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Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccination and Influenza Vaccination of Pregnant and Postpartum Women

Colleen M. McCormick
Wright State University - Main Campus

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Colleen M McCormick

MD/MPH Candidate

Wright State University Boonshoft School of Medicine

Physician Leadership Development Program

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Abstract

Introduction: Infants ≤2 months are at greatest risk for morbidity/mortality from pertussis. Tdap vaccines given in late pregnancy or postpartum can protect infants from pertussis. Pregnancy increases risks for maternal and perinatal complications. Influenza vaccine (FLUV) given in pregnancy can protect women and newborns.

Objectives: To determine Tdap and FLUV rates in pregnant and postpartum patients and identify factors associated with vaccination.

Methods: Miami Valley Hospital delivery records from 01/2009-12/2011 were retrospectively reviewed. Data reviewed included age, insurance, race/ethnicity, and county of residence. Descriptive statistics analyzed prevalence of immunization, timing, and demographics. Chi-square and odds ratios detected differences between characteristics.

Main Findings: A total of 13704 charts were reviewed. Tdap was administered to 42%, with 93% vaccinated within 10 days after birth. Tdap uptake was significantly greater among younger mothers (49%, p=0.023), those with government insurance (48%, p<0.0001), and in black mothers (46.8%, p=0.023). FLUV was given to 18% during the study period with 78% vaccinated between the third trimester and the 6-week postpartum visit. FLUV vaccination was significantly greater among mothers living within Montgomery County (19.4%, p<0.0001) and among black (17.63%, p=0.008) mothers. Vaccination rates for both Tdap and FLUV increased over the study period, from 30% to 53% and 11% to 23%, respectively.

Conclusions: Despite current recommendations, only a minority received vaccinations during pregnancy or postpartum. Vaccination rates increased over time and with certain demographics. Improved strategies may increase FLUV and Tdap administration in this population.

Keywords*: pertussis, influenza, vaccination, maternal*

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Infectious diseases continue to cause significant morbidity and mortality in the infant population despite advances in prevention. Two such airborne diseases, influenza and pertussis, can be prevented in many infants; these are the only two diseases in which immunization during pregnancy is recommended to reduce disease in infants (Fortner, Kuller, Rhee, & Edwards, 2012). Most pertussis-related hospitalizations and deaths occur in infants $\leq$2 months (Bisgard et al., 2004; Castagnini et al., 2012; CDC, 2010a; Gerbie & Tan, 2009; Wendelboe, Hudgens, Poole, & Van Rie, 2007a; Wendelboe et al., 2007b). Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccines administered in late pregnancy or in the early postpartum period have been shown to protect infants from pertussis (Bisgard et al., 2004; Castagnini et al., 2012; CDC, 2008; CDC, 2010b; Gall, Myers, & Pinchichero, 2011; Gerbie & Tan, 2009; Murphy et al., 2008).

Influenza is a respiratory disease caused by the influenza virus, which similarly leads to infection in all age groups, with extensive morbidity and mortality in the infant population, elderly population, and pregnant population. Pregnancy increases the risk for maternal influenza complications (CDC, 2011b; CDC, 2011c) and influenza during pregnancy may result in adverse perinatal or delivery complications (Bloom-Feshbach et al., 2011; Steinhoff et al., 2012). As with pertussis, the influenza vaccine (FLUV) given in pregnancy can protect women and newborns (Benowitz, Esposito, Gracey, Shapiro, & Vazquez, 2010; Bloom-Feshbach et al., 2011; Louie, Acosta, Jamieson, Honein, & California Pandemic [H1N1] Working Group, 2010; Murphy et al., 2008; Poehling et al., 2011; Steinhoff et al., 2012).

The Advisory Committee on Immunization Practices (ACIP) recommends that all postpartum women who were not previously vaccinated with Tdap receive the vaccine prior to hospital discharge (Murphy et al., 2008). In July 2011, the ACIP recommended that pregnant women at >20 weeks gestation also receive the Tdap vaccine. Finally, the ACIP recommends that all pregnant women receive the influenza vaccine (CDC, 2012b).

Purpose Statement

The purpose of this cross-sectional analysis is to examine the proportion of pregnant and postpartum women who receive the pertussis and influenza vaccines as recommended. A second objective of this study is to determine barriers to universal Tdap and FLUV immunization in unvaccinated women.

Research Questions

1) What percentage of women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011 is vaccinated against pertussis?
2) What percentage of women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011 is vaccinated against influenza?
3) What is the timing of vaccination for women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011?
4) What are the subpopulations not receiving these vaccinations of women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011?
5) What are the trends in vaccination of women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011?
6) What are the barriers to vaccination of women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011?

7) What are successful means of improving vaccination rates of women who gave birth at Miami Valley Hospital between January 1, 2009 and December 31, 2011?

Deliminations and Limitations

This study was designed to look specifically at one hospital system in Dayton, Ohio. While there are other delivery centers in the area, Miami Valley Hospital is the largest and draws from all areas in the region, therefore it was assumed that this population would be most representative of the general population. However, since only one center was chosen, a limitation of this data set is that an unknown number of women delivered at Miami Valley Hospital but received their pre- and/or post-natal care at outside facilities. Those women may have been vaccinated at other medical centers, and their vaccination records may not be available within the Miami Valley Hospital records. Therefore, the data set is likely incomplete.

Review of Literature

Disease Course, Pertussis

Pertussis is one of the few vaccine-preventable diseases that still cause significant morbidity and mortality in the United States. Despite preventative recommendations for vaccination, deaths from pertussis continue to occur, with the majority of deaths (93%) from 2005-2006 occurring in infants <12 months (CDC, 2008). Most cases of pertussis are amenable to treatment, and recovery occurs in the majority. Early infection with pertussis can be treated with antibiotics to prevent symptoms and spread of the disease, whereas treatment in later stages of the disease is only symptomatic (CDC, 2010b). However, some infants have the propensity to develop malignant pertussis, in which the bacterial infection leads to severe acute respiratory failure. In a 2010 retrospective cohort study conducted in France, ten infants between the ages of 0.6 and 3 months were diagnosed with pertussis (Bouziri et al., 2010). Nine out of ten infants subsequently died due to complications from this infection. Researchers retrospectively determined that due to their age and susceptibility to disease, these infants had malignant pertussis, and therefore were at increased risk for severe morbidity and mortality. Pertussis leads to more extensive morbidity when compared to other respiratory infections in infants, with hospitalization in infants approaching 50% (de Greeff et al., 2010); it also leads to increased lengths of stays, increased need for oxygen, and longer duration of illness (Castagnini & Munoz, 2010).

Although the disease is usually present in the population at low levels, with only a few cases per 100,000 people, there are cyclic, epidemic-like increases in incidence due to the contagiousness of the bacteria. These epidemics usually occur with a periodicity of 2-5 years (Broutin, Viboud, Grenfell, Miller, & Rohani, 2010). Nationwide, there has been a recent increase in pertussis infections, most notably in California. From January through June 2010, California experienced a 418% increase in pertussis infections when compared to 2009 incidence. As of August 2010, the state of California reported over 2,700 cases of pertussis for the calendar year, with eight infants dying from infection (CDC, 2010a). In general, infants infected with pertussis have the most serious and life-threatening illnesses compared with other age groups. With this national increase in pertussis infections, it is important to determine how infants are exposed to the illness in order to prevent illness and death.

Disease Course, Influenza

Influenza causes disease in all populations, with increased severity seen among infants and pregnant women. Seasonal influenza occurs nearly every year and leads to increased hospitalizations, especially among infants <6 months and children with co-existing medical conditions (Yen, Louie, & Schechter, 2012). It is estimated that 9-30 per 10,000 children are hospitalized with influenza during any particular season (Dawood et al., 2010). While the disease is usually self-limited, symptoms include headaches, myalgias, cough, malaise, and anorexia. The disease can also lead to severe complications including pulmonary disease (pneumonia, asthma, croup, bronchitis), as well as heart, neurologic, and renal complications (Nicholson, 1992). When pregnant women are infected with influenza, they have an increased risk of dying from influenza; in addition, their infants are more likely to be small for gestational age and preterm (CDC, 2011b).

Epidemics are also seen with the influenza virus, typically from November to March (CDC, 2011c). Seasonal epidemics occur yearly, though the timing and severity varies greatly from year-to-year. Occasionally, pandemics occur when the virus' genetic material changes drastically. Two major pandemics are pertinent to this research study. The first is the 1918 "Spanish" influenza pandemic, which caused the death of 500,000 people in the United States alone and caused illness in even more (CDC, 1999). During the 1918 influenza pandemic the birth rate was markedly reduced, likely related to an increase in first-trimester miscarriages (Bloom-Feshbach et al., 2011). A second epidemic that occurred more recently was the 2009-2010 H1N1 pandemic. This greatly increased the morbidity and mortality among pregnant women (Louie et al., 2010) and infants (Yen et al., 2012). During H1N1, infected infants manifested disease as gastrointestinal illness (36%), neurologic changes (10%), and pneumonia (34%); ten percent of infected children required admission to the Pediatric ICU (Blumental et al., 2011). Similar to pertussis, it is important to determine how infants are exposed in order to effectively prevent the disease.

Vaccines and Recommendations, Pertussis

Two types of pertussis vaccines exist: whole cell (wP) and acellular (aP) vaccines. The whole-cell vaccine, which is the older vaccine, is often heterogeneous in composition, with an efficacy ranging from 46% to 92% (Pertussis Vaccines, 2010). This vaccine often composes the type given to infants within developing countries; however, the whole-cell type is not found in adolescent or adult pertussis vaccines. The newer, more expensive acellular vaccine was developed in 1981 in Japan and is the type used in the United States. Heterogeneity in the number of acellular components exists, but research has shown that vaccines with three or more components are the most effective: efficacy is about 89% for these vaccines when multiple doses are given (CDC, 2010b). In addition, local and systemic reactogenicity is likely lower in aP vaccines compared to wP vaccines (Pertussis Vaccines, 2010).

Natural infection with pertussis only leads to antibody development in 80-85% of those infected (Pertussis Vaccines, 2010). Therefore, the protection conferred by such antibodies is not necessarily life-long. Similarly, immunity wanes after vaccination. Immunity lasts approximately 4-20 years after natural infection and approximately 4-12 years after immunization (Wendelboe, Van Rie, Salmaso, & Englund, 2005). Therefore, multiple vaccinations with the diphtheria-tetanus-acellular pertussis (DTaP) vaccine and later with a booster vaccine is recommended for all infants and adults, respectively, in order to prevent future infections and prevent the spread of disease to susceptible infants.

The current US recommendations for prevention against pertussis include giving children four doses of the diphtheria, tetanus, and pertussis (DTaP) vaccine at two, four, six, and fifteen-eighteen months of age. A DTaP booster dose is recommended for children aged 4-6 years of age, and a Tdap booster is recommended at 11-12 years of age (CDC, 2012a). Due to waning immunity in the population, the ACIP has recommended that all adults, including postpartum women, substitute one Tdap vaccine for a Td booster (typically given every 10 years). Finally, it is now recommended that pregnant women at 20 weeks gestation or greater receive the Tdap vaccine (CDC, 2012a). Caregivers in close contact with any infant, including fathers, grandparents, siblings, and other caregivers, should receive the Tdap vaccine (Castagnini et al., 2012). Not only do these recommendations limit the spread of infection to infants, but also they have been found to be cost-effective compared to the cost of treating pertussis infections (Scuffham & McIntyre, 2004).

Vaccines and Recommendations, Influenza

Influenza vaccine efficacy varies among populations. In healthy children, the efficacy is estimated to be 79% (Jefferson et al., 2005a), while for elderly living in long-term care facilities, the efficacy is closer to 45% (Jefferson et al., 2005b). While vaccinating elderly is not as effective as vaccinating children, the vaccination of healthy children can provide protection to the elderly through herd immunity, with approximately a 60% reduction in influenza (Loeb et al., 2010; Loeb, Russell, Fonseca, Webby, & Walter, 2011). The US Department of Health and Human Services (2011) recommends that 80% healthy and 90% high-risk individuals receive the influenza vaccine each year; however, vaccination rates have rarely crossed 50% of the population. In particular, rates of vaccination among pregnant women were only 15% prior to the H1N1 pandemic, although they jumped to approximately 50% during the pandemic (CDC, 2011a). It remains to be seen if these trends will continue in subsequent influenza seasons. Despite widespread availability of the vaccines, which are available at most pharmacies, supermarkets, physician offices and hospitals, influenza has been described as “the least controlled vaccine-preventable disease” (Glezen, 2004, p. 39).

The immunity conferred by natural infection with influenza has been estimated to be similar to vaccine immunity. Like immunity from the vaccine, natural immunity does not provide protection from year-to-year because of the antigenic drift and shift of the virus. Therefore, yearly vaccination is recommended for all persons >6 months of age. During the H1N1 pandemic (2009-2010 influenza season), it was recommended that all eligible persons receive both the seasonal vaccine and the H1N1 vaccine. In addition, vaccination of pregnant women was recommended with both H1N1 and seasonal influenza vaccines. When examining serum antibody levels, it was shown that vaccination with H1N1 and infection with H1N1 conferred similar levels of immunity to infants via analysis of cord blood (Fisher et al., 2012), thereby protecting both the mother and fetus against the epidemic strain.

The CDC recommends that the influenza vaccine, usually available from September through April, be given annually to all persons 6 months and older. This includes pregnant women, or women who will be pregnant during flu season, as well as household contacts and caregivers of children less than five years old (CDC, 2012a). Influenza infection among infants is greatly reduced if the mother is vaccinated (Benowitz et al., 2010; Poehling et al., 2011); the effectiveness of vaccinating the mother to protect the infant is estimated at 91-92% (Benowitz et al., 2010). In addition, other infant respiratory illnesses are greatly reduced when the mother has been vaccinated (Steinhoff et al., 2012).

Vaccination Strategies, Pertussis

Even when DTaP vaccination is initiated at 6 weeks of age, infants are not fully immune until they have received multiple doses of the vaccine (CDC, 2010b). Therefore, it is important to determine how infants are exposed to the illness in order to decrease their risk of disease. A 2010 study from the Netherlands showed that in cases where an infant is diagnosed with pertussis, the source of infection often came from the household (de Greeff et al., 2010). The source was discovered in 60% of cases, with a sibling being responsible for 41% of cases, a mother causing 38% of cases, and a father causing 17% of cases. Another study found that siblings were the cause of infection in 36% of cases (with 3-4 year olds responsible for the majority), parents in 24% of cases, other family members in 21% of cases, and friends in 13% of cases (Jardine, Conaty, Lowbridge, Staff, & Vally, 2010). In a 2004 study by Bisgard et al., mothers were deemed to be the source in 32% of infections, while another family member was responsible in 43% of cases. More often than not, an infant who is exposed to pertussis infection receives the bacteria from a close family member.

Immunizing family contacts against pertussis could greatly reduce the incidence of infection in young infants; this method of prevention is known as cocooning. Cocooning is accomplished by protecting close contacts from pertussis infection via immunization with Tdap, thereby reducing disease transmission to infants and others. A study of the Tdap vaccine during a pertussis outbreak on the US Virgin Islands found the vaccine to be 65.6% effective in preventing illness among adolescents (95% CI: -35.8% to 91.3%) and the relative risk of infection with pertussis in an unvaccinated adolescent compared to a vaccinated adolescent was 2.9 (Wei et al., 2010). A second efficacy study conducted in Australia found that the Tdap vaccine was 78% effective (95% CI: 60.7% to 87.6%) in preventing infection with pertussis among adolescents (Rank, Quinn, & McIntyre, 2009). As estimated in mathematical modeling, cocooning through vaccination of mothers and fathers can decrease the disease incidence by 65-70% (Van Rie & Hethcote, 2004). However, a recent 2012 study showed that the number needed to vaccinate to prevent one infant death was estimated at 1 million persons (Skowronski et al., 2012). A second study looking at implementation of cocooning in a high-risk population described several barriers, including inaccurate recall of prior immunization (Healy, Rench, & Baker, 2011). It remains to be seen whether the barriers to cocooning reduce cost-effectiveness; yet, the ACIP and other organizations continue to promote vaccination of close contacts as a method of protecting infants.

In addition to cocooning, herd immunity can be used to prevent the spread of infection throughout the population. This utilizes the principle and calculations of disease reproduction. When the number of individuals protected from infection (*f*) is greater than a calculated threshold (*1-1/Ro*, where Ro is the basic reproductive number), disease transmission will be eliminated. It is not necessary to immunize 100% of the population to prevent an epidemic (Anderson & May, 1990). Based on this equation, the threshold estimated to eliminate pertussis is between 90-94% (Ward et al., 2005). In order to maintain the disease at "non-epidemic" proportions, where secondary cases may occur without causing an epidemic, vaccination rates of approximately 65% are required (Coudeville, Van Rie, & Andre, 2008). A 2010 study conducted in Spain looked at this principle in three population groups: 6-9 years, 15-24 years, and 45-54 years (Plans, 2010). By measuring the levels of antibody, and therefore immunity against pertussis, they discovered that only 42% of the population was immune. Antibody prevalence was highest in the 6-9 years age group (the group most recently vaccinated). Utilization of the Tdap vaccine in US adolescents and adults will likely increase *f* in these populations, but it is unclear if the vaccine can provide enough herd immunity to decrease or eliminate secondary cases of the disease.

Another principle to protect infants is passive immunity, in which the fetus receives antibodies through the mother's placenta during gestation (IgG antibodies), and later through colostrum (IgA antibodies); those IgG antibodies typically last several weeks, with IgA lasting as long as breastfeeding occurs, thereby providing the infant with an immune system until he/she can develop his/her own (Baxter, 2007). While antibody transfer does occur with pertussis antibodies (Gall et al., 2011; Quinello, Quintilio, Carneiro-Sampaio, & Palmeira, 2010), it is still unclear how effective these antibodies are at preventing disease in infants.

Vaccination Strategies, Influenza

Influenza contributes to approximately 36,000 deaths each year and over 200,000 hospitalizations (US Department of Health and Human Services, 2011). The rates of coverage with influenza vaccine have typically been low. Among pregnant women, the rate was approximately 2.5% in 2003-2004 in one study. With education and vaccine promotion among providers, the rate increased to 37.4% in 2008-2009 (the season prior to H1N1) (Mouzoon et al., 2010).

Influenza vaccines are not available for children until they have reached six months of age; so, direct vaccination is a method that cannot be currently employed to protect infants. However, similar to cocooning in pertussis, influenza vaccination of caregivers and close contacts may protect infants from the virus (Rimmelzwaan, Bodewes, & Osterhaus, 2011). While research on cocooning to prevent pertussis is rampant, there is little research on the benefits of cocooning to prevent influenza and its complications. In the US, influenza vaccination rates are low, especially among caregivers of infants. Rates range from 10-40% in healthy persons and 39-67% in high-risk individuals (CDC, 2011c).

As described above, herd immunity can be protective for a population, even if 100% immunity is not achieved. The threshold for herd immunity for influenza varies depending on the virus strain, seasonal attack rates, the vaccine effectiveness (which changes from year-to-year) and the epidemic year. It has been estimated to be between 0% and 100%, depending on the variables described above (Plans-Rubio, 2012). One study in Japan found that immunizing schoolchildren was an efficient method of achieving herd immunity. By vaccinating just 420 children in the community, one death from influenza could be prevented (Reichert et al., 2001). While a specific range for herd immunity is not available for preventing influenza, mathematical modeling by Plans-Rubio (2012) supports the Healthy People 2020 goals that 80% of pregnant women and 90% of high-risk persons should be vaccinated against influenza to prevent the spread of disease throughout the population (US Department of Health and Human Services, 2011). In addition, it has been shown that vaccinating children provide herd immunity to the elderly (Cohen, Chui, & Naumova, 2011) in a cost-effective manner (Loeb et al., 2010).

The most studied method of disease prevention in infants is vaccinating pregnant mothers to confer passive immunity to infants. IgG antibodies will cross the placenta, thereby providing protection for the infant (Kohler & Farr, 1966; Hobbs & Davis, 1967); as shown in a 2012 randomized controlled trial, vaccinating pregnant women with influenza led to a 63% decrease in influenza infections among infants (Steinhoff et al., 2012). A second study showed that vaccinating pregnant women was 91.5% effective in preventing hospitalizations among infants due to influenza infection (Benowitz et al., 2010).

This study aims to quantify and describe (by demographic variables) the number of postpartum women who qualify for Tdap immunization but are not receiving Tdap immunization before discharge from the hospital. This study will also quantify and describe the number of pregnant and postpartum women who do not receive the influenza vaccine. A secondary objective will be to describe factors associated with failure to vaccinate. The analysis will determine whether providers are following ACIP and hospital recommendations with respect to influenza and pertussis immunization in this population, as these may significantly affect the rate of disease in infants. It may also identify subpopulations at risk for not receiving the vaccines. The findings will support changes in hospital immunization protocols and quality measures.

Methods

Subjects

The subjects included all women who gave birth at Miami Valley Hospital in Dayton, Ohio between January 2009 and December 2011. No patients were excluded from the study. No limitations were placed on study participants regarding age, county of residence, insurance status, race, or ethnicity.

Measurement

The dependent variables in this study were: 1) vaccination with Tdap and, 2) vaccination with FLUV. Timing of these vaccinations was recorded and compared to time of birth. These dependent variables were measured as both continuous and categorical (Table 1). The following independent variables were identified to be measured during analysis: age, county of residence, insurance status, race, and ethnicity (Table 1).

Table 1.
Dependent and Independent Variables

Dependent Variables	Description	Level of Measurement
Tdap vaccine	Receipt of vaccine and timing of vaccination	Continuous; Categorical: yes/no; timing: pre-conception, during pregnancy, immediate postpartum, within 6-weeks postpartum
FLUV vaccine	Receipt of vaccine and timing of vaccination	Continuous; Categorical: yes/no; timing: pre-conception, during pregnancy, immediate postpartum, within 6-weeks postpartum
Independent Variables	**Description**	**Level of Measurement**
Age	Mother's reported age at the time of infant's birth	Continuous; Categorical: <20, 20-34, >=35
County of Residence	Mother's reported county of residence at the time of infant's birth	Categorical: Montgomery, Outside of Montgomery
Insurance Status	Mother's reported insurance status at the time of infant's birth	Categorical: Commercial, Government, Other
Race	Mother's reported race at the time of infant's birth	Categorical: White, Black, Other
Ethnicity	Mother's reported ethnicity at the time of infant's birth	Categorical: Hispanic or Latino, Not Hispanic or Latino

Data Collection and Descriptive Analysis

This is a retrospective, descriptive analysis of the labor and delivery medical records at Miami Valley Hospital in Dayton, Ohio, which has been approved by the Miami Valley Hospital Institutional Review Board. Data was collected by querying the Epic electronic medical record database for all postpartum patients; all charts from January 2009-December 2011 (36 months) were examined for influenza and pertussis vaccination status of new mothers. Each medical record was assigned a random code, and all data was stored under this random code in a password-protected Excel spreadsheet. The patient medical record number linked to the random code was stored in a separate password-protected Excel spreadsheet, and that information will be destroyed at the end of the study. No hard-copy data was obtained during this study. A history of vaccination with Tdap or influenza by other caretakers was unavailable.

Using a Microsoft Excel spreadsheet, all data was organized into categories such as "Date of Delivery," "Vaccine Received," and "Timing of Vaccine." Each delivery at Miami Valley Hospital was assessed for vaccination with Tdap at any time, and vaccination with influenza during that particular flu season. The time of vaccination was recorded and compared to the time of birth. The number of women receiving (a) Tdap prior, during, and within 6 weeks post-delivery, and, (b) seasonal FLUV or H1N1 before or just after delivery at this hospital was collected. Standard demographic data was also collected, including age, payer status (government, private, charity, etc.), county of residence, zip code, race, and ethnicity (See Appendix A). Women were considered to have received the Tdap vaccine if it was administered up to 4 years prior to delivery, through the gestational period, and up to 6 weeks post-partum. If a woman received the vaccine outside of that period, it was not counted as a positive history of vaccination. Women were considered to have received the FLUV vaccine if it was given during pregnancy, or in the influenza season immediately preceding pregnancy if the woman conceived outside of flu season. For example, if a woman conceived during May and was given a flu vaccine during March, that was considered a positive vaccination status. A delivery was only counted once, regardless of whether the woman delivered one or multiple infants in that delivery.

A separate Microsoft Excel spreadsheet was created to analyze Tdap data. In this spreadsheet, a woman was only counted once in the entire study period, even if she had multiple deliveries. If a woman had delivered multiple times throughout the study period, the delivery positively associated with Tdap vaccination was included in the spreadsheet. If a women had not received the Tdap vaccine with any pregnancy, or if a women had received the Tdap vaccine with two or more pregnancies, the delivery to be included in the study population was chosen at random. Random selection entailed rotating through the three years in the study period: in the first instance of multiple deliveries, the delivery occurring at the earliest date was selected; in the second instance of multiple deliveries, the delivery occurring at the second earliest date was selected; and so on. Descriptive statistics were employed to describe the population, determine the prevalence of vaccination, and determine the timing of vaccination. The de-identified data was then transferred to SAS for statistical analysis.

Statistical Analysis

Using SAS, Chi-Square was performed on both pertussis and influenza data to determine if the means among populations were significantly different. Logistic regressions were performed on the same data sets. P values of <0.05 were considered statistically significant for all analyses. In addition, odds ratios were calculated to compare categories within the independent variables.

Statement Regarding IRB Approval

Miami Valley Hospital's Institutional Review Board reviewed and approved this study prior to initiating data collection or analysis. IRB approval was obtained to ensure the protection of human subjects. IRB renewal was obtained in 2011 so that the study could be continued for another year.

Results

Patient Demographics

Between January 1, 2009 and December 31, 2011, 13,704 deliveries occurred at Miami Valley Hospital. Of these deliveries, 10.8% of women were less than 20 years of age; 78.4% of women were between the ages of 20 and 35; and 10.8% of women were aged 35 or greater. Sixty-two percent of women were residents of Montgomery County. In regards to insurance status, 40.9% of women had private insurance, 54.8% of women had government insurance, and 4.3% of women had other forms of payment (self-pay, charity care, etc.). Of women delivering during the study period, 70% were white, 23% were black, and 7% were of another race. Ninety-six percent of women did not consider themselves Hispanic/Latino (Table 2).

Table 2. ***Demographic Characteristics of Study Participants (n=13,704)***		
		n (%)
Age		
	<20	1486 (10.8%)
	20-34	10740 (78.4%)
	35 or greater	1478 (10.8%)
County of Residence		
	Montgomery	8457 (61.7%)
	Outside of Montgomery	5247 (38.3%)
Insurance Status		
	Commercial	5605 (40.9%)
	Government	7506 (54.8%)
	Self-Pay	99 (0.7%)
	Charity	240 (1.8%)
	Other	253 (1.8%)
Race		
	White	9600 (70.1%)
	Black	3091 (22.6%)
	Other	1013 (7.4%)
Ethnicity		
	Not Hispanic/Latino	13204 (96.4%)
	Hispanic/Latino	477 (3.5%)

Vaccination Rates, Pertussis

During the 36-month study period, 5,304 women delivering babies, or 42% of subjects, received the Tdap vaccine at Miami Valley Hospital. Broken down by year, 30% of women in 2009 received the vaccine; 42% of women in 2010 received the vaccine; and, 53% of women in 2011 received the vaccine. This 77% increase in immunizations over the study period was statistically significant ($p<0.0001$). Forty-nine percent of women less than 20 years old received the vaccine, while 41.5% of women aged 20-34 and 36.2% of women 35 or greater received the vaccine (p=0.0225). Of women living in Montgomery County, 42.8% received the vaccine, while 40.1% of women living outside the county received the vaccine (p=0.1395). Thirty-three percent of women with commercial insurance received the vaccine, while 48.2% of women with government insurance received the vaccine (p<0.0001). In regards to race, 39.5% of white women received the vaccine and 46.8% of black women received the vaccine (p=0.0225). Fifty-one percent of Hispanic/Latino women and 41.4% of non-Hispanic/Latino women received the vaccine (p=0.4394; Table 3).

Table 3.
Analysis of Tdap Vaccination by Demographic Variables

	Vaccinated n (%)	Not vaccinated n (%)	Chi-Square
Year			<0.0001*
2009	1301 (30.15%)	3014 (69.85%)	<0.0001*
2010	1798 (42.47%)	2436 (57.53%)	<0.0001*
2011	2205 (53.02%)	1954 (46.98)	-
Mother's Age			0.0225*
<20	672 (49.12%)	696 (50.88%)	-
20-34	4120 (41.50%)	5807 (58.50%)	0.0458*
>or=35	512 (36.23%)	901 (63.77%)	0.0234*
County			0.1395
Montgomery County	3336 (42.76%)	4466 (57.24%)	-
Outside Montgomery County	1968 (40.11%)	2938 (59.89%)	-
Insurance			<0.0001*
Commercial	1718 (32.92%)	3500 (67.08%)	<0.0001*
Government	3338 (48.17%)	3592 (51.83%)	-
Self-Pay	34 (38.20%)	55 (61.80%)	0.0205*
Charity	136 (59.65%)	92 (40.35%)	0.1676
Other	78 (32.23%)	164 (67.77%)	<0.0001*
Race			0.0225*
White	3530 (39.47%)	5413 (60.53%)	0.0374*
Black	1325 (46.82%)	1505 (53.18%)	-
Other	438 (48.40%)	467 (51.60%)	0.3365
Ethnicity			0.4394
Not Hispanic/Latino	5072 (41.41%)	7175 (58.59%)	-
Hispanic/Latino	225 (51.37%)	213 (48.63%)	-

Note. * signifies that the value is significant as p<0.05.

The odds of receiving the vaccine were 1.55 times higher in 2011 than in 2010 (CI 1.42-1.69) and 2.67 times higher in 2011 than 2009 (CI 1.42-1.69). In addition, the odds of receiving the vaccine were 1.13 times higher for mothers less than 20 years old compared to mothers aged 20-34 (CI 1.00-1.27), and 1.21 times higher than mothers 35 years old or greater (CI 1.03-1.42). Women with government insurance were 1.85 times more likely to be vaccinated than those with commercial insurance (CI 1.70-2.01); 1.69 times more likely than women self-paying (CI 1.08-2.63); 2.03 times more likely than women with other types of insurance (CI 1.53-2.70). There was no significant difference in the odds of being vaccinated between women with government insurance and those with charity care. The odds of being vaccinated based on county of residence or ethnicity was not significant (Table 4).

Table 4.
Odds Ratios of Tdap Vaccination by Demographic Variables

	Odds Ratio	Confidence Intervals
Year		
2011 vs 2009	2.67	2.44-2.93*
2011 vs 2010	1.55	1.42-1.69*
Mother's Age		
<20 vs 20-34	1.13	1.00-1.27*
<20 vs >or=35	1.21	1.03-1.42*
County		
Outside Mont. County vs Mont. County	0.94	0.87-1.02
Insurance		
Government vs Commercial	1.85	1.70-2.01*
Government vs Self-Pay	1.69	1.08-2.63*
Government vs Charity	0.82	0.62-1.09
Government vs Other	2.03	1.53-2.70*
Race		
Black vs White	1.11	1.01-1.22*
Black vs Other	0.91	0.74-1.11
Ethnicity		
Hispanic/Latino vs Not Hispanic/Latino	1.11	0.85-1.45

Note. * signifies that the value is significant as $p<0.05$.

In regards to timing of immunization, 93% of vaccinated women received the Tdap vaccine in the immediate post-partum period. Four percent of women were vaccinated with Tdap prior to conception. Two percent of women received the vaccine during pregnancy, and 1% received the vaccine in the 6-week post-partum period. Broken down by year, the percentage of women vaccinated between 20 weeks gestation and birth increased by 41% over the study period, from 1.8% in 2009 to 2.5% in 2011. In addition, the percentage of women vaccinated prior to gestation increased by 60%, from 3.5% in 2009 to 5.7% in 2011 (Figure 1).

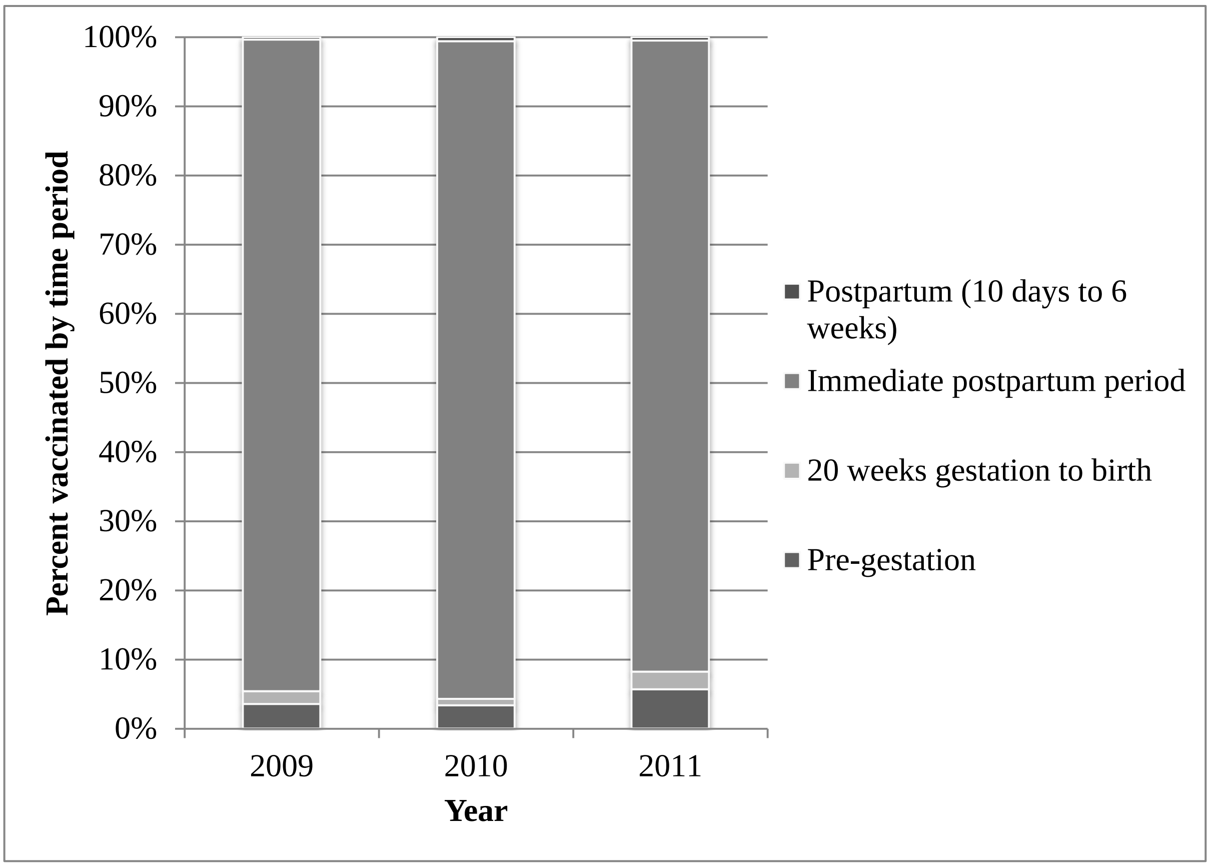

Figure 1. Timing of Tdap immunization by year of delivery using data collected from Miami Valley Hospital.

Vaccination Rates, Influenza

From 2009-2011, 18% of women delivering at Miami Valley Hospital received an influenza vaccine, either seasonal or H1N1. Broken down by year, 11.4% of women delivering in 2009 received the vaccine; 19% of women delivering in 2010; and, 23% of women delivering in 2011 received an influenza vaccine. This 100% trend increase over the study period was statistically significant ($p<0.0001$). During the H1N1 season, only 1.7% of women received both the seasonal influenza and H1N1 vaccines. Other significant variables were county of residence, insurance status, race, and ethnicity. Nineteen percent of women less than 20, 18% of women 20-34 years old, and 16% of women 35 years or greater received the vaccine ($p=0.6133$). Of women living in Montgomery County, 19% were vaccinated; 15% of women living outside Montgomery County received the vaccine ($p<0.0001$). Sixteen percent of women with commercial insurance, 19% of women with government insurance, and 33.8% of women with charity care received FLUV ($p<0.0001$). Regarding race, 17.4% of white women and 17.6% of black women received the vaccine, while 23% of women of other races received the vaccine ($p=0.0194$). Twenty-seven percent of Hispanic/Latino women received the vaccine, while only 17.5% of non-Hispanic/Latino women received the vaccine ($p=0.0044$) (Table 5).

Table 5.
Analysis of Influenza Vaccination by Demographic Variables

	Vaccinated n (%)	Not vaccinated n (%)	Chi-Square
Year			<0.0001*
2009	536 (11.33%)	4194 (88.67%)	<0.0001*
2010	857 (19.10%)	3631 (80.90%)	<0.0001*
2011	1050 (23.40%)	3437 (76.60%)	-
Mother's Age			0.6133
<20	279 (18.78%)	1207 (81.22%)	-
20-34	1925 (17.92%)	8815 (82.08%)	-
>or=35	239 (16.17%)	1239 (83.93%)	-
County			<0.0001*
Montgomery County	1643 (19.43%)	6814 (80.57%)	<0.0001*
Outside Montgomery County	800 (15.25%)	4447 (84.75%)	-
Insurance			<0.0001*
Commercial	900 (16.06%)	4705 (83.94%)	0.0011*
Government	1426 (19.0%)	6080 (81.00%)	-
Self-Pay	9 (9.09%)	90 (90.91%)	0.0123*
Charity	81 (33.75%)	159 (66.25%)	0.0002*
Other	26 (10.28%)	227 (89.72%)	0.0009*
Race			0.0194*
White	1669 (17.39%)	7931 (82.61%)	0.0075*
Black	545 (17.63%)	2546 (82.37%)	-
Other	226 (22.99%)	757 (77.01%)	0.0788
Ethnicity			0.0044*
Not Hispanic/Latino	2312 (17.51%)	10892 (82.49%)	0.0044*
Hispanic/Latino	129 (27.04%)	348 (72.96%)	-

Note. * signifies that the value is significant as p<0.05.

The odds of receiving the vaccine were 1.27 times higher in 2011 than in 2010 (CI 1.15-1.41) and 2.36 times higher in 2011 than 2009 (CI 2.10-2.64). Women living within Montgomery County were 1.33 times more likely to receive FLUV than women living outside the county (CI 1.21-1.47). Women with government insurance were 1.18 times more likely to be vaccinated than those with commercial insurance (CI 1.07-1.31); 2.41 times more likely than women self-paying (CI 1.22-4.83); 0.58 times as likely as women receiving charity care (CI 0.44-0.77); and, 2.02 times more likely than women with other types of insurance (CI 1.22-3.06).

White women were 0.85 times as likely as black women to receive FLUV (CI 0.76-0.96); women of other races were 0.81 times as likely as black women to be vaccinated, although this was not statistically significant. The odds of being vaccinated based on maternal age were not significant (Table 6).

Table 6.
Odds Ratios of Influenza Vaccination by Demographic Variables

	Odds Ratio	Confidence Intervals
Year		
2011 vs 2009	2.36	2.10-2.64*
2011 vs 2010	1.27	1.15-1.41*
Mother's Age		
<20 vs 20-34	1.02	0.88-1.18
<20 vs >or=35	1.10	0.90-1.34
County		
Mont. County vs. Outside Mont. County	1.33	1.21-1.47*
Insurance		
Government vs Commercial	1.18	1.07-1.31*
Government vs Self-Pay	2.41	1.22-4.83*
Government vs Charity	0.58	0.44-0.77*
Government vs Other	2.02	1.22-3.06*
Race		
White vs Black	0.85	0.76-0.96*
Other vs Black	0.81	0.63-1.03
Ethnicity		
Hispanic/Latino vs Not Hispanic/Latino	1.55	1.15-2.09*

Note. * signifies that the value is significant as $p<0.05$.

The timing of influenza vaccination varied from year to year. In regards to timing of immunization, 3.5% of women received FLUV during the 1st trimester, 15% of women received the vaccine in the 2nd trimester, and 30.2% of women received the vaccine in the 3rd trimester. Two percent of women were vaccinated during the influenza season just prior to conception, and 48% of women were vaccinated in the postpartum period (from birth to six weeks of age). There was a 67% increase over the study period in the percentage of women vaccinated in the 2nd trimester, from 9% to 15%. There was also a 35% increase in the percentage of women vaccinated in the postpartum period, from 39.8% to 53.8%. In conjunction with these increased rates, there was a 45% decrease in the percentage of women vaccinated in the 3rd trimester, from 45.4% to 25%. Overall, 78% of women were vaccinated either in the 3rd trimester or in the postpartum period (Figure 2).

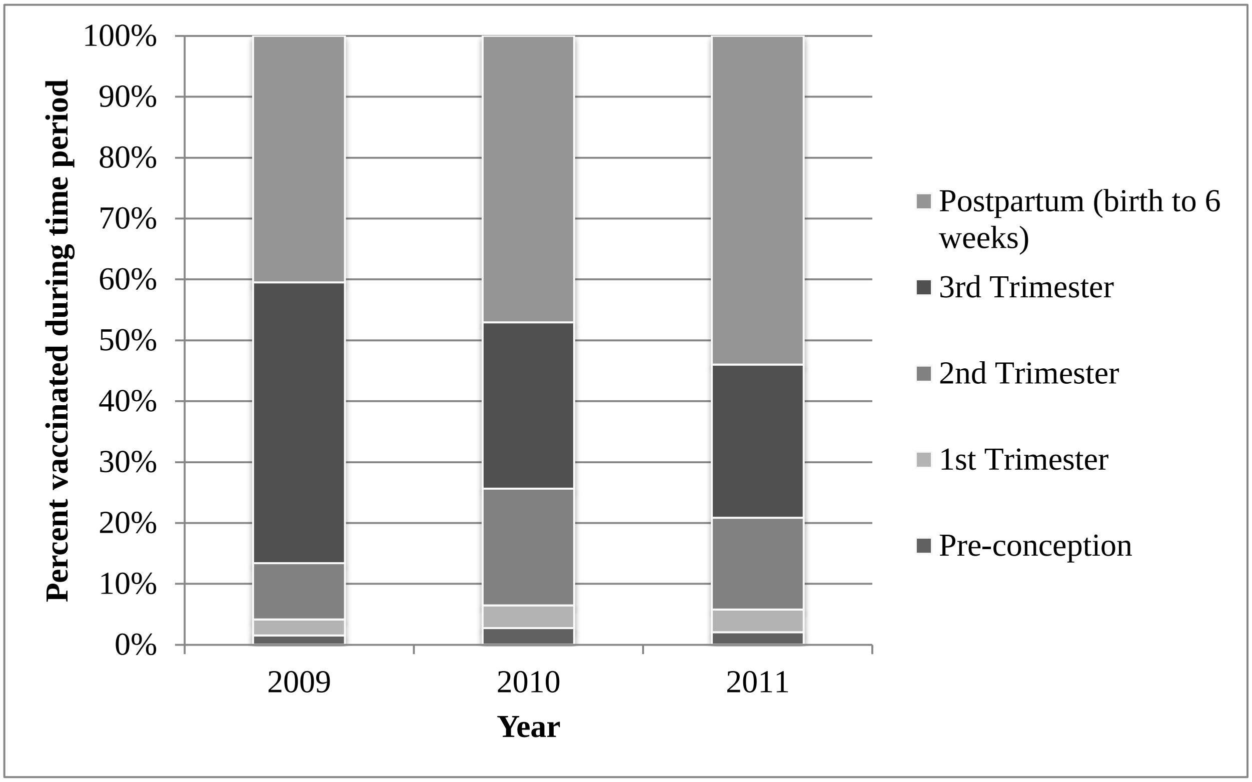

Figure 2. Timing of Influenza immunization by year of delivery using data collected from Miami Valley Hospital.

Discussion

Purpose of the Study with Research Questions

This study examined the percentage of pregnant and postpartum women who received the pertussis and influenza vaccines as recommended. A second objective of this study was to identify barriers to universal Tdap and FLUV immunization in unvaccinated women. The results showed that 42% of mothers delivering at Miami Valley Hospital (MVH) received the Tdap vaccine during the study period, and 18% received FLUV. Very few women received both seasonal and H1N1 influenza during the epidemic season, as recommended by the CDC. The large majority of mothers who received Tdap were vaccinated in the immediate postpartum period, between birth and 10 days postpartum. Women who received FLUV were most often vaccinated in the third trimester or immediate postpartum period, while very few women were vaccinated pre-conception or early in pregnancy.

Women were less likely to receive the Tdap vaccine if they were older than 20 years, if they had commercial insurance or were self-pay, or if they were white. Mothers were less likely to receive FLUV if they were living outside Montgomery County, if they had commercial insurance or were self-pay, if they were white, and if they were not Hispanic/Latino. Interestingly, age was not a significant variable for receipt of FLUV, while it was significant for Tdap. In addition, county residence was a significant variable for receipt of FLUV, while it was not significant for receipt of Tdap.

One of the main goals of Healthy People 2010 was to reduce health disparities, including disparities in vaccination coverage among population subgroups within the United States. Using data from the National Immunization Survey, Zhao and Luman (2010) found that overall vaccination coverage increased from 2000 to 2008 and most disparities surrounding vaccination were reduced during this period. However, as of 2008 significant disparities among some demographic factors still remain. When adjusted for other factors, white children had significantly lower vaccination coverage compared to Hispanic children. Also, children with more than one sibling were significantly less likely to be vaccinated compared to children with no siblings (Zhao & Luman, 2010).

While the data by Zhao and Luman (2010) does not directly analyze maternal demographic variables, white women may be less likely to be vaccinated across the US population, as was shown in the MVH study. It is unclear why race would play a direct role in vaccine uptake. It is possible that there are racial barriers in terms of access to vaccines. In addition, racial disparities could be accounted for by provider bias. Cultural factors may also play a role in vaccine uptake. Interestingly, the MVH study showed that women with government insurance were more likely to receive both vaccines. This may be because the immunizations were fully covered by insurance, while women with commercial insurance may have a co-payment (and women self-paying have to cover the entire cost). However, insured mothers may be more likely to seek care in a private physician's office, of which there were no records in this study. Therefore, it is possible that insured mothers are just as likely, or even more likely, than women with government insurance to receive these vaccines.

Other disparities have been shown to affect vaccination rates, and therefore incidence of disease. In a recent study, Broutin, Viboud, Grenfell, Miller, and Rohani (2010) showed that periodicity in pertussis epidemics was a function of birth rate: the higher the birth rate, the shorter the periodicity. Additionally, it is known that increased fertility is associated with poverty, high child mortality, low social status of women, and female illiteracy (Lindstrand et al., 2006). Children below the poverty line are less likely to be vaccinated, and mothers with <12 years of education are less likely to vaccinate their children (Zhao & Luman, 2010). While these disparities were studied in the context of childhood vaccination, they may also affect maternal vaccine uptake.

For both Tdap and FLUV, the percentage of vaccine uptake increased each year, by 77% with Tdap and by 100% with FLUV. This is in accordance with national trends. As Tdap vaccine safety is being studied in pregnant women, over time providers and patients should be more likely to utilize the vaccine. In addition, as there is a national pertussis epidemic on-going in the United States, providers in all areas of health care are looking for ways to decrease the disease burden; therefore, they may be more likely to prescribe the vaccine to pregnant mothers in 2011 compared to 2009. In terms of the influenza vaccine, rates increased tremendously, to nearly 50% of mothers vaccinated, during the H1N1 epidemic. Rates also increased in this study, and 2011 data suggests that the trends are continuing. This could be related to increased media exposure of the importance of the influenza vaccine, improved patient and provider education, and increased availability of the vaccine.

Barriers to Vaccination

Despite ACIP recommendations to vaccinate all postpartum women and close contacts against pertussis, some providers have been reluctant to adopt these standards, pushing the responsibility off to others in the medical field. A 2006 study by Clark, Adolphe, Davis, Cowan, and Kretsinger found that only 78% of physicians would recommend Tdap for women during the postpartum stay even with national recommendations. Barriers to implementation of vaccination in obstetrics-gynecology, with FLUV, Tdap, and others, include time constraints for counseling, lack of adequate knowledge regarding immunizations, financial burdens in maintaining stock of vaccines, and unknown immunization status of the woman (Clark, Adolphe, Davis, Cowan, & Kretsinger, 2006; Power et al., 2009; Ross et al., 2009; Tan, Bhattacharya, & Gerbie, 2011). Hospital records are often inadequate to provide immunization data, and many women do not know their immunization status. In a study of primary care providers, only 53% of providers reported having vaccination records on greater than 50% their patients (Tan et al., 2011). One study found that a majority (74%) of obstetricians felt that not knowing the date of the patient’s last Td booster was a barrier to Tdap vaccination. In the same study, 46% of obstetricians felt that patient resistance to vaccination was a barrier to receiving Tdap (Clark et al., 2006). Not only do obstetricians identify barriers to influenza vaccination in pregnant mothers, but also other health care works such as nurses, medical assistants, receptionists and administrators are hesitant to encourage influenza vaccination. In a 2009 study (Broughton, Beigi, Switzer, Raker, & Anderson), 31% of health care workers did not believe that vaccines were a safe and effective way to prevent disease; only 56.6% believed that pregnant women are at increased risk of disease from influenza infections; and, only 65% would recommend the influenza vaccine to pregnant mothers if indicated.

Overall, lack of near-universal vaccination despite national recommendations can be explained by multiple barriers in both medical care and socioeconomics. While specific barriers were not directly assessed in this research study, extrapolations from the data can be made as to why vaccination rates remain low. To begin, it is likely that some obstetricians/gynecologists are not recommending the influenza and Tdap vaccines for numerous reasons (financial constraints, lack of knowledge, lack of self-efficacy, lack of time, etc). In addition, as shown by Broughton et al. (2009), other health care providers are also wary of recommending vaccines during pregnancy. Finally, mothers are wary of accepting vaccines during pregnancy, often due to concerns about safety and efficacy of the vaccine. All of these barriers can be improved with better communication and education amongst healthcare providers and patients.

Implications for Public Health Practice

Social factors such as the failure to take up vaccination services even when available, ethnic and migrant status, and poorly trained health workers all affect vaccination uptake and influence whether mothers will be vaccinated (Zhao & Luman, 2010; Lindstrand et al., 2006).

These concepts contrast with the theory that vaccination is a “default” behavior, driven by demand and independent of social factors (Leach & Fairhead, 2007). To increase uptake of vaccines, public health and medical providers must address these supply-side factors. More emphasis is needed on education for patients, including the health illiterate and immigrant populations; on improving access for lower socioeconomic status patients; and, on improving training of healthcare workers.

This data analysis at MVH shows that medical providers can do a better job to vaccinate mothers and other caregivers in order to protect infants. Therefore, the next steps are to design an intervention that will target women- those who have already given birth, those who are pregnant, and those of childbearing age. One way to target this group is through local public health campaigns. These campaigns could include advertising at public events, radio or television ads, and other marketing strategies. Other interventions should come from the medical side- obstetricians might create interventions such as educational brochures or develop one-on-one educational sessions with trained healthcare workers to encourage women to accept the vaccines. Primary care physicians should also improve education and awareness of the benefits of vaccination during pregnancy. In addition, pediatricians can target mothers and other caregivers, both in clinics and in hospital settings, to get vaccinated. Pediatricians can educate mothers that caring for their own health, which includes vaccination, can lead to a healthier life for their children. Finally, standing protocols in birthing centers and even emergency departments may be an efficient intervention to increase vaccination rates, as has been shown in a hospital system in Chicago (Tan & Gerbie, 2010).

Maternal vaccination within the MVH population is low, in terms of both influenza and Tdap vaccines. However, as shown in the literature, other caregivers are often responsible for disease transmission to infants (de Greeff et al., 2010; Jardine et al., 2010; Bisgard et al., 2004). While it is commendable that the CDC and ACOG encourage vaccination of mothers in order to protect infants, these and other medical bodies involved in public health should encourage fathers, grandparents, siblings, and other caregivers to be vaccinated, as they are often responsible for spreading the disease. By fully cocooning the infant, disease transmission can be halted, leading to decreased infections, hospitalizations, and deaths. In order to improve cocooning for influenza, more education is needed for parents and caregivers (Grizas, Camenga, & Vazquez, 2012). In addition, for cocooning to be effective, immunization of all close contacts must take place at least four weeks prior to delivery so that a full immune response can occur. However, more research is needed in this area to determine if the strategy is efficient and cost-effective.

To address waning immunity as seen with both Tdap and FLUV, some proposed solutions are to create more antigenic vaccines, promote vaccination among patients and caregivers (FLUV and Tdap), and improve health infrastructure to eliminate access problems. One of the current challenges in controlling pertussis infections is the waning immunity that occurs with both natural infection and vaccination. The newer Tdap vaccine should prevent waning immunity and disease transmission to susceptible populations by increasing the proportion of immune individuals, but it will only be successful if it is promoted by the medical and public health communities and accepted by patients. Since access to health care is often a greater barrier for adults than for children, FLUV and Tdap immunization coverage of mothers and caregivers prior to pregnancy will likely be low until health infrastructure changes. One innovative prevention tactic that could improve vaccination would be to implement standing order protocols at primary care centers. These protocols would encourage vaccination of all women of childbearing age with both FLUV and Tdap; they would also promote vaccination of fathers, grandparents, and other caregivers. By encouraging vaccination of women before they become pregnant, one of the greatest barriers (concern over vaccine safety during pregnancy) can be circumvented.

Limitations and Impact on Results

One of the greatest limitations of this analysis is that the dataset was incomplete. While the dataset was large, a positive vaccination status was only identified if a woman received the vaccine within the Miami Valley Hospital system. Therefore, if a woman were vaccinated within a different hospital system, at a private physician's office, or at a local drugstore, the vaccination data would be missing from this dataset. The rates of vaccination coverage in this study are an underrepresentation of the true percentage. However, as the dataset was constant from year to year, the upward trends in vaccination for both FLUV and Tdap can be assumed to be generalizable to the local population. A second limitation is that this analysis is a retrospective review, rather than a stronger prospective cohort study. A third limitation is that there is no data for why a women did not receive a vaccine- whether it had not been offered, whether the woman had previously been vaccinated, or whether the woman declined for personal or religious reasons. Therefore, analysis of the barriers to vaccination was limited.

Conclusions

Multiple medical organizations recommend vaccination with FLUV and Tdap for pregnant and postpartum mothers. In the Miami Valley Hospital community, immunization with FLUV is less than 50%, and immunization with Tdap is approximately 50%. In addition, vaccination with both FLUV and Tdap is occurring late, either in the third trimester for FLUV or the postpartum period for Tdap. While receipt of the vaccine is important and applauded, disease prevention might be more effective if the vaccines are given prior to pregnancy or earlier during pregnancy. This may be achieved by improving education of healthcare providers (both physicians and other caregivers) and by improving patient education. In addition, improved health infrastructure can make immunization more accessible and cost-effective, leading to increased vaccination rates. Finally, the study shows that older women, white women, and women with commercial insurance or self-payment are less likely to receive vaccines during pregnancy or postpartum. These populations should be targeted specifically in public health interventions to improve immunization rates. Promisingly, trends from 2009-2011 show that Tdap and FLUV vaccination rates are increasing. Additional interventions by medical professionals, local public health districts, policymakers, and national campaigns may lead to improved vaccination rates, thereby decreasing morbidity and mortality for infants.

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Appendices

Appendix 1. Tier 1 Core Public Health Competencies Met

Domain #1: Analytic/Assessment
Describe the characteristics of a population-based health problem (e.g., equity, social determinants, environment)
Use variables that measure public health conditions
Use methods and instruments for collecting valid and reliable quantitative and qualitative data
Identify sources of public health data and information
Recognize the integrity and comparability of data
Identify gaps in data sources
Adhere to ethical principles in the collection, maintenance, use, and dissemination of data and information
Describe the public health applications of quantitative and qualitative data
Collect quantitative and qualitative community data (e.g., risks and benefits to the community, health and resource needs)
Use information technology to collect, store, and retrieve data
Describe how data are used to address scientific, political, ethical, and social public health issues
Domain #2: Policy Development and Program Planning
Gather information relevant to specific public health policy issues
Describe how policy options can influence public health programs
Demonstrate the use of public health informatics practices and procedures (e.g., use of information systems infrastructure to improve health outcomes)
Domain #3: Communication
Participate in the development of demographic, statistical, programmatic and scientific presentations
Domain #4: Cultural Competency
Recognize the role of cultural, social, and behavioral factors in the accessibility, availability, acceptability and delivery of public health services
Domain #5: Community Dimensions of Practice
Recognize community linkages and relationships among multiple factors (or determinants) affecting health (e.g., The Socio-Ecological Model)
Identify stakeholders
Domain #6:Public Health Sciences
Describe the scientific foundation of the field of public health
Relate public health science skills to the Core Public Health Functions and Ten Essential Services of Public Health
Identify the basic public health sciences (including, but not limited to biostatistics, epidemiology, environmental health sciences, health services administration, and social and behavioral health sciences)
Describe the scientific evidence related to a public health issue, concern, or, intervention
Retrieve scientific evidence from a variety of text and electronic sources
Discuss the limitations of research findings (e.g., limitations of data sources, importance of observations and interrelationships)
Describe the laws, regulations, policies and procedures for the ethical conduct of research (e.g., patient confidentiality, human subject processes)
Domain #7: Financial Planning and Management – N/A
Domain #8: Leadership and Systems Thinking
Incorporate ethical standards of practice as the basis of all interactions with organizations, communities, and individuals
Identify internal and external problems that may affect the delivery of Essential Public Health Services
Use individual, team and organizational learning opportunities for personal and professional development

Appendix 2. Data Collection Tool

Data Collection Instrument	
	A password protected Excel spreadsheet will be used to store the data.
	The following parameters will be collected from each chart review:
1	Medical Record Number (will be de-identified)
2	Delivery Time and Date
3	Mother Birth Date
4	County of Residence
5	Zip code
6	Payer Status (Medicaid, private, military, etc.)
7	Race
8	Ethnicity
9	Received Tdap immunization
10	If received, date of immunization
11	Received Influenza immunization
12	If received, date of immunization

Appendix 3. IRB Approval Letter

Miami Valley Hospital
Premier Health Partners

One Wyoming St.
Dayton, Ohio 45409
(937) 208-8000
www.mvh.org

Clinical Research Center
Institutional Review Board
937-208-4469
Email: slklinger@mvh.org

October 04, 2011

Sherman Alter, MD
Children's Medical Center
Children's Infectious Disease, Dept Pediatrics
One Children's Plaza
Dayton OH 45404-1815

Dear Dr. Alter:

MVH Study # 11-0039

Protocol Title: Analysis of Pertussis Immunization Status of Postpartum Women in Dayton, Ohio

This letter is to acknowledge that the Institutional Review Board of Miami Valley Hospital is in receipt of the information identified below and has been reviewed and approved by the expedited method.

Our Internal #: 11125
Type of Change: Amendment
Expedited: Yes
Renewal Date: 7/20/2012
Approval Date: 10/4/2011
Date Received: 9/13/2011
On Meeting Date: 10/19/2011
Description: Amendment to include data for years 2009 and 2010. PI requested the addition of data for influenza vaccine.

Sincerely,

PhD DABCC CIP Vice Chair

H. Stanley Jenkins, MD
Chair, Institutional Review Board

Appendix 4. IRB Renewal Letter

WRIGHT STATE
UNIVERSITY

Office of Research and Sponsored Programs
201J University Hall
3640 Col. Glenn Hwy.
Dayton, OH 45435-0001
(937) 775-2425
(937) 775-3781 (FAX)
e-mail: rsp@wright.edu

DATE: June 13, 2012

TO: Sherman Alter, M.D., Faculty
Children's Infectious Diseases

FROM: B. Laurel Elder, Ph.D.
Chair, WSU-IRB

SUBJECT: SC# 4824
'Analysis of Pertussis Immunization Status of Postpartum Women in Dayton, OH'

Your study/amendment/continuing review referenced above has been recommended for approval. If this is a VA proposal, you must still receive a letter of approval from the Research and Development Committee prior to beginning the research project.

If this approval is for a new or continuing protocol, please take note of the expiration date on the Action Form to see when this approval will terminate. (Approval of amendments does not affect the current approval period.) You will be reminded prior to this date of the need to submit a progress report and the procedure for requesting approval of a further continuation of this protocol. Also note that any change in the protocol must be approved by the IRB; otherwise approval is terminated.

This action will be referred to the full Institutional Review Board for ratification at its next scheduled meeting. If you have any questions or require additional information, please call Jodi Blacklidge, Program Coordinator at 775-3974.

Thank you!

Enclosure