there was an increase of ~16.2% in Tdap vaccination rates), a better flag system is necessary for the clinic to achieve the ACOG recommendations of 100% of vaccine-eligible patients receiving the vaccine.

Prior to the intervention, the clinic staff were utilizing evidence-based best practices like referring to the VIS and the CDC guidelines. However, the staff were not providing the VIS to every pregnant patient with each initial prenatal visit, a necessary step for increasing the mother's opportunity to make an informed decision regarding the Tdap vaccination with each of her pregnancies.

All 338 women in the sample were given the initial verbal recommendation from the provider at their first OB appointment, and they were given the VIS within their prenatal orientation packet. The vast majority of the OB patients accessed early prenatal care as reflected in the mean gestational age at first prenatal appointment in our sample. All Tdap vaccinations were appropriately documented within NEXTGEN. Patients' refusals to receive the vaccine (10 of the 207 (5%) vaccine-eligible women) affected the overall goal of reaching a 100% vaccination rate for vaccine-eligible patients.

Limitations

The absence of a flagging system within the electronic medical record for the gestational age and need for vaccination, was an intervention limitation. The absence of a vaccine-alert increased the MAs workload and accountability for ensuring that the daily patient brief included this notification. Additionally, a task box for documentation of the provider recommendation of Tdap vaccination was not included in NEXTGEN. This created an added responsibility for the provider to manually document Tdap recommendations within the patient encounter note. The lack of task boxes and flagging systems placed an additional burden on the staff who were then responsible for looking within the providers' documentation to see if (a) educational materials and provider recommendations were given to the patient, and (b) whether the patient's chart was flagged for being within the recommended gestational window for the vaccination.

During the clinic assessment, the MAs conveyed that they were overwhelmed with the current workload and adding any additional tasks to their day was a concern. Initially, there was excitement by the staff and providers for the intervention, given the benefits to both mother and infant. However, midway through the implementation, the COVID-19 pandemic dramatically effected clinical operations. The OB/GYN providers began practicing out of one clinic that provided services for only OB/GYN patients. Therefore, the clinic staffing ratios changed and only one MA was sent to work with both providers. The MA was able to integrate the intervention tasks into her routine, but without the added assistance of the other two MAs she was solely responsible for flagging the daily brief, providing the education materials, and administering the vaccinations. The providers were committed to the intervention and all steps were maintained despite the COVID modifications in patient appointments. Nevertheless, seven patients that were eligible did not receive the vaccine.

Recommendations

Initiating discussions about the Tdap vaccination with OB patients should begin prior to the recommended gestational window, typically within the first prenatal visit. There were approximately 207 women who were eligible for the Tdap vaccination between February 3, 2020 and May 3, 2020, and 190 women were administered the vaccination.

Sustainment of the intervention and possible modifications could address the issues for the vaccine-eligible women choosing not to receive the vaccination, despite receiving both provider recommendations and education. Suggestions for addressing these women's' concerns or hesitation could involve developing clearer educational materials, confronting financial barriers, or even assisting women in accessing transportation services to attend prenatal appointments.

Alerts systems within the EMR and standing orders for vaccination are recommended to alert the staff when administration is due. Task boxes added within the EMR would streamline documentation and improve provider/staff participation in the intervention. These additions within the EMR would promote evaluation of adherence to the protocol and reduce the number of patients that missed the window to receive Tdap.

Implications for Practice

This evidence-based practice project increased awareness of the importance of the Tdap vaccination for all pregnant women. It provided the entire clinic staff with an opportunity to implement an evidence-based practice change. ACOG recommendations and CDC guidelines were used to guide the project. The clinic assessment revealed practices that prevented the identification of OB patients within the recommended gestational window, and therefore prevented vaccine-eligible women from receiving the Tdap vaccination as recommended. By addressing this issue, in addition to developing patient and staff educational materials and a

clinic protocol, prenatal Tdap vaccination rates at the host clinic increased, which will ultimately improve health outcomes (Abraham et al. 2018).

The host clinic accepted the evidence-based practice changes to the prenatal immunization protocol/process. Piloting of the intervention identified that the agreed-upon process changes could be easily integrated and sustained within the host clinic.

Summary

Establishing a strong relationship with an OB/GYN provider for preventative and early comprehensive prenatal care can lead to improved quality of care. Many women are unaware of the importance of prenatal immunizations and the benefits for both themselves and for their unborn child. The combination of implementing clinic protocols and educating staff on these protocols, educating patients on the importance of vaccinations, and provider recommendations all contributed to increased rates of prenatal vaccinations. Prenatal visits become vital opportunities for recommending, educating, and administering vaccinations.

This prenatal immunization program intervention improved access to general medical education and immunization awareness for pregnant women. The intervention, based on ACOG recommendations and CDC guidelines, were found to be effective within this project and can be replicated in other OB/GYN clinic settings seeking to increase rates of Tdap vaccinations.

References

Abraham, C., Pichichero, M., Eisenberg, J., & Singh, S. (2018). Third-trimester maternal vaccination against pertussis and pertussis antibody concentrations. *Wolters Kluwer Health, 131*(2), 364-369. doi: 10.1097/AOG.0000000000002438

Ackerman, T. (2019, December 19). Memorial Park area school closes because of whooping cough outbreak. *Houston Chronicle.* https://www.houstonchronicle.com/news/houston-texas/houston/article/Memorial-Park-area-school-closes-because-of-14917612.php

American College of Obstetricians and Gynecologists. (2017). Update on Immunization and Pregnancy: Tetanus, Diphtheria, and Pertussis Vaccination Committee on Obstetric Practice Immunization and Emerging Infections Expert Work Group, (718). https://www.acog.org/clinical/clinical-guidance/committeeopinion/articles/2017/09/update-on-immunization-and-pregnancy-tetanus-diphtheria-and-pertussis-vaccination

Batalova, J., & Zong, J. (2016). Language diversity and English proficiency in the United States. *The Online Journal of the Migration Policy Institute*. https://www.migrationpolicy.org/article/language-diversity-and-english-proficiency-united-states

Baxter, R., Bartlett, J., Fireman, B., Lewis, E., & Klein, N. P. (2017). Effectiveness of vaccination during pregnancy to prevent infant pertussis. *Pediatrics, 139*(5). https://doi.org/10.1542/peds.2016-4091

Centers for Disease Control and Prevention. (2015). *Pregnant women and Tdap vaccination, internet panel surveys, United States, April 2014 and April 2015.* https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/tdap-report.html

Centers for Disease Control and Prevention. (2013). *Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant women – Advisory Committee on Immunization Practice (ACIP), 2012*. 62(07), 131-135. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm

Centers for Disease Control and Prevention. (2019). *Vaccine Information Statement (VISs).* https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

Communicare Health Centers. (2019). *Mission, vision & values.* http://www.communicaresa.org/whoweare.php

Furuta, M., Sin, J., Ng, E. S. W., & Wang, K. (2017). Efficacy and safety of pertussis vaccination for pregnant women: A systematic review of randomized controlled trials women observational studies. *BMC Pregnancy and Childbirth, 17*(1), 390. https://doi.org/10.1186/s12884-017-1559-2

Halperin, S. A., Langley, J. M., Ye, L., MacKinnon-Cameron, D., Elsherif, M., Allen, V. M., Smith, B., Halperin, B. A., McNeil, S. A., Vanderkooi, O. G., Dwinnell, S., Wilson. R. D., Tapiero, B., Boucher, M., Le Saux, N., Gruslin, A. Vaudry, W., Chandra, S., Dobson, S., & Money, D. (2018). A randomized controlled trail of the safety and immunogenicity

of tetanus, diphtheria, and acellular pertussis vaccine immunization during pregnancy and subsequent infant immune response. *Infectious Disease Society of America, 67,* 1063-1071. doi:10.1093/cid/ciy244

Institute of Medicine. (2001). *Crossing the quality chasm: A new health system for the 21st century.* National Academy Press.

Kahn, K. E., Black, C. L., Ding, H., Fiebelkorn, A. P., Havers, F., D'Angelo, D., Ball, S. W., Fink, R., Devlin, R., & Greby, S. M. (2018). *Pregnant women and Tdap Vaccination, internet panel survey, United States, April 2017.* Report for the Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/tdap-report-2017.html

Kriss, J., Albert, A., Carter, V., Jiles., A., Liang, J., Mullen, J., Rodriguez, L., Howards, P. P., Orenstein, W. A., Omer, S. B., & Fisher, A. (2019). Disparities in Tdap vaccination and vaccine information needs among women in the United States. *Maternal and Child Health Journal, 2019,* 201-211. http://doi.org/10.1007/s10995-018-2633-8

O' Halloran, A. C., Lu, P. J., Williams, W. W., Ding, H., & Meyer, S. A. (2016). Tetanus, diphtheria, and acellular pertussis vaccination among women of childbearing age- United States, 2013. *American Journal of Infection Control, 44,* 786-793. doi: 10.1016/j.ajic.2016.03.048

Payakachat, N., Hadden, K., & Ragland, D. (2015). Promoting Tdap immunization in pregnancy: Association between maternal perception and vaccinations rate. *Elsevier*, *34*, 179-186 http://dx.doi.org/10.1016/j.vaccine.2015.09.062

Tan, T. Q., & Gerbie, M. V. (2013). Pertussis, a disease whose time has come: what can be done to control the problem? *Obstetrics and gynecology*, *122*, 370–373.

Texas Department of State Health Services. (2018). *Regional analysis of maternal and infant health in Texas public health region 8.* Community Health Improvement Division Maternal & Child Health Epidemiology. https://www.dshs.state.tx.us/mch/epi/Reports.aspx

U.S. Census Bureau. (2017). *ACS Demographic and Housing Estimates 2013-2017 American Community Survey 5-year Estimates*. https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=F

Appendix A

Letter of Support

CommuniCare HEALTH CENTERS

December 4, 2019

Communicare Health Centers
Dr. Yadira Anca, MD, FACOG
Obstetrics & Gynecology
10002 Westover Bluff
San Antonio, Texas, 78251
dr.yanca@communicasa.org
Phone: 210-233-7000
Fax: 210-257-5113

Re: Letter of support for Tarshera K. Reyna, BSN, RN Doctoral Student

In my capacity as an obstetrician and gynecologist (OB/GYN) physician of the Communicare Potranco OB/GYN clinic, among the Communicare Health Centers, I fully support Tarshera K. Reyna, BSN, RN Doctoral Student, in her doctor of nurse practice (DNP) project entitled *A System Intervention of Tetanus, Diphtheria, and Pertussis (Tdap) Vaccinations for Pregnant Women in Primary Care.*

The proposed DNP project is in the OB/GYN area which is highly relevant and well in line with the focus of the clinic approach to prevent pertussis in newborn babies.

The Communicare Potranco OB/GYN Clinic and the Communicare Health Centers guarantee the availability of the necessary facilities in order to ensure a successful setting for the project.

Yours sincerely,

Yadira Anca MD

Appendix B

Survey Questionnaire

Survey Questionnaire: Tdap Vaccine during Pregnancy

1. Have you heard of the Tdap vaccine before today? ____Yes or ____No
2. Does the healthcare provider recommend the Tdap vaccine during pregnancy? _____Yes or _____No
3. What does the Tdap vaccine prevent? _____
4. What is the recommended gestational age do the pregnant patient receive the Tdap vaccine? _____
5. Do you administer the Tdap vaccine after 36 weeks of gestation? _____Yes or ____ No
6. Do pregnant women receive the Tdap vaccine with each pregnancy? ____Yes or ____No
7. How does the Tdap Vaccine help the baby? _____
8. At what age can the baby receive their first vaccines? _____
9. Is the Tdap vaccine harmful to the fetus? _____Yes or _____No
10. Is the Tdap vaccine harmful to the mother during pregnancy? _____Yes or _____No
11. When do you provide educational material to the pregnant patient about the Tdap vaccine? _____
12. What is the name of the educational material given to the pregnant patient? _____
13. On what website can you find the vaccination information sheet (VIS)? _____
14. Do the family or close contacts get the Tdap vaccine prior to the baby's birth? _____ Yes or _____ No
15. Is the Tdap vaccine covered by most insurances? _____ Yes or _____No

Appendix C

Vaccine Information Statement

Retrieved from the CDC at https://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.pdf.

VACCINE INFORMATION STATEMENT

Tdap (Tetanus, Diphtheria, Pertussis) Vaccine: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Tdap vaccine can prevent **tetanus, diphtheria**, and **pertussis**.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **PERTUSSIS (aP)**, also known as "whooping cough," can cause uncontrollable, violent coughing which makes it hard to breathe, eat, or drink. Pertussis can be extremely serious in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

2 Tdap vaccine

Tdap is only for children 7 years and older, adolescents, and adults.

Adolescents should receive a single dose of Tdap, preferably at age 11 or 12 years.

Pregnant women should get a dose of Tdap during every pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Adults who have never received Tdap should get a dose of Tdap.

Also, **adults should receive a booster dose every 10 years**, or earlier in the case of a severe and dirty wound or burn. Booster doses can be either Tdap or Td (a different vaccine that protects against tetanus and diphtheria but not pertussis).

Tdap may be given at the same time as other vaccines.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis**, or has any **severe, life-threatening allergies**.
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP, DTaP, or Tdap)**.
- Has **seizures or another nervous system problem**.
- Has ever had **Guillain-Barré Syndrome** (also called GBS).
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**.

In some cases, your health care provider may decide to postpone Tdap vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting Tdap vaccine.

Your health care provider can give you more information.

CDC U.S. Department of Health and Human Services Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

- Pain, redness, or swelling where the shot was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Tdap vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
Tdap (Tetanus, Diphtheria, Pertussis) Vaccine

Office use only

04/01/2020 | 42 U.S.C. § 300aa-26

Appendix D

List of Educational Videos for Staff Training

Centers for Disease Control and Prevention (CDC). (2019, May 9). *Dr. Pamela Rockwell's Flue and Tdap Vaccine Recommendation to Pregnant Patients* [Video]. YouTube. https://www.youtube.com/watch?v=USf7nLybajg

Centers for Disease Control and Prevention (CDC). (2019, May 9). *Nurse-Midwife Carol Hayes on Improving Practices' Maternal Vaccination Rates* [Video]. YouTube. https://www.youtube.com/watch?v=DG-1Yfeq0BI

Centers for Disease Control and Prevention (CDC). (2019, May 9). *Nurse-Midwife Carol Hayes on Tdap Vaccine: Importance and Recommendations* [Video]. YouTube. https://www.youtube.com/watch?v=jiIuqap4eQs

Centers for Disease Control and Prevention (CDC). (2016, Jan. 12). *Pregnant? Help Protect Your Baby from Whooping Cough* [Video]. YouTube. https://www.youtube.com/watch?v=SkafS5pwMuo

U.S. Department of Health and Human Services. (2018, July 31). *Your Best Shot – Whooping Cough Vaccines* [Video]. YouTube. https://www.youtube.com/watch?v=AC58by5_iqo