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Protecting Infants through Tdap Vaccination during Pregnancy: A Qualitative Analysis of the Perspectives of Obstetrician-Gynecologists

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Abstract

Protecting Infants through Tdap Vaccination during Pregnancy: A Qualitative Analysis of the Perspectives of Obstetrician-Gynecologists

By: Arpita Mehrotra

Background: Pertussis or whooping cough is an acute and contagious pulmonary disease that has becoming an increasingly widespread problem in the United States. Despite the disease being vaccine preventable, newborns and infants show the highest mortality rate across the nation. In response to this, the CDC's Advisory Committee on Immunization Practices (ACIP) has made several recommendations over the years. Pursuant to ACIP's most recent recommendation in 2013 for receipt of the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine during the third trimester of every pregnancy, we sought to assess physician attitudes, perspectives, and clinical practices regarding Tdap administration for pregnant patients. Our overarching aim was to inform new strategies to improve patient-physician communication and physician administration of the Tdap vaccine in in order to ultimately reduce pertussis related morbidity and mortality among infants.

Methods: In-depth interviews were conducted with a national sample of forty obstetrician-gynecologists (OB/GYNS) in two discrete phases. Analyses of the transcripts were performed using the grounded theory approach using deductive and inductive coding strategies followed by intercoder reliability assessment.

Results: Four major themes emerged: (1) Pertussis susceptibility was perceived as a low health threat (2) Physicians recognize Tdap benefits associated with administration during pregnancy; (3) Most physicians recommend Tdap to their patients, but variation was observed in their clinic administration and stocking practices; and (4) A lack of insurance reimbursement and storage logistics can serve as barriers to practice administration of Tdap during pregnancy; patient vaccine refusal was cited by physicians as an occasional barrier.

Conclusions: Our findings indicate that while most OB/GYNs recognize the benefits of Tdap and recommend vaccination during pregnancy, barriers such as insurance reimbursement and financial barriers outweigh perceived benefits for those OB/GYNs choosing not to stock and administer Tdap to pregnant patients. Future recommendations to address these concerns include 1) structural support for administration of Tdap in OB/GYN practices; 2) CME-equivalent educational interventions that address management techniques, vaccine coding, and other relevant information; and 3) interventions to assist physicians in understanding and communicating the importance of Tdap vaccination during pregnancy.

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CHAPTER 1. INTRODUCTION

Pertussis or “whooping cough” is one of the most common vaccine-preventable illnesses that remain endemic throughout the world. In 2014, the World Health Organization (WHO) reported 139,786 cases of pertussis in the world and approximately 89,000 estimated deaths ("Pertussis," 2015). While most cases have been detected in developing countries, the United States has had numerous epidemics in the past decade, despite the introduction of routine vaccination programs. Of all the American outbreaks, the 2010 California epidemic resulted in the highest pertussis rates seen in over sixty years (Winter, Glaser, Watt, & Harriman, 2014).

During this outbreak, there were approximately 9,000 cases reported, with 808 hospitalizations and 10 infant deaths, resulting in a statewide incidence of 24.6 cases per 100,000 people (Chiappini, Stival, Galli, & de Martino, 2013; Winter et al., 2014). In June of 2014, California declared a second pertussis epidemic with reported incidence five times greater than baseline. Between January 1 and November 26 of that year, a total of 9,935 cases of pertussis with onset were reported to the California Department of Public Health (CDPH). The disease incidence among infants less than 12 months was 174.6 cases per 100,000 during this time period (Winter et al., 2014). In 2014, overall there were 32,971 reported cases in the United States and 3,330 cases reported among infants six months of age or younger. This showed a 15% increase compared to the 28,639 cases reported in 2013 ("About Pertussis ", 2015).

While pertussis is serious for all patients, it is particularly dangerous for infants under a year old due to their high susceptibility to developing complications from the disease (Chu & Englund, 2014). These complications can include pauses in breathing, sleep apnea, pneumonia, seizures, potential brain disease, and death ("Pregnancy and Whooping Cough," 2015). Because

infants do not begin their own vaccine series against pertussis (DTaP) until 2 months of age, there is a window of significant vulnerability for newborns. Many infants appear to contract serious pertussis infections from family members and caregivers. Due to this, only antibodies from their mother can be used to protect them in the first few months of their lives (Chu & Englund, 2014; Lindsey, Kampmann, & Jones, 2013).

Strategies to Decrease Pertussis Transmission

In an effort to decrease pertussis transmission among newborns, the Center for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) has released several recommendations over the years regarding the Tdap (tetanus-diptheria-acellular pertussis) vaccine. One of the first strategies was implemented in 2006, when ACIP recommended the use of "cocooning". This practice pertains to the use of Tdap vaccine for postpartum women and household contacts who have not previously received the vaccine (Kretsinger et al., 2006). This approach proved to be challenging and insufficient when used alone to prevent neonatal pertussis infections for a variety of reasons. Most importantly, cocooning leaves vulnerable newborns without any endogenous protective antibody until they begin their own vaccine series at 2 months of age, requiring the newborn to be solely dependent on the immunity of those around them for the first 2-3 months of their life. In June of 2011, ACIP issued a new recommendation for Tdap vaccination during the third trimester for unvaccinated women. The aim of this practice is to confer maternal antibodies to the fetus in order to provide direct protection when the baby is born. This eliminates a window of lack of protection when the infant is too young to get his or her own Tdap vaccine series (CDC, 2011). In October 2012, the ACIP reconsidered the topic due to dramatic and persistent increases in pertussis disease in the United States. Additionally, it became imperative to lower the burden of

disease in vulnerable newborns (CDC, 2012). In February of 2013, ACIP recommended that the vaccine be given to pregnant women during the third trimester (preferably between 27 to 36 weeks gestation) of every pregnancy, irrespective of their prior history in receiving the vaccine. This was done to optimize protection during each pregnancy (CDC, 2013)

In addition to ACIP's recommendation, The American Congress of Obstetricians and Gynecologists (ACOG) also issued an update on the Tdap vaccine during pregnancy in June of 2013. Like the ACIP guidelines, this update recommended that physicians should give a dose of Tdap during every pregnancy, preferably between 27 to 36 weeks gestation. The ACOG guidelines reinforced the importance of close family members receiving the vaccine as well to protect the newborn baby ("Update on immunization and pregnancy: tetanus, diptheria, and pertussis vaccination. Commitee Opinion No. 566. American College of Obstetricians and Gynecologists,").

Despite these recommendations with the aim of providing maternal and infant protection from pertussis, there is a clear lack of data on Tdap receipt during pregnancy. Recent studies have ranged in estimates from indicating that 14% of publicly insured pregnant women in Michigan to 82% of pregnant women delivering at a University hospital received the Tdap vaccine (Goldfarb, Little, Brown, & Riley, 2014; Housey et al., 2014). The combination of the lack of data on Tdap receipt during pregnancy and the high morbidity and mortality provide rationale for further investigation on influential factors for Tdap vaccine uptake.

Study Justification

Previous studies have shown that Tdap vaccine uptake in women is likely determined by a combination of patient and physician related factors, with physician recommendations having a significant influence (Bonville, Cibula, Domachowske, & Suryadevara, 2015; Collins, Alona,

Tooher, & Marshall, 2014). As such, it is important to investigate the attitudes, beliefs, and practices of prenatal healthcare physicians in the United States regarding Tdap vaccination and the corresponding motivating factors, barriers, and other possible factors in recommending and administering this vaccine to their pregnant patients.

There is a gap in the literature regarding the awareness and attitudes of OB/GYN physicians regarding the new Tdap vaccine recommendation for pregnant women, as well as barriers and facilitators for physicians in both recommending and administering the vaccine. This study aims to use the constructs of the Health Belief Model to determine OB/GYNs' perceptions. Additionally, the study aims to recognize the key barriers to Tdap vaccine recommendation and administration among OB/GYNs. This information can then be used to formulate a policy and/or communication intervention among OB/GYNs to improve Tdap vaccination rates nationwide.

Research Questions:

This study sought to address the following questions

1. What are the perceptions and practices of OB/GYNs nationwide regarding Tdap vaccination for their pregnant patients?
2. What extent does the Health Belief Model and its constructs serve as an explanatory framework for recommendation and administration of the Tdap vaccine among OB/GYNs?
3. Based on the messages delivered by OB/GYN physicians and applications of HBM constructs, how can these viewpoints be reconciled to develop interventions with the aim of improving vaccination recommendation and administration rates in OB/GYN clinics nationwide?

Theoretical Framework

The interview guide developed for this qualitative study utilized constructs of the Health Belief Model to capture the understanding of the accurate perceptions and practices of physicians regarding Tdap vaccination during pregnancy. While the Health Belief Model is usually applied to a population or individual at risk for contracting a disease or engaging in a risk behavior, the model can also be applied to healthcare physicians. This model was originally developed to understand the lack of preventive health services and to design effective interventions. The simplistic nature of the model, specifically in it's ability to address a broad range of populations, health behaviors, and responses to health related conditions are positive attributes of the model which make it applicable to various studies. There are five components or constructs that are associated with this model: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and self-efficacy. These constructs are hypothesized to predict why people engage in prevention, screening, and other health conditions (Glanz, 2008).

The Health Belief Model exhibits many positive attributes, however there have also been several critiques or challenges posed by the simplistic nature of the model. The main weakness of the model is variability in the measurement of the constructs. Depending on the study, each construct holds variable amounts of weight. Additionally, application of this model emphasizes the importance of using all constructs, however this is not always the case in most studies.

Several studies that investigate the role physicians play in the vaccination decisions of pregnant women have directly applied the Health Belief Model. For instance, one study in Australia used a cross-sectional survey with questions borrowing from the constructs of HBM to assess vaccine uptake during pregnancy, as well as women's intentions to vaccination and barriers (Collins, Alona, Tooher, & Marshall, 2014). Another study in Australia used qualitative

semi-structured interviews to ask pregnant women about their views on vaccination. Inductive data analysis techniques were utilized along with HBM. The interviews conducted specifically focusing on individual perceptions, modifying factors, and likelihood of actions when considering health behaviors such as vaccination during pregnancy (Hayles, Cooper, Wood, Skinner, & Sinn, 2015). As such, The Health Belief Model is the appropriate theoretical framework model for this qualitative study due to the nature of the research questions.

While the original interview guide was informed using constructs of the Health Belief Model, data analysis was conducted using the Grounded Theory Approach. This methodology allows for the construction of theory solely from the data. This allows for the identification of general concepts as well as the development of new theoretical explanations and insights. This process is unique because a specific theory is not chosen prior to data analysis. This approach is innovative and useful because it allows for the examination of topics and related behaviors from several different angles. Ultimately, the grounded theory approach has several positive attributes that include the conceptualization of data, a systematic approach to data analysis, and allowing for more depth in the analysis for data. Limitations of the approach include difficulty in managing data and no standard rules to follow (Bryant, 2007; Corbin, 2015). Chapter 3 of this thesis discusses how the grounded theory approach was applied to this specific study.

CHAPTER II. LITERATURE REVIEW

Introduction

This chapter will provide a brief overview of the characteristics of pertussis and health disparities evident in research for both the disease and maternal vaccination. Additionally, relevant research on the various strategies to reduce pertussis among infants, increase Tdap vaccination uptake among pregnant women, and significant factors, including barriers and facilitators, that influence patients and healthcare providers in their decision making process.

Pertussis Epidemiology

Pertussis is an acute infectious disease caused by the bacterium *Bordetella* pertussis. Transmission most commonly occurs by the respiratory route through contact with respiratory or airborne droplets of secretions. The disease has no distinct seasonal pattern, but it may increase in the summer or fall. Pertussis is highly communicable, as evidenced by secondary rates of 80% among susceptible household contacts. Individuals with the disease are most infectious during the catarrhal period and the first two weeks after cough onset, which typically lasts 21 days. Classic pertussis is characterized by three phases of illness: catarrhal, paroxysmal, and convalescent. During the catarrhal phase, which generally lasts 1—2 weeks, infected persons experience an acute inflammatory contagious disease involving the upper respiratory tract called coryza. The paroxysmal phase usually lasts 4—6 weeks and is characterized by spasmodic cough, vomiting, and inspiratory whoop. Symptoms slowly improve during the convalescent phase, which generally lasts 2—6 weeks, but can last months ("About Pertussis ", 2015). Complications can occur during the course of pertussis, including hypoxia, pneumonia, weight loss, seizures, encephalopathy, and death (Kretsinger et al., 2006). Due to the severe symptoms

and potential complications attributed with pertussis disease, several strategies have been utilized to reduce morbidity and mortality rates.

Outcomes of Strategies Used to Decrease Transmission of Pertussis

As mentioned previously, ACIP's previous strategies for decreasing the transmission of pertussis in infants have consisted of cocooning, post-partum vaccination, and vaccination during pregnancy (Kretsinger et al., 2006) **CDC, 2012)**. There have been several studies that assess the strengths and limitations of these strategies. One study did a decision and cost-effectiveness analysis using a cohort model reflecting 2009 births and the associated Tdap schedules. Additionally, it was found that pregnancy vaccination could reduce annual cases by 33% vs. the 20% from cocooning. Additionally, hospitalizations would be reduced by 38% versus 19%, and deaths by 49% versus 16%. Additional cocooning doses in a father and 1 grandparent could avert an additional 16% of cases but at higher cost. As such, pregnancy dose vaccination is the preferred alternative to preventing infant pertussis (Terranella, Asay, Messonnier, Clark, & Liang, 2013).

Another study compared outcomes of patients that received the vaccine during pregnancy versus those who waited postpartum to get the booster. It was found that women who were vaccinated against pertussis during pregnancy were more likely to have received a pertussis booster vaccine recommendation, as well as have had their health professional recommend this vaccine during pregnancy. These women who were vaccinated against pertussis during pregnancy also reported no vaccine safety concerns ($p=0.006$), held the perception that whooping cough was 'common' in their community ($p=0.018$), and less frequently reported transport barriers to accessing their family doctor to receive a vaccine (0.032) (Hayles et al., 2015). Both of these studies revealed the need to revert to vaccination during pregnancy when compared to

the other methods and focused on the importance of physician recommendation during pregnancy in order to ensure that women do receive the vaccine at the appropriate time. There are also several challenges that arise with using cocooning as a strategy. This strategy is expensive and resource intensive and also requires acceptance from several people. One study, using a Markov cohort model, found that the pregnancy booster was projected to be more cost-effective, and also associated with a reduction in pertussis-related outcomes in infants. The pregnancy booster could attenuate the number of cases by 33% (vs 20% for cocooning), hospitalizations by 38% (vs 19%) and deaths by 49% (vs 16%). This approach proved to be challenging and insufficient when used alone to prevent neonatal pertussis infections for a variety of reasons (Forsyth, Plotkin, Tan, & Wirsing von Konig, 2015). Most importantly, cocooning leaves vulnerable newborns without any endogenous protective antibody until they begin their own vaccine series at 2 months of age. This leaves the newborn to be solely dependent on the immunity of those around them for the first 2-3 months of their life ("Update on immunization and pregnancy: tetanus, diptheria, and pertussis vaccination. Commitee Opinion No. 566. American College of Obstetricians and Gynecologists,"). Based on cost effectiveness and logistical barriers, I it is clear that cocooning is not an effective strategy to reduce pertussis morbidity and mortality. However, vaccination during pregnancy has several associated benefits that have been explored by various studies.

Health Disparities

As previously mentioned, the highest incidence of pertussis occurs among infants that are too young to have completed their primary DtaP vaccine series (infants less than 6 months old). Several studies mention that this trend has been evident among Hispanic infants, however there is a dearth of research on explanations for this. One study explained that in the 1990's, the mean

annual incidence of pertussis was 74% higher among Hispanic infants than among non-Hispanic infants. More recently, disease incidence in California among infants younger than 12 months was 174.6 cases per 100,000 during the pertussis epidemic from January 1-November 24, 2014. Incidence was significantly higher among Hispanic infants (RR=1.7, 95% CI=1.5-2.1)(Healy, Rench, Wootton, & Castagnini, 2015). A more recent study looked at pertussis risk factors for Hispanic Infants in Metropolitan Portland, Oregon. After looking at ethnicity, household size, infant birth weight, maternal age and pertussis vaccination status, the study concluded that the risk for pertussis is higher among individuals who live in households with greater than four people and that the risk was not different when Hispanic and non-Hispanic infants were compared (Levri et al., 2016). As such, it is uncertain whether ethnic disparities for pertussis exist and further studies need to be conducted to explore existence of other dimensions of disparity.

There have been few studies that have assessed health disparities in vaccine uptake during pregnancy. One study that assessed vaccine coverage among pregnant women enrolled in a publicly funded insurance program in Michigan found that white women were more likely to receive Tdap during pregnancy compared to blacks, Asians, and Arabs. No significant difference in Tdap coverage was observed between white women and Hispanic women(Housey et al., 2014). A retrospective cohort study in a university hospital found that black women were 60% less likely to receive the Tdap vaccine during pregnancy when compared to other women (Goldfarb et. al, 2014).

Tdap Vaccine Uptake during Pregnancy

Vaccination during pregnancy is one of the most effective interventions strategy in modern medicine. The potential for dual coverage for mother and baby through transplacental antibody transmission and production of pathogen specific antibodies is an effective mechanism for the prevention of pertussis. As previously mentioned, little has been published on the uptake of the Tdap vaccination among pregnant women after the ACIP recommendations. After the 2011 ACIP recommendation, the first strategy that utilized vaccination during pregnancy to protect newborns, a study was done in Michigan to assess vaccine coverage among pregnant women enrolled in a publicly funded insurance program. Using Medicaid administrative claims data and statewide immunization information system records, it was found that 14.3% of publicly insured women who delivered their first child in between November 2011-February 2013 received the Tdap vaccine during pregnancy. The study also found that infant gestational age and maternal age at delivery were significant predictors of Tdap vaccination and adequacy of prenatal care was not a predictor of Tdap vaccination (Housey et al., 2014).

Another study aimed to determine the uptake of the Tdap vaccine following the 2011 ACIP guidelines among pregnant women delivering at a university hospital between February and June 2013. This retrospective cohort study found that in a sample of 1467 women, 81.6% received the Tdap vaccine during pregnancy. The study found that despite high vaccine uptake, the timing of the vaccine was late in gestation and thus revealed that the hospital's vaccine campaign did not address optimal timing. Additionally, it was found that women who received the influenza vaccine during pregnancy were more likely to get the Tdap vaccine (Goldfarb et al., 2014).

Safety and Effectiveness of the Tdap Vaccine During Pregnancy

The release of the recommendation for Tdap vaccination during pregnancy brought up many concerns regarding the safety of the vaccine itself. Several recent studies have focused on infant outcomes after the mother received the Tdap vaccine during pregnancy. One prospective observational study looked at infant outcomes and found no increased adverse events in infants or mother that had been exposed in utero to the vaccine (Munoz et al., 2014; Walls, Graham, Petousis-Harris, Hill, & Austin, 2016). Other studies have estimated vaccine effectiveness and have found that vaccinating pregnant women during their third trimester is 91% protective against infants developing pertussis in the first two months of their life (Amirthalingam et al., 2014). Another study compared medically attended acute events such and adverse birth outcomes, such as preterm delivery, low birth weight, and being small for gestational age, in women receiving concomitant Tdap and influenza vaccines and women receiving sequential vaccination. It was found that concomitant administration of both Tdap and flu were not associated with a higher risk of adverse acute outcomes when compared to sequential vaccination (Sukumaran et al., 2015). Despite being a primary concern for patients, the Tdap vaccine is both safe and effective as shown by several recent scientific studies.

Summary of Barriers and Facilitators

According to previous studies, there are several factors that influence vaccine acceptance among pregnant women. In terms of barriers, reported reasons of refusal include: safety concerns, lack of knowledge on vaccination, lack of perceived need, and concerns about vaccine effectiveness (Chamberlain, Seib, Ault, Orenstein, et al., 2015). Reasons for accepting vaccines include the belief that they will protect from disease and also trust of their physician's recommendations (Bonville et al., 2015; Chamberlain, Seib, Ault, Orenstein, et al., 2015; Collins

et al., 2014). Trust of physician's recommendation includes receiving counseling and educational materials from physicians, positive messages regarding vaccination, onsite administration, peer or family influence, and past actions regarding vaccinations. While all these facilitators of vaccine acceptance are important to consider, it is clear that the influence of a healthcare physician plays a significant role in acceptance (Bonville et al., 2015; Collins et al., 2014).

Provider Influence on Patients

While there are many patient related barriers to vaccination, it has been repeatedly demonstrated that recommendation through one's healthcare provider is the greatest predictor of vaccine acceptance among pregnant women (Bonville et al., 2015; Collins et al., 2014). For instance, one study in Houston among postpartum women in a public hospital, found that 93% of the respondents would be willing to receive both the influenza and Tdap vaccines during pregnancy, if recommended by their physician (Beel, Rench, Montesinos, Mayes, & Healy, 2013).

Additionally, in one qualitative study, it was found that whether a woman decided to receive a recommended vaccine during pregnancy was strongly linked to whether her healthcare physician had discussed it with her and in particular, made a positive recommendation. This study used the Health Belief Model theoretical framework and found that the most significant cue to action for the mother was endorsement from their healthcare physician. Women in this study were more aware of potential risks to their unborn child and as a result were hesitant to accept any kind of treatment, including vaccinations, if there could be any potential risk of harm to their unborn child. It was, however, found that any concerns could be ameliorated by a healthcare physician recommendation to receive a vaccine. It was also found that the majority of the women in the study had not received any recommendation from their healthcare physician

about recommended immunizations before, during, or after the pregnancy, signifying lack of knowledge as a major barrier. This study also showed that women are more likely to accept vaccinations if they are incorporated in their antenatal plan (Collins et al., 2014). OB/GYN acceptance and recommendation of the Tdap vaccination during pregnancy heavily influences the decisions of pregnant women and is an important factor to consider when developing an intervention to increase vaccination rates.

Provider Attitudes and Practices

Since healthcare provider recommendation influences vaccine acceptance and uptake, it is important to study the attitudes and practice of providers regarding Tdap vaccination. While there is a gap in research on provider perspectives, a few studies highlight current understanding of provider attitudes and practice. Bonville et. al. highlighted the attitudes and practices of physicians in New York state regarding the recommendation for pertussis vaccination during pregnancy. One year after the ACIP recommendation for Tdap vaccination for women in the third trimester of each pregnancy, it was found that 92% of the physicians surveyed stated knowledge of this recommendation, but only 80% routinely recommended the vaccine to their patients and 67% administered the vaccine in their office. 40% referred patients elsewhere for the vaccine. Additionally, it was found that physician recommendation was associated with patient vaccine acceptance, but not offering vaccine administration in the office is a significant barrier to vaccine uptake due to the obstacle it adds for vaccine delivery. The most common reasons provided for not administering vaccines in the office in this study and several others, included cost of vaccine and lack of reimbursements (Bonville et al., 2015).

Provider Barriers

Obstetrical care physicians have the responsibility of informing their patients of positive health behaviors and outcomes, such as vaccination. OB/GYN's play a significant role in the decision making process and if they do not discuss, recommend, and offer the vaccines at their office, additional barriers are created. Some of the prominent barriers for physicians include lack of knowledge about maternal immunizations, particularly the fact that pregnant women and/or their newborns are at more of a risk from vaccine-preventable diseases (VPDs) like influenza and pertussis. One study surveyed 227 physicians (family and OB's) and 40% did not know that pregnant women were at a higher risk of VPD related complications (Tong, Biringer, Ofner-Agostini, Upshur, & McGeer, 2008).

In addition to education, other barriers include safety concerns, OB/GYN's belief that recommending immunizations is not their job, financial, and liability barriers. There are many OB/GYNs who don't think that immunization is part of their routine patient care activities and that it is more of the family physician or internist's responsibility. While this still remains a barrier for many physicians and their subsequent lack of vaccination recommendations, some studies have shown that attitudes are changing and many physicians are recognizing the importance of immunizations as an integral component of obstetric care. For instance, an ACOG survey found that 310/394 fellows reported that they stocked and administered at least one vaccine in their practice. The most commonly stocked vaccines in OB/GYN offices are human papillomavirus (HPV) (91%), influenza (67%) and Tdap (30%). The Tdap vaccine still remains the least commonly stocked vaccine in OB/GYN practices (Power et al., 2009).

Financial Barriers

For most OB/GYNs, the most significant barriers to offering vaccines in their practice are financially related. Costs with vaccine administration include startup costs (i.e. purchasing a refrigerator, vaccine storage, etc.) as a well as reimbursement for the vaccine and administering it. Inadequacy in reimbursement is a major issue, especially because of the variety of insurance plans their patients tend to have. One study found that 25% of physicians reported that they had submitted insurance claims for vaccine administration, but had not received any payment. Another study showed that many insurance plans refuse reimbursement for some OB/GYN services because they are not the patient's primary care physician. As such, many practices get stuck with the burden of paying for their patients' vaccinations due to inability to get reimbursed (Power et al., 2009). Other administrative costs associated with vaccines include personnel costs for managing inventory, proper vaccine storage and handling costs, insurance against loss, and immunization injury liability concerns.

Insurance Reimbursement for Vaccination

Practices must properly code the vaccines they give to their patients so that they can be reimbursed. Proper coding consists of giving an accurate description of "what" was performed and "why", as well as proper documentation through the medical record. Third party payers have different regulations for what services are covered and clinical practices are responsible for investigating if a patient's insurance will cover the vaccine. Medicare Part B only covers preventive vaccines for three conditions: influenza, pneumococcal polysaccharide, or Hepatitis B. Other vaccinations are not covered unless they are directly related to treatment of an injury or direct exposure to a disease or condition, such as tetanus or rabies. The prescription drug plan, Medicare Part D, does cover other preventive vaccines. There are two scenarios that explain how

the reimbursement process works with Medicare Part D. In states that license pharmacists to provide vaccines, physicians can ask the patient to purchase the vaccine at a pharmacy and then bring it into the office for administration. Alternatively, the physician can supply the vaccine, administer it in the office and ask the patient for full payment at the time of the service. The patient can then be given a claim form to submit to her Part D plan for reimbursement of her costs (ACOG, 2013)

Medicaid only reimburses for routine immunizations for covered individuals up to 21 years of age. Patients between 19-20 years of age can also receive immunizations through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT). Physicians can bill Medicaid for the vaccines and the administration as a fee-for-service. This public program for low-income and medically indigent individuals is administered on a state-by-state basis. Thus, the extent of immunization coverage for adults varies state by state. Patients 18 years or younger receive vaccinations through the state's Vaccines for Children (VFC) Program (ACOG, 2013).

Vaccine coverage in private or employer-provided commercial health insurance programs varies from plan to plan. Some plans don't offer any coverage for preventive medicine services and patients must bear the cost "out of pocket". One of the biggest burdens for clinical practices is that they must contact their patients' insurance plans to verify coverage for specific vaccines (ACOG, 2013).

Provider Targeted Interventions

There have been few studies that have implemented an intervention for providers to overcome barriers to vaccine administration in their practices. One prospective, longitudinal study aimed to assess the impact of ACOG's immunization toolkits with resources to educate OB/GYNs on maternal immunization. The toolkit also had tools for the physicians to integrate

immunizations into routine care. Pre-intervention and post-intervention surveys were conducted among ACOG members who received the toolkit. The results of the study found that post-intervention survey physicians were more likely to report that they routinely offered Tdap vaccinations to all patients during pregnancy. As such, the study concluded that communication and strategy based materials were effective interventions for physicians, in terms of increasing vaccination rates among their patients and ultimately help improve maternal vaccination rates, including Tdap (Jones, Carroll, Hawks, McElwain, & Schulkin, 2016). Another study, specifically a randomized cluster trial, utilized an intervention package to assess practice, provider, and patient focused interventions on improving Tdap and flu vaccination rates. Intervention practices adopted an intervention package that included identification of a vaccine champion, provider-to-patient talking points, educational brochures, posters, lapel buttons, and iPads loaded with a patient-centered tutorial. While this intervention wasn't completely provider focused, it found, similar to other studies, that provider recommendation was a significant factor in vaccine uptake (Chamberlain, Seib, Ault, Rosenberg, et al., 2015). Overall, there have been more interventions that focused on patients as opposed to providers. As such, it is important to also investigate and implement provider focused interventions to successfully improve Tdap vaccine uptake.

Summary

It is evident that the Tdap vaccine is a safe and effective way to prevent infant mortality and morbidity due to pertussis. However, despite recommendations by the CDC and ACOG, Tdap vaccination among pregnant women remains low. There are several factors that provide an adequate understanding of why Tdap uptake is low, however most of these allude to physician recommendation and administration. While significant research has been done on identifying

both patient and physician barriers and facilitators to Tdap vaccination as well as research on effective communication methods to promote vaccination, there is a dearth of literature that focuses on the descriptive aspect of the reasoning behind physician perceptions and practice. Further qualitative research on this topic will provide information on the factors that influence recommendation and administration of the Tdap vaccination among physicians and these messages can be reconciled to create effective communication and policy based interventions to increase vaccine uptake and lower morbidity and mortality rates of pertussis.

CHAPTER III. METHODS

Study Population Recruitment and Sample

The participants in this study were healthcare physicians, specifically those specializing in obstetrics and gynecology. A professional healthcare marketing research firm called Westat recruited the OB/GYNs who participated in the in-depth interviews. There were two rounds of interviews conducted in the study with a total of 40 interviews (24 in Round 1 and 16 in Round 2).

Round 1

Physicians that were part of the sample were segmented based on whether the majority of their patient population was Hispanic or not. This was done in an attempt to explore any unique barriers among physicians who serve Hispanic patients, given the disproportionate burden of pertussis morbidity and mortality in this population as described above. Additionally, recruitment of a mixture of physicians who did and did not recommend the Tdap vaccine as well as a mix of those who did or did not stock the Tdap vaccine in their offices were also sought in the study. For round 1 of the study, the respondents were segmented into two groups (1) OB/GYNs with a patient population of less than 50% Hispanic and (2) OB/GYNs with a patient population of greater than or equal to 50% Hispanic.

Exclusion Criteria

The physicians were excluded if they weren't OB/GYNs and if they didn't offer prenatal care as part of their regular practice.

Round 2

As in round 1, physicians that were part of the sample were required to offer prenatal care as part of their routine practice. The aim of Round 2 was to focus on the needs of the physicians who referred their pregnant patients elsewhere to receive the Tdap vaccine.

Exclusion Criteria

The physicians were excluded if they did not recommend the Tdap vaccination to their pregnant patients, if they stocked the Tdap vaccine in their office, and if most of their patients received the Tdap vaccination postpartum.

Procedures

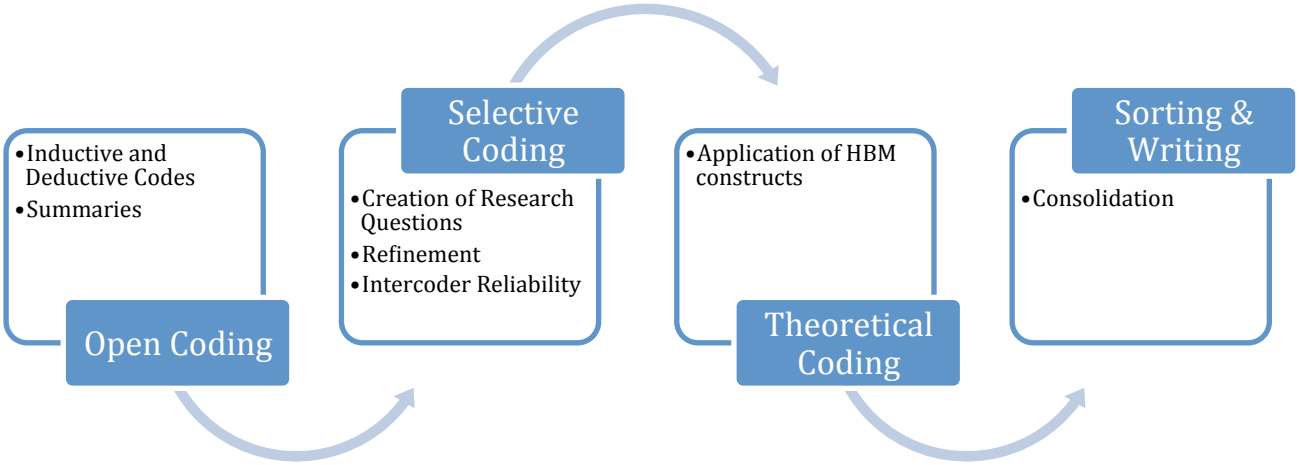
Data collection for this study was done through forty in-depth interviews conducted over the phone using a national database. All research protocols and instruments were reviewed and approved by the Westat Institutional Review Board (IRB) prior to the initiation of the study, with CDC IRB deferring to Westat for IRB approval.

During the first round, twenty-four in-depth interviews were conducted for exploratory research and in the second round, sixteen additional interviews were conducted for materials testing among physicians who refer patients elsewhere for Tdap vaccination. The interviews were each about sixty minutes long. Two moderators used semi-structured interview guides to lead the interviews. Purposive sampling was used to for this study. Westat used a vendor that maintained a non-probability national health care physician database of over 300,000 healthcare physicians with diverse clinical specialties, practice sizes, geographic locations, and patient populations. Audio recordings of the interviews were made and transcribed subsequently. These trancripts were uploaded to Nvivo 10.0 to begin the analysis process.

Data Analysis

A grounded theory approach guided the data analysis for this study. There are 4 main stages that describe the analysis process: open coding, selective coding, theoretical coding, and the sorting and writing of the results (Corbin, 2015).

Figure 1. Data analysis stages and associated steps



The first step of analysis was open coding during which the initial codebook was created using the domains and probes from the interview guide. During this initial stage of analysis, there were no formulated research questions and the transcripts were coded with the initial codes using Nvivo. While reading the transcripts, deductive codes and short summaries of the central points of each transcript were also added. The next analysis step was selective coding during which the specific research questions were created. The codes were also collapsed and refined to match these research questions. At the end of this stage, intercoder reliability was assessed through double coding. An additional coder was trained on the codebook and the corresponding code definitions. This coder cross-coded 20% of the transcripts for both round one and two to establish intercoder reliability. The third stage of analysis was theoretical coding. After reading

through all of the transcripts several times and applying both deductive and inductive codes, it was clear that there were some constructs of Health Belief Model evident in the data. The codebook was modified slightly to include applicable HBM constructs. For instance, the codes that applied to the Tdap vaccine specifically "importance" and "effectiveness" were placed under the structural code "perceived benefits", reflecting one of the main HBM constructs. The final codebook consisted of five general domains: physician demographic information, physician perceptions, physician current practices, cues to action, and barriers. Within each code category or "parent node", there were additional subcodes or "child nodes", many of which reflected HBM constructs, as well as inductive and deductive codes created during the entire process. The last stage of analysis was consolidating the coded transcripts and memos and making sure all central themes were accounted for. This was then used to draft the results of the study.

Intercoder Reliability Assessment

Intercoder reliability was established by comparing the codes assigned to 20% of the transcripts in Round 1 and Round 2. The overall reliability for round 1 was 99.3% (which is above the suggested 90% agreement level). The individual codes also achieved high agreement levels and ranged from 94.2-100%. The overall reliability for round 2 was 98.7% with individual codes ranging from 92.6-100%. The coding was completed from March 2015-June 2015.

Figure 2.Concept Map of central codes and themes

CHAPTER IV. RESULTS

Study Population

A total of 40 qualitative interviews with healthcare physicians throughout the United States were conducted. 24 interviews were conducted in Round 1 and 16 were conducted in Round 2. The interviews in Round 1 consisted of a mix of physicians in terms of their beliefs and practices regarding recommending, administering, and stocking the Tdap vaccine during pregnancy. The interviews in Round 2 consisted of healthcare physicians that recommended the Tdap vaccine, however neither stocked nor administered the vaccination and referred their patients elsewhere to receive the vaccine.

Round 1

Demographics

The sample for Round 1 of the interviews consisted of mostly male OB/GYNs (n=22), with only 2 females. Half (n=12) of the interviews were conducted with OB/GYNs who stated that their patient population was at least 50 percent Hispanic, while the remainder of participating physicians (n=12) stated that they saw fewer than 50 percent Hispanic patients. In general, the physicians were experienced OB/GYNs who had been in practice (post-residency) for a minimum of 12 years. Of those interviewees who specifically noted their years of practice (n=20), it ranged from 12-35 years. In terms of patient volume, the OB/GYNs in the sample generally saw between 60-150 patients per week (for both obstetrics and gynecology).

Perceptions of Pertussis

The main aim of the first part of the study was to elicit perceptions of physicians regarding pertussis disease both nationally and also within the community they practiced in.

Perceptions of pertussis are operationalized by three main codes: perceived susceptibility of pertussis, perceived severity of pertussis, and perceptions of ethnic and racial disparities.

Perceived Severity of Pertussis

The perceived severity of pertussis refers to the physician's perception of the seriousness of mothers and their babies contracting the disease and the consequences that may follow. Many physicians emphasized that they knew about recent outbreaks of pertussis, but did not think it was a large enough issue to warrant attention. However, most physicians did agree that if an individual, specifically a newborn, contracted pertussis than the effects could be very severe. One physician explained,

> *"Well, I guess there, you know, the last couple of years have been these outbreaks of whooping cough with some very disastrous results for the newborns that get it. You know, I don't think it's a huge number. But you know when it does happen it's a very serious problem and so it is, you know, it is a bigger issue for the newborn than it is for the mom"*

In general, OB/GYN's felt that there were more important issues to focus on than prevention against pertussis. When asked why the practice didn't make more of an effort to follow up with patients that they refer out for the vaccine, one physician responded,

> *"To be honest with you, I mean you told me to be honest in this conversation, I think with everything else that we have to worry about taking care of these patients and their unborn children, and we have a lot of patients who are really sick and they have between diabetes and the multiple gestations and the twins and preterm labor and bleeding and they're growth restriction and I can go on and on and on, the last thing on my mind is this vaccine. So I really think we're making a huge deal out of something that is not life threatening and earth shattering"*

In addition to the persistent belief that there are other pregnancy concerns that are more important than Tdap vaccination, several physicians didn't think contracting pertussis was a major concern. One physician said,

> *"My son, who's thirty two now, I didn't vaccinate him for pertussis and he had pertussis, he had a bout of it, and, you know, it turned out to be nothing, you know, he went through it like most kids do"*

Overall, physicians understood that the resurgence of pertussis has become an issue over the course of the past few years. However, most physicians believed that there were more important issues to focus on in their obstetrics practice, particularly because none of the physicians interviewed had seen a case among their patients and did not understand the severity of symptoms aside from what they had heard or read.

Perceived Susceptibility of Pertussis

The perceived susceptibility of pertussis disease refers to the physician's perception of the likelihood of mothers and their newborns contracting the disease (Glanz et al., 2008). This can be operationalized by the physician's perceptions of the incidence of pertussis within the United States and the community their practice is located in. When asked about incidence, all physicians stated that they had never seen a case among their own patients, but realized that the incidence among newborns has increased over the past few years. When asked about the incidence of pertussis in the United States in the last few years, one physician responded,

> "*Yeah, it's not high. I mean we still have herd immunity, I mean it's, I mean I think they're making a big deal out of it. I'm not, I'm not convinced it's a big of a problem as they're saying it is, but, you know, I don't see it"*

Some physicians said that they knew about the incidence through the news, CDC materials, literature, and conferences they had attended. One physician said,

> *"Well I mean there's been more and more information about pertussis going up, that there's more and more people having it. Never used to really hear about it too much, but now you do on occasion"*

While the overall sentiment of the physicians interviewed was that pertussis was not a significant problem in the United States, that majority of the physicians interviewed agreed that newborn babies were more susceptible to pertussis than their mothers. One physician explained,

> *"I think the main importance of the vaccine is to confer immunity, you know, in the newborn, before they can be vaccinated, because, again, newborns are very susceptible to pertussis and it's potentially a lethal disease"*

Physicians were also aware of the fact that infants are susceptible due to the fact that the Tdap vaccine isn't given to newborns until they are about 2 months old which allows for a time period that they are not protected during. One physician demonstrated his knowledge,

> *"I mean, the Tdap vaccine I think kids don't get it until they are two months old if I remember well from my kids, so that these two and it takes time to build up immunity, so during that time the baby is not protected and my understanding of a few years ago, over the past few years, we've been hearing for, we've been hearing more and more outbreaks of pertussis"*

Physicians explained that they were often made aware of the susceptibility of pertussis through information from the CDC, ACOG, and other reputable sources. One physician said,

> *"For our particular specialty, we've been made very aware, I think through the efforts of the CDC and other national governing bodies as it relates to the morbidity of pertussis in the neonatal and early childhood period"*

The overall sentiment of the physicians interviewed was that newborn babies were the most susceptible to pertussis due to the information they had been given by reputable sources. They also recognized that there is a post-natal time period during which the infant can't be vaccinated leading to increased period susceptibility.

Racial and Ethnic Disparities

The physicians were all asked if they noticed any pertussis or Tdap vaccine receipt related racial or ethnic disparities. Only one physician interviewed stated that he noticed racial and ethnic disparities in pertussis incidence. He said,

> "*We have a large Hispanic population, also fair Asian population, but I've seen some stuff more recently, particularly Hispanic"*

In terms of receipt of the Tdap vaccine, the majority of physicians interviewed responded by stating that they were not aware of any disparities. Some physicians made speculations and associated lower rates of Tdap vaccination with attributes such as being part of a minority population, lower socioeconomic status, and/or access to prenatal care services. One physician speculated,

> *"Well, minority women are less likely to get prenatal care or start prenatal care early. So, hence, they're less likely to get vaccinated"*

Another physician, who reported that his practice served about 1/3rd Spanish-speaking clientele, explained that racial disparities were not present in his practice. He also noted that racial linkages in vaccination behavior were more random. He said,

> "*If I had guesses, and everyone guesses. Well in other words some of our patients don't get prenatal care. Some of them just show up in labor kind of thing. So obviously those people haven't become vaccinated. Yeah and then, of course, we have some patients that decline vaccination. I haven't noticed a racial linkage with that though"*

Physicians were also asked to explain why they thought these disparities existed. The main reason that came up was socioeconomic status. One physician stated,

> *"I think that it's essentially socioeconomic, I think a lot of the people don't necessarily get the care or the chance to get the vaccine that they should. I think even if mom is getting it, that other caretakers may not be getting the vaccine that we would like them to have"*

Overall, physicians were not aware of any specific pertussis or Tdap vaccine receipt related racial disparities in both the United States and the location of their practices. However they acknowledged the presence of non-ethnic/racial related disparities, such as socioeconomic status and access to prenatal care.

Physician Perceptions of Tdap Vaccination

In addition to the addressing perceptions of pertussis, the study also aimed to elicit physician perceptions of the Tdap vaccination during pregnancy in terms of the perceived benefits of giving the vaccine during pregnancy and the perceived safety of giving the vaccine during pregnancy. Eliciting information on these perceptions aimed to gain an overall understanding of the factors that influenced physician recommendation and administration.

Perceived Benefits

Perceived benefits address the physician's perceptions of how useful Tdap vaccination during pregnancy is in term of decreasing the risk of pertussis in both the mother and baby. Two subthemes were used to operationalize the perceived benefits: perceived importance and perceived effectiveness.

Perceived Importance

Physicians asked to discuss how important they felt the Tdap vaccine was for both the protection of the pregnant women and the baby. The majority of the physicians agreed that the Tdap vaccine wasn't as important for mothers as it was for the babies because many adults have received the Tdap vaccine at some point in their life and still have some immunity. There were, however, a few outliers who believed that the Tdap vaccine was important for the mother. The reason given for this included compliance to the older cocooning technique of vaccinating everyone that will come in contact with the newborn baby. One physician in the sample said that

he felt that the vaccination was only important for the protection of the mother and not the newborn at all. This physician, an outlier in the sample, explained his views,

> *"Well, there's studies actually in the, in the CDC report, there's actually a reference to a study that indicated that the benefit if anything was a very, very negligible or slight benefit for the patient receiving it to protect her baby. It's, you know, when you use this product I would imagine you're using it more with the intention of protecting the mother, not with the intention of, of providing passive immunity to the baby"*

Other physicians mentioned that they weren't concerned with adults getting pertussis because they had never seen a case among their own pregnant patients. One physician explained,

> *"As much as we care about the severity of the occasional outbreaks of pertussis, in all my years of practicing I don't think I've ever seen any of my pregnant patients ever get pertussis so even though it is a concern, I just don't see it as much. So I still think it is important but if they weren't pregnant I wouldn't give them the vaccine just to prevent pertussis in themselves"*

Despite this, there were still several physicians who provided the same rating for the importance of the Tdap vaccine to protect the mother's health and the baby's health. The physicians that supported vaccination during pregnancy all agreed that the Tdap vaccine was important to protect the babies. One physician explained his reasoning,

> *"The source of the pertussis is more likely going to be the mother and if a baby gets pertussis, it's possible the baby is going to get sick, wind up in the hospital and potentially die"*

Ultimately, all physicians agreed that the vaccine was important in transferring antibodies and conferring immunity in either the mother, baby, or both. However, the perception of importance was decreased due to the fact that providers in general did not think that pertussis was a big enough problem. One provider explained,

> *"Well, I guess, you know, the only reason I don't give it a 5 is I don't think it's such a widespread issue, you know, that it's a huge problem. You know, on an individual basis, it's a 5. You know, on a societal basis, excuse me, you know, I just give it a 4 because I didn't think it was all that common"*

All in all, despite recognizing that Tdap vaccination is important, many providers didn't view the practice of vaccinating during pregnancy as high priority because they didn't see pertussis as a huge threat to their patients.

Perceived Effectiveness

Physicians were asked to state their beliefs regarding the effectiveness of the vaccine in protecting both pregnant women and the baby. There was agreement in that the vaccine did not protect the mother, however the effectiveness in protection of the baby received mixed responses. Some physicians stated that they felt the vaccine was effective and they believed that the lower incidence of pertussis confirmed this. One physician stated,

> *"I think it's effective, and I don't see a lot people with pertussis, so I assume its working"*

However, there were also several physicians who felt that there was not enough evidence to conclude that the vaccine is beneficial when given during pregnancy. One physician stated,

> "*From what I've read, it doesn't seem to be any compelling reason to give it during the pregnancy. There is, at very best, negligible benefit to the fetus of giving this and getting passive immunity. That would be the only reason that I would give it, if I was convinced that there was more of a passive immunity effect on the fetus, I'd probably be more likely to give it, but the studies have really not been there"*

Many physicians still believed that postpartum vaccination was more effective and wanted more credible evidence to change their practices. These physicians were asked if more evidence on the effectiveness of the vaccine on the fetus when given during pregnancy would convince them to change their views. To this one physician responded,

> "*I mean, it might, however, I will tell you that, you know, I would have to see the, I'd, I'd really want to research that, that study and I'd want to make sure that, you know, it was done in a credible, a credible and a scientific fashion. Again, for me to, to try to do something that's going to be difficult for me to do and implement in my own office, I'd really have to be convinced that giving it postpartum was not the right way to do it"*

While most providers understood the concept of antibody transfer and how it contributed to the effectiveness of the vaccine, there was one outlier who did not understood the effectiveness of vaccinating the mother during each pregnancy, irrespective of previous vaccination status,

> *"If some woman got vaccinated say two to three years ago, she probably has some antibodies to pertussis that are still present and therefore will be transmitted to the baby. Now then, I don't understand them to be as high as if she get revaccinated, but there's probably some protection still remaining"*

Overall, the majority of physicians interviewed agreed that vaccination during pregnancy was an effective strategy. The few that didn't think it was completely effective stated that they would like more evidence in the literature, however this was not a common concern. All in all, despite ACOG and CDC's recommendation, physicians understood the effectiveness of vaccination during pregnancy, specifically antibody transfer as a protection mechanism.

Perceived Safety

Physicians were asked to state how safe they felt the Tdap vaccine was for both pregnant women and their babies. All physicians stated that they believed the vaccine was safe for both the mother and the baby. The recommendations by ACOG and the CDC, as well as the medical literature were cited as the main reasons why physicians trusted the safety of the Tdap vaccine. One physician stated,

> *"I think it's very safe. Again, I know ACOG is a incredibly cautious in their recommendations and I think for them to, to recommending that it be given speaks volumes for its safety and just, besides that I think I haven't seen anything to, to disprove that"*

In addition to the literature, physicians who administered the vaccine themselves spoke from their own patient experiences. One physician confirmed,

> *"I've not had a patient that's had a reaction or any kind of problem from the vaccine. And again you know we have a fairly large population of patients that we've been following, I know we've been doing this for at least a year"*

The perceived safety of the Tdap vaccine was the only theme that all physicians in the sample agreed completely on in the study.

Physician Practice Regarding the Tdap Vaccine

The second part of the study aimed to gain information on the current practices of the physician in terms of recommendation, administration, stocking, and referral of the Tdap vaccine. Each of these themes had several barriers and facilitators to vaccination associated with them. Nearly all recruited OB/GYN's (92%, n=22) recommended the Tdap vaccine to their patients during pregnancy. A small subset (16%, n=2) recommended the Tdap vaccine postpartum. Additionally, 58 percent (n=14) of ob-gyns stocked the vaccine and 42 percent (n=10) did not.

Recommendation

The physician's recommendation and the effect it had on women getting the vaccine were two important points explored throughout the interview. All of the physicians interviewed recommended the Tdap vaccine to their patients, however there were many that were still recommending the vaccine post-partum. Among the physicians who were still recommending post-partum vaccination, there were many who felt that it wasn't their responsibility as OB/GYN's to recommend the Tdap vaccine to their pregnant patients. One physician expressed their views on this topic,

> *"Here's where I'm going to get in to trouble. I don't, I don't think it's the OB/GYN. I think it should be the OB/GYN in the confines of the postpartum unit of the hospital, I think it's the hospital actually that bears the, the benefit, bears the responsibility there"*

Many physicians felt that as OB/GYNs there were many other aspects of patient care that they needed to focus on and that the responsibility of vaccination was the hospital or primary care physician's. Additionally, physicians were asked to express their opinions regarding low Tdap

vaccination coverage among pregnant women. Some physicians mentioned that Tdap vaccination was not a large part of the counseling provided to pregnant women. One physician admitted,

> "*We probably are little lax in recommending it is my guess. I don't know what my nurse practitioners do. You know they're usually more, I hate to say it, all inclusive in their counseling of pregnant women. But you know after this conversation, I'm sure going to start recommending it more"*

When asked about reasons why some physicians did not recommend the Tdap vaccine to patients, several physicians specified that they did not feel a recommendation to patients was necessary if they didn't administer the vaccine at their office. One physician pointed out,

> "*Since we don't administer the Tdap vaccine, there's not an automatic trigger to discuss it"*

Other providers mentioned that they briefly mentioned it if they didn't stock the vaccine, but didn't feel the need to emphasize the specifics, particularly if they knew the patient would get it at the hospital anyway. One provider explained his recommendation conversation with patients,

> "*Well, usually, it's, oh we recommend this and we don't have it available in the office, we just want you to understand that you will be getting it in the hospital, and if the patient has concerns, or doesn't want it, I mean, they wouldn't, you know, state that otherwise, it's sort of much, hey, you're getting this, that's it"*

Some providers mentioned that they didn't feel it was necessary to recommend the vaccine, but would discuss it with their patients if they brought it up themselves. One provider explained,

> *"I never bring it up so if the patient doesn't bring it up, that conversation does not occur. But if the patient brings it up the conversation would probably go something like listen I read about the Tdap vaccine what do you think of it, do you think I should get it and then I will respond, yes, you should get it, the recommendations are that you should get it but we do not give it in our office and you probably, the best way to get it is through your primary care doctor's office"*

Some physicians explained that they had various procedures to ensure that they did not forget to recommend the vaccine to their patients. These systems include checklists and flow sheets to ensure that Tdap vaccination is on the list of important procedures. One physician explained when asked when and how they recommended the vaccine,

> "*It's a combination. We keep some sort of record of, you know, what blood tests have been done and recommendations, you know, at each stage of pregnancy, and, you know, what should be done as far as vaccines and, you know, genetic screening, all that sort of stuff. So the nurses might notice, you know, in filling out the forms, oh, you're at twenty eight weeks, you know, if it's possible to get you the vaccine, we would do that, if not we'll do it post partum"*

All in all, the majority of the physicians stated that they recommended the Tdap vaccine to their patients around their third trimester of pregnancy. These physicians also explained that they discussed the increasing incidence of pertussis, antibody transfer, and explained factors such as safety, effectiveness, and importance of the vaccine during pregnancy. Among the physicians who did not actively recommend it, reasons such as not having the vaccine stocked in the office and also the belief that pertussis was not a large enough concern was cited as the primary reasons.

Administration and Stocking of the Tdap Vaccine

After physicians were asked if they recommended the vaccine, they were asked to specify if their practice administers it on site. In the first round of interviews, the answers varied. Among those that recommended it, some practices administered it, while other referred to a nearby pharmacy, primary physician, or in some cases health department. One physician explained that he did not administer the vaccine, due to the convenience for patients to get it elsewhere. He stated

> "*I would start by saying that we do not stock in our office, that doesn't preclude me from prescribing it, where you can go to the pharmacy, get the vaccine as a medical benefit, like a prescription, bring it back here and we can give you the shot. Alternatively, if you're in the hospital for any pregnancy complications, they readily have it stocked and available, you can get. Thirdly, I hadn't mentioned this, you can actually go to Walgreens, you know, walk in clinics, pay cash for it, which I believe is about two hundred dollars and just get it, if you insurance does not cover it as a pharmacy benefit. And fourthly, if you elect not to get it during pregnancy, you get it as part of the normal post partum routine in the hospital while you're here after delivery"*

Overall, physicians didn't think that their lack of administering and stocking the vaccine was a major barrier to patients. Additionally, many physicians were willing to administer the vaccine if the patients were able to acquire it. The general consensus among physicians was that it was not inconvenient for patients to receive the vaccine elsewhere, particularly if there is a primary care physician or pharmacy within walking distance of the OB/GYN clinic.

Referral

Physicians that stated that they recommended the Tdap vaccine, but referred their patients to another source to receive the vaccine were asked to state how many of their patients actually took the referral. This source was usually a primary care physician or a pharmacy. Many physicians were unsure of the number of referred patients that actually got vaccinated. One physician speculated:

> *"My guess is only the ones who inquire about it, who are already familiar with it and are motivated to go"*

Additionally, physicians were asked if there was any procedure at their practice that followed up with patients to see if they received the vaccine. One physician explained,

> "*so basically there is no follow up. So essentially if they don't get it or if they do get, it we really don't know"*

Despite this, there were several physicians that stated that they had a procedure in place that allowed the patients to report if they received the vaccine. One physician explained,

> *"Well, they can, we tell to bring the paperwork if they go outside, and they bring that to the office and we can put it into the electronic health records system we can enter into our, scan it into the computer, and then I can document it in their OB charting, that they had received it. There's an immunization section in Epic that we can document things like that"*

Physicians mentioned that they often referred their patients to their primary care providers and that this was not a concern since they had been made aware of the recommendation. Some physicians even mentioned that there was a primary care provider in the same building or nearby to their office and so accessibility, in their eyes, would not be a problem. One physician explained their relationship with primary care providers,

> *"We've been, we've been very successful in educating some primary care physicians who have not been aware of the recent recommendations or just having them be aware and having these patients come and be accommodated as new patients to initiate vaccines first and then carry on their care for whatever other primary care needs they may have in the future"*

While many physicians followed up patients and some had a protocol in place to ensure that patients received the Tdap vaccine, referral created a major access barrier for patients who have to be motivated enough to go elsewhere to receive the vaccine. However, the main barrier present in the Round 1 interviews was the lack of follow up protocol by physicians to check if their patients received the vaccine. Other referral related barriers were evident in the Round 2 interviews and are discussed later.

Cues to Action

The last part of the study aimed to elicit information from physicians on their current Tdap vaccine promotion strategies in terms of communication materials and other strategies.

Physicians were also asked to explain what materials, strategies, and other factors would help them with not only giving strong recommendations to their patients, but also facilitate administration of the Tdap vaccine in their practice.

Current Communication Materials and Strategies

The majority of physicians agreed that communication was the best way to promote the Tdap vaccine to their pregnant patients and it is also evident that this could be a potential way to start patient provider conversations and make recommendation easier. Physicians were asked to discuss their current communication methods with their patients, particularly with providing them with specific information on Tdap vaccination during pregnancy. Many physicians talked about handouts that they gave their patients at the beginning of their pregnancy and that the handout mentioned getting the Tdap vaccine during pregnancy. Some physicians mentioned that, while they liked handouts, they understand that their patients get most of their information online. One physician explained,

> *"I mean, I'm old school, and I like paper, but I would tell you from observing patients, most of them don't get their information that way anymore. So, I might give them a pamphlet, but I guarantee they're going to go look up something online. Like, for example, if the CDC sent us some, you know, periodic handouts about Tdap, flu vaccine, giving those out, we would, but I don't think a lot of us would spend a lot of money and time buying pamphlets, increasing overhead by doing so, if the patients can just go online and do it themselves"*

Online materials would make things easier and cheaper for both the provider in terms of giving a recommendation to patients, but it would also be more user friendly for the patients. One physician also talked about how they gave different materials to different patients depending on how the patient felt about the vaccine or if they were on the fence about getting it.

> *"I have a bunch of different materials to give the patients, one is I think it is from the CDC because I remember seeing their logo on it, but a colleague of mine gave it to me, it talks about pertussis and I think it actually has some real life stories in there, it's like a*

> *three or four page handout and it actually has some real nice stories where a mother talks about her baby dying from pertussis. So I hand those out to the women that are really negative about it because I don't want to scare everyone about it if they're on the fence and I have material from the American College of OB/GYN that I give all pregnant women, it's like a question and answer sheet and I think that's good information to give the patient as well"*

This communication strategy is useful for both physicians and patients because the information delivered is efficient, but also appropriate to the concerns of the specific patient. Many providers mentioned using other communication strategies within their office, including setting reminders in a patient's chart that reminded them to discuss Tdap vaccination at the appropriate time.

There were also several physicians who did not recommend the vaccine during pregnancy and supported postpartum recommendation instead. These physicians pointed out flaws in commonly used communication materials and strategies. For instance, one physician explained,

> *"I mean I've gotten packets that I've pretty much thrown in the garbage. I, I don't really want to, you know, I, again, I think I'm doing what I'm supposed to do, and I would almost rather my patient not be presented with an option that, hey, your doctor can do this for you during the pregnancy, because I don't do that. I mean, I think I can make it very clear to them, yes, I think this is a good thing you should do, I explain to them the reasons why I think they should do it, to go into more depth or detail to discuss the differences between giving an antepartum and the differences be giving a postpartum, I don't want to do that"*

This provider did not use communication materials specifically because he did not want patients to even be presented with the option of getting the vaccine during pregnancy because he doesn't see anything wrong with the patient receiving the vaccine post-partum.

Overall, the majority of physicians had some sort of handout to give to their patients that discussed the Tdap vaccine to some extent. Physicians were also more likely to trust the information and distribute to their patients if sources such as the CDC had endorsed the communication materials. Additionally, physicians were supportive of communication materials if they were brief, but shared personal stories to engage their patients in the topic.

Future Suggestions

In addition to sharing their current communication practices, physicians also gave their insight on other strategies they felt would increase Tdap vaccination rates, as well as make it easier for them to administer the vaccine in their office. When asked to select a specific medium, among television, pamphlets, and other forms of communication, many physicians responded that they felt a mixed approach is best to target pregnant women.

> *"I would probably use all of it. I don't think one single modality is, is going to be a hundred percent for anything. I think a variety would be helpful"*

Another strategy that came up was giving their patients handouts in a file to read when they check-in. One physician said,

> *"You know, I didn't think about it before, but now that we're talking about it, it just crossed my mind. When patients come to our clinic for example they get like a file or whatever it is called, and it has information about the clinic and information about different other things, sometimes birth control is included in it, so it does not harm also to put a little pamphlet about vaccinations in pregnancy and maybe include both influenza and pertussis as part of it"*

In general, physicians advocated making the communication materials more accessible and user friendly. One physician explained,

> *"A lot of people watch television and I think that's how a lot of people are reached, is through the media or even if radio did it. I mean, you have to put the information where people are going to receive it, and that's where a lot of people receive it"*

Other physicians weren't enthusiastic about trying new communication methods and felt that handouts worked well for them. One physician stated,

> *"Besides the handouts that we use, I can't really think of anything else. As I said, we don't have a whole lot of resistance to the vaccine, so it seems to be working"*(LH05).

Despite the fact that there are several venues of communication including social media and television, physicians were still supportive of pamphlets and handouts to give to their patients at

check in. Another popular method of communication was to talk about the Tdap vaccine recommendation online through either the practice website or provide links to reputable sources, such as ACOG and the CDC websites, for patients to read. Overall, physicians understood the value of communication materials and were advocates of traditional pamphlets and posters, but wanted to use different strategies of distribution to ensure that the patients read the materials and asked questions if needed.

In addition to communication materials, many physicians mentioned additional things that would serve as motivation to administer the vaccine. Some physicians mentioned that the government providing free vaccines as they had done in the past with flu would be a motivational factor to administer. As one physician stated,

> "*Because you have to buy it when you're in private practice, and it costs money. The government doesn't provide vaccines for free that we can, the only time I've ever administered the flu vaccine, for example, was a few years ago when we an epidemic of the flu, and all of the Obs were provided flu vaccines to distribute to their patients that we did not have to purchase. But nobody in private practice in this town, if they're in a group practice, it's different, but nobody in private practice administers these vaccines."(LH03).*

In addition to communication materials, there were several other strategies physicians hoped to see implemented, including government involvement and funded vaccine programs.

Round 2

Demographics

Interviewees during Round 2 consisted of physicians that recommended the Tdap vaccine, but did not administer or stock it in their office. The sample for Round 2 was evenly split between male (n=8) and female physicians (n=8). Similar to Round 1, the physicians were generally experienced OB/GYN's who had been in practice (post-residency) for a minimum of 13 years. Years in practice ranged from 13-32 years. Patient volume was variable with physicians seeing in between 5-70 patients per week.

Physician Current Practices

The interviews in Round 2 focused more on current practices instead of setting the stage with perceptions like in Round 1. Like in Round 1, the most common themes were recommendation, administration, stocking, and referral.

Recommendation

All physicians included in Round 2 stated that they recommended the vaccine to all of their pregnant patients. All physicians interviewed stated that they gave the vaccine during the end of the second trimester or third trimester. Physicians explained that the recommendation itself did not create any barriers to patients, particularly because patients tend to use the internet and other resources to look up information. One physician explained,

> *"Most of my patients are pretty intelligent, and they're the type people who've done their own reading on the internet before I've even told them something. So, most of them are pretty on board. Once they understand that vaccinations are safe in pregnancy, then, or certain vaccinations, non live, then they're OK with it"*

Physicians were also asked what percentage of their patients they thought took their recommendation and received the vaccine. The percentages varied, but in general most

physicians stated that the number was about 70% or higher. Some physicians weren't too concerned with their patients not taking their recommendation because they were still going to get it at some point, even if it was postpartum. One physician emphasized this when asked how many of his patients took his recommendation,

> *"Well, I wish it was a hundred percent. But, we, they all eventually get it postpartum, but I'd prefer them to get it before then, but, you know, I would prefer them to get it ideally before then"*

It is evident that physicians were in favor of recommending the vaccine during pregnancy, but did not think it was top priority among the services they provided as an obstetrician. As captured by the last quote, the physicians in Round 2 were advocated of vaccination during pregnancy, but did not think it was a huge concern if they were vaccinated during postpartum.

Administration/Stocking

All of the physicians interviewed in round 2 recommended the Tdap vaccine to their patients during pregnancy. However none of them administered nor stocked the Tdap vaccine based on the initial screening test taken to be included in round 2. A few physicians stated that while they did not actually stock the vaccine, they were willing to order it for patients on an individual basis. One physician explained this process,

> *"Well, I mean, we order it in on a per patient basis, and, therefore, we get it, and when we get it, the patient comes in, I mean we have it all set up in advance, the patient would, with all my vaccines. The patient will come in and they'll, they'll get a shot, I mean they'll get it and they'll pay for it"*

In this situation, physicians were adamant that they would only order the vaccine for individual patients if they had proof that their insurance would cover it. As one physician said,

> *"No, they don't have to go to another location, they can if they don't want to pay for it, if their insurance isn't going to cover it for some reason, then they can go someplace else and get it, because I mean, I'm not going to subsidize it for them. And it happens*

occasionally, where they just, you know, they're not planning to pay for it, and I'm not planning to, you know, I can't afford to, I'm, I have to pay my rent"

Physicians explained that one of the biggest barriers for patients, despite agreeing to stock the vaccine on a patient by patient basis, was that the patients would need to make an additional appointment. One physician noted,

"Well, I think it, not so much difficulty, but it's, I must admit it's a nuisance for them to then, you know, make an appointment to go, you know, a lot their primary cares won't have a special day, you know, where they'll vaccinations or just as a nurse visit for a vaccination, you know"

Despite understanding the access barriers patients faced due to their decision to not administer and stock the vaccine, physicians didn't view this as a primary concern and felt that it was a disadvantage to their practice to administer and stock the vaccine. Similar to Round 1, physicians cited reimbursement as why they did not administer and stock the Tdap vaccine in their office. Reimbursement was the primary issue, along with financial barriers. One physician explained this,

"Well, you know, I'm not the, I'm not the, the business, you know, I mean and we have some say, but, you know, a lot of this is business decisions that are being made, you know, financial, fiscal reasons. And it's, it's, sometimes it becomes difficult to get these reimbursed, so I'm told, I must admit I don't know, I know I should, but I don't know all the ins and outs of the reimbursement of these vaccines and how each company is, or each insurance company looks upon this."

Overall the administration and stocking patterns in round 2 were similar to that of round 1 with the exception of a few providers who mentioned they would be willing to stock the vaccine on a patient by patient basis.

Referral

All of the physicians in Round 2 stated that they referred their patients to a vaccine clinic, their primary care physician, or a pharmacy to get the Tdap vaccine. The majority of physicians

interviewed stated that there was a pharmacy or primary care physician in the vicinity or even in the building and so they felt that referring a patient out was not a burden due to the easy accessibility.

While all physicians said that they referred the patients to an alternate source to receive the vaccine after giving the recommendation, few physicians had a procedure in place for this referral process, aside from giving a list of places either verbally or written down. Some physicians had an efficient system that allowed them to work in sync with the primary care physicians or vaccine clinics in the neighborhood. One physician explained his practice's procedures of referral to a nearby injection clinic,

> *"So, the patient is in say my office. Then, my computer is linked up to the injection area. If I place an order, then that order would go to the injection room nurse, and then the nurse sees the order, so when the patient shows up, then she can administer whatever vaccine I've ordered"*

Physicians were also cognizant of the fact that referring patients to another source to receive the vaccine creates an inconvenience and additional barrier for patients since they have to take another appointment to receive the vaccine. One physician explained,

> *"Well, the recommendation is communicated to all patients. The issue is that it is not, if I say, OK, you need a Tdap vaccine, or you need a DPT, then, basically, the patient cannot get it at that exact time period, which means the inconvenience for them is that they have to set up another appointment. They have to get in within, either a special appointment or do it at their next appointment. But, they have to, you know, they have to make special arrangements"*

Physicians also explained that they referred their patients to primary care physicians because their insurance policy would not allow OB/GYN's to administer the vaccine regardless of whether they stocked or not. One physician explained this situation,

> *"A large number of my patients are HMO patients and, because they're HMO patients, immunizations are, are given by their primary care doctors and, and so that's what, so that's what we do"*

Other physicians avoided referring their patients to primary care physicians due to the additional expenses and paperwork. When asked if he preferred to refer his patients to primary care physicians, one physician replied,

> *"Not usually, just because that causes more, that's more expensive and they're less likely to go in and fill out all the paperwork that would be required there, it's easier, it's more streamlined to get it at the other places"*

The general consensus among physicians was referring was easier than administering the Tdap vaccine. For many physicians it didn't make sense to deal with the additional costs and barriers of stocking the vaccine, when there are primary care physicians, pharmacies, and other places in the vicinity where patients can get the vaccine. Some physicians understood that it created an additional barrier for patients since they had to go to another place, while other physicians didn't think it was much of a barrier.

Overall Barriers to Recommendation and Administration

Recommendation, administration, stocking, and referral of the Tdap vaccine emphasized several physician barriers in both Rounds 1 and 2. However, there were also many other barriers physicians faced in terms of recommending and administering the vaccine to their patients. These barriers are important to consider when designing an intervention to improve vaccination rates and reduce pertussis morbidity and mortality among infants.

Insurance Reimbursement

The most common barrier to vaccine administration that came up among the sample of physicians interviewed was insurance reimbursement. Physicians were not willing to take the risk that a patient's insurance may not cover the Tdap vaccine and that their practice would have

to take care of the cost in this situation. In order to avoid this risk, many physicians mentioned that they did not administer or stock the vaccine. One physician explained,

> *"I think the biggest issue is really reimbursement, and just the hassles of trying to, you know, we physicians, we're getting squeezed in every possible direction. And, there again, I don't really want to get in a situation where it can --- . The supplier is not going to tell me, I can't tell a supplier 50 percent of my patients didn't pay, they'll say who cares, they just bill"*

While the overall sentiment was that reimbursement was a major barrier, there were several physicians who mentioned that they did not see reimbursement as a barrier to administration. One provider explained when asked if reimbursement and cost were concerns.

> "*No, no, we order it from PSS, and comes by, in a box of ten, costs about four hundred thirty dollars for a box of ten. It hasn't been a problem"*

Other physicians were unaware of the costs of the actual vaccine, but chose not to administer because they didn't want to favor patients that could pay over those that couldn't. One physician explained the dilemma,

> "*I don't want to set a dual standard care where you give or take a public assistance patient and you can't give them a vaccine being reimbursed but then you're giving them to some people that can pay. So, my limitation on that is the inability to get reimbursed for, on a consistent basis. Otherwise, I would probably push it"*

Physicians that administered the vaccine discussed positives associated with providing the vaccine free of charge to patients. One physician said

> *"I don't how other states do it and other people, because it's everybody's private opinion, but we buy this vaccine and we give it to patients free, basically, of charge. And because they are not attached to be responsible for payment, then the probably we in, we increased almost to hundred percent agreement to being vaccinated as far as we don't ask them to pay for it"*

Despite the fact that insurance reimbursement was a significant concern among physicians due to the possibility that their practice would have to front the cost, there were still several physicians who explicitly stated that cost was not a concern for them.

> "*No, not really. You know, we certainly have personnel who are very comfortable giving injections, they do it for a number of different reasons, so that's not an issue, cost is not really, you know, cost is reasonable, storage, I really, I don't see anything that's really gotten in the way of us offering that"*

Reimbursement barriers was a primary concern among physicians and was the most cited reason as to why physicians chose not to administer and stock the vaccine in their office.

Logistics

Another important theme and barrier that physicians mentioned was coordination of the logistics that are involved in vaccine administration. This includes having an individual in charge of ordering and stocking the vaccine, as well as initiating the process if the practice were to start and continue vaccine administration. One physician explained the logistical barriers in his reasoning behind why the Tdap vaccine was not administered or stocked in his practice,

> *"Well I mean there's, I mean it's complicated, you know what I mean, I mean I just know in terms of vaccines, we do the flu vaccine you know. I don't know, I mean because I'm like not the administrator person in our office, you know, I don't get too involved in, you know, but storage, you know how long, expiration, I mean there's like a lot of stuff that goes on I think that, you know, is complicated. And we work in, you know we're basically in an office that has three other OB practices that we work closely with, and a lot of times it's more just bureaucracy, you know getting through, I mean someone has to really take the initiative to be like this is what I'm going to do, you know I'm going to making these decisions"*

Another barrier, logistically, for some physicians in terms of administering the vaccine is availability. Several physicians discussed that sometimes the vaccine hasn't been readily available, particularly to private practices. One physician said,

> "*You know in the fall we had a period of time where we did not have it and I want to say that was about maybe a month to six weeks and we actually sent the patients to the health department to get it, which was a little bit of an issue because most of them, well not most of them, but some of them depend on public transportation and so we actually had to figure out how they were going to get from the building that we are in"*

In addition to costs and reimbursement issues, another logistical problem practices face is navigating insurance policies. For instance, some insurance policies may cover the flu vaccine, but not the Tdap. Additionally, some insurance policies will only cover the Tdap vaccine if it is administered by a primary care physician and not a prenatal care physician. One physician explained how their practice was able to avoid these strict rules,

> "*Well we had a couple of issues with insurance. We get it, as I say I'm a hospital employee, that's not a problem. We had two issues actually, one was with the Blue Cross HMO, who wanted patients to go to their primary doctor for it, and actually I am really, I've know the medical director of the [state] Blue Cross, we were in medical school together and we go out for dinner every so often, and I said what about this, and he said, what do you mean, he didn't know that that was an issue. He said we like vaccines. So he checked up to it, and we haven't had any problem with them ever since*

This physician also explained how their practice had a similar issue with Medicaid.

> "*There's another Medicaid program that insists on patients going to their primary doctor to get it or the flu shot, and sometimes they need a little education, because for the primary docs, because they'll say oh you've already had the shot, and no, no, that doesn't count, and so often with these people I'll write a little note on a prescription that current recommendation is Tdap for all pregnant women at this stage and usually at that point they don't give them a problem"*

As a result of some insurance policies, pregnant women often have to take the extra step to get the Tdap vaccine from their primary care physician. The presence of this extra step can be a barrier to vaccination.

The importance of having an individual advocate for Tdap vaccine stocking and administration is evident due to the bureaucratic nature of some offices. While logistics wasn't a

major theme, it is important to realize that there are other things that need to be addressed besides financial aspects of administration and stocking.

Patient Refusal

Patient refusal is another common barrier cited by physicians in terms of administering the Tdap vaccine. This barrier came up among physicians that both administered the Tdap vaccine in their office and those that referred to another source. Physicians mentioned that one of the common reasons patients tended to refuse included the fact that they not like needles or didn't feel like it was necessary. One physician described a vaccine refuser,

> "*She just didn't like vaccines in general and she didn't think she needed it, and she just doesn't want to expose her baby to anything, and she didn't feel she needed it"*

Physicians with patients that declined vaccination were also asked how they responded to the situation. Many physicians admitted to being unable to convince their patient once they refused vaccination. One physician responded,

> "*Well, yeah I just try to explain the thought behind the whole vaccination process like with the whole pertussis protection, flu protection, the way that these vaccines are tested very carefully and extensively and that the CDC recommended or the ACOG] recommends it, but some people are, you know, that you're just not going to change your mind"*

Several physicians mentioned that most patients come in with a set mindset and it is hard to change their mind. When asked if physicians changed their recommendation or pushed harder with patients that were vaccine refusers or hesitant, the majority of physicians said that they did not. Patient refusal is a barrier that is often not evident when considering provider barriers, however it was cited explicitly by many physicians as a personal barrier to vaccine administration.

Summary

The major themes evident in the data provided information on both perceptions and practices of physicians. The first part of the study addressed provider perceptions of pertussis and then for Tdap vaccination as a practice. Next, the study addressed current practices in terms of recommendation, administration, stocking, and referral. Upon eliciting information on perceptions and practices, cues to action were addressed, both in terms of measures physicians currently took and also future strategies they would like to implement. The last part of the study revealed barriers, as well as implied facilitators, to vaccine administration for both round 1 and 2.

CHAPTER V. DISCUSSION

Summary of Results

Preventive health behaviors, particularly vaccination, are heavily influenced by physician perceptions and practice. In the case of Tdap vaccination during pregnancy, the recommendation made by ACIP and endorsed by ACOG is relatively recent and thus all patients are not familiar with it. Several studies have shown that patients are more likely to receive vaccinations during pregnancy, including Tdap, if their provider recommends it during visits and also provides easy access to it. In order to understand why pertussis morbidity and mortality among infants still remain high, this study aimed to elicit information from OB/GYNs on their perceptions and practices regarding pertussis disease and Tdap vaccine recommendation, administration, and referral.

Perceptions of Pertussis

The overall sentiment among physicians interviewed regarding pertussis was that they had heard about recent outbreaks through the news and conferences they had attended. However, they hadn't had any outbreaks in the area they practiced, nor had they had a patient with pertussis. As a result, they did not think that the severity of pertussis was high and warranted any additional actions. In terms of susceptibility, all providers agreed that infants were a vulnerable population in terms of contracting pertussis because the symptoms of the disease were much more severe and potentially lethal. Providers were not as concerned about their pregnant patients contracting the disease. All in all, the low perceived severity of pertussis among the physicians interviewed is a cause for concern. In order to recommend and administer the Tdap vaccine, it is imperative that physicians are aware of the severity of the disease in the United States and have an impetus to provide preventive measures to their patients.

Perceptions of Tdap Vaccination

After eliciting a general response regarding perceptions of pertussis among the physicians in the sample, the study aimed to understand physician's perceptions on the action of administering the Tdap vaccine to pregnant patients. It was evident that all physicians interviewed were familiar with the most recent recommendation of giving the Tdap vaccine during the third trimester of every pregnancy. The majority of physicians stated that they felt that the vaccine was important and effective due to the transfer of pertussis antibodies from the mother to the fetus. There were some outliers who did not feel that there was enough literature to prove the effectiveness of giving the vaccine during pregnancy. These physicians still believed that the vaccine was important and instead preferred to recommend the vaccine postpartum, knowing that their patients would receive it at the hospital after giving birth. In terms of safety, all physicians interviewed agreed that the Tdap vaccine was safe to give during pregnancy.

Current Practice

In this study, perceptions of pertussis and Tdap vaccination did not necessarily influence the current practice of the physicians. Physicians were asked about their practices regarding recommending the vaccine to their pregnant patients, administering and stocking the vaccine on site, and referring their patients to alternative sources if needed. All physicians recommended the vaccine to their patients, although there were two physicians that recommended the vaccine postpartum. As mentioned previously, the overall sentiment among physicians was that they tried to recommend the vaccine to their patients during pregnancy, but did not think it was a huge deal if the patient did not follow through and receive the vaccination or seemed hesitant because they would receive the vaccine postpartum anyway. This shows lack of awareness and education on the physicians end about the benefits of vaccinating during pregnancy. This finding does not

correlate with the overall perspective of physicians on the effectiveness of the vaccine during pregnancy. As such, it is important to conduct more studies on the perceptions of providers.

In terms of the recommendation itself, the strength of the recommendation varied among physicians. Some physicians said that they just mentioned the ACIP recommendation to their patients, while some said that they thoroughly explained the concept of antibody transfer to their patients and were willing to discuss questions and concerns. In terms of administering and stocking the vaccine, 14 physicians stocked the vaccine and 10 did not. Physicians discussed several barriers such as reimbursement, logistics, and patient refusal as why they did not administer the vaccine on site. However, the main theme was that overall physicians did not think that their lack of administering and stocking the vaccine in their office served as a barrier to patients. As such, this is something that needs further investigation in future studies.

Barriers

Physicians who did not administer or stock the Tdap vaccine where asked to explain why they made the decision not to. The major barriers were reimbursement issues, logistics, and patient refusal. Physicians discussed that the Tdap vaccine was not reimbursed by all of the insurance companies and often times after giving the vaccine, practices realize that the vaccine was not covered by a particular insurance company and have to front the cost themselves. Based on this and the fact that the physicians in this study did not view pertussis as a major concern, providers said that they felt that it was financially better for their practice to not administer and stock the vaccine. Logistical barriers were another concern among providers and these included things like having a central point person to order and properly stock them and other costs associated with vaccine administration. When asked about other barriers to administration, many physicians mentioned patient refusal, specifically those that were hesitant towards vaccines or

believed that there was a link towards autism. Physicians mentioned that there was not much they could do if their patient was hesitant towards vaccines. This was primarily a concern among providers who administered and stocked the vaccine on-site.

Future Recommendations

The results from this study on perceptions, practice, and information needs regarding Tdap vaccination provided a lot of information on the healthcare provider perspective of this issue. After triangulation of the literature and the results of this study, three main recommendations for the future include the need for structural support through policy based interventions, provider interventions to increase education and awareness, and overall health communication and promotion interventions.

Structural Support: Policy Based Interventions

The largest barrier mentioned by providers in administering and stocking the Tdap vaccine was reimbursement. According to the literature, many vaccines, including the Tdap are not covered under private insurance, Medicare, and Medicaid unless they are directly related to treatment of an injury or direct exposure to a disease or condition. Furthermore most insurance plans, particularly HMO's only allow primary care providers to administer vaccines such as the Tdap. While primary care providers are essential, pregnant women tend to have their OB/GYN serve as their primary care provider during pregnancy and thus will not see their PCP after they give birth. The fact that most insurance plans do not cover maternal immunizations is one of the main reasons OB/GYN's do not stock and administer the vaccine because they know that if the patient can't pay for the vaccine then the practice has to cover the costs. As such, all types of insurance need to cover and reimburse essential vaccines like the Tdap, in order to eliminate the main provider barrier to administration and stocking.

Education and Awareness: Provider Interventions

Education initiatives are an integral part of improving Tdap vaccination rates. This can be in the form of CME modules for providers or additional communication materials support. One of the biggest barriers found in the study was that providers either did not know about the CDC and ACOG Tdap recommendations or they did not understand the difference between giving the vaccine during pregnancy versus postpartum. The results showed that most providers were not too concerned that their patients were getting the vaccine post-partum because at least they were still receiving the vaccine. There are many possible venues for education which includes health promotion campaigns, educational sessions at conferences for providers, CME modules, and other pamphlets and materials designed for providers specifically.

Health Communications and Promotion

Lack of provider education often contributes to their inability to explain the importance of the Tdap vaccine to their patients. As such, a communication intervention should have components that address both the provider and the patients. In the data, many providers stated that they trusted materials and literature by organizations such as the CDC and ACOG. Additionally, they said that getting materials from these organizations was very useful in health promotion particularly advocating Tdap vaccination. As such, the results conclude that separate health communication interventions should be created to target both providers and pregnant women. Additionally, handouts and pamphlets remain the ideal venue of communication for providers, however literature and past studies suggest that it may be beneficial to try other communication strategies including phone applications, social media, and television among other things.

Overall Factors Contributing to Tdap Administration among Physicians

As mentioned previously, the interview guide for this study was informed using constructs of the Health Belief Model. However, upon using the grounded theory approach for data analysis a variation of the Health Belief Model was found to be true in explaining physician influential factors to Tdap administration during pregnancy

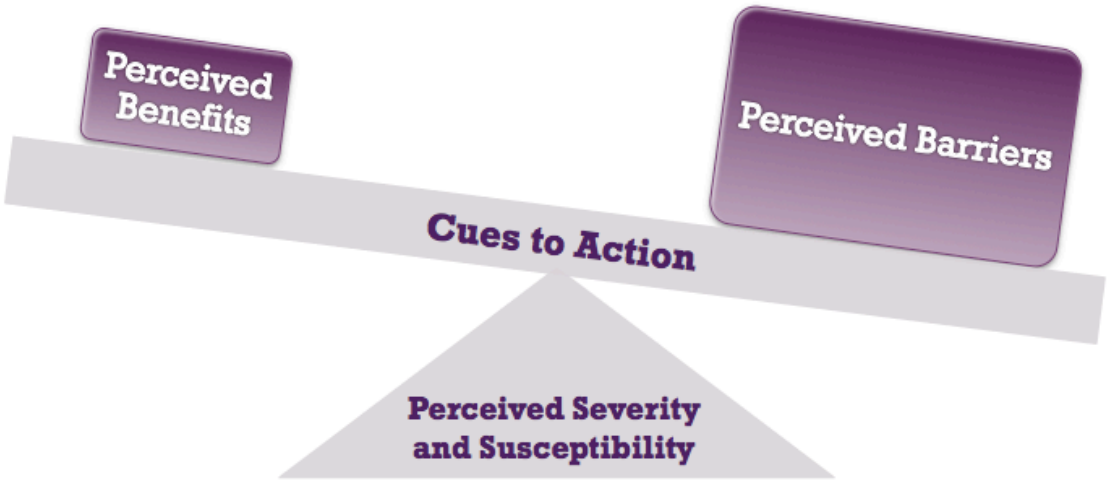


Figure 3. Theoretical Model for Study using HBM Constructs

Perceived severity and susceptibility make up the fulcrum of the diagram because they serve as universal factors that directly influence all constructs that are present in this study. In terms of the decision making process for physicians, perceived barriers has the greatest influence among all of the constructs. While perceived benefits of Tdap vaccination during pregnancy holds some influence, it is clear that the barriers outweigh the benefits. Physicians recognize the

benefits of Tdap vaccination during pregnancy, but the reimbursement barrier and also the overall perception that pertussis is not a severe concern in the United States lower the intensity of perceived benefits in the decision making process. The cues to action, specifically future strategies, aim to reduce the barriers, address benefits, and educate providers on why pertussis is a problem that they should address in their practice. Self-efficacy is an HBM construct that was not addressed in this study.

Study Limitations

The intended sample was supposed to consist of a diverse mix of providers with patients with different socioeconomic statuses, ethnicities, and types of insurance. However, the sample size ended up not being diverse with most providers seeing middle to high income population. Social desirability bias is also a primary concern in this study because the physicians are asked to express their views on vaccination attitudes and practices and it's possible that many physicians were not entirely truthful in their answers due to the fact that they were being interviewed. Additionally, the interview guide focused heavily on barriers to administration and recommendation but did not focus on asking providers about facilitators and other factors that would motivate providers to recommending and administering the vaccine. Additionally, while the interview guide asked providers what the main concerns and barriers as to why they did not administer and stock the vaccine, however follow up questions on what other resources might be needed once barriers such as reimbursement was addressed were not included. Finally, due to the qualitative nature of this study, findings are not representative and therefore not generalizable to the entire population. While this study poses several limitations, it provides an understanding of provider perceptions, practices, and other influential factors associated with Tdap vaccination.

Public Health Implications

Healthcare providers as an integral part of the healthcare system and recommendations provided by them carry a heavy weight in patient care and compliance. As a result, it is important that providers understand not only the importance of their role in advocating health behaviors and practices, but also stay up to date with current recommendations and strategies. Tdap vaccination is one of many areas where provider recommendations are extremely important and impact patient behavior and ultimately outcomes. While this study is specific to Tdap vaccination during pregnancy, many of the factors addressed in the interviews and themes that came up in the data exemplify implications for future research in healthcare practice in the United States. Like pertussis, there are many diseases that are easily prevented, yet still remain a problem and engaging healthcare providers is key in addressing these concerns. Understanding the factors that influence the decision making of healthcare providers, as well as barriers and facilitators through targeted interventions is essential in improving healthcare delivery and access across the nation.

Conclusion

Despite the fact that overall perceptions of providers regarding the Tdap vaccine are positive, there are low rates of recommendations and administration and thus vaccination. Often times an individual's perceptions inform their practices, but in the case of the healthcare providers in this study, this does not hold true. As the literature explained, barriers to recommendation and administration of the vaccine include reimbursement, insurance, logistical barriers, patient refusal, informational barriers, among others. Providers tend to have no concerns when it comes to the Tdap vaccine itself, but do not find it cost effective or efficient for their

practice to administer or stock. As such, while it's important to target pregnant women in interventions related to this topic, there should also be interventions targeted at providers as they provide the vehicle to Tdap vaccination and ultimately lower rates of pertussis morbidity and mortality among susceptible infants. While this study specifically focuses on Tdap vaccination during pregnant as a prevention mechanism, the results can be used in the broader sense of disease prevention. Physician perceptions and practice impact disease prevention significant and it is important to address physician barriers, in addition to the barriers of the population at risk to get a complete picture of the situation.

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Appendix A: IRB Determination Letter

EMORY UNIVERSITY

Institutional Review Board

March 13, 2015

Paula Frew, PhD, MPH, MA
Assistant Professor of Medicine
Emory University School of Medicine
Atlanta, GA 30322

RE: Determination: No IRB Review Required
eIRB#: 80281
Title: *Providers and Pregnant Women's Perspectives to Inform Pertussis Communication*
PI: Paula Frew, PhD, MPH, MA

Dear Dr. Frew:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definitions of research with "human subjects" or "clinical investigation" as set forth in Emory policies and procedures and federal rules, if applicable. Instead, this is a secondary analysis of qualitative data provided by the Centers for Disease Control. The data provided by the CDC is from a study that was conducted by CDC contractor, Westat, to gather insights about OB/GYN current practices, knowledge, attitudes and beliefs related to Tdap vaccination during pregnancy. A third party handled recruitment, and Westat and CDC did not have access to participants' contact information. The CDC will provide you with deidentified transcripts from the focus groups and interviews to analyze.

Please note that this determination does not mean that you cannot publish the results. If you have questions about this issue, please contact me.

This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Carolyn Sims, MPA
Research Protocol Analyst

Codes	Definitions
Perceptions of Pertussis	Physician views about trends in the severity, susceptibility, and racial/ethnic disparities in pertussis disease.
Perceived Severity	Physician views on the seriousness of the mother and baby contracting pertussis and the consequences that may follow.
Perceived Susceptibility	Physician views on the likelihood of the mother and baby contracting pertussis.
Racial/Ethnic Disparities	Physician views/recognition on racial or ethnic trends in the spread of pertussis.
Perceptions of Tdap Vaccination	Physician views on the action of Tdap vaccination during pregnancy and implications of the ACIP recommendation.
Perceived Benefits	Physician views on potential benefits of Tdap vaccination during pregnancy.
Importance	Physician opinions on the reasoning behind why the Tdap vaccine should be given to pregnant patients.
Effectiveness	Physician perceptions of how well the Tdap vaccine serves its intended purpose of conferring maternal antibodies to the unborn child.
Safety	Physician perceptions of the safety of giving the Tdap vaccine during pregnancy.
Current Practice	Physician practices regarding Tdap recommendation, administration, stocking, and referral.
Recommendation	If the physician recommends the vaccine, the practices and strategies used for recommendation, and other factors that influence and determine Tdap vaccine recommendation among pregnant patients.
Administration	If the physician administers the vaccine, concerns regarding administration, and other factors influencing Tdap vaccine administration on-site.
Stocking	If the physician stocks the vaccine in his/her office and other factors influencing the decision and practice of stocking.
Referral	Whether or not the physician refers patient to an outside source to receive vaccine and the specific location (s) and procedure for referring and following up.
Cues to Action	Factors that currently lead to or will in the future lead to physicians recommending and administering the vaccine.
Current Materials & Strategies	Current Tdap vaccine promotion communication materials and strategies used by physician i.e. pamphlets, reminders, etc.
Future Suggestions	Communication methods and strategies that they physician feels will be useful in the future for both spreading the message and making recommendation and administration easier.

Perceived Provider Barriers	Barriers to recommendation and administration as cited by the physicians themselves.
Reimbursement	Lack of reimbursement from various patient insurance companies (private, Medicaid, etc.), leads to practice having to fund delivery of vaccines where patients insurance doesn't cover.
Logistics	Structure and coordination related practice barriers among physicians Ex. Staff in charge of facilitating, follow up, storage and associated costs
Patient Refusal	Mention of patient refusal due to anti-vaccination views and patient hesitancy as a barrier