Capstone Project

Improving the Rates of Pertussis Vaccination in the Retail Clinic Setting Through Provider Education

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Abstract

Problem: Pertussis is an emerging public health risk with the infant population posing greatest risk of morbidity and mortality. Over the past two decades, the incidence of pertussis has been increasing in the United States, making it the most common preventable childhood illness by vaccine. Despite recommendations from the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control (CDC), the rates of vaccination against pertussis remain low, with only 56 percent of adolescents and 5.9 percent of adults having obtained the Tdap vaccine. The National Foundation for Infectious Diseases posited that many providers are unaware of the ACIP guidelines for adolescents and adults or have personal reservations about vaccination, therefore, are less likely to recommend routine vaccinations. Retail clinics present an opportunity to reach target patient populations through convenience and affordability; every patient visit is an opportunity to address patients' vaccination status. There is evidence that education can be an effective tool to increase immunization frequency, both for providers and patients when combined with other strategies such as making vaccinations affordable and convenient.

Purpose: The purpose of this capstone project was to determine if an electronic educational intervention in the provider's weekly newsletter increased the number of Tdap vaccinations in a clinical retail setting.

Methods: The educational intervention and retrospective chart review was conducted over a ten week period from February to April 2013 across twelve states. Data were collected four weeks prior to the first educational intervention, two weeks following the first educational intervention, two weeks following the second educational intervention, and four weeks following the second intervention. The rate of Tdap vaccination per visits was analyzed across each of the five two-week periods.

Results: Twelve states were selected to participate in this project. On average, each state had an average of 6,583 visits per two-week period, with 5.7 Tdap vaccines being given. Using Friedman's ANOVA, there was a difference in the rates of Tdap vaccinations (x^2 (4) = 11.25, $p < 0.05$. Wilcoxon signed-rank tests were used to follow up on this finding. A Bonferroni correction was applied so all effects are reported at the 0.005 level. None of the tested pairs were statistically significant at the 0.005 level.

Conclusion: Despite a lack of statistical significance, the project demonstrated the importance of using an electronic educational intervention as a plausible method to educate providers in clinical retail settings on standards of practice. Individually, some of the states demonstrated changes in trends, which indicates the clinical significance of the intervention. Educating providers on best standards for routine vaccinations is a necessary strategy in order to promote adherence to national guidelines.

Acknowledgements

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I. Overview and Background

In the United States, pertussis poses a significant public health risk for people of all ages with infants being at greatest risk of morbidity and mortality from this disease. Pertussis is a severe respiratory illness caused by the bacterium *Bordatella pertussis* and is spread from person to person through contact with an infected person's droplet spray from a cough or sneeze (Centers for Disease Control (CDC, 2010). The early symptoms of pertussis seem similar to an upper respiratory infection with rhinorrhea, cough, and mild pyrexia so it can be easily misdiagnosed. The toxins from the pertussis bacteria attack the airway having a paralytic effect and interfering with a person's ability to clear respiratory secretions (CDC, 2012a). The adverse effects of the bacteria persist, leading to worsening inflammation of the cilia of the airway triggering severe and violent coughing, post-tussive vomiting, and impairment of oxygenation (CDC, 2010). Most infant deaths from pertussis are associated with a secondary pneumonia (McIntyre & Wood, 2009) but complications , such as neurological disorders, seizures and encephalopathy, can occur as a result of persistent hypoxia or toxins from the pertussis bacteria (CDC, 2012a). Because of the severity of pertussis symptoms in infants, protecting them from this disease is an important public health concern.

Over the past two decades the incidence of pertussis has been increasing in the United States, making it the most common vaccine-preventable childhood illness (The Joint Commission, 2011). Before a pertussis vaccine was available for children, there were more than 200,000 cases of pertussis and approximately 7,000 deaths annually; with the production of a childhood vaccine in the 1940s the incidence of pertussis illness and death has dropped significantly with less than 3,000 cases of pertussis per year from 1980-1990 (CDC, 2012a; Paisley, Blaylock & Hartezell, 2012). Rates have been on the rise and approximately 27,600

cases and 27 pertussis related deaths were reported in 2010 (CDC, 2012a). Infants do not receive their first pertussis vaccination until they are two months of age and do not have full immunity until they have received at least two doses of Diphtheria, Tetanus and acellular Pertussis (DTaP) vaccine (Grizas, Camenga, & Vazquez, 2012).

According to the Centers for Disease Control, over the past 5 years 10,000-27,000 cases have been reported each year (CDC, 2012b). Although the rates of illness and death are highest in infants less than one year, adults and adolescents may exhibit milder symptoms leading to under diagnosis in this population (Rittle, 2010). Immunity to pertussis from the childhood vaccination wanes over time which places adolescents and adults at risk of contracting a pertussis infection and spreading it to infants before they even realize that they are infected (Rittle, 2010; Grizas, et al., 2012; Schweon, 2011; Kirchner, 2011). Conventional research indicates that household members such as parents, siblings or grandparents, are responsible for 75-83 percent of transmission of pertussis to infants due to waning immunity from childhood vaccinations and under diagnosis of pertussis infections (Kirchner, 2011).

The loss of immunologic protection in adolescents and adults and increasing incidence of pertussis infections was the impetus for the Advisory Committee on Immunization Practices (ACIP) to recommend a pertussis vaccine booster. In 2005, the Food and Drug Administration licensed two booster vaccines (TJC, 2011) and vaccination with a single dose of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) was recommended by the ACIP for all persons aged 11 through 64 (CDC, 2012c). The guidelines were expanded in February 2012 to include all adults aged 65 and older who would like to receive the vaccine with strong recommendation for vaccination if they are in contact with an infant less than one year of age (CDC, 2012d). The primary objective of providing a booster against pertussis is to prevent

tetanus, diphtheria and pertussis illness in adolescents and adults but the booster meets a secondary objective of providing a "cocooning" effect for young infants. Cocooning is a strategy in vaccination in which those in close contact with an infant too young to be vaccinated, such as family members, are immunized in an effort to provide indirect protection (Grizas, et al., 2012; Rittle, 2010). Although the booster for pertussis has been offered since 2005 the rates of vaccination for adults and adolescents remain less than optimal to reduce the burden of pertussis in the United States.

The Problem: Lack of Knowledge or Adherence to Vaccination Guidelines

ACIP recommendations are considered the standard of care for vaccination practices in the United States and should be considered best practice by providers (IAC, 2011). Despite recommendations by the CDC and ACIP, the rate of vaccination in most recent data was 56 percent in adolescents and only 5.9 percent in adults ages 18 to 65 (TJC, 2011). Vaccination rates for adolescents have improved as many high schools and colleges require proof of vaccination prior to entry but no system is in place which tracks adult immunization status unless they are part of an organization such as a health care facility or a member of the military.

According to a survey by the National Foundation for Infectious Diseases, many providers are unaware of the ACIP guidelines for adolescents and adults (TJC, 2011). Providers also have been noted to have bias against vaccines from their own personal concerns which cause them to discourage vaccination or provide misinformation to their patients regarding routine vaccinations (TJC, 2011). Providers need to feel comfortable discussing the risks, benefits and safety of vaccinations with their patients as well as to be prepared to make information available to them through printed handouts or referrals to websites which are easily

understood and culturally appropriate (TJC, 2011). Every patient visit to a provider should be considered an opportunity to inquire about vaccination status and provide a Tdap vaccination if it is indicated (Kretsinger et al, 2006). Provider education is an integral step to increase vaccination against pertussis because patients have implied that they would be more likely to obtain vaccinations if they were suggested by their provider (TJC, 2011; Tan & Gerbie, 2010; Grizas, et al., 2012).

Purpose/Significance of the Capstone Project

To increase vaccination rates against pertussis, provider and patient education must be improved. The purpose of this capstone project was to determine if an electronic educational intervention in the provider's weekly newsletter increased the number of Tdap vaccinations in a clinical retail setting. After being supplied with information about pertussis and the Tdap vaccine, the desired outcome was for providers to follow best practice and address immunizations with every patient encounter, immunizing all patients whom are eligible and require a pertussis booster.

This capstone project was conducted in a cohort of private for-profit retail clinics in the United States. Retail clinics present a great opportunity to reach people for preventative health care through convenience and affordability. Increasing the rates of Tdap vaccination would not only provide direct protection for adolescents and adults against pertussis but also provide indirect protection for infants against this preventable disease. Thus, the purpose of this capstone project is to determine if the use of a bi-weekly electronic update on the best practices for Tdap vaccines increases the rates of Tdap vaccinations for patients ages eleven and older in a retail outpatient setting.

Theoretical Framework

Lewin's change theory is useful to relate to organization transformation (See Table 2). Lewin viewed change as driving forces and resisting forces that pushed in opposing directions (Bishop, 2011). In order to unfreeze behavior, creating the motivation for change is the first step. The driving force is to push the provider to make a change and follow best practice in relationship to vaccinating patients according to the ACIP guidelines. Attempts to understand the rationale for any resistance are important to change behavior and encourage adherence to best practice. Based on a review of the evidence, resistance could be due to various reasons such as lack of awareness of the public health implications of pertussis, lack of time to educate patients and provider beliefs related to immunization safety.

The first step of unfreezing involved working with the key stakeholders in the health care organization to inform them on both the lack of provider knowledge regarding the need for vaccination related to pertussis and its direct impact on the increasing incidence of this disease in the U.S. Educating providers on the importance of Tdap vaccination and addressing any questions or doubts that they may have (which would hinder them from encouraging patients to obtain Tdap), was the next step to begin to unfreeze behavior in the providers. Changing involves the process of convincing providers that a knowledge gap exists, essentially the need to fully realize the importance of Tdap vaccination, and the importance of addressing vaccination at every patient visit. Education was offered to the providers to give them a tool to address Tdap vaccination with patients as well as websites with provider and patient information. The final step involved "refreezing" and compelling providers to establish the habit of offering the

pertussis booster to all patients so that best practice becomes the standard of care. In order to maintain the desired behavior (increased vaccination), a follow up reminder through a second educational entry into the company newsletter with tips and guidelines on indications of administration for Tdap, as well as additional online websites, was implemented (Table 2).

II. Literature Review

Resurgence of Pertussis

Pertussis is a leading cause of infant mortality worldwide, for this reason the resurgence of pertussis in developed nations such as the United States, despite the accessibility of vaccines to prevent this disease, is of great concern. The reported incidence of pertussis has tripled since the 1980s (Grizas, et. al, 2012). After the introduction of a pertussis vaccine the annual incidence of pertussis declined with an average of 2,900 cases per year between 1980 and 1990 (CDC, 2012a). But since the early 1980s the incidence of pertussis has again been on the rise with a peak of 27,550 pertussis cases and 27 deaths in 2010 (CDC, 2012a). Of greatest concern is the morbidity and mortality of infants infected with pertussis. Of 84 pertussis related deaths reported from 2004-2006, 84 percent were in children three months of age or younger (Olyarchuk, Willoughby, Davis & Newsom, 2012).

Once thought to be only a disease of infants, it is now known that pertussis affects adolescents and adults at higher rates than infants. In 2004 and 2005, approximately 60 percent the reported incidence of pertussis was in those ages 11 and older (CDC, 2012a). Although the risk of mortality as a result of pertussis infection is highest in infants, a pertussis infection in adolescents and adults can cause significant morbidity. The most common complication from

pertussis is pneumonia with approximately 5.2% of all cases developing this complication from 1997 to 2000 (CDC, 2012a). Pertussis infections in adolescents and adults have also been associated with conditions such as rib fractures, intracranial bleeding, and pneumothorax (Schweon, 2011). It was once thought that vaccination or disease gave lifetime immunity to pertussis, but the exact timing of waning immunity seems to be unknown. Current literature reports that waning occurs approximately four to twenty years after infection and four to twelve years after vaccination (Schweon, 2011; Grizas et al, 2012).

Household members such as parents, siblings or grandparents, are thought to be responsible for 75-83 percent of transmission of pertussis to infants (Kirchner, 2011). Cocooning is a strategy of vaccination in which those close to an infant under twelve months of age are vaccinated in an effort to prevent the transmission of disease. Preferably all household members should receive the Tdap vaccine at least two weeks before birth of the infant to develop full immunity and provide maximum protection from cocooning (IAC, 2011). This strategy has the potential to lead to a 70 percent reduction of pertussis in infants three months of age or less and 65 percent reduction in infants/toddlers aged four to twenty-three months (Rittle, 2010).

Even though cocooning is considered a cost-effective strategy to protect infants, many providers are not adhering to the recommendations from the ACIP and CDC. Currently, a single dose of Tdap is the best known way to prevent pertussis in adolescents and adults (CDC, 2012e). Until immunization programs become effective at reaching adolescents and adults via pertussis boosters, the prevalence of pertussis will likely continue to increase. Providers play an important role in the acceptance and immunization of their patients and represent a strong "first line of defense" in the fight against pertussis (Olyarchuk, et al, 2012, p. 92).

A review of the literature was conducted utilizing the databases Cochrane, CINAHL, MEDLINE Ovid and MEDLINE EBSCO using the main search terms "Tdap" or "pertussis vaccine" combined with the keyword "barriers," "immunization programs," or "education." The literature search was limited to the English language and articles no older than seven years since publication were included, chiefly because the Tdap vaccine was introduced in 2005. The title and abstract of articles were scanned and chosen for applicability to the capstone focus. Other sources were obtained by footnote identification relevance and evaluating the current guidelines/recommendations from expert sources such as the CDC, IAC and ACIP. The first segment of this literature review will examine the safety, cost-effectiveness and efficacy of the Tdap vaccine as well as Tdap vaccination guidelines. The second segment will reexamine the available evidence on the impact of providers on immunization, perceived barriers to immunization, and strategies to enhance immunization.

Tdap vaccine-efficacy, cost-effectiveness and safety

Efficacy

Two pertussis booster vaccines for adolescents and adults were approved for use in the United States by the Food and Drug Administration (FDA) in 2005, Adacel and Boostrix. Adacel is licensed for patients aged 11 to 65 (Sanofi Pasteur, 2012) and Boostrix was recently licensed for patients 10 years and older including those over the age of 65 (GlaxoSmithKlein, 2012). For the purpose of this literature review both preparations of the pertussis booster vaccine will be referred to as Tdap. Both vaccines contain less of the diphtheria and tetanus toxoid components currently found in the infant and childhood vaccine diphtheria, tetanus toxoids and acellular pertussis (DTaP) (Medical Letter, 2006). After review of both published and unpublished data

from clinical trials for Boostrix and Adacel, ACIP indicates that the response to *B. pertussis* antigens is noninferior to the immune response elicited from the three dose series of infant DTaP (CDC, 2011a). The duration of protection from vaccination with acellular pertussis vaccines is not yet known. Since there have been cases, in the current literature, where patients were found to have no protection after ten to twelve years post vaccination, further research is needed to evaluate the potential for more frequent pertussis boosters (Olyarchuk, et al, 2012).

Cost-effectiveness

Although protecting infants through cocooning is a main objective of providing Tdap vaccinations to ages eleven years and older, approximately 50 percent of cases of pertussis are diagnosed in adolescents and adults (Olyarchuk, et al, 2012). A review of the literature by Olyarchuk et al (2012) evaluated the cost benefits of adult pertussis vaccination. The review evaluated data from institutional outbreaks of pertussis in hospital and university settings, specifically the costs associated with screening, treatment and loss of work.

One pertussis outbreak in a French suburban hospital, involving three confirmed cases of pertussis was presented. After screening was completed, seventeen cases were confirmed and most were health care workers (HCW). The cost was 46,661 euros, or approximately 65,000 U.S. dollars. After two different hospitals in Washington State finished managing their pertussis outbreaks, the cost was estimated to be over $260,000 for one and $120,000 for the second (Olyarchuk, et al, 2012). Based on this review, Olyarchuk et al (2012) estimated that requiring Tdap vaccination for all HCWs as a part of routine employment requirements could save a hospital system millions of dollars in pertussis-related expenses.

The benefit to vaccinating against pertussis is realized as the economic consequences of pertussis infection and outbreaks can be costly. It is projected the administering the Tdap booster to adolescents would cost $20,000 per quality-adjusted life-year saved (Davis et al., 2006). Additionally, the Infectious Diseases Society of America (ISDA) say immunizations are one of the most cost-effective disease prevention measures (Pickering et al., 2009, p 817). Through cost benefit analysis, the effectiveness of immunizing adults and adolescents against pertussis appears to be more cost effective than dealing with outbreaks.

Safety of Tdap

When Tdap was first introduced, the administration of the pertussis booster was complicated by the lack of a vaccine that simply contained an acellular pertussis component. All of the available pertussis preparations are combinations of pertussis with other vaccines such as diphtheria and tetanus in the United States as well as the addition of polio in other countries (Beyout, et al, 2009). Until recently, it was recommended to wait two years between Td and Tdap administration except under special circumstances, which caused alarm for people who may need the vaccine for an urgent situation such as the birth of an infant, school entry or occupational requirements (Beyout, et al, 2009).

Halpern et al. (2006) included 7,001 children and adolescents in an observational study. All of the eligible students were administered a Tdap vaccine and observed for fifteen minutes for any immediate adverse reactions. After vaccination the participants were instructed to record any adverse effects in a diary for twenty eight days. Although swelling and erythema at the vaccination site were increased in the students with a shorter time period than two years between Td and Tdap, the side effects did not differ greatly in those for whom the last Td booster had

been greater than two years. As a result, the authors deemed that a period as short as eighteen months between Td and Tdap was likely safe for adolescents. A major limitation of the study was that it only included children and adolescents and could not be generalized to adults age 18 and older.

Similarly, Talbot et al (2010) evaluated the administration of Tdap less than two years after a Td immunization during a pertussis outbreak. Approximately 12 percent of the HCWs vaccinated had received Td/tetanus toxoid (TT) less than two years previously. The moderate or severe injection site reactions were not any more frequent in the HCWs who had an interval shorter than two years, between Td/TT and Tdap, when compared to the HCWs whom had received a Tdap less than 2 years prior. In contrast to the previous observational study, intervals less than two years were not associated with any increase in frequency of erythema, edema or fever.

Beyout et al. (2009) assessed whether an interval of Tdap one month after a Td was associated with an increase in adverse reactions. Subjects in the study group (N=249) were given Td- Inactivated Polio Vaccine (IPV) followed by a Tdap-IPV one month later. The control group (N=251) was given a placebo followed one month later with Tdap-IPV. A period of one month was chosen to maximize efficacy and "correspond with the antibody response peak" while also realizing that few people would require a Tdap less than one month after a Td (Beyout et al., 2009, p 319). None of the participants exhibited any immediate adverse effects after vaccination and results on follow up indicated Tdap-IPV to be well tolerated at an interval of one month after Td-IPV. Limitations included a self-report diary and possible desensitization from previous reactions leading the study group to underreport adverse effects. Another limitation was the small sample size, which affects generalizability to the general population. Despite these

limitations, administration of Tdap one month after Td did not increase the likelihood of post-vaccination side effects and was considered safe in this RCT.

It is speculated that the Tdap vaccine gives adolescents and adults protection against pertussis, although the duration of protection is yet to be established. The cost of administering the Tdap vaccine is less than the cost of dealing with pertussis outbreaks. Also, the administration of Tdap in intervals less than two years has not been associated with any increase in side effects from the vaccine even as short as one month following a Td vaccine. Based on the available research, Tdap is a safe and cost effective strategy to protect adolescents and adults against pertussis and reduce the burden of the disease in this population.

Tdap Vaccination Guidelines

Children and Adolescents

The original guidelines for Tdap administration were published by the ACIP in 2006 and have been adapted as new research emerges. In 2006, ACIP recommended a single dose of Tdap for persons aged eleven to eighteen as a replacement of the Td and a one-time booster of Tdap for everyone aged nineteen to sixty-four (Broder et al, 2006). Despite this recommendation, the rate of vaccination in adolescents and adults remained low with Tdap vaccination administered to approximately 56 percent of adolescents and only 5.9 percent of adults ages 18 to 65 (TJC, 2011). Rates of pertussis have been on the rise with approximately 27,600 cases and 27 pertussis related deaths reported in 2010 (CDC, 2012a). Because the safety of a shortened time period for administering Tdap after Td had not been studied, the original recommendation encouraged a two year waiting period between the two vaccines, unless a situation called for a shortened wait time, such as the birth of an infant. In October 2010, after reviewing the new available evidence,

the ACIP changed their recommendations for the Tdap vaccine to include no waiting period between Td and Tdap (CDC, 2011a). Children aged seven to ten who had not had the full DTaP series in childhood were also recommended for Tdap vaccine. The immune response to Tdap in this age group was found to be comparable to the DTaP dose administered to children between the ages of four to six (CDC, 2011a).

Increasing immunization rates in adolescents aged thirteen to fifteen years is identified as a goal for Healthy People 2020, but the rates of 80 percent coverage of one time booster for Tdap have not been met to date; approximately half this number of adolescents obtained the Tdap vaccine (Healthypeople.gov, 2012). Recommendations for adolescents aged eleven to eighteen remain unchanged; a one-time booster of Tdap with the optimum age eleven to twelve in place of the Td is advised for this age group. All necessary vaccines may be given at the same time as Tdap but should be given in a different anatomical site with a separate syringe (IAC, 2012). Studies that evaluate the timing between when vaccines are administered and when immunity wanes or disappears are needed so that the decision related to whether additional Tdap vaccine boosters can be better estimated.

Adults

The recommendations for those aged nineteen to sixty-four have remained the same; a one- lifetime booster of Tdap is encouraged for everyone in this age group. Evidence of the safety of Tdap in adults over the age of sixty-five was not available, but in October 2010, adults aged sixty-five and older were advised to obtain Tdap if they were in contact with an infant less than twelve months old. This would include: grandparents, child-care providers and health care providers (CDC, 2011a). Both preparations of Tdap were not indicated for anyone over sixty-

four at that time, but an exception was made in special circumstances. After the ACIP analyzed published and unpublished data, recommendations that Tdap is safe in people 65 and older were released (CDC, 2012f). Boostrix was approved by the FDA in July 2011 for adults over sixty-four and the ACIP amended its recommendations to include this age group in February 2012 (CDC, 2012f). Unlike Boostrix, Adacel is not approved by the FDA for those over sixty-four. However, either preparation may be given if the person qualifies for Tdap, so that providers do not miss an opportunity to vaccinate (CDC, 2012f).

Pregnancy

The Tdap vaccine should preferably be given to adult women before they conceive but when a pregnant woman has not had the pertussis booster it is recommended that it be given to protect the newborn from the deleterious effects of pertussis. Because the majority of pertussis cases are spread to infants by a close family member and infants less than three months have the most significant mortality from this disease, the protection of the infant must be weighed against the unknown effects of the vaccine on the fetus. With the recent resurgence of pertussis, the American College of Obstetricians and Gynecologists (ACOG) released a "Committee Opinion" on the practice of vaccinating with Tdap in pregnancy (ACOG, 2012).

In ACOG recommendation, Tdap administration was encouraged in pregnancy, with the preferred time of administration being in the third trimester. By administering the vaccine in the third trimester, maternal antibodies are transferred to the fetus and may provide protection to the infant until they are able to obtain the first DTaP at two months old (CDC, 2011b). If Tdap was not administered during pregnancy, it should be administered immediately post-partum to provide immunity to the mother thereby providing indirect protection to the infant. The

disadvantage to administration of the vaccine to the mother after the birth of the infant is that it can take up to two weeks for the mother to have full immunity. This delay of antibody response may prove to be inadequate to protect an infant in their first two weeks of life (CDC, 2011b). ACOG (2012) also recommends vaccinating family members who will be in close contact with the infant; again a time frame of at least two weeks before the birth is preferred to provide indirect protection to the newborn infant.

Barriers to Tdap Vaccination

Childhood and Adolescent vaccination

Barriers to vaccination have been identified in the literature and can be personal, system or provider related. Personal beliefs may cause parents not to obtain vaccinations for their children. Although most children are required to show proof of vaccination to enter into school, parents are able to obtain exemptions in many states for religious or personal beliefs (Spratling & Carmon, 2010). In a study by Gust, Kennedy, Shui, Smith, Nowak and Pickering (2005) the authors evaluated the parents' perceptions for not vaccinating their children. Only two-thirds of parents felt that they had received enough information to make a decision. Importantly, the authors found that lack of information and lack of trust in the provider contributed to parents' attitudes toward vaccination. Taylor, et al (2002) suggested that a child's immunization status was less related to the parents' characteristics or geographic location but more associated with their independent provider. Taylor et al (2002) conjectured that recommendation by a provider was associated with higher immunization rates for the inactivated polio virus vaccine.

Adult Vaccination

Some of the most common reasons that adults do not obtain routine vaccinations seem to stem from lack of knowledge or lack of recommendation from their provider (NFID, 2007; TJC, 2011; Miller, et al, 2011). A 2007 survey by the National Foundation for Infectious Diseases (NFID) on awareness of adult vaccination elicited reasons for those adults who chose not to get vaccinated. The rationale included: the lack of knowledge that vaccination in childhood did not provide life-long immunity, lack of concern that they were reservoirs of disease to their family members and the belief that vaccine preventable illnesses were not serious or life-threatening (TJC, 2011).

A survey by Miller et al (2011) of 3558 unvaccinated participants was performed to evaluate barriers to Tdap vaccination. This survey cited common reasons that people would not obtain a Tdap vaccination; the main rationale for choosing no vaccination was that they did not perceive a real risk of contracting pertussis. One of the most prevalent reasons for reluctance to accept Tdap was that the participants did not feel that they had enough information to make a decision. Only 19 percent of the survey respondents had ever heard of Tdap and only about 9 percent of them had reported having received a recommendation to obtain the Tdap vaccine from their health care provider. When asked if they would be willing to obtain a Tdap if it was recommended by their health care provider, almost 82 percent stated they would be willing to be vaccinated, which demonstrates the importance a provider plays in the role of vaccination.

The rate of vaccination against pertussis is less than seven percent in the adult population. Adults may desire to obtain a vaccination, but the cost may be too prohibitive and Tdap is not always covered by insurance companies, with the exception relating to wound prophylaxis (Kichner, 2011; Schweon, 2011; TJC, 2011; Rittle, 2010). Patients over sixty-five are currently

only covered for the Tdap vaccine under Medicare Part D (Kirchner, 2011) which means that the cost of the Tdap vaccine, which averages from thirty to sixty-seven dollars (Healthcare Blue Book, 2012) could be exorbitant to manage on a fixed income if they do not have this benefit. However, with the implementation of the Affordable Care Act, vaccines recommended by the ACIP will be covered with no co-payments or other cost-sharing requirements as long as the provider is within the patient's network (HealthCare.gov, 2012). This is a step in a positive direction and will allow people to obtain these much needed vaccinations by eliminating the barrier of cost for those who are insured.

Provider Barriers

Patient barriers affect immunization for preventable illnesses, but provider barriers can also play a significant role in vaccination rates. Evidence on the attitudes and preferences regarding Tdap administration obtained through surveys have attempted to identify provider barriers to Tdap administration. For example, Davis et al (2006) mailed surveys to pediatrician and family practice physicians. A total of 297 usable surveys were analyzed, resulting in 154 pediatricians and 143 family physicians. Only 57 percent of the physicians felt that pertussis was serious enough that a pertussis booster was necessary. Adolescents were less likely to obtain regular preventative care than younger children and 44 percent of providers felt that this was a barrier to following vaccination recommendations. Lack of reimbursement and record keeping were also cited as barriers to vaccinating adolescents, but pediatricians were more likely than family physicians to follow guidelines and support Tdap in place of Td (Davis, et al., 2006).

Similarly, Dempsey et al (2009) performed a survey to evaluate the extent to which ACIP guidelines were being followed by physicians and if a difference persisted between specialties.

Overall, 87 percent of providers recommended Tdap to eleven to twelve year olds and 89 percent recommended Tdap to thirteen to eighteen year olds who had not had a previous Td booster. Additionally, it was posited that physician specialty and availability of Tdap were significantly linked to recommending Tdap vaccination. Although 90 percent reported that they stocked Tdap vaccines, pediatricians were more likely to stock Tdap than family physicians.

Physicians who stocked Tdap in their practices were evaluated for barriers to administration and again, lack of adolescent preventative care visits was identified as a major factor. Other reasons included: (a) problems with supply or reimbursement, (b) lack of time during adolescent visits, (c) and record keeping (Dempsey et al., 2009). The survey also identified a lack of provider knowledge on the current ACIP guidelines since almost half of the surveyed physicians would wait 5 years after the Td booster to administer the Tdap vaccine and 10 percent of the physicians would not administer Tdap with the meningococcal conjugate vaccine, (MCV4) which is not contraindicated (Dempsey et al., 2009).

Davis, Kretsinger, Cowan, Stokley, and Clark (2007) focused on attitudes and preferences of primary care providers on the Tdap vaccine for adults. Only half (50 percent) of the respondents felt that pertussis was a serious illness, which warranted the administration of a Tdap booster in place of a Td booster, but 81percent said they would recommend Tdap to all their adult patients who had not received the booster. Cost of the Tdap vaccine for providers was cited as a barrier for providers recommending the Tdap vaccine to their patients as well as stocking Tdap in their practices. Although half did not consider pertussis a serious illness for adults, 73 percent felt that infant pertussis was serious enough to warrant vaccination of those who would come in contact with an infant six months of age or less; but identifying these

patients was considered a challenge for the providers and 74 percent felt that the role of promotion for Tdap in this population was the role of the pediatrician.

A survey of family practice (FP), obstetrician/gynecologists (OB/GYN), and general internists (IM) evaluated awareness, perceptions and knowledge of recommended adult vaccination schedules among primary care providers (Tan, Bhattacharya, & Gerbie, 2011). The authors included OB/GYN physicians in the survey because studies have shown that many OB/GYNs consider themselves to provide primary care to women and greater than 55 percent of women consider the OB/GYN as their primary care provider. The authors found that knowledge of the current recommendations of adult vaccinations differed among primary care providers with OB/GYNs significantly less aware. Only about 40 percent of the providers obtained an immunization history on new patients and about 53 percent kept a vaccination record on at least half of their current patients. Major barriers cited for not adhering to recommended guidelines were problems with reimbursement, lack of knowledge about vaccines and not receiving training in vaccine administration.

In conclusion, research has demonstrated that many patients depend on their primary care providers to recommend routine vaccinations. Barriers that physicians have identified in surveys for providing routine vaccinations are: (a) lack of Tdap supply, (b) cost of the Tdap vaccine, (c) lack of reimbursement from insurance companies, (d) lack of time, (e) inadequate record keeping, and (f) a lack of provider knowledge on the current ACIP guidelines. Provider education and motivation are critical components to promoting adherence to vaccination guidelines.

Using Education as a Strategy to Increase Tdap Immunization

Given the current state of the literature, it is logical to conclude the need for strategies to address these challenges related to vaccinations. The literature is replete with examples that the education of providers may enhance the adoption of offering vaccines to patients. Specifically, Ehresmann, Mills, Loewenson, & Moore (2000) concluded that educational efforts are necessary to ensure the success of offering new vaccines. Taylor, et al, (2002) found that the role of the provider is critical to increasing rates, thus educating providers regarding the benefits of vaccines may be a key element in enhancing patient compliance.

The Joint Commission (2011) released a report on *Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel: Strategies from Research and Practice* in which they discuss the resurgence of pertussis and overview strategies to enhance coverage. In the overview, multicomponent interventions which included education were "strongly recommended" (TJC, 2011, p 72). Similarly, The Infectious Diseases Society of America (IDSA) also released clinical practice guidelines in 2009 with strategies to improve vaccination of infants, adolescents and adults (Pickering et al). Pickering et al (2009) suggested that all providers who immunize patients should be properly educated as well as receive continuing education on immunization practices. Health care providers should be responsible for knowing the most current immunizations schedules and be held responsible to follow the established guidelines. Surprisingly, Pickering et al (2009) determined that missed opportunities for patient vaccination were related to providers being unduly cautious when administering vaccinations to patients.

However, The Task Force on Community Preventative Services (2005) evaluated the effect of education alone on vaccination uptake, and evidence was lacking to support education

alone is enough to improve vaccination rates (Ndiaye et al). TJC (2011) posited that other strategies such as decreasing out-of-pocket costs, making Tdap vaccines available without a physical exam, incorporating clinic times where no appointment is necessary for vaccination and making hours more convenient will enhance vaccination compliance.

Using Non-Traditional Settings as a Strategy to Increase Tdap Immunization

Interestingly, the use of complementary or nontraditional immunization settings is addressed by both the TJC and IDSA as plausible solutions to improve vaccination and reach patients who may have limited access to care. Nontraditional settings are operationally defined as an immunization site that exists outside the traditional healthcare setting, such as schools, shopping malls and pharmacies (Pickering, et al, 2009), and include the recent advent of retail clinics in major department stores and pharmacies. The first retail clinics opened in Minnesota in 2000 and offered an inexpensive option for patients as compared to the emergency department or urgent care (MinuteClinic, 2012). Most retail clinics follow evidence-based guidelines and a collaborative physician is available for consultations as needed. Since 2000, retail clinics have expanded their services, including vaccinations.

These organizations are mandated to follow similar standards of care when screening for eligibility, documenting, and administering vaccines (TJC, 2011). Providers in nontraditional settings abide by the same quality standards, such as proper storage and handling of vaccines, regulatory issues, and ability to educate patients on the risks and benefits of immunizations (Pickering et al., 2009). Providers who immunize in nontraditional settings should provide a record of immunization to the patient's medical home and encourage routine follow ups with their primary care provider (Pickering et al., 2009).

The use of nontraditional settings such as retail health for vaccination can offer several benefits. Retail clinics do not require appointments and hours are convenient with many providing extended weekday and weekend hours which can eliminate patient barriers of time constraints. Retail clinics provide vaccines with no copay required, which makes vaccination more attainable for patients that have high insurance deductibles/co-payments.
Many times vaccines are offered at a lower out-of-pocket cost which can increase access for patients who are uninsured or have insurance that does not cover vaccines. A copy of the visit summary is printed and given to the patient as well as an electronic copy which is sent to their primary care provider with the patient's permission, which keeps the medical home updated on patient immunization status. Thus, the use of the retail clinics may be a plausible solution to improve Tdap vaccination rates in adolescents and adults.

Conclusion

The lack of an organized vaccine administration structure coupled with the lack of provider knowledge or adherence to vaccination guidelines has contributed to low vaccination rates in the United States. As a consequence, pertussis has re-emerged as the most prevalent preventable illness by vaccine. Advanced practice providers have an opportunity to educate and vaccinate patient populations whom might not have other access to care by addressing vaccination at every patient encounter.

III. Methodology

Design

This educational intervention and retrospective chart review was conducted over a ten week period from February to April 2013 following IRB exemption. The educational

intervention was part of the weekly company newsletter over the course of one month, being presented every other week for one month. The educational information was designed and tailored to address provider barriers identified in the literature review by including websites, patient education resources and links to various experts on vaccination such as the CDC, IAC and ACIP. The first educational entry was geared towards increasing provider comfort in discussing the disease pertussis with patients and the rationale of cocooning to protect the most vulnerable population, infants under the age of 6 months (See appendix 2). The focus of the second educational entry was discussion of the recommendations for the pertussis booster from ACIP, indications for administration and special instructions (See appendix 3). Following the educational intervention, a retrospective chart review was completed to compare rates of vaccinations prior to the educational intervention and after the educational intervention.

Procedures

This immunization education program followed two phases. The first phase involved development of a proposal and submission of that proposal to the retail clinics' Research Committee. The first step included identifying a corporate contact person, who could be a resource to reach out to other Research Committee members. Once key stakeholders were identified, the process of writing the research proposal according to the corporate guidelines was performed and the proposal submitted to be reviewed at the next Research Committee meeting. In the second step, the Research Committee returned the proposal with suggestions for changes with requests for the planned education. The suggested changes were performed and the revised proposal with education resubmitted to the committee for reevaluation. Once the final approval from the Research Committee was obtained, the Chief Medical Officer and Chief Nursing

Officer viewed and approved the proposal. The final step in development was consultation of the corporate legal resources to assure that the proposal was free from any potential security violations.

The second phase involved implementation of the proposal. Contacts for the weekly corporate newsletter were identified and the interventional educational material (See Appendices 2 and 3) was be submitted with instructions to publish the education once every two weeks, for one month. The educational intervention involved an initial education entry followed two weeks later by a second education entry into the newsletter along with links to websites for providers to review and encourage refreezing of the change in behavior.

Following the second appearance of education in the corporate newsletter, data was pulled by the IT department and put into an excel spreadsheet. The data included each state included in the project, total number of visits to the state, as well as total number of Tdap vaccinations administered by the states included in the project. This data was used to evaluate if a statistical significance was noted after an educational intervention in the retail clinic's corporate newsletter.

Subjects and setting

A convenience sample of private, for-profit retail clinics was chosen. Inclusion criteria included: 1) ownership by MinuteClinic, 2) the clinic offers vaccinations, 3) use of MinuteClinic EMR system. Exclusion criteria included: 1) privately owned clinics, 2) use of a newly piloted EMR system. The vaccination rates were compared in two weeks segments over a 10 week period. Data were collected four weeks prior to the first educational intervention, two weeks following the first educational intervention, two weeks following the second educational

intervention, and four weeks following the second intervention. The rate of Tdap vaccination per visits was analyzed across each of the five two-week periods.

The retail clinics selected for participation in the project were under corporate ownership and located in 12 states: Arizona, Florida, Georgia, Illinois, Maryland, Minnesota, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, and Virginia. Other states were excluded because they were privately owned. Clinics in the state of Massachusetts were excluded from the project as a new EMR system was piloted in those sites. The educational entries appeared in the corporate newsletter on the second and fourth week of March and data was collected from four weeks prior to the first education in the corporate newsletter until four weeks after the second education in the corporate newsletter.

Variables and Measures

The independent variable was the educational intervention, operationally defined as the information presented in the newsletter for the first and third week of one month (See appendix 2 and 3 for specific education). The outcome variable, rates of Tdap vaccination divided by the total number of visits, was assessed to evaluate provider compliance with best practice in addressing Tdap vaccination at each visit. Providers were encouraged to vaccinate patients as appropriate with the assumption that after the providers have been presented information on the disease pertussis and the need/indications for administration of Tdap, compliance would be evidenced by a change in Tdap vaccination rates.

Human Subjects Protection

Education was provided via an electronic newsletter for providers at retail clinics. Because no identifiable information was accessed, the risk to providers was minimal. Vaccinations were offered according to the established ACIP guidelines and administered only if a patient is eligible, therefore, presenting no increased risk to patients as compared to a normal visit. Data was presented in a spreadsheet from the SQL database and only contained: (a) number of Tdap vaccinations for each state, and (b) total visits to the state. A query was made to the IRB and exemption granted from the IRB prior to any data collection. After IRB exemption and the Capstone Committee approval, the project commenced.

Data Collection

Information from the electronic medical record was transferred to the SQL database for each state. Because the requested information from the SQL database included only the number of vaccinations and total visit counts for each state, no identifying information was collected. An excel spreadsheet to organize the study data was requested and created by the information technology (IT) department, which was accessible by the investigator. SQL database querying language is useful because it "allows users to define the structure and organization of stored data...and define relationships between the stored data" (McGonigle & Mastrian, 2012, p 225). The data was housed on the corporate servers and password protected and access to the data was limited to the investigator alone.

Data Analysis

The results of the data printout from the SQL database were manually entered into the *Statistical Package for the Social Sciences* (SPSS) for statistical analysis. Testing was

performed to answer the question: "Does provider education, which consists of two entries into the weekly corporate newsletter (What's Up Wednesday/WUW), discussing the importance of Tdap vaccination, increase vaccination rates of tetanus, diphtheria and pertussis (Tdap) in patients greater than 11 years old in a retail clinic setting?" As a result of provider education the goal was to identify a statistically significant change in the rates of vaccination post intervention in the convenience sample of retail clinics.

The data was broken down into five, two week segments. The first two segments were from February 13th to 26 and February 27th through March 12th, and then the first education intervention appeared in the electronic newsletter on March 13th. Then next two week segment was from March 13th through March 26th, and then the second education intervention appeared in the electronic newsletter on March 27th. The final two week segments were from March 27th to April 9th and April 10th to April 23rd. To perform testing, the number of Tdap visits divided by the number of visits gave the percentage of Tdap/vistis. These percentages were used to compare the five, two week time periods.

Most of the clinics give fewer than 5 Tdap vaccinations in a two week period so the distribution of the data was positively skewed. Also, with a small sample size of twelve states and very small percentages to the thousandth place, repeated measures analysis of variance (ANOVA) was not a good statistical test to evaluate the data. Friedman's ANOVA is a nonparametric test that compares three or more paired groups and is useful for non-normally distributed data because it uses ranks to compare data. The percentages from each state were ranked and then each week averaged to obtain a mean rank. Friedman's ANOVA was used to determine if there was a difference between the five two week time periods. The Wilcoxon

signed rank test was performed for post hoc analysis and a Bonferroni correction made for the multiple tests.

Results

The results of a query of the retail corporation's database in twelve states were analyzed. Using Friedman's ANOVA, there was a difference in the ranks of Tdap vaccinations across the five 2-week study periods (x^2 (4) = 11.25, $p < 0.05$). Wilcoxon signed-rank tests were performed for post hoc analysis to test for statistical significance between the time periods. A Bonferroni correction was made to account for the multiple tests which were run, making the alpha significant at 0.005. None of the tested pairs were statistically significant at the 0.005 level.

IV: Discussion

Clinical vs. Statistical Significance

TJC and the ISDA have implied that provider education along with multicomponent strategies has the potential to increase Tdap vaccination rates (TJC, 2011; Pickering et al, 2009). Although no statistical significance was noted, when examining the data further, trends emerge and the clinical significance of the project is realized. After plotting the ranks from Freidman's ANOVA over the five, two week time intervals you can see that from the first plot to the fourth plot there was an increase in the number of Tdap vaccines administered (See Table 3). This is where a difference would be expected since the second educational intervention occurred in this time frame. Florida and Texas lead for number of visits in the ten week time period, but Florida

did not give as many Tdap vaccines as Texas. This could likely be due to an older population being served at the retail clinics in Florida (See tables 4 and 5). Oklahoma has the fewest number of visits, but had the largest percentage of change of Tdap vaccination from time 1 to time 4 (See tables 5 and 6). Illinois has an average amount of visits but they lead in the number of Tdap vaccinations (See table 5). It would be interesting to ascertain why Illinois gives so many vaccines compared to other states. Could there be an OB/GYN clinic or birthing hospital close by which refers patients to the retail clinics? Also, it is interesting to note that some of the states had a larger increase in the rates of vaccination pre-intervention versus post-intervention. Although the number of vaccinations per visit dropped time 5, Texas and Virginia had numbers of Tdap vaccines at least double time 5 when compared to time 1. Although post hoc testing found no significant difference, looking at the data plotted on a graph can produce interesting trends.

Limitations of the Project

As with any project, there are limitations to this capstone project. The sample size was a convenience sample with only twelve states included in the analysis. If the sample size is too small, it may be difficult to detect significant differences (Munro, 2005). The retail clinic treats patients eighteen months and older and the analysis included all patient visits. The project was focused on Tdap vaccinations, which are usually given to patients eleven and older and the number of visits, which account for patients ages eighteen months to ten, could have affected the statistical analysis. The number of visits for patients over the age of eleven should have been requested so the true number of patients eligible for the Tdap vaccine would have been counted.

Although reading the newsletter is a requirement of the position, there is no way to track if the provider actually read the education. Even though there was no way to determine if the providers read the newsletter, with a large corporation that has clinics in several states the electronic newsletter was an effective way to reach all of the providers without having to meet face to face. With this project, there was no way to track if the providers were asking the patients about the Tdap vaccine. Because the rates of vaccination increased, it is assumed that providers were more aware of the need for vaccination and were asking their patients if they had obtained the Tdap. Providers may have been asking the patient if they would like to obtain a Tdap vaccine but there was also no way to track if the patient accepted or declined. Some patients may have already obtained the Tdap so it would have been beneficial to document a reason why the patient declined the vaccine.

Despite the limitations, an electronic newsletter was found to be a plausible solution for provider education. Education has the potential to promote adherence to best practice but multicomponent strategies are needed to ensure the adoption and continuation of best practice by the providers. Recurring reminders such as an EMR prompt have been found to increase rates of vaccination in target populations.

Plans for Translation

This project showed improvement in the rates of vaccination through provider education, but a prompt in the retail clinic's EMR could prove to be more effective to continued success of increasing Tdap vaccine administration. EMRs can be helpful to organize data and improve provision of guideline based care by utilizing decision support through computer reminders or alerts (McGonigle & Mastrian, 2012). Prompts have been shown to increase rates of vaccination