ASSESSMENT OF TDAP ADMINSTRATION IN THE THIRD TRIMESTER OF PREGNANCY

by

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DEDICATION

This Doctor of Nursing Practice Project is dedicated to the babies who fall ill, victims of pertussis. To their mothers, fathers, brothers, sisters, and loved ones who watch them suffer. To the doctors and nurses who treat them, heal them, and care for them. The intention of this project is to gather information, illuminate barriers, and provide for further developments in the safe administration of Tdap vaccinations to pregnant women. My hope is to improve our protection of the tiny miracles we have the privilege of bringing into this world.

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ABSTRACT

Introduction: In 2012, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention expanded their recommendation for the Tdap vaccination to include the antepartum period. Regardless of immunization history, the recommendation states that medical practitioners should administer the Tdap vaccination to every pregnant woman in each occurring pregnancy (Munoz, et al., 2014; Shakib, et al., 2013; Goldfarb, Little, Brown, Riley, 2014).

Methods: To describe treatment practices and uptake of Tdap vaccine, a cross-sectional descriptive survey design was utilized. The purpose of survey is to gather information regarding prevalence, distribution, and interrelations of variables within a population (Polit & Beck). In this study, the survey questionnaire was conducted in an online format.

Results: Of the six HBM questions included in the study, except for question four, the results of the chi-squared analysis suggest that any single measured dimension of the HBM cannot predict a health behavior, in this case receipt of the Tdap vaccination. The population is split regarding infants' perceived susceptibility to pertussis infection. Strong agreement to the benefit of vaccination was revealed. Question six regarded available information, although the majority were satisfied a significant percentage indicated a desire for more information.

Discussion: This Doctorate of Nursing Practice project developed a survey based on the Health Belief Model with the intention of assessing perceived susceptibility, perceived severity, perceived benefits and perceived barriers to the health care preventative action of receiving the Tdap vaccination in the third trimester of pregnancy. Through in-depth literature review,

consideration of the updated ACIP guidelines, and support of a developed theoretical framework, an eight-question survey was developed. The data examined in this project may serve to illustrate limitations in provider care that can be immediately improved upon, such as information sharing. The primary limitation of the study is in the sample size of 44 eligible survey responses and the uniform demographics of the population. Despite these limitations, the survey design may be extended to other populations of interest, with greater demographic variation for further study.

LITERATURE REVIEW

Introduction

The respiratory tract infection pertussis, or whooping cough, carries significantly greater risk of morbidity and mortality to infants less than 6 months old (Gall, Myers, & Pichichero, 2011; Munoz, et al., 2014). The primary diphtheria and tetanus toxoids and acellular pertussis (DTaP) immunization series begins at 2 months of age, followed by further vaccination at 4 months and 6 months. Prior to completing the infant vaccination series babies less than 6 months, and specifically less than 2 months of age are vulnerable to pertussis infection, and subsequent hospitalization and complications. Due to this window of opportunity for pertussis infection the transfer of passive maternal antibodies to the newborn through third trimester Tdap vaccination is the recommended method of prevention against pertussis infection (Munoz, et al., 2014). Pertussis infection in the vaccinated child or adult can be asymptomatic, or present as a cough with a long duration. In the unvaccinated infant the pertussis infection presents as spasmodic coughing followed by an inspiratory whoop (Shea-Lewis, Hill, & Soper, 2011). Pertussis infected infants can experience apnea, respiratory failure, neurologic complications, and in some instances, death (Kharbanda, et al., 2014).

In 2012 the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention expanded their recommendation for the Tdap vaccination to include the antepartum period. Regardless of immunization history the recommendation states that medical practitioners should administer the Tdap vaccination to every pregnant woman in each occurring pregnancy. Optimal timing is described by the ACIP as between 27 and 36 weeks' gestation. This timing allows for the best possible passive antibody transfer from mother

to child as third trimester Tdap immunization results in higher antibody concentrations in infant cord blood at delivery in comparison to maternal serum (Munoz, et al., 2014; Shakib, et al., 2013; Goldfarb, Little, Brown, Riley, 2014). The recommendation from ACIP presents a challenge to the healthcare community. Theoretical reasons include both patient and practitioner concerns regarding safety of the vaccination in pregnancy and misrepresentation or misunderstanding of the benefits of the vaccine to the newborn. A surveillance study released by the CDC in 2011 reported a vaccine uptake of only 2.6% after a previous ACIP change to the recommendation (Goldfarb, et al., 2014). One possible reason for poor adherence to the ACIP vaccination recommendation may be the number of changes in recent years. Expectant mothers may be hesitant to adopt or trust new recommendations (Silverman, 2014).

This literature review was developed through a search of EBSCO Host Cinahl plus full text. Two independent searches yielded the research articles presented. The first search used the phrase pertussis and included the limits full text; publication date between 2010 and 2014; age was defined as infant 1 to 23 months; language of English. Source was limited to academic journals. These combined criteria yielded 103 results. The second search phrase used was pertussis AND vaccine AND pregnancy. The limitations were available full text and that the source be an academic journal. The second search returned 40 results. Of the combined 143 articles presented through the above-illustrated searches, a comprehensive systematic review of the evidence identified 15 articles to be included in this literature review. The performance of a systematic review is a five-step process. The first step is to formulate a question for review (Khan, K., Kunz, R., Kleijnen, J., & Antes, G., 2003). The presented question in this review is, how does the administration of the Tdap vaccine in the third trimester of pregnancy affect patient

outcomes and pertussis outbreaks? The identified population in question is pregnant females. The intervention is the administration of the Tdap vaccination during the third trimester of pregnancy versus the vaccination not being administered in pregnancy. Identified outcomes include the safety of the mother and child following Tdap vaccination in the third trimester of pregnancy, and the rate of mortality in the infant population related to the protection formed from Tdap vaccination of the mother in the third trimester of pregnancy. The second step in a systematic review is the identification of relevant publications (Khan, et al., 2003). Articles for review were selected from the search results based on relevance to the identified research question, after the application of limits such as year of publication. The third identified step is the assessment of study quality. The design of the study in question is the first marker of quality; randomized controlled trials typically yield quality results (Khan, et al.). Given that the proposed question suggests an implementation involving the population of pregnant females and newborn infants, most of the studies selected for review are observational studies. Step four is the summarization of the evidence, and step five is interpreting the findings (Khan, el al.). The presented literary review summarizes the findings of the selected articles and concludes with an interpretation of the summarized findings.

Significance of Pertussis

The bacteria *Bordetella Pertussis* causes a respiratory tract infection. This infection is highly contagious, potentially fatal, and vaccine preventable (Munoz, et al., 2014; Kharbanda, et al., 2014; Shakib, et al., 2013). This contagious infection is spread via coughing and sneezing, thus spreading respiratory droplets into the environment (Lloyd, K., 2013). Research has illustrated that close person contacts, most frequently the child's mother, can be identified as the

infected relative responsible for transmission of the *Bordetella Pertussis* infection (Cantey, Sanchez, Tran, Chung, & Siegel, 2014). Adult infection with pertussis has a milder presentation, often asymptomatic, or a cough that lasts approximately three months (Kharbanda, et al., 2014). The presentation of the pertussis infection in infants is severe. Symptoms can include a rapid cough followed by a characteristic inspiratory whoop, apnea, and cyanosis related to exhaustion. Accompanying exhaustion, the infant can experience dehydration, electrolyte imbalance, and the occurrence of opportunistic infections such as pneumonia. The infection in infants may lead to respiratory failure, encephalopathy, neurologic complications, and potentially death (Kharbanda, et al.; Lloyd, 2013; Silverman, 2014).

Infants too young to be protected from the pertussis infection via vaccination carry the greatest risk of morbidity and mortality (Goldfarb, et al., 2014; Lloyd, 2013). Reported cases of pertussis infection have shown a substantial increase. "Provisional case counts for 2012 have surpassed the last peak year, 2010, with 41,880 pertussis cases and 14 deaths in infants aged <12 months" ("Updated Recommendations for Use of," 2012). The pertussis infection has a cyclical pattern with a small increase in the number of cases reported is anticipated every three to five years. In the United States the reported number of pertussis cases is higher than this pattern would predict, with the national incidence being 11.6 cases/100,000 persons (Lloyd, 2013). Possible theories as to why the incidence of pertussis is increasing includes greater awareness and testing for the infection and the possibility that new vaccines may be less potent or provide protection for a shorter duration of time. Additionally, decreases in vaccination rates and other healthcare barriers may be contributing to the increased incidence of pertussis infection (Glanz, et al., 2013).

The study by Glanz et. Al. 'Risk of Pertussis in Children by Undervaccination' concludes that approximately 36% of pertussis cases occurring in the population can be attributed to under vaccination of children age 3 to 36 months. This matched case-control study, examined the association between under vaccination, by 1, 2, 3, or 4 doses of DTaP and the occurrence of pertussis infection in children 3 to 36 months of age. In children under vaccinated by 3 doses, results demonstrated the chance of pertussis diagnosis to be 18.56 times more likely. Chance of pertussis diagnosis was 28.38 times more likely in patients under vaccinated by 4 doses of DTaP. Results were not statistically significant for children under vaccinated by 1 or 2 doses of DTaP. Risk of pertussis infection for 1 or 2 missed doses were 2.25 and 3.41 times more likely to receive a diagnosis of pertussis as compared to the age-appropriately vaccinated control group.

The study data collection process may have under-represented children under vaccinated by only 1 or 2 doses of DTaP. This group is represented by children 22 months of age who have already had 3 doses of DTaP, allowing for some protection against infection. The group also represents children 3 months of age who have only missed one dose of DTaP but who would not have received any prior doses and have no antibodies against *Bordetella Pertussis*. The study method leaves open the opportunity for diagnostic bias or sample biases only children tested for laboratory confirmed pertussis were reviewed in the study. Diagnostic bias describes the bias of the provider in choosing to administer a diagnostic test for pertussis to an under vaccinated child, while potentially not administering the same test to a fully vaccinated child (Glanz, et al., 2013). Regardless of these limitations, the results of the study clarify the risk of under vaccination. The sample of children studied concluded in 2010, an updated report of under vaccination and its

effect on the vulnerable infant population could benefit efforts of vaccination promotion and pertussis prevention.

In the United States, the childhood primary pertussis vaccine series begins at two months of age. Three to four DTaP vaccinations are required before infants are considered to have achieved protection from pertussis. The series begins at two months, is continued at four months, with a third vaccination at six months (Shakib, et al., 2013; Lloyd, 2013). Ninety-three percent of pertussis related deaths reported between the years of 2000 and 2006 to the Centers for Disease Control and Prevention occurred in children under twelve months of age (Shakib, et al.). The population at greatest risk is infants under the age of three months. In the United States this age range reports the greatest number of hospitalizations and deaths related to pertussis infection (Silverman, 2014). The reported data suggests that infants too young to be fully vaccinated are the most vulnerable to pertussis infection and possibly death (Harriman & Winter, 2014). These young infants, less than 2, 4, or 6 months of age, depend on the transfer of passive maternal antibodies to have some form of protection from the pertussis infection (Munoz, et al., 2014). In order to promote protection of the vulnerable infant population, current vaccination recommendations must be utilized. New data suggests that Tdap vaccination during one pregnancy does not continue to provide adequate maternal antipertussis antibodies to the infant in subsequent pregnancies ("Updated Recommendations for Use of," 2012).

The randomized clinical trial 'Safety and Immunogenicity of Tetanus Diphtheria and Acellular Pertussis (Tdap) Immunization During Pregnancy in Mothers and Infants' concluding evidence supports the ACIP recommendation to immunize during each pregnancy. The concentration of pertussis antibodies was measured in maternal serum, infant cord blood at birth,

and after infant receipt of 3 and then 4 doses of DTaP. Significantly higher concentrations of pertussis antibodies were reported in infants at birth and age 2 months whose mother had received Tdap during pregnancy (Munoz, et al., 2014). The participant sample size of 48 healthy pregnant women and 32 nonpregnant woman limits the influence of the results, as a much larger sample size will need to be studied to increase the confidence that the results were not impacted by confounding variables and identify the efficacy of maternal immunization for the protection of infants. This study further illustrated a variation in immune response of the infant to DTaP immunization following maternal Tdap immunization. The infant antibodies following the third DTaP immunization were notably lowered in the population that received the Tdap vaccination during pregnancy.

This study did not fully account for the anomalous results, or the impact of the blunted antibody response in the infant following the third DTaP immunization. Other preliminary studies indicate that this variation is not significant when contrasted with the potential for pertussis protection in the newborn period (Jimenez-Truque & Edwards, 2014). No record was found in the literature of studies evaluating the effect of maternal Tdap immunization on the infants' antibody response to all vaccinations recommended in the childhood immunization series.

The Center for Disease Control and Prevention (CDC) reports evidence citing the effectiveness of the administration of the Tdap vaccination in the third trimester of pregnancy, in protecting infants during their most vulnerable period. Sources from the United Kingdom report a 90% protection from Pertussis infection for infants of mothers vaccinated with Tdap during pregnancy. Studies in the United States provide concurrent data noting significantly lower risk of

hospitalization, intensive care admission, and shorter duration of hospital admissions. The question of the effectiveness of the DTaP series after antepartum inoculation with Tdap is also addressed by the CDC, although investigation will continue, preliminary information concludes that the benefit of the protection from the Tdap vaccination provided during the antepartum period is of greater benefit to the infant than the DTaP series alone ("Vaccine Effectiveness", 2017).

Recommendation by ACIP for Prevention

The Advisory Committee on Immunization Practices (ACIP) is composed of 15 health professionals appointed by the Secretary of the U.S. Department of Health and Human Services (DHHS). These nationally recognized experts in areas of health research develop recommendations for the safe use of vaccinations (Lloyd, 2013). This paper focuses on the recommendation from the ACIP for the administration of the Tdap vaccine in the third trimester of pregnancy. The ACIP began adjusting the guidelines for Tdap vaccination in 2005, this prescription for prevention focused on vaccinating women in the early postpartum period (Goldfarb, et al., 2014). The recommendation also promoted the practice of cocooning, or the immunization of all adolescents and adults who may have close contact with the infant (Munoz, et al., 2014; Lloyd, 2013). Vaccination to enact the process of cocooning can best prevent infant pertussis if completed prior to the birth of the newborn (Lloyd, 2013). Although the ACIP will continue to develop the Tdap recommendations for pregnant females, the prescription of cocooning the newborn will remain as an adjunct measure to prevent infant pertussis infection (Cantey, et al., 2014). This recommendation illuminated two concerning factors; firstly the limited effectiveness of the cocooning strategy, and secondly the two-week period in which is

required for a postpartum mother to mount an antibody response after receiving the Tdap vaccine (Lloyd, 2013; Silverman, 2014). This period of 14 days allows for a period of risk to the infant during which the mother is not prevented from being a vector of pertussis infection (Lloyd, 2013). These notable concerns led to new recommendation from the ACIP, including the consideration of maternal immunization during gestation (Silverman, 2014).

The next recommendation from the ACIP was proposed in 2011 (Munoz, et al., 2014). The new prescription stated that all unvaccinated women should receive a Tdap vaccination during pregnancy (Munoz, et al.; Goldfarb, et al., 2014). This recommendation, known as antepartum cocooning demonstrated the unique cost benefit of providing protection to two individuals at one time (Lloyd, 2013). The intention of antepartum vaccination is to promote the formation of maternal antibodies against pertussis (Zheteveva, Moro, Tepper, Rasmussen, Barash, Revzina, & Broder, 2012). The mother's pertussis antibodies will then be transferred via the placenta, to the fetus (Zheteveva, et al., 2012; Silverman, 2014; "Updated Recommendations for Use of," 2012). There are several advantages to the antepartum Tdap vaccination; including, preventing the mother from becoming a vector of pertussis infection in the early postpartum period (Lloyd, 2013). Additionally, the maternal pertussis antibodies provide the newborn with passive immunity from pertussis infection, at the time of birth (Lloyd, 2013; Silverman, 2014). In 2012, the ACIP further developed the recommendation to the Tdap vaccination. The new recommendation corrects the 2011 guideline that excluded pregnant women previously vaccinated with Tdap. All pregnant females, regardless of prior Tdap immunization, are recommended to receive the Tdap vaccine during each pregnancy ("Updated Recommendations for Use of," 2012; Munoz, et al.; Kharbanda, et al., 2014). This literature review found no studies

analyzing the risk of local reaction to Tdap associated with the receipt of Tdap in each occurring pregnancy. Any historical studies for this period will be limited by the changes in the formulation of tetanus containing immunizations in previous years. The ACIP indicated plans for enhanced monitoring of the Vaccine Adverse Events Reporting System (VAERS) and Vaccine Safety Datalink (VSD) to assess outcomes associated with repeat doses of Tdap in closely occurring pregnancies ("Updated Recommendations for Use of," 2012).

After the 2012 recommendation new research concluded that Tdap antibodies decreased rapidly post vaccination. One study indicated that low levels of Tdap antibodies at term were recorded in pregnant women who had received the Tdap vaccine in the first or second trimester of the current pregnancy. It was also found that prior to 30 weeks' gestation, there was not substantial active transfer of maternal immunoglobulin G ("Updated Recommendations for Use of," 2012; Harriman & Winter, 2014). It is known that the antibody response to a Tdap immunization peaks approximately two weeks after administration, followed by rapidly waning antibody response. To achieve optimal antibody transfer to the fetus, the vaccination is recommended to be administered between 27 and 36 weeks' gestation (Harriman & Winter, 2014). The study did not eliminate the chance of effects on immune response outside of those considered, the effect of breast milk derived antibodies following maternal immunization, and other barriers to effective uptake of maternal immunizations (Beigi, 2014). The evidence to support antepartum vaccination reveals higher concentrations of pertussis antibodies in the cord blood collected from newborns that were born to vaccinated mothers (Silverman, 2014). A separate study reflected that babies up to 2 months of age had higher antibody concentrations when compared to babies of mothers vaccinated postpartum (Jimenez-Truque & Edwards, 2014).

This information supports the current ACIP recommendation, exemplifying the concept of maternal antibody transfer to the newborn.

A limitation of the cited study is the small sample size given the potential for confounding variables, new features may be revealed by a larger sample, potentially the efficacy of antepartum Tdap vaccination (Jimenez-Truque & Edwards, 2014). In the fall of 2012 the ACIP, after reviewing ongoing research, adjusted the Tdap recommendation, specifying that all pregnant females regardless of prior Tdap vaccine administration would be advised to receive a Tdap during each pregnancy and during the third trimester of pregnancy (Shakib, et al., 2014; Goldfarb, et al., 2014; "Updated Recommendations for Use of," 2012; Lloyd, 2013; Cantey, el al., 2014; Jimenes-Truque & Edwards, 2014). This recommendation was further clarified to state that the time frame of 27 to 36 weeks of gestation would be optimal for Tdap antibody transfer and infant protection at birth (Harriman & Winter, 2014; Cantey, et al.; Lloyd, 2013; Shakib, et al.; Goldfarb, et al.). There is no existence of demonstrated or theoretical evidence that suggests the possibility of adverse fetal outcomes, related to providing pregnant women Tdap, an inactivated antigenic agent, during pregnancy (Silverman, 2014). Studies so far suggest no adverse fetal outcomes, however, changing treatment practices and patient behaviors suggest a need for continued study and vigilance.

Further Research and Barriers to Implementation

The most recent guideline from the ACIP recommends maternal vaccination with Tdap between the 27th and 36th week of fetal gestation (Goldfarb, et al., 2014; Cantey, et al., 2014). The timing of fetal gestation is significant as a two-week period is required for the mother to mount an adequate immune response to the vaccination (Goldfarb, et al.). Implementation of a

vaccine program aimed at promoting vaccine uptake during this time would likely decrease the risk of pertussis infection in infants until the DTaP vaccination series can be initiated (Gall, et al., 2011). This study (Gall, et al.) compared paired samples of maternal serum and umbilical cord blood, to a model of expected outcomes drawn from a wider population. The results illustrated significantly higher concentrations in the maternally vaccinated population. Including data points from before and after for each patient and using a paired sample t-test could have improved the statistical confidence in the observed results (Gall, et al.).

The administration of Tdap during the antepartum period is a realistic and effective strategy for the prevention of pertussis infection in infants (Harriman & Winter, 2014; Kharbanda, et al., 2014; Munoz, et al., 2014). Both antepartum vaccination and cocooning recommendations require increased efforts to improve Tdap vaccination uptake and delivery (Cantey, et al., 2014). The study 'Pertussis: A Persistent Cause of Morbidity and Mortality in Young Infants' reviewed medical records and interviewed mothers of patients diagnosed with *Bordetella Pertussis* during a 2012 pertussis outbreak in Dallas County. The results included that less than 50% of the mothers interviewed were vaccinated with Tdap in the postpartum period. In relation to the effect of cocooning, the study provided that greater than 50% of sick contacts were other household members and not the mother. As of this study, there is no cocooning program that supports vaccination of all close household contacts. This study is limited in scope, only children tested for pertussis were identified, only those treated at Children's Medical Center Dallas were evaluated, and only the vaccination status of the mother was confirmed. Overall, the results support the most recent recommendations from the ACIP, and encourage greater effort from providers to promote cocooning and protection for the infant (Cantey, et al.).

The effect of antepartum vaccination has been studied in comparison to the effects of pre-pregnancy and post-partum vaccination (Gall, et al., 2011). Severe disease was noted in infants whose mothers received Tdap vaccination pre-pregnancy and post-partum (Cantey, et al., 2014). Pre-pregnancy vaccination, as little as two years prior to conception, resulted in poor protection for the infant, with the suggested cause being the rapid decline in antibody concentrations of diphtheria, pertussis toxin, and fimbriae 2/3 recorded in newborns (Gall, et al.; Munoz, et al., 2014). By comparison, the pre-pregnancy antibody counts of newborns are elevated in contrast to newborns whose mothers received their Tdap vaccination in the postpartum period (Munoz, et al.). These results suggest that maternal Tdap has the potential to prevent neonatal infection with pertussis, and that active maternal antibody transfer elevates newborn antibody levels (Gall, et al.). Additional studies have shown high concentrations of pertussis antibodies throughout the first two months of the infants' life. The highest risk for pertussis infection occurs during this period. These results suggest that through antepartum vaccination in the third trimester of each pregnancy, infants could be protected, thus lowering pertussis associated mortality and morbidity (Munoz, et al.).

Safety of the mother and infant is the paramount concern when recommending third trimester vaccination with the Tdap vaccine (Jimenez-Truque & Edwards, 2014). The Tdap vaccine is composed of a pertussis antigen, purified from the *B. Pertussis* bacterium. These components are inactive. It is not possible for vaccination with Tdap to be the cause of pertussis infection in the vaccinated adult or unborn child, as no live bacteria exists in the vaccination (Silverman, 2014). The reviewed articles found no adverse events following the administration of the Tdap vaccination in the third trimester; the vaccination has an excellent safety record

(Jimenez-Truque & Edwards, 2014; Zheteveva, et al., 2012; Munoz, et al., 2014; Gall, et al., 2011). A comprehensive review spanning greater than 5 years of the VAERS spontaneous reporting system identified no safety concerns related to Tdap vaccine administration in pregnancy (Zheteveva, et al.). Although no adverse events have been reported and Tdap has a good safety record, further studies must be conducted to ensure the safety of mothers and infants following the most recent ACIP recommendations. Further safety studies must include assessment of serologic interference of antepartum Tdap on DTaP and other vaccine antigens administered as part of the childhood vaccination series. While the ACIP recommends Tdap vaccination during each pregnancy, the safety and immunogenicity of repeated doses, potentially received within one to two years of each other, must be studied to ensure the safety of mom and baby, and assess for a potential blunted antibody response (Jimenez-Truque & Edwards, 2014).

The implementation of the ACIP recommendation to vaccinate pregnant women with the Tdap vaccine during the third trimester of each pregnancy presents itself as a healthcare challenge (Goldfarb, et al., 2014). The reported estimate of vaccine uptake for 2012-2013 is between 2.6% - 10% (Chamberlain, et al., 2015). A few barriers to implementation have been identified through a survey of obstetricians-gynecologists and hypothesis (Shea-Lewis, Hill, & Soper, 2011; Goldfarb, et al.). The collected data suggests barriers such as safety concerns, the attitude of the healthcare provider, a perception that immunization is not within the scope of practice, and the financial implications of vaccination (Harriman & Winter, 2014; Goldfarb, et al.). A lack of education regarding the vaccination's benefit to newborns is another suggested barrier. As the ACIP has released several updated recommendations in a short period of time, providers may find it difficult to implement the new recommendations in a timely manner, while

feeling confident in their understanding and the safety of the recommended vaccination (Goldfarb, et al.). Additional information that has not been collected includes how many pregnant women are offered the Tdap vaccination, and what number of these patients accepts vaccination. In regards to financial barriers, Tdap vaccination is a covered benefit of most insurance plans. Regardless, inadequate reimbursement for the ordering, storage, maintenance, and administration of the vaccination does not cover the actual cost to the provider, thus discouraging the provider from promoting and providing the Tdap vaccination in accordance with the ACIP guidelines (Harriman & Winter, 2014). The improvement of pertussis vaccine delivery will require increased efforts by medical providers (Cantey, et al., 2014).

Studies presented to the Infectious Diseases Society of America emphasized a notable increase in vaccine uptake if the patients' physician made the recommendation (Kuehn, 2010). The powerful impact of the healthcare providers' recommendation for Tdap vaccination in the third trimester of pregnancy cannot be overlooked as it improves the likelihood of vaccine receipt (Goldfarb, et al., 2014; Kuehn, 2010). The Pregnancy Risk Assessment Monitoring System (PRAMS) provides estimates regarding Tdap uptake; a median percentage of 55.7% was reported in 2011 of women with live births who received Tdap before, during, or after pregnancy. Of the accounted for Tdap vaccinations, less than 10% of the reported immunizations were provided during a pregnancy (Munoz, 2016). In 2012, data gathered from the California Vaccine Safety Datalink indicated vaccination coverage of only 19.5%. In 2013, the year following the updated ACIP recommendation, a survey conducted in California reported 25% vaccine uptake during pregnancy (Winter, Glaser, Watt, & Harriman, 2014). Efforts to improve vaccine uptake can include the initiation of education programs for medical and administrative

staff. With greater education, understanding, and vaccine promotion the uptake of the Tdap vaccination by pregnant women between the period of 27 and 36 weeks of gestation can be greatly improved (Goldfarb, et al.). Obstetric offices as the primary providers to pregnant females are the first source for information regarding current programs for vaccine promotion. Surveys of obstetric staff could also illustrate the level of education and understanding regarding the benefits of Tdap immunization during pregnancy (Kuehn, 2010; Harriman & Winter, 2014; Goldfarb, et al.).

This presentation of literature offers only one randomized clinical trial (RCT). The absence of large scale RCTs limits the researchers' ability to derive statistically significant results. The reviewed literature is mostly composed of observational studies and reviews of clinical data. Although all the information presented is valuable, gaps in knowledge related to the administration of the Tdap vaccination in the third trimester of pregnancy exist. Beginning with barriers to implementation of the ACIP recommendation, uptake of the vaccination and factors affecting the decision to become immunized or not. Further studies must also be conducted on the noted blunted antibody response in infants born to mothers who were vaccinated in pregnancy. Although the antibody response of infants appears to level out at the completion of the DTaP immunization series, better data is required for complete understanding of the antibody response. No data has been collected on the effect of antibody response of other vaccinations in the childhood series related to maternal Tdap immunization. Finally, although Tdap has a strong safety record, the vaccination of pregnant females in each occurring pregnancy must be closely studied, as multiple consecutive pregnancies could put the mother at greater risk of side effects from the Tdap immunization.

THEORETICAL FRAMEWORK

Health Belief Model

The Health Belief Model (HBM) predicts the actions of a population presented with options regarding disease prevention and screening tests for early disease identification. In the early 1950s a group of social psychologists at the U.S. Public Health Service developed the HBM in response to the reluctance of the population to undergo screening tests for tuberculosis, cervical cancer, and the administration of immunizations (Pender, N., Murdaugh, C., & Parsons, M.A., 2011; Janz, N. & Becker, M., 1984). The HBM predicts health behavior based on the perceived threat, the perceived benefit of action, and the barriers to action. The original model, Figure 1, presented four dimensions: *perceived susceptibility*, *perceived severity*, *perceived benefits*, and *perceived barriers* (Janz & Becker, 1984). Additional dimensions such as *self-efficacy*, *cue to action*, and the inclusion of *demographic variables* have elaborated on the HBM to assist in the prediction of health actions (Janz & Becker, 1984).

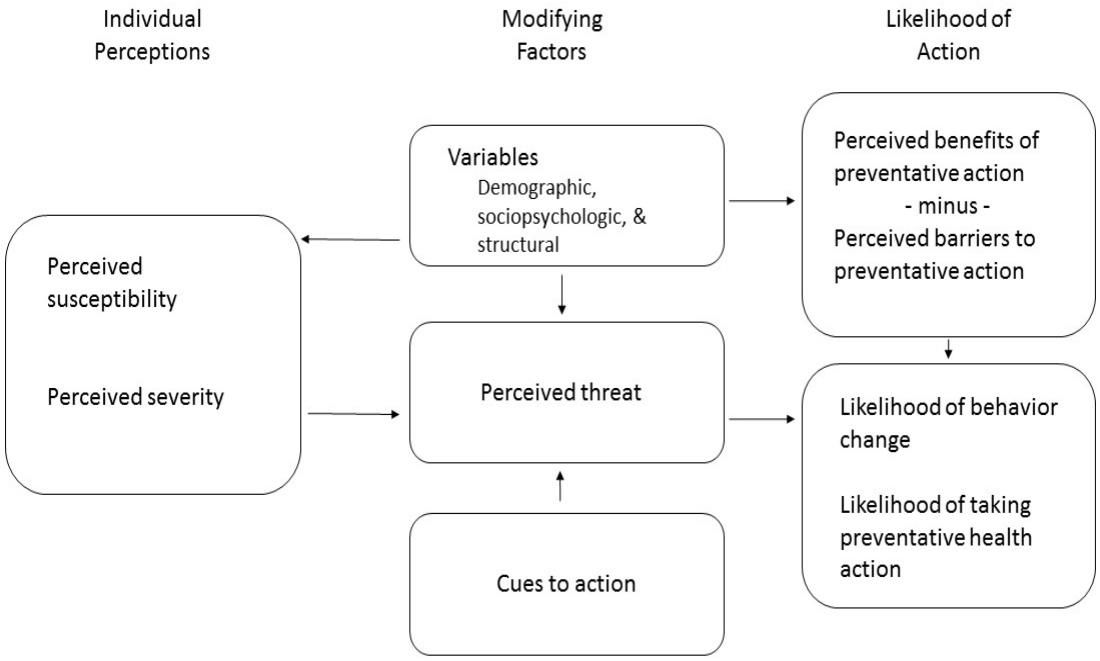


FIGURE 1. Health Belief Model. *(Recreated from Janz & Becker, 1984, & Pender, Merdaugh, & Parsons, 2011.)*

Health Belief Model Dimensions

Perceived susceptibility is an individuals' subjective perception of the risk of contracting an illness, or experiencing an injury or disease. Each individual experiences the perceived vulnerability or chance of occurrence singularly, creating a wide variation among the population (Janz & Becker, 1984; Pender, et al., 2011). The perceived susceptibility refers to the parents' assumption of risk or likelihood that their newborn will be in contact with or contract pertussis. If the parents have never heard of pertussis, then the perceived susceptibility may be low.

However, if the parents have personal experience with a child contracting pertussis their perceived susceptibility will likely be high. The HBM compiles these experiences, coupled with the other dimensions of the model, in order to predict the health behavior or action that might be taken.

Perceived severity is the subjective measure of seriousness related to an illness or injury. The individual evaluation of severity includes the consideration of medical consequences, such as death, and social consequences, such as the effect the illness may have on work or family life (Janz & Becker, 1984). Perceived severity in the context of pertussis is the belief of the parent regarding the possible effect of the newborn contracting pertussis. For instance, a parent may regard the infection of pertussis as not significantly severe, perhaps rationalizing the illness as 'just a cough'. The opposing understanding of the severity of pertussis infection in the infant would measure the consequence of the death of the infant, the emotional consequence of the loss of the infant, and the social consequences related to the death of the infant in their degree of perceived severity. One study reportedly found a strong association between the perception of pertussis severity for the infant and the parents' intention to receive the Tdap vaccination in the antepartum period (Chamberlain, et al., 2015).

Perceived benefits refer to the belief in the effectiveness of the recommended health action. If the weight of the perceived susceptibility and perceived severity justify to the individual the need to take preventative action then the recommended healthcare options will be considered, and weighed by their perceived benefit. Benefit refers to the success of the action in reducing the threat of the disease or illness (Janz & Becker, 1984). In relation to the preventative healthcare action of receiving the Tdap vaccination in the third trimester of pregnancy, the

mother would need to believe in the effectiveness of the vaccination, as well as the evidence regarding the importance of the vaccine timing during pregnancy. Vaccine effectiveness has been estimated at 93% by a recent case-control study for the protection offered via the Tdap vaccination to newborn infants (Vilajeliu, Garcia-Basteiro, & Bayas, 2015). If the mother does not perceive the benefit of receiving the vaccination in pregnancy to be greater than her perceived risk, then she would be unlikely to follow the recommended vaccine schedule. In this case the mother must also measure the perceived benefit of the Tdap vaccination to her unborn baby.

Perceived barriers of a health action can include cost, perception of risk, experience of the action, convenience, and time-consumption. An individual weighs the perceived benefits of a preventative health action against the potential negative aspects of the recommended health action. The individuals' personal experience predicts the likelihood of adopting the preventative healthcare action (Janz & Becker, 1984). There are many theoretical barriers to adoption of the health action of receiving the Tdap vaccination in the third trimester of pregnancy. Perceived barriers may include the possible personal expense of receiving the vaccination, the inconvenience of obtaining the vaccination if not administered by the obstetric provider, the time required in waiting for the vaccination or seeking out a location that carries and administers the vaccine and the unpleasant sensation of receiving the injection. Specifically, in relation to the administration of Tdap in pregnancy, the barrier of safety, or perception of risk is a significant decisive factor for the mother, as they must consider their unborn child. The compiled scientific evidence agrees, the Tdap vaccination is safe for the pregnant female and the unborn baby (Vilajeliu, et al., 2015). A 2015 observational study comparing infant outcomes, found no

evidence of increased adverse events in the infant whose mother received the Tdap vaccination in pregnancy when compared with baseline population rates (Walls, Graham, Petousis-Harris, Hill, & Austin, 2015).

Self-efficacy relates to an individuals' confidence in their ability to execute the recommended preventative health action. This dimension could be considered as a component of perceived barriers to successful action (Pender, et al., 2011). The dimension of self-efficacy applies to preventative health behaviors such as eating healthy or quitting smoking, actions that require dedication over the course of time to achieve or maintain the benefit. Self-efficacy would not typically be applied to the action of receiving a vaccination. One possible exception is if the individual had a fear of injection; this fear would present itself as a barrier to accomplishing the recommended health action.

Cues to action are triggers for behavior change or adoption of a health action. These events can be external, such as social media influence, or internal, such as the presentation of symptoms (Janz & Becker, 1984). In reference to Tdap in pregnancy, cues to action can include mass media campaigns for the prevention of pertussis, advice from other pregnant mothers, obstetrician recommendation, the presence of the illness in a family member or friend, and newspaper, magazine, or social media articles (Pender, et al., 2011). The occurrence of pregnancy itself is a cue to action for the administration of Tdap.

Demographic variables such as age, sex, race, and ethnicity may affect the individuals' perception. As the dimensions of the HBM are based on the personal subjective perception of an illness or event, demographic variables should be considered (Pender, et al., 2011; Janz & Becker, 1984). In the proposed survey of pregnant females regarding the reception of Tdap

immunization in pregnancy, demographic variables will be considered, as cultural and generational perceptions of vaccinations are likely to exist.

Summary

The Health Belief Model (HBM) was an appropriate model to serve as a framework for the study of Tdap administration in the third trimester of pregnancy. The classic rendition of the HBM was developed with the intention of evaluating and predicting programs of vaccination against infectious disease (Janz & Becker, 2011). In this study the HBM is used to illustrate the perception of mothers faced with the choice of adopting the preventative health behavior of following the ACIP recommendation for Tdap administration in the third trimester of each occurring pregnancy. Rates of Tdap vaccination uptake during the third trimester of pregnancy have been low in the reports cited. This project will primarily focus on the perceived barriers to Tdap administration in the third trimester of pregnancy. The objective is to administer the survey to women who have experienced a pregnancy after the most recent ACIP Tdap recommendation. The survey will identify what number of mothers received the Tdap vaccination in the third trimester of pregnancy, in each occurring pregnancy. The perceived susceptibility, perceived severity, and perceived benefits of Tdap administration will not be directly assessed, however, clarity regarding these aspects of the HBM may be presented in the course of the study. Assessment of cue to action and self-efficacy will not be a component of the study. Demographic variables will be considered to identify an accurate rate of Tdap uptake during pregnancy for the identified population. The results of the study are expected to provide detailed information regarding variations in Tdap receipt over identified demographic variables. Moving forward this

information may inspire vaccine promotion programs, the developments of educational materials directed at a specific demographic, or encourage the continuation of current programs.

METHODS

Introduction

This section details methods used to describe prescription and uptake of Tdap immunization during the third trimester of pregnancy as mandated by the Advisory Committee on Immunization Practices (2012). The present study intended to uncover information that may lead to the development of new interventions designed to reduce barriers and improve treatment practices. The study addressed uptake of the vaccination, availability of the vaccination, refusal of the vaccination, and investigated the potential impact of information shared regarding medical recommendations, benefits and risks. The primary research question was: what proportions of suburban Texas women were offered and received the Tdap vaccination during the third trimester of pregnancy?

Design

To describe treatment practices and uptake of Tdap vaccine, this study uses a cross-sectional descriptive survey design. Outcomes research encompasses a global evaluation of nursing and health care services, in this case assessing factors leading to decision-making regarding the administration of Tdap in pregnancy (Polit & Beck, 2008). The purpose of survey research is to gather information regarding prevalence, distribution, and interrelations of variables within a population (Polit & Beck, 2008). Surveys obtain information through self-reporting. In this study, the survey questionnaire was conducted in an online format.

Population and Sample

The population sample was middle-class suburban mothers living in Texas who were recruited from a fitness group, Baby Boot Camp Katy (BBCK). Baby Boot Camp (BBC) is a group supporting fitness-based activities that can be done with children in attendance. The group promotes a supportive atmosphere for all aspects of motherhood, nutrition, and fitness. Kristen Horler founded Baby Boot Camp (BBC) in 2001. Currently there are approximately 85 active Baby Boot Camp franchises across the United States. In Texas alone there are nine separately owned franchises, five of which operate in close proximity to Houston, Texas. Each Baby Boot Camp group is linked via social media, specifically Facebook. The Facebook website and application enables public or private groups' shared calendars, commentary, and discussion over the Internet. A distinct Facebook group with validated membership exists for the Baby Boot Camp Katy franchise (Retrieved from: https://www.facebook.com/groups/591187397612610/). The survey link is presented to the Baby Boot Camp Katy (BBCK) population through a private social media Facebook group composed of 142 members, with permission from the local group owner. The survey sample is composed of members of the BBCK group who volunteer to complete the survey. Prior to providing the survey to the members of BBCK, the study received approval from the university of Arizona Institutional Review Board (IRB).

Instrumentation

The instrument of choice for this study was a survey. The purpose of the survey was to gather individual information regarding knowledge, attitudes, beliefs, and feelings (LoBiondo-Wood & Haber, 2014). The online application selected for this study is Qualtrics (Qualtrics, 2017). This survey service is provided free through the University of Arizona in association with

Qualtrics. The application allows for complete customization, including providing consent forms prior to opening the survey, privacy settings such as password protection, and an unlimited number of survey participants. Survey construction through Qualtrics preserves individual autonomy, maintained confidentiality, and upheld privacy standards for survey participants. Transport Layer Security (TLS) encryption (also known as HTTPS) is utilized by Qualtrics for the protection of all transmitted data. Additionally, secure data centers eliminated the need for data cloud utilization. Qualtrics security practices exceed the Health Information Technology for Economic and Clinical Health Act requirement for HIPPA rules intended to protect information.

The presented questions require answer choices on a Likert scale. Likert scales provide responses ranging from strongly agree to strongly disagree, with five selection options (LoBiondo-Wood & Haber, 2014). The use of the Likert scale allows for data collection to be quantitative, that is information collected in discrete numeric form. This allows for quantitative analysis, or the manipulation of the data through statistical procedures to describe phenomena or relationships in the results (Polit & Beck, 2008). In the survey, the first six questions will provide responses on a Likert scale; with options ranging from strongly agree with the numeric value of one, to strongly disagree with the numeric value of five.

The survey questions were constructed specifically for this study and developed consistent with the theoretical framework of the study, the Health Belief Model (HBM). Survey questions were formed after extensive literature review and with consideration of the HBM. The proposed questions reflect the four original dimensions of the HBM: *perceived susceptibility, perceived severity, perceived benefits, and perceived barriers* (Janz & Becker, 1984). Face validity was established through consultation with three nurse practitioners that are experts in

Pediatrics and Women's Health. The HBM framework has previously been used to predict health behaviors in various clinical settings. Prediction of health behavior is achieved through the identification of psychological factors, such as the individuals' subjective belief of risk, harm, benefit, and barrier (Fridman, et al., 2011). The HBM applies to complex preventative and sick-role health behaviors. The dimensions of the HBM were formulated from social psychology theory, emphasizing cognitive factors focused on goal attainment (Hall, 2011).

The administration of the Tdap vaccination in the third trimester of pregnancy is an indirect preventative action with the goal of providing protection from pertussis infection in the newborn. Perceived susceptibility addresses the subjective risk related to a specific condition in a determined time period (Champion, 1984). An example of questions addressing the dimension of perceived susceptibility include, "I think I have a risk of acquiring 'swine flu'" and "I think pregnant women have a higher risk of getting 'swine flu' than non-pregnant women" (Fridman, et al., 2011, p. S125). Applying the dimension of perceived susceptibility, the corresponding question in the presented survey is, 'I believe my baby (less than 1-year-old) is or was at risk of becoming infected with pertussis/whooping cough'. Following, the dimension of perceived severity is described as the degree of personal threat or harmful consequence of the condition (Champion, 1984). Examples of questions assessing perceived severity include "I am afraid that I can be very sick", and "'Swine flu' is a serious disease" (Fridman, et al., p. S125). This Tdap survey presents one question assessing perceived severity, 'I believe pertussis/whooping cough can result in severe illness in an infant (less than 1-year-old)'.

The HBM dimension of perceived benefit focuses on the belief in the effectiveness of the health intervention. The beliefs in the interventions ability to prevent or detect disease, maintain

health, or cure or lessen consequences of an illness (Champion, 1984). An example question regarding perceived benefit is, “I think that the shot for ‘swine flu’ protects me” (Fridman, et al., 2011, p. S125). Considering the dimension of perceived benefit, two questions are proposed in the Tdap survey. ‘I believe the benefits of the Tdap vaccination outweigh the risks’ and ‘I believe the Tdap vaccination administered in the third trimester of pregnancy is beneficial and effective in preventing pertussis/whooping cough in the newborn’. The final assessed dimension of perceived barriers can be described as the negative components of an intervention or behavior. Negative aspects can include but are not limited to monetary consequences, side effects, inconvenience, or pain (Champion, 1984). Example questionnaire statements assessing perceived barriers include, “I think that ‘swine flu’ vaccine is harmful for my baby”, “A ‘swine flu’ shot has unpleasant side-effects for me”, and “I am usually against getting flu shots” (Fridman, et al., p. S125). The presented Tdap survey includes two questions assessing perceived barriers. ‘I believe that there is little to no risk to receiving the Tdap vaccination in the third trimester of pregnancy’ and ‘I believe adequate information was provided to me regarding the Tdap vaccination in pregnancy’.

The last two statements of the survey ‘I was offered the Tdap vaccination in the third trimester of pregnancy’ and ‘I received the Tdap vaccination in the third trimester of pregnancy’, have three answer choices, yes, no, and unsure.

TABLE 1. *Questionnaire*

Demographic Survey
1. How old were you at delivery? (Answer: open ended short answer response)
2. How old are you now?

(Answer: open ended short answer response)
3. What is the highest degree or diploma you have completed? If currently enrolled, highest degree received. (Answers: some high school/no diploma, high school graduate/diploma/equivalent, some college credit/no degree, trade/technical/vocational training, associate's degree, bachelor's degree, master's degree, professional degree, doctoral degree, other)
4. Please specify your ethnicity. (Answers: white, Hispanic or Latino, black or African American, Native American or American Indian, Asian/Pacific Islander, other)
5. What is your marital status? (Answers: single/never married, married/domestic partnership, widowed, divorced, separated, other)
6.Current employment status: (Answers: employed for wages, self-employed, out of work and looking for work, out of work and not currently looking for work, a homemaker, a student, military, retired, unable to work, other)

Tdap Vaccine in Pregnancy
1. I believe my baby (less than 1-year-old) is or was at risk of becoming infected with pertussis/whooping cough. (Answers: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4, Strongly Disagree = 5)
2. I believe pertussis/whooping cough can result in severe illness in an infant (less than 1-year-old). (Answers: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4, Strongly Disagree = 5)
3. I believe the benefits of the Tdap vaccination outweigh the risks. (Answers: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4, Strongly Disagree = 5)
4. I believe the Tdap vaccination administered in the third trimester of pregnancy is beneficial and effective in preventing pertussis/whooping cough in the newborn. (Answers: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4, Strongly Disagree = 5)
5. I believe that there is little to no risk to receiving the Tdap vaccination in the third trimester of pregnancy. (Answers: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4, Strongly Disagree = 5)
6. I believe adequate information was provided to me regarding the Tdap vaccination in pregnancy. (Answers: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4, Strongly Disagree = 5)
7. I was offered the Tdap vaccination in the third trimester of pregnancy. (Answers: Yes, No, Unsure)

8. I received the Tdap vaccination in the third trimester of pregnancy. (Answers: Yes, No, Unsure)

Data Collection

Following approval from the Institutional Review Board (IRB), a verbal invitation and study description was presented to the members of Baby Boot Camp Katy during a regularly scheduled exercise session. After initial recruitment, the survey was made available to the Baby Boot Camp Katy (BBCK) members via the private Facebook group. The day that the survey opened for BBCK member's participation a disclosure statement thanking members for agreeing to participate was made available to the group. The statement informed the members that their participation in the study may increase understanding of the factors associated with Tdap prescription and use in the third trimester of pregnancy. The survey was available for completion for a two-week period. During these two-weeks, one verbal reminder was given during BBCK classes. It is expected that convenience of the survey, minimizing the time needed for participation and a verbal reminder increased the number of completed surveys. As the survey is available through the social media platform Facebook, two reminders via this interface were provided during the two-week period. The first reminder was on day eight of the surveys available two-week period, and the final reminder was 24 hours prior to the designated end time.

Once the two-week time frame for survey completion closed, assessment of the sample size determined how many members of BBCK participated in the study. If the number of participants was less than 28, approximately 20% of the BBCK group, then the survey would have been extended for another two-week period with expanded recruitment efforts, including looking for alternative recruitment sites. There are five other Baby Boot Camp groups in the

Houston area. Each Baby Boot Camp group is individually owned, expanded recruitment would have required permission from each site. If the group owner approved the study for presentation to the group then the groups private Facebook page would be used to present the survey, provide reminders during the two-week open period, and thank the group for their time.

Once the survey closed to all participation, the data was available to download from Qualtrics. Qualtrics uses Transport Layer Security encryption for all communicated data. Data stored through Qualtrics is maintained in secure data centers. Both data as numeric values and data as choice text is available for download to a password protected personal computer. File types for download include SPSS and CSV file types, eliminating the potential for human error in dictation of the data. The downloaded data was analyzed with the purpose of answering research questions directly related to this study. Upon completion of the study, the downloaded data was deleted. At the completion of the practice inquiry project the Qualtrics survey was closed, data collected will be stored in a secure Qualtrics data center for a period of six years as per IRB storage and retention regulations. After this period the data will be destroyed.

Data Analysis

Analysis of the collected data characterized the variables, identified associations between variables and variable groupings, and then tested for relationships between the survey questions reflecting the dimensions of the health belief model and actual uptake of the Tdap vaccination. The null hypothesis was that there is no relationship between participant responses to questions one through six, assessing the dimensions of the health belief model, and responses to question eight, ‘I received the Tdap vaccination during the third trimester of pregnancy’. A chi-squared test was performed on each HBM variable and demographic variable in relation to both question

seven ‘I was offered the Tdap vaccination in the third trimester of pregnancy’, and question eight, ‘I received the Tdap vaccination during the third trimester of pregnancy’. For Likert and categorical variables descriptive statistics and measures of central tendency described the sample’s responses to items on the questionnaire (LoBiondo-Wood & Haber, 2014). Each item in the survey referencing the health belief model, questions one through six, were reported using frequencies, and the six demographic variables were analyzed using descriptive statistics.

The measure of central tendency, mode, determines the most frequently occurring result in a distribution of data. Mode can be applied to categorical data, such as education level, and ordinal data (Polit & Beck, 2008). The data collected using Likert scales is ordinal level data, the responses were ordered from strongly agree to strongly disagree. Ordinal level data can also be described by the median, a measure of the distribution center. The median does not incorporate the quantitative values and thus is not affected by outlying values in the distribution (Polit & Beck, 2008). Frequency distributions, often presented graphically, provide a visual representation of the data. The shape of the frequency distribution may reveal characteristics of the data, such as having a bimodal rather than a single central tendency (Polit & Beck, 2008). These statistical analyses applied to questions such as ‘I believe the benefits of Tdap vaccination outweigh the risks’ described the data sets, illustrating a distribution of the data results.

Statistical tests can also examine correlation, or the degree of association between variables. The Pearson’s product moment correlation coefficient can illustrate a negative correlation, positive correlation, or near-zero association between the variables (LoBiondo-Wood & Haber, 2014; Polit & Beck, 2008). Correlation can indicate the degree of relationship between survey questions related to the HBM and if the Tdap was offered or if the Tdap was received.

Answering the research question: Do the results of the survey questions referencing the HBM predict, or have a relationship with the results of question eight, 'I received the Tdap vaccination during the third trimester of pregnancy'. The null hypothesis expects there to be a near-zero correlation. The Pearson product moment correlation coefficient assesses the relationship between the resulting score from the HBM variables and question eight, regarding receipt of the Tdap vaccination. Statistical analysis reveals associations between demographics, such as age, marital status, and education, identifying relationships between these factors and survey questions.

TABLE 2: *Research Questions and Analysis*.

Research Question	Analysis	Purpose
Is there a relationship between each survey question reflecting a dimension of the HBM (questions one through six) and question eight (regarding Tdap receipt)?	Chi-squared test on each variable (questions one through six) in combination with question eight	To determine if the response to a question representing a dimension of the HMB (such as perceived severity) has a statistically significant relationship with the respondents' choice regarding Tdap receipt.
Do the results of the survey questions referencing the HBM predict, or have a relationship with the results of question eight, regarding Tdap receipt?	Person's Product Moment Correlation Coefficient	Utilizing the survey as a scored instrument to determine if a statistically significant relationship between answers to the HBM dimension questions results in a predictable choice regarding Tdap vaccination receipt.

Summary

The purpose of this study was to understand the current culture regarding receipt of the Tdap vaccination in pregnancy from the perspective of mothers. This study used a questionnaire guided by the Health Belief Model framework. Through analysis of survey responses, perceived susceptibility to pertussis, severity of pertussis, benefit of vaccination, and risk of vaccination were assessed. Statistical analysis of the data identified relationships between population characteristics and Tdap vaccination uptake.

RESULTS

This section presents results as sample demographics followed by descriptive statistics for questions one through six of the survey followed by inferential test results that portrayed relationships between the items of the survey and question eight, and Tdap vaccine uptake in the third trimester of pregnancy.

Sample Demographics

Fifty participants were recruited for the study. However, six were excluded because they did not complete the online survey leaving a total sample size of 44. Current age range for the sample was 27 to 40 years with a mean age of 32.98 +/-3.14 years. At delivery, participant ages ranged from 25 to 36 years, with a mean age of 30.2 +/- 2.8. See Table three for sample demographic details.

TABLE 3: *Demographic Details*

		N = 44
Ethnicity	White	37
	Hispanic or Latino	6

	Asian	1
Education	Some college credit/no degree	1
	Associate's degree	1
	Bachelor's degree	25
	Master's degree	16
	Doctoral degree	1
Employment	Homemaker	29
	Employed for wages	8
	Self-employed	5
	Out of work & looking for work	1
	Student	1
Relationship	Married/domestic partnership	43
	Single/never married	1

Responses to Items 1-6 on the Questionnaire

Health Belief Model elements were represented by questions one through six of the survey questionnaire. Each had a five-level Likert scale response profile, or ordinal level data. Table four details response frequencies.

TABLE 4. *Response Frequencies for Questions 1-6 on the Questionnaire*

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
HBMQ1 Risk of Infection	9%	23%	20%	36%	11%
HBMQ2 Severe Illness	0%	0%	5%	32%	64%

HBMQ3 Benefit Greater than Risk	2.5%	5%	2.5%	34%	57%
HBMQ4 Tdap Vaccine Beneficial	5%	2.5%	7.5%	50%	36%
HBMQ5 Low Risk	7.5%	2.5%	18%	50%	23%
HBMQ6 Adequate Information	7.5%	16%	14%	43%	20%

Responses to questions seven and eight are detailed in Table five. Only three respondents did not answer identically to both questions, e.g. *yes* and *yes*, *no* and *no*. These three participants reported being offered the Tdap vaccination but not receiving it. No respondent reported not being offered the Tdap vaccination but receiving it.

TABLE 5: *Offered and Received Question Analysis*

	YES	NO
HBMQ7 Offered Tdap Vaccination	82%	16%
HBMQ8 Received Tdap Vaccination	75%	23%

Relationship of Questionnaire Item 1-6 and Question 8 (Receiving Tdap Vaccine)

To determine the relationship between each survey question reflecting a dimension of the HBM and Question eight (Tdap receipt) chi-squared tests were conducted. See Table six for the chi-squared value, p-value, and either support or rejection of the null hypothesis.

TABLE 6: *Chi-Squared Results Comparing HBM Questions 1-6 to Question 8*

	X-Squared	P-Value	Null Hypothesis
HBM Q1 Risk of Infection	5.05	0.75	Accept Null
HBM Q2 Severity of Illness	2.00	0.73	Accept Null
HBM Q3 Benefit Greater than Risk	12.85	0.12	Accept Null
HBM Q4 Tdap Vaccination Beneficial	16.38	0.04	Reject Null
HBM Q5 Low Risk of Vaccination	18.29	0.05	Approaches Rejecting Null
HBM Q6 Adequate Information	10.64	0.22	Accept Null

Chi-squared analysis tested for a relationship between question seven of the HBM survey, 'I was offered the Tdap vaccination in the third trimester of pregnancy', and question eight, 'I received the Tdap vaccination in the third trimester of pregnancy'. The resulting p-value <0.05 indicates for rejection of the null hypothesis and the presence of a statistically significant relationship between the two variables.

TABLE 7: *Pearson's Product Moment Correlation Coefficient Comparing HBM Questions 1-6 to HBM Question 8.*

	HBM Question 8 Pearsons Product Moment Correlation
HBM Q1 Risk of infection	0.20
HBM Q2 Severity of Illness.	0.16

HBM Q3 Benefit Greater than Risk.	0.45
HBM Q4 Tdap Vaccination Beneficial.	0.52
HBM Q5 Love Risk of Vaccination.	0.38
HBM Q6 Adequate Information.	0.22

Pearson's Product Moment Correlation Coeffients depicted the strength of the relationship of questions one through six and question eight of the survey. See Table seven for details. Notice the strongest relationships were between the belief that Tdap is beneficial and Tdap uptake followed by the belief that the benefit is greater than the risk and Tdap uptake.

DISCUSSION

The discussion begins with the sample size and sample demographics, followed by a discussion of the questionnaire items numbers 1 through 6 and their relationship with question 8. The statistical analysis using Chi-Squared and the Pearson's Product Moment Correlation Coefficient will be discussed before reviewing the strengths and limitation of the study and recommendations for future research.

Sample Size

Prior to participant recruitment, sample size goal was set at 27, which was 20% of the target group. However, 50 participants actually volunteered. Six participants were excluded because they failed to complete the online survey. This greater than anticipated participant response may be due to a number of factors including the education level of the participants, the minimal time commitment required to complete the survey, or the accessibility of the survey online through the Baby Boot Camp Katy (BBCK) private Facebook group. Additionally, the group's foundation is health and wellness, which may have motivated women to volunteer and complete data collection.

The use of the online survey service Qualtrics was simple and effective. The survey was created and delivered online. Results were compiled and accessed through the Qualtrics website. No issues emerged in regards to the survey software, ability to access and utilize the survey, or collect data from the survey. Although some participants failed to complete the survey for unknown reasons, these participants' incomplete submissions were easily identified and removed prior to data analysis.

Sample Demographics

The mean age at delivery for the present sample was 30.2 years +/- 2.8 with a range of 25 to 36 years. A Similar study that investigated Tdap vaccination in the childbearing years reported a mean age range of 28.1 +/- 6.7 (Munoz et al., 2014). In relation to the average age of childbearing women in the United States, the Baby Boot Camp Katy (BBCK) survey sample reflects a slightly older population. The mature age of the sample may reflect the education status

of the participants, their interest in health, or the culture of the region among white, married or partnered women.

The present sample had a high level of education with almost all completing at minimum a bachelor's degree. The population of Baby Boot Camp (BBC) is attractive to women with higher levels of education, who are engaged in child bearing and child rearing, with an interest in health and fitness. It is notable that although the sample reflects a high level of education, it also indicates that the majority of the participants are homemakers. Data from the Pew Research Center gathered in 2013 found that 49% of their sample of stay-at-home mothers held a High School Diploma or less (Cohn & Caumont, 2014). This data drastically differs from the Baby Boot Camp Katy sample; however, the target population of the study was a group focusing on health and fitness activities participated in with children present, which may explain some of the demographics findings.

Results of the Questionnaire

Individual survey question results indicated the degree of support, such as 'agree' or 'strongly agree' for questions one through six. There was a notable shift in the survey responses between Health Belief Model question four (HBM Q4) and HBM question five (HBM Q5). In response to question four assessing the perceived benefit of the Tdap vaccination, responses were typically positive. Question five assessed the perceived barrier presented by potential risk of the vaccine. The responses to question five shift notably towards 'strongly disagreed' and 'neither agreed nor disagreed'. This occurrence reflects a factor outlined regarding the hypothetical relationship of the HBM to taking a health-related action. Rosenstock, et. Al. stated "The belief that following a particular health recommendation would be beneficial in reducing the perceived

threat, and at a subjectively-acceptable cost" (Rosenstock et al., 1988, p. 177). Cost is equivalent to the perceived risk of the vaccination. In order for the preventative health action to be taken the perceived benefit of the action must outweigh the perceived risk (Janz & Becker, 1984). This factor as outlined by the HBM is supported in the responses by the present sample to the Tdap survey.

Question six of the HBM survey assessed a perceived barrier to Tdap uptake. The question details the respondents' perception of the information provided to them regarding vaccination in the third trimester of pregnancy. Although the majority of the responses were favorable, 36% of the survey participants selected the answer choices 'neither agree nor disagree', 'disagree' and 'strongly disagree'. These results may be useful to providers in suggesting that more information be provided to expectant mothers regarding the recommendations for the Tdap vaccination in the third trimester of pregnancy. It is possible that the desire for more information may be reflective of the population studied. Present study participants were likely interested in health and fitness activities and the majority have a high level of education.

As expected there was a high level of agreement between question seven and question eight assessing whether the participant was offered the Tdap vaccination during pregnancy and whether the participant received the Tdap vaccination during pregnancy. This information is suggestive of the positive impact a health care provider, including nurse practitioners, can have on a patient by offering the vaccine with explanations of benefit versus risk. The number of participants who reported being offered the vaccination but did not receive the vaccination was three, or less than 7% of the sample. Prior evidence has suggested that patients of providers who

suggest the Tdap vaccination are more than three times as likely to opt to receive the Tdap vaccination in the third trimester of pregnancy, in contrast to those who refuse the vaccination (Kuehn, 2010). The present study did not include reasons for not accepting the vaccination offered. It would be important in future studies to include such questions, as that could be a springboard for designing interventions that bolster Tdap uptake in the third trimester of pregnancy.

The sample of this study reported a 75% uptake of the Tdap vaccination in the third trimester of pregnancy. This is a positive rate of uptake for the Tdap vaccination during the antepartum period and is significantly higher than the 44% intention to receive Tdap rate found by Chamberland and colleagues (2015). Shakib and colleagues (2013) analyzed data from 162,448 pregnancies from May 2005 to August 2009 and found a low .08% Tdap uptake. Of the 138 immunized women, only 20% received the Tdap vaccination during the third trimester of their pregnancy. The high rate of uptake within the present study sample may be related to the higher education level of the participants, the populations invested interest in health and fitness, or the local providers offering of the Tdap vaccination in the third trimester of pregnancy, as reported by 82% of the sample.

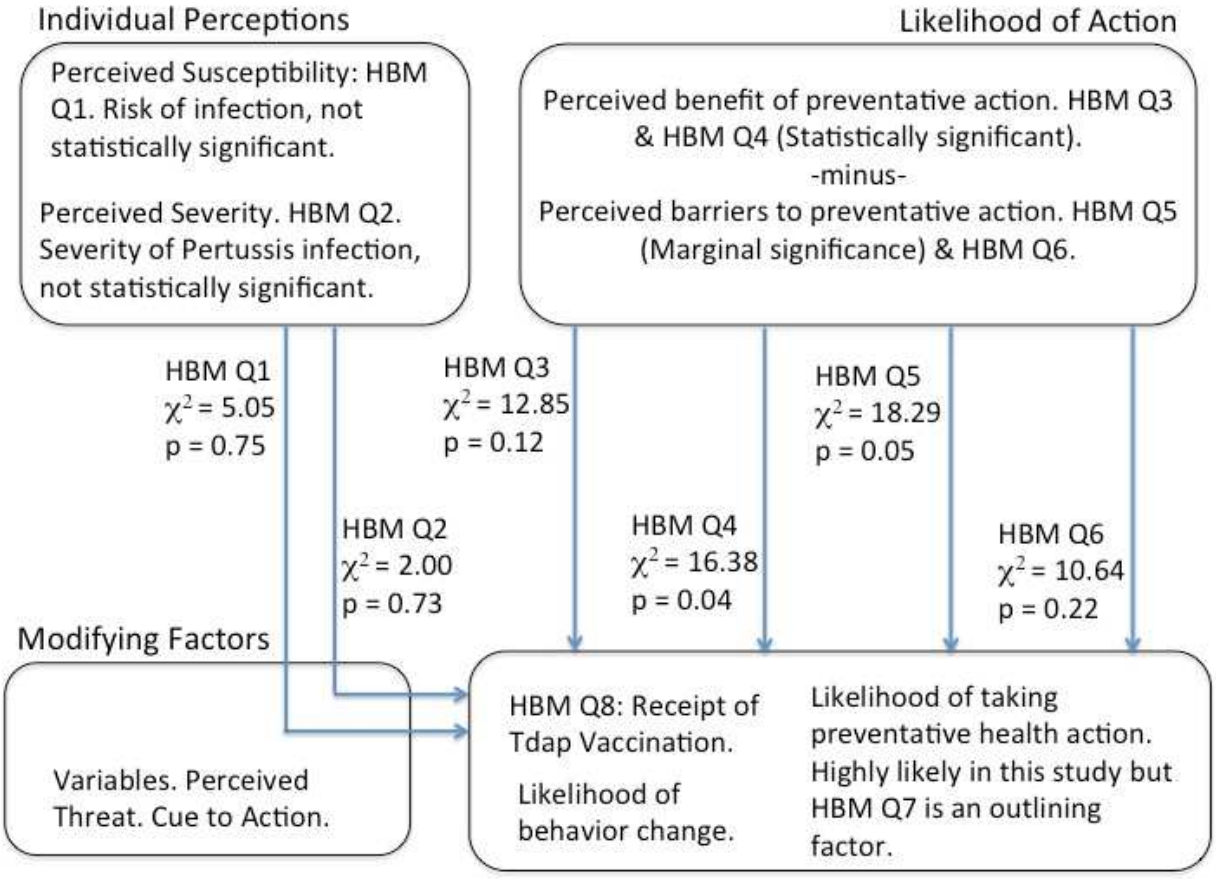
Chi-Squared Analysis

Of the six HBM questions included in the study, the results of the chi-squared analysis suggest that the majority of the measured dimensions through this survey cannot predict a health behavior, in this case receipt of the Tdap vaccination. Health Belief Model question four was the only statistically significant correlation indicating rejection of the null hypothesis. Unsurprisingly question four, which proposed to measure the perceived benefit of the Tdap

vaccination, signified that the participants who believed in the benefit of the vaccination received the vaccination. HBM question five was the only other chi-squared statistic suggestive of significance. Question five intended to measure the perceived barrier of risk of the Tdap vaccination, in this case it is understood that the sample was impacted by their perception of risk of vaccination during the third trimester of pregnancy. It is consistent with the educational level and health interests of present participants who felt there was little risk to receiving the vaccination did trend towards getting vaccinated.

The Health Belief Model as the theoretical framework for the development of the questionnaire regarding receiving the Tdap vaccination in the third trimester of pregnancy as a preventative health action was appropriate. The only aspect of the HBM that indicated significance was perceived benefit. The perceived barrier of risk of vaccination reported a result suggesting significance. Other aspects of the HBM questionnaire did not demonstrate significance to uptake of the Tdap vaccination. There may be several reasons why the other elements of the HBM did not correlate with Tdap receipt. The small sample size acquired could limit the results; the presented questions may not accurately measure a factor of the HBM, and other variables that were not assessed may alter the interpretation of the data.

Figure 2: Health Belief Model with Survey Information Included



Correlation

The Pearson's Product Moment Correlation reflected the strength of the association between each individual question in the HBM survey to question eight. The strongest association was between question four, which assessed perceived benefit of the Tdap vaccination and question eight, actual Tdap receipt. It is understandable that the participants who held strong feelings of agreement for the benefit and effectiveness of the Tdap vaccination would then decide to receive the vaccination. Question three also assessed perceived benefit and suggests a

strong correlation with the response to question eight. This result demonstrates that participants who believe that the benefit of the Tdap vaccination outweigh the risks of the Tdap vaccination will then opt to receive the Tdap vaccination. The correlation between HBM questions two and question eight was weak. Participants did not agree with the severity of the pertussis infection in the infant population. This point may be an important factor for practitioners to include when providing education to patients regarding the Tdap vaccination and Pertussis.

Strengths

This project has a number of strengths. First, recruitment was highly effective, such that more participants were recruited than anticipated. The 44 completed surveys far exceeded the study aim of 20% of the target population, or 27 completed surveys. In addition; only 12% (n=6) of the participants did not complete the entire questionnaire. The survey instrument took little time for participants to complete, thus reducing participant burden. This was an important strength of this project that likely led to very low loss of participants.

The present study is one of the first to report Tdap uptake in the third trimester of pregnancy. It was also theory driven and provided initial data on elements of the Health Belief Model that were significantly related to Tdap uptake.

The final notable strength of the study was the high rate of uptake of the Tdap vaccination in the third trimester of pregnancy reported by the sample. Previous reports found much lower rates of Tdap being offered in the third trimester of pregnancy as well as lower rates of uptake. Together these data points support clinicians' following national recommendations by offering Tdap in the third trimester and women's acceptance of its value.

Limitations

The primary limitation of the study was the small sample size. Although more participants were recruited than expected, a sample size of 44 could not necessarily detect significant relationships between elements of the health belief model and Tdap uptake. The limited variation in ethnicity, education, and employment negatively impacts the potential for the data to be generalized to other populations. The population identified as a group with interest in health and fitness is another limitation of the study, as their general interest in health and wellness coupled with high education level may have impacted the data gathered.

A final limitation of the study may be recall bias. The participants reported an average of two years between age at time of delivery and age at time of submitting the survey. This length of time between the action of receiving the Tdap vaccination and the survey suggests the possibility of recall bias. However, this was a well-educated participant group with high interest in health and wellness that had little difficulty with access to and completion of the survey.

Future Research

Future study investigating the Tdap uptake in the third trimester of pregnancy should continue investigating the Health Belief Model as a framework to better understand relationships among elements of the model and Tdap uptake. A larger sample size would provide greater power to detect significant relationships. Moreover, it would be beneficial to include women with ethnic, socio-economic, and geographic diversity to expand knowledge of this phenomenon.

The questionnaire developed for this study requires evaluation for content validity. The instrument must be relevant and representative of the constructs, such as perceived susceptibility, it is presuming to measure. The psychometric properties of the questionnaire must be determined

prior to progressing forward with this instrument as a tool representing the Health Belief Model. The development of other studies to better understand components of the data collected from this study would be beneficial. For example, using Kurt Lewins Change Theory to investigate the impact of providing adequate health information regarding Tdap vaccination in pregnancy.

Conclusion

The finding of greatest significance was in relation to HBM question four, assessing the perceived benefit of the Tdap vaccination and Tdap receipt. Belief in the benefit and effectiveness of the vaccine directly correlated with the uptake of the Tdap vaccination in the third trimester of pregnancy. Other notable factors were revealed by HBM question five and HBM question six both assessing perceived barriers. HBM question five indicated that belief in the vaccination being low risk improved the uptake of Tdap. HBM question six can be directly improved upon. Question six determined that participants do not feel adequate information regarding the Tdap vaccination is being provided. Women's health nurse practitioners can directly affect this occurrence by improving Tdap vaccine information communication in their practice. Finally, the study found that offering the vaccination is the most significant predictor of vaccine uptake. Practitioners must continue to advocate for their patients health and wellness by providing information and offering recommended preventative health care actions such as administration of the Tdap vaccination in the third trimester of pregnancy.

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