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Working Toward Tetanus, Diptheria, Acellular Pertussis in Every Pregnancy: Protecting Our Most Vulnerable Population

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WORKING TOWARD TETANUS, DIPHTHERIA, ACELLULAR PERTUSSIS IN EVERY PREGNANCY: PROTECTING OUR MOST VULNERABLE POPULATION

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EXECUTIVE SUMMARY

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Pertussis is a highly contagious, acute respiratory illness caused by the bacteria *Bordetella pertussis*. This illness can last for several months and is most notable by a paroxysmal cough on inspiration. Pertussis affects all ages and genders without discrimination but has a disproportionately high rate of morbidity and mortality in infants less than three months old. Protection from pertussis comes in the form of the tetanus, diphtheria, acellular pertussis (Tdap) vaccine for adults and the diphtheria, tetanus, acellular pertussis (DTaP) vaccine for children and infants.

The first whole cell pertussis vaccine was introduced in the 1940s, which brought about a dramatic decrease in pertussis rates. This vaccine was associated with high fevers and seizures in children. This version of the vaccine was removed from the market in the 1980s and a safer acellular alternative was introduced. The acellular vaccine had fewer side effects; however, immunity was noted to wane and pertussis incidence began to increase. Infants who did not receive their first dose of Tdap until two months of age were left vulnerable after exposure to adolescents and adults with pertussis. In October 2012, the Centers for Disease Control (CDC; 2013b), in conjunction with the American Council for Immunization Practices (ACIP), released a national recommendation to provide every pregnant woman with a Tdap vaccine between 27- and 36-weeks gestation.

Vaccination during pregnancy would induce an immune response, creating antibodies passed on to the fetus.

The purpose of this project was to improve the rates of Tdap in the pregnant population at North Colorado Family Medicine (NCFM) in Greeley, Colorado. The project included three specific interventions: (a) update of an existing provider reminder tool located in every obstetric patients chart to include a prompt to give the Tdap vaccine between 27 and 36 weeks, (b) inclusion of a patient-oriented CDC (2015c) factsheet in the new patient packet given to every pregnant patient at the initial intake visit, and (c) an educational session provided to the clinic's medical assistants to offer education on the purpose of the Tdap during pregnancy and their role in administering the vaccine under the clinic's standing order.

This project was implemented over a 14-week intervention period and results were measured with comparison of pre- and post-intervention vaccine rates and provider/medical assistant surveys. Pre-intervention rates were calculated after chart review of all pregnancy and delivery codes for 2013-2015 after the initial recommendation. Prior to the intervention, a total of 394 women delivered and 274 of those women were given the vaccine (69%). Post-intervention chart reviews showed a total of 74 pregnant women were seen in the intervention window and 65 of those women were given the vaccine (88%). Post-intervention provider and medical assistant surveys were distributed with a return rate of 48% for providers and 75% for medical assistants. Survey results showed participating medical assistants and providers agreed or strongly agreed the interventions would be beneficial in reminding them to provide the Tdap vaccine to pregnant women between 27- and 36-weeks gestation. Indirectly, an increase

in Tdap vaccination rates in pregnant women would likely decrease pertussis rates and, therefore, the morbidity and mortality in infants less than three months of age. This project was sustainable with future implications in practice as it utilized up-to-date evidence in an effort to increase rates of adherence to national recommendations and reduce rates of pertussis in a vulnerable population. As the clinic is part of a larger system, the interventions can be disseminated to the different Banner health clinics and have a wider impact on pregnant women throughout the western United States.

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LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
CDC	Centers for Disease Control and Prevention
DTaP	Diphtheria, Tetanus, acellular Pertussis
DTP	Diphtheria, Tetanus, Pertussis
EHR	Electronic Health Record
IRB	Institutional Review Board
MA	Medical Assistant
MMR	Measles, Mumps, Rubella
NCID	National Center for Infectious Diseases
NCFM	North Colorado Family Medicine
NFID	National Foundation for Infectious Diseases
NIH	National Institutes of Health
NP	Nurse Practitioner
OB	Obstetric
PCR	Polymerase-chain Reaction
QALY	Quality Adjusted Life Years
QI	Quality Improvement
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance

SGA	Small for Gestational Age
Tdap	Tetanus, Diphtheria, acellular Pertussis
WHO	World Health Organization

CHAPTER I

PROBLEM STATEMENT

Introduction

Historically, with the introduction of vaccines in the United States and around the world, there has been a decrease in the number and severity of deadly diseases. Vaccines brought with them the eradication of small pox and polio, and near eradication of diseases such as measles, mumps, and rubella. One disease, however, continues to plague countries around the world despite the ability to vaccinate: pertussis. Pertussis has had many names over the years; it was first named in the middle-ages as *the kink*, a Scottish term for fit or paroxysm, or *kindhoest* from the German language meaning child's cough (Cherry, 1996). Cherry (1996) describes the history of pertussis; the first epidemic was reported in Paris, France in 1578. The causative agent of pertussis was unknown until 1906 when the *Bordetella pertussis* bacteria was finally isolated (Cherry, 1996). Over the century, pertussis has been called the 100-day cough due to its longevity and whooping cough--so named from the classic inspiratory whooping noise made when the cough is most severe (Cherry, 1996).

Prior to the introduction of the first pertussis vaccine in 1933, children were affected by pertussis more than any other age group (Nitsch-Osuch et al., 2015). In this pre-vaccination era, immunity in adolescents and adults came from natural immunity gained from persistent exposure to the illness. Mothers would then pass this natural

immunity gained from exposure to the disease to their infants through the transfer of maternal antibodies through the placenta (Nitsch-Osuch et al., 2015). With the introduction of the whole-cell pertussis vaccine--diphtheria, tetanus, and pertussis (DTP), disease rates in children dropped and natural immunity that would protect adults and adolescents was reduced. Childhood vaccines brought a significant decrease in the incidence of pertussis, thus decreasing the overall morbidity and mortality associated with this disease.

With the decreased incidence of pertussis, the nation's focus shifted from concern about the disease to concern about the vaccine. Severe local reactions at the vaccine site and systemic reactions that included high fevers and seizures would bring about an anti-vaccination movement that would eventually end the mainstream use of the DTP vaccine (Allen, 2013). The DTP vaccine was replaced with a safer alternative: the DTaP--diphtheria, tetanus, acellular pertussis. This new vaccine was purified, including only killed pieces of the pertussis bacteria, and was introduced as a safer alternative that would continue to protect the world from pertussis without the side effects of the vaccine. After a short time, researchers realized this new, safer vaccine had come at a great cost--the immunity did not last (Allen, 2013). Adolescents and adults were left unprotected, marking the start of a rapid rise in pertussis that has persisted to present day. So began the pertussis paradox: vaccine uptake increased with the safer acellular pertussis vaccine but the incidence of pertussis started to climb (Allen, 2013).

While adults and adolescents with waning immunity have the highest disease rate, infants less than three months of age are at the greatest risk. Nitsch-Osuch et al. (2015) reported adults and older siblings are responsible for at least three-quarters of pertussis

infections in infants. Infants cannot receive their first DTaP vaccine until two months of age; with their developing immune systems, infants have the highest morbidity and mortality associated with pertussis infection (Sawyer & Long, 2015). With this grim realization, the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) have tried different strategies focused on protecting infants from pertussis (CDC, 2014b). The first of these strategies included a recommendation for a one time adult and adolescent booster of Tdap in 2005 to try and reduce the incidence in illness in the population believed to be responsible for the highest transmission to infants (CDC, 2014b). Another recommendation was released in 2008 for a one-time maternal immunization with Tdap in the immediate postpartum period with the goal of protecting the mother and thus protecting the infant with whom she would have the most contact (CDC, 2014b). It was determined that only protecting the mother would not offer enough protection to the infant so a new strategy--providing a booster to any unvaccinated adults or adolescents who would have contact with infants--was recommended in 2011 (CDC, 2014b). While effective, this strategy called cocooning was not financially feasible on a grander scale and still left the infant without any immunity of his or her own. (CDC, 2014b)

With emerging evidence of placental transfer of antibodies producing passive immunity in infants, maternal immunization during pregnancy was determined a key strategy to reduce the burden of pertussis in infants. In 2012, the CDC and ACIP announced the recommendation to provide the Tdap vaccine to all pregnant women between 27- and 36-weeks gestation regardless of previous vaccine status (Nesin, Read, Koso-Thomas, Isaacs, & Meulen, 2015). Despite the recommendation from the CDC and

ACIP as well as an increasing amount of evidence supporting the safety and efficacy of the Tdap during pregnancy, national vaccine rates remained low and the incidence of pertussis remained high. The purpose of this quality improvement project was to find an effective means of increasing the uptake of the Tdap vaccine in pregnancy in the primary care setting. This project addressed the following problem/patient/population, intervention, comparison, and outcome (PICO) question: In pregnant women 27-36 weeks gestation, how does the implementation of an intervention bundle including patient educational material, medical assistant education on existing standing order, and an updated provider checklist with visual reminder tool compared with no change in current practice affect Tdap vaccination rates in a large, urban primary care clinic?

Background

Pertussis is a highly contagious, acute respiratory disease caused by the bacteria *Bordetella pertussis* or *B. pertussis* (Yeh & Mink, 2016). This disease is most notable by its paroxysmal cough that can lead to post-tussive emesis and is characterized by the "whooping" sound made on inspiration (Cornia & Lipsky, 2015). Pertussis is a gram-negative bacteria transmitted only between humans through respiratory secretions (Yeh & Mink, 2016). It has a longer incubation period than most other viral respiratory infections, ranging from one to three weeks, in stark contrast to typical viral infections whose incubation period is usually only one to three days (Cornia & Lipsky, 2015).

There are three stages of pertussis: catarrhal, paroxysmal, and convalescent. Yeh and Mink (2016) described the catarrhal stage as the early stage of pertussis where the aerosolized droplets are most contagious and there is the highest risk for transmission. During this stage, the illness most resembles an upper respiratory infection with mild

cough, sneezing, watery eyes, and low-grade fever without the notable paroxysmal cough and inspiratory whooping. It is assumed the similarities between the common cold and the catarrhal stage of pertussis are primarily the reason for the high rates of transmission from adults and adolescents to unprotected infants. The catarrhal stage typically lasts between one and two weeks. The paroxysmal stage is where the severity of illness increases and infants have the highest rates of mortality. Yeh and Mink described this stage as distinctive--there are long periods of coughing without the ability to inspire, causing the infants to become cyanotic and appear apneic. The paroxysmal stage is where there is the typical inspiratory whoop and post-tussive emesis with coughing spells. Infants are more at risk for complications at this stage with reported cases of bradycardia, tachycardia, apnea, seizures, respiratory distress, respiratory failure, pneumonia, hypotension leading to shock, renal failure, and death (Yeh & Mink, 2016). This stage can last up to eight weeks where the paroxysmal cough worsens over the first couple of weeks, remains at a high intensity for two or three weeks, and then gradually lessens. According to Yeh and Mink, the last stage, the convalescent stage, can last several weeks to months with symptoms gradually subsiding until resolved.

Treatment for pertussis varies depending on the age of the individual. Adults and adolescents can be treated with antibiotics and usually recover at home without any complications (Yeh, 2016). Children greater than one year of age may require some more supportive therapy, such as fluid administration and nutritional support, but are rarely hospitalized (Yeh, 2016). Infants less than six months old have a higher morbidity and mortality associated with pertussis and often require supportive therapy in the hospital setting. Infants who are in respiratory distress will be admitted to the hospital for

supportive therapy where the diagnosis of pertussis is then established through clinical indications or polymerase-chain reaction assays (PCR). Infants are placed in droplet isolation and have an intravenous catheter established for parenteral fluids and antibiotics (Yeh, 2016). Supportive therapy is continued until the infant is able to tolerate paroxysmal coughing episodes without subsequent hypoxia requiring oxygen and is able to eat independently (Yeh, 2016).

Prior to the introduction of the vaccine, the highest incidence of pertussis in the United States occurred in 1934 with 250,000 reported cases (Cornia & Lipsky, 2015). The first vaccine came in 1933 when the pertussis bacteria, suspended in a phenolyzed saline, was introduced (Cherry, 1996). Over the next decade, scientists tried different ways to create an effective vaccine. Then in the early 1940s, the whole cell vaccine was introduced and a significant decrease was seen in the incidence of pertussis around the world (Cherry, 1996). The whole cell organism was then combined with the tetanus and diphtheria vaccine and the first DTP vaccine was mass produced and widely distributed in developing countries. Cornia and Lipsky (2015) reported the DTP vaccine saw high rates of localized and systemic reactions but by 1976, a disease that had once been responsible for millions of illnesses and hundreds of thousands of deaths had decreased dramatically in developing countries. In the United States, with the DTP vaccine mainstreamed and widely used, the lowest reported incidence of pertussis in 1976 was just 1,010 cases (Cornia & Lipsky, 2015).

The whole cell pertussis vaccine contained killed *B.pertussis*, diphtheria, and tetanus (Allen, 2013). Side effects associated with the whole cell pertussis vaccine included high fevers and seizures, which started an anti-vaccine movement in the early

1980s and led to manufacturers being sued and pulling out of the vaccine market (Allen, 2013). During this anti-vaccine movement, studies were done showing no identifiable link between the vaccine and any permanent brain impairment but the damage to the public's perception of the vaccine's safety was done, compelling manufacturers to start looking at a safer version of pertussis immunization. The new vaccine replaced the whole cell killed *B. pertussis* component with pieces of the bacteria that had been purified to remove any possible contributors to the side effects experienced with the whole cell vaccine (Allen, 2013). Soon after the DTP vaccine was taken off the market and replaced with the diphtheria, tetanus, acellular Pertussis (DTaP) vaccine, it was discovered the side effects of the original DTP vaccine were from an endotoxin released from the bacteria's cell membrane (Allen, 2013). The newer DTaP quickly had the component associated with the endotoxin removed from the vaccine and became the new and widely used replacement of the whole cell vaccine.

Allen (2013) wrote that soon after the wide-spread use of the acellular vaccine, antibody responses to the vaccine were as high, if not higher than the whole cell vaccine, without the fevers and seizures that started the anti-vaccine movement in the 1980s. All was well until data started to emerge about increasing incidences of pertussis in adolescents and young adults who had been among the first cohorts of children to receive the DTaP. Cornia and Lipsky (2015) described how the emergence of pertussis in this age group led researchers to the conclusion that the newer, safer acellular pertussis vaccine had a waning immunity the whole cell pertussis vaccine did not have. This waning immunity created a resurgence of pertussis in adolescents and adults with less

severe disease symptoms, was often mistaken for other respiratory illnesses, and led to unintended exposure to unprotected infants (Cornia & Lipsky, 2015).

Significance

Trending data from the introduction of the acellular pertussis vaccine in the mid-1990s showed a steady increase in pertussis rates in the United States. The highest numbers were seen in the peak epidemic of 2012 with 48,277 cases of confirmed pertussis in all age groups. Of the total cases reported that year, more than half were in adults and adolescents where immunity was believed to have waned from childhood vaccinations (CDC, 2013a). There were 20 confirmed deaths from pertussis in 2012 and 15 of those deaths were in infants less than three months old, accounting for 75% of the pertussis-related deaths that year (CDC, 2013a). There were 13 total deaths from pertussis in 2013 and 12 of those deaths were in infants less than three months old, accounting for 92% of the pertussis-related deaths (CDC, 2014a). In 2014, there were 13 deaths related to pertussis and eight of those deaths were in infants less than three months old, accounting for 61% of the pertussis-related deaths that year (CDC, 2015a). The burden of pertussis in infants is significantly higher than that of children, adolescents, and adults. Infants with the disease have the highest rate of hospital admissions and carry the highest morbidity and mortality rate (Goldfarb, Little, Brown, & Riley, 2014). The 2012 pertussis epidemic raised new concerns for healthcare providers on how to more effectively protect this vulnerable population.

Financial Impact

Pertussis illness brings with it a heavy economic burden. The financial burden of pertussis can be measured in the cost of treatment and hospitalizations as well as loss of

productivity for those caring for the ill. Even in countries that have implemented vaccination programs targeted at reducing pertussis illness, the persistence of the pertussis endemic remains a significant public health concern. The true economic burden of pertussis is hard to measure as it is assumed this disease is widely underdiagnosed and underreported. Greenberg and Caro (2005) offered some idea of the cost of pertussis on an individual level. For infants younger than the age of two months, the estimated cost of pertussis disease was $2,822, which would increase with hospitalization and complications to as much as $6,337 per infant. The authors also reminded the readers these costs were for direct care costs and did not include productivity and income lost when parents were missing work to care for their sick child (Greenberg & Caro, 2005).

Caro et al. (2013) examined the true cost and burden of the pertussis illness. This study found the highest direct medical costs of pertussis were in the infant population. The direct medical costs reported by Caro et al. were in line with those reported by Greenberg and Caro (2005) but this study expanded on the indirect costs of pertussis illness by lost days of work. Caro et al. found the average number of days lost when caring for an ill family member with pertussis was six days of work with an estimated cost of $767 per family when caring for an ill family member at home and $1,025 per family when caring for a hospitalized infant.

O'Brien and Caro (2005) reported costs of pertussis hospitalizations by age group. Data were gathered from hospital discharge databases from 1,000 hospitals in four different U.S. states between 1996 and 1999. The results of this study found infants less than one-year-old made up the majority of pertussis-related hospitalizations and those hospitalizations were costlier than the older cohorts. The mean cost of an average six-

day hospital stay for infants was $9,586 compared to a mean cost of $4,729 for adolescents and adults (O'Brien & Caro, 2005).

To determine whether or not a vaccine strategy would be cost effective, the first step has been to define the value of life. This value in literature was often measured as quality adjusted life years (QALY), which is a method of assigning value to years of life gained through disease prevention and/or treatment. Lugnér, van der Maas, van Boven, Mooi, and de Melker (2013) performed a cost-effective analysis by examining three different vaccine strategies in an effort to reducing the burden of pertussis illness on newborns and infants: neonatal vaccination, maternal vaccination, and cocooning. From strictly a monetary standpoint, this cost-effective analysis found cocooning was more cost-effective than the maternal vaccination strategy. With regard to QALY gained, the maternal vaccine strategy found higher QALY gained for the maternal vaccination strategy (Lugnér et al., 2013).

Terranella, Asay, Messonnier, Clark, and Liang (2013) conducted a study using a cohort model that looked at all U.S. births in 2009 and analyzed cases of pertussis, hospitalizations, and deaths of infants less than one-year-old. They also looked at the direct and indirect costs of pertussis illness in infants less than one year of age. These numbers were analyzed to simulate the cost of maternal vaccination versus the post-partum cocooning strategy and looked at cost-effectiveness and quality adjusted life year. The results of this study found maternal immunization reduced pertussis rates by 33% whereas postpartum vaccination reduced pertussis rates by 20%. Hospitalizations were reduced by 38% with the maternal vaccination method and 19% by the postpartum method. Deaths related to pertussis illness in infants less than one-year-old were reduced

by 49% in infants whose mothers received the Tdap vaccine during pregnancy compared with 19% whose mothers were vaccinated after pregnancy. Cost was calculated based on QALY saved and was significantly lower for maternal immunization versus postpartum vaccination--$414,523 versus $1,172,825, respectively (Terranella et al., 2013).

Improving Tetanus, Diphtheria, and Acellular Pertussis Immunization Rates Using the Reach, Efficacy, Adoption, Implementation, and Maintenance Framework

Introduced in 1999, the purpose of the reach, efficacy, adoption, *i*mplementation, and maintenance (RE-AIM) model was to give researchers a theoretical model to evaluate how well an intervention would reach and impact a community (Glasgow, Vogt, & Boles, 1999). It seemed relevant that health promotion interventions in the public and community health settings were only as good as could be measured through effective evaluation. A systematic review of the use of RE-AIM described the use of the framework from early and planning stages of an intervention, providing guidance throughout the process and a structured method for evaluation as valuable on the impact of public health and community-based initiatives (Gaglio, Shoup, & Glasgow, 2013). The purpose of RE-AIM is to determine the real-world applicability and viability through methodical and standardized assessment as a way to ensure generalizability and sustainability in the community and population (Virginia Tech, 2015). By carefully reviewing the RE-AIM framework, Gaglio et al. (2013) described the most efficacious use of this model is when all five dimensions are discussed individually and comprehensively.

Reach

Identification of a target population is among one of the first steps in initiating a community-based intervention. The target population for this capstone intervention was pregnant women at a large, urban primary care and family medicine clinic in Greeley, Colorado. This group was chosen because improving immunization rates for tetanus, diphtheria, and acellular pertussis (Tdap) during pregnancy would not only benefit the mother but had the end goal of preventing pertussis illnesses in her unborn child. Reach, the first evaluation dimension in the RE-AIM network, determined what percentage of pregnant women targeted by this capstone would participate in the intervention. Prior to initiation of this intervention bundle, it was estimated approximately 11% of the population at the target clinic were being seen for pregnancy-related health maintenance. The first goal was to reach 100% of the target population by providing every pregnant patient with educational material regarding the safety and efficacy of the Tdap during pregnancy at their initial intake visit. It was determined the percentage of pregnant women who participated (received the vaccination) also depended on education provided to medical assistants and providers. The optimal way to reach 100% of medical assistants was to attend two required monthly meetings and provide verbal education regarding an existing standing order to provide every pregnant patient between 27 and 36 weeks with a Tdap booster. To reach the providers, the intervention thought to have the most impact was to update an existing provider checklist that would be placed in every pregnant patient's physical obstetrics chart.

Effectiveness

The RE-AIM framework (Virginia Tech, 2015) defined an effective initiative or intervention as having a positive impact on the quality of life and health outcomes of individuals, communities, and populations. The effectiveness of any intervention describes the end result at the individual level, i.e., the target population was reached and participated and there were positive outcomes (Glasgow et al., 1999). The goal of this intervention was to increase Tdap rates in an effort to decrease the rates of pertussis in the infant population by offering passive immunity through the transference of maternal pertussis antibodies. Pertussis does not discriminate. It affects individuals of all ages, races, ethnicities, and cultures. It does not target specific populations based on socio-economic status, income levels, or educational levels. Children, adolescents, and adults who are infected by *B. Pertussis* can be sick for weeks or even months but typically recover without any long-term sequela. On the other hand, infants have a longer duration of illness, can have lengthy and costly hospitalizations, and have the single highest rate of mortality from pertussis (Cornia & Lipsky, 2015). The effectiveness of this intervention bundle was intended to improve Tdap vaccination rates at the individual level, increase the likelihood of population-based generalizability, and to affect vaccine rates at a national and global level. Preventing illness in newborns and infants through maternal vaccination will have a long term impact on the health outcomes of individuals, communities, and populations, as well as having a positive economic impact by reducing vaccine preventable illnesses that can lead to costly hospitalizations and death.

Adoption

Adoption of the intervention bundle was measured at the organizational level through compliance of all clinic staff, medical assistants, and providers. Adoption differs from reach in that it measures use and compliance in the setting and at community and population-based levels; reach looks only at the individual level. Use of the Tdap vaccine during pregnancy has been well-researched and is backed at local, state, national, and global levels through widespread recommendations by the National Institutes of Health (NIH), Centers for Disease Control (CDC), American College of Obstetricians and Gynecologists (ACOG), World Health Organization (WHO), and various other institutions around the world (CDC, 2013b). The plan for adopting this intervention was assessed through medical assistant and provider surveys. The surveys assessed the effectiveness of the medical assistant educational sessions to evaluate the intervention as well as any barriers the medical assistants found when ordering and giving Tdap vaccines to pregnant patients. The providers were also given a survey to assess the effectiveness of the provider reminder tool and CDC (2015c) pertussis factsheet as well as barriers and opportunities for improvement.

Implementation

Implementation is different from adoption and/or effectiveness in that it looks at how well or not a program was initiated as originally intended (Glasgow et al., 1999). Planas (2008) further described implementation as having intervention fidelity or holding true to/committing to implementing an intervention as planned and proposed. The intervention for this capstone consisted of three quality improvement strategies implemented at the provider and medical assistant levels in an effort to increase

compliance and rates of Tdap during pregnancy. The interventions are described in greater detail in Chapter III but in summary, they included an update to an existing provider reminder checklist in use prior to the intervention, two educational sessions for medical assistants regarding the use of an already existing standing order that included Tdap during pregnancy, and the inclusion of a CDC authored educational handout discussing the safety and efficacy of the vaccine during pregnancy in pre-existing patient education packets. To maintain intervention fidelity, the same educational material was provided to all pregnant patients, the education provided to the medical assistants was done at the monthly meetings using the same educational PowerPoint, and the current checklist used by providers was updated to ensure each provider was given the same information. The purpose of each intervention was to enhance practices already established in this clinic to improve the likelihood of maintenance.

Maintenance

Maintenance refers to long-term outcomes and sustainability at both the individual and organizational levels (Planas, 2008). Maintenance of this quality improvement project at the individual level was reflected by increased compliance in receiving the vaccine at the right interval, which was intended to lead to a reduction in pertussis rates in northern Colorado. Measuring maintenance at the individual level could only be completed by measuring compliance as measuring associations between the vaccine and decreased pertussis rates were out of the scope of this project. Maintenance at the organizational level was reflected in the increased rates of the Tdap vaccine given during pregnancy and was measured through retrospective chart review. Planas (2008) described several factors that influenced the long-term uptake and success

of an intervention. The first factor described was the manner in which the site was initially approached with the intervention plan. Interventions rooted in a research nature were determined to have a lower likelihood of long-term success as the participants often saw the interventions and results as short term. Interventions such as this one, which was approached as quality improvement, were often viewed more as long term with a higher likelihood for adoption and compliance (Planas, 2008). This intervention was meant to be long term as it was not a practice change but rather an update and improvement of interventions already in place. This quality improvement project used key personnel who were already in place and described as being vital to successful implementation and maintenance (Planas, 2008). The last factor described by Planas was the meaningfulness of the intervention to stakeholders. Stakeholders in this intervention were pregnant women, medical assistants, and clinic providers. This intervention was anticipated to be meaningful to the majority of pregnant women as this intervention provided optimal protection to newborn infants from pertussis. Providers and medical assistants, with the understanding they were providing a meaningful service, were predicted to maintain this practice for the benefit of their individual patients, families, and communities.

Project Objectives

This intervention plan focused on providing resources and education to office providers including physicians, nurse practitioners, and medical assistants. There were three primary objectives for the project:

- Update and improve current practice to increase the rate of Tdap immunizations in pregnant women at North Colorado Family Medicine.

- Increase provider awareness and compliance with the national recommendations of providing every pregnant patient with a Tdap vaccine between 27- and 36-weeks gestation.
- Increase medical assistant awareness and compliance with current standing order to administer all pregnant patients with Tdap vaccine.

Intervention methods were implemented and evaluated based on these three primary objectives and are described in more detail in the methods section.

Congruence of Intervention Plan with Organization's Strategic Plan

North Colorado Family Medicine is part of a larger system (Banner Health) with clinics located in Arizona, Alaska, California, Colorado, Nebraska, Nevada, and Wyoming (Banner Health, 2016a). Banner Health (2016a) considers itself one of the top nonprofit organizations in the country--their primary focus being to excel in their mission to make a difference in the lives of every person who interacts with the system. Banner Health describes its strategic plan as providing the best care and health services to communities it serves rather than just focusing on generating profits. By following this strategic model, Banner Health reinvests all of the money earned into updating technologies, attracting provider talent, paying employee salaries, and improving every clinic and hospital to the highest standards. Banner Health (2016a) describes in their own words their mission, vision, and values:

> **Mission.** To make a difference in people's lives through excellent patient care (para. 1).
> **Vision.** We will be a national leader recognized for clinical excellence and innovation, preferred for a highly coordinated patient experience, and distinguished by the quality of our people (para. 7).

This quality improvement project sought to align with the strategic plan, mission, and vision of Banner Health by providing the safest and most up-to-date care to pregnant women and their unborn children. The Tdap in every pregnancy is a national initiative supported by research regarding the safety and efficacy of the vaccine and is a relatively low cost and easy initiative with long-lasting benefits (National Foundation for Infectious Diseases [NFID], 2014).

Summary

Pertussis is a respiratory illness that is gravely dangerous to infants less than three months old. There have been 35 reported deaths in infants less than three months old related to pertussis in the last three years in the United States (CDC, 2103a, 2014a, 2015a). Infants in this age range are highly susceptible to this illness because the first immunization protecting babies from pertussis is not given until two months of age, the full series is not completed until 12-18 months of age, and a booster shot is given between four and six years old (CDC, 2015c). Adults, older children, and adolescents act as the primary source of infection to these newborns and young infants as the early symptoms in adults and adolescents often present as the common viral cold. Vaccinating every mother with the Tdap vaccine during pregnancy offers passive immunity to the newborn for the first two months of life until the first Tdap vaccine can be safely administered (CDC, 2015b). Care of the pregnant patient is done in many settings including obstetric offices, family care clinics, and hospital settings. Vaccines are commonplace in most office settings and it is assumed the majority of providers are knowledgeable about the safety and efficacy of the Tdap vaccine. Pregnant women rely on their providers to maintain the most up-to-date knowledge regarding the

recommendations, safety and efficacy of vaccines. In following the most updated recommendations, providers have a responsibility to discuss the Tdap vaccine with every pregnant patient, reduce vaccine hesitancy with increased patient education during office visits, and then offer and administer the vaccine to every pregnant patient.

CHAPTER II

LITERATURE REVIEW

A literature search was conducted using PubMed, CINAHL, Cochrane library, and Google Scholar. The search was done using various combinations of the following key words and phrases: immunizations in pregnancy, Tdap in pregnancy, pertussis and pregnancy, safety of Tdap immunization in pregnancy, pregnancy outcomes and Tdap, immunizations and birth outcomes, immunogenicity of Tdap in pregnancy, vaccine hesitancy and pregnancy, Tdap vaccine uptake and pregnancy, vaccine perceptions and pregnancy, vaccination improvement strategies and Tdap, epidemiology and pertussis, and effectiveness of Tdap in pregnancy. For the scope of this project, the entirety of literature regarding Tdap vaccines during pregnancy was not included and studies were chosen based on relevance to the current project. The literature review parameters included only studies published in the last five years and all types of studies were included. Studies from different countries were included based on relevance to the current project. Studies were sorted into the following categories: vaccine safety, vaccine effectiveness, immunogenicity, vaccine hesitancy, and vaccine uptake improvement strategies.

Vaccine Safety

Five studies and one systematic review were included that assessed the safety of the Tdap vaccine in pregnancy. Different outcomes measured included unspecified

adverse events, infant growth and development, small for gestational age (SGA), preterm birth, major malformations, chorioamnionitis, Apgar score, cord blood pH, hypertensive disorders in pregnancy, and spontaneous abortion and stillbirth rates.

Kharbanda et al. (2014) measured different obstetric outcomes in mothers and any adverse events in newborns just after birth. Specific events and outcomes measured were SGA births, chorioamnionitis, preterm birth, and hypertension in pregnancy. This study was a retrospective, observational cohort study that measured the outcomes of 123,494 women between 2010 and 2012. Data for this study were pulled from the California Vaccine Safety Datalink database. Of the 123,494 women studied, 26,229 received the Tdap vaccine during pregnancy. No association was found between the Tdap vaccine and any adverse obstetric or birth outcomes.

Kharbanda et al. (2016) measured adverse outcomes in a large observational study of women who received the Tdap vaccine between 2007 and 2013. Specific outcomes included neurologic events, thrombotic events, new onset proteinuria, gestational diabetes, cardiac events, and thrombocytopenia. Data were collected from the California Vaccine Safety Datalink. No acute adverse events were measured in the cohort of women who received the vaccine during pregnancy.

In a retrospective cohort study, Morgan et al. (2015) compared pregnancy outcomes among women who received Tdap during pregnancy, women who did not receive Tdap during pregnancy, and multiparous women who had received Tdap in a previous pregnancy within the last five years. Outcomes measured were rate of stillbirths, major malformations, chorioamnionitis, five-minute Apgar score, and cord blood pH. The study did not find any increase in adverse outcomes in the group that

received the Tdap vaccine during pregnancy; however, the study did find significantly increased rates of preterm birth and SGA births in the unvaccinated group.

Munoz et al. (2014) conducted a phase 1-2, randomized, double-blind, placebo-controlled clinical trial measuring outcomes in women who received the Tdap immunization between 2008 and 2012. The primary outcomes looked for any adverse outcomes with receipt of the vaccine but were not specific. The study also measured post-partum pertussis illness and the growth and development of the infant through the first 13 months of life. There were no measurable adverse events after receipt of the Tdap vaccine during pregnancy and growth and development were similar in all groups.

In a retrospective cohort study that looked at 138 women who had received the Tdap vaccine during pregnancy, Shakib et al. (2013) measured birth outcomes including rates of preterm births, spontaneous abortions, and SGA births. This study found no increased risk for preterm birth, spontaneous abortion, and SGA birth for women who had received the Tdap vaccine during pregnancy.

One systematic review included in this literature review related to the safety of the Tdap vaccine during pregancy. Keller-Stanislawski et al. (2014) looked at the overall safety of vaccines during pregnancy and was not restrictive to Tdap. After review of literature from 1946 to May 2013, it was concluded the benefit of antenatal vaccines outweighed any potential risks with the exceptions of the live influenza and live mumps/measles/rubella vaccines. No safety concerns were specifically identified for the acellular pertussis.

Vaccine Effectiveness

This literature search included two studies that looked at the effectiveness of the maternal Tdap vaccination in reducing the incidence of or preventing pertussis illness in infants. In a case-control study conducted between October 2012 and July 2013, Dabrera et al. (2015) looked at rates of pertussis infection in infants of mothers who received the Tdap vaccine during pregnancy versus the rate of infants whose mothers were unvaccinated. There were 58 cases of pertussis; only 10 of the mothers had received the Tdap vaccine during pregnancy whereas 39 of the 55 mothers in the control group had received the vaccine. This study found a 93% vaccine effectiveness rate in mothers who had received the vaccine versus mothers who had not received the vaccine. In an observational study of pregnant women during a pertussis outbreak in England in October 2012, Amirthalingam et al. (2014) looked at vaccine effectiveness by comparing vaccine coverage in a group of women whose infants were diagnosed with pertussis versus the general population of pregnant women. After widespread Tdap vaccination during pregnancy, England saw a 79% reduction in infant deaths from pertussis--from 2.02 per 100,000 live births in 2012 (before the implementation of vaccination recommendation) to 0.43 per 100,000 live births in 2013. With an estimated vaccine effectiveness rate of 91%, recommendations to vaccinate all pregnant women between 27- and 36-weeks gestation have continued as the preferred approach in the reduction of pertussis illness.

Immunogenicity

The literature search yielded seven original research studies that measured immunogenicity, antibody levels in infants, the effect of timing on the levels and avidity of maternal antibodies, the humoral and cell mediated response to the Tdap vaccine in

pregnant and nonpregnant women, and passive immunity provided to the infant through breast milk after antenatal vaccination. The primary outcome of five of the studies looked at the transfer of maternal antibodies to the newborn after antenatal vaccination.

Four of these studies were conducted at the Bnai Zion Medical Center in Faifa, Israel. A prospective study by Raya, Srugo, Kessel, Peterman, Bader, Gonen et al. (2014) looked at the effect of the timing of maternal vaccination and how this could affect antibody transference through measures of maternal serum and cord serum antibody levels at birth. Women were vaccinated at different stages in pregnancy--one group between 27 and 30 weeks, one group between 31 and 36 weeks, and the last group from 36 weeks to term. Women who were vaccinated between 27 and 30 weeks had the highest concentrations and women vaccinated after 36 weeks had the lowest concentrations of maternal pertussis antibodies.

The next study by Raya, Bamberger et al. (2015) assessed the binding strength between antibody and antigen and their relative avidity in relation to the timing of the Tdap vaccine during pregnancy. The relative avidity of the maternal immunoglobulin G to the pertussis toxin was measured between 23 and 38 weeks through newborn cord serum. The higher the avidity of the pertussis toxin to the immunoglobulin G, the higher the protective effects it would have on the infants. This study found the highest avidity and, therefore, the highest level of protection to infants when their mothers were vaccinated between 27 and 30 weeks.

In a prospective study, Raya, Srugo et al. (2015) wanted to assess how significant the decline of pertussis antibodies would be in women who were vaccinated late in pregnancy and whether or not there would be any lasting protection into subsequent

pregnancies. The results of this study showed a significant decline in pertussis-specific antibodies in maternal serum at nine months and 15 months postpartum. This study was significant as it enforced the importance of receiving the Tdap vaccine in every pregnancy regardless of previous vaccination status.

The last study by Raya, Srugo, Kessel, Peterman, Bader, Peri et al. (2014) wanted to assess if there was any significant transfer of maternal pertussis-specific antibodies in the breastmilk of women vaccinated with Tdap late in their pregnancy. Colostrum pertussis antibody levels were measured and found to be significantly higher in women who had received the Tdap vaccine after their 20th week. This study not only augmented the data behind the support of vaccination during pregnancy but also the data supporting breastfeeding.

Vilajeliu et al. (2015) conducted an observational study that sought to determine maternal transference of pertussis-specific antibodies from mother to unborn infant. Serum was measured in mothers prior to vaccination and then maternal and infant serums were again measured after vaccination. It was found infants whose mothers were vaccinated during pregnancy had higher levels of the anti-pertussis antibodies, enough to protect them for at least the first two months of life.

Munoz et al. (2014) conducted a phase 1-2, randomized, double-blind clinical trial whose primary outcome measured adverse events but whose secondary outcome measured anti-pertussis antibody levels in infants at birth, two months, and after third and fourth doses of DTaP. Antibodies measured at birth and two months were significantly higher in infants whose mothers had received the Tdap vaccine and did not show any decrease in response to the DTaP vaccine received in infancy. This study was significant

because it showed the Tdap vaccine in pregnancy did not alter the infant's response to actively building immunity to the DTaP vaccine starting at two months.

The last study related to immunogenicity by Huygen, Caboré, Maertens, Van Damme, and Leuridan (2015) measured humoral and cell-mediated immune responses in pregnant and non-pregnant women. Antibody response levels were measured at one month and one year after immunization and it was found pregnant and non-pregnant women had similar humoral and cell-mediated responses to the vaccine. What was significant about this study was the follow up at one-year post vaccination. Antibody levels had waned to the extent that there would not be sufficient transfer of maternal antibodies in any subsequent pregnancies, supporting the recommendation for repeat vaccination with every pregnancy.

Vaccine Hesitancy

Regarding maternal perceptions and hesitancy of the Tdap vaccine during pregnancy, this literature review found four studies and one systematic review that met inclusion criteria. Healy, Rench, Montesinos, Ng, and Swaim (2015) conducted a prospective, convenience survey of women during pregnancy at a large urban health center. There were 796 surveys completed by pregnant women and 63 surveys by providers assessing women's attitudes toward their provider's recommendations, knowledge of recommended vaccines during pregnancy, and willingness to receive those vaccines. Survey results showed pregnant women saw their provider as the most trusted source of information (84%) and the majority of women would be willing to receive the Tdap or influenza vaccine if educated on the vaccine and recommended by their provider (83%).

In a randomized, prospective study, Payakachat, Hadden, and Ragland (2016) examined whether or not educational material, specifically a vaccine information sheet, would improve maternal vaccine uptake of the Tdap vaccine. This study was conducted at two urban women's clinics where two groups were randomized to receive the CDC (2015c) vaccine information sheet (VIS) and a modified VIS. There was no statistical difference in the vaccine uptake between the two groups but the authors described that of 250 women who were included in the study--whether they received the VIS or the modified VIS, there was a significant increase in uptake of the Tdap vaccine to 47% compared to the previous rate of 13%. The authors described this study as significant as the higher rate of uptake could be directly attributed to increased education provided to the patients regarding vaccines during pregnancy.

Donaldson et al. (2015) conducted a cross-sectional survey of an ethnically diverse group of 200 women who received prenatal care through a large public health system in London. The purpose of this survey was to glean a better understanding of what determined uptake of vaccines during pregnancy. Of the women surveyed, only 26% received the Tdap vaccine during pregnancy. Regarding this poor uptake, it was determined only 34% of the women survey had even been offered the vaccine and only 24% of the women reported having a discussion with their practitioner regarding the vaccine. This study found the greatest barriers to vaccine uptake were lack of recommendation by providers and lack of accurate and timely information and education regarding the vaccine during pregnancy.

Larson et al. (2015) and the World Health Organization's (WHO) Strategic Advisory Group on Experts (SAGE) on Immunization sought to define the various

reasons for vaccine hesitancy through the development of a survey tool. This survey tool was valuable as a way of monitoring vaccine hesitancy--one of the major influences keeping vaccine uptake low. These authors described the importance of their work in separating the vaccine refusal group from the vaccine hesitancy group and focusing efforts to improve uptake by targeting the vaccine hesitancy group. This article was included not because it provided research data on vaccine uptake or hesitancy, but rather a focus for researchers and providers to aim their efforts in improving vaccination rates. The survey was sorted into key factors affecting vaccine uptake: contextual, vaccine specific, and individual or group in relation to the decision to accept, delay, or refuse vaccine recommendations.

A systematic review conducted by Wilson, Paterson, Jarret, and Larson (2015) systematically assessed the most up-to-date literature regarding factors that influence vaccine acceptance during pregnancy. A total of 155 articles were included in the search looking at vaccine hesitancy regarding influenza, tetanus, and pertussis vaccines during pregnancy. After review of these 155 articles, it was determined the factors affecting uptake of vaccines during pregnancy most cited and relevant to pregnant women included vaccine safety, vaccine effectiveness, no recommendation from provider, lack of education regarding vaccines during pregnancy, access to vaccines, cost, and conflicting recommendations. The barriers most cited by providers and other health care professionals included inadequate training, reimbursement issues, and increased workload. This systematic review on the global perspectives about vaccinations during pregnancy offered more concise areas to target for vaccine improvement strategies.

Vaccine Uptake and Improvement Strategies

This literature search yielded five studies that met inclusion criteria related to vaccine uptake and improvement strategies. In a retrospective study of all women delivering at one hospital between February and June of 2013, Goldfarb et al. (2014) looked at the different demographics and what potential predictors influenced whether or not women received the Tdap vaccine during pregnancy. The authors identified 1,467 women, 1,194 (81.6%) of whom received the Tdap vaccine during pregnancy. Through multivariable logistic regression, three factors were found to influence women in receiving the Tdap vaccine during pregnancy. The first factor found women were more likely to receive the Tdap vaccine if they had already received the influenza vaccine during their current pregnancy. The next variable showed Black women were least likely to receive the Tdap vaccine. The last variable found women who delivered prematurely were less likely to have received the Tdap vaccine. The purpose of this study was to identify disparities in women who did or did not receive the Tdap vaccination during pregnancy so further research could be conducted to minimize these disparities.

Forsyth, Plotkin, Tan, and von König (2015) reviewed all available literature regarding which strategies were best for protecting newborns against pertussis. Available strategies that have been used in recent years in an effort to reduce infant mortality included Tdap in every pregnancy, immunizing all family members and anyone with close contact to infants less than six months old (also known as cocooning), immunizing both parents in immediate postpartum period, and immunizing only the mother in immediate postpartum period. The authors of this article came from different countries around the world as experts in the Global Pertussis Initiative (GPI; Forsyth et al., 2015).

Through expert review of available evidence and literature, the GPI recommended Tdap in every pregnancy as the most effective method for reducing the burden of pertussis on infants. Cocooning and immunizing either parents, or only mothers, were considered sufficient if Tdap was not or could not be given during pregnancy.

Healy, Ng, Taylor, Rench, and Swain (2015) reviewed uptake of Tdap in pregnancy at a large urban hospital between April 2013 and June 2014. They reviewed 6,577 deliveries over the course of this one+ year period. In April 2013, the uptake of Tdap during pregnancy was approximately 36%. Over the next year, provider recommendations increased after the release of the ACOG toolkit as well as provider trainings and reminders at meetings. With the implementation of these reminders, uptake of Tdap increased from 36% to greater than 61% and sustained above that percentage starting in November, 2013. Of note, women were categorized into different age ranges and race/ethnicities and like Goldfarb et al. (2014), Black women were the least likely to receive the Tdap immunization. The authors reported no clear reason why this group of women was significantly less likely to receive the Tdap during pregnancy; further research will be needed to discern the exact nature of this disparity. The overall conclusion of this study suggested providing education to providers and provider recommendations to patients are important factors in increasing the uptake of Tdap during pregnancy.

Morgan et al. (2015) evaluated how using a best-practice alert in the electronic health record (EHR) improved Tdap rates in pregnancy. In a groundbreaking effort to reduce the burden of pertussis on infants, implementation of a best-practice alert increased the uptake of Tdap in pregnancy from 48% to 96.8%. This best-practice alert

was programmed to appear starting at 32-weeks gestation and continue to appear with every visit until documented receipt of the vaccine or delivery occurred. Use of a best-practice alert was clearly an advantageous tool to remind providers to give Tdap during pregnancy but offered a logistical problem to groups of providers that could not get approval for changes in or did not use an EHR.

In a systematic review of evidence, Bechini, Tiscione, Boccalini, Levi and Bonanni (2012) analyzed use of the Tdap vaccine in high-risk groups such as pregnant women, healthcare workers, newborns, and adolescents. Literature supported the use of Tdap vaccine in pregnancy as a useful tool for reducing the burden of pertussis on the infant population. Studies in immunogenicity showed a correlation with higher antibody levels and a reduction in the risk of developing pertussis. This review supported the current recommendation to provide the Tdap vaccine in every pregnancy as the primary strategy for protecting infants from pertussis.

A cluster-randomized trial by Chamberlain et al. (2015) examined the results of a multi-component antenatal vaccine package targeted at improving Tdap and influenza uptake during pregnancy. Chamberlain et al. offered different strategies for increasing vaccine rates during pregnancy including posters, brochures, lapel buttons, a vaccine champion, education materials at the practice and patient levels, and provider education at the provider level. This study did not find a statistically significant increase in the uptake of vaccines during pregnancy but the authors believed that because it was introduced late in the flu season, the results were confounded. One statistically significant finding from this study was the correlation between provider recommendation and vaccine uptake. Patients reported the single most convincing reason they would

accept the Tdap or influenza vaccine was if the recommendation came from their provider.

Summary

This literature review offered a summary of evidence regarding vaccine safety, vaccine effectiveness, immunogenicity, vaccine hesitancy, and different strategies that had been used to increase vaccine uptake during pregnancy. Studies looking at the safety of the Tdap vaccine found no significant adverse events related to infant growth and development, major congenital malformations, or any complications of pregnancy such as preterm birth, spontaneous abortions, small or large for gestational age babies, or stillbirths. Two major studies regarding vaccine effectiveness found the Tdap vaccine given during pregnancy had a greater than 93% effectiveness rate at preventing pertussis in infants less than two months old. Immunogenicity studies measured amounts of antibodies passed from mother to infant through serum, colostrum, and breast milk, and found infants received the highest number of antibodies if the vaccine was given between 27- and 36-weeks of pregnancy.

The studies examining vaccine hesitancy and uptake improvement methods were important in the development of this capstone project. Multiple studies showed providers were the most trusted source of information regarding vaccine safety and effectiveness; provider recommendation yielded the most success in improving the rates of Tdap immunization during pregnancy. There was no gap in evidence supporting the safety, efficacy, or immunogenicity of the Tdap vaccine during pregnancy but was a gap in the translation of this evidence to the care of pregnant women and their families. Therefore, increasing provider adherence to national recommendations through targeted strategies

was likely to yield the best outcomes and have the highest likelihood of success in increasing rates of Tdap immunization during pregnancy.

CHAPTER III

METHODS AND EVALUATION

Providing the Tdap immunization to mothers while pregnant reduces newborn and infant complications from pertussis illnesses; yet, there remains a disparity between the evidence and immunization rates. The exact nature of this disparity is not fully understood but studies revealed provider recommendation remained the single most effective way of increasing Tdap immunization rates in pregnancy. This project was a quality improvement (QI) process that focused on updating and improving current practice in an effort to increase the rate of women who would receive the Tdap vaccine during pregnancy with the end result of preventing pertussis illness in newborns and infants less than two months old. There were three primary objectives of this QI project: (a) update and improve the current provider reminder tool, (b) increase provider awareness of national recommendations, and (c) increase medical assistant (MA) awareness and compliance with the current adult standing order for Td/Tdap vaccine in adults. Each objective had an associated intervention, evaluation plan, and measurable outcomes. The next section describes the setting, methods in detail, and evaluation plan.

Setting

North Colorado Family Medicine (NCFM) is a large family medicine clinic and physician residency program located in the center of Greeley, Colorado. This family medicine clinic sees patients of every age, gender, ethnicity, and socioeconomic status.

As one of few family medicine clinics in Greeley that accepts Medicaid, these patients comprise a large portion of the patient population. On a typical day, this clinic will have 19-20 patients per provider and 10-12 providers per day. The clinic consists of attending/faculty physicians, residents of medical and osteopathic medicine, podiatry residents, nurse practitioners, medical assistants, and ancillary administrative staff. North Colorado Family Medicine is part of a larger hospital system in northern Colorado but functions independently of the system with regard to day-to-day operations.

The first step in implementing the process improvement plan was to understand what daily practice was and where there might be an opportunity for improvement. North Colorado Family Medicine has a specific process in caring for pregnant patients from planning and conception through birth. When women find out they are pregnant and inform their providers or clinic staff, the first step is to schedule an obstetrics (OB) intake visit that focuses mainly on history including the woman's medical and surgical history as well as pregnancy history and risk factors. Prior to the OB intake visit, the clinic staff puts together a physical chart that includes questions related to history, past pregnancies, a checklist regarding pregnancy education that is broken down by trimester, and a checklist regarding specific interventions meant to guide the provider in avoiding missing important diagnostic tests and interventions throughout the pregnancy.

This visit is an opportunity for the provider to answer questions and provide an overview of pregnancy education items and the timeline for specific interventions. Lab work is ordered at the OB intake visit; patients are escorted to the lab after their visit or have the opportunity to come back prior to the next visit to have their blood drawn. After the OB intake visit is completed, an OB physical is scheduled. This visit includes a

complete physical exam, pelvic exam, pap smear if indicated, and review of lab work. Once these initial visits are completed, the remainder of the visits are considered OB maintenance visits where interventions such as immunizations and additional tests are completed as part of those routine visits. The physical OB chart is pulled for every visit including the routine maintenance visits as a resource for the provider so that it can be referenced for timing and recommendations for testing and interventions.

Three interventions in this quality improvement project targeted the three primary objectives. These interventions included an updated provider reminder tool that was laminated and placed in the physical OB chart, an educational fact sheet on the Tdap in pregnancy, and an educational meeting with medical assistants. Each intervention and evaluation method are discussed in more detail in the next section.

Intervention Plan

Objective One: Provider Reminder Tool

Considering current practice at North Colorado Family Medicine, the focus of this intervention was to build on and improve current practice by utilizing a provider reminder method already in use. Prior to the intervention, a provider reminder checklist was in use per the description of current practice. This checklist was divided by trimesters and included when to order specific diagnostic and lab tests as well as when to initiate interventions. It was noted that this reminder checklist did not include administration of vaccines during pregnancy as recommended by ACOG and the Advisory Committee on Immunization Practices for the CDC (2016).

This checklist was widely used by providers and did not require any education as to its existence. This checklist was printed on pink paper so it would stand out to

providers, was laminated, and reusable in order to reduce waste. A picture of the checklist used in previous practice can be found in Appendix A followed by the updated checklist that replaced the previous list at the start of the project (see Appendix B). The purpose of improving the previous checklist was to use a system already in place by adding a visual reminder to providers to ensure the Tdap was given in every pregnancy. Due to timing of this intervention, improving uptake of the influenza vaccine during pregnancy was not formally included in this process improvement. However, at the request of the medical director and nursing supervisor, a reminder to administer the influenza vaccine was also added to the checklist. This was not part of this capstone and was not evaluated but was added to the updated reminder checklist at the clinic's request. In an effort to improve the likelihood of providers recognizing the updated checklist, the new list was printed on purple paper, laminated in the clinic, and given to administrators in the medical records office who were responsible for putting together the physical charts.

This clinic serves as a residency clinic in northern Colorado so it was expected there would be gaps in knowledge between first year residents, second year residents, third year residents, attending physicians, and nurse practitioners. The provider reminder tool exists to bridge the knowledge gaps for newer providers and has been in existence at the clinic for several years. Current practice has attending physicians, residents in their second and third years, and nurse practitioners orienting newer residents to the use of the physical chart used for OB patients so there was no need for this author to provide any additional education regarding the use of the reminder tool.

Objective Two: Educational Material in Patient Information Packet

Prior to this intervention, the process was to provide every new obstetric patient with an informational packet that included general pregnancy education, diet tips, local classes, and available resources for all pregnant women. Information in these packets was pre-approved by the nursing and medical directors for the clinic, put together by existing ancillary administrative staff, and then distributed to patients at the time of their intake appointment. Packets were given to the patients at check-in by the front desk staff with the expectation that the provider doing the intake appointment would go over the educational material with every individual patient. Prior to this intervention, these packets did not contain any information regarding the safety and efficacy of vaccines during pregnancy. Whether or not this education was routinely provided by each provider was not formally evaluated.

To meet the second objective--increasing provider awareness and compliance with the national recommendations of providing every pregnant patient with a Tdap vaccine between 27- and 36-weeks gestation, a CDC (2015c) patient information sheet (see Appendix C) was placed in all of the patient education packets. This information sheet was available on the CDC website at no charge, printed at the clinic, and placed in the packets by ancillary staff. Although this sheet was written with pregnant women as the primary target audience, the objective of this intervention was to offer a reminder to every provider of the existing recommendation to offer the Tdap in every pregnancy. This intervention not only provided a visual reminder to start the conversation with the patient regarding the Tdap during pregnancy at the initial OB intake visit but had an

added benefit of augmenting patient education regarding the safety and efficacy of the Tdap vaccine during pregnancy.

Objective Three: Medical Assistant Education

The next tier of this intervention plan was to include two educational sessions with the clinic's medical assistants (MA). It was in the scope of every MA at North Colorado Family Medicine (NCFM) to initiate the order for and administer all childhood and adult vaccinations. The MAs at NCFM have two existing standing orders for adults and children over seven-years-old, specifically for the Td/DTaP/Tdap vaccines. These standing orders delineate that Tdap is to be given to pregnant women between 27 and 36 weeks (see Appendix D), and are based on the CDC Adult Vaccine Schedule (see Appendix E). In observing the MA workflow, it was noted that Tdap vaccines during pregnancy were rarely initiated by the MA; administration relied on the provider placing the order and giving the MA a verbal order to administer the vaccine. At the start of this project, it was assumed the percentage of MAs aware of this standing order was low.

Medical assistant education was provided at two separate mandatory staff meetings. The MAs were presented with a short PowerPoint presentation that included a picture of the standing order, the gestational ages at which the Tdap should be administered during pregnancy, and background information on pertussis and why the vaccine is so important to mothers and their unborn children (see Appendix F). The MAs were instructed to defer all refusals to providers so education could be augmented by physicians and nurse practitioners in an effort to improve Tdap vaccine rates.

The first educational sessions were offered at the first two mandatory meetings in June and July. The initial meeting was targeted at the majority of the staff but accounting

for possible sick days and staff turnover, the second educational session offered the same PowerPoint and education to any new staff or staff who had missed the first meeting. Attendance at the meetings was approved by the office manager as well as the nursing director per the Statement of Mutual Agreement (see Appendix G).

No changes were made to the current standing order for the clinic as it covered all adult and adolescent patients, including those who were pregnant, to receive the Tdap vaccine. The purpose of the education provided to the MAs was to serve as a reminder of a standing order for Tdap and pregnancy, provide education as to the timing of the vaccine, and provide information regarding why the vaccine is important related to decreased incidence of pertussis in the newborn and infant population. Increasing patient education was an important piece of this intervention bundle; however, it was not considered an objective as it was not feasible to evaluate the outcomes of this education in the current patient population within the project timeframe.

Timeline

- May 20, 2016--Capstone proposal defense
- May 26, 2016--Submit to University of Northern Colorado Institutional Review Board (IRB; see Appendix H)
- June 13, 2016--Initiation of capstone quality improvement project following IRB approval
    - Checklist updated and given to administration for printing and laminating
    - PowerPoint completed for medical assistant education

    - Patient educational material distributed to administrators for inclusion into new patient OB packs by nursing director
- June 13, 2016--Initiate chart review to determine current uptake of Tdap during pregnancy in clinic from 2012 to present
- June 14, 2016--First meeting with medical assistants and nursing director
- July 5, 2016--Second meeting with medical assistants and nursing director
- September 23, 2016--Completion of capstone quality improvement project
- September 26, 2016--Distribution of evaluations to providers, residents, and medical assistants
- September 26, 2016--Initiate chart review for compliance of Tdap vaccine uptake between June 13 and September 23, 2016
- October 18, 2016--Capstone defense

Resources

This project did not require many resources for implementation, evaluation, and maintenance. The three interventions included in this project were meant to build upon and improve existing practice flow. This clinic consists of family medicine residents, attending physicians, nurse practitioners, medical assistants, 28 patient exam rooms, four minor treatment rooms, one major procedure room, in-house laboratory, nutritional counselor, and in-house behavioral specialists. Ancillary administrative staff include individuals who work at the front desk to check patients in, hand out and collect patient information, update patient charts, and answer questions. There are individuals who work to set up referrals, code charts, medical records, billing, residency services, and office management. Office supplies are plentiful and included in the pre-existing budget.

The clinic has printers, scanners, copy machines, laminating machines, and computers in-house that are provided for all staff and residents.

The cost to implement and maintain this intervention plan was minimal and was absorbed into the pre-existing clinic budget. The educational materials were available at no cost on the CDC (2015c) website. The link for this material was emailed to the nursing director at her request and then the task of printing and placing in the new OB packets was assigned to one of the administrative front desk staff. There was no need to hire additional personnel as the task of making the packets had already been assigned so the addition of the educational material was not an extra burden on the clinic.

Feasibility and Sustainability

This project was based on improving three activities already in place at North Colorado Family Medicine (NCFM). Providing patients with educational material at the OB intake visit was standard practice so the addition of the Tdap patient education material served as supplemental material to reinforce the safety and efficacy of the vaccine for pregnant patients and family members who might be hesitant or might not even know of the recommendation to immunize every pregnant patient. This educational material was available to all providers through the CDC (2015c) website free of charge. Minimal additional costs included the paper, ink, and wear on the printer but these costs were insignificant and did not require that additional materials be purchased. The time spent on creating the new OB educational packets was standard at the clinic so the extra time spent adding the Tdap educational sheet was negligible regarding the increased cost to pay staff and decreased productivity. There was no intention to change practice

regarding the use of the new pregnant patient educational material so this project should be easy to maintain.

The education to the MAs was provided at a regularly scheduled monthly staff meeting so no additional costs were required to pay staff to attend. The PowerPoint and educational materials were completed by this author at no cost to the facility. This intervention is sustainable as the use of standing orders is regular practice for the MAs in this clinic setting.

In October 2014, the Public Health Service office through the CDC sent out a letter to providers imploring their cooperation with their efforts in improving vaccine rates during pregnancy (NFID, 2014). This letter (see Appendix I) reiterates to providers how important it is to ensure the Tdap vaccine is provided in every pregnancy and reminds providers that research confirms the provider recommendation for vaccines during pregnancy as being essential in uptake (NFID, 2014). The CDC outlined steps for increasing vaccination rates during pregnancy with the following four steps: (a) always review the immunization status of every patient at every visit, (b) recommend any vaccines due at the time of the visit if indicated by the adult vaccination schedule, (c) administer the vaccine or refer to a provider who is able to administer the vaccine, and (d) document all vaccines given in electronic health record as well as state registry if possible. This call to action by the CDC reminds all providers of their duty to provide vaccines during pregnancy in an effort to reduce mortality in infants from vaccine preventable illnesses (NFID, 2014).

As per the Statement of Mutual Agreement (see Appendix G) and agreed upon by the nursing director and medical director, the providers of North Colorado Family

Medicine are invested in working toward ensuring Tdap in every pregnancy. It has been demonstrated that pertussis prevention in infants is a priority of national organizations such as the CDC, ACIP, American Academy of Family Physicians, American College of Nurse-Midwives, American Academy of Pediatrics, and ACOG (NFID, 2014). The providers are invested in providing the best care to every patient as outlined by the Banner Health (2016a) mission and vision, ensuring the sustainability of this intervention.

Evaluation Plan

After IRB approval was obtained (see Appendix H), initiation of this project started with a retrospective chart review of every patient who received her prenatal care through North Colorado Family Medicine between October 2012 and December 2015. The only feasible way of obtaining the data needed for evaluation of this project was through individual chart review. The office manager pulled all of the delivery codes for the specified time frame and provided the names and birthdays of those patients for chart review. The chart review provided a baseline percentage of patients who received the Tdap during pregnancy after release of the national recommendations (CDC, 2013b). It was anticipated that compliance would have increased since the national recommendations for Tdap in every pregnancy were published so an average of the years 2013, 2014, and 2015 were calculated and reported as the baseline percentage of compliance. Patient confidentiality was maintained throughout the process by only conducting reviews in the clinic setting through a secure database after obtaining written permission from the office manager. No identifying markers were used in this process,

no patient identifiers were recorded, and the identity of all patient health information was kept confidential by clinic and organizational standards.

Establishing a Baseline: National Rates

National rates of Tdap uptake during pregnancy have fluctuated based on different factors including year, location, socioeconomic status, and ethnicity. National studies have found uptake of Tdap during pregnancy between 14.3%-55.7%, depending on the size and location of the populations measured (Ahluwalia et al., 2015; Harriman & Winter, 2014; Housey et al., 2014). These studies also found the lower percentages of Tdap vaccine uptake were associated with the amount and quality of prenatal care received.

Establishing a Baseline: County and State Rates in Colorado

No data were available on the rates of Tdap vaccination during pregnancy in Colorado; thus, there was no way to determine if the percentage determined by chart review of patients receiving prenatal care at North Colorado Family Medicine was representative of county or state rates. There was speculation that women who received the vaccine from a family practice clinic had higher uptake rates versus those who received their prenatal care at an OB/GYN due to the availability of vaccines in the primary care setting (Cherry, 2015). This speculation was based on the fact that the United Kingdom has had higher vaccine uptake rates since their recommendation to start vaccinating all women with Tdap in 2013 and the majority of women in the United Kingdom received their prenatal care through family practice clinics versus OB/GYNs (Cherry, 2015).

The retrospective chart review established a baseline from which the overall vaccine improvement rates could be measured. The percentage measured for evaluation of the intervention was not an accurate representation of the overall increase in vaccine rates because of the short project timeframe relative to the overall length of pregnancies. The intervention timeframe was 10 weeks; since it was unknown how many pregnant patients would be appropriate for the Tdap vaccine during this timeframe, an additional evaluation method was used to measure the outcomes of the three objectives. Each objective was measured by a separate post-intervention survey. Each survey included two questions that were measured by a 5-point Likert scale with the following answer options: *Strongly Agree, Agree, Neutral, Disagree,* and *Strongly Disagree*. The two provider surveys were combined into one to minimize the use of clinic resources. Examples of each survey can be found in Appendix J.

Evaluation Method for Objective One

The first objective was to update and improve current practice to increase the rate of Tdap immunizations in pregnant women at North Colorado Family Medicine. This objective was met by updating and improving an existing provider reminder system that was well established in current practice. The expected outcome of this intervention was to improve Tdap vaccination rates in pregnant patients by reminding providers to offer the vaccine. It was evaluated in two ways: (a) pre- and post-intervention chart reviews of Tdap vaccine rates in pregnant women seen at North Colorado Family Medicine and (b) post-intervention provider survey assessing use of implemented reminder tool (see Appendix J).

Once the pre-intervention baseline percentage of Tdap immunization rates during pregnancy was established, then evaluation of the intervention was done through post-intervention chart review. This method was described in detail earlier in this section and the expected outcome of this intervention was an increase in the rate of Tdap immunizations during pregnancy. A secondary method of evaluation was used to assess the usefulness of the updated provider reminder tool by using a post-intervention provider survey. This survey was measured on a 5-point Likert scale (see Appendix J) and included two statements:

1. This tool will be useful in reminding you to facilitate the administration of the Tdap vaccine in every pregnant patient at 27-36 weeks.
2. This updated tool will be beneficial in current practice.

Evaluation Method of Objective Two

The second objective was to increase provider awareness and compliance with the national recommendations of providing every pregnant patient with a Tdap vaccine between 27 and 36 weeks gestation. This objective was met by placing a patient education sheet in the patient education packet distributed to every patient and discussed in detail by providers at initial appointment. There were two expected outcomes for this intervention: (a) initiate a reminder to providers to discuss safety and efficacy of the Tdap vaccine and to make an initial recommendation to have the vaccine given during an office visit between 27 and 36 weeks, and (b) increase uptake of the Tdap vaccine during pregnancy. The post-intervention chart review was the primary method of evaluation for each objective and the secondary method of evaluation for each individual objective was the post-intervention survey. For this objective, the providers were given a survey

measured on a 5-point Likert scale (see Appendix J) that included the following statements:

1. The Tdap in pregnancy educational material reminded you to discuss the vaccine with your patients during the OB intake.
2. This educational material will be beneficial in current practice.

Evaluation Method for Objective Three

The third objective was to increase medical assistant awareness and compliance with the current standing order of administering the Tdap vaccine to all pregnant patients. This objective was met by providing education to the medical assistants regarding the existence of an adult vaccine standing order. This standing order was already in use at the clinic prior to the intervention. The intervention focused on educating all MAs to its existence with additional education regarding when the vaccine should be given and what steps to take if the patient should refuse. The expected outcome of this intervention was an increase in the rates of Tdap vaccines given and was evaluated by comparison of pre- and post-intervention chart review and post-intervention survey evaluating the educational sessions and how they improved the use of the current clinic standing order. Evaluation of this last objective--increasing MA compliance with the existing standing order--was measured by a Likert scale similar to the provider survey (see Appendix J) that included the following questions.

1. Prior to the educational session, were you aware that it is within the scope of your practice to initiate the Tdap vaccine in all pregnant women between 27 and 36 weeks?

2. After the educational session provided, will you now administer the Tdap vaccine to every pregnant woman between 27 and 36 weeks?
3. If a patient refuses the Tdap vaccine, will you refer this refusal to the patient's provider to provide additional education about the vaccine?

Each intervention was targeted at a specific point in the care of the pregnant patient where there would be the greatest chance for omission of the national recommendation to administer the Tdap vaccine to every pregnant patient between 27 and 36 weeks. To this end, each objective was evaluated with a comparison of post-intervention vaccine rates with pre-intervention vaccine rates. The post-intervention rates were measured at the end of the 10-week intervention period and are reported in the following chapter. Each individual objective was then measured by provider and MA surveys and reported as a percentage of providers and MAs who indicated agreement with the intervention as (a) beneficial to practice, (b) neutral, and (c) did not find the intervention beneficial.

Institutional Review Board

This quality improvement (QI) project was approved by the IRB at the University of Northern Colorado (see Appendix H). As this QI project did not involve collecting data from human subjects, only medical records including pre- and post-intervention chart review of existing pregnant patients, it was granted expedited status. Education provided to the pregnant patients during the OB uptake and to the medical assistants during monthly meetings was already standard practice in the clinical setting so no addition resources were needed. North Colorado Family Medicine is a medical residency program where each doctor is required to do a similar capstone project to complete his or

her residency. Due to the large volume of capstone projects completed through NCFM every year, the medical director, representing the Banner system, had implemented a review system that gave the medical director of the clinic authority to determine if a project was exempt from IRB review through Banner Health. Per the medical director of NCFM, this capstone met requirements to be exempt from review through the Banner Health IRB. Any information obtained through the clinic for use within this project remains confidential to protect the patients as well as the integrity of the clinic. Further, any data reported about the project were group or aggregate data and did not involve patient or staff identifying information.

Summary

Pertussis is highly contagious but preventable due to the widespread use of vaccines. The national recommendation (CDC, 2013b) to immunize every pregnant woman as a method for protecting unborn infants was released in 2012 yet nationwide uptake has remained low. This QI project was aimed at improving and updating existing practices at North Colorado Family Medicine to align with the national recommendation. National and international research offered evidence to support the use of the Tdap vaccine during pregnancy as a method of reducing the burden of the pertussis illness on newborns and infants. The benefits of this QI project included providing passive immunity to newborns and infants for pertussis, offering additional protection to mothers, and increasing provider awareness of the importance of providing the Tdap in every pregnancy.

CHAPTER IV

RESULTS AND OUTCOMES

The purpose of this project was to improve the rates of Tdap in the pregnant population at North Colorado Family Medicine (NCFM) in Greeley, Colorado. The recommendation to providers to give a Tdap in every pregnancy was published in October 2012 by the Centers for Disease Control (2013b) in conjunction with the American Council for Immunization Practices. This project was targeted at improving the rates of Tdap vaccines given to pregnant women by offering education and reminders to clinic providers and medical assistants (MA) as the available literature suggested provider recommendation offered the highest success rates for improving Tdap rates in other settings.

Three specific and measurable objectives were implemented:

1. Update and improve current practice to increase the rate of Tdap immunizations in pregnant women at North Colorado Family Medicine.
2. Increase provider awareness and compliance with the national recommendations of providing every pregnant patient with a Tdap vaccine between 27 and 36 weeks gestation.
3. Increase medical assistant awareness and compliance with current standing order to administer all pregnant patients with Tdap vaccine.

The first step in the evaluation process was to determine the population of pregnant women seen in the clinic to predict sustainability and generalizability in the general population. In 2015, there were 18,650 patient visits at NCFM with 2,035 of those visits coded for pregnancy. This number was only an approximation but aligned with the pre-intervention estimate that the pregnant population accounted for roughly 11% of the patient population in northern Colorado.

It was anticipated the rate of compliance with the national recommendations would fluctuate after the new recommendation was implemented in October 2012. Therefore, to determine a pre-intervention baseline, the average rates for 2013, 2014, and 2015 were examined. Pre-intervention vaccine rates were computed by individual chart review after delivery codes were provided by the clinic office manager. In 2013, there were 112 deliveries; 65 of those women were given the Tdap vaccine and 47 women did not receive the vaccine for a compliance rate of 58%. In 2014, there were 145 total deliveries; 99 of those women were given the Tdap vaccine and 46 women did not receive the vaccine for a compliance rate of 68%. In 2015, there were 137 deliveries; 110 of those women were given the Tdap vaccine and 27 did not receive the vaccine for a compliance rate of 80%. As predicted, there was a steady increase in compliance from the publication of the national recommendation (CDC, 2013b). The average of those three years (69%) was used as the pre-intervention baseline as this was estimated to more likely represent the general population.

It is important to note the delivery codes were only provided for Banner associated hospitals; thus, women who received care at NCFM but delivered outside of the system were excluded. Another confounding variable included women who might

have been given the vaccine at another location or might have received prenatal care from an unassociated provider.

Outcomes of Objectives

Objective One

The first objective was to update and improve current practice to increase the rate of Tdap immunizations in pregnant women at North Colorado Family Medicine. This objective was accomplished by updating a pre-existing provider checklist to include a reminder to give the Tdap vaccine between 27 and 36 weeks. This objective was measured by evaluation and comparison of pre- and post-intervention vaccine rates in pregnant women. The established baseline pre-intervention compliance rate was 69%. Post-intervention chart review included 74 patients who received prenatal care in the intervention time frame. Of the 74 pregnant patients seen in the intervention timeframe, 65 received the Tdap vaccine for a compliance rate of 88%.

The second method of evaluation to measure the outcomes of objective one was with a post-intervention provider survey to assess whether or not the providers found this updated checklist beneficial by asking the following two questions:

1. Will this tool be useful in reminding you to facilitate the administration of the Tdap vaccine in every pregnant patient at 27-36 weeks?
2. Will this updated tool be beneficial in current practice?

This survey was measured on a 5-point Likert scale from 1 = *Strongly disagree* to 5 = *Strongly agree*. Of the 35 surveys distributed to the faculty physicians, nurse practitioners, and medical residents, 17 surveys were returned for a return rate of 49%. All of the providers who returned the survey agreed or strongly agreed this updated

checklist was a useful tool for reminding him or her to administer the Tdap vaccine at 27-36 weeks of pregnancy.

Key facilitators. No education was required on the implementation or use of the updated checklist because its use was already well-established in current practice. The medical residents found this tool especially helpful in developing their practice with OB patients as the checklist of tasks in the three trimesters can be overwhelming to unexperienced providers. The faculty physicians and nurse practitioners informally reported they appreciated the update as the new checklist and new paper color offered a visual reminder to existence of the tool.

Key barriers. A few barriers were associated with this intervention including a minor delay in the rollout process, the start of a new cohort of medical residents, and the rollout of the new electronic health record. The new residents started the first week of July, which was assumed to create a transient decrease in vaccine compliance that likely improved after the first two to three weeks. There was a delay in the rollout of the checklist as the nursing director took this opportunity to update other parts of it.

The last barrier was the implementation of the new electronic health record, Cerner, which occurred three weeks into the intervention window. This was estimated to be the most significant barrier and might have resulted in either inaccurate or reduced post-intervention vaccine rates. The office manager pulled ICD-10 codes for pregnancy related visits as well as the codes for administration of the Tdap vaccine. Possible barriers related to this process included pregnant patients who received the vaccine where there was missed documentation, women who were not given the vaccine at the appropriate time related to the stress caused to the providers and MAs during the rollout

process, or charts that were missed due to this author's relative unfamiliarity with the new electronic health record compared to the previous system. The significance of these barriers on vaccine rates was unknown but there was likely only a minor decrease in rates due to the relatively long intervention window.

Objective Two

The second objective focused on increasing provider awareness and compliance with the national recommendation (CDC, 2013b) of providing every pregnant patient with a Tdap vaccine between 27 and 36 weeks gestation. This objective was met by placing a CDC (2015c) authored patient education sheet in the patient education packet that was distributed to every patient. Standard practice in the clinic is the provider discusses the content of the packet with each pregnant patient at the initial OB intake visit. There were two expected outcomes for this intervention: (a) Providers would be reminded to discuss safety and efficacy and make initial recommendations to be vaccinated during an office visit between 27 and 36 weeks, and (b) administration rates of the vaccine during pregnancy would increase. These objectives were measured by evaluation and comparison of pre- and post-intervention vaccine rates in pregnant women. The established baseline pre-intervention compliance rate was 69%. Post-intervention chart review looked at 74 patients who received prenatal care in the intervention time frame; 65 of 74 pregnant women received the vaccine for a compliance rate of 88%.

The second method of evaluation to measure the outcomes of objective two was with a post-intervention provider survey to assess whether or not the providers found this updated checklist beneficial by asking the following two questions:

1. Did the Tdap in pregnancy educational material remind you to discuss the vaccine with your patients during the OB intake?
2. Will this educational material be beneficial in current practice?

This survey was measured on a 5-point Likert scale from *Strongly disagree* to *Strongly agree*. Of the 35 surveys distributed to the faculty physicians, nurse practitioners, and medical residents, 17 surveys were returned for a return rate of 49%. Of the 17 providers who returned a survey, 15 agreed or strongly agreed the Tdap in pregnancy educational material reminded them to discuss the vaccine with their patients at the initial intake appointment and felt that this tool would be useful to their practice. One provider noted he/she was not aware of the material and one provider left feedback that the timing of the educational material was too early in the pregnancy to be useful.

Key facilitators. As with the first objective, this intervention focused on updating and improving on existing practice. The use of the educational packet was established practice and did not require any education for physicians and nurse practitioners. The information sheet was free from the CDC (2015c) and did not require any additional resources or special permission for use. This educational material targeted the pregnant patient population and while acting as a reminder to the providers and had the added benefit of providing additional education to patients and families. The outcome of patient education was not in the scope of this capstone project and the benefit is only predicted informally.

Key barriers. The barriers for achievement of this objective were much the same as with the first objective with regard to the start of a new cohort of medical residents as well as the switch to the new electronic health record. These barriers were expected to

only minimally affect the outcomes of the chart review for compliance rates. There was a slight cost in printing the new CDC educational material as the clinic did opt to print these materials in colored ink for the benefit of the patients.

Objective Three

The third objective was implemented in an effort to increase medical assistant awareness and compliance with the current standing order to administer the Tdap vaccine to all pregnant patients. This objective was met by providing education to the medical assistants regarding the existence of an adult vaccine standing order based on the most current adult vaccine schedule. This vaccine schedule recommended administering the Tdap to all pregnant patients between 27 and 36 weeks. The intervention focused on educating all MAs to its existence with additional education regarding when the vaccine should be given and what steps to take if the patient should refuse. The expected outcome of this intervention was an increase in the rates of Tdap vaccines given and was evaluated by comparison of pre- and post-intervention chart review and post-intervention survey evaluating the educational sessions and how they improved the use of the current clinic standing order. The established baseline pre-intervention compliance rate was 69%. Post-intervention chart review looked at 74 patients who received prenatal care in the intervention time frame. Of the 74 patients reviewed, 65 women received the Tdap vaccine for a compliance rate of 88%.

The second method of evaluation to measure the outcome of objective three was with a post-intervention provider survey to assess whether or not the providers found this updated checklist beneficial by asking the following two questions:

1. Prior to the educational session, were you aware that it is within the scope of your practice to initiate the Tdap vaccine in all pregnant women between 27 and 36 weeks?
2. After the educational session provided, will you initiate Tdap vaccine to every pregnant woman between 27 and 36 weeks?
3. If a patient refuses the Tdap vaccine, will you defer this refusal to the patient's provider to provide additional education about the vaccine?

This survey was measured on a 5-point Likert scale from *Strongly disagree* to *Strongly agree*. Of the 12 surveys distributed to the medical assistants, nine surveys were returned for a return rate of 75%. Nine of the nine MAs agreed or strongly agreed the educational sessions helped them feel more empowered to initiate the Tdap vaccine to pregnant patients between 27 and 36 weeks gestation. Of the nine surveys returned by the medical assistants, seven were not aware of the standing order to give this vaccine prior to the educational session but post-intervention survey results showed all MAs would initiate the Tdap vaccine during pregnancy. All of the medical assistants who returned surveys agreed or strongly agreed to defer all refusals to the patient's provider for further education. This researcher felt this last piece of the intervention was especially important as vaccine refusals had not always been reported to the providers; the literature indicated provider education and recommendation had the highest rate of success for improving vaccine administration rates.

Key facilitators. This objective was relatively easy to accomplish as the education provided to the medical assistants was done at mandatory monthly meetings and did not require any additional time at the clinic. The medical assistants were paid for

this educational session as it was mandatory. The PowerPoint was made by this researcher prior to the educational meeting, did not utilize any clinic resources, nor was it associated with any added cost. The presentation was built into the meetings by the nursing director and did not detract from any additional clinic education.

Key barriers. The barriers for achieving this objective were much the same as the first two objectives with regard to the switch to the new electronic health record. The new workflow process with the new electronic health record required the providers to order all vaccines given whereas previous workflow allowed for the MAs to order vaccines given. It was assumed to be a barrier in the overall outcome of vaccine rates as there were likely fallouts in the ordering and documentation of the vaccine administration. Another barrier likely affecting the overall outcomes of this objective was the high turnover rate of MAs in the office.

Unintended Consequences

This capstone project had the overall intention of improving the Tdap rates in pregnancy to offer passive immunity and indirectly decrease the morbidity and mortality rates associated with pertussis in newborns and infants. It was out of the scope of this capstone to measure any associated decrease in pertussis rates in this age group but any indirect decrease in pertussis rates was considered a positive consequence of this project.

Due to the seasonal timing of this intervention, it was not possible to include a strategy to improve influenza vaccine rates in pregnant women. At the request of the nursing director, a reminder to give the influenza vaccine at any stage in pregnancy during flu season was added to the provider checklist (see Appendix B). There was no

way of estimating the unintended consequences of this intervention but it was assumed this would only be a benefit to the providers and patients.

Summary

The results of this intervention showed an increase in the rates of Tdap given to the pregnant population seen at North Colorado Family Medicine. The medical assistants provided positive feedback that the educational sessions provided were beneficial. The MAs provide the majority of the vaccines to patients in the clinic and are often the first line in initiating the recommendation for vaccination. The providers, while having a baseline understanding of the purpose of giving the Tdap during pregnancy, are often so busy they might forget to order the vaccine. Providers who returned surveys all agreed or strongly agreed the updated checklist and patient education sheet would be helpful as a reminder in practice to order the Tdap vaccine. Collectively, the intervention was successful at increasing the rates of Tdap provided to pregnant women in Greeley, Colorado with the overall goal of reducing pertussis rates in the infant population and reducing the morbidity and mortality of a vaccine preventable disease.

CHAPTER V

RECOMMENDATIONS AND IMPLICATIONS FOR PRACTICE

North Colorado Family Medicine (NCFM), as a representative of Banner Health in the northern region of Colorado, prides itself on providing the most up-to-date and evidence-based care to patients and the community. This project targeted only a small and specific population in Northern Colorado but was predicted to have rippling benefits. The topic of vaccinations in any population remains a controversial one with patient opinions and decisions based on ever-expansive access to the internet. Despite the opinions of some, vaccinations remain one of the single most effective methods of disease prevention in the general public. Data in this project supported individuals educated by their healthcare professionals are more likely to agree to be immunized. With the culture of health care being focused on prevention, the job of providing expansive preventive care rests primarily on the shoulders of primary care providers. Projects such as this capstone could help improve outcomes in the primary care setting by improving access to and offering reminders for health promotion and disease prevention.

Recommendations for North Colorado Family Medicine

One of the benefits of this project was the ease with which it could be maintained, sustained, and applied to the general population. This project focused on improving well-established and current practice by revising and improving existing tools used in provider practice. The provider reminder checklist and patient education factsheet are now

established and will remain in use after the conclusion of this project. A further recommendation that could improve pregnancy outcomes would be the inclusion of an influenza factsheet in the patient packet along with the pertussis factsheet. This project offered other avenues for projects to improve overall vaccine rates and preventive care provided to the Greeley community. Each medical resident is also required to do a capstone project at the end of their third year at the clinic, which offers unlimited opportunities for process improvement. With medicine changing at such a fast pace, clinics such as NFCM, which are so readily willing to adopt new ideas and/or improve current practice, will have better outcomes that will not only affect the patient population but the community at large.

A limitation noted in Chapter IV discussed the outcomes of objective three being confounded by the high rate of medical assistant turnover at NCFM. In the 14-week span of time from the initiation of the project, there was a large turnover in MAs at the clinic and this rate of turnover is not expected to slow down. It was determined that a third educational session given in the 14week intervention window would have been beneficial to cover for the unpredicted turnover that occurred. In an effort to push for sustainability, the educational PowerPoint was provided to the nursing director for future education of new MAs. In discussing this with the nursing director, this high turnover rate is not uncommon as this job can often be considered a stepping stone to other roles in health care. Influence on vaccination rates by the MAs at NCFM will require ongoing education to the incoming staff by the nursing director, providers, and existing MAs. It is the recommendation of this researcher that the presentation be given quarterly at mandatory staff meetings as well as being incorporated into the MA new hire orientation.

This will offer reminders to existing staff as well as providing education to any new and incoming MAs.

Possible Applications in Other Settings

With the ease of sustainability of this project at NCFM, this author believes this project can be expanded. The CDC website has ample educational material available at no charge including a toolkit available to all providers for increasing Tdap vaccination rates in pregnancy and educational materials for patients, families, and members of the community. Examples of this include posters that can be strategically placed in clinic waiting rooms and exam rooms, scripting resources for providers to answer questions about the safety and efficacy of the vaccine, and tips for coding immunizations to ensure the clinic receives reimbursement for the Tdap vaccine.

As a member of Banner Health, a large multi-state health system with sites in Nebraska, Arizona, Colorado, Alaska, California, Nevada, and Wyoming, this project could be disseminated throughout the system to other clinic sites, targeting a wider group of pregnant women with the intention of having a greater impact on pertussis rates in the western United States. As discussed in Chapter I, this project aligned with Banner Health's (2016b) strategic plan for providing high quality and excellent care to all of its patients. As of October 2012, best practice in the care of pregnant women is to provide the Tdap vaccination between 27 and 36 weeks. Banner Health's strategic plan involves acting on opportunities and change, constantly improving care, and focusing on protecting one of our most vulnerable populations.

Contribution to Personal Leadership Goals

This researcher sees the role of the Doctor of Nursing Practice (DNP) as having a substantial impact on illness prevention and health promotion in the future of health care. It was the goal of this DNP candidate to work toward shifting the focus to primary prevention in a population health setting. Projects such as this that target a vulnerable population have the ability to have a larger and more substantial impact on the future of health care. It was this researcher's goal to use the knowledge and experience gained through the implementation of this project to implement future population-focused illness prevention and health promotion projects in rural settings in need of such expertise. Projects such as this one have the ability to expand and grow, leading to a ripple effect that has the ability to make a significant impact on the lives of those it affects. If this project prevented even one infant from contracting pertussis, then that impact will have made enough of a difference in the lives of individuals otherwise affected. Thus, this researcher's goal of having a positive impact on the community will have been reached.

Summary

Pertussis is highly contagious and can lead to costly hospitalizations and even death in infants less than three months old but is preventable with vaccines. Available literature and research are overwhelmingly in support of the safety and efficacy of the Tdap vaccine during pregnancy. Mothers use their own immune system to create antibodies that will protect their infants through the first few months of life and providers are in a unique position to improve vaccine rates through education and recommendation.

This project targeted individual pregnant patients with the goal of impacting the greater community through the reduction of pertussis rates in the population most

vulnerable and susceptible to the high rates of morbidity and mortality. This project used a quality improvement process directly aimed at established practices as well as provider and patient education to bring about practice improvement. Vaccines remain one of the best tools for improving community and population health. By circling the wagons around infants, families and communities will be strengthened by the outcomes of improving immunization rates in pregnant women. Infants are susceptible to pertussis; it is up to parents, providers, and the community at large to offer protection to this vulnerable population.

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APPENDIX A

PROVIDER REMINDER TOOL CURRENTLY USED IN PRACTICE

Prenatal care highlights

Initial visit from 5-11 weeks:

- Labs including CBC, Hep B, HIV, RPR, Blood type/Rh, urine culture, STI
- Medical history
- Obstetric history including # deliveries and types, PPH, DM, complications
- Establish an idea of pregnancy risk
- Ge early U/S for dating (not the pregnancy resource center)
- Education/community referrals

Next visit is OB PE;

- Pap if indicated
- STI

Second Trimester:

- Quad screen at 16-19 weeks. Sometimes needs to be recalculated based on EDC
- Dating u/s if not done already
- U/S for anatomy at 19-22 weeks
- Referral to MFM if determined high risk (quad screen should be done first)
- Fetal movement
- Immunizations

Third Trimester:

- 26 weeks: glucose screen; 1 hour to be done on high-risk patients
- 28-28 weeks: Rhogam if needed; recommended to repeat Ab screen
- 32 weeks: h/h for anemia and treat if necessary
- 34 weeks: Consider repeat 3 hour GTT if the first was mildly abnormal
- Tubal papers if appropriate
- 37 weeks: GBS to be done if not already positive
- NST as indicated: DM, GDM, post-dates, IUGR etc.

Other things to consider:

*When a positive Chlamydia is obtained anytime, a repeat test of cure needs to be done four weeks later

*GBS is good for five weeks; you may need to repeat it if your patient goes post-dates

*Trace to 1+ protein during the pregnancy is likely related to dehydration and does not need a work-up

*In patient with a history of genital herpes, recommend prophylactic treatment starting about 36 weeks to decrease the chance of outbreak at time of delivery.

*If patient is high risk for HIV (eg; hx of drug abuse), then recommend a repeat HIV to be done at 36 weeks.

APPENDIX B

UPDATED PROVIDER REMINDER TOOL TO INCLUDE TETANUS, DIPHTHERIA, ACELLULAR PERTUSSIS VACCINATION

Prenatal care highlights

Initial visit from 5-11 weeks:

- Labs including CBC, Hep B, HIV, RPR, Blood type/Rh, urine culture, STI
- Medical history
- Obstetric history including # deliveries and types, PPH, DM, complications
- Establish an idea of pregnancy risk
- Ge early U/S for dating (not the pregnancy resource center)
- Education/community referrals

Next visit is OB physicial

- Pap if indicated
- STI

Second Trimester:

- Quad screen at 16-19 weeks. Sometimes needs to be recalculated based on EDC
- Dating U/S if not done already
- U/S for anatomy at 19-22 weeks
- Referral to MFM if determined high risk (quad screen should be done first)
- Fetal movement

IMMUNIZATIONS

- Influenza Vaccine given anytime in pregnancy during flu season
- Tdap vaccine given 27-36 weeks despite previous vaccine status

Third Trimester:

- 26 weeks: glucose screen; 1 hour to be done on high-risk patients
- 28-28 weeks: Rhogam if needed; recommended to repeat Ab screen
- 32 weeks: h/h for anemia and treat if necessary
- 34 weeks: Consider repeat 3 hour GTT if the first was mildly abnormal
- Tubal papers if appropriate
- 37 weeks: GBS to be done if not already positive
- NST as indicated: DM, GDM, post-dates, IUGR etc.

Other things to consider:

- When a positive Chlamydia is obtained anytime, a repeat test of cure needs to be done four weeks later
- GBS is good for five weeks; you may need to repeat it if your patient goes post-dates
- Trace to 1+ protein during the pregnancy is likely related to dehydration and does not need a work-up
- In patient with a history of genital herpes, recommend prophylactic treatment starting about 36 weeks to decrease the chance of outbreak at time of delivery.
- If patient is high risk for HIV (eg hx of drug use), then recommend a repeat HIV to be done at 36 weeks.

APPENDIX C

CENTERS FOR DISEASE CONTROL AND PREVENTION PATIENT EDUCATIONAL MATERIAL

You can start protecting your baby from **whooping cough** before birth

Information for pregnant women

When you get the whooping cough vaccine during your 3rd trimester, your baby will be born with protection against whooping cough.

Whooping cough (sometimes called pertussis) is a serious disease that can cause babies to stop breathing. Unfortunately, babies must be 2 months old before they can start getting their whooping cough vaccine. The good news is you can avoid this gap in protection by getting the whooping cough vaccine (also called the Tdap shot because it protects against tetanus, diphtheria, and pertussis) in your third trimester, preferably between your 27th and 36th week of pregnancy. By getting vaccinated, you will pass antibodies to your baby so she is born with protection against whooping cough.

Why do I need to get a whooping cough vaccine while I am pregnant?

The whooping cough vaccine is recommended during your third trimester so that your body can create antibodies and pass them to your baby before birth. These antibodies will help protect your newborn right after birth and until your baby gets his own first whooping cough vaccine at 2 months of age. During the first few months of life, your baby is most vulnerable to serious complications from this disease.

Is this vaccine safe for me and my baby?

Yes. The whooping cough vaccine is very safe for you and your baby. The most common side effects are mild, like redness, swelling or pain where the shot is given in the arm. This should go away within a few days. You cannot get whooping cough from the vaccine. The vaccine does not contain any live bacteria.

Doctors and midwives who specialize in caring for pregnant women agree that the whooping cough vaccine is safe and important to get during the third trimester of each pregnancy. Getting the vaccine during pregnancy does not put you at increased risk for pregnancy complications like low birth weight or preterm delivery.

If I recently got this vaccine, why do I need to get it again?

The amount of antibodies in your body is highest about 2 weeks after getting the vaccine, but then starts to decrease over time. That is why the vaccine is recommended during every pregnancy – so that each of your babies gets the greatest number of protective antibodies from you and the best protection possible against this disease.

Are babies even getting whooping cough anymore in the United States?

Yes. In fact, babies are at greatest risk for getting whooping cough. We used to think of this as a disease of the past, but it's making a comeback. Recently, we saw the most cases we had seen in 60 years. Since 2010, we see between 10,000 and 50,000 cases of whooping cough each year in the United States. Cases, which include people of all ages, are reported in every state.

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

www.cdc.gov/whoopingcough

American Academy of Family Physicians
American Academy of Pediatrics
American College of Nurse-Midwives
The American College of Obstetricians and Gynecologists

February 2015

Mom, only you can provide your newborn baby with the best protection possible against whooping cough.

*You may have heard that your baby's father, grandparents, and others who will be in contact with your baby will need to get their whooping cough vaccine as well. This strategy of surrounding babies with protection against whooping cough is called "cocooning." However, cocooning might not be enough to prevent whooping cough illness and death. This is because cocooning does not provide any direct protection (antibodies) to your baby, and it can be difficult to make sure **everyone** who is around your baby has gotten their whooping cough vaccine. Since cocooning does not completely protect babies from whooping cough, it is even more important that you get the vaccine while you are pregnant.*

How dangerous is whooping cough for babies?

Whooping cough is very serious for babies. Many babies with whooping cough don't cough at all. Instead it can cause them to stop breathing. About half of babies younger than 1 year old who get whooping cough are hospitalized. Since 2010, about 10 to 20 babies die from whooping cough each year in the United States. Most whooping cough deaths are among babies who are too young to be protected by their own vaccination.

How could my baby be exposed to whooping cough?

Whooping cough spreads from person to person when coughing or sneezing or when spending a lot of time near one another where you share breathing space, like when you hold your newborn on your chest. Some people with whooping cough may just have a mild cough or what seems like a common cold. Since symptoms can vary, children and adults may not know they have whooping cough and can end up spreading it to babies they are in close contact with.

Why is the vaccine recommended during pregnancy instead of in the hospital after my baby is born?

When you get the whooping cough vaccine during pregnancy, you will pass protective antibodies to your baby before birth, so both you and your baby have protection.

The whooping cough vaccine used to be recommended for women to get in the hospital after giving birth. This helped prevent moms from getting whooping cough and passing it on to their babies. Unfortunately, the babies did not benefit from the protective antibodies and could still get whooping cough from others.

Is it safe to breastfeed after getting the whooping cough vaccine?

Yes, in fact you can pass some whooping cough protection to your baby by breastfeeding. When you get a whooping cough vaccine during your pregnancy, you will have protective antibodies in your breast milk that you can share with your baby as soon as your milk comes in. However, your baby will not get protective antibodies immediately if you wait to get a whooping cough vaccine until after you give birth. This is because it takes about 2 weeks after getting vaccinated before your body develops antibodies.

Where can I go for more information?

Pregnancy and Whooping Cough website:
www.cdc.gov/pertussis/pregnant

Immunization for Women website:
www.immunizationforwomen.org/immunization_facts/vaccine-preventable_diseases/pertussis

Vaccines during Pregnancy website:
www.midwife.org/omot-vaccines-during-pregnancy

American Academy of Family Physicians website:
www.aafp.org/patient-care/immunizations/disease-population.html

Tdap Vaccine Information Statement (VIS):
www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html

Ask your doctor or midwife about getting the **whooping cough vaccine** during your 3rd trimester.

APPENDIX D

STANDING ORDER FOR ADULTS AND ADOLESCENTS

STANDING ORDERS FOR
Administering Tdap/Td Vaccine to Adults

Purpose

To reduce morbidity and mortality from tetanus, diphtheria, and pertussis infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1 Assess Adults for Need of Vaccination against tetanus, diphtheria, and pertussis based on the following criteria:

- Lack of documentation of ever receiving a dose of tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) as an adolescent or adult
- Currently pregnant and no documentation of Tdap given during current pregnancy
- Lack of documentation of receiving at least 3 doses of tetanus- and diphtheria-containing toxoids (Tdap/Td)
- Completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with no documentation of receiving a booster dose in the previous 10 years
- Recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years

2 Screen for Contraindications and Precautions

Contraindications

- Do not give Tdap or Td to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of either vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- Do not give Tdap to a person who has experienced encephalopathy within 7 days following DTP/DTaP/Tdap not attributable to another identifiable cause.

Precautions

- History of Guillain-Barré syndrome within 6 weeks of a previous dose of tetanus toxoid-containing vaccine
- History of an arthus-type hypersensitivity reaction after a previous dose of tetanus or diphtheria toxoid-containing vaccine; in such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine
- Moderate or severe acute illness with or without fever
- For Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures or progressive encephalopathy until the patient's treatment regimen has been established and the condition has stabilized

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.").

CONTINUED ON THE NEXT PAGE ▶

Technical content reviewed by the Centers for Disease Control and Prevention
IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3078.pdf • Item #P3078 (10/15)

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	⅝*–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* A ⅝" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

5 Administer Tdap or Td Vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following criteria and schedule:

The routine schedule for Tdap/Td vaccination is to administer a 3-dose series at 0, 1, and 6 month intervals, including one dose of Tdap, preferably as the first dose, followed by a Td booster every 10 years

HISTORY OF PREVIOUS Td/Tdap VACCINATION	DOSE AND SCHEDULE FOR ADMINISTRATION OF Tdap AND Td
0 documented doses, or none known	Give 0.5 mL Tdap as dose #1. Give dose #2 (Td) at least 4 weeks later, and dose #3 (Td) 6–12 months after dose #2.
1 previous dose, Td	Give 0.5 mL Tdap as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td) in 6 months.
1 previous dose, Tdap	Give 0.5 mL Td, as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td) in 6 months.
2 previous doses, both Td	Give 0.5 mL Tdap as dose #3 at least 6 months after dose #2.
2 previous doses, 1 Td and 1 Tdap	Give 0.5 mL Td at least 6 months after dose #2.
3 or more previous doses, Td only	Give 0.5 mL Tdap as soon as possible, but at least 4 weeks after last Td. (You do not need to wait 10 years from previous dose.)
3 or more previous doses, including 1 dose of Tdap	Give 0.5 mL Td booster every 10 years unless patient needs prophylaxis for wound management sooner.

Tdap vaccination for pregnant women

Pregnant women should receive Tdap during **each** pregnancy, preferably during 27 through 36 weeks' gestation, regardless of number of years since prior Td or Tdap vaccination.

6 Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical chart: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

CONTINUED ON THE NEXT PAGE ▶

7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8 Report all Adverse Events to VAERS

Report all adverse events following the administration of tetanus-, diphtheria-, and pertussis-containing vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Forms are available on the website or by calling (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____
NAME OF PRACTICE OR CLINIC

until rescinded or until _____.
DATE

Medical Director's signature _____ Signature date _____ Effective date _____

Standing Orders for Administering Tdap/Td to Children Age 7 Years and Older

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

Procedure

1. Identify children and teens age 7 years and older in need of vaccination against diphtheria, tetanus, and pertussis based on the following criteria:
   a. lack of documentation of at least 4 doses of diphtheria, tetanus, and pertussis vaccine, with at least one of the doses given after age 4 years and with the most recent dose given a minimum of 4 calendar months after the preceding dose,
   b. lack of documentation of at least 3 doses of diphtheria and tetanus vaccine (i.e., DT, Td),
   c. lack of history of pertussis-containing vaccine given at age 10 years or older,
   d. currently pregnant and no documentation of Tdap given during the current pregnancy, or
   e. completion of a 3-dose primary series of diphtheria and tetanus toxoid-containing vaccine with receipt of the last dose being 10 years ago or longer.
2. Screen all patients for contraindications and precautions to Td or Tdap:
   a. **Contraindications:**
      • a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf
      • for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP/Tdap not attributable to another identifiable cause
   b. **Precautions:**
      • history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
      • history of an arthus-type hypersensitivity reaction following a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine
      • moderate or severe acute illness with or without fever
      • For Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
3. Provide all patients (or, in the case of minors, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL Td (or a one-time dose of Tdap, if indicated) intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a ⅝" needle may be used for patients weighing less than 130 lbs [60 kg] for injection in the deltoid muscle *only* if the subcutaneous tissue is not bunched and the injection is made at a 90 degree angle.)
5. Schedule vaccination as follows:
   a. For children and teens age 7 years and older who meet the criteria described in 1 above, administer one dose at the earliest opportunity and then complete the remaining doses (as needed) by observing minimum intervals of 4 weeks between the first and second doses, and 6 calendar months between the second and third doses. A dose of Tdap should be substituted for one of the doses of Td, preferably the first.
   b. For children and teens age 11 through 18 years without a history of pertussis-containing vaccine given at age 7 years or older, administer Tdap routinely at age 11 through 12 years or as catch-up at 13 through 18 years; no minimum interval since previous Td needs to be observed.
   c. For pregnant adolescents, administer Tdap during each pregnancy (preferably during 27 through 36 weeks' gestation), regardless of number of years since prior Td or Tdap vaccination.
   d. Administer further boosters as Td every 10 years.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p3078a.pdf • Item #P3078a (4/13)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

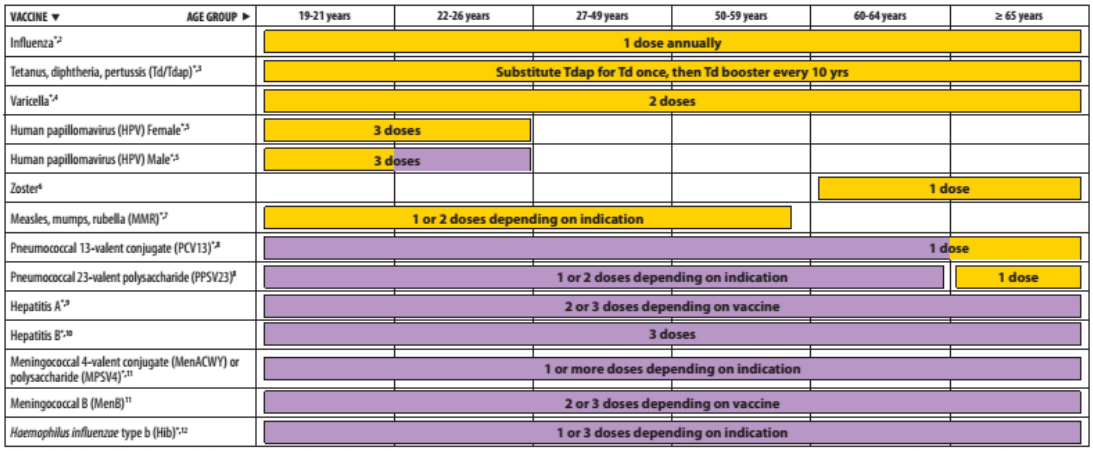
APPENDIX E

ADULT VACCINATION SCHEDULE

Recommended Adult Immunization Schedule—United States - 2016

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended immunization schedule for adults aged 19 years or older, by vaccine and age group[1]



*Covered by the Vaccine Injury Compensation Program

Recommended for all persons who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection; zoster vaccine is recommended regardless of past episode of zoster

Recommended for persons with a risk factor (medical, occupational, lifestyle, or other indication)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

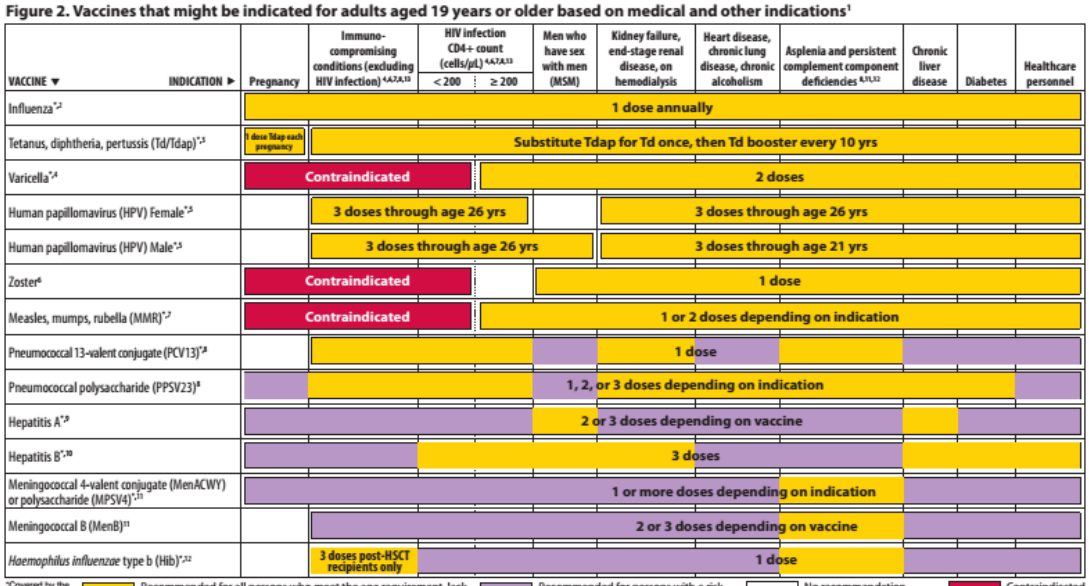
Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the America College of Physicians (ACP), the American College of Obstetricians and Gynecologists (ACOG) and the American College of Nurse-Midwives (ACNM).

Figure 2. Vaccines that might be indicated for adults aged 19 years or older based on medical and other indications[1]



*Covered by the Vaccine Injury Compensation Program

Recommended for all persons who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection; zoster vaccine is recommended regardless of past episode of zoster

Recommended for persons with a risk factor (medical, occupational, lifestyle, or other indication)

No recommendation

Contraindicated

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

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly recommended for adults aged ≥19 years, as of February 2016. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/hcp/acip-recs/index.html). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Footnotes—Recommended Immunization Schedule for Adults Aged 19 Years or Older: United States, 2016

1. Additional information
- Additional guidance for the use of the vaccines described in this supplement is available at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- Information on vaccination recommendations when vaccination status is unknown and other general immunization information can be found in the General Recommendations on Immunization at www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.
- Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) is available at wwwnc.cdc.gov/travel/destinations/list.
- Additional information and resources regarding vaccination of pregnant women can be found at www.cdc.gov/vaccines/adults/rec-vac/pregnant.html.

2. Influenza vaccination
- Annual vaccination against influenza is recommended for all persons aged ≥6 months. A list of currently available influenza vaccines can be found at http://www.cdc.gov/flu/protect/vaccine/vaccines.htm.
- Persons aged ≥6 months, including pregnant women, can receive the inactivated influenza vaccine (IIV). An age-appropriate IIV formulation should be used.
- Intradermal IIV is an option for persons aged 18 through 64 years.
- High-dose IIV is an option for persons aged ≥65 years.
- Live attenuated influenza vaccine (LAIV [FluMist]) is an option for healthy, non-pregnant persons aged 2 through 49 years.
- Recombinant influenza vaccine (RIV [Flublok]) is approved for persons aged ≥18 years.
- RIV, which does not contain any egg protein, may be administered to persons aged ≥18 years with egg allergy of any severity; IIV may be used with additional safety measures for persons with hives-only allergy to eggs.
- Health care personnel who care for severely immunocompromised persons who require care in a protected environment should receive IIV or RIV; health care personnel who receive LAIV should avoid providing care for severely immunosuppressed persons for 7 days after vaccination.

3. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination
- Administer 1 dose of Tdap vaccine to pregnant women during each pregnancy (preferably during 27–36 weeks' gestation) regardless of interval since prior Td or Tdap vaccination.
- Persons aged ≥11 years who have not received Tdap vaccine or for whom vaccine status is unknown should receive a dose of Tdap followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-toxoid-containing vaccine.
- Adults with an unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series including a Tdap dose.
- For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.
- For incompletely vaccinated (i.e., less than 3 doses) adults, administer remaining doses.
- Refer to the ACIP statement for recommendations for administering Td/Tdap as prophylaxis in wound management (see footnote 1).

4. Varicella vaccination
- All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
- Vaccination should be emphasized for those who have close contact with persons at high risk for severe disease (e.g., health care personnel and family contacts of persons with immunocompromising conditions) or are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
- Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health care facility. The second dose should be administered 4–8 weeks after the first dose.
- Evidence of immunity to varicella in adults includes any of the following:
  - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
  - U.S.-born before 1980, except health care personnel and pregnant women;
  - history of varicella based on diagnosis or verification of varicella disease by a health care provider;
  - history of herpes zoster based on diagnosis or verification of herpes zoster disease by a health care provider; or
  - laboratory evidence of immunity or laboratory confirmation of disease.

5. Human papillomavirus (HPV) vaccination
- Three HPV vaccines are licensed for use in females (bivalent HPV vaccine [2vHPV], quadrivalent HPV vaccine [4vHPV], and 9-valent HPV vaccine [9vHPV]) and two HPV vaccines are licensed for use in males (4vHPV and 9vHPV).
- For females, 2vHPV, 4vHPV, or 9vHPV is recommended in a 3-dose series for routine vaccination at age 11 or 12 years and for those aged 13 through 26 years, if not previously vaccinated.
- For males, 4vHPV or 9vHPV is recommended in a 3-dose series for routine vaccination at age 11 or 12 years and for those aged 13 through 21 years, if not previously vaccinated. Males aged 22 through 26 years may be vaccinated.
- HPV vaccination is recommended for men who have sex with men through age 26 years who did not get any or all doses when they were younger.
- Vaccination is recommended for immunocompromised persons (including those with HIV infection) through age 26 years who did not get any or all doses when they were younger.
- A complete HPV vaccination series consists of 3 doses. The second dose should be administered 4–8 weeks (minimum interval of 4 weeks) after the first dose; the third dose should be administered 24 weeks after the first dose and 16 weeks after the second dose (minimum interval of 12 weeks).
- HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. If a woman is found to be pregnant after initiating the vaccination series, no intervention is needed; the remainder of the 3-dose series should be delayed until completion or termination of pregnancy.

6. Zoster vaccination
- A single dose of zoster vaccine is recommended for adults aged ≥60 years regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the U.S. Food and Drug Administration for use among and can be administered to persons aged ≥50 years, ACIP recommends that vaccination begin at age 60 years.
- Persons aged ≥60 years with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.

7. Measles, mumps, rubella (MMR) vaccination
- Adults born before 1957 are generally considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine or laboratory evidence of immunity to each of the three diseases. Documentation of provider-diagnosed disease is not considered acceptable evidence of immunity for measles, mumps, or rubella.

Measles component:
- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who:
  - are students in postsecondary educational institutions,
  - work in a health care facility, or
  - plan to travel internationally.
- Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type during 1963–1967 should be revaccinated with 2 doses of MMR vaccine.

Mumps component:
- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who:
  - are students in a postsecondary educational institution,
  - work in a health care facility, or
  - plan to travel internationally.
- Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health care facility) should be considered for revaccination with 2 doses of MMR vaccine.

Rubella component:
- For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health care facility.

Health care personnel born before 1957:
- For unvaccinated health care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.

8. Pneumococcal vaccination
- General information
  - Adults are recommended to receive 1 dose of 13-valent pneumococcal conjugate vaccine (PCV13) and 1, 2, or 3 doses (depending on indication) of 23-valent pneumococcal polysaccharide vaccine (PPSV23).
  - PCV13 should be administered at least 1 year after PPSV23.
  - PPSV23 should be administered at least 1 year after PCV13, except among adults with immunocompromising conditions, anatomical or functional asplenia, cerebrospinal fluid leak, or cochlear implant, for whom the interval should be at least 8 weeks; the interval between PPSV23 doses should be at least 5 years.
  - No additional dose of PPSV23 is indicated for adults vaccinated with PPSV23 at age ≥65 years.
  - When both PCV13 and PPSV23 are indicated, PCV13 should be administered first; PCV13 and PPSV23 should not be administered during the same visit.
  - When indicated, PCV13 and PPSV23 should be administered to adults whose pneumococcal vaccination history is incomplete or unknown.
- Adults aged ≥65 years (immunocompetent) who:
  - have not received PCV13 or PPSV23: administer PCV13 followed by PPSV23 at least 1 year after PCV13.
  - have not received PCV13 but have received a dose of PPSV23 at age ≥65 years: administer PCV13 at least 1 year after PPSV23.
  - have not received PCV13 but have received 1 or more doses of PPSV23 at age <65 years: administer PCV13 at least 1 year after the most recent dose of PPSV23. Administer a dose of PPSV23 at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23.
  - have received PCV13 but not PPSV23 at age <65 years: administer PPSV23 at least 1 year after PCV13.
  - have received PCV13 and 1 or more doses of PPSV23 at age <65 years: administer PPSV23 at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23.
- Adults aged ≥19 years with immunocompromising conditions or anatomical or functional asplenia (defined below) who:
  - have not received PCV13 or PPSV23: administer PCV13 followed by PPSV23 at least 8 weeks after PCV13. Administer a second dose of PPSV23 at least 5 years after the first dose of PPSV23.
  - have not received PCV13 but have received 1 dose of PPSV23: administer PCV13 at least 1 year after the PPSV23. Administer a second dose of PPSV23 at least 8 weeks after PCV13 and at least 5 years after the first dose of PPSV23.

(Continued on next page)

Footnotes—Recommended Immunization Schedule for Adults Aged 19 Years or Older: United States, 2016

- have not received PCV13 but have received 2 doses of PPSV23: administer PCV13 at least 1 year after the most recent dose of PPSV23.
- have received PCV13 but not PPSV23: administer PPSV23 at least 8 weeks after PCV13. Administer a second dose of PPSV23 at least 5 years after the first dose of PPSV23.
- have received PCV13 and 1 dose of PPSV23: administer a second dose of PPSV23 at least 8 weeks after PCV13 and at least 5 years after the first dose of PPSV23.
- If the most recent dose of PPSV23 was administered at age <65 years, at age ≥65 years, administer a dose of PPSV23 at least 8 weeks after PCV13 and at least 5 years after the last dose of PPSV23.
- Immunocompromising conditions that are indications for pneumococcal vaccination are: congenital or acquired immunodeficiency (including B- or T-lymphocyte deficiency, complement deficiencies, and phagocytic disorders excluding chronic granulomatous disease), HIV infection, chronic renal failure, nephrotic syndrome, leukemia, lymphoma, Hodgkin disease, generalized malignancy, multiple myeloma, solid organ transplant, and iatrogenic immunosuppression (including long-term systemic corticosteroids and radiation therapy).
- Anatomical or functional asplenia that are indications for pneumococcal vaccination are: sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, and splenectomy. Administer pneumococcal vaccines at least 2 weeks before immunosuppressive therapy or an elective splenectomy, and as soon as possible to adults who are newly diagnosed with asymptomatic or symptomatic HIV infection.

- Adults aged ≥19 years with cerebrospinal fluid leaks or cochlear implants: administer PCV13 followed by PPSV23 at least 8 weeks after PCV13; no additional dose of PPSV23 is indicated if aged <65 years. If PPSV23 was administered at age <65 years, at age ≥65 years, administer another dose of PPSV23 at least 5 years after the last dose of PPSV23.
- Adults aged 19 through 64 years with chronic heart disease (including congestive heart failure and cardiomyopathies, excluding hypertension), chronic lung disease (including chronic obstructive lung disease, emphysema, and asthma), chronic liver disease (including cirrhosis), alcoholism, or diabetes mellitus, or who smoke cigarettes: administer PPSV23. At age ≥65 years, administer PCV13 at least 1 year after PPSV23, followed by another dose of PPSV23 at least 1 year after PCV13 and at least 5 years after the last dose of PPSV23.
- Routine pneumococcal vaccination is not recommended for American Indian/Alaska Native or other adults unless they have an indication as above; however, public health authorities may consider recommending the use of pneumococcal vaccines for American Indians/Alaska Natives or other adults who live in areas with increased risk for invasive pneumococcal disease.

9. Hepatitis A vaccination

- Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
  - men who have sex with men;
  - persons who use injection or noninjection illicit drugs;
  - persons working with HAV-infected primates or with HAV in a research laboratory setting;
  - persons with chronic liver disease and persons who receive clotting factor concentrates;
  - persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (see footnote 1); and
  - unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity of hepatitis A (see footnote 1). The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
- Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix), or 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21–30 followed by a booster dose at 12 months.

10. Hepatitis B vaccination

- Vaccinate any person seeking protection from hepatitis B virus (HBV) infection and persons with any of the following indications:
  - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than 1 sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection drug users; and men who have sex with men;
  - health care personnel and public safety workers who are potentially exposed to blood or other infectious body fluids;
  - persons who are aged <60 years with diabetes as soon as feasible after diagnosis; persons with diabetes who are aged ≥60 years at the discretion of the treating clinician based on the likelihood of acquiring HBV infection, including the risk posed by an increased need for assisted blood glucose monitoring in long-term care facilities, the likelihood of experiencing chronic sequelae if infected with HBV, and the likelihood of immune response to vaccination;
  - persons with end-stage renal disease (including patients receiving hemodialysis), persons with HIV infection, and persons with chronic liver disease;
  - household contacts and sex partners of hepatitis B surface antigen–positive persons, clients and staff members of institutions for persons with developmental disabilities, and international travelers to regions with high or intermediate levels of endemic HBV infection (see footnote 1); and
  - all adults in the following settings: STD treatment facilities, HIV testing and treatment facilities, facilities providing drug abuse treatment and prevention services, health care settings targeting services to injection drug users or men who have sex with men, correctional facilities, end-stage renal disease programs and facilities for chronic hemodialysis patients, and institutions and nonresidential day care facilities for persons with developmental disabilities.
- Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second dose should be administered at least 1 month after the first dose; the third dose should be administered at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule may be used, administered on days 0, 7, and 21–30, followed by a booster dose at 12 months.
- Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 mcg/mL (Recombivax HB) administered on a 3-dose schedule at 0, 1, and 6 months or 2 doses of 20 mcg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

11. Meningococcal vaccination

- General information
  - Serogroup A, C, W, and Y meningococcal vaccine is available as a conjugate (MenACWY [Menactra, Menveo]) or a polysaccharide (MPSV4 [Menomune]) vaccine.
  - Serogroup B meningococcal (MenB) vaccine is available as a 2-dose series of MenB-4C vaccine (Bexsero) administered at least 1 month apart or a 3-dose series of MenB-FHbp (Trumenba) vaccine administered at 0, 2, and 6 months; the two MenB vaccines are not interchangeable, i.e., the same MenB vaccine product must be used for all doses.
  - MenACWY vaccine is preferred for adults with serogroup A, C, W, and Y meningococcal vaccine indications who are aged ≤55 years, and for adults aged ≥56 years: 1) who were vaccinated previously with MenACWY vaccine and are recommended for revaccination or 2) for whom multiple doses of vaccine are anticipated; MPSV4 vaccine is preferred for adults aged ≥56 years who have not received MenACWY vaccine previously and who require a single dose only (e.g., persons at risk because of an outbreak).
  - Revaccination with MenACWY vaccine every 5 years is recommended for adults previously vaccinated with MenACWY or MPSV4 vaccine who remain at increased risk for infection (e.g., adults with anatomical or functional asplenia or persistent complement component deficiencies, or microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*).
  - MenB vaccine is approved for use in persons aged 10 through 25 years; however, because there is no theoretical difference in safety for persons aged >25 years compared to those aged 10 through 25 years, MenB vaccine is recommended for routine use in persons aged ≥10 years who are at increased risk for serogroup B meningococcal disease.
  - There is no recommendation for MenB revaccination at this time.
  - MenB vaccine may be administered concomitantly with MenACWY vaccine but at a different anatomic site, if feasible.
  - HIV infection is not an indication for routine vaccination with MenACWY or MenB vaccine; if an HIV-infected person of any age is to be vaccinated, administer 2 doses of MenACWY vaccine at least 2 months apart.
- Adults with anatomical or functional asplenia or persistent complement component deficiencies: administer 2 doses of MenACWY vaccine at least 2 months apart and revaccinate every 5 years. Also administer a series of MenB vaccine.
- Microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*: administer a single dose of MenACWY vaccine; revaccinate with MenACWY vaccine every 5 years if remain at increased risk for infection. Also administer a series of MenB vaccine.
- Persons at risk because of a meningococcal disease outbreak: if the outbreak is attributable to serogroup A, C, W, or Y, administer a single dose of MenACWY vaccine; if the outbreak is attributable to serogroup B, administer a series of MenB vaccine.
- Persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic: administer a single dose of MenACWY vaccine and revaccinate with MenACWY vaccine every 5 years if the increased risk for infection remains (see footnote 1); MenB vaccine is not recommended because meningococcal disease in these countries is generally not caused by serogroup B.
- Military recruits: administer a single dose of MenACWY vaccine.
- First-year college students aged ≤21 years who live in residence halls: administer a single dose of MenACWY vaccine if they have not received a dose on or after their 16th birthday.
- Young adults aged 16 through 23 years (preferred age range is 16 through 18 years): may be vaccinated with a series of MenB vaccine to provide short-term protection against most strains of serogroup B meningococcal disease.

12. *Haemophilus influenzae* type b (Hib) vaccination

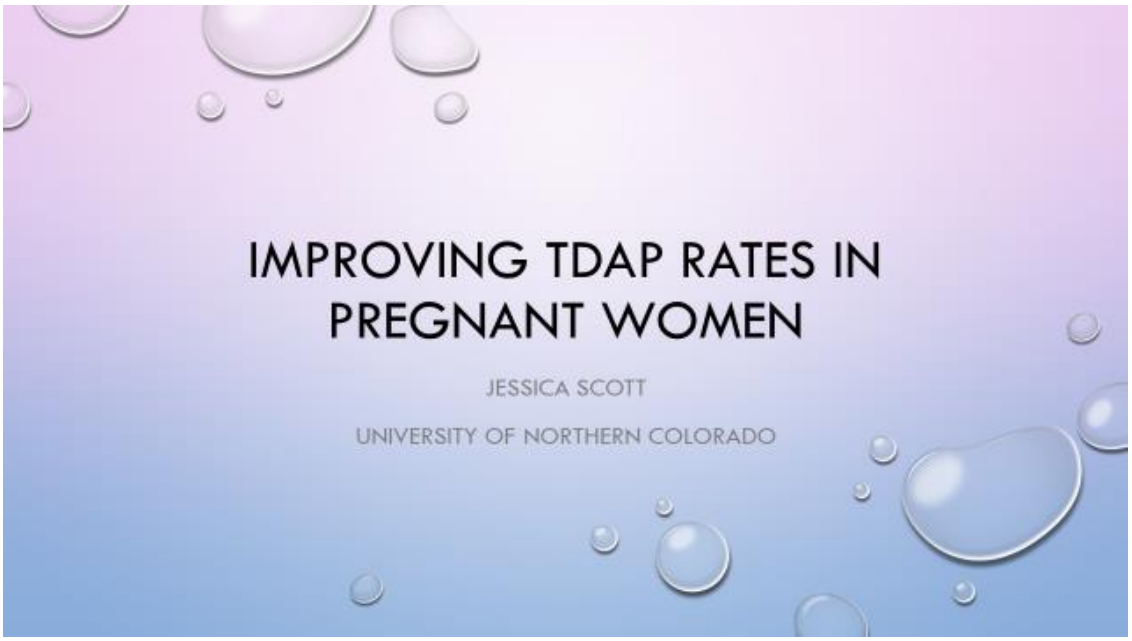
- One dose of Hib vaccine should be administered to persons who have anatomical or functional asplenia or sickle cell disease or are undergoing elective splenectomy if they have not previously received Hib vaccine. Hib vaccination 14 or more days before splenectomy is suggested.
- Recipients of a hematopoietic stem cell transplant (HSCT) should be vaccinated with a 3-dose regimen 6–12 months after a successful transplant, regardless of vaccination history; at least 4 weeks should separate doses.
- Hib vaccine is not recommended for adults with HIV infection since their risk for Hib infection is low.

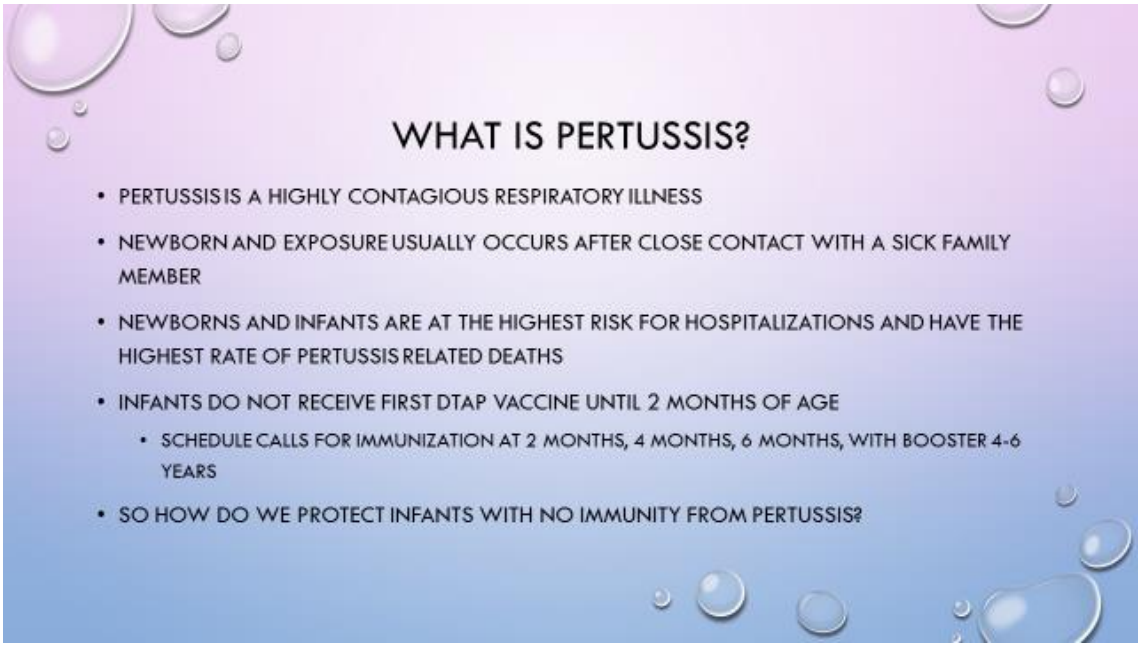
13. Immunocompromising conditions

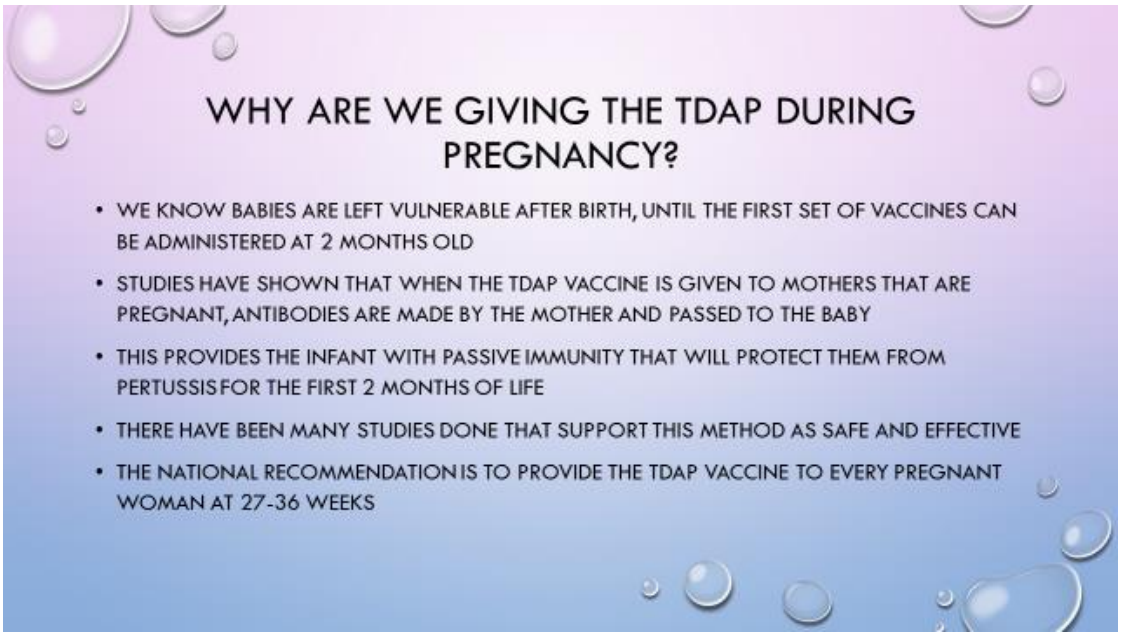
- Inactivated vaccines (e.g., pneumococcal, meningococcal, and inactivated influenza vaccines) generally are acceptable and live vaccines generally should be avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at www.cdc.gov/vaccines/hcp/acip-recs/index.html.

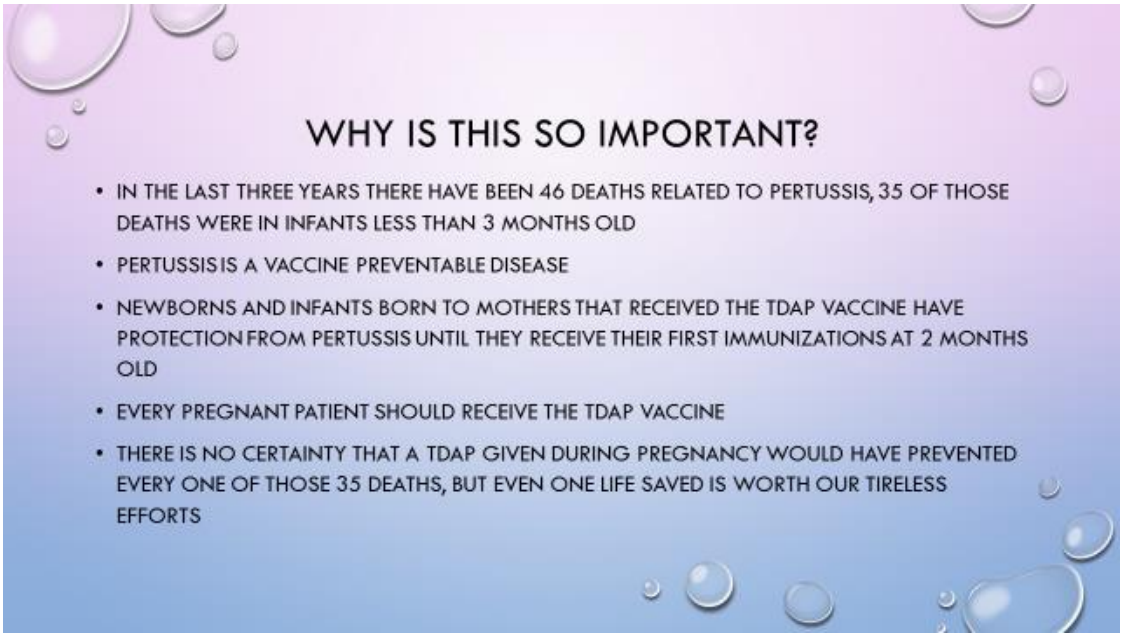
APPENDIX F

POWERPOINT EDUCATION FOR MEDICAL ASSISTANTS


IMPROVING TDAP RATES IN PREGNANT WOMEN
JESSICA SCOTT
UNIVERSITY OF NORTHERN COLORADO


WHAT IS PERTUSSIS?
• PERTUSSIS IS A HIGHLY CONTAGIOUS RESPIRATORY ILLNESS
• NEWBORN AND EXPOSURE USUALLY OCCURS AFTER CLOSE CONTACT WITH A SICK FAMILY MEMBER
• NEWBORNS AND INFANTS ARE AT THE HIGHEST RISK FOR HOSPITALIZATIONS AND HAVE THE HIGHEST RATE OF PERTUSSIS RELATED DEATHS
• INFANTS DO NOT RECEIVE FIRST DTAP VACCINE UNTIL 2 MONTHS OF AGE
• SCHEDULE CALLS FOR IMMUNIZATION AT 2 MONTHS, 4 MONTHS, 6 MONTHS, WITH BOOSTER 4-6 YEARS
• SO HOW DO WE PROTECT INFANTS WITH NO IMMUNITY FROM PERTUSSIS?


WHY ARE WE GIVING THE TDAP DURING PREGNANCY?
• WE KNOW BABIES ARE LEFT VULNERABLE AFTER BIRTH, UNTIL THE FIRST SET OF VACCINES CAN BE ADMINISTERED AT 2 MONTHS OLD
• STUDIES HAVE SHOWN THAT WHEN THE TDAP VACCINE IS GIVEN TO MOTHERS THAT ARE PREGNANT, ANTIBODIES ARE MADE BY THE MOTHER AND PASSED TO THE BABY
• THIS PROVIDES THE INFANT WITH PASSIVE IMMUNITY THAT WILL PROTECT THEM FROM PERTUSSIS FOR THE FIRST 2 MONTHS OF LIFE
• THERE HAVE BEEN MANY STUDIES DONE THAT SUPPORT THIS METHOD AS SAFE AND EFFECTIVE
• THE NATIONAL RECOMMENDATION IS TO PROVIDE THE TDAP VACCINE TO EVERY PREGNANT WOMAN AT 27-36 WEEKS


WHY IS THIS SO IMPORTANT?
• IN THE LAST THREE YEARS THERE HAVE BEEN 46 DEATHS RELATED TO PERTUSSIS, 35 OF THOSE DEATHS WERE IN INFANTS LESS THAN 3 MONTHS OLD
• PERTUSSIS IS A VACCINE PREVENTABLE DISEASE
• NEWBORNS AND INFANTS BORN TO MOTHERS THAT RECEIVED THE TDAP VACCINE HAVE PROTECTION FROM PERTUSSIS UNTIL THEY RECEIVE THEIR FIRST IMMUNIZATIONS AT 2 MONTHS OLD
• EVERY PREGNANT PATIENT SHOULD RECEIVE THE TDAP VACCINE
• THERE IS NO CERTAINTY THAT A TDAP GIVEN DURING PREGNANCY WOULD HAVE PREVENTED EVERY ONE OF THOSE 35 DEATHS, BUT EVEN ONE LIFE SAVED IS WORTH OUR TIRELESS EFFORTS

WHAT IS YOUR ROLE?

IN EVERY PREGNANT PATIENT BETWEEN 27 AND 36 WEEKS:

- ASSESS IMMUNIZATION STATUS
- IF PATIENT HAS NOT ALREADY RECEIVED THE TDAP VACCINE YOU MAY INITIATE GIVING THE VACCINE
- PROVIDER WILL STILL "PLACE ORDER" AS WITH ANY VACCINES GIVEN DURING CLINIC

WHAT IF THE PATIENT DECLINES THE VACCINE?

- PLEASE DEFER ANY PATIENT THAT DECLINES THE TDAP VACCINE BACK TO THE PROVIDER
- ADDITIONAL EDUCATION REGARDING THE SAFETY AND EFFICACY OF THE VACCINE WILL BE PROVIDED BY THE PHYSICIAN OR NP
- PROVIDER EDUCATION AND RECOMMENDATION HAS THE HIGHEST SUCCESS RATE FOR INCREASING TDAP RATES IN PREGNANT WOMEN

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APPENDIX G

STATEMENT OF MUTUAL AGREEMENT

Statement of Mutual Agreement
University of Northern Colorado
Doctorate of Nursing Practice Capstone Project
Jessica M Scott
February 4, 2016

The purpose of the "Statement of Mutual Agreement" is to describe the shared view between North Colorado Medical Center and Jessica M Scott, DNP Candidate from University of Northern Colorado, concerning her proposed capstone project.

Proposed Project Title: Improving Tdap Vaccination Rates in Pregnant Women in the Primary Care Setting: Safeguarding our Most Vulnerable Population.

This quality improvement project will focus on answering the following PICO question:

In pregnant women 27-36 weeks gestation, how does the implementation of an intervention bundle including patient education material, medical assistant standing order, and an updated provider checklist with visual reminder tool, compared with no intervention, affect Tdap vaccination rates in the primary care setting?

Brief Description of Proposed Project: Infants less than 2 months old have the highest mortality rate when infected with pertussis. The goal of the ACIP and CDC recommendations for Tdap administration during pregnancy is to provide passive immunity to infants. Existing literature shows antibodies present in the serum of infants whose mothers were vaccinated with Tdap during pregnancy for up to 6 months after birth. These recommendations were officially announced in October 2012 and have since met resistance in uptake. National uptake continues to hover around 56%, with higher and lower rates in different parts of the country. With the extensive evidence not only supporting the safety and efficacy of the Tdap vaccine during pregnancy, but the benefit that it offers to the unborn child, there is little reason why the vaccine rates should remain so low.

Goal of Capstone Project: Increase compliance with ACIP and CDC recommendations to provide pregnant women with Tdap vaccine between 27 and 36 weeks to greater than 90%.

Proposed On-site Activities: The proposed activities will be broken down into three separate components:

1. The first part of the intervention will focus on providing patient education speaking to the safety and efficacy of the Tdap vaccine during pregnancy. To accomplish this, the proposed activity will involve adding a CDC authored educational pamphlet to the patient education packet given to every new OB patient.
2. The second activity will focus on improving a provider reminder system by updating an existing checklist that resides inside every OB chart. This checklist will be updated to include administration of Tdap vaccine after 27 weeks.

3. Existing Medical Assistant (MA) standing orders will be updated to include timeframe of Tdap in pregnancy recommendation.

Confidentiality of Patient Records: All patient records will remain confidential as per system protocol. No confidential patient information will be recorded, discussed, or published in any manner that would be a violation of patient rights. All confidential information will remain onsite and protected.

The designated Capstone Community/Agency member will agree to participate in the review and approval of the proposal and presentation of the final version of the project. He/she will attend (on campus or remotely) the meetings for both.

The DNP Capstone project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency preferences in how it is to be named (or not) in the work.

2/9/16
Signature of Student Date

Tanya Unrein RN 2/9/16
Signature of Agency Member Date

Rhonda D Squires 2-17-16
Signature of Capstone Chair Date

APPENDIX H

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	June 13, 2016
TO:	Jessica Scott
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[914403-1] Working towards Tdap in Every Pregnancy: Protecting Our Most Vulnerable Population
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	June 13, 2016
EXPIRATION DATE:	June 13, 2017
REVIEW TYPE:	Expedited Review

Thank you for your submission of New Project materials for this project. The University of Northern Colorado (UNCO) IRB has APPROVED your submission. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of June 13, 2017.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

Thank you for a clear and well-written proposal. You may begin this project. Best of luck with your research.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX I

LETTER TO PROVIDERS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

October 9, 2014

Dear Colleague,

Pregnant women and their babies are at increased risk for influenza-related complications, including premature labor and preterm birth. Additionally, pertussis outbreaks continue to occur in the United States with infants at highest risk of severe illness, including hospitalization and death. Influenza vaccination is recommended in any trimester for all women who are pregnant or who plan to become pregnant during the influenza season, and a pertussis vaccination (Tdap) is recommended between 27 and 36 weeks of each pregnancy.[1] Immunization rates for these vaccines are low, leaving many pregnant women and their infants unprotected against these serious vaccine-preventable diseases.

We ask you to recommend the influenza vaccine to your pregnant patients throughout the current influenza season. We ask that you also recommend the Tdap vaccination to your pregnant patients as they enter their third trimester. **Studies confirm that your recommendation and offer of vaccines are essential.** One study showed that patients who were offered influenza vaccination during an office visit were 7 times more likely to be vaccinated for influenza than patients who reported their provider did not recommend or offer vaccination. Patients who received a recommendation alone were twice as likely to be vaccinated as those that received no recommendation.[2]

We encourage you to adopt the National Adult Immunization Practice Standards to help ensure that your patients receive influenza and Tdap vaccinations as well as all other indicated vaccinations. We ask you to complete the following steps at each patient encounter:

- **Assess** the immunization status of each patient.
- **Recommend** the indicated vaccines to each patient
- **Administer** any necessary vaccines or, if you do not stock the vaccine, **refer** the patient to a provider or location that can vaccinate the patient.
- **Document** the vaccinations that your patient is given, ideally in your state or local immunization registry.

Your pregnant patients might be concerned about receiving a vaccination while pregnant. Influenza and Tdap vaccines are safe and important for pregnant women and their infants. Infants in the first several months of life are at the greatest risk of severe illness from influenza and pertussis but are too young to be directly immunized, thus vaccination during pregnancy is critical.

You play a crucial role in helping keep pregnant women and their newborns healthy. Assuring your patients are protected by recommended vaccines is key. For more information about the influenza vaccine, please visit: http://www.cdc.gov/flu/professionals/index.htm. For more information about the Tdap vaccine and pregnancy, please visit: http://www.cdc.gov/pertussis/pregnant/hcp/. For information about all vaccines for pregnant women visit: http://www.cdc.gov/vaccines/pubs/preg-guide.htm.

We thank you for your dedication to ensure the health and safety of pregnant women and their infants.

[1] http://www.cdc.gov/vaccines/hcp/acip-recs/index.html
[2] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a3.htm?s_cid=mm6337a3_w

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

Reid B. Blackwelder, MD
President
American Academy of Family Physicians

Gerald F. Joseph, Jr., MD, FACOG
Vice President, Practice Activities
American College of Obstetricians and Gynecologists

Edward R.B. McCabe, MD, PhD
Senior Vice President & Chief Medical Officer
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Marie-Michèle Léger, MPH, PA-C
Director, Clinical Education
American Academy of Physician Assistants

Lawrence L. Sanders, Jr, MD, MBA
President
National Medical Association

Lynn Erdman, MN, RN, FAAN
Chief Executive Officer
Association of Women's Health, Obstetric and Neonatal Nurses

Patrick Joseph, MD
President
National Foundation for Infectious Diseases

Vincenzo Berghella, MD
President
Society for Maternal-Fetal Medicine

Mitchel C. Rothholz, RPh, MBA
Chief Strategy Officer
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James M. Perrin, MD, FAAP
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American Academy of Pediatrics

Anne Schuchat, MD
RADM, United States Public Health Service
Assistant Surgeon General
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Debbie Hatmaker, PhD, RN, FAAN
Executive Director
American Nurses Association

Elena Rios, MD, MSPH
President & CEO
National Hispanic Medical Association

Ginger Breedlove, CNM, PhD, APRN, FACNM
President
American College of Nurse-Midwives

APPENDIX J

PROVIDER AND MEDICAL ASSISTANT SURVEYS

UNIVERSITY of NORTHERN COLORADO

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Working towards Tdap in Every Pregnancy: Protecting Our Most Vulnerable Population

Researchers: Jessica M. Scott (BSN-DNP Student), School of Nursing
e-mail: mayh3489@bears.unco.edu

The aim of this process improvement project is to improve Tdap rates in pregnant patients at North Colorado Family Medicine. This project is targeted at increasing the rates of provider recommendations for Tdap immunizations during pregnancy. This project will include two components that target providers: 1) an update to the prenatal highlights provider reminder tool that is located in the OB chart, and 2) a CDC authored factsheet on the safety and efficacy of the Tdap vaccine in pregnancy that will be placed in the patient education packet to be handed out at the OB intake visit.

All surveys will be distributed to provider clinic mailboxes and will be returned to the Dottie Schulte's clinic mailbox upon completion. It is anticipated that it will take you approximately 2-3 minutes to complete the survey.

The purpose of this survey is to evaluate the effectiveness of the updated prenatal highlights tool to include a reminder for Tdap immunization in pregnancy, and the addition of a CDC authored Tdap in pregnancy factsheet into the OB intake education packet as reminder tools for providers to make the recommendation for Tdap in every pregnant patient at North Colorado Family Medicine. Participation is **voluntary** and your responses will be **anonymous**. There are no foreseeable risks to participants, as this is a process improvement project of a current program already in place and is based on national vaccine recommendations. Participants may benefit directly from this project by ensuring that best practice is followed based on national recommendations to vaccinate every pregnant patient with the Tdap vaccine between 27 and 36 weeks.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please access and complete the attached document "Improving Tdap Rates in Pregnancy: Provider

Survey". Return completed surveys to Dottie Schulte's mailbox. If at any time you have any questions please contact one of the undersigned. **By completing the questionnaire, you will give us permission for your participation.** You may keep this form for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

Dottie Schulte FNP-BC
dottie.schulte@bannerhealth.com
970-810-2710

Jessica Scott, DNP (c), RN, BSN
mayh3489@bears.unco.edu

Improving Tdap Rates in Pregnancy

Provider Survey

Updated Provider Reminder Tool

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
This tool will be useful in reminding you to facilitate the administration of the Tdap vaccine in every pregnant patient at 27-36 weeks	1	2	3	4	5
This updated tool will be beneficial in current practice	1	2	3	4	5

CDC Patient Educational Material

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The Tdap in pregnancy educational material reminded you to discuss the vaccine with your patients during the OB intake	1	2	3	4	5
This educational material will be beneficial in current practice	1	2	3	4	5

UNIVERSITY of NORTHERN COLORADO

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Working towards Tdap in Every Pregnancy: Protecting Our Most Vulnerable Population

Researchers: Jessica M. Scott (BSN-DNP Student), School of Nursing
e-mail: mayh3489@bears.unco.edu

The aim of this process improvement project is to improve Tdap rates in pregnant patients at North Colorado Family Medicine. This project is targeted at increasing the rates of Tdap immunizations during pregnancy by empowering Medical Assistants to initiate the immunization process. At the end of the education session(s), the Medical Assistants will be able to verbalize the purpose of the Tdap vaccine during pregnancy, the window of pregnancy in which the immunization can be given (27-36 weeks), and the process if a patient or family member should decline the vaccine. This project will target Medical Assistants at North Colorado Family Medicine through education provided at regularly scheduled monthly staff meetings.

All surveys will be distributed to individual Medical Assistant clinic mailboxes and will be returned to the Dottie Schulte's clinic mailbox upon completion. It is anticipated that it will take you approximately 2-3 minutes to complete the survey.

The purpose of this survey is to evaluate the effectiveness of the education provided to Medical Assistants regarding the purpose and process of administering the Tdap immunization in every pregnant patient at North Colorado Family Medicine between 27 and 36 weeks, and if the vaccine should be declined, deferring education back to the provider to offer additional education, and make further recommendations. Participation is **voluntary** and your responses will be **anonymous**. There are no foreseeable risks to participants, as this is a process improvement project of a current program already in place and is based on national vaccine recommendations. Participants may benefit directly from this project by ensuring that best practice is followed based on national recommendations to vaccinate every pregnant patient with the Tdap vaccine between 27 and 36 weeks.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please access and complete the attached document "Improving Tdap Rates in Pregnancy: Provider Survey". Return completed surveys to Dottie Schulte's mailbox. If at any time you have any questions please contact one of the undersigned. **By completing the questionnaire, you will give us permission for your participation.** You may keep this form for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

Dottie Schulte FNP-BC
dottie.schulte@bannerhealth.com
970-810-2710

Jessica Scott, DNP (c), RN, BSN
mayh3489@bears.unco.edu

Medical Assistant Survey

Medical Assistant Educational Session

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Prior to the educational session you were aware that it is within the scope of your practice to initiate the Tdap vaccine in all pregnant women between 27 and 36 weeks	1	2	3	4	5
After the educational session provided, you will now initiate Tdap vaccine to every pregnant woman between 27 and 36 weeks	1	2	3	4	5
If a patient refuses the Tdap vaccine, you will defer this refusal to the patient's provider to provide additional education about the vaccine	1	2	3	4	5