THE STRATA STUDY: STRUCTURAL ANTECEDENTS OF TDAP ADMINISTRATION IN OBSTETRICAL PRACTICES IN THE MIDWESTERN UNITED STATES

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by
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ABSTRACT

Every year in the United States, young infants die from pertussis. The incidence of pertussis among infants exceeds that of all other age groups. Protection is only available if the mother receives the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine during pregnancy, providing passive immunity to the infant. Infants with pertussis whose mothers received Tdap during pregnancy have a significantly lower risk of hospitalization, intubation, and death. Despite the evidence of their effectiveness, maternal Tdap vaccination rates remain suboptimal. Reasons for stagnant Tdap vaccination rates are complex and multi-factorial. Evidence suggests that a recommendation from a provider and availability of the vaccine are the strongest indicators of vaccine receipt among pregnant women. However, not all obstetrical providers offer the Tdap vaccine on site.

The structure and processes of vaccine programs within obstetrical practices in the U.S. is unknown, and this lack of understanding limits our ability to improve outcomes for young infants. The purpose of this STRATA (Structural Antecedents of Tdap Administration) study was to understand the existing structure of vaccine programs in

obstetrical practices through the discovery of structural antecedents and processes that facilitate onsite Tdap administration. Framed within Donabedian's Structure-Process-Outcome Quality of Care Model, a cross-sectional survey was conducted among rural and urban/suburban obstetrical practices in the Midwestern U.S. Fifty obstetrical practices in four states participated. Ninety percent (n = 45) of practices provided Tdap on-site, and those that did not referred patients elsewhere for the vaccine, possibly indicating that more practices are following maternal vaccine recommendations than in the past. The results of this study suggest that several structural elements are antecedents to on-site Tdap administration, including administering other types of vaccines on-site, having a vaccine storage unit on-site, having an advanced registered nurse practitioner or physician assistant deliver care, having standing orders for vaccine administration, and having staff trained to assess vaccine history. The limitations of the study include its small sample size, lack of diversity of the sample, and low response rate. Additional research with a larger sample of practices from other regions of the U.S. is recommended. Collection of scale/continuous level data in future research would allow for more robust statistical tests, such as factor and correlational analyses.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the College of Nursing & Health Studies, have examined a dissertation titled "The STRATA Study: Structural Antecedents of Tdap Administration in Obstetrical Practices in the Midwestern United States," presented by Kristen Leigh Myers, candidate for the Doctor of Philosophy degree, and hereby certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

INTRODUCTION

In 2012, the United States saw 2,269 cases of pertussis in infants less than three months of age; fifteen of those infants died, followed by eight more in 2013-2014 (Centers for Disease Control and Prevention [CDC], 2015a). In 2016, there were 1,253 cases of pertussis among infants less than six months of age, with 44% requiring hospitalization (CDC, 2017). Most pertussis-related deaths occur in infants less than three months of age, with a case fatality rate of 1.3%. Indeed, in 2010, during the California pertussis epidemic, all deaths and most hospitalizations occurred in infants younger than three months old (Winter et al., 2012). Many vulnerable newborns contract serious pertussis infections from their mothers or other family members (American College of Obstetricians and Gynecologists [ACOG], 2017). Young infants cannot receive the first dose of the pertussis vaccine until two months of age and must rely, instead, on passive immunity from the mother if she received the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine during pregnancy. The Advisory Committee for Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommends that pregnant women receive the Tdap vaccine at between 27 and 36 weeks of every pregnancy. The problem is that not all obstetrical (OB) providers offer the Tdap vaccine onsite, which is a known barrier to vaccine receipt among pregnant women. However, their reasons for not doing so are neither known nor understood.

Likewise, the structure and processes of onsite vaccine programs within OB practices in the U.S. are unknown.

A lack of understanding of the structure and processes of vaccine programs in this unique practice setting limits our ability to improve outcomes for infants. The purpose of the STRATA (Structural Antecedents of Tdap Administration) study was to understand the existing structure of vaccine programs in OB practices through the discovery of structural antecedents and processes that facilitate onsite Tdap administration.

Significance

In the United States, incidences of pertussis occur in a cyclical pattern, with peaks every three to five years (Winter, Glaser, Watt, & Harriman, 2014). In 2010, there was a significant resurgence of pertussis in the U.S. when California experienced an outbreak of more than 9,000 cases, resulting in ten infant deaths; the highest incidence rate was among infants less than two months of age (CDC, 2011). In 2011, in response to the ongoing outbreak, the CDC recommended implementation of a Tdap vaccination program for pregnant women who had not been vaccinated. The number of new pertussis cases, however, continued to rise nationwide. An epidemic was declared in 2012, with 2,520 cases reported in Washington by June 16 of that year (DeBolt et al., 2012). The highest rates of pertussis in that state were observed in infants less than one year of age (DeBolt et al., 2012). The year 2012 had the highest incidence of pertussis cases since the 1930s, with 48,277 cases and 20 pertussis-related deaths; a majority of those deaths occurred in infants less than three months of age (CDC, 2015a).

The incidence of pertussis among infants continues to exceed that of all other age groups. Protection is only available if the mother receives the Tdap vaccine between twenty-

seven and thirty-six weeks of the pregnancy, providing passive immunity to the infant. The passive immunity effect of maternal Tdap vaccination is very effective (Abu Raya et al., 2014; Hardy-Fairbanks et al., 2013; Healy et al., 2004; Healy, Rench, & Baker, 2013; Vilajeliu et al., 2015), as children whose mothers are vaccinated during pregnancy exhibit a 91% reduction in risk of pertussis during the first two months of life (Baxter, Bartlett, Fireman, Lewis, & Klein, 2017). Infants with pertussis whose mothers received Tdap during pregnancy have a significantly lower risk of hospitalization, intubation, and death (Winter, Nickell, Powell, & Harriman, 2017).

Despite the evidence of its effectiveness, maternal Tdap vaccination rates remain suboptimal, with only 14% of pregnant women receiving the Tdap vaccine between 2007 and 2013 (Housey et al., 2014; Koepke et al., 2015). However, analysis of the Vaccine Safety Datalink from 2007 to 2013 did show evidence of increasing Tdap vaccination rates each year; by 2013, 41.7% of pregnant women received the vaccine, primarily during the third trimester (Kharbanda et al., 2016). Vaccination rates among this population are slowly rising, but the rates are still inadequate. From October 2017 to January 2018, only 54.4% of pregnant women received Tdap during their pregnancies (Kahn et al., 2018). Ideally, a 100% vaccination rate should be achieved. Although some progress has been made toward this goal, optimal vaccination rates have yet to be achieved.

Background

Obstetrical practices in the U.S. have not been traditional sites for vaccine programs, yet a recommendation from a provider and vaccine availability are the strongest indicators of vaccine receipt among pregnant women (Ahluwalia et al., 2010; Shavell, Moniz, Gonik, & Beigi, 2012; Vitek et al., 2011). In the U.S., pregnant women are five times more likely to

receive a vaccine if the OB provider stocks and administers it on-site (National Vaccine Advisory Council [NVAC], 2015). However, not all OB practices provide Tdap on-site and some providers refer pregnant women elsewhere to receive it, either because the vaccine is not stocked or administered on-site, time is not permitted during appointments, or there is no staff available to administer it (Arao, Rosenberg, McWeeney, & Hedberg, 2015; Bonville, Cibula, Domachowske, & Suryadevara, 2015; Vijayan, Zangwill, Keneeth, Mink, & Yeh, 2013). These factors, coupled with maternal vaccine hesitancy, have contributed to stagnant Tdap vaccine rates among pregnant women (Chamberlain et al., 2015a; Dempsey et al., 2015; Healy, Rench, Montesinos, Ng, & Swaim, 2015; Kharbanda et al., 2011).

Vaccine Hesitancy

Vaccine hesitancy is defined as the intention to delay, defer, avoid, or omit routine vaccines that are routinely recommended by the Advisory Committee on Immunization Practices (ACIP, 2008; Domachowske & Suryadevara, 2013). The SAGE Working Group on Vaccine Hesitancy defined vaccine hesitancy as "the delay in acceptance or refusal of vaccination despite the availability of vaccination services. Vaccine hesitancy is complex, context specific, [and] varying across time, place, and vaccines. It is influenced by factors such as complacency, convenience, and confidence" (MacDonald, 2015, p. 4161). Vaccine hesitant individuals may reject some vaccines but accept others. Alternatively, they may delay receiving them. Choosing to receive a recommended vaccine is considered a personal health behavior. When that choice could also affect an unborn baby, the decision-making process becomes more complex.

Accepting a vaccine is the outcome of a complex decision making process in which multiple internal and external factors influence the decision maker (MacDonald, 2015).

These factors include existing knowledge, past experiences, family histories, feelings of control, risk perceptions, beliefs and attitudes, local vaccination cultures, media and Internet messages, pressure from providers, subjective norms, and the historical, political, and socio-cultural contexts in which a vaccination occurs (Dube et al., 2013; MacDonald, 2015). Many of these factors elicit negative feelings toward and provoke uncertainty or hesitancy regarding the acceptance of certain vaccines, including Tdap. Vaccine hesitancy can be problematic because the delay or omission of Tdap vaccination during pregnancy denies the unborn baby an adequate level of protection from disease during the first few months of life (until they are old enough to be eligible for the vaccine).

Safety of Tdap During Pregnancy

The documented low receipt of Tdap by pregnant women, coupled with the resurgence of pertussis and associated ongoing infant mortality, provide a significant argument in support of maternal Tdap vaccination. However, the safety of maternal Tdap vaccination has been questioned, and this has likely affected vaccine decision-making among pregnant women.

In a survey study, Moniz et al. (2013) found that 61% (n = 573) of pregnant women reported having a concern about the effects of vaccines on their pregnancy. Thirteen percent of respondents were concerned about the ingredients in vaccines and 20% were afraid of the possible side effects. Despite their reported concerns, 89% of these women said that they were willing to accept a vaccine during pregnancy if their obstetricians recommended one (Moniz et al., 2013). These results raise the question of why, if pregnant women stated a willingness to accept the Tdap vaccine with a provider's recommendation, their receipt of the vaccine is still so low. A number of non-safety related barriers to maternal Tdap vaccination

have been identified in the literature and are discussed later in the literature review of this dissertation.

Contrary to patient concerns, Tdap has been deemed safe for administration during pregnancy (Sawyer, Liang, Messonnier, & Clark, 2013) and is supported by the NVAC (2015) and the American College of Obstetricians and Gynecologists (ACOG, 2013). One randomized, double blind, placebo-controlled clinical trial (n = 42) showed no Tdap-associated serious adverse events in pregnant women, in postpartum women, or in their infants (Munoz et al., 2014). In a case-control study (n = 138) conducted to compare pregnancy and birth outcomes in infants born to mothers who either did or did not receive the Tdap vaccine during pregnancy, Shakib et al. (2013) found that the incidence of spontaneous abortion was no greater in the Tdap cases than in a control group; there were also no significant differences in preterm delivery, gestational age, or birth weight between the groups. The study showed that there was no increase in adverse outcomes in infants born to women receiving Tdap compared to those who did not. Finally, a more recent case-control study (n = 413,034) using data from the Vaccine Safety Datalink from 2004 to 2014 showed no association between maternal vaccination and risk of infant hospitalization or death during the first six months of life (Sukumaran et al., 2018).

Final Recommendation

The ACOG (2013; 2014) and the CDC (2011) both emphasize the importance of incorporating vaccinations, especially Tdap, into routine practice. Since this emphasis is only a recommendation, not a mandate, OB practices across the U.S. are now challenged with the choice of whether or not to obtain the resources they need to implement and sustain on-site vaccine programs.

An integrative review of the literature reveals several gaps in the existing literature on Tdap vaccinations (Myers, 2016). Patient-focused research has been abundant and adequately supported by theory, although the selection of theories overall between studies was somewhat limited. Provider-focused research, by contrast, is relatively sparse and not supported by theory. The largest gap in knowledge is at the organizational and health system level. Examination of the logistical and structural barriers to vaccine programs in OB practices appeared to be absent from the literature, and no research related to the structural antecedents of Tdap vaccine programs has been conducted. Providers in only a few states in the U.S. have been directly surveyed regarding practice site logistics supporting, and available resources for, on-site vaccine programs; these studies were limited to single geographical locations and small sample sizes (Arao et al., 2015; Bonville et al., 2015; Lu et al., 2012; Vijayan et al., 2013), did not directly assess the structure of vaccine support, and were not supported by theory (Myers, 2016).

Specific Aims and Research Questions

Questions remain about the relationship between the structural characteristics of OB practice settings and the on-site administration of Tdap. Hence, this STRATA study examined structural antecedents to on-site Tdap administration in OB practices. The following research questions were addressed:

1. How many OB practices administer on-site Tdap vaccines?
2. What is the structure and process of vaccine programs in OB practices?
3. What structural factors are antecedents to on-site Tdap administration?

The study aimed to support the Healthy People 2020 goal of reducing the cases of pertussis among children under one year of age by providing a better understanding of which structural

changes and resources are still needed for OB practices to be able to administer Tdap vaccines on-site. The results of this study may serve as a stepping-stone for future research on the structure and processes of vaccine programs that are unique to OB practices. Nurses and other health care leaders can use the information from this study to advocate for OB practices as they seek administrative support for vaccine program resources.

CHAPTER 2

LITERATURE REVIEW

Chapter 2 represents a published integrative review titled *Predictors of Maternal Vaccination in the United States: An Integrative Review of Literature* (Myers, 2016). The reference list from this integrative review is incorporated into the references for the dissertation as a whole.

Abstract

Introduction

The purpose of this literature review was to identify, analyze, and synthesize existing research related to patient and provider predictors of maternal vaccination in the United States, strategies used to increase maternal vaccination rates, and major theoretical frameworks used to guide maternal vaccination research.

Methods

A search for evidence was conducted in CINAHL, PubMed, PsychINFO, Cochrane Systematic Reviews, and Google Scholar. Twenty-two articles—five randomized control trials, one randomized trial, one mixed methods study, twelve observational cohort studies, and three qualitative studies—were identified as providing the best evidence for inclusion in this review.

Results

Patient-focused predictors of maternal vaccination included provider recommendation; knowledge, attitudes, and beliefs; cues to action; and race and ethnicity. Provider-focused predictors included knowledge, attitudes, and beliefs; multi-component intervention packages; standing order protocols; and practice site logistics. The major theoretical frameworks that emerged from the literature review were the Health Belief Model, Theory of Reasoned Action/Theory of Planned Behavior, and Message Framing/Prospect Theory. Provider recommendation was the single most important predictor of vaccine receipt among pregnant women.

Conclusions

An abundance of theoretically supported, patient-focused research was found in the literature. A minimal number of U.S. based, provider focused research was found, and none used a theoretical framework. Therefore, additional research into the logistical barriers to maternal vaccination programs at obstetrical practice sites in other geographical locations within the U.S. is warranted. Future provider-focused research needs to be grounded in theory. The field of implementation science may offer the theoretical guidance necessary to help providers better understand problems in obstetrical practice workflows related to the streamlining of vaccinations.

Predictors of Maternal Vaccination in the United States: An Integrative Review of Literature

Every year in the United States, over four million women give birth (CDC, 2015b). In 2012, the CDC reported 41,880 cases of pertussis, with eighteen of the cases resulting in death; fourteen of those deaths were of infants younger than twelve months of age (Sawyer,

Liang, Messonnier, & Clark, 2013). In the same period, during the 2012-2013 influenza season, eighteen infants younger than six months of age died from influenza (NVAC, 2015). Although the number of infant deaths due to pertussis and influenza is small compared to the total number of births each year, every such death is a tragedy because they result from vaccine-preventable diseases. Infants cannot receive the first pertussis vaccine until two months of age (CDC, 2000) or the influenza vaccine until six months of age (CDC, 2015c). For this reason, maternal vaccination is necessary to providing passive immunity to the infant for protection from these diseases during the first few months of life (Abu Raya et al., 2014; Hardy-Fairbanks et al., 2013; Healy et al., 2004; Healy et al., 2013; Vilajeliu et al., 2015).

Despite the evidence of their effectiveness, maternal vaccination rates remain suboptimal in the U.S., with only 50% of pregnant women receiving the influenza vaccine during the 2014-2015 influenza season (Ding et al., 2015) and only 14% receiving the Tdap vaccine from 2007 to 2013 (Housey et al., 2014; Koepke et al., 2015). Kharbanda et al. (2016) acknowledged these low Tdap vaccination rates but, drawing on an analysis of Vaccine Safety Datalink (VSD) data from 2007 to 2013, they were able to demonstrate evidence of increasing rates: By 2013, 41.7% of pregnant women (n = 438,487) received the vaccine, primarily during the third trimester. Although some progress has been made, optimal vaccination rates have yet to be achieved, and low maternal Tdap vaccination presents a significant risk to the health and well being of pregnant women and young infants.

This literature review will present a synthesis of evidence related to patient, provider, and health system predictors of maternal vaccinations in the U.S and will also identify the theoretical frameworks that have been used to describe, explain, and predict vaccine

decision-making behaviors among pregnant women and providers. The research questions that guided this literature review were the following: In the U.S.,

1. What are the predictors of maternal vaccination?
2. What strategies have been used to increase maternal vaccine acceptance?
3. What theoretical frameworks have been used to guide maternal vaccine-related research?

The results of this literature review support an argument for the need to use an alternative theoretical approach to address a major gap in provider- and health system-focused research.

Background

The CDC's Advisory Committee on Immunization Practices (ACIP, 2008), supported by NVAC and the American College of Obstetricians and Gynecologists (ACOG, 2014), recommends that all women who are or who will be pregnant during the influenza season receive one dose of the influenza vaccine, when available, during every pregnancy (ACOG, 2014; ACIP, 2008; NVAC, 2015). Likewise, it has been recommended that pregnant women receive one dose of Tdap between twenty-seven and thirty-six weeks for every pregnancy (ACOG, 2013; NVAC, 2015; Sawyer & Long, 2015).

The integration of vaccinations into obstetrical practice has not always been customary, but this has changed in recent years as the health care system has begun to emphasize disease prevention and health promotion. In 2013, ACOG called for obstetrical providers to embrace vaccinations as a routine part of their practice. ACOG (2013) further recommended that providers include screening, education, and vaccinations as part of women's annual health assessments and provide both the influenza and Tdap vaccines during pregnancy. Unfortunately, not all providers agree with or follow these recommendations, as

evidenced by one study in which only 60.3% of obstetrical providers reported always discussing vaccines with pregnant patients (Healy et al., 2015b). Further complicating this practice is the reality that even when vaccines are offered to pregnant patients, not all of these patients will readily accept them. The difference between vaccine acceptance and vaccine receipt should be noted here: Vaccine acceptance refers to an intention to receive the vaccine and not the actual administration (receipt) of the vaccine itself.

Methods

A literature search was conducted in CINAHL, PubMed, PsychINFO, Cochrane Systematic Reviews, and Google Scholar (Figure 2.1).

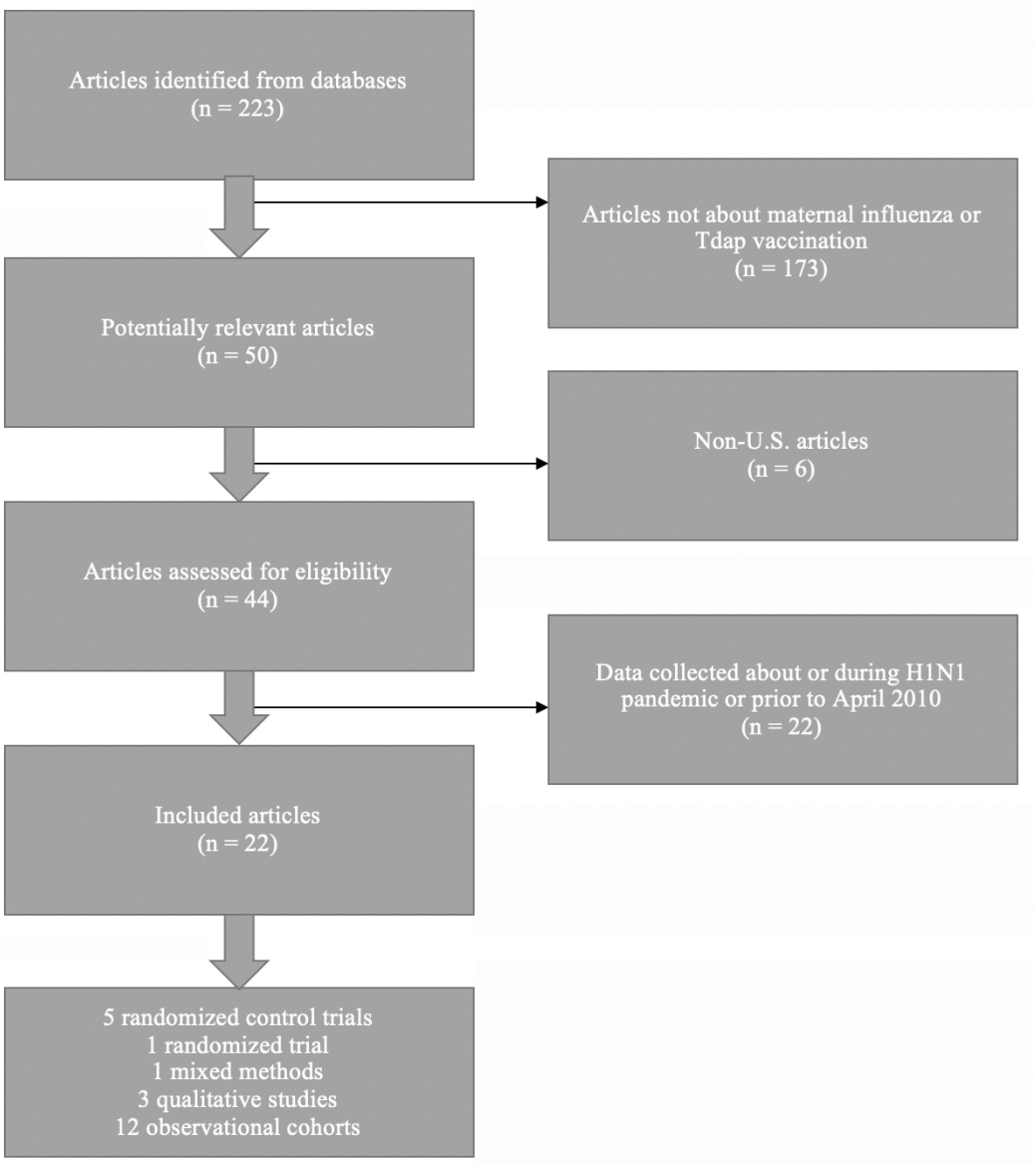

Figure 2.1. Article search and selection process.

The limiters set included *English*, *humans*, *female*, and *research studies*. Major keywords used to search the databases included *pregnant women*, *vaccine receipt*, *pertussis*, *Tdap*, *influenza*, *maternal vaccination*, *predictors*, and *barriers*. The search and selection process required consideration of two potential confounding factors: (a) the H1N1 influenza

pandemic during the 2009-2010 influenza season, during which a high proportion of pregnant women were either hospitalized or died from the infection; and (b) the resurgence of pertussis outbreaks in the U.S. in 2010. When selecting articles for this review, it was hypothesized that these events significantly influenced the attitudes and beliefs of pregnant women, providers, and society as a whole regarding vaccines; therefore, article selection was limited to research conducted from April 2010 to the present. Studies that were conducted outside of the U.S. were excluded because the purpose of this literature review was to identify potential barriers and facilitators to maternal vaccination within the unique health care system of the U.S.

Based on these criteria, a total of 22 studies—five randomized control trials, one cluster randomized trial, one mixed methods study, 12 observational studies, and three qualitative studies—were identified as providing the best evidence for this review. Information about study design, vaccine focus, sample and setting, theoretical framework, and variables of interest were extracted from each article and organized into a matrix table (Table 2.1).

Table 2.1

Summary of Selected Articles Included in Integrative Review of Literature

Author/Year	**Design**	**Vaccine**	**Sample/Setting**	**Variables of Interest**
Arao et al. (2015)	Descriptive, cross-sectional survey	Influenza	Random sample of 102 OBs and 85 family practice physicians in Oregon	Vaccine recommendation by physician specialty, KAB of providers
Beel et al. (2013)	Descriptive, cross-sectional survey	Both	Random convenience sample of 511 postpartum women in Houston, TX; predominately Hispanic and underinsured	KAB of patients
Bonville et al. (2015)	Descriptive, cross-sectional survey	Both	Convenience sample of 133 OB providers in New York; majority private practice	KAB of providers
Chamberlain et al. (2015a)	Descriptive, cross-sectional survey	Both	325 unvaccinated pregnant women from Emory MOMVAX study	KAB of patients
Chamberlain et al. (2015b)	Cluster randomized trial	Both	325 unvaccinated pregnant women from 10 obstetrical practices in Georgia	Practice, provider, and patient-focused vaccine promotion package
Dempsey et al. (2015)	Descriptive, cross-sectional survey	Tdap	Convenience sample of 316 pregnant women from 3 clinics in Colorado; 26% Spanish-speaking and >65% of patient served by the clinics were Hispanic	KAB of patients
Frew et al. (2014a)	Randomized control trial	Influenza	Venue-based sample of 272 pregnant women of racial and ethnic minority in Atlanta, GA; majority African-American	Patient immunization history, gain-or loss-framed message exposure, sociodemographics
Frew et al. (2014b)	Mixed methods	Influenza	Venue-based sample of 251 pregnant women of racial and ethnic minority in Atlanta, GA	Gain- or loss-framed message exposure, multilevel social and community factors
Gorman et al. (2012)	Descriptive, cross-sectional survey	Influenza	199 pregnant women from VAMPSS parent study; majority Caucasian non-Hispanic	HBM constructs as predictors of vaccination, KAB of patients

Author/Year	Design	Vaccine	Sample/Setting	Variables of Interest
Goldfarb et al. (2014)	Descriptive, retrospective EMR review	Tdap	1,467 postpartum women in one university center in Massachusetts	Predictors and barriers to vaccination
Healy et al. (2015a)	Descriptive, prospective, cross-sectional survey	Both	Convenience sample of 796 pregnant women and 63 providers from large metro hospital in Houston, TX	Patient and provider KAB
Healy et al. (2015b)	Descriptive, retrospective EMR review	Tdap	6,577 postpartum women from one children's and women's hospital in Houston, TX	Pre/post vaccine receipt, practice and provider-focused multi-component vaccine promotion interventions
Henninger et al. (2015)	Descriptive, cross-sectional survey	Influenza	1,105 pregnant women enrolled in the Pregnancy and Influenza Project (PIP) through Kaiser Permanente Northwest and Kaiser Permanente Northern California.	KAB of patients
Henninger et al. (2013)	Descriptive, prospective, cross-sectional survey	Influenza	552 pregnant women from a larger study with Kaiser Permanente Northwest and Marshfield Clinic.	KAB of patients
Kharbanda et al. (2011)	Qualitative, focus groups	Influenza	Convenience sample of 40 pregnant women from two community health centers in New York City	KAB of patients, interest in targeted educational text messaging
Marsh et al. (2014)	Qualitative, semi-structured interviews	Both	21 pregnant African-American women from urban OB/GYN clinics in Atlanta, GA	KAB of patients
Meharry et al. (2013)	Qualitative, semi-structured interviews	Influenza	Purposive sample of 60 third-trimester and post-partum women from two postpartum units and adjoining hospital-based prenatal clinics in Connecticut	KAB of patients
Meharry et al. (2014)	Randomized control trial	Influenza	135 pregnant women from three prenatal clinics and private OB/GYN practices in Connecticut	Teaching pamphlet, versus teaching pamphlet with benefit statement, versus usual care/no direct information from the study
Moniz et al. (2013)	Randomized control trial	Influenza	204 pregnant women from an academic center's outpatient prenatal clinic in Pennsylvania	Weekly educational text messages regarding general preventive health in pregnancy, versus the same weekly messages plus the importance of influenza vaccination during pregnancy

Author/Year	Design	Vaccine	Sample/Setting	Variables of Interest
Payakachat et al. (2016)	Randomized trial	Tdap	291 women from two women's clinics in an academic medical center in Arkansas	Standard CDC VIS statement, versus modified VIS statement
Stockwell et al. (2014)	Randomized control trial	Influenza	1,153 pregnant women from five community-based clinics affiliated with an academic medical center in New York City	Automated educational text messages, versus usual care
Zakrzewski et al. (2014)	Descriptive, retrospective EMR review	Influenza	2,883 pregnant women from three academic centers' clinics and one private community practice in Los Angeles, CA	Nurse-driven vaccine protocol, versus physician-driven vaccine protocol

Results

Theoretical Frameworks

Twelve studies, all of which were patient-focused, used a theoretical framework (Table 2.2). Three prominent theories emerged from these studies: Health Belief Model (HBM), Theory of Reasoned Action/Theory of Planned Behavior (TRA/TPB), and Message Framing/Prospect Theory (MFPT).

Table 2.2

Theoretical Frameworks and Constructs of Selected Articles

	HBM					Shared ← →	TRA/TPB		MFPT	
Article	**Benefits**	**Barriers**	**Susceptible**	**Severity**	**Cues to Action**	**Self-Efficacy**	**Intention**	**Social Norms**	**Gain-framed**	**Loss-framed**
Chamberlain et al. 2015a	X			X			X			
Dempsey et al. 2015	X	X	X	X		X		X		
Frew et al. 2014a			X				X	X	X	X
Frew et al. 2014b	X		X					X	X	X
Gorman et al. 2012	X	X	X	X	X			X		
Henninger et al. 2013	X	X	X	X	X					
Henninger et al. 2015	X	X	X	X	X					
Kharbanda et al. 2011	X	X			X					
Marsh et al. 2014	X		X	X				X	X	X
Meharry et al. 2013	X	X	X	X				X		
Meharry et al. 2014	X	X	X	X						
Payakachat et al. 2015	X	X	X	X		X	X	X		

Health Belief Model (HBM). The HBM attempts to explain and predict the health behaviors of individuals by focusing on their attitudes and beliefs about those behaviors (in this context, vaccination). HBM includes six constructs: perceived benefits, perceived barriers, perceived susceptibility, perceived severity, self-efficacy, and cues to action (Glanz, Rimer, & Viswanath, 2015). All twelve theoretically based studies used one or more of the HBM constructs.

Theory of Reasoned Action/Theory of Planned Behavior. The TRA/TPB aims to explain human behavior and decision-making, especially relationships between beliefs and behaviors (Payakachat, Hadden, & Ragland, 2015). A woman's beliefs about pertussis, influenza, and vaccination may influence her intention to accept a vaccine. TRA/TPB concepts were evident in eight of twelve theoretically based studies.

Message Framing/Prospect Theory. Gain-framed messages emphasize the desirable outcomes of engaging in a specific health behavior (i.e., vaccination), while loss-framed messages emphasize the undesirable consequences of failure to engage in a health behavior (O'Keefe & Nan, 2012). Prospect Theory examines individual decision-making under conditions of risk, positing that "people normally perceive outcomes as gains or losses rather than as final states of wealth or welfare" (Kahneman & Tversky, 1979). Message framing, when supported by Prospect Theory, suggests that gain-framed messages make individuals want to avoid risks while loss-framed messages make them want to take risks (Frew et al., 2014b; Glanz et al., 2015). However, when it comes to vaccinations, gain-framed and loss-framed messages do not significantly differ in terms of their persuasiveness (O'Keefe & Nan, 2012). MFPT constructs of gain-framed and loss-framed messages were used in three of the

twelve studies uncovered in this review, but they were always used in combination with one or more of the HBM or TRA/TPB concepts (Frew et al., 2014a, 2014b; Marsh et al., 2014).

This review of the theoretically based literature found no provider- or health system-focused studies supported by a theoretical framework. The absence of theoretically based studies examining provider and health system predictors of maternal vaccination demonstrates a significant gap in maternal vaccination research.

Patient-Focused Predictors of Vaccine Acceptance

Of the twenty-two studies selected for this review, sixteen were patient focused and three were both patient and provider/health system focused. Four major categories of predictors emerged: provider recommendation; patient knowledge, attitudes, and beliefs; cues to action; and race or ethnicity.

Provider recommendation. A common conclusion in the patient-focused studies was that the provider has the most influence on pregnant women's perceptions of maternal vaccinations (Meharry, Colson, Grizas, Stiller, & Vazquez, 2013). Vaccination is considered a social practice insofar as an individual's decision to not vaccinate has implications for others (Leask, Champman, Hawe, & Burgess, 2006). Providers, meanwhile, play a significant role in the social acceptance of vaccinations and in promoting vaccine acceptance among individuals. Pregnant women consider their healthcare providers the most important and trusted sources of information during pregnancy (Beel, Rench, Montesinos, Mayes, & Healy, 2013; Healy et al., 2015b; Kharbanda et al., 2011). In fact, pregnant women prefer to hear about the influenza vaccine from a provider more than from any other source (Marsh et al., 2014). A provider recommendation is strongly associated with antenatal receipt of both the influenza and the Tdap vaccines (Chamberlain et al., 2015b; Healy et al., 2015b). Moniz

et al. (2013) found that more than half of the two hundred and four pregnant women surveyed said that they would get or would consider getting the influenza vaccine if their provider recommended it. Mothers who receive a recommendation from a healthcare provider are more likely to accept vaccines (Beel et al., 2013; Frew et al., 2014; Gorman, Brewer, Wang, & Chambers, 2012; Healy et al., 2015b; Henninger et al., 2015). The strong association between a provider recommendation and vaccine acceptance indicates the need to examine maternal barriers to acceptance in order to identify and remove provider barriers to implementation.

Knowledge, attitudes, and beliefs (KAB). The KABs of pregnant women related to acceptance of influenza and Tdap vaccines during pregnancy are complex. Any element of KAB could serve as either a barrier or facilitator to vaccination. Receipt of vaccine information, whether that information is accurate or inaccurate, can alter vaccine KAB. Healy et al. (2015b) found that 87% of pregnant women who knew that they needed vaccines during pregnancy said that they got the information from their provider. Among the same women, although 26% had some concerns about receiving a vaccine during pregnancy, 82.8% said that they would get the vaccine if their provider recommended it (Healy et al., 2015b). Also influencing pregnant women's KAB are gain-framed (GF) and loss-framed (LF) messages from a variety of sources, including the media (Frew et al., 2014a, 2014b), social norms (Frew et al., 2014a; Marsh et al., 2014), and social networks/social media (Frew et al., 2014b; Marsh et al., 2014).

Further influencing maternal KAB are constructs of the HBM, which are important predictors of vaccination decisions (Gorman et al., 2012) and are useful for educating providers so that they better understand the predictors of vaccination for pregnant women

(Henninger et al., 2013). Perceptions of vaccine efficacy (perceived benefits) and perceived susceptibility to influenza or pertussis during pregnancy are significant factors in determining maternal intent to be vaccinated during pregnancy (Frew et al., 2014a). Furthermore, pregnant women are motivated to protect the health of their babies (Kharbanda et al., 2011). When pregnant women have higher perceptions of susceptibility to infection during pregnancy and believe that an infection could have severe consequences on their health and the health of their baby, they have heightened intent to receive a vaccine (Frew et al., 2014b). Chamberlain et al. (2015a) found that 73% of pregnant women surveyed believed that influenza infection was serious during pregnancy, 81% believed that getting pertussis during pregnancy was serious, and 87% and 92% believed that influenza and pertussis infection would be serious to their newborn. In another study, however, only 34% and 44% of women reported the intent to receive the influenza or Tdap vaccine, respectively, during a current pregnancy (Chamberlain et al., 2015a). The discrepancy between perceived susceptibility/perceived severity and intent to be vaccinated further adds to the challenge and complexity of our understanding of maternal vaccine decision-making.

Cues to action. A recommendation from a provider serves as an effective cue to action that motivates vaccine acceptance among pregnant women (Meharry, Cusson, Stiller, & Vazquez, 2014). The use of text messaging as a cue to action has also been explored in the literature. Text messaging is a culturally acceptable, fast, and confidential way to transmit vaccine information and reminders to pregnant women (Moniz et al., 2013). The authors of two different studies found that pregnant women liked such text messages, felt that they were beneficial, and wanted to continue receiving text messages about how to stay healthy during pregnancy, but text messaging did not significantly increase their receipt of the influenza

vaccine (Moniz et al., 2013; Stockwell et al., 2014). These findings related to the use of text messaging in obstetrical practice suggest that while text messages might increase patient satisfaction with care and promote healthy pregnancies, they are not an effective stand-alone strategy for increasing maternal vaccination rates.

Race and ethnicity. Four of the twenty-two studies selected for this review revealed a disparity in Tdap vaccinations among pregnant African-American women (Dempsey et al., 2015; Goldfarb, Little, Brown, & Riley, 2014; Healy et al., 2015a, 2015b), showing that African-American women were less likely than any other race to receive the Tdap vaccine during pregnancy. Goldfarb et al. (2014) also found that being African-American was a negative predictor of Tdap vaccine receipt: African-American women in their study were 60% less likely than all other races to receive the Tdap vaccine. Supporting these findings, Dempsey et al. (2015) found that Spanish-speaking women were more likely to have concerns about vaccine safety and efficacy than other races. These racial and ethnic disparities may show a need for understanding cultural differences in attitudes toward vaccination among pregnant women to develop and promote effective educational materials that will help to optimize vaccine receipt. These disparities may also indicate inequities in how providers offer vaccines to different patients based on demographics and biological characteristics.

Provider-Focused Predictors of Maternal Vaccination

Five studies selected for this review were provider-focused (Bonville et al., 2015; Chamberlain et al., 2015a; Healy et al., 2015a, 2015b; Zakrzewski et al., 2014). Four categories of provider-focused predictors of maternal vaccination were evident in the literature: provider KAB, multi-component intervention packages, standing order protocols,

and practice site logistics. Standing order protocols and practice site logistics could also fall under the category of "health system-focused predictors," which adds more complexity to maternal vaccination implementation.

Knowledge, attitudes, and beliefs. Like maternal KABs, provider KABs are important predictors of maternal vaccination. Few current U.S.-based studies exist that describe provider KAB and practices regarding the influenza and Tdap vaccinations. KAB may influence providers to recommend or offer vaccines to pregnant patients (Arao et al., 2015). Ninety-five percent of providers in one survey reported having no concerns about giving vaccines during pregnancy (Healy et al., 2015a). However, in another survey (Bonville et al., 2015), providers reported specific attitudes and beliefs as reasons for not providing these vaccines in their practice. Their reasons included vaccine safety concerns, discomfort with providing vaccine education to patients, lack of vaccine efficacy data, perceptions of low incidence of pertussis and influenza in the area, and anticipation that the Tdap vaccine, in particular, would be given postpartum in the hospital (Bonville et al., 2015).

For a recommendation to occur, provider KABs need to be amenable to maternal vaccination (Arao et al., 2015). If obstetrical providers are unable or unwilling to provide vaccines on-site, they may refer the patient elsewhere for vaccination. Forty percent of obstetrical providers in one study reported referring pregnant patients elsewhere for vaccination (Bonville et al., 2015). However, the problem with routinely referring patients elsewhere is that the patient may not always follow through with the referral, which may explain why there is a discrepancy between the higher percentage of providers who say they recommend the vaccines and the comparatively lower percentage of pregnant women reporting that they received the vaccines (Arao et al., 2015). For instance, Arao et al. (2015)

found that 89.2% of providers reported recommending the influenza vaccine to pregnant patients during the 2010-2011 influenza season, but the national maternal influenza vaccination average at that time was 51% (CDC, 2011).

Provider knowledge does not seem to be a barrier to maternal vaccination. Ninety-two percent of providers in one survey reported knowing the ACIP Tdap recommendations; however, only 80% reported recommending Tdap to all eligible patients and only 67% provided Tdap in their offices (Bonville et al., 2015). In the same survey, 100% of providers knew the ACIP influenza vaccine recommendations for pregnant women, but only 95% recommended the vaccine and only 85% administered the vaccine in their offices (Bonville et al., 2015). Due to limited available research on provider-focused barriers to maternal vaccination, the reasons for these discrepancies are not understood, but not offering vaccine administration in the office is a known barrier to vaccine receipt among pregnant women because it creates an added obstacle to vaccine delivery (Bonville et al., 2015). To bypass this barrier, organizational and health systems interventions—such as multi-component intervention packages, standing order protocols, and evaluation of practice site logistics—may be necessary.

Multi-component interventions. Three studies examined multi-component interventions (i.e., patient and provider education, vaccine champions, posters, EMR alerts), but the studies used different designs with different levels of evidence. One study was a cluster randomized trial (Chamberlain et al., 2015b). The other two studies were observational: Goldfarb et al. (2014) and Healy et al. (2015b) performed a retrospective analysis of the EMR records of post-partum women to observe the effects of several interventions that had already taken place within the practice setting.

Goldfarb et al. (2014) and Healy et al. (2015b) observed similar outcomes of the multi-component interventions. Goldfarb et al. noted that 81.6% of pregnant women had received the Tdap vaccine during a recent pregnancy, while Healy et al. only noted that 55.5% had. Healy et al.'s study revealed that the vaccination rate increased from 36% before the introduction of all the interventions to a sustained rate of over 61% seven months after implementation of the interventions. Although Goldfarb et al. revealed a relatively high vaccination rate (>80%), they did not determine a pre-intervention vaccination rate with which to compare the post-intervention rate; therefore, it is difficult to conclude what the true "gain" was from the interventions.

Given the observational nature of these studies, individual interventions could not be isolated to determine which were more or less effective. Confounding factors potentially influencing the observed increases in vaccination rate were (a) staff becoming more familiar with integrating vaccinations into routine practice as time passed, (b) the removal of provider barriers to vaccination via the standing orders and a hard stop in the EMR, and (c) providers being cued to offer the vaccination because of the presence of the interventions.

In a cluster randomized trial, Chamberlain et al. (2015b) compared the effects of a multi-component vaccine promotion package on vaccine receipt among pregnant women. Interventions were either practice focused, provider focused, or patient focused. The results of their study revealed that although antenatal vaccine receipt was slightly higher in the intervention group, the absolute differences in antenatal vaccine receipt between the groups were modest and non-significant (Chamberlain et al., 2015b). Of greatest significance, they found that provider recommendation was strongly associated with maternal vaccine receipt

While Goldfarb et al. (2014), Healy et al. (2015b), and Chamberlain et al. (2015b) all examined multi-component vaccination interventions, Chamberlain et al.'s study was a cluster randomized trial, which provides a higher level of evidence than retrospective observational studies. The differences in the findings of these studies may suggest that maternal vaccination is far more complex than we currently understand and that it likely needs to be approached from additional or alternative directions.

Health System-Focused Predictors of Maternal Vaccination

Standing order protocols. The multi-component interventions that Healy et al. (2015b) examined included a standing order protocol, and they found a positive correlation between the interventions and maternal vaccine receipt. Zakrzewski et al. (2014) examined standing order protocols for pregnant women by comparing a nurse-driven protocol to a physician-driven protocol for influenza vaccination. The nurse-driven protocol was associated with an increased offering of the influenza vaccine compared to the physician-driven protocol, but no significant change in the effective vaccination rate was observed. This finding suggests there are other possible barriers to maternal vaccination besides any staff in a particular practice setting offering the vaccine.

Practice site logistics. Only two studies selected for this review alluded to practice site logistics as significant barriers to maternal vaccination. Bonville et al. (2015) examined the vaccination attitudes and practices of obstetrical providers in New York. Of the one hundred and thirty-three obstetricians who returned their survey, twenty-five provided specific logistical reasons for not administering vaccines in their office. The most common reasons cited were cost, concerns about lack of reimbursement for administering vaccines, and lack of staff to administer the vaccines. Arao et al. (2015) found that obstetricians and

family practice physicians cited additional logistical barriers. Rural obstetrical practices were less likely to have the vaccines available in their offices (87.2%) compared to family practice clinics (98.5%). Rural obstetrical practices were also less likely than family practice clinics to have appropriate vaccine storage units available (Arao et al., 2015). Although the differences between the two practice settings were significant, the small sample size of these two studies limited the generalizability of their findings. Given the lack of available research on practice site logistical barriers to maternal vaccination, further investigation is necessary to determine whether these barriers are present in other obstetrical and family practice clinics in other geographical locations of the U.S.

Conclusion

This review revealed several gaps in the existing literature on maternal vaccination. An abundance of patient-focused evidence was found to describe, explain, and predict the vaccine decision-making behaviors of pregnant women. The patient-focused research appears to be adequately supported by theory, although the range of theories selected was somewhat limited. There is also a lack of current research examining the KABs of nurse midwives in the U.S. While the existing literature did include data on both obstetricians and family practice physicians, there was an absence of analysis of KABs and interventions specific to nurse midwives and women's health nurse practitioners. An understanding of cultural considerations related to vaccinations among specific cultural groups of pregnant women also appeared to be lacking in the literature. Finally, this review revealed a lack of theoretically based, provider- and health system-focused research related to maternal vaccination in the U.S. In particular, practice site logistics among providers for an in-house

maternal vaccination program emerged as a potentially significant barrier to vaccine implementation.

Implications

This review of the literature suggested that a vaccine recommendation from a provider was the strongest predictor of maternal vaccine acceptance. The review also revealed that providers claimed that they are (although perhaps not to the fullest extent possible) recommending the vaccines to pregnant women. However, for various logistical reasons, not all obstetrical providers reported being able to store and provide vaccines in their practices, and they resorted to referring patients elsewhere for vaccination. Still, the questions of why only half of the pregnant women in the U.S. are receiving the influenza and Tdap vaccines, why obstetrical providers are not able or willing to provide the vaccines in their offices, and whether removal of the logistical barriers to maternal vaccination would increase obstetrical provider integration of vaccinations into routine practice remains unanswered.

Recommendations for Future Research

Research examining health system barriers to maternal vaccination programs at obstetrical practice sites in other areas of the U.S. is warranted. Examining the best practice site logistics necessary for successful in-house vaccination programs (e.g., cost, vaccine storage, standing orders, time during consults, and vaccine administration processes) may be of particular interest. It would be useful to examine more locations in the U.S. to determine if these barriers exist on a larger scale. Examining the KAB and vaccine practices of nurse midwives and women's health nurse practitioners may also be of benefit, as it would expand our current understanding of the maternal vaccination phenomenon. The cultural implications

of maternal vaccine disparities among specific cultural groups of pregnant women could also be explored further. Overall, additional evidence related to health system barriers to maternal vaccination programs is needed to progress toward resolving disparities in maternal vaccine receipt.

Implementation science. Because evidence-based practice originates from theory, future research on practice site logistical barriers to maternal vaccination programs should be grounded in theory. The field of implementation science may offer the theoretical guidance needed for providers to better understand the problems in obstetrical practice workflows and the streamlining of vaccinations. Implementation science investigates and addresses major social, behavioral, economic, and management barriers to the effective implementation of new approaches to practice (National Institue of Health [NIH], n.d.).

Vaccination program implementation occurs at a broader health system level. Introducing a new vaccine or simply a new recommendation for a particular vaccine (i.e., influenza and Tdap for pregnant women) can have both positive and negative effects on the immunization system (Hyde et al., 2012). A comprehensive review of vaccine implementation literature by Hyde et al. (2012) found that the introduction of a new vaccine had mixed effects on existing immunization systems but that such an introduction often presented an opportunity to strengthen the system. Blending the premise of implementation science with current understandings of vaccine implementation in the U.S. may provide an understanding of how and why maternal vaccination programs become embedded in routine obstetrical practice and why some processes stick while others do not.

CHAPTER 3

THEORETICAL FRAMEWORK AND METHODOLOGY

Theory is practice: The relationship between theory and research is reciprocal and mutually beneficial (Polit & Beck, 2017; Shadish, Cook, & Campbell, 2002). Scientific theories have three main purposes: (a) to facilitate a description and understanding of a phenomenon being studied, (b) to explain and make sense out of what is being observed in a study, and (c) to predict future relationships between a given set of variables (Butts & Rich, 2015). As McEwen and Wills (2011) noted, "The purpose of research is to build knowledge in a discipline through the generation and/or testing of theory" (p. 452). To build this knowledge effectively, the research process should be placed within a theoretical context so that the theory guides the formation of the research questions and aids in the design, analysis, and interpretation of the study (McEwen & Wills, 2011). As noted in Chapter 2, there is a paucity of theoretically based research on maternal vaccinations. Little research has been completed to understand the structure, processes, and outcomes of Tdap vaccine programs in obstetrical practices, and little guidance exists for the application of these concepts in nursing practice.

Theoretical Framework

Translational science focuses on understanding the scientific and operational principles underlying each step of the translational process (NIH, n.d.). Stemming from this broad field is implementation science, which promotes the actual receipt of evidence into

routine clinical and organizational practice. Implementation science "seeks to understand the behavior of healthcare professionals and other stakeholders as a key variable in the sustainable receipt, adoption, and implementation of evidence-based interventions" (NIH, n.d.). A relatively new framework in the field of dissemination and implementation science is the Consolidated Framework for Implementation Research (CFIR). The CFIR framework aided in the development of the present STRATA study.

Consolidated Framework for Implementation Research

The CFIR (2009) was developed by researchers affiliated with the Veterans Affairs Diabetes Quality Enhancement Research Initiative (QUERI), which was part of a system-wide transformation of health care for veterans aimed at improving quality and increasing innovation in routine clinical practice. The framework was developed to advance implementation science by "providing consistent taxonomy, terminology, and definitions on which a knowledge base of findings across multiple contexts can be built" (Damschroder et al., 2009, p. 2).

The CFIR is a meta-theoretical framework and synthesis of existing theories that integrates dissemination, innovation, organizational change, implementation, knowledge translation, and research receipt theories to address barriers to implementation that may arise at the patient, provider, organizational, and policy levels of health care delivery (Damschroder et al., 2009). The CFIR emphasizes the need to acquire "understanding of the dynamic interplay between individuals and the organization within which they work, and how that interplay influences individual and organizational behavior change" (Damschroder et al., 2009, p. 5). The framework offers a deductive reasoning approach to understanding, describing, explaining, and predicting implementation processes within organizations.

Meaning and logical adequacy. There are five interrelated key domains in the CFIR framework: (a) intervention characteristics, (b) outer setting, (c) inner setting, (d) individuals involved, and (e) process. Embedded in each domain are multiple constructs and sub-constructs; however, the framework was not intended to illustrate interrelationships between constructs, to identify specific ecological levels, or to develop hypotheses (Damschroder et al., 2009). Damschroder et al. (2009) contended that the CFIR is strictly a consolidation of existing theories and constructs intended to promote theory development, application, and effectiveness across multiple contexts.

Usefulness, generalizability, and parsimony. The CFIR is a comprehensive, explanatory framework consisting of 39 constructs that are sub-divided among five major domains. Its (sub)-constructs can be used to help predict whether an implementation may or may not succeed (Breimaier, Heckemann, Halfens, & Lohrmann, 2015). The CFIR provides a practical taxonomy of constructs with the potential to influence implementation effectiveness (Breimaier et al., 2015). Despite its complexity, the framework has been reported as both useful and user-friendly because it is simple to apply due to its conceptual clarity and wide coverage of the five domains (Breimaier et al., 2015).

Due to its standardized implementation-related constructs, the CFIR is useful across a broad spectrum of implementation research (Kirk et al., 2016). The CFIR is considered a dissemination and implementation (D&I) framework as it serves to

1. ensure that essential implementation strategies are included (University of Colorado [UoC], 2013),
2. enhance the effectiveness of interventions through processes focused on behavioral change, and

3. enhance the interpretability of study findings.

CFIR constructs can be used to raise awareness about potential influences (Breimaier et al., 2015) by allowing for the systematic assessment of potential barriers and facilitators in preparation for the implementation of an innovation (Consolidated Framework for Implementation Research [CFIR] Team, n.d.). Furthermore, it can help to guide the selection of strategies that may help to overcome or that may affect influential factors (Breimaier et al., 2015). The CFIR can be customized to a variety of organizational settings, and it promotes the consistent use of constructs, systematic analysis, and the organization of findings from implementation studies (CFIR Team, n.d.). To date, however, the CFIR has been used minimally in nursing research.

Testability. A challenge to testing the CFIR is that the framework does not provide an all-encompassing tool for measurement, nor does every one of its 39 constructs present a specific utilization tool. Since the CFIR is a consolidation of several previously established frameworks, some individual constructs do have a valid tool for their measurement while some have more than one such tool available. Constructs/sub-constructs from the CFIR that inspired this STRATA study included the *structural characteristics* and *available resources* of practice settings.

Structural characteristics. The structure of the inner setting of an organization refers to the social architecture, age, maturity, and size of the organization. Structure depends on how many people there are clustered into smaller groups (teams) and how they work together to produce a product or service. Higher numbers of units and departments represent diversity of knowledge in an organization (Damschroeder et al., 2009). The more stable the teams, the more likely an implementation will be successful. Structure is also related to the ratio of

managers to employees and how decision-making happens within the organization (Damschroeder et al., 2009).

Available resources. For the successful implementation of a change to occur, an organization requires resources—including money, training, education, physical space, and time—to be dedicated to implementation and ongoing operations (CFIR Team, n.d.). Within the context of the STRATA study, these resources include staff to administer vaccines, staff training in the assessment of patient vaccine history, staff training on the vaccine administration processes, vaccine storage units, and the special temperature monitoring equipment recommended by the CDC in its vaccine storage and handling toolkit guidelines.

Theory Strengths

Since CFIR is a comprehensive framework that offers many choices among constructs, it can be applied to any organization or implementation situation in need of guidance. Its constructs can be used to systematically assess potential barriers and facilitators in preparation for the implementation of an innovation (CFIR Team, n.d.). While the CFIR framework can be customized to a variety of organizational settings, it promotes the consistent use of constructs, systematic analysis, and organization of findings in implementation studies (CFIR Team, n.d.).

Theory Limitations

Although the use of the CFIR in research has increased since it was established in 2009, no formal reviews have been conducted to determine its effects on implementation research (Kirk et al., 2016). Few CFIR constructs have specific, validated measurement tools, and there is no overall measurement tool for the framework itself. Specifically, no tool exists for measuring *structural characteristics* and *available resources*. Tools used for

measurement are at the discretion of the researcher and appear to be selected from other research studies. There is a dearth of literature supporting methods or logic for selecting constructs or domains for a research study. This gap does not align with the guidance published by the authors of the CFIR, who recommended that researchers report each decision and rationale for selection, measurement, and reporting of CFIR constructs (Kirk et al., 2016). Further limiting the usability of the CFIR is that all constructs have equal weight, as the framework does not discriminate between the relative importance of its different constructs (Varsi, Ekstedt, Gammon, & Ruland, 2015). This makes it difficult to discern which constructs might be more or less influential compared to others.

As mentioned previously, the CFIR is a synthesis of existing theories that integrates dissemination, innovation, organizational change, implementation, knowledge translation, and research receipt theories. Given its size, complexity, and aforementioned limitations, the CFIR, as a whole, was deemed too broad for the purposes of the STRATA study. Instead, the CFIR served as a guide for finding and selecting Donabedian's Structure-Process-Outcome Quality of Care Model, which is a mid-range implementation model that better suited the design, measurement, and evaluation of the variables associated with structure (Donabedian, 2005).

Donabedian's Structure-Process-Outcome Quality of Care Model

According to Donabedian's Structure-Process-Outcome Quality of Care Model, care can be conceptualized as divided into three domains: structure, process, and outcomes. Donabedian's (2005) model was selected for this study because of the relevance of its constructs to the study's variables and its ability to directly guide research and practice (Donabedian, 2005). The Donabedian framework supports an audit methodology for

examining elements of a health service. The relationships between structure, process, and outcome are not completely understood, but they are best expressed as "a chain of events in which each event is an end to the one that comes before it and a necessary condition to the one that follows" (Donabedian, 2005, p. 713). As noted in the literature review, there is a paucity of theoretically based research on maternal vaccinations and little evidence available to understand the antecedents, structure, processes, and outcomes of on-site Tdap vaccine administration in obstetrical practice. Hence, this STRATA study aims to examine the concepts of *structure* and *process* as antecedents to the *outcome* of on-site Tdap administration.

Structure. *Structure* refers to the setting in which care is delivered, including facilities and equipment, the qualifications of care providers, administration structure, and standard operating procedures (Donabedian, 2005). The antecedents of this first concept in Donabedian's model include factors that influence structure and process such as environment and patient factors. Structure should be examined within the context of these antecedents, as they establish what the organization is, what it does, and who it serves. According to the model, improvements in the structure of care should lead to improvements in processes that, in turn, improve patient outcomes (Moore, Lavoie, Bourgeois, & Lapointe, 2015). Analysis of structure relates to the contextual features that are needed to support the successful implementation of the physical, material, professional, and collegial elements of a health service. No instruments exist to measure structure, however, because structural variables are often concrete and accessible, making them relatively easy to assess (CDC, 2019).

Process. *Process* effects the appropriateness, acceptability, completeness, and competency of care provided. An assessment of structure and process may include

assessment of the administrative processes that support and direct the provision of care, the adequacy of facilities and equipment, the qualifications of the medical staff and the organization, and the administrative structure and operations of programs (Donabedian, 2005). Ways to assess structure and process include direct observation and indirect methods to ascertain behaviors and opinions, from which inferences may be drawn (Donabedian, 2005). Structure and process can, therefore, be assessed by observing and talking to providers in a practice setting, reviewing medical records, and collecting survey data.

A global, validated tool does not exist to measure structure and process, as the components of this assessment are tailored to the context and setting of interest. Measurement depends on the development of standards; in the medical system, standards emerge from actual practice and from the sources that set the standards of knowledge and practice (Donabedian, 2005). Standards are determined by beliefs about "the best" care, so the validity of standards depends on the extent of agreement about them within a profession. For the purposes of this STRATA study, the guidelines and checklist from the CDC's (2018) *Vaccine Storage and Handling Toolkit* served as the standards for measuring the structure and processes of vaccine programs in OB practices.

Outcome. *Outcomes* are the endpoints of care, and the validity of an outcome as a dimension of quality of care is rarely questioned (Donabedian, 2005). Outcomes are usually concrete and precisely measured. Due to multiple influences, outcomes can be difficult to measure, however; therefore, we cannot simply examine outcomes or results by themselves to determine if what we did was right or best. Rather, we must understand how the outcome came to be by examining the dynamic interplay of structural and procedural antecedents to

the outcome. A disadvantage of Donabedian's model is the difficulty of establishing the relationship between structure, process, and outcome.

Methodology

For this STRATA study, a cross-sectional survey design was used. The purpose of a survey is to generalize from a sample to a population so that inferences can be made about characteristics of the target population (Creswell, 2014). Within the context of the STRATA study, a purposive sample of OB practices from Iowa, Kansas, Missouri, and Nebraska was selected to represent the larger target population of OB practices in the Midwest. Administration of a survey instrument was chosen as the preferred type of data collection procedure for this study because it is economical and could reach many OB practices.

Data were collected, at one point in time, to understand the structure and processes of vaccine programs in OB practices and to identify any relationships between practice structure, process, and on-site Tdap administration. Clinical nurse managers of OB practices were asked to complete a self-administered questionnaire on the Internet or over the telephone concerning the demographics of their facility, the roles and responsibilities assumed for vaccine coordination, any protocols for vaccine administration, available vaccine storage and handling equipment, and available resources for on-site vaccine administration.

To encourage participation, a mixed-mode approach was used as a means to communicate with respondents (Dillman, Smyth, & Christian, 2014). Communication began with a mailing that directed respondents to the Internet to complete the questionnaire. To achieve adequate coverage and response rates, non-responders were contacted by telephone.

This mixed-mode approach improved coverage, decreased non-response rates, and minimized survey error (Dillman et al., 2014).

Target Population and Setting

Participants were recruited from obstetrical practices located within rural and urban/suburban counties in Iowa, Kansas, Missouri, and Nebraska. The use of these two groupings aligned with the U.S. Census Bureau's classifications of rural and urban geographic areas (U.S. Census Bureau, 2016).

Obstetrical practices serve both pregnant and post-partum women. The age range of their patients varies, as women can become pregnant from early adolescence up into their forties and fifties. The number of women that each practice serves is dependent upon its location with respect to the size of the surrounding population as well as the preferences and availability of the OB provider. Insurance coverage of OB patients varies, with women using private insurance, Medicaid, or no insurance. For this study, respondents were asked to provide demographic information about their practice to provide a rich understanding of the characteristics of the populations that they serve.

Sampling Frame

An address-based sampling technique was used to generate a directory of OB physicians (MD or DO), physician assistants (PA), advanced registered nurse practitioners (ARNP), and certified nurse midwives (CNM) using the publicly available "Find a Doctor" feature on the Wellmark Blue Cross and Blue Shield (BCBS) of Iowa's website (Wellmark, 2018). Wellmark is the leading private health insurance company in the Midwest, with a majority of actively licensed health care providers, including OB providers participating or having a contract with Wellmark, Inc. (J. W. Tran, personal communication, February 23,

2018); coverage error was, therefore, minimal. One clinic nurse manager, or someone equally knowledgeable, from each practice address served as the respondent to the questionnaire. A computer with Internet access within the practice or a mobile phone with Internet access was required for completion of the Internet questionnaire.

Sampling Design

The sampling unit for this study was individual OB practices located in rural and urban/suburban counties in Iowa, Kansas, Missouri, and Nebraska. One clinic nurse manager, or someone equally knowledgeable, from each practice address served as the respondent to the questionnaire. Eligible practices were those that provide care to women who are pregnant. Practices that only provide gynecological and/or infertility care were excluded as they do not focus on pregnancy and childbirth. Some family practice and primary care clinics provide OB services and were, therefore, included in the sample if they were listed in the Wellmark directory. The outcome variable of interest of this STRATA study was the presence or absence of on-site Tdap administration; therefore, eligibility for participation was not affected by this factor.

The estimated total number of OB practices that existed in the selected Midwest states at the time of this study was 400. An ideal sample size was computed using a 95% confidence interval and 5% margin of error, resulting in an ideal sample size of 196. Non-response rate and non-response errors were taken into consideration when planning for the sample size because nonresponse rates are understood to be direct measures of survey quality (Groves et al., 2009). Response rates to surveys are extremely varied, ranging from as low as 10% to over 90% (Kalton, 1983). While response rate alone is no longer considered the gold standard of survey quality, a response rate of 60% is considered acceptable by many

biomedical journals (Livingston & Wislar, 2012). Similar survey-based research among OB practices in other geographical locations of the U.S. have had a similar sample size (Arao et al., 2015; Bonville et al., 2015).

Using a non-probability sampling method, a purposive sample of OB practices was selected from the sampling frame for inclusion in this study. Given the risk of low response rates associated with a survey study and given that only a few hundred OB practices were available for recruitment in the selected areas of the Midwest, all OB practices on the generated Wellmark directory were selected for the recruitment process to eliminate sampling bias. Practice names and addresses associated with each provider were generated from the Wellmark directory and compiled into a list. Duplicate addresses were excluded. The stratification of each address into one of two groups (rural or urban/suburban) ensured that certain segments of the population were not either overrepresented or underrepresented (Groves et al., 2009). The final sample included a fairly equitable number of rural and urban/suburban practices.

Participants and Recruitment

As this research was considered non-human subjects research, the Institutional Review Board at the University of Missouri-Kansas City determined the STRATA study did not require approval. The primary investigator (PI) identified respondents from a publicly available directory of OB practice addresses generated from Wellmark Blue Cross and Blue Shield of Iowa's website. The PI made initial contact with the clinic nurse manager at each practice address through an initial mailing via the U.S. Postal Service, directing respondents to complete a questionnaire on the Internet. Respondents were informed of the purpose and risks of participation in the initial cover letter and again on page 1 of the Internet

questionnaire. Completion and submission of the Internet questionnaire implied consent. The questionnaire took approximately five minutes to complete. The risk to respondents was minimal, as all information provided on the questionnaire was confidential. The goal was an 80% rate of return; however, based on previous survey research with this population, a response rate as low as 40% was expected.

The sampling unit for this STRATA study was the address of an OB practice, through which respondents were recruited via U.S. Postal Service. The direct mailings addressed to the "OB/GYN Clinic Nurse Manager" were the primary method of recruitment. The term "OB/GYN" was necessary in the recipient line because some OB practices are located within a hospital and share the address of that hospital, so the deliverer needed to know to which department the mailing should be routed. The PI and research assistant (PA) prepared the mailings. The first mailing included a cover letter inviting the respondent to complete the questionnaire as a contribution to the advancement of his or her career field (Appendix A). To further entice participation, $2.00 cash was included in the initial mailing. To avoid tying respondents' data to their names and contact information while still tracking of completion of the survey, a separate link was provided after submission of the questionnaire that took the respondent to a form that collected these data.

The intention behind addressing the envelope to the "OB/GYN Nurse Manager" with no specific name was that an eligible respondent within that unit would identify themselves as that person or would direct the mailing to the appropriate person. According to the American Association for Public Opinion Research (American Association for Public Opinion Research [AAPOR], 2016), when mail surveys are addressed to unnamed persons, it is assumed that within each sampled unit some form of within-unit respondent selection will

be used to determine if there is at least one eligible respondent to complete the questionnaire. A risk associated with this recruitment method was that no individuals in the sampling unit would identify themselves or someone else as the clinic nurse manager, the mailing would not be opened, and the questionnaire would never be completed.

Due to a low response rate after the initial mailing, the PI and RA made phone calls to non-responders and some respondents completed the questionnaire over the telephone. The purpose of the phone calls was to collect structural and procedural data about an organization/facility and not human subjects, therefore additional IRB approval was not necessary. Care was taken with the phone calls in terms of how the interviewer read the questions and spoke to the respondent because intonation, speed, and clarity of voice could cause interviewer-related or questionnaire-related error. To ensure consistency and accuracy, the PI and RA used transcripts of these phone calls to collect data.

Disposition codes adapted from AAPOR's (2016) final disposition codes for mail surveys of unnamed persons were used for the questionnaire. Knowing the disposition of every element drawn from the survey sample allowed for assessment of whether the sample contained nonresponse errors and the potential reasons for that error. Figure 3.1 shows the survey methods used in, and flow of respondents through, this study.

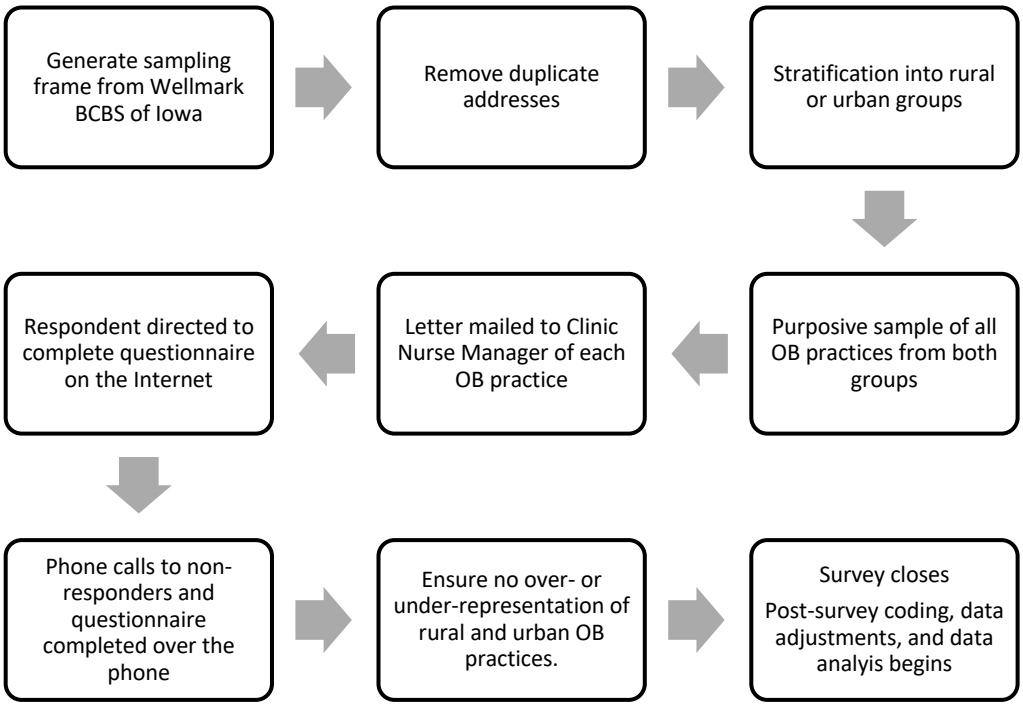

Figure 3.1. Visual diagram of survey methods and flow of respondents through the STRATA study.

Data Collection

Applying the guidelines and checklist established by the CDC in its *2018 Vaccine Storage and Handling Toolkit*, a self-administered questionnaire (SAQ; Appendix B) was designed and administered using Research Electronic Data Capture (REDCap). Movement from item to item within the Internet questionnaire was controlled by contingencies when necessary. The layout of the question and answer elements on the screen and the principles of visual design and visual communication were important to consider during the design process, as these factors can affect measurement error. Respondent literacy was necessary for completing the Internet questionnaire.

The validity and reliability of the questionnaire were inherently sound, given that its elements came directly from published guidelines from a reliable organization and that the variables measured were primarily nominal or dichotomous (yes/no). To further increase validity, before the questionnaire was administered to respondents, it was reviewed by a team of research experts. Once it was revised per feedback from this panel of experts, eight nurses in Polk County, Iowa field-tested the questionnaire. This testing improved the questions and format, and comments from the nurses were incorporated into the final instrument revisions. Pre-test subjects were not included in the final survey and pre-test data were not used in the final analysis of the surveys.

Data Processing

The questionnaire was designed and administered directly through REDCap. REDCap immediately and securely captured and stored all demographic and variable data collected from respondents. Raw data were exported from REDCap directly into SPSS for analysis. The data were arranged within SPSS in rows and columns, with variable names and labels assigned. In SPSS, the PI was able to view individual data points and manipulate them as needed. Next, the PI cleaned the raw data by identifying unreliable or invalid data. When problems were apparent at the variable level, the PI attempted to triangulate a reasonable answer on that variable. When no reasonable fix was possible, problem data were coded as missing. Imputing missing data was not possible in most cases because questions were nominal or dichotomous and making a guess for this level of data would jeopardize the validity of the results (Polit & Beck, 2017).

Data Analysis

The dependent variable of this STRATA study was the concept of *outcome* from Donabedian's Structure-Process-Outcome Quality of Care Model. The measure of outcome for this study was the presence or absence of on-site Tdap administration. Data measured by the questionnaire were primarily nominal and categorical, describing the target population and measuring relationships between the outcome variable and each of the following independent structural variables: the demographics of OB practices, vaccine coordination, protocols for vaccine administration, vaccine storage equipment, and available resources for on-site vaccine administration. Table 3.1 summarizes the concepts, variables, and measures included in the questionnaire.

Table 3.1

Summary of Concepts, Variables, Measures, and Research Questions of the STRATA Study

	Concept	Variable	Measures (Antecedents)	Level of Measurement	Research Questions
ANTECEDENTS	Structure (IV)	Demographics	Provide care to pregnant women	Dichotomous	Descriptive research question: How many OB practices administer Tdap on-site?
			Respondent credentials	Nominal	
			Rural or urban/suburban setting	Dichotomous	
			Type of facility	Nominal	
			Staff by credential	Nominal	
			Number of patients served per month	Continuous	
			Primary age of patients served	Nominal	
			Primary race of patients served	Nominal	
			Type of insurance patients use	Nominal	
		Vaccine storage	On-site vaccine storage unit	Dichotomous	Descriptive research question: What is the structure and process of vaccine programs in OB practices?
			Vaccine storage unit type	Nominal	
			Temperature monitoring device	Nominal	
			Logs for monitoring and recording storage unit temperature	Dichotomous	
			Logs for storage unit maintenance	Dichotomous	
			Logs for temperature monitoring device maintenance	Dichotomous	
		Available resources	Staff who administer vaccines	Nominal	Inferential research question: What structural factors are antecedents to on-site Tdap administration?
			Other vaccines on-site	Nominal	
			Standing order for vaccines	Dichotomous	
			Staff education and training	Dichotomous	
			Electronic medical record	Dichotomous	
			Alert in EMR for vaccines	Dichotomous	
		Vaccine coordination	Primary vaccine coordinator	Nominal	
			Secondary vaccine coordinator	Dichotomous	
			Roles and responsibilities of vaccine coordinator	Nominal	
	Process (IV)		Perceived barriers to on-site vaccine programs	Qualitative	
			Referrals elsewhere for Tdap	Dichotomous	
	Outcome (DV)	On-site Tdap vaccine administration	Presence or absence of on-site Tdap vaccine administration	Dichotomous	

Note. The main concepts of structure, process, and outcome originate from Donabedian's (2005) Structure-Process-Outcome Quality of Care Model.

The PI conducted the data analysis with support from a biostatistician as needed. The research questions were as follows.

Descriptive Research Questions

RQ1: How many OB practices administer on-site Tdap vaccines?

RQ2: What is the structure and process of vaccine programs in OB practices?

These first two research questions were answered with univariate, descriptive statistical analyses that described and synthesized the data. The variables examined included all measures associated with the concepts of structure and process. Structural variables were either nominal or dichotomous. Process variables where either dichotomous (referral elsewhere for Tdap) or qualitative (perceived barriers to on-site vaccine programs). The one qualitative variable was analyzed by compiling all narrative responses together and examining the compilation for keywords and themes. The themes were converted into three categories: patient factors, provider factors, and health system factors. Narrative responses were then summarized under their respective categories.

Inferential Research Question

RQ3: What factors are structural antecedents for on-site Tdap administration?

For this question, the dependent variable was dichotomous: Did the OB practice administer Tdap on-site (yes or no)? The independent variables were nominal and included all of the measures for the concepts of structure, some of which were dichotomous and some of which were nominal with multiple categories. Bivariate correlations were calculated using 2x2 cross-tabulation and Fisher's exact tests to determine if there was a statistically significant relationship between two nominal or dichotomous variables. The significance of the results

was interpreted using alpha .05. If a relationship was found to be significant, the strength of the association between variables was determined using phi (Kellar & Kelvin, 2013).

Survey Ethics

Participation in the STRATA survey was voluntary. Respondents were informed in the initial mailing and on page 1 of the Internet questionnaire of the risks and benefits of participation. Respondents had the option to not complete the questionnaire. For those who did choose to participate, completion and submission of the questionnaire implied consent. For purposes of completion tracking, respondents were asked to provide their contact information after submission of the questionnaire. Contact information was separate from the main survey questionnaire, viewed by the PI only, and not tied to respondents' survey data. No personally identifiable information was collected from the participants who were called; only the phone number and address of the facility was documented for tracking purposes.

Risks to respondents included discomfort when selecting answers to questions that may be interpreted as suggesting that their practice was not using best practices for maternal vaccinations. Respondents may have feared that revealing this information would negatively affect their relationship with the organization. Risk was minimized by keeping all information provided on the questionnaire confidential and not tied to respondent contact information. Information about specific OB practices was not shared with anyone other than the PI and RA.

The benefits of the research to the respondents and others included contributing to the advancement of the obstetrical field, which is continuing to make efforts toward increasing maternal vaccination rates and reducing infant mortality from pertussis. The outcomes of this study supported future research on vaccine program structure and processes unique to OB

practices. The findings gleaned from this study could be used to advocate for OB practices as they seek administrative support for the acquisition of vaccine program resources.

CHAPTER 4

RESULTS

Chapter 4 provides a report of findings related to the research questions. This chapter is organized by, first, reporting the details of the survey response, followed by a summary of the findings. The findings are organized according to the concepts of Donabedian's Structure-Process-Outcome Quality of Care Model, with *outcome* being reported first, followed by *antecedents of structure*, *structure*, and then *process* (Figure 4.1).

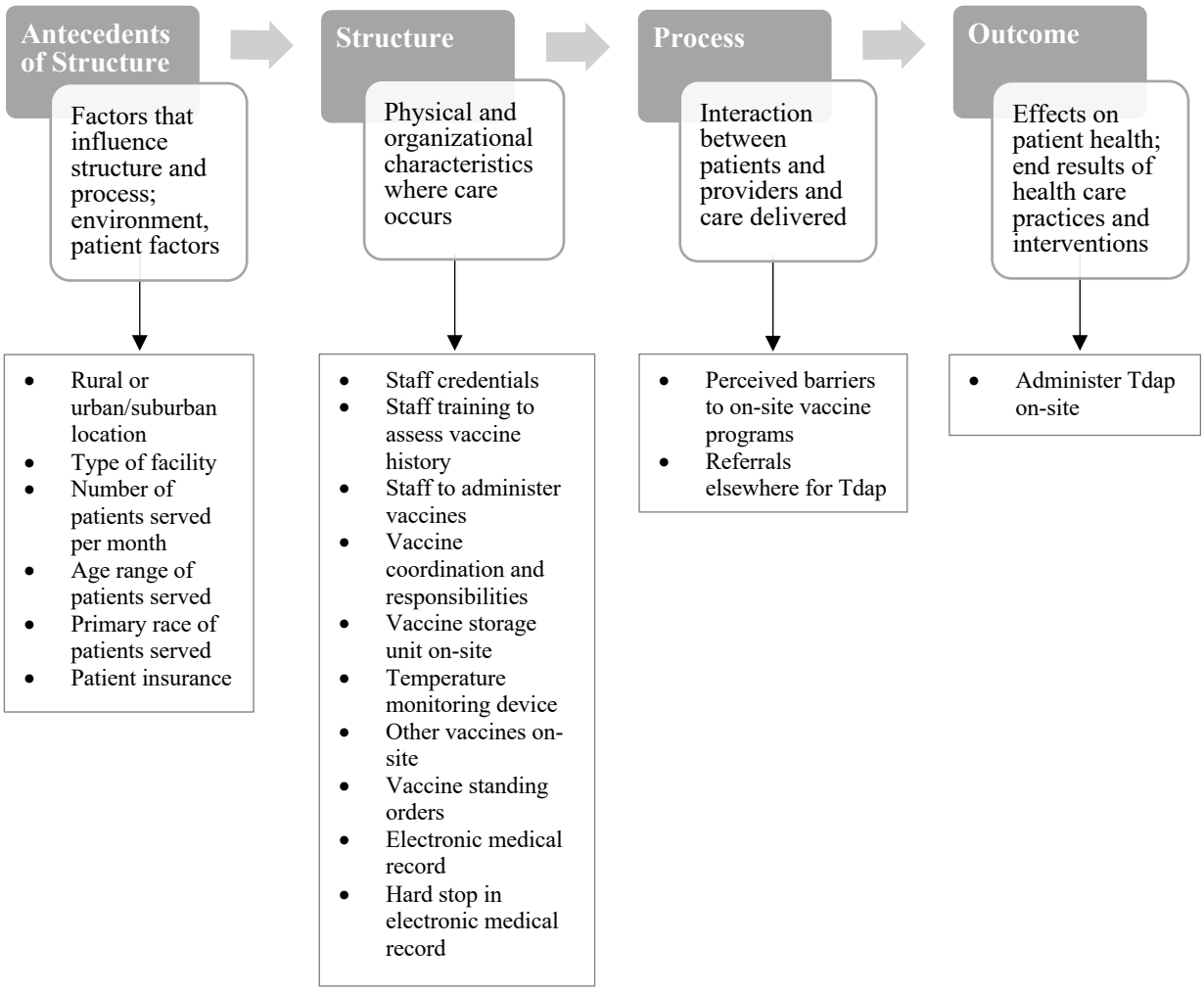

Figure 4.1. Visual diagram of Donabedian's Structure-Process-Outcome Quality of Care Model adapted for the STRATA study.

Survey Response

Three hundred eighty-one letters were mailed to OB practices in the Midwestern states of Iowa, Kansas, Nebraska, and Missouri on November 12, 2018. The survey period closed on December 31, 2018. The final sample size for data analysis was 50. The response rate for the STRATA study was 22% and the nonresponse rate was 77%. Table 4.1 shows the final disposition and distribution of the survey responses and non-responses.

Table 4.1

Final Sample Disposition

Completed	*n*	%
Completed online questionnaire	46	
Completed telephone questionnaire	4	
Total response	50	22
Eligible, Refusal	***n***	**%**
Telephone refusal	1	
Mailed refusal	2	
Total noncooperation	3	1
Unknown Eligibility	***n***	**%**
Nonresponse	173	77
Not Eligible, Contact	***n***	
Completed online questionnaire (too incomplete to process)	2	
Completed online questionnaire (do not provide OB care)	2	
Postal mail/email response (do not provide OB care)	90	
Total not eligible, contact	94	
Not Eligible, Noncontact	***n***	
USPS: undeliverable as addressed	52	
Non-working telephone number	9	
Total not eligible, noncontact	61	

Note: The denominator for calculation of the response and nonresponse rates included completed + eligible refusals + unknown eligibility ($N = 226$).

Most respondents who completed the questionnaire were registered nurses (Table 4.2). Some respondents reported themselves as holding another ("other") type of credential. No pharmacists or CNMs completed the questionnaire.

Table 4.2

Respondent Credential (N = 49)

Credential	*n*	%
RN	33	67
LPN/LVN	3	6
ARNP	3	6
CMA	2	4
Secretary/office assistant	2	4
DO/ MD	1	2
Other	5	10

Note: 1 respondent skipped this item.

Findings

Outcome

On-site Tdap administration. The outcome of interest in this STRATA study was whether Tdap was administered on-site to pregnant patients. Of the fifty practices that completed a survey, 90% (*n* = 45) provided Tdap on-site, while 10% (*n* = 5) did not.

Antecedents of Structure

Location of facility. The final sample size for analysis was 50 OB practices, of which 40% (*n* = 20) were located in a rural county and 60% (*n* = 30) in an urban/suburban county. Table 4.3 displays the number of OB practices sampled in each state.

Table 4.3

Sample of OB Practices per State (N = 50)

State	*n*	%
Iowa	27	54
Nebraska	14	28
Missouri	5	10
Kansas	4	8
Totals	50	

To investigate whether OB practices located in rural or urban/suburban communities differed with respect to whether or not they provide Tdap on-site, a Fisher's exact statistic analysis was conducted. All assumptions were met, as two cells had expected cell counts of fewer than five. Table 4.4 shows the Fisher's exact results and indicates that rural and urban/suburban practices are not significantly different in terms of whether or not they provide the Tdap vaccine on-site ($p = .636$). Urban/suburban practices were not found to be more likely than expected to provide Tdap on-site than rural practices.

Table 4.4

Fisher's Exact Analysis of Prevalence of On-site Tdap among Rural and Urban/Suburban Obstetrical Practices (N = 50)

Community Type	*n*	On-site Tdap		*p*
		No	Yes	
Rural	20	1	19	
Urban/suburban	30	4	26	
Total	50	5	45	.636

Note: Significance set at .05.

Type of facility. A majority (80%, $n = 40$) of respondents represented either a private practice or a non-private practice (Table 4.5). Most of the practices that did not provide Tdap on-site were private practices unaffiliated with any hospital or health care system ($n = 4$). One practice that did not provide Tdap on-site was non-private and was affiliated with, as well as connected to, a hospital or health care system.

Table 4.5

Sample of OB Practices by Facility Type (N = 50)

Type of Facility	*n*	%
Private, not affiliated	18	36
Non-private, affiliated, connected	15	30
Non-private, not affiliated, not connected	7	14
Academic medical center	2	4
County health department	2	4
Other	6	12

Number of patients served. The mean number of pregnant women served per month by all sampled OB practices was 159 (range 2-1000). Urban/suburban practices served the most pregnant women per month ($\bar{x}$ = 237), compared to rural practices ($\bar{x}$ = 39). Academic medical centers served the most patients ($\bar{x}$ = 280), followed by private practices ($\bar{x}$ = 246). Table 4.6 shows the mean number of pregnant women served for all facility types.

To investigate whether OB practices that do administer Tdap on-site (n = 45) and those that do not (n = 5) differ with respect to the average number of patients served per month, an independent samples t-test was computed. Inspection of the two group means did not reveal a statistically significant difference in the number of patients served per month (Table 4.7). Practices that served a higher number of pregnant women per month were not found to be more likely to administer Tdap on-site.

Table 4.6

Mean Number of Pregnant Women Served Per Month by Facility Type (N=48)

Type of Facility	*N*	$\bar{x}$	SD
Private, not affiliated	17	246.9	357.8
Non-private, affiliated, connected	14	115.6	158.5
Non-private, not affiliated, not connected	7	141.4	212
Academic medical center	2	280	169.7
County health department	2	55	21.2
Other	6	24.2	26.7
Total	48	158.8	252.5

Note: Two respondents skipped this item.

Table 4.7

Comparison of OB Practices With and Without On-site Tdap Administration on Number of Patients Served per Month (n = 45 with and 5 without)

Variable	*M*	*SD*	*t*	*df*	*p*
Number of patients served			-.990	46	.327
Without on-site Tdap	39	32.92			
With on-site Tdap	169.64	261.07			

Note: Significance set at .05.

Age range of patients served. Sampled practices primarily served pregnant women between the ages of 18 and 29 (Table 4.8). A few practices primarily served women age 30 and above. No practices primarily served minors under the age of 18.

Table 4.8

Age Range of Pregnant Women Served (N = 49)

Age	*n*	%
18-24	10	20
25-29	34	69
30-35	4	8
Over 35	1	2

Note: One respondent skipped this item.

Primary race of patients served. Most of the OB practices surveyed primarily served Caucasian/White women (*n* = 43), while a few mainly served Hispanic/Latino women (*n* = 5; Table 4.9). No practices reported primarily serving African American or Native American/Alaskan Native women.

Table 4.9

Primary Race of Pregnant Women Served (N = 49)

Race	*n*	%
Caucasian/White	43	88
Hispanic/Latino	5	10
Asian/Pacific Islander	1	2

Note: 1 respondent skipped this item.

Health insurance. The surveyed practices served patients with private insurance, Medicaid, and no insurance (Table 4.10). A majority of their patients used private insurance, while fewer used Medicaid or had no insurance.

Table 4.10

Type of Insurance Used (N = 49)

Insurance Type	*n*	%
Private	29	59
Medicaid	18	37
No insurance	2	4

Note: 1 respondent skipped this item.

Structure of Vaccine Programs

Staff credentials. Practices varied in terms of which types of professionals worked there (Table 4.11). Registered nurses and medical doctors were the most prevalent professions represented. Physician assistants and CNMs were the least prevalent.

Table 4.11

Health Care Professions in Sample of OB Practices (N = 50)

Profession	*n*	%
RN	45	90
MD	39	78
ARNP	37	74
LPN/LVN	35	70
DO	34	68
CMA	34	68
PA	30	60
CNM	20	40

Crosstabulation of the credentials of providers in rural versus urban/suburban locations was conducted to understand the distribution of providers in these areas (Table 4.12). Health care professionals of all credentials practiced most often in an urban/suburban location and least often in a rural location. However, the margin of difference was small.

Table 4.12

Distribution of Provider Credentials in OB Practices in Rural Versus Urban/Suburban Locations (N = 50)

Location		Credential					
	n	DO	MD	PA	ARNP	PA	CNM
Rural	20	14	16	15	14	15	7
Urban/Suburban	30	20	23	15	21	15	13

Of the obstetrical practices that had ARNPs and/or CNMs on staff ($N = 37$), all but one provided Tdap on-site (97%, $n = 36$), compared to only 88% ($n = 42$) of practices with DOs, MDs, and/or PAs ($N = 47$). To investigate whether obstetrical practices that employed ARNPs and/or CNMs were more likely to provide Tdap on-site, a Fisher's exact statistical analysis was conducted. Assumptions were checked and were met, as two cells had expected cell counts of less than five. Table 4.13 and 4.14, which show the Fisher's exact results, indicate a small but statistically significant relationship between practices that employed ARNPs and those that administer Tdap on-site (phi = .364, $p = .024$). There was, however, not a significant relationship between practices that employed CNMs and those that administered Tdap on-site ($p = .636$).

Table 4.13

Fisher's Exact Analysis of Prevalence of ARNPs and On-site Tdap Among Obstetrical Practices (N=50)

ARNP on Staff	*n*	On-site Tdap		*p*
		No	Yes	
No	15	4	11	
Yes	35	1	34	
Totals	50	5	45	.024

Note: Significance set at .05.

Table 4.14

Fisher's Exact Analysis of Prevalence of CMNs and On-site Tdap Among Obstetrical Practices (N = 50)

CNM on Staff	*n*	On-site Tdap		*p*
		No	Yes	
No	30	4	26	
Yes	20	1	19	
Totals	50	5	45	.636

Note: Significance set at .05.

There were similar findings among DOs, MDs, and PAs. To investigate whether obstetrical practices that employed DOs, MDs, and PAs were more likely to provide Tdap on-site, a Fisher's exact statistical analysis was conducted, which revealed that assumptions were met, as two cells had expected cell counts of less than five. Tables 4.15, 4.16, and 4.17, which show the Fisher's exact results, indicate no significant relationship between practices that employed DOs and MDs and those that administered Tdap on-site (p = .650 and p = .301, respectively). There was, however, a moderately significant relationship between practices that employed PAs and those that administered Tdap on-site (phi = .408, p = .007).

Table 4.15

Fisher's Exact Analysis of Prevalence of MDs and On-site Tdap (N = 50)

MD on Staff	*n*	On-site Tdap		*p*
		No	Yes	
No	11	2	9	
Yes	39	3	36	
Totals	50	5	45	.301

Note: Significance set at .05.

Table 4.16

Fisher's Exact Analysis of Prevalence of DOs and On-site Tdap (N = 50)

DO on Staff	*n*	On-site Tdap		*p*
		No	Yes	
No	16	2	14	
Yes	34	3	31	
Totals	50	5	45	.650

Note: Significance set at .05.

Table 4.17

Fisher's Exact Analysis of Prevalence of PAs and On-site Tdap (N = 50)

PA on Staff	n	On-site Tdap		p
		No	Yes	
No	20	5	15	
Yes	30	0	30	
Totals	50	5	45	.007

Note: Significance set at .05.

Staff to administer vaccines. Among the 46 practices that administered vaccines on-site, the staff nurse or CMA (93%, *n* = 43) and/or physician, ARNP, or PA (9%, *n* = 4) usually administered vaccines. No pharmacists administered vaccines.

Staff training. All respondents were asked if staff in their respective practices were trained to assess a patient's vaccine history, to which 69% (*n* = 34) responded "yes" and 31% (*n* = 15) responded "no." More staff were trained on vaccine administration processes within the practice, with 84% (*n* = 41) responding "yes" and 16% (*n* = 8) responding "no." One respondent did not answer either question about staff training.

To investigate whether OB practices that provided training to staff on how to assess a patient's vaccine history were more likely to administer Tdap on-site, a Fisher's exact statistical analysis was conducted. Assumptions were checked and were met, as two cells had the expected cell counts of less than five. Table 4.18, showing the Fisher's exact results, indicates a small, statistically significant relationship between practices that train their staff

and those that administer Tdap on-site (phi = .343, p = .031). Obstetrical practices that train their staff to assess a patient's vaccine history were found to be more likely than expected to administer the Tdap vaccine on-site.

Table 4.18

Fisher's Exact Analysis of Prevalence of Staff Training and On-site Tdap Among Obstetrical Practices (N = 50)

Staff Training to Assess	*n*	On-site Tdap		*p*
		No	Yes	
No	16	4	12	
Yes	34	1	33	
Totals	50	5	45	.031

Note: Significance set at .05.

Vaccine coordination. All of the practices surveyed, regardless of whether they provided vaccines on-site, were asked if they had a primary vaccine coordinator. A majority responded that they did have a coordinator (74%, n = 37), while eight practices did not; five were unsure. Among practices that reported administering the Tdap vaccine on-site (n = 45), 82% (n = 37) had a primary vaccine coordinator while 16% (n = 8) did not. The vaccine coordinators were most likely to be registered nurses (Table 4.19). Among practices with a primary vaccine coordinator, only 70% (n = 26) had a secondary coordinator.

Table 4.19

Credential of Primary Vaccine Coordinator (N = 37)

Credential	*n*	%
RN	25	68
LPN	4	11
PharmD	4	11
Other	4	11

The makeup of responsibilities of the vaccine coordinators varied among practices. The most common responsibilities included ordering vaccines (84%), overseeing proper receipt and storage of vaccines when they are delivered (81%), and organizing vaccines within storage units (78%). Table 4.20 summarizes the distribution of responsibilities among all practices with vaccine coordinators.

Table 4.20

Responsibilities of Primary Vaccine Coordinator (N = 37)

Responsibility	*n*	%
Ordering vaccines	31	84
Overseeing proper receipt and storage of vaccine deliveries	30	81
Organizing vaccines within storage units	29	78
Setting up temperature monitoring devices	27	73
Removing expired vaccines from storage units	27	73
Ensuring staff is properly trained in vaccine storage, handling, and administration	27	73
Monitoring operation of storage equipment and systems	27	73
Documenting vaccine delivery information	26	70
Overseeing proper vaccine storage transport	26	70
Responding to out of range temperatures	25	68
Maintaining all documentation such as inventory and temperature logs	25	68
Overseeing emergency preparations (tracking inclement weather and ensuring appropriate handling of vaccines during a disaster or power outage)	24	65
Responding to out of range temperatures	24	65
Maintaining all documentation, such as inventory and temperature logs	24	65
Reading and recording storage unit temperatures	23	62
Uncertain	6	16

Note: The CDC recommends in their 2018 *Vaccine Storage and Handling Toolkit* the above responsibilities for vaccine coordinators.

Vaccine storage unit. Eighty percent (n = 40) of the OB practices surveyed had a vaccine storage unit on-site. Only slightly less than half (48%, n = 19) of OB practices that stored and administered vaccines on-site used a purpose-built pharmaceutical refrigerator, which is the preferred type of unit per the CDC's *Vaccine Storage and Handling Toolkit* guidelines. The other most common storage unit was a standalone top-bottom household refrigerator (25%, n = 10). A few practices used a dormitory/bar-style refrigerator for their vaccines (20%, n = 8); these refrigerators, according to the CDC, should never be used for that purpose. Table 4.21 summarizes the findings regarding vaccine storage unit types. In its toolkit, the CDC recommends that logs and records of any storage unit repairs be kept. Of the practices that had a vaccine storage unit on-site, 90% (n = 36) followed this recommendation.

Table 4.21

Type of Storage Unit for Vaccines (N = 40)

Type of Unit	*n*	%
Purpose-built/pharmaceutical	19	48
Standalone/household, top-bottom	10	25
Dormitory/bar-style	8	20
Standalone/household, side-by-side	1	2
Uncertain	9	23

Note: Respondents could select more than one answer for this item if they had multiple types of storage units on-site.

To investigate whether OB practices with their own storage units stored and administered the Tdap vaccine on-site, a Fisher's exact statistical analysis was conducted.

Assumptions were checked and were met, as two cells had the expected cell counts of fewer than five. As Table 4.22 shows, the Fisher's exact results indicated a strong statistically significant relationship between practices that had a vaccine storage unit and those that administered Tdap on-site (phi = .667, p = .000). Obstetrical practices that had their own vaccine storage units were more likely than expected to administer the Tdap vaccine on-site.

Table 4.22

Fisher's Exact Analysis of Prevalence of Vaccine Storage Units and On-site Tdap Among Obstetrical Practices (N = 50)

Vaccine Storage Unit	*n*	On-site Tdap		*p*
		No	Yes	
No	10	5	5	
Yes	40	0	40	
Totals	50	5	45	.000

Note: Significance set at .05.

Temperature monitoring device (TMD). The CDC recommends the use of a digital data logger (DDL) for continuous temperature monitoring and recording. Only 58% (n = 21) of OB practices used a DDL in their vaccine storage units. Some practices reported using non-recommended TMDs, including alcohol-mercury thermometers (19%, n = 7) and infrared devices (6%, n = 2). Respondents from ten (28%) practices were uncertain what type of TMDs they used. The CDC toolkit recommends that the TMD be checked and logged routinely to ensure that storage unit temperatures are acceptable. All practices that reported

using a TMD followed this recommendation. Most practices also kept logs documenting any repairs to their TMDs (87%, *n* = 33).

Other vaccines on-site. Ninety-two percent (*n* = 46) of practices that completed a survey stored and administered other vaccines on-site; four practices did not. The most common vaccines administered on-site were Tdap, influenza, human papillomavirus (HPV), and HepB (Table 4.23).

Table 4.23

Other Vaccines Administered On-site (N = 46)

Vaccine	*n*	%
Tdap	45	98
Influenza	42	91
HPV	37	88
HepB	36	86
Pneumovax	28	67
HepA	28	67
MMR	27	64
Td	25	60
Shingles	25	60
Hib	25	60
Varicella	24	53
MCV4	19	45
MenB	19	45
Other	13	29

To investigate the relationship between OB practices that administered other vaccines on-site and those that administered Tdap on-site, a Fisher's exact statistical analysis was conducted. Assumptions were checked and were met, as three cells had expected cell counts of less than five. Table 4.24 shows the Fisher's exact results, which indicated a strong,

statistically significant relationship between practices that administered other vaccines on-site and those that administered Tdap on-site (phi = .885, p = .000). Obstetrical practices that administered the other vaccines on-site were more likely than expected to also administer the Tdap vaccine on-site.

Table 4.24

Fisher's Exact Analysis of Prevalence of On-site Tdap and Other Vaccines On-site Among Obstetrical Practices (N = 46)

On-site Influenza	*n*	On-site Tdap		*p*
		No	Yes	
No	4	4	0	
Yes	46	1	45	
Totals	50	5	45	.000

Note: Significance set at .05.

A discrepancy was found to have occurred with this item on the questionnaire. In a previous question, the respondent was already asked whether or not they stored and administered Tdap on-site, to which 45 of 50 responded 'yes.' On a later item asking respondents to multi-select what other vaccines they administered on-site, three of the 45 respondents who had previously said 'yes' to administering Tdap on-site did not select Tdap again on the multi-select list, despite selecting several other vaccines from the same list. The PI decided to change these 'no' responses to 'yes' to match the first question the respondent was asked about on-site Tdap. This decision was based on the knowledge that as respondents complete a long questionnaire, they can become fatigued and make errors, they may become

unmotivated to finish the survey due to task difficulty, or they may begin to satisfice, meaning they provide quick, "good enough" answers rather than carefully considered answers (Hamby & Taylor, 2016). After adjusting for this discrepancy, descriptive statistics for this questionnaire item indicated that the Tdap and influenza vaccines were closely matched in terms of how many OB practices stored and administered them on-site (98% and 91%, respectively).

To investigate the relationship between OB practices that administered the Tdap vaccine on-site and those that administered the influenza vaccine on-site, a Fisher's exact statistical analysis was conducted. Assumptions were checked and were met, as three cells had expected cell counts of less than five. Table 4.25 shows the Fisher's exact results, which indicated no statistically significant relationship between practices that administered Tdap vaccines and those that administered influenza vaccines on-site (p = .087). Obstetrical practices that administered the influenza vaccine on-site were not more likely than expected to also administer the Tdap vaccine on-site.

Table 4.25

Fisher's Exact Analysis of Prevalence of On-site Tdap and Influenza Vaccines Among Obstetrical Practices that Administer Other Vaccines On-Site (N = 46)

On-site Influenza	*n*	On-site Tdap		*p*
		No	Yes	
No	4	1	3	
Yes	42	0	42	
Totals	46	1	45	.087

Note: Significance set at .05.

Referral elsewhere. Five practices did not provide the Tdap vaccine on-site; however, all five (100%) referred their patients elsewhere to receive it. Patients were usually referred to more than one place, including the patient's primary care provider (*n* = 3), an outpatient pharmacy such as Walgreens, Walmart, or Target (*n* = 4), or somewhere else (*n* = 1).

Vaccine standing orders. Standing orders refer to a protocol in place for allowing a licensed staff member (RN, LPN, CMA, etc.) to administer certain vaccines without having to obtain an order from the provider. Respondents from 74% (*n* = 34) of practices that administered vaccines on-site (N = 46) said that they had a standing order for vaccines, with 91% (*n* = 31) of those orders including the Tdap for pregnant women. Twenty-four percent (*n* = 11) of practices did not have such standing orders.

To investigate whether OB practices that used standing orders for vaccines were more likely than those that did not to administer Tdap on-site, a Fisher's exact statistical analysis was conducted. Assumptions were checked and were met, as two cells had the expected cell counts of less than five. As Table 4.26 shows, these Fisher's exact results indicated a moderate, statistically significant relationship between practices with standing orders for vaccines and those that administered Tdap on-site (phi = .470, *p* = .012). Obstetrical practices that used standing orders for vaccines were more likely than expected to administer the Tdap vaccine on-site.

Table 4.26

Fisher's Exact Analysis of Prevalence of Vaccine Standing Orders Among Obstetrical Practices that Administered Tdap On-Site (N = 45)

Vaccine Standing Orders	*n*	On-site Tdap		*p*
		No	Yes	
No	11	3	8	
Yes	34	0	34	
Totals	45	3	42	.012

Note: Significance set at .05.

Electronic medical records and alerts. Nearly all practices surveyed (96%, *n* = 48) utilized an electronic medical record (EMR); only two practices did not. Some practices with an EMR (33%, *n* = 16) had an alert or pop-up in the EMR system that prompted the user to assess a patient's vaccine history. Most EMRs, however, did not have this feature (67%, *n* = 32). The EMRs that did have an alert or pop-up usually included the Tdap vaccine (75%, *n* = 12) as part of the assessment prompted by the alert.

Perceived barriers to on-site vaccines. While perceived barriers to on-site vaccination were not the focus of the STRATA study, one item at the end of the questionnaire asked respondents to comment on what they believed were barriers to OB practices administering on-site vaccinations. Nineteen respondents noted a variety of perceived barriers. Table 4.27 summarizes the themes that could be identified from the respondents' narrative comments, categorized under patient factors, provider factors, and health system factors.

Table 4.27

Perceived Barriers to On-site Vaccine Programs in OB Practices (N = 19)

Patient Factors	*n*
Afraid vaccines will harm the unborn baby.	1
Lack of health insurance.	1
Lack of understanding about the need for vaccines.	5
Pregnant minors need parental consent for non-mandatory vaccines.	1
Received the vaccine elsewhere already.	2
Refusal.	2
Vaccine history unknown.	1
Provider Factors	
Attitudes about provider role in giving vaccines.	1
Forgetting to assess for/administer vaccines.	1
Forgetting to order vaccines.	1
Lack of knowledge about recommended vaccines.	4
Not prescribing, educating about, or encouraging vaccination.	3
Continuing education for staff.	1
Cost of implementing vaccine program.	3
HIPAA and OSHA compliance issues.	1
Health System Factors	
Improper handling of vaccines.	1
Lack of availability of vaccines.	2
Lack of reimbursement of vaccine services for providers.	1
Lack of time to address the subject with the patient.	1
Willingness of practice to adhere to regulations.	1

CHAPTER 5

DISCUSSION

The purpose of this STRATA study was to understand the structure of vaccine programs in OB practices through the discovery of structural antecedents and processes that facilitate on-site Tdap administration. Chapter 5 includes a discussion of its major findings, framed within the study's three central research questions and related to the literature on barriers to and facilitators of on-site Tdap administration and vaccine receipt among pregnant women in the United States. Implications of the findings that may be valuable to health care providers, nurses, administrators, and public health professionals working in maternal-child health are also discussed. The chapter concludes with a discussion of the limitations of the study and areas for future research.

Interpretation of Findings

RQ1: How Many Obstetrical Practices Administer Tdap On-site?

The findings of this study revealed that most OB practices that completed the survey did provide the Tdap vaccine on-site (n = 45, 90%). However, given the small sample size and low response rate, this finding must be interpreted with caution because it is possible that only practices that provide Tdap completed this study. National maternal Tdap vaccination rates were only 41.7% in 2013 (Kharbanda et al., 2016) and 54.5% in 2017 (Kahn et al., 2018), so if this finding were more reliable, it would be reassuring. This finding may indicate that more OB practices are following CDC recommendations for maternal vaccination, but

again, this must be interpreted cautiously in the absence of a larger, more representative sample. A small number of practices surveyed in this study did not provide Tdap on-site (n = 5); if magnified on a larger scale across the U.S., this could still equate to many pregnant women not being given the vaccine. Although all of the OB practices that said they did not administer Tdap on-site did refer their patients elsewhere to receive the vaccine, the literature suggests that not providing Tdap on-site and referring patients somewhere else is a known barrier to vaccine receipt (Arao et al., 2015). Indeed, pregnant women are five times more likely to receive a vaccine if the OB provider stocks and administers it on-site (NVAC, 2015), and a provider's recommendation is the greatest predictor of vaccine receipt among pregnant women (Ahluwalia et al., 2010; Shavell, Moniz, Gonik, & Beigi, 2012; Vitek et al., 2011). Therefore, OB practices not administering Tdap on-site should consider implementing on-site vaccines to increase vaccination rates for this vulnerable population of patients.

RQ2: What is the Structure and Process of Vaccine Programs in Obstetrical Practices?

The last time any information on the structure of obstetrical care in the U.S. was published was in 1989, with research by the Institute of Medicine's (IOM) Committee to Study Medical Professional Liability and the Delivery of Obstetrical Care. Quantifying and describing the larger population of OB practices in the U.S. is problematic because no current, easily compiled database of demographic information exists, which makes it difficult to compare certain aspects of the sample of practices in this study with a larger population of similar practices. It is unknown exactly how many OB practices exist, the type of communities in which they are located, how many of each type of facility there are (i.e., private, non-private, hospital-based, academic medical center, etc.), or how many of each type of provider works in them. Although organizations such as the American College of

Obstetricians and Gynecologists (ACOG) and the American College of Nurse-Midwives (ACNM) exist and can report how many physicians and CNMs are currently members, not all providers are members of such organizations; thus, a total count of practices derived from these sources would be an underestimation.

Antecedents of structure. Antecedents of structure are characteristics that describe the demography of an organization, what the organization is, where it is, and who it serves. These factors precede yet co-occur with the structure of an organization and help to define it.

Facility and provider characteristics. While the sample size in this study was small, it was composed of a fairly proportionate number of rural and urban/suburban settings with all types of health care professionals represented, potentially making it generalizable to the larger population of OB practices. In the 1980s, providers of obstetrical services were classified into only three categories: obstetrician-gynecologists, family physicians, and "other practitioners," including nurse-midwives and lay midwives (IOM, 1989). Physician assistants and general nurse practitioners were not mentioned in the IOM's publication, likely because they were not mainstream at the time. The findings of this STRATA study may indicate that the composition of providers has changed since then, as there are now many types of providers in the obstetrical field, including MDs, DOs, PAs, ARNPs, and CNMs; but again, this finding must be interpreted with caution due to potential lack of representativeness of the sample.

In the past, it was reported that most obstetrician-gynecologists worked in metropolitan areas (Institute of Medicine [IOM], 1989). Organized facilities, including hospitals, public health agencies, health maintenance organizations, the military, and university health services, employed most nurse-midwives, while the remaining nurse-

midwives worked in private practices operated by nurse-midwives themselves or physicians. Like physicians, most nurse-midwives worked in metropolitan areas. Today, PAs, ARNPs, and CNMs fill some of the gaps in access to care by providing services in rural areas (Ricketts, 2005). It is not uncommon, though, for physicians to work in rural areas as well. In that respect, this STRATA study may have revealed that the composition of providers across rural and urban/suburban locations is now more proportionate than it was in the past. Given the structure of our current health care system, it could be presumed this is the case across the U.S. and that such a distribution of providers is not isolated to the Midwest, but additional research is necessary to confirm this.

In the 1980s, most women received prenatal care in a private physician's office either from obstetrician-gynecologists or family/general physicians (IOM, 1989). Only 20% of OB care was provided in the outpatient departments of a public hospital, by community health centers, or by county health departments, and the patients who used those facilities tended to be low-income, African-American, or unmarried (Klerman & Scholle, 1988, as cited in IOM, 1989). The present study revealed that women continue to receive care in these settings, but the proportions may have changed, with the number of private practices and non-private practices affiliated with hospitals or health care systems being more proportionate today.

Patient characteristics. The CDC identifies women of childbearing age as those from 15 to 44 years of age. The practices surveyed in this STRATA study cared for women within this age range, with a majority of their patients in the range between 18 and 29 years of age, which is consistent with the age distribution of most pregnant women across the U.S. (March of Dimes, 2019).

Age. No surveyed practices reported providing care primarily to pregnant adolescents. The item on the questionnaire that collected this data may not have been formatted in the best way to collect this information, however. The question asked respondents to choose the age range of the pregnant patients for whom they primarily (most often) care, which narrowed the possible answer to only one range of ages. Although the number of adolescent pregnancies per year is less than adult pregnancies, it can be assumed that most OB practices have cared for a pregnant minor at one time or another. One respondent, in fact, commented that giving non-mandatory vaccines like Tdap to pregnant minors can be challenging because parental consent is necessary. The literature, meanwhile, shows that parental/guardian hesitancy influences vaccine receipt and that such vaccine hesitancy or refusal is often the result of limited or incorrect parental and adolescent knowledge or understanding of vaccines and vaccine safety (Roberts et al., 2015). No information exists on Tdap receipt among pregnant adolescents in particular or on how to handle parents who are resistant to vaccination; therefore, future research with this population may be warranted.

Race. Most of the practices surveyed in this study served primarily Caucasian women. Like the question about the age range of patients, the way this question was worded limited the possible response to only one race. Based on the limited data about race gathered in this study, though, facilities primarily serving African-American, Native American, Hispanic, and Asian women were under-represented. In vaccine research, the finding that African-American pregnant women are underrepresented is common. This study's integrative review, in fact, suggests that more research is needed on low rates of Tdap vaccination among pregnant African-American women, as they are less likely than any other race to receive the Tdap vaccine during pregnancy (Dempsey et al., 2015; Goldfarb et al., 2014;

Healy et al., 2015a, 2015b). There is also a need for additional research on vaccine receipt among minority populations overall.

Health insurance. Most of the practices in this study provided care to women who had some type of health insurance (either private insurance or Medicaid), which might explain why so many practices in the sample offered vaccines on-site. Strong associations exist between health insurance coverage and the receipt of preventive services like vaccinations (IOM, 2002). Health insurance coverage is also associated with better health outcomes, which are attributable to more, and more appropriate, uses of health services (IOM, 2002). One respondent surveyed in this study commented that a lack of reimbursement from health insurance for vaccine services was a barrier to that clinic having an on-site vaccine program. The health insurance utilization among a patient population may affect the financial resources available for some OB practices to purchase vaccines and the equipment necessary to administer them on-site. Practices with a higher rate of insured patients will likely have more patients accessing services, thus allowing those organizations to make more money from health insurance reimbursement, which may afford those practices the means to invest in vaccine programs. Future research into Tdap vaccine receipt by uninsured women versus insured women is recommended.

Disproportions exist between different regions of the U.S. in terms of uninsured women. All practices in this study were from the Midwest, and over half of the practices were located in Iowa. In 2017, only 5.5% of women in Iowa were uninsured, which is low compared to other states in the Midwest (March of Dimes, 2019). For example, in 2017, Nebraska had 12.4%, Missouri had 13.1%, and Kansas had 11.3% of women in those states uninsured. In 2017, Mississippi had 17.2%, Florida had 18%, and Maine had 11% of women

in those states uninsured. Overall, the Midwest appears to have lower rates of uninsured women than other regions of the U.S.; therefore, the sample from this study may not be representative of regions where uninsured rates are higher. Given that this study's sample of practices was predominantly from Iowa, which has one of the lowest rates of uninsured pregnant women in the country, caution should be taken when interpreting the relationship between patient insurance and on-site vaccine programs.

Structure of vaccine programs. Structure refers to the physical and organizational characteristics where care occurs.

Staff credentials and training. The findings of this study showed that it is not just nurses who administer vaccines, but also medical assistants, nurse practitioners, physician assistants, and physicians. According to the CDC's (2019) new toolkit, "Vaccine storage and handling practices are only as effective as the staff that implement them" (p. 6). Well-trained staff are essential to ensuring vaccine supply potency and patient safety (CDC, 2019). All staff who administer vaccines should be trained in vaccine-related practices and be familiar with their facility's standard operating procedures (SOPs). While 84% of practices in this study trained their staff on vaccine administration processes, only 68% trained them to assess vaccine history. Assessing a patient's vaccine history must precede administering vaccines; otherwise, patients may receive unnecessary vaccines or miss an opportunity for a necessary (e.g., Tdap or influenza) vaccine. The insufficiency in vaccine history training identified in this STRATA study suggests a need for facilities to evaluate their training processes, consider adding vaccine assessment as part of new employee orientation, and providing this training annually as a refresher for all staff involved in vaccine storage and handling activities (CDC, 2019).

Vaccine coordination and responsibilities. The CDC (2019) recommends that a primary vaccine coordinator be appointed at facilities to ensure that all vaccines are stored and handled correctly. This STRATA study found that most practices have a primary vaccine coordinator; however, some do not, and the absence of a primary vaccine coordinator could lead to inconsistencies in vaccine storage, handling, and administration. The overall make-up of responsibilities of vaccine coordinators in the sample varied, with some coordinators carrying out just a few of the responsibilities and others carrying out all responsibilities per the CDC's vaccine storage and handling toolkit. Obstetrical practices without a vaccine coordinator should consider the value of appointing one to serve as an expert in handling SOPs. Only 70% of the practices surveyed in this study had a secondary vaccine coordinator to support the primary coordinator, but the CDC recommends that all OB practices consider appointing a secondary coordinator when evaluating their vaccine programs.

Vaccine storage unit. In their 2018 and 2019 *Vaccine Storage and Handling Toolkit*, the CDC recommends that vaccines be stored in a purpose-built/pharmaceutical grade refrigerator because these are designed specifically for the storage of biologics, including vaccines. The temperature control in these units is more sensitive and precise than in standard refrigerators, and the fan-forced air circulation promotes uniform temperatures and fast temperature recovery. If such a purpose-built refrigerator is not available, the CDC (2019) concedes that a stand-alone household refrigerator can be used if the refrigerator compartment is used only for storing vaccines. The risk of using these types of storage units is that they can have cold spots and temperature fluctuations, and air circulating from the freezer compartment could expose refrigerated vaccines to temperatures that are too cold of (CDC, 2018).

Having a storage unit on-site increases the likelihood that a provider will offer most types of vaccines, including Tdap and influenza (Arao et al., 2015; NVAC, 2015). This STRATA study found that while 80% of practices have a vaccine storage unit on-site, only half of them used the preferred type of unit (a purpose-built refrigerator). About 30% used an acceptable unit (household refrigerator), while 20% used an unacceptable storage unit (dormitory/bar-style refrigerator). Practices using unacceptable storage units may not be aware that these units are unacceptable; therefore, more education is warranted. Practices without storage units should review CDC and ACOG recommendations for maternal vaccinations, evaluate their resources, and consider advocating the purchase of a storage unit.

Temperature monitoring device (TMD). Only half of OB practices that responded to the survey used the appropriate temperature monitor. An accurate temperature history is critical for protecting vaccines. The CDC (2019) recommends the use of a digital data logger (DDL) for continuous temperature monitoring and recording. Digital data loggers use a buffered temperature probe, which provides the most accurate storage unit temperature information, including information about how long a unit has been outside the recommended temperature range (CDC, 2018). Certain types of TMDs should never be used to measure vaccine storage unit temperatures because they only show the temperature at the exact time it is being checked and, thus, fail to detect temperatures that fall outside of the recommended range (CDC, 2018). Specifically, alcohol or mercury thermometers, bi-metal stem TMDs, food TMDs, chart recorders, and infrared TMDs should be avoided. Alcohol or mercury-based devices should never be used, even if they are placed in a fluid-filled biosafe liquid vial. Several practices in this study reported using unacceptable TMDs in their vaccine

storage units, especially alcohol/mercury-based devices. Given the insufficiencies found in TMD compliance in this study, additional education is again warranted.

Other vaccines on-site and referral elsewhere. Over 90% of the respondents to this study reported that their OB practices provide other vaccines on-site. This finding is reassuring because it shows the culture of obstetrics is changing. Earlier literature found issues with OB providers not believing that vaccines were their responsibility and rather that of the primary care provider (Bonville et al., 2015). Providers would either not mention the vaccines to their patients or would recommend the vaccine during a routine visit but tell the patient to go get it from their primary care provider or somewhere else because they do not give the vaccine on-site. The problem with this process is the patient may forget to do what was recommended. Additionally, the added step of having to make a separate appointment somewhere else and take the time to actually might detour some patients from following through. While there were a few practices in this study that did not provide Tdap on-site, all of them indicated they refer the patient elsewhere to either their primary care provider or an outpatient pharmacy. While not ideal for the reasons mentioned above, at least the vaccine is being recommended, which is better than no recommendation at all. With a majority of practices in this study providing Tdap and other vaccines on-site, findings suggest the obstetrical field is moving in the right direction of making vaccines everyone's responsibility in health care.

Vaccine standing orders. Standing order protocols remove a provider-influenced barrier to vaccination by taking provider attitudes and beliefs about Tdap out of the equation. As was found in the review of the literature, nurse-driven standing order protocols for vaccine administration are positively correlated with vaccine receipt (Healy et al., 2015b;

Zakarzewski et al., 2014). The results of this study indicated that only some OB practices surveyed (68%) used standing orders as part of their SOPs for vaccines, and of those that do use them, 91% included Tdap. The high rate of inclusion of Tdap in standing orders shows that Tdap is viewed as important in obstetrical care. Practices that do not have standing orders for vaccines might benefit from exploring the value and benefits they provide to patient outcomes and consider adding them to their SOPs.

Electronic medical records and alerts. Most practices in this study had an EMR, but less than half (33%) had vaccine alerts or pop-ups in the EMRs to prompt the user to assess a patient's vaccine history. The literature refers to this feature as a "hard stop" in the EMR, and it naturally increases vaccine receipt by reminding the clinician to assess the patient's vaccine history to identify any important vaccines for which the patient may be eligible (Chamberlain et al., 2015; Goldfarb et al., 2015; Healy et al., 2015b). Obstetrical practices should assess the capabilities of their EMR systems and consider adding this pop-up feature to avoid missed opportunities for vaccination and to increase receipt for all vaccines, not just Tdap.

Perceived barriers to on-site vaccines. Results from the last item on the STRATA questionnaire, which asked respondents to report perceived barriers to vaccination, gleaned data that is consistent with the existing literature. The broad themes could be categorized into the same three factors found in the literature review: patient, provider, and health system. Identified factors included fear of vaccine safety (patient), lack of knowledge about recommended vaccines (patient and provider), and cost and lack of availability of vaccines (health system). Several respondents indicated that the provider not prescribing, educating, or encouraging vaccination was a barrier to implementation. Previous studies have established

that a provider recommendation is the strongest predictor of vaccine receipt among pregnant women (Beel et al., 2013; Frew et al., 2014a; Gorman et al., 2012; Healy et al., 2015a; Henninger et al., 2015). While it was unsurprising that lack of a provider recommendation was reported as a perceived barrier, it is concerning that this barrier continues to exist despite the amount of published evidence indicating its importance and the need for change. These findings indicate that our work to change provider knowledge, attitudes, beliefs, and behaviors related to vaccines in obstetrical care is not finished.

RQ3: What Structural Factors are Antecedents to On-site Tdap Administration?

The main purpose of this STRATA study was to discover structural antecedents to on-site Tdap; therefore, statistical tests were conducted between the *outcome* of administering Tdap on-site and each of the aforementioned elements of *structure*. The results of this analysis suggest that several elements of structure are statistically significant antecedents to on-site Tdap administration. Those antecedents include administering other types of vaccines on-site, having a vaccine storage unit on-site, having an ARNP or PA delivering care, having standing orders in place for vaccine administration, and having staff who are trained to assess vaccine history.

The results of this study showed that providing any vaccines on-site increases the likelihood that Tdap will also be administered on-site. Having other vaccines available on-site likely means that a vaccine storage unit is present, and both factors (other vaccines and a storage unit on-site) are statistically significant antecedents of on-site Tdap availability. While a statistically significant relationship was not found between practices that provide Tdap on-site and those that provide the influenza vaccine on-site, a majority of practices surveyed provided these vaccines (91% influenza and 98% Tdap). The influenza and Tdap

vaccines are the two most important vaccines for pregnant women to receive because they are the only vaccines currently known to provide passive Tdap immunity to the infant during the first few months of life (Abu Raya et al., 2014; Hardy-Fairbanks et al., 2013; Healy et al., 2004; Healy et al., 2013; Vilajeliu et al., 2015). This finding could suggest that efforts to increase influenza vaccine receipt in pregnant women should be paired with Tdap efforts, or vice versa, rather than targeting only one vaccine with an intervention. Perhaps a focus on implementing vaccine programs that include both the Tdap and influenza vaccines would be more effective than programs targeting a single vaccine.

Another significant finding of this STRATA study is that practices with ARNPs and PAs are more likely to provide Tdap on-site compared to practices with physicians. Conversely, this study found that CNMs were not more likely to provide Tdap. This discrepancy may be due to the way that the study identified ARNPs and CNMs, with each having its own category of profession/credential. In reality, CNMs are actually ARNPs with special training in midwifery. This may have confused respondents when they were asked to choose between one and the other even though the credentials are inherently the same. Had ARNPs and CNMs been paired together in a single category, perhaps the relationship with on-site Tdap would have been statistically stronger. Nonetheless, the reasons for this difference between other types of providers and physicians have not been studied, and they warrant further investigation.

One reason for the differences in results between ARNPs and CNMs may be differing practice regulations in the states of the practices surveyed in this sample. State laws and regulations influence a nurse practitioner's scope of practice and allow ARNPs in some states more autonomy than in others. In some states, CNMs, although they are inherently ARNPs,

have different practice limitations than general nurse practitioners. An ancillary analysis was conducted to examine the distribution of ARNPs and CNMs in this study's sample. The analysis found most practices with ARNPs and CNMs were located in Iowa, followed by Nebraska.

According to the American College of Nurse Midwives (Kinzelman & Bushman, 2017), of the states sampled in this STRATA study, Iowa is the only state where CNMs can practice obstetrics autonomously. Nebraska requires a physician to supervise the midwife's practice, while Kansas and Missouri require midwives to have a collaborative agreement with a physician. Conversely, for general ARNPs, Iowa and Nebraska both allow an autonomous practice, while Kansas requires a collaborative agreement with a physician and Missouri requires physician supervision. These differences raise the question of whether autonomous ARNP practices are associated with greater vaccine receipt, compared to CNM practices. If the knowledge, attitudes, and beliefs about maternal vaccines differ between CNMs/ARNPs and physicians, it is possible that practice autonomy equates to higher influenza and Tdap vaccination rates. Regardless of these additional questions, these were important findings of this study in that practices with ARNPs and PAs are more likely to provide Tdap on-site compared to practices with physicians. The results of this STRATA study suggest that ARNPs and PAs may be leaders in maternal vaccine implementation, and reasons for this need to be identified and translated across professions and all OB practice settings.

On-site Tdap administration is associated with the presence of staff who are trained to assess vaccine history. This finding makes sense because if a patient's vaccine history is deliberately assessed during an OB visit, the intended outcome of such an assessment is to

identify and administer vaccines for which the patient may be eligible. For untrained personnel, the CDC's recommended vaccine schedule for adults might be confusing; if the patient is pregnant, this might create even more doubt, leading to missed vaccine opportunities. The findings of this study suggest that practices that train their nurses and medical assistants in how to assess a patient's vaccine history are more likely to administer Tdap on-site because the need for Tdap (and/or influenza) would result from a skilled assessment. In this same vein, practices with standing orders that allow nurses and medical assistants to administer certain vaccines without obtaining an order from the provider are associated with on-site Tdap administration. Practices that have a process for staff to assess a patient's vaccine history, determine whether Tdap is needed, and then seamlessly administer the vaccine without having to stop to involve the provider might have higher vaccination rates than practices without such standard operating procedures, but additional research is needed to test this hypothesis.

Limitations

A major limitation of this STRATA study was the low response rate, which yielded a small sample size, thus creating added problems with external validity, reliability, and generalizability. It is highly possible that practices that did not participate in this study did not provide Tdap vaccinations on-site. Nonresponse bias is often a problem with mail surveys (Dillman et al., 2008). Future research should attempt to control for nonresponse bias by utilizing other methods to collect survey responses, such as site visits, telephone surveys, and in-person interviews.

This study involved a cross-sectional survey of a purposive sample in one region of the U.S. A purposive sample is a non-probability sample, which threatens external validity

due to the potential for selection bias. The PI controlled for this threat by selecting all practices from the sample frame generated by the Wellmark Blue Cross Blue Shield provider search feature so that all practices had an equal chance of being selected for inclusion. Despite the generation of the Wellmark list of practices in real time, the sample frame was found to be somewhat outdated and to include some errors, as evidenced by the number of practices responding that they do not provide obstetrical care, mailings returned as undeliverable, and phone numbers that were no longer in service. Finding a more reliable sample frame would be a better approach in future studies. The sample of OB practices also lacked diversity in terms of location and patient characteristics. The practices in this study were all from the Midwest and they primarily served Caucasian women with health insurance. Future research in other regions of the U.S., with minority populations, and with uninsured women may glean different results than those revealed in this study.

Most of the data collected by the survey were nominal and categorical, which did not allow for the more robust statistical analyses required to make predictions and establish correlations. Future research with continuous variables related to structural antecedents would allow for other statistical tests, such as factor analysis, to determine whether particular groupings of factors predict administration of Tdap on-site.

Conclusion

The review of the literature concluded that further research was needed on the structural and logistical barriers to vaccine implementation in OB practices. This STRATA study aimed to address part of this need. The information in this study informs the science of vaccine implementation in obstetrical practices and contributes to the growing knowledge of barriers and facilitators to Tdap vaccine receipt among pregnant women. Several structural

factors within OB practices are antecedents of on-site Tdap vaccination, including administering other types of vaccines on-site, having a vaccine storage unit on-site, having an ARNP or PA delivering care, having standing orders for vaccine administration, and having staff trained to assess vaccine history. Some of the significant relationships between structural factors and on-site Tdap need to be interpreted cautiously due to this study's limited sample size, non-response bias, and lack of sample diversity.

Implications

Results of the STRATA study have important implications for nursing practice and policy. Given that vaccine administration is a common part of nursing practice, opportunities exist for nurses to take the lead in educating patients and providers about the importance of maternal vaccines. Assessing a patient's vaccine history is within the nurse's scope of practice. Since nurses are often the first person a patient encounters upon entering the exam room of an OB practice, it is important for nurses to educate themselves and other nurses on how to properly assess vaccine history. Nurses can also advocate for the acquisition of technology, necessary storage equipment, and standing orders or policies for vaccines, all of which would facilitate on-site vaccine administration.

Future Research

Future research should include a larger sample from other regions of the U.S. where the predominant race is not Caucasian and where there is a greater number of pregnant women without health insurance. Research involving pregnant adolescent-parental experiences with maternal vaccinations is also warranted because Tdap and influenza vaccination rates among this population are currently unknown. Data collected in future research would ideally be continuous rather than nominal to allow for more robust statistical

analyses (e.g. factor analysis, logistic regression, and analysis of variance). Use of such statistical tests could determine correlations and suggest causation between structural factors like standing orders, staff training, having other vaccines onsite, and provider credentials. Understanding which factors are the stronger predictors of onsite vaccination would be beneficial. Lastly, additional research comparing differences in vaccine knowledge, attitudes, beliefs, and practices of CNMs, ARNPs, PAs, and physicians would further contribute to the growing body of knowledge surrounding maternal vaccines and potentially improve implementation of vaccine programs in OB practices.

APPENDIX A

PARTICIPATION RECRUITMENT LETTER

UMKC School of Nursing and Health Studies

The STRATA Study

November 15, 2018

Dear Clinic Nurse Manager,

My name is Kristen Myers and I am a PhD in nursing student from the University of Missouri-Kansas City. I reside in Iowa and am a nursing professor at Grand View University in Des Moines. I am conducting an important public health study that could have a positive impact on obstetrical practices in the United States. The STRATA study is a survey of **Str**uctural **A**ntecedents of **T**dap **A**dministration in obstetrical practices in the Midwest.

It is unknown at this time if all obstetrical practices have the resources necessary to be able to administer Tdap on-site to pregnant women. The purpose of this survey is to help health care organizations, quality improvement organizations, vaccine coalitions, and obstetrical providers understand the current state of vaccine programs in obstetrical practices and identify structural and procedural barriers to administering Tdap on-site.

Your participation in this survey is voluntary and your answers will be anonymous. After submitting your survey, you will be taken to a separate form and asked to provide the address and zip code of your practice location. This is for completion tracking purposes only and your survey responses will *not* be connected to this information in any way.

The survey is available on the Internet and should take 10 minutes or less to complete. **Please accept the enclosed $2.00 as a token of appreciation in advance for your time and participation in this important study.**

Should you have any questions or concerns related to this survey, please contact me at kmpy8@mail.umkc.edu **or 515-708-3778.**

Kind Regards,

Kristen Myers MSN, RN

Kristen Myers, MSN/MPH, RN, CIC, CNE, CPH

Link to Internet Survey:

https://is.gd.stratastudy

APPENDIX B

STRATA QUESTIONNAIRE ADMINISTERED ON THE INTERNET

PART 1: SCREENING QUESTION TO DETERMINE ELIGIBILITY
The first question will be used to determine your eligibility to participate in this survey.

1. Does your facility provide obstetrical care to pregnant women?
    a. Yes
    b. No……*SKIP TO DISQUALIFICATION PAGE*

PART 2: DEMOGRAPHICS OF YOUR FACILITY
The next few questions will ask you about the general demographics of your facility.

2. In what city is your facility located? _____

3. What is the zip code of your facility? _____

4. What type of facility is your OB practice?
    a. Private, stand-alone clinic
    b. Private clinic, physically connected to or within a hospital
    c. Stand-alone clinic, affiliated with a hospital or health care system
    d. Clinic affiliated with and physically connected to or within a hospital
    e. County health department or clinic
    f. Academic medical center
    g. Other

5. What is your primary credential or position within your facility?
    a. Registered nurse - RN
    b. Licensed practical or vocational nurse - LPN/LVN
    c. Certified medical assistant - CMA
    d. Nurse practitioner - ARNP
    e. Physician – DO/MD
    f. Physician assistant - PA
    g. Pharmacist - PharmD
    h. Office assistant or secretary
    i. Scheduler
    j. Lab tech
    k. Phlebotomist
    l. Other

6. Which of the following healthcare professions work in your facility? Please select all that apply.
    a. Nurse - RN/LPN
    b. Medical assistant – CMA
    c. Physician – DO or MD

d. Physician assistant – PA
e. Nurse practitioner – ARNP
f. Nurse midwife – CNM
g. Midwife (non-nurse)

7. Approximately how many pregnant women does your facility serve each month?
   _____

8. Into which age group would you say most of your pregnant patients fall?
   a. Under 18
   b. 19-24
   c. 25-29
   d. 30-35
   e. Over 35

9. What race or ethnicity would you say most of your pregnant patients identify with?

   a. African American/Black
   b. Asian/Pacific Islander
   c. Caucasian/White
   d. Hispanic/Latino
   e. Native American/American Indian

10. Which type of insurance would you say most of your pregnant patients have?
    a. Private
    b. Medicaid
    c. Medicare
    d. No insurance

PART 3: VACCINE COORDINATION

The questions in this next section will ask about the vaccine coordination in your facility. These questions refer to ANY vaccines, not just Tdap.

11. Does your facility have a primary vaccine coordinator who is responsible for ensuring all vaccines are ordered, stored, and handled correctly?
    a. Yes
    b. No……*SKIP TO Q14*
    c. I am uncertain

12. What is the credential of the primary vaccine coordinator?
    a. Registered nurse – RN
    b. Licensed practical or vocational nurse – LPN/LVN
    c. Certified medical assistant – CMA
    d. Physician – DO/MD

e. Physician assistant – PA
f. Nurse practitioner – ARNP
g. Nurse midwife – CNM
h. Midwife (non-nurse)
i. Pharmacist – PharmD
j. Other (please specify) _____
k. I am uncertain

13. Does your facility have a secondary staff member to serve as an alternate in the absence of the primary vaccine coordinator?
    a. Yes
    b. No
    c. I am uncertain

14. What are the responsibilities of your facility's primary vaccine coordinator? (please select all that apply or select "p" if you are uncertain)
    a. Ordering vaccines
    b. Overseeing proper receipt and storage of vaccine deliveries
    c. Documenting vaccine delivery information
    d. Organizing vaccines within storage units
    e. Setting up temperature monitoring devices
    f. Reading and recording storage unit temperatures
    g. Reviewing and analyzing temperature data for any shifts in temperature trends
    h. Rotating stock
    i. Removing expired vaccines from storage units
    j. Responding to out-of-range temperatures
    k. Maintaining all documentation, such as inventory and temperature logs
    l. Ensuring staff is properly trained in vaccine storage, handling, and administration
    m. Monitoring operation of storage equipment and systems
    n. Overseeing proper vaccine storage transport
    o. Overseeing emergency preparations (tracking inclement weather and ensuring appropriate handling of vaccines during a disaster or power outage)
    p. I am uncertain

PART 4: PROCESS FOR VACCINE ADMINISTRATION

The next few questions will ask you about your facility's protocols for on-site vaccine administration. For the purposes of this survey, "on-site" refers to vaccine(s) being physically stored and administered in your facility, or, your facility is directly connected to or located within a hospital and you have immediate access to that facility's pharmacy where the vaccine is stored.

15. Have you or your medical staff received any education or training on how to assess patients' vaccine history?
    a. Yes

b. No

16. Have you or your medical staff received any education or training on vaccine administration processes in your facility?
    a. Yes
    b. No

17. Does your facility have a standing order protocol in place allowing a licensed staff member (RN, LPN, CMA, etc.) to administer vaccines without having to obtain an order each time from the provider? This question applies to ANY vaccines, not just Tdap.
    a. Yes
    b. No…….*SKIP TO Q17*

18. Does the standing order or protocol include the Tdap vaccine for pregnant women?
    a. Yes
    b. No

19. Does your facility use an electronic medical record for patient care?
    a. Yes
    b. No…….*SKIP TO Q19*

20. Does your facility have an alert or pop-up in the electronic medical record that prompts the medical staff to assess for and/or administer vaccines to pregnant patients? This question applies to ANY vaccines, not just Tdap
    a. Yes
    b. No…….*SKIP TO Q20*

21. Does the alert or pop-up in the electronic medical record include the Tdap vaccine for pregnant women?
    a. Yes
    b. No

PART 5: ON-SITE TDAP VACCINE ADMINISTRATION

The next few questions will ask you about your facility's on-site Tdap vaccine administration processes and practices.

22. Does your facility administer the Tdap vaccine on-site to pregnant women?
    a. Yes
    b. No……..*SKIP TO Q22*

23. Who in your facility administers the Tdap vaccine to pregnant women? (please select all that apply)
    a. Staff nurse or medical assistant…….*SKIP TO Q29*

b. Physician, nurse practitioner, nurse midwife, or physician assistant...*SKIP TO Q29*
c. Pharmacist……*SKIP TO Q29*
d. Other……*SKIP TO Q29*

24. Given that your facility does not administer the Tdap vaccine on-site, are pregnant women referred elsewhere to receive the vaccine?
    a. Yes
    b. No……..*SKIP TO Q29*
    c. I am uncertain

25. When pregnant women are referred elsewhere, where are they usually referred to? (please select all that apply or select "e" if you are uncertain)
    a. Primary care provider's office
    b. County health department
    c. Outpatient pharmacy (e.g. Walgreens, Wal-Mart, Target, Hy-Vee, Medicap)
    d. Other
    e. I am uncertain

26. To your knowledge, has your facility ever referred a pregnant woman elsewhere for the Tdap vaccine due to the provider's concerns about safety and/or efficacy of Tdap during pregnancy?
    a. Yes
    b. No
    c. I am uncertain

27. To your knowledge, has your facility ever referred a pregnant woman elsewhere for the Tdap vaccine due to lack of staff available to administer it?
    a. Yes
    b. No
    c. I am uncertain

28. To your knowledge, has your facility ever referred a pregnant woman elsewhere for the Tdap vaccine due to lack of time available to administer it during an appointment?
    a. Yes
    b. No
    c. I am uncertain

29. To your knowledge, has your facility ever referred a pregnant woman elsewhere for the Tdap vaccine due to insufficient quantity of vaccine available?
    a. Yes
    b. No
    c. I am uncertain

30. To your knowledge, has your facility ever needed to refer a pregnant woman elsewhere for the Tdap vaccine due to insufficient quantity of supplies necessary to administer the vaccine (needles, syringes, alcohol swabs)?
    a. Yes
    b. No
    c. I am uncertain

PART 6: OTHER VACCINES

The next question asks about other vaccines you may or may not store and administer on-site. Remember, for the purposes of this survey, "on-site" refers to vaccine(s) being physically stored and administered in your facility, or, your facility is directly connected to or located within a hospital and you have immediate access to that facility's pharmacy where the vaccine is stored.

31. Does your facility store and administer any other vaccines on-site?
    a. Yes
    b. No

32. Which vaccine(s) does your facility store and administer in-house? (please select all that apply)
    a. HepA
    b. HepB
    c. Hib
    d. HPV
    e. Influenza
    f. MMR
    g. MCV4
    h. MenB
    i. Pneumovax
    j. Td
    k. Tdap
    l. Shingles
    m. Varicella
    n. Other

PART 7: VACCINE STORAGE EQUIPMENT

This next section will ask questions about how your facility stores and handles vaccines. Remember, for the purposes of this survey, "on-site" refers to vaccine(s) being physically stored and administered in your facility, or, your facility is directly connected to or located within a hospital and you have immediate access to that facility's pharmacy where the vaccine is stored.

33. Does your facility have a vaccine storage unit on-site?
    a. Yes
    b. No……*SKIP TO Q37*

34. Which type(s) of vaccine storage unit do you have in your facility? Please select all that apply.
    a. Dormitory/bar-style
    b. Purpose built/pharmaceutical grade
    c. Stand-alone household – side by side
    d. Stand-alone household – top bottom
    e. I am uncertain

35. Does your facility use and maintain logs for storage unit maintenance and repairs?
    a. Yes
    b. No

36. Does your facility use a temperature monitoring device for your vaccine storage unit(s)?
    a. Yes
    b. No……*SKIP TO Q37*

37. Which type of temperature monitoring device(s) does your facility use in the vaccine storage unit?
    a. Alcohol or mercury thermometer (including those placed in a fluid-filled bio-safe liquid vial)
    b. Bi-metal stem temperature monitor
    c. Food temperature monitor/device
    d. Infrared temperature monitor/device
    e. Digital data logger
    f. Other
    g. I am uncertain

38. Does your facility use and maintain logs for monitoring and recording storage unit temperatures?
    a. Yes
    b. No
    c. I am uncertain

39. Does your facility use and maintain logs for temperature monitoring device maintenance and repairs?
    a. Yes
    b. No
    c. I am uncertain

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PART 8: IMPLEMENTATION BARRIERS

The last question is open-ended and asks you to share your perceptions of barriers to providing vaccines on-site. These questions refer to ANY vaccines, not just Tdap.

40. What do you believe are barriers to being able to provide vaccines on-site in obstetrical practices?

END OF SURVEY

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VITA

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