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ORIGINAL RESEARCH

Correlation between Accessibility and Patient Education with Tdap Utilization among Pregnant Patients

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INTRODUCTION

When the term vaccine is mentioned during pregnancy, a spectrum of emotions may occur in patients. Many may experience feelings of fear, unsureness, anxiety, or lack of knowledge on the topic, while others experience a sense of relief, protection, self-preservation, and safety. However, when a patient cannot access desired vaccines or experiences a lack of knowledge regarding the topic, those emotions may change. In the 1920s and 1940s, many families in the United States experienced the loss of a loved one related to what are now considered preventable diseases, including diphtheria, polio, and measles (Healthy Children, 2015). Reportedly, in the early 20th century diphtheria claimed more than 10,000 lives a year in the United States while measles affected nearly a half million children (Healthy Children, 2015). The Centers for Disease Control and Prevention (CDC) reported that during the 20th Century, pertussis had a significant impact on childhood mortality rates in the US, and was labeled one of the most common childhood disease (CDC, 2020). Today, vaccinations are more widespread, however accessibility and lack of patient and provider education remain commonly reported barriers to their use. As access restrictions and a lack of education continue, pertussis has been—and continues—to be on the rise, with outbreaks continually occurring in the US. A 2017 CDC report notes that an average of 1,000 infants are hospitalized, and between 5 to 15 infants die each year due to a pertussis infection (CDC, 2017). The resurgence and ongoing persistence of pertussis infections reinforces the need for increased vaccine education and accessibility.

This study focused on the tetanus, diphtheria, and pertussis vaccine (Tdap). The Centers for Disease Control Advisory Committee (ACIP, 2020) recommends a single dose of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) with each pregnancy in order to reduce the pertussis incidence in infants, regardless of prior history of vaccination (CDC, 2020). The recommendation by the American College of Obstetricians and Gynecologists (ACOG, 2020) is the same, a single dose of Tdap for all pregnant women. The World Health Organization (WHO, 2015) reports the most effective means of preventing pertussis infections and decreasing mortality of infants too young to be vaccinated is vaccination during pregnancy. All three organizations endorse a single

dose of Tdap during each pregnancy and recommend that it be administered between 27 and 36 weeks of gestation.

Review of Literature

BACKGROUND

In the United States in the 1920s, diphtheria claimed more than 10,000 lives a year (Healthy Children, 2015). In the 1940s, measles affected nearly half a million U.S. children, while polio impacted thousands (Healthy Children, 2015). The resurgences of pertussis infection in the United States has gained recent attention following a CDC (2021) study which reported 15,609 pertussis cases in 2018, a stark difference from the 1,010 reported cases in 1976. Patient-reported barriers to vaccination include a lack of provider education on vaccine needs during pregnancy, thus leading to a lack of patient education on vaccines offered by providers during pregnancy. (Wiley et al., 2013). Inadequate patient education by providers has further created skepticism among patients regarding the need for vaccines during pregnancy (Wiley et al.). For decades, vaccine accessibility and education have been commonly reported barriers to vaccine use (Wiley et al.). The literature continues to suggest that variables currently exist which may act as barriers to vaccine uptake, and there is an immediate need for interventions to improve vaccine uptake during pregnancy (Mohammed, 2019).

PREVENTATIVE CARE

There is continued debate over the pros and cons of vaccination in the United States with some arguing that vaccinations are harmful, while others argue that they are a necessity (National Vaccine Information Center, 2016). In their 2012 article, Adegbola et al note that, “Infectious diseases remain the most important cause of childhood morbidity and mortality worldwide, accounting for two thirds of the estimated 8.8 million deaths in children aged less than 5 years in 2008” (p. S28). Vaccinations during pregnancy are often controversial or bothersome for patients and their families (National Vaccine Information Center, 2016). In studies, patients have reported multiple barriers to vaccination uptake during and outside of pregnancy, including lack of knowledge regarding vaccination safety or the importance of vaccinations during pregnancy, lack of vaccine discussion by providers, lack of access to vaccines, and lack of reminders for vaccine needs (Head, Vanderpool, & Mills). In his research into Tdap, Long found that “Pertussis cases have surged to more than 48,000 nationwide in 2012, exceeding the number of cases reported annually since the 1950s” (Long, 2014, p. 1). Tamma et al (2009) report that vaccination rates remain the lowest in the pregnant population, yet vaccinations continue to be “the most effective method for preventing severe influenza illness and its sequelae” (p. 547). In their research, Hibberd (2015) discussed vaccination statistics and noted that immunization rates remain unacceptably low for younger adults. Hibberd recommends strategies to improve vaccination rates, including the use of safe, dual vaccine administration, and the responsibility of health care professionals to ensure proper reporting. Other suggested strategies to increase vaccine uptake include addressing patient and provider concerns of vaccine safety, improvement of vaccination

delivery systems, and taking advantage of vaccination opportunities during all health care visits (Hibberd).

ACCESS TO CARE/EDUCATION

Wilson, Paterson, Jarrett and Larson (2015) studied factors influencing vaccination acceptance during pregnancy, and noted that the main barriers include: vaccination safety, not recommended by the healthcare provider, low knowledge about vaccines, access issues, cost, and conflicting advice. Eilers, Krabbe, and Melker (2015) completed a literature review to assess factors related to poor vaccine uptake in the population. Six themes influencing vaccine uptake were identified: attitudes and beliefs, perceived risk, complete knowledge of the vaccine, education from health care workers, accessibility and affordability (Eilers et al.). In their 2014 Cochran database review of Randomized Controlled Trials (RCT), Thomas and Lorenzetti studied interventions to increase influenza vaccine uptake in people aged 60 and older. The study analyzed 57 RCTs with 896,531 participants and found themes/gaps affecting vaccine use, including: access to care, cost of vaccine, and patient education regarding the influenza vaccine. Recommendations to improve vaccination rates included enhancing vaccine access, providing patient reminders, and increasing education to patients and providers (Thomas & Lorenzetti).

NATIONAL RECOMMENDATIONS

In 2014, WHO completed a research study on immunization, vaccines and biologicals focused on pertussis disease, discussing how the virus is spread, signs and symptoms, causative agent, and related statistics. The report confirmed the purpose of the pertussis vaccine is to reduce the risk of severe pertussis in infancy: "WHO estimates that in 2008, global vaccination against pertussis prevented approximately 687,000 deaths" (WHO, 2014). The report further recommended treating all hospital staff, indicating that maternity and pediatric staff were the most critical to vaccinate.

Methods

The objective of this study was to assess whether there was an effect on maternal Tdap vaccine utilization rates when common barriers (e.g., lack of education or decreased access) were rectified. The pre- vs. post-intervention study was conducted at a 52-bed north Georgia hospital that sees approximately 350 deliveries annually (Piedmont Health Care, 2016). To determine the study sample size, the researcher conducted a power analysis for a one sided McNemar test, using a power (1-β) of .80 and an α (Type I error) of .05. The analysis indicated a minimum sample size of 18 needed to detect a significant improvement in vaccination rates of at least 45% before and after the educational intervention. To allow for the detection of smaller changes in vaccination rates, the researcher chose a sample of 20. The 20 participants were selected from the prior admission log over a two-week admission period using a random numbers tables.

During their antepartum period, participants were contacted via phone and an interviewer administered the "Vaccination and Barriers" section of the Pregnancy Risk Assessment Monitoring System (PRAMS) questionnaire. Immediately following the

questionnaire, participants were provided with education on the importance getting a Tdap vaccine during pregnancy, and were notified that their obstetrician's office could provide the vaccine. After delivery, postpartum data was gathered via a second interviewer-administered PRAMS questionnaire prior to the patient's discharge home from the hospital.

The two independent variables of interest were (1) access to Tdap vaccine and (2) patient education on Tdap vaccine. The dependent variable of interest was Tdap vaccine utilization.

DATA ANALYSIS PROCEDURES

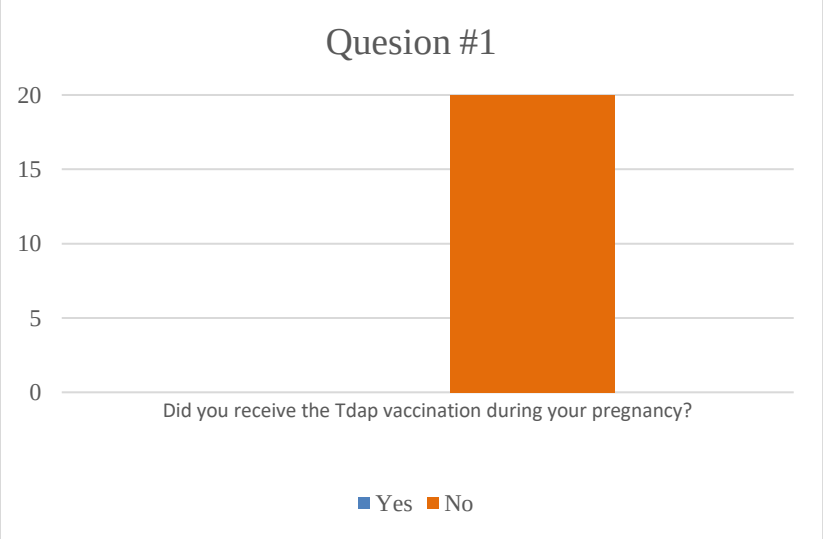
All data was analyzed using SPSS (v.21). Vaccination status was coded as 1 (vaccinated) or 0 (not vaccinated) for each of the two stages of the study: antepartum and postpartum. Data was categorical, and the descriptive analysis performed included an examination of counts and percentages of survey responses. The researcher chose the McNemar test to assesses if a statistically significant change in proportions occurred on a dichotomous trait (vaccination status) at two time points on the same population (antepartum and postpartum). The McNemar analysis aligns well with the correlational design of the study, which aimed to detect whether the intervention (educational call) was associated with higher vaccination rates.

Results

The descriptive statistics are followed by the discussion of the results from the McNemar tests.

Descriptive Statistics. The results for antepartum participants are provided in Figures 1 and 2. Figure 1 depicts the results of Question #1, which study participants answered prior to delivery of their infant. The results show that all 20 participants (antepartum) reported not having received the Tdap vaccine during their current pregnancy.

Figure 1. Antepartum Rate of Tdap Vaccination



The data presented in Figure 1 and Figure 2 provide a reference point for the data obtained from antepartum participants and was compared with the data obtained from postpartum participants in Figure 3 and Figure 4.

The results from the postpartum administration of the PRAMS questionnaire are provided in Figure 3 and Figure 4. Figure 3 depicts the results of the postpartum participants answer to Question #1; fifteen of the 20 participants reported having received the Tdap vaccine after being provided vaccine education and information on how to access the Tdap vaccine.

Figure 3. Postpartum Participants Reported Rate of Tdap Vaccination Utilization

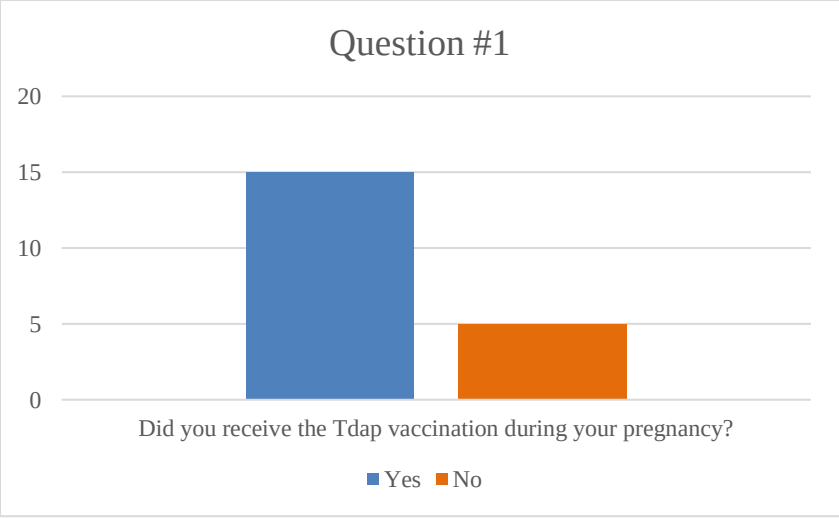


Figure 4. Postpartum reasons for not receiving the Tdap Vaccine

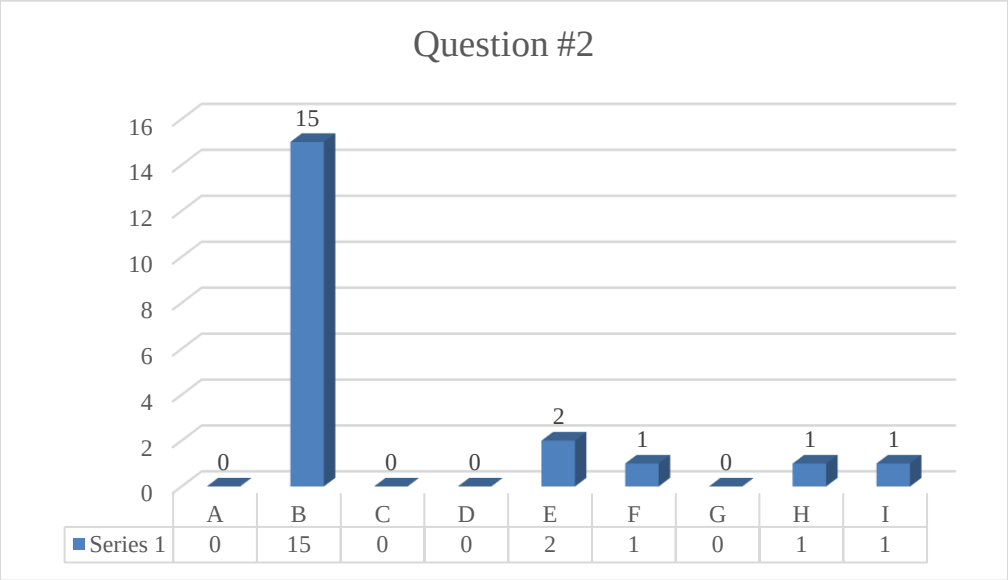


Figure 4 depicts the various answers received from the postpartum participants.

The categories presented in Figure 4 reflect the response options included in the PRAMS questionnaire or Question # 2:

A= I received the Tdap vaccine *before I got pregnant* with my new baby
B= I received the Tdap vaccine *after my new baby was born*
C= My health care provider did not offer or recommend it
D= My health care provider did not have the vaccine
E= I don't like to get vaccinated
F= I don't think the vaccine is safe during pregnancy
G= I don't think the vaccine is safe while nursing my baby
H= I am worried about the side effects of the vaccine
I= Other → Please tell us: _____

The data shows a positive correlation between the intervention (patient education telephone calls and improved accessibility) with patient Tdap vaccine utilization rates. Postpartum, 15 out of 20 participants reported having received the Tdap vaccine.

Results of McNemar Tests. In order to conduct the McNemar statistical test for the first clinical question, data were organized in a 2x2 contingency table. This section presents the results of the McNemar tests, separately for each clinical question.

McNemar tests are nonparametric tests that allow principal investigators to assess change for longitudinal studies involving repeated-measures. In particular, for the first clinical

question, the McNemar test determines whether the difference in vaccination rates varies significantly before and after the intervention (educational telephone calls and increased accesibility). Before conducting the McNemar test for this question, the data obtained through the PRAMS questionnaire were organized in a 2x2 contingency table *(see Table 1)*, where the cells contain frequencies of outcomes. Four outcomes are summarized in the table: received vaccination before delivery (Antepartum-Y), did not receive vaccination before delivery (Antepartum-N), received vaccination after delivery (Postpartum-Y), and did not receive vaccination after delivery (Postpartum-N).

The information presented in the first row captures the following mutually exclusive groups: number of subjects who received the Tdap vaccination neither before nor after delivery (5); number of subjects who were not vaccinated antepartum but received the vaccine after delivery (15), and the total number of subjects who were not vaccinated before delivery. Similarly, the second row breaks down the number of subjects who were vaccinated before delivery (0) by their vaccination status after delivery. Since no subjects received the vaccine before delivery, all cells in the second row are 0. As the table indicates, none of the 20 participants received Tdap immunization during pregnancy, before the calls were made (0% vaccination rate). Following the educational calls, 15 of the 20 participants reported that they were vaccinated (75% vaccination rate) after delivery.

Table 1. Contingency Table for McNemar Analysis: Tdap Vaccination Rates Before and After Intervention

	Postpartum-N	Postpartum-Y	Total
Antepartum-N	5	15	20
Antepartum-Y	0	0	0
Total	5	15	20

Table 2 captures the results of the McNemar test: The Chi-Square statistic, which tests for the equality of vaccination rates between the two points in time (antepartum and postpartum); the total number of subjects included in the test (n=20), degrees of freedom for the McNemar test, which is the number of time points being compared minus one (2-1=1); and the *p* value or the significance level for the test, which represents how likely the result found would occur by chance. Specifically, there is only a 2.5% probability (p = .025) that the difference we found in vaccination rates before and after the intervention may have been due to chance or other factors. In other words, we can say that if we were to repeat this study with different samples, the observed difference in vaccination rates would be expected to occur by chance only 2.5 in 100 times in repeated tests on different samples of the population of pregnant women. As with any other Chi-Squared test, a *p* value for the McNemar test that is less than .05 indicates that the difference between antepartum and postpartum vaccination rates was statistically significant at the .05 level.

The results of the test *(see Table 2)* indicate that the rate of vaccination differs significantly before and after the educational-based telephone calls ($\chi^2(1,20)= 5.00$, p

=.025). That is, the antepartum to postpartum increase in vaccination rates from 0% to 75% was statistically significant at the .05 level.

Table 2. McNemar Test Results for Clinical Question 1

Statistic	Value
McNemar's Chi-Square	5
N	20
Df	1
P	0.025

To allow the calculation of the McNemar's Chi-Squared, data were organized in a 2x2 contingency table (see Table 3), displaying in rows the number of patients who had/did not have access to the Tdap vaccine in their obstetrician's office before delivery (Yes or No) while the columns indicated the postpartum vaccination status (Yes or No). A total of 13 participants responded that they were either not offered or recommended the vaccine by their obstetrician (response c), or that their obstetrician's office did not have the vaccine (response d). All 13 participants in this group (100%) reported that they received the vaccine after their baby was born. Seven participants reported that they had access to the vaccine before delivery, but that they refused to receive immunization due to various reasons. Most of the reported reasons can be related to lack of education about the vaccine, even after the principal investigators educational calls: E= I don't like to get vaccinated, F= I don't think the vaccine is safe during pregnancy, G= I don't think the vaccine is safe while nursing my baby, H= I am worried about the side effects of the vaccine, I= Other. Only two of these seven participants (29%) received vaccination after their baby was born.

Table 3. Contingency Table for McNemar Analysis: Effect of Access to Vaccine on Tdap Vaccination Rates

	Postpartum Vaccination		Total
Antepartum Access to Vaccine in Obstetrician Office	No	Yes	
No	0	13	13
Yes	5	2	7
Total	5	15	20

Table 4 displays the results of the McNemar test and reports the following numbers: Total number of subjects included in the test (n=20); degrees of freedom for the McNemar test, which is the number of groups of subjects being compared minus one (2- 1=1); and the *p* value or significance level for the test (*p* = .059), which indicates that if we were to repeat this study with different samples, the observed difference in vaccination rates would be expected to occur by chance 6 in 100 times in repeated tests on different samples of the population of pregnant women. In other words, there is a 6% probability that the difference we found in vaccination rates before the two groups was due to chance, and not

to being able to access the vaccine in the obstetrician's office.

The *p* value obtained for the Chi Square test is higher than .05, which means that the difference between the vaccination rates of the two groups was not statistically significant at .05. In the behavioral and social sciences, the conventional cutoff *p* values for statistically significant results are .05 or .01. To be significant at the .05 level, the McNemar Chi-Square statistic would have to be higher than 3.84.

Therefore, the results of the McNemar test indicate that the difference in postpartum vaccination rates between the two groups—patients without access to the vaccine and patients who had access but refused to be vaccinated—was only marginally significant at the .10 level ($\chi^2(1, 20)= 3.55$, $p = .059$).

Table 4. McNemar Test Results for Clinical Question 2

Statistic	Value
McNemar's Chi-Square	3.55
N	20
Df	1
P	0.059

Despite the marginal statistical significance obtained for the McNemar test (perhaps due to the small sample), it is clear from the contingency table *(Table 3)* that educational calls with information about access to the vaccine increased access to the vaccine, which subsequently led to an increase in vaccination rates from 0% to 100% for the patients who did not have access to the vaccine during pregnancy. The calls were less effective, however, for the seven patients who did have access to the vaccine during pregnancy, but refused to be vaccinated (29% vaccination rate).

ASSUMPTIONS, LIMITATIONS, DELIMITATIONS

The following assumptions were present in this study:

1. It is assumed that there is an association between low vaccine utilization during pregnancy and a lack of education of patient regarding the importance of the Tdap vaccine during pregnancy.
2. It is assumed that there is an association between low vaccination utilization during pregnancy and lack of accessibility to the vaccine.

The limitations related to this study included (a) PRAMS data only being available for the 20 participants in this study limiting it to only participants in the state of Georgia; (b) only patients at a single hospital located in Georgia were included in this study; and (c) the PRAMS data was reported by two different modalities.

Delimitations recognized in this study included:

1. There was no discussion of other vaccines that are recommended during pregnancy included in this study. The educational phone calls and follow up surveys only included education related to the Tdap vaccine.
2. There was no review or discussion of barriers to vaccine utilization other than lack of education and lack of accessibility included in this study.
3. There was no inclusion of pregnant participants outside of a north Georgia hospital included in this study.

DISCUSSION

The significance of this study is the protection of mothers and their newborns from potentially life-threating diseases or their sequelae. Information regarding the Tdap vaccine and its accessibility options may allow patients an opportunity to make a more informed decision. By identifying possible barriers and solutions related to poor vaccine utilization rates during pregnancy, practice improvements may be made. McCarthy et al (2012) described the influenza vaccine as being effective in preventing serious maternal and infant respiratory illness. This study only focused on the Tdap vaccine. However, literature provided throughout the study mentioned other recommended vaccines for the purpose of aiding in statistical validation for the Tdap vaccine and the possible related barriers to underutilization of the vaccine.

The Tdap vaccine is comprised of three different components, thus giving it the ability to protect against three different diseases—tetanus, diphtheria, and pertussis (CDC, 2015). However, the only way the vaccine can protect patients and their newborns is if they receive the vaccine. Health care professionals must not be stagnant in efforts to improve patient outcomes. If changes are not made in practice, patients and their families are at risk for possible life-threating sequela related to vaccine-preventable disease. When vaccinations are not obtained during pregnancy, both pregnant women and their unborn child or children can suffer serious sequel (Kalan et al., 2014). By remaining vigilant in efforts to improve vaccine uptake, health care professionals can significantly influence not only patients, but the health care system as a whole.

The information obtained during the study can be transferred to providers and used in hospital-based or community-based settings to increase vaccination uptake. With the continued exploration of possible barriers, information can be gained that will allow for changes in education or access to the Tdap vaccine, as needed. For example, if education and accessibility are proven to be barriers, methods to increase patient education and accessibility will be assessed and suggested. The literature and evidence presented throughout this study substantiate the need for additional research into vaccine utilization, and possible related barriers.

The implications for this study include two changes in practice: (1) provide pregnant patients with education on the safety and necessity of Tdap vaccine, and (2) provide patients with information on where they can receive a Tdap vaccine. The benefits of such

a change have the potential to decrease reported cases of pertussis and tetanus, especially among mothers and infants.

CONCLUSIONS

The study findings indicate that improved accessibility and improved patient education on Tdap vaccine can make a substantial difference in vaccine utilization rates among pregnant patients. Although the study showed statistical significance, more importantly, it showed clinical significance. The findings contribute to the literature on the correlation between patient education and access to vaccines, and vaccine use rates, as well as provide recommendations for possible improvements to further increase Tdap vaccine utilization during pregnancy.

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