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An Assessment of the Role of Florida Pharmacists in the Administration of Inactivated Influenza Vaccine to Pregnant Women

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Assessment of the Role of Florida Pharmacists in the Administration of Inactivated Influenza
Vaccine to Pregnant Women

by

Oluyemisi O. Falope

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
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College of Public Health
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Dedication

To those in the past, present, & future working for elimination of Vaccine Preventable Diseases.

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Firstly, I would like to thank God, the hope that holds me, the stronghold to shelter me, and my great confidence. I thank Him for providing the wisdom, support system, and all I needed to accomplish this work. I would also like to thank several amazing individuals through which the completion of this dissertation was made possible.

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Abstract

Influenza vaccine is a safe and effective vaccine in preventing influenza infection in the general population. The Centers for Disease Control (CDC) recommend that pregnant women receive the influenza inactivated vaccine (IIV) due to the high morbidity and mortality associated with influenza infection in pregnant women. Despite the recommendation, the U.S. national influenza vaccine uptake rates among pregnant women continue to remain low. Studies have shown barriers to influenza vaccine uptake in pregnant women to include issues with access, unavailability of vaccine, and lack of time during prenatal visits. These barriers can be overcome using pharmacists because among healthcare providers, pharmacists are the most accessible; approximately 250 million individuals make a trip to the pharmacy every week, however, there are few qualitative studies on pharmacists' perspectives on the role they can play to increase influenza vaccine uptake in pregnant women. This study aims to qualitatively study explore: (a) The course content related to influenza immunization and how pharmacy students perceive it, and (b) Influenza vaccine administering practices among licensed pharmacists. The objectives will be achieved qualitatively through the use of in-depth interviews and focus groups. Exploration of pharmacy school curriculum revealed a need for pregnancy-specific immunization content. Qualitative interviews with licensed pharmacists revealed that most pharmacists believe they have a role to play in providing influenza immunization to pregnant women. This study suggests that systematically implementing more pregnancy-specific content into pharmacy school curricula would be effective in intervening with pharmacy students. Findings also indicate the need for continued education intervention with practicing pharmacists, as access to immunization services should not be mitigated by a lack of knowledge and personal beliefs.

Introduction

Purpose of the Study

Pregnancy is a unique immunological state, in which the immune system is modulated as a result of placental response and its tropism for specific pathogens and viruses. These affect the pregnant woman's susceptibility to certain infections (Mor & Cardenas, 2010). Research has shown an increase of about a four-fold in influenza antibody titers during pregnancy. (Mak, Mangtani, Leese, Watson, & Pfeifer, 2008). In between influenza epidemics, and during influenza pandemics, pregnant women are usually more susceptible to contracting influenza and its subsequent complications such as pneumonia, spontaneous abortions, preterm births, birth defects and fetal loss (Mak et al., 2008; Rasmussen, Jamieson, & Bresee, 2008). Usually the morbidity from influenza in this population is low, however during the influenza pandemics such as 1918, 1957, 2009 and other influenza outbreaks, there were high death rates in pregnant women (Callaghan, Chu, & Jamieson, 2010; Mak et al., 2008; Thompson et al., 2011).

During the 1918 influenza pandemic in the U.S., 27% of pregnant women died, also in the 1957 pandemic influenza, 20% of influenza-associated deaths occurred in pregnant women (Rasmussen et al., 2008). There is four times risk of hospitalization in pregnant women compared to the non-pregnant individual (Hamborsky, Kroger, & Wolfe, 2015). This increase in mortality during influenza pandemics is a significant cause for concern, thereby placing pregnant women as a priority group for recommending the inactivated influenza vaccine (IIV) (Callaghan et al., 2010; Thompson et al., 2011). Also, uptake of IIV during pregnancy has a two-fold

benefit, as it protects the mother and the baby for its first few months of life (Simonsen & Hayney, 2011). This protection for the baby is essential, as there is no licensed influenza vaccine for infants under six months of age, and also because, during influenza outbreaks, children experience the highest infection rates (Simonsen & Hayney, 2011).

The purpose of this study was to explore the role pharmacists can play to increase IIV uptake among pregnant women in Florida. Using the Theory of Planned Behavior (TPB), this study sought to explore and understand what pharmacy students are being taught regarding immunization with respect to pregnant women, and the day to day experiences of licensed pharmacists as they provide immunization services generally and with respect to pregnant women. In addition, the study examined pharmacy schools curricular to understand how the course content on immunization is being taught and what it entails. A qualitative analysis design, involving in-depth interviews with academic deans and licensed pharmacists, and focus groups with pharmacy students was employed to meet these objectives. The goal of this study was to create a set of recommendations to pharmacy schools and the department of health regarding pregnancy immunization content in pharmacy curriculum and advocate for additional avenues through which pregnant women can obtain IIV.

Background and Significance

Influenza in its epidemic form can cause mortality and morbidity in as much as twenty percent of the population in the United States. During the 2009/2010 flu pandemic, pregnancy was identified to be a risk factor for extreme cases influenza; among women aged 18-29, influenza-pregnancy related deaths occurred in about 16% and hospitalizations in 29% (Biggerstaff, Cauchemez, Reed, Gambhir, & Finelli, 2014; Memoli, Harvey, Morens, & Taubenberger, 2013). Influenza viruses are RNA viruses; there are three types namely, A, B, and

C, of which A and B are known to cause major seasonal outbreaks with associated illnesses and deaths (Cox & Subbarao, 2000). The Influenza viruses change regularly either through "antigenic drifts," which are minor points of mutation or through major "antigenic shifts," which are major points of mutation (Biggerstaff et al., 2014; Cox & Subbarao, 2000). These antigenic drifts and shifts can cause a new version or strain of the influenza virus to be introduced into the human population of which individuals are yet to receive the vaccine, causing epidemics and pandemics (Biggerstaff et al., 2014; Cox & Subbarao, 2000; Treanor, 2004). As a result of these changes, the pattern of new pandemics will be hard to predict (Biggerstaff et al., 2014). Influenza virus disease is the 8th leading cause of death in the U.S. and is responsible for influenza-related deaths in about 12,000-56,000 people (Arnold, Luong, Rebmann, & Chang, 2019).

Several groups of individuals are considered as high risk for major influenza illness and mortality, and they include pregnant women, children, adults aged 65 years or older, and individuals who have chronic conditions such as diabetes, immunodeficiencies, heart disease, obesity, and asthma. (Nowak, Sheedy, Bursey, Smith, & Basket, 2015). About 31 million individuals contacted the influenza virus disease in during the 2016/2017 influenza season, and about 50% visited a healthcare provider (Arnold et al., 2019). The economic cost of seasonal influenza in the United States is estimated to be about \$11 billion including direct medical costs of about 10 billion and missed workdays, and loss in productivity account for the bulk of the burden; these consequences emphasize how much influenza illness is a drain on the U.S. economy (Arnold, et al., 2019; Molinari et al., 2007; Nowak et al., 2015).

Influenza virus overview. The influenza virus is an RNA virus which depending on the annual genetic change and severity of the illness can be grouped as seasonal or pandemic. The influenza virus is transmitted through inhaling aerosols contaminated with the virus (Iwasaki &

Pillai, 2014). Influenza epidemics occur yearly all over the world. In the U.S. they cause significant comorbidities and deaths in about 20% of the U.S. population annually (Biggerstaff et al, 2014). The Influenza viruses change regularly either through "antigenic drifts," which are minor points mutations of through major "antigenic shifts" which are mayor points mutations (Biggerstaff et al., 2014; Cox & Subbarao, 2000). The pandemic strains of the virus, which occur every ten to twenty years, are as a result of the “antigenic shift”, while the “antigenic drift is responsible for the seasonal strain of the influenza virus (Iwasaki & Pillai, 2014). These antigenic drifts and shifts can cause a new version or strain of the influenza virus to be introduced into the human population of which individuals are not yet immune against hence, causing epidemics and pandemics (Biggerstaff et al., 2014; Cox & Subbarao, 2000; Treanor, 2004). As a result of these changes, the pattern of new pandemics will be hard to predict (Biggerstaff et al., 2014). Vaccines remain the best tool to prevent illness from the influenza virus (WHO, 2012).

Influenza vaccines. Inactivated influenza vaccines (IIV) have been licensed for use since 1945 in the United States (Fiore, Bridges, Katz, & Cox, 2012), while the live attenuated type was first made available in 2003 (Plotkin & Plotkin, 2013). The effectiveness of the seasonal influenza vaccine is reviewed periodically so the current circulating strain of the virus can be included when developing the vaccine (Weir & Gruber, 2016). The review process is coordinated worldwide by the World Health Organization (WHO) and it is based on updated surveillance data obtained every February for countries in the Northern Hemisphere. The report is sent to the respective countries where composition and formulation of the vaccines is undertaken pending approval of the regulating agencies, which is the FDA in the United States (U.S.) (Weir & Gruber, 2016).

In the U.S., the two types of influenza vaccines available are the live attenuated influenza vaccine (LAIV), and the inactivated influenza vaccine (IIV). The formulations include the quadrivalent influenza vaccines which contain A(H1N1), type A(H3N2), and two type B strains, while the trivalent contains type A(H1N1), type A(H3N2), and one type B strain (Hamborsky, Kroger, & Wolfe, 2015). The IIV is the only recommended for uptake in pregnant women (Hamborsky, Kroger, & Wolfe, 2015).

Influenza vaccination guidelines. The Advisory Committee on Immunization Practices (ACIP) recommends that all individuals 6 months or older receive the influenza vaccine, as it remains the most effective way to prevent influenza illness and its comorbidities (Lu et al., 2018). The CDC prioritizes influenza vaccination in several groups of individuals considered high risk or priority, and especially if vaccine shortage occurs. These individuals include children aged six months to fifty-nine months, people 50 years and older, pregnant women or women who plan get pregnant during the influenza season, health care personnel, residents of chronic care centers and nursing homes, people aged six months to 18 years on long term aspirin treatment who with the influenza illness can develop Reye syndrome, individuals who are Alaskan natives or American Indians, and contacts and caregivers of adults 50 and older and children younger than 5 years, with an important focus on children aged younger than 6 months (CDC, 2016a, 2016b). Other groups of individuals who are also considered as priority or high risk for major influenza illness and mortality, such as individuals who have chronic conditions such as diabetes, immunosuppression, obesity and, asthma (Nowak et al., 2015).

History of influenza vaccine recommendation in pregnant women. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) in 1997 added recommending the influenza vaccine for pregnant and breastfeeding women (Arden,

Izurieta, Fukuda, Cox, & Schonberger, 1998; CDC, 2003; Fiore et al., 2010). This was added to the influenza vaccine recommendation guideline following a study of the effect of influenza virus infection in pregnant women during seventeen interpandemic influenza infection seasons (Arden et al., 1998). It was documented that there is an associated increase in morbidity in pregnant women in their second and third trimesters; it was also concluded that one out of two hospitalizations or admissions in pregnant women could be avoided per 1000 women who get the influenza vaccine (Arden et al., 1998). The influenza vaccine remains the best way to prevent influenza illness among this population (Naleway, Smith, & Mullooly, 2006).

The American College of Obstetricians and Gynecologists (ACOG) in 2004 sent out a directive to all its members to use the ACIP recommendation that all pregnant women should receive the influenza vaccine (ACOG, 2004; Fiore et al., 2010; Thompson et al., 2011). The ACOG has the following recommendations regarding the annual inactivated influenza vaccine (IIV) uptake for pregnant women: (i) all pregnant women or women planning to be pregnant should receive the vaccine; (ii) healthcare providers should recommend, advocate and counsel pregnant women about the twofold benefits of the vaccine for them and their baby, and the safety of the vaccine; (iii) OB/GYNs should administer the vaccine to the women and also stock the vaccine; (iv) If OB/GYNs do not stock the vaccines, they should refer patients to other providers such as pharmacies or other healthcare providers; (v) OB/GYNs should ensure their staff receives the vaccine every year; (vi) Women with a history of allergy to eggs with reactions such as hives can receive the vaccine; (vii) Women with allergic reactions that are worse than hives should receive the vaccine on an inpatient or outpatient basis; (viii) Pregnant women with influenza-like illnesses should receive antiviral medication regardless of their vaccine status; and (ix) Pregnant women should receive post-exposure antiviral chemoprophylaxis once daily for ten

days, to avoid the morbidity associated with the infection (ACOG, 2018).

Table 1. Trends of Influenza vaccine uptake rates among pregnant women

Flu Season	Influenza Vaccine Uptake in Pregnant Women
2011-2012	44.0%
2012-2013	46.4%
2013-2014	52.2%
2014-2015	50.3%
2015-2016	49.9%
2016-2017	53.6%
2017-2018	35.6%

*CDC 2011-2018 data source

Despite the ACIP recommendations, IIV uptake remains suboptimal in pregnant women. As of November 2017, IIV uptake among pregnant women was 35.6% (CDC, 2017). Also, previous CDC influenza surveys show that the overall vaccine coverage in this population has been low (see Table 1). All these vaccination rates are much lower than the targeted 90% coverage proposed by the healthy people 2020 goals (Lu, Bridges, Euler, & Singleton, 2008; Plans-Rubió, 2012; Whitley & Monto, 2006; Xakellis, 2005).

According to ACOG, during pregnancy, a woman can receive basic level prenatal care from healthcare providers such as OBs, family physicians, advance-practice nurses, and certified nurse-midwives (American Academy of Pediatrics, & American College of Obstetricians and Gynecologists, 2002). While these women do not obtain prenatal care from pharmacists, they can when referred by prenatal health care providers, obtain the IIV at pharmacies. Pharmacists have been shown to be the first healthcare provider that is questioned on medication advice.

Literature, however, has shown that they usually do not feel equipped about providing

information to pregnant women and would instead refer them to their respective physicians (Samuel & Einarson, 2011).

Justification for the Study

Studies have shown barriers to IIV uptake in pregnant women to include concerns with safety for their unborn child and themselves; lack of awareness of the “two-fold” benefit of the vaccine; and women in their first or second trimester (Chamberlain et al., 2015; Meharry, Colson, Grizas, Stiller, & Vázquez, 2013; Wheelock et al., 2013). Other barriers to influenza vaccine uptake in this population include access, lack of time, distance to care centers, lack of transportation to a health care center, and lack of availability of influenza vaccine at providers’ office (Arao, Rosenberg, McWeeney, & Hedberg, 2015; Healy, Rench, Montesinos, Ng, & Swaim, 2015; Meharry et al., 2013).

Among providers, reasons for low IIV uptake in pregnant women included insufficient time during prenatal visits, allergic reaction to the vaccine, and their lack of knowledge about the vaccines (Healy et al., 2015). Providers also reported that the prior beliefs held by the women, their lack of enthusiasm when recommending the vaccine and insufficient time to explain the benefits of the vaccine during visits are some reasons for low influenza vaccine uptake in pregnant women (Arao et al., 2015). A study by Wallis et al. reported that obstetric practices had lower influenza vaccination rates versus family physicians, and larger health (group practices vs. private/solo practices) care centers had lower vaccine recommendation rates (Wallis, Chin, Sur, & Lee, 2006). Some healthcare workers also reported a non-belief in the safety and effectiveness of the IIV in pregnant (Broughton, Beigi, Switzer, Raker, & Anderson, 2009).

Additionally, several interventions have been developed to improve influenza vaccine uptake (Odone et al., 2015). Most influenza vaccine intervention studies have focused on vaccine

campaigns, computerized reminders, the use of text message reminders, social networks, and web-based portals, and a few of these interventions have focused on pregnant women (Odone et al., 2015). This serves as a potential limitation, as pregnant women encounter other barriers that are not the same as the general population such as concerns with the baby and issues with access, such as unavailability of the vaccine at the healthcare providers clinic during an initial visit, and a failure of a provider to recommend or prescribe the vaccine in subsequent visits (Arao et al., 2015; Healy et al., 2015; Meharry et al., 2013).

Community-level determinants of vaccine uptake in pregnant women, which include transportation issues (Beel et al., 2013; Healy et al., 2015), distance from the clinic (Ballas et al., 2015; Beel et al., 2013) will be classified as problems with access to the vaccine. Problems with access, lack of availability of the vaccine at care providers clinic, and lack of time during visits from providers' perspective are barriers that can be overcome using community pharmacies. Individuals have access to community pharmacies over more extended hours and days (Grabenstein, 1998; Steyer, Ragucci, Pearson, & Mainous III, 2004). The study by Steyer et al. showed that in states that allowed pharmacists to administer immunization, the vaccine rate increased significantly in adults between the ages of 18-64 years. Among health care providers, pharmacists are the most accessible, as approximately 250 million individuals make a trip to the pharmacy every week (Steyer et al., 2004). In the year 2000, the ACIP recommended standing order programs, which authorize pharmacists and nurses to administer vaccines to adults ((McKibben, Stange, Sneller, Strikas, & Rodewald, 2000). This recommendation followed studies that demonstrated that having nurses and pharmacists administer vaccines improved vaccination rates in adult populations. Implementation of programs such as this helps to take the pressure off physicians and increase adult vaccine coverage (McKibben et al., 2000).

Some studies have identified gaps and barriers in the role of pharmacists in administering and offering vaccines, and gaps have also been identified among pharmacy students. A study by Bain and Cullison (2009) reported that only about 38% of U.S pharmacy schools have immunization lectures and training as part of their core curricula (Bain & Cullison, 2009). Recent studies, however, report that almost all pharmacy schools in the U.S. provide a form of instruction on immunization (Prescott & Bernhardt, 2019). It is unclear, however, if it provides information specific to pregnant women. Several studies have identified various barriers to pharmacists administering vaccines in general, and they include; not being immunization certified, legal liability, inadequate training, lack of time, and lack of support from staff and management, (Burson et al., 2016; Neuhauser et al., 2004; Pace et al., 2010). Other barriers identified include lack of acceptance by the public, lack of a compensation structure from insurance companies, and lack of clarity of roles with other health professionals (Goad & Durham, 2013).

With regards to administering the influenza vaccines to pregnant women, a study showed that majority of pharmacists were less likely to believe they had an important role in administering inactivated influenza vaccines to pregnant women, compared to the general public (Dolan et al., 2012). There are few studies that try to qualitatively explore the role pharmacists play in administering vaccines, especially from the perspective of the pharmacists themselves. Some studies have qualitatively explored the perceptions of the community and other health care personnel on the role pharmacists have played, but no studies available exploring the pharmacist's perspective (Blake, Blair, & Couchenour, 2003). A quantitative study by Dolan et al (2012), assessed pharmacists' knowledge attitudes and practice as it relates to treatment and vaccination of pregnant women during the 2009 influenza virus pandemic. They reported that

pharmacists did not believe they had an important role in administering inactivated influenza vaccines to pregnant women (Dolan et al., 2012). The study, however, aims to explore the role pharmacists play in inactivated influenza vaccine administration in pregnant women practice, and this will be carried out qualitatively. This study attempts to fill these gaps by investigating and exploring the course content in pharmacy schools in Florida and also explore the perceptions of licensed Florida pharmacists about their role in offering and administering inactivated influenza vaccines to pregnant women. According to a study by Kennedy et al., the state of Florida had a 21.6% IIV coverage among pregnant women during the 2009-2010 influenza season, and it also ranked the lowest among the states studied (Kennedy et al., 2012). For this reason, the study will be carried out in Florida.

Public Health Significance

The next step in the research course for improving IIV uptake among pregnant women is innovative and important, as it seeks to understand the role pharmacists can play in increasing accessibility of the influenza vaccines in pregnant women. This formative research will contribute to future research and the development of interventions aimed to increase IIV uptake rates among pregnant women. Additionally, this research responds to several national research priorities. The American College of Obstetricians and Gynecologists calls for more efforts to improve the rate of IIV uptake among pregnant women (ACOG, 2018). The Centers for Disease Control and Prevention (CDC) also calls for implementation of “standing orders” for vaccination to increase IIV uptake in pregnant women (Ding et al., 2017). This research also addresses the Healthy People 2020 goal of increasing the coverage of IIV among pregnant women to 90% coverage annually (Lu, Bridges, Euler, & Singleton, 2008).

Finally, this research is relevant to the call for how pharmacists can improve preventive

healthcare services and help address the shortage of primary care providers in the United States (Manolakis & Skelton, 2010). Therefore, it is important to understand the perceptions of pharmacists when it comes to administering IIV in pregnant women. The influenza vaccine uptake rate in this population remains suboptimal, exploring the role of pharmacists is important as this problem still persists.

Research Design

The long-term goal is to increase IIV uptake rates in pregnant women, ultimately increasing protection for pregnant women and their fetuses during influenza outbreaks. The design of this study focused primarily on the role of pharmacists in increasing IIV among pregnant women through a qualitative process. However, to understand the bigger picture regarding influenza vaccine administration practices among pharmacists in the state of Florida, an additional qualitative assessment of pharmacy school curricular and pharmacy students learning content regarding such practices were carried out. The study was conducted qualitatively using both in-depth interviews and focus groups. Thus, the scope of the study was expanded beyond understanding the perceptions of licensed pharmacists, in order to assess pharmacy education and how it may enhance or limit the role of pharmacists. For the study, both aspects of the qualitative analysis will be conducted concurrently, the pharmacy school's curricular analysis provides a supportive role for the overall aim of the study.

Specific aims and research questions. This study has two purposes: Firstly, the course content related to influenza immunization and how pharmacy students perceive it will be assessed. Secondly, the influenza vaccine administering practices among licensed pharmacists will be explored. The objectives will be achieved through the following specific aims, using in-depth interviews and focus groups. This study used the Theory of Planned Behavior (TPB)

approach for study design by informing the interview guide development for both pharmacists and pharmacy students.

1. Aim 1a: To understand how the course content of the six accredited schools of pharmacy in Florida is taught regarding vaccine administration in pregnant women, with a focus on inactivated influenza vaccine (IIV).

Research Questions

a.) What courses and lectures regarding influenza vaccine administration, in general, are provided in the required courses of the accredited schools of pharmacy in Florida?

b.) What courses and lectures regarding IIV administration in pregnant women are provided in the required courses of the accredited schools of pharmacy in Florida?

2. Aim 1b: To understand how 3rd and 4th-year pharmacy students perceive vaccine administration course content regarding vaccine administration in pregnant women, with a focus on IIV.

Research Questions

a.) What did pharmacy students learn about the inactivated influenza vaccine (IIV) administration in pregnant women in their pharmacy school classes?

b.) What are the projected practices of IIV administration in pregnant women practices among pharmacy students after graduation?

3. Aim 2: To explore the knowledge, attitudes, social factors, affect, and facilitating conditions that influence IIV in pregnant women administration practices among licensed pharmacists.

Research Questions

- a.) How does knowledge affect the inactivated influenza vaccine (IIV) administration in pregnant women practices among licensed pharmacists in Florida?
- b.) How do attitudes affect the inactivated influenza vaccine (IIV) administration in pregnant women practices among licensed pharmacists in Florida?
- c.) How social factors affect inactivated influenza (IIV) vaccine administration in pregnant women practices among licensed pharmacists in Florida?
- d.) How does perceived control affect the inactivated influenza vaccine (IIV) administration in pregnant women practices among licensed pharmacists in Florida?

Overview of Methods. To achieve these specific aims, a qualitative study design will be conducted. For the first aim which has two components: (a) in-depth key informant interviews were conducted with the six academic deans in the accredited pharmacy schools in the state of Florida, and (b) three focus group sessions with about 2-8 participants was conducted with 3rd and 4th year pharmacy students in three Florida schools. For the second aim, in-depth interviews were conducted with licensed pharmacists in Florida with a sample size of 18 stratified by the type of pharmacist's workplace, such as community vs clinical. The research questions as informed by the TPB were designed to be open-ended, to allow the participants to describe their personal opinions, experiences, and perceptions regarding inactivated influenza vaccine administration in pregnant women practices. Interview participants were recruited through emails (academic deans), and flyers for licensed pharmacists and pharmacy students. All 6 academic deans of the accredited pharmacy schools in Florida, and 18 licensed pharmacists out of the 28 that were recruited, participated in in-depth interviews, and 3 focus groups with

pharmacy students (n=18) were conducted. Interviews were digitally recorded and transcribed verbatim, and a second coder independently coded the majority of interviews.

Implications

Findings from this formative research will inform a quantitative survey utilizing the TPB theory to expand this research to a larger sample of pharmacists and increase the generalizability. Moreover, it will inform campaign messages for pregnant women to obtain the IIV from the pharmacy, giving the pharmacists more credibility to perform this function and ultimately improving IIV uptake among pregnant women. Future theory-based interventions developed from these findings will utilize the TPB theory approach for designing strategies to increase the implementation of guidelines (Francis et al., 2004). Moreover, future research should triangulate the findings from this study among pharmacists with pregnant women, and also with physicians and other health care providers that attend to pregnant women. While previous research indicates patients and sometimes providers do not view pharmacists as qualified providers of immunization services (Blake, Blair, & Couchenour, 2003), an understanding of how this bias occurs, and the barriers that may be needed to overcome them is required.

This study has the potential to advance public health practice and theoretical methodology. Azjen in 1985 proposed the use of TPB to understand determinants for intention to engage in a behavior, based on its constructs; attitudes, subjective norms, and perceived behavioral control (Glanz et al., 2008). Previous research has been conducted using the TPB to predict pharmacist's intention to provide medication disposal education (Tai, Hata, Wu, Frausto, & Law, 2016), and this study uses it to predict pharmacists behavior in administering IIV in pregnant women, and also providing education to pregnant women regarding the vaccine. Therefore, there is the potential to expand the utility and application of TPB theory to other

health care professionals and new procedures.

Definition of Key Terms

Vaccine uptake. Is a situation where vaccines are made accessible to individuals, and the individuals accept the vaccines (Thomson, Robinson, & Vallée-Tourangeau, 2016). Vaccine uptake continues to be suboptimal and the reasons for this are context-dependent and complex and are much broader than just accessibility and acceptance (Gargano et al., 2011; Thomson et al., 2016). There are several determinants of vaccine uptake and they include, access, affordability, acceptance, activation, and awareness (Thomson et al., 2016). Acceptance is the degree to which persons refuse, accept or question the vaccine, and it is influenced by factors such as, perceived efficacy, perceived severity, health beliefs, past behavior, social norms, and health care provider influence (Halliday, Thomson, Roberts, Bowen, & Mead, 2003; Thomson et al., 2016). Activation is the degree to which persons are coerced to take a vaccine. It is influenced by factors such as workplace policies and reminders and prompts (Halliday et al., 2003; Thomson et al., 2016). Awareness is the degree to which persons know the recommendation for, availability of and the need for vaccines alongside their perception of the risks and benefits (Thomson et al., 2016). This is influenced by factors such as lack of knowledge about the vaccine, and vaccine schedule, also, poor education (Thomson et al., 2016; Zhang, While, & Norman, 2011).

Several studies have shown a positive influence of health care provider recommendation and sometimes administration on vaccine uptake (Ding et al., 2017; Rosenthal et al., 2011; Wiley et al., 2013; Ylitalo, Lee, & Mehta, 2013). The study by Ding et al (2017), also reported that among the 1893 pregnant women surveyed, 67.3% of women received both the inactivated influenza vaccine IIV recommendation and offer by their physicians, the uptake or coverage rate

among them was 70.5%. About 12% of the women received influenza vaccine recommendation but no offer, and the vaccine uptake or coverage rate among them was 43.7% (Ding et al., 2017). Based on these, for this study, healthcare provider recommendation will not be treated as a factor influencing acceptance. Instead, it will be treated as a factor directly affecting vaccine uptake. Hence, for this study, vaccine uptake will be defined as a situation where vaccines are available, healthcare providers recommend the vaccine and individuals accept the vaccine (figure 1).

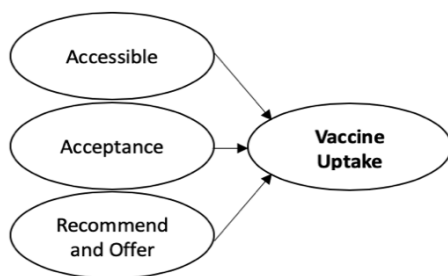


Figure 1. Diagram of modified definition of vaccine uptake as applied to the study.

Vaccine hesitancy. This can broadly be defined as arousal or delay in receipt of vaccines despite the availability of immunization services. It is multifaceted and context-specific, varying across time, place and vaccines, and is influenced by factors such as (i) confidence, which is when individuals do not trust the provider or the vaccine, (ii) convenience, which has to do with access, and (iii) complacency, which has to do with individuals not perceiving the need for the vaccine (Larson, Jarrett, Eckersberger, Smith, & Paterson, 2014; MacDonald, 2015). There are three determinants of vaccine hesitancy namely, contextual factors, individual and group influences, and vaccine and vaccination specific issues (Larson et al., 2014).

Herd Immunity. The term herd immunity has been defined in various ways by different authors and researchers. It was defined in the Dorland’s illustrated medical dictionary as “the resistance of a group to attack by a disease because of the immunity of a large proportion of the

members and the consequent lessening of the likelihood of an affected individual coming into contact with a susceptible individual" (John & Samuel, 2000; Saunders, 1994). It can also be defined as "Immunity to the unimmunized individuals by the secondary spread of the attenuated viruses or bacteria in the vaccine" (Paul, 2010). Other benefits vaccines have on the community that is similar to herd immunity include herd protection and herd effect, and they have been used interchangeably in various studies (John & Samuel, 2000; Paul, 2010).

One of the limitations of the herd immunity is that it is not a naturally acquired type of immunity, which makes individuals protected by the indirect herd effect to be completely susceptible to the infection when exposure occurs (Fine, Eames, & Heymann, 2011). An example was the 1993 congenital rubella epidemic that occurred in Greece and affected pregnant women and their fetuses (Panagiotopoulos, Berger, & Valassi-Adam, 1999). It was caused by delays in unvaccinated individuals coming down with the infection as a consequence of herd immunity from MMR which is a live vaccine. Pregnant women are at risk for coming down with these vaccine-preventable illnesses when they do not receive the vaccine or have been exposed to the wild virus. Hence, there is a need to increase vaccine coverage in such populations (Fine et al., 2011).

Conceptual Framework

There usually exists a gap between research evidence and day to day practice among healthcare providers. Several factors can affect clinical behavior adoption among healthcare providers such as individual level, organizational level, political level and economic factors (Grol & Wensing, 2004). Usually, individual decision making is key to adopting a behavior (Knabe, 2012). To achieve the best possible outcomes for individuals to adopt a behavior (pharmacists for this study), it is essential to design interventions that target or improve behavior

change. For this study it is hypothesized that if pharmacists intend to administer inactivated influenza vaccines to pregnant women, then they will have positive attitudes towards administering the influenza vaccine to pregnant women, they will perceive important individuals think they should administer the vaccine, and their perceived control over this action will increase. Based on this rationale the theory of planned behavior is going to be used as the conceptual framework for the study.

Theory of planned behavior overview. The Theory of Planned Behavior (TPB) is an intrapersonal level theory that has been extensively used in various types of health research that show reasons that can envisage why an individual would or would not engage in a behavior (Glanz et al., 2008). Central to this theory is an individual's intention regarding a specific planned behavior and the theory posits that behavioral intention is the best predictor of behavior. Furthermore, it is believed that determinants of this intention are behavioral attitudes, social norms surrounding the behavior, and the perceived behavioral control regarding the behavior (Glanz et al., 2008, pp 68).

Theoretical underpinnings. Icek Ajzen first described TPB in 1985; it is an expansion of the Theory of Reasoned Action (TRA), which was developed earlier by Ajzen and Fishbein (Ajzen & Fishbein, 1980). TRA assumes that individuals are rational and make informed choices based on the information they have available. The TRA assumes that individuals contemplate the repercussions of their actions before they make decisions regarding performing a behavior or not (Ajzen & Fishbein, 1980). The TRA has two constructs; subjective norms and attitudes, however, the effect of these factors in influencing an individual's intention differs from person to person (Ajzen & Fishbein, 1980). TRA was developed to explain volitional behaviors, while TPB was developed to include actions that are not entirely volitional. The TPB has an added

construct, perceived behavioral control (Ajzen & Fishbein, 1980; Glanz et al., 2008), and was developed to resolve the shortcomings involving the fact that behaviors are not entirely volitional that were identified by the originators through their research (Glanz et al., 2008; Montano & Kasprzyk, 2015). The TPB includes three determinants for intention to engage in a behavior: attitudes, subjective norms, and perceived behavioral control (see Table 2 for the description of each construct and sub-construct and an example application to inactivated influenza vaccine administration by pharmacists to pregnant women).

TPB application to pharmacists providing medication disposal education. As previously stated, the TPB was initially developed as a behavioral framework to predict if an individual intends to participate in an activity. To predict their intention, it is essential to know if they are in favor of engaging in the activity (attitude), the effect of the social pressure they feel (subjective norm), and if the person feels they are in control of the activity in question (perceived behavioral control) (Francis et al., 2004). Previous research has been conducted using the TPB to predict pharmacist's intention to provide medication disposal education (Tai, Hata, Wu, Frausto, & Law, 2016). Using this theory, Tai et al. (2016), posited that pharmacists would have a favorable attitude, social norm, and perceived behavioral control, which would increase their intention to provide medication disposal information.

Regarding attitude, most pharmacists were comfortable in providing medication disposal education to patients. However, 40% of them felt providing the education would lead to an increase in their workload. For subjective norm, most pharmacists believed that other health professionals and patients would be okay with them providing medication disposal education. Lastly, for perceived behavioral control, most pharmacists indicated that they would be able to keep themselves updated with required rules and regulations and would have sufficient time to

provide medication disposal education (Tai et al., 2016). The authors of this study highlighted the unique structure of the TPB theory constructs for pharmacists providing medication disposal education to patients, and they were able to identify shortcomings in pharmacists providing the education. These shortcomings, such as the increase in workload should be targeted when developing interventions (Tai et al., 2016). Moreover, the findings from this study have implications for this study. All three constructs report heuristic beliefs, individual influences, and influences from other healthcare providers and patients that translate for the pharmacist's role in administering inactivated influenza vaccines to pregnant women. The results of this study were applied in using the TPB constructs to develop the in-depth interview and focus group guide instrument for the study. For healthcare professionals, the TPB is a useful tool when designing strategies to assist in increasing the implementation of guidelines (Francis et al., 2004).

TPB theory application to the study. The TPB theory applies to this study because it provides a potential framework for the study as it can be used to study or understand the role pharmacists can play in inactivated influenza vaccine administration in pregnant women practices. TPB addresses the problem with partial volitional control (Ajzen, 2002). The three constructs of the TPB have a direct positive relationship. The more the attitude and subjective norms to engage in a specific practice become favorable, the more the perceived behavioral control, and the intention to participate in the behavior increases (Ajzen, 1991, 2002).

There are motivational implications for intentions with perceived control, in which individuals who do not have the opportunity and means to engage in a behavior will not likely have a strong intention regardless of their attitudes or norms (Ajzen, 1991). Perceived control also can directly predict behavior or as an alternative measure of control (figure 2). Perceived control as a determinant of intention is especially relevant to the study because a pharmacists'

ability for inactivated influenza vaccine administration to pregnant women may vary based on the perceived difficulty or ease of offering and administering the vaccine. That is, vaccine administering practices of pharmacists may not be under their volitional control. For example, if a pharmacist is not comfortable administering the inactivated influenza vaccine to a pregnant woman and does not want to give the vaccine but perceives that if she or he refuses that they may be fired or reprimanded, the pharmacists may decide to administer the vaccine anyway. For the purposed study, however, the theory will be modified to include “knowledge” as one of the constructs to be tested (Table 2). This is to account for the fact that subjective norm has been considered to be a weak predictor of intention (Knabe, 2012). Though the theory does not include knowledge as a predictor of behavior, in his work, Ajzen noted that "at the most basic level of explanation, behavior is assumed to be a function of salient information, or beliefs, relevant to the behavior” (Dwivedi, Wade, & Schneberger, 2011). Several studies that have applied the use of TPB has found it to be useful in predicting intention (Knabe, 2012).

Table 2. Modified TPB Model Constructs Application to Study

Construct and Subconstructs	Definition	Application
Attitude i. behavioral belief ii. evaluation	A Person's belief regarding performing a behavior The notion that doing a particular thing has specific outcomes The value associated with behavioral outcome	Information on what pharmacist feel about how beneficial administering influenza vaccines to pregnant women is, and how comfortable they feel regarding administering the influenza vaccines to pregnant women (their favorable/unfavorable disposition towards doing the behavior)

Table 2 Continued

Subjective norms i. normative beliefs	Notions of how certain individuals view and approve or disapprove of performing a behavior A Person's engagement in a particular action if they feel people close to them think they should	Information on how other healthcare providers, and pregnant women attitudes towards pharmacists can influence administering influenza vaccines to pregnant women
ii. motivation to comply	Motivation to engage in practice based on what the individual thinks	
Perceived control	How much a person feels that engaging or not engaging in a behavior is under their volitional control	Information on how much control pharmacists think they have as regards to administering influenza vaccines in pregnant women
Knowledge	Theoretical or practical understanding of a subject	Information on pharmacist's general knowledge of influenza vaccines, especially as it relates to pregnant women

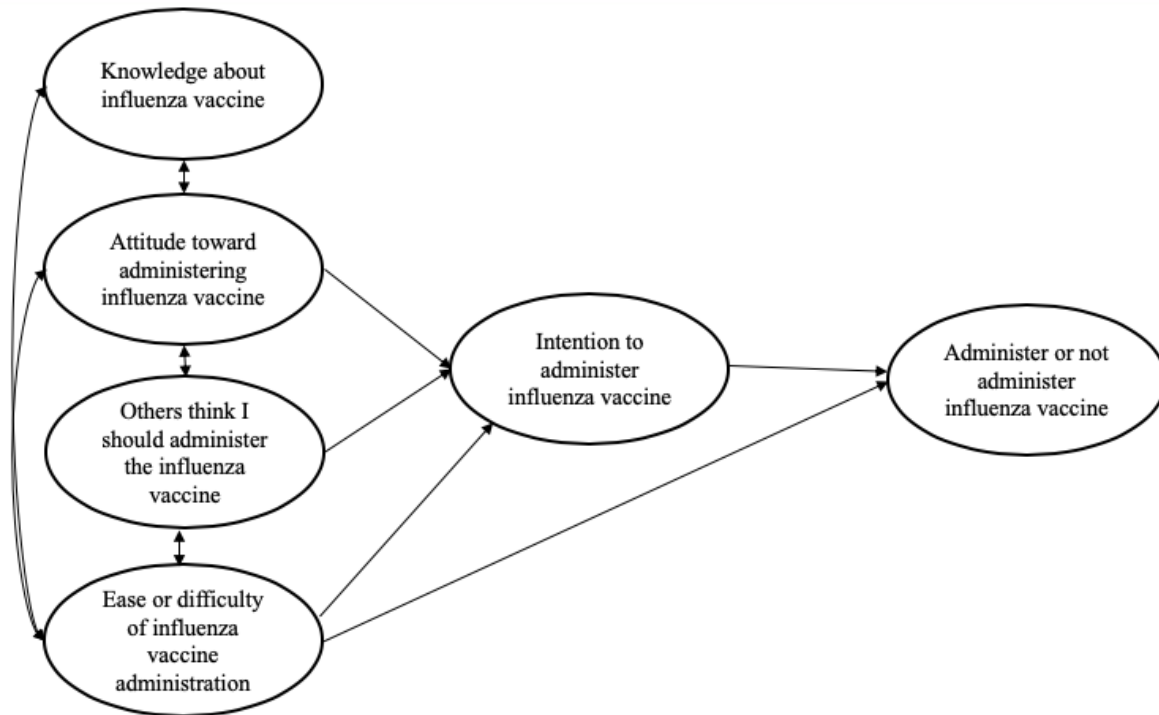


Figure 2. Diagram of the modified Theory of Planned Behavior applied to the study.

Criteria for the theory. According to Glanz et al., for a theory to be regarded as suitable for use in a research study, it should have (i) internal consistency, which refers to the idea

assumptions that a theory must be logically consistent and not be contradictory; (ii) parsimony, which refers to the simplicity of the concept the theory aims to measure, it should be generally relevant as it is using a controllable sum of concepts; and (iii) plausibility, which refers to the theory fitting in a reasonable way with other current theories (Cramer, 2013; Glanz et al., 2008). Other criteria to judge the utility and validity of a theory include (iv) comprehensiveness, which refers to a theory encompassing a broader scope to explain a phenomenon (Cramer, 2013), (v) precision and testability, which refers to a theory having constructs that are well defined, closely interrelated, and are readily open to valid measurements, and (vii) applied value, which is the extent to which a theory can offer practical solutions to life's problems (Cramer, 2013). The TPB meets all the criteria and is appropriate to guide the research.

In summary, the TPB is the most appropriate theoretical framework for guiding the research to understand the reasons why pharmacists may or may not want to administer inactivated influenza vaccine to pregnant women, and the reasons for why this behavior may or may not be favorable to them. This modified theory comprises of knowledge, attitudes, social norms and perceived behavioral control factors that can be applied to this research. In order to keep pregnant women and her baby healthy during the influenza season, and to promote vaccine uptake behaviors in these women, uptake of the influenza vaccine reduces the risk of developing the influenza illness and its subsequent complication (Simonsen & Hayney, 2011). Thus, it is necessary to understand ways we can close the gaps of vaccine accessibility using pharmacists. In addition, it is important to understand how pharmacists perceive themselves to act in this role.

Manuscripts

This study was designed to explore the role of pharmacists in increasing influenza vaccine uptake in pregnant women. The results of this study are presented in two separate

manuscripts. As described above, to get a better understanding of what is going on with influenza vaccine teaching and practice in pharmacy schools and among licensed pharmacists respectively in the state of Florida, two manuscripts were developed as follows:

- 1) “An Assessment of Pharmacy School Curricula in Florida on Influenza Vaccine Administration to Pregnant Women”. This manuscript addresses Research Aim 1a and b, and their associated research questions.
- 2) “The Role of Pharmacists in Administering Inactivated Influenza Vaccines to Pregnant Women. This manuscript addressed Research Aim 2, and its associated research questions.
- 3) Community-pharmacist-led inactivated influenza vaccine administration in pregnant women in the United States. This manuscript provides a theoretical concept of physician-pharmacists partnership as emerged from the results of Aims 1 and 2.

Conclusion

In order to keep pregnant women and her baby healthy during the influenza season, and to promote vaccine uptake behaviors in these women, uptake of the influenza vaccine reduces the risk of developing the influenza illness and its subsequent complication (Simonsen & Hayney, 2011). Thus, it is necessary to understand ways we can close the gaps of vaccine accessibility using pharmacists. In addition, it is important to understand how pharmacist perceive themselves to act in this role.

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Manuscript 1: An Assessment of Pharmacy School Curricula in Florida regarding Inactivated Influenza Vaccine Administration to Pregnant Women

Abstract

Background: There is a high risk for morbidity and even mortality in pregnant women as a result of the influenza virus illness. Vaccine uptake rates remain lower than the targeted Healthy People 2020 goals despite recommendations from the CDC. Few studies have examined the role of the pharmacist in providing immunization services to pregnant women, fewer studies have directly examined the PharmD curricula and the perspectives of pharmacy students on how they perceive their role in providing influenza vaccines to pregnant women. Purpose: This study examined the PharmD curricula instruction with regards to immunizing pregnant women and how pharmacy students perceive it. The study also explored the projected inactivated influenza vaccine administration in pregnant women practices among 3rd and 4th year pharmacy students in Florida. Methods: Semi-structured, in-depth, in-person qualitative interviews were conducted with the 6 Academic Deans of the accredited schools of pharmacy in Florida. The study also conducted 3 focus group sessions among 3rd and 4th year pharmacy students (n=18) in Florida. A thematic comparative analysis was conducted to examine outcomes. Results: The majority of the Academic Deans reported providing instruction on immunization in schools with respect to vaccine administration in pregnant women and called for a need for all schools to make it compulsory to include pregnant women-specific content. Pharmacy students reported a gap in knowledge of content related to administering the influenza vaccine in pregnant women. Despite that pharmacy students believe that when presented with the opportunity, they will be willing to

provide influenza vaccines to pregnant women. Conclusions: Pharmacists are in a good position and play an important role in increasing inactivated influenza vaccination rates among pregnant women. Implications for practice include the need for incorporation of pregnancy-specific content to immunization curricula.

Introduction

A key epidemiologic finding during influenza epidemics and pandemics is the increased risk for severe morbidity and mortality in various at-risk populations, such as the elderly, young children and pregnant women and their fetuses (Memoli, Harvey, Morens, & Taubenberger, 2013). During the 2009/2010 flu pandemic, pregnancy was a major risk factor for serious cases influenza; among women aged 18-29, influenza-pregnancy related deaths occurred in about 16% and hospitalizations in 29% (Biggerstaff, Cauchemez, Reed, Gambhir, & Finelli, 2014; Memoli et al., 2013). Pregnant women continue to be at risk for influenza-associated diseases that are usually fatal (Memoli et al., 2013; Callaghan, Chu, & Jamieson, 2010; Mak et al., 2008; Thompson et al., 2011). Influenza infection in these women lead to complications such as pneumonia, spontaneous abortions, preterm births, birth defects and fetal loss (Arnold et al., 2019; Mak et al., 2008; Rasmussen, Jamieson, & Bresee, 2008). Also, uptake of inactivated influenza vaccine during pregnancy has a two-fold benefit, as it protects the mother and the baby for its first few months of life (Simonsen & Hayney, 2011). This protection for the baby is essential, as there is no licensed influenza vaccine for infants under six months of age, and also because, during influenza outbreaks, children experience the highest infection rates (Simonsen & Hayney, 2011).

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) in 1997 added recommending the inactivated influenza vaccine for pregnant and

breastfeeding women (Arden, Izurieta, Fukuda, Cox, & Schonberger, 1998; CDC, 2003; Fiore et al., 2010). It is said that one out of two hospitalizations or admissions in pregnant women could be avoided per 1000 women who get the influenza vaccine (Arden et al., 1998). Despite the recommendations, inactivated influenza vaccine uptake remains suboptimal in pregnant women. As of November 2017, inactivated influenza vaccine uptake among pregnant women was 35.6% (CDC, 2017). Also, previous CDC influenza surveys show that the overall vaccine coverage in this population has been lower than the targeted 90% coverage proposed by the Healthy People 2020 goals (Lu, Bridges, Euler, & Singleton, 2008; Plans-Rubió, 2012; Whitley & Monto, 2006; Xakellis, 2005).

Several interventions have been developed to improve influenza vaccine uptake (Odone et al., 2015). Most influenza vaccine intervention studies have focused on vaccine campaigns, computerized reminders, the use of text message reminders, social networks, and web-based portals (Odone et al., 2015). This serves as a potential limitation, as there are other barriers such as problems with access among pregnant women such as distance to care centers, lack of transportation and availability of the vaccine at care providers clinic (Arao et al., 2015; Healy et al., 2015; Meharry et al., 2013; Ballas et al., 2015). The importance of maintaining high immunization rates to curb the spread of infectious diseases cannot be over emphasized, as there is a need to prevent high mortality and morbidity rates (Prescott & Bernhardt, 2019). The standing order which authorizes other health care providers including pharmacists to administer vaccines was instituted in the year 2000, by the ACIP (McKibben, Stange, Sneller, Strikas, & Rodewald, 2000).

Current Perspectives. In 2016, the Accreditation Council for Pharmacy Education (ACPE), which is the National agency for the accreditation of professional degree programs in

pharmacy and providers of continuing pharmacy education published the accreditation standards and key elements for the professional program in pharmacy leading to the Doctor of Pharmacy degree. For a pharmacy school to become accredited by the ACPE, they must meet minimum requirements as stipulated by the ACPE (Accreditation Council for Pharmacy Education, 2015; Prescott & Bernhardt, 2019). Among the required elements of the Doctor of Pharmacy curriculum, some topics have to be covered in the required content areas and should be taught within integrated or individual courses and may be covered under multiple disciplines (Accreditation Council for Pharmacy Education, 2015; Prescott & Bernhardt, 2019). It is required that under the topic “public health” which deals with advancing public health and wellness, students should be provided an avenue through which certification in administering vaccines can be earned (Accreditation Council for Pharmacy Education, 2015).

Since pharmacists got involved in providing immunization to the general population, legislation has been pushed by all states in the U.S. as of July 2016 to allow pharmacists to provide such services (Kamal, Madhavan, & Maine, 2003; Prescott & Bernhardt, 2019). With the expansion of the roles of pharmacists in administering vaccines, pharmacy schools have started to place emphasis on immunization training at their schools (Kamal, Madhavan, & Maine, 2003), and instruction is usually delivered through the American Pharmacists Association (APhA), and others such as the Minnesota College of Pharmacy Immunization Delivery Program, and the Collaborative Education Institute Immunization Training (Kamal, Madhavan, & Maine, 2003; Prescott & Bernhardt, 2019). According to the study by Prescott & Bernhardt (2019), almost all pharmacy schools in the U.S. provide a form of instruction on immunization (Prescott & Bernhardt, 2019), another study by Turner et al (2007), showed that pharmacy students can successfully administer vaccines to adults when trained to (Turner et., al 2007). However, when

it comes to pregnant women, studies have demonstrated reluctance by pharmacists to immunize this population (Dolan et al., 2012).

This study aims to explore the course content and perception of pharmacy students regarding pharmacy school curricular training on vaccine administration to pregnant women with a focus on the inactivated influenza vaccine. The study attempts to fill these gaps by investigating the pharmacy school curricular and exploring the knowledge and perceptions of pharmacy students about their role in offering and administering inactivated influenza vaccines to pregnant women using the Theory of Planned Behavior (TPB) as a guiding framework.

Methods

Overview. This qualitative research study employed a use of interviews and focus groups. The study involved two major research aims and their additional research questions. The main aims utilized separated qualitative methods to address each related research question. The first aim was addressed through a brief interview with the 6 Academic Deans of the 6 accredited schools of pharmacy in Florida. The second aim was addressed through focus groups with third- and fourth-year pharmacy students at four of the six accredited schools of pharmacy in Florida. Put together, the findings show what is taught to pharmacy students, what the pharmacy students learned, and how the pharmacy students perceived their future influenza vaccine administration in pregnant women practices. This study explored both education and perception of pharmacy students regarding influenza vaccine administration in pregnant women.

The study was approved by the University of South Florida Institutional Review Board (IRB). All records were stored on the USF Box folder and in locked filing cabinets in a locked room at USF. This project was non-invasive and presented a minimal risk to human subjects.

Aim 1: Review of Pharmacy School Curricula.

Target population & sampling frame. The first research aim, to understand how the course content of the six accredited schools of pharmacy in Florida is taught regarding vaccine administration in pregnant women, with a focus on influenza vaccine, was addressed through a short interview with the Academic Deans of the 6 accredited schools of pharmacy in the state of Florida. The and seventh school of pharmacy in Florida, currently has a candidate status by the Accreditation Council for Pharmacy Education (ACPE) and was therefore excluded. The Academic Deans of the 6 accredited schools were chosen as the target population for this study aim as they are usually responsible for the school curricula and are the most knowledgeable about it. Also, the accredited schools were chosen as pharmacy students must graduate from such schools to become licensed to practice in the U.S.

The following four letters were constructed and emailed to all 6 Academic Deans: (a) a pre- notice mail, (b) an informed consent form, (c) sample interview questions, and (d) a thank you/reminder letter. Their email addresses and phone numbers were retrieved from the various schools' websites, and the pre-notice emails were followed up with a phone call if no response two to three days after. The interview asked the Academic Dean's questions pertaining to the curricula offered in their Pharm. D. programs regarding vaccine administration in general and then in pregnant women, with a focus on influenza vaccine, they also identified appropriate course titles and numbers. Electronic copies of the syllabus were identified, retrieved, reviewed and summarized by the investigator.

The study participants were usually the Academic Deans, and, in some cases, it was the individuals overseeing the school curriculum. Names of the particular schools and Academic Deans were kept confidential and were not linked to the data. The participants were asked to

provide a verbal informed consent prior to participating in the interview. Interviews were conducted for approximately ten minutes and were audio-recorded. All 6 Academic Deans of the accredited schools of pharmacy in Florida or their equivalent participated in in-depth or telephone interviews. All notes, audio recordings and other pertinent materials collected during the interviews were kept confidential. The documents were stored in a locked cabinet and no personal identifiers were utilized. Additionally, considerations were made to utilize curricula found on school websites to find information on immunization content had all the deans not been reached. Data was collected, transcribed and analyzed.

The Academic Deans interview was piloted with the Director of the Doctor of Public Health Program at the USF College of Public Health. The primary purpose of this pilot test was to assess the feasibility, validity, and acceptability of the interview guide. Qualitative interviews are usually pilot tested with a few interviews among people that have similar characteristics to the population of interest (Hennink, Hutter, & Bailey, 2011).

Aim 2: Pharmacy Student Focus Groups.

Target population & sampling frame. The second research aim, to understand how 3rd and 4th-year pharmacy students perceive vaccine administration course content regarding vaccine administration in pregnant women, with a focus on influenza vaccine, was addressed through focus groups at three of the six accredited schools of pharmacy in Florida. All three schools were contacted regarding their participation in the focus groups and gave their approval. The focus groups offered insight into how the curricula regarding vaccine administration in pharmacy schools are perceived and operationalized by pharmacy students. The sampling frame was both third- and fourth-year pharmacy students at the three accredited schools of pharmacy in Florida and the samples for the focus groups were created through purposive sampling. The Pharm. D.

degree it a four-year program, with the first two years dedicated to course work, and by the end of 3rd year, they are done with course work and the last year is used for advanced practicum, where pharmacy students participate in clinical rotations to apply what they have been taught in class. Hence, third- and fourth-year pharmacy students were recruited as they will have already completed the majority of their coursework.

Focus group discussion guide. The focus group guide was developed topically by the researcher to (a) understand what pharmacy students learned about influenza vaccine administration in pregnant women in their pharmacy school classes, (b) understand the projected practices of influenza vaccine administration in pregnant women among pharmacy students after graduation. The focus group guide was also developed guided by the Theory of Planned Behavior (TPB) to understand pharmacy students' attitudes, subjective norms, and perceived control regarding administering influenza vaccines to pregnant women. The focus group guide was piloted with the graduate students (n=8) at the USF College of Public Health to assess the feasibility, validity, and acceptability of the focus guide.

Sampling plan. Each of the three accredited pharmacy schools was contacted and asked if focus groups could be conducted with students at their institutions. A total of three focus groups were conducted; one at each school. Emails and flyers which briefly introduced the study and announced the time and date for the focus groups, and how to contact the researcher were sent to pharmacy students to recruit study participants. The schools all supported and participated in the dissemination of the flyers and helped in the recruitment of students. One focus group each was held at each of the four schools and aimed to recruit 10 students and only 3rd and or 4th year students.

Each focus group consisted of a moderator (researcher) who facilitated the focus group

discussion and an assistant who took notes and distributed gift cards, refreshments, and participants' identification numbers. Study participants were asked to give verbal informed consent at the beginning of the focus group discussion. Students were presented with a \$10 gift certificate to Starbucks for their participation at the beginning of the discussion, should they decide to leave during the discussion. Focus groups lasted for approximately one hour and were audio-recorded. A moderator and an assistant to take notes were present during the focus group sessions. A total, 18 third- and fourth-year pharmacy students participated in the focus group discussions (8, 2, and 8). After informed consent was obtained, the demographic survey was administered, and the focus group conducted. All notes, audio recordings and other pertinent materials collected during the focus groups were kept confidential. The documents were stored in a locked cabinet and no personal identifiers were utilized. Data were collected, transcribed and analyzed.

Recruitment challenges. The recruitment process for the pharmacy students' focus groups was achieved over a seven-month period between February and August 2019, as 3rd and 4th year pharmacy students are usually undergoing clinical rotations and are scattered around the State. Although about 8-10 students were recruited for each focus group, on one occasion only one student during one of the school focus groups showed up for the focus group session and it was canceled. On another occasion at another school, only two students showed up for the focus group session, but the focus group was still conducted. Morgan, 2016, argues that two-three person focus groups provide value as they still create interactive discussions, provide depth and detail from each participant, and help with the difficulty of recruitment (Morgan, 2016). However, to help assist the recruitment process for the pharmacy students focus groups, a more rigorous recruitment strategy was employed where deans of student affairs were approached to

assist in the recruitment, and flexibility for the student to be able to call in via zoom. Through the second round of recruitment, an additional eight students were recruited and 8 participated in the focus group.

Data Analysis.

Data management. To ensure reflexivity through the research process, comprehensive field notes were taken that documented the focus groups and interviews, thoughts on them, and potential causes of bias that may interfere with interpreting results (Miles, Huberman, & Saldana, 2013). The recorded interviews and focus groups were transcribed word for word and were crosschecked for accuracy. All demographic information and transcripts were uploaded on MAXQDA analysis software which was used to analyze and manage data.

Data condensation. An a priori codebook was developed that had themes based on the interviews and focus group guides and the guiding modified TPB theory (i.e. knowledge, attitudes, perceived control and subjective norms). The analysis was carried out concurrently as interviews were being conducted and transcribed, and emergent codes were added to the codebook with revised definitions as needed. The codebook contained the names of the codes, what the code signified (inclusion criteria for applying the code), what it does not signify (exclusion criteria for when no to apply the code), as well as a sample of the type of quote that should be used with the code (Bernard et al., 2016). The codebook development was an iterative and continuous process, as new themes emerged during analysis. The codebook was imported into the MAXQDA software and was applied to relevant parts of the transcripts. The inductive thematic process involved the development of themes from the transcripts was then employed in the study to analyze interview and focus group data to examine conditions and interactions, and determine categories that clustered together (Guest et al., 2011). To identify themes and

subthemes, the transcripts were read two times, as well as looking out for repetition, metaphors, and content that was related to the TBP theory that guided the study in the text (Bernard et al., 2016). After themes were selected, the portions of texts that represented the themes were then identified (Bernard et al., 2016).

Data display and analysis. This employed the use of a matrix table in which codes and coded texts were displayed for the purpose of analysis (Miles et al., 2013). Analytic memos were used to note considerations and anything else that came up during the analytic process (Miles et al., 2013). The analysis was carried out by two independent coders. The primary investigator coded all the interviews (9) and the second researcher (LB) coded 10% (1) of the transcripts independently to produce an inter-rater reliability measure. Ongoing discussions of codes and themes continued through the analyses process, and discrepancies in the codes were discussed and a decision on the appropriate approach to go forward was determined. A Cohen's kappa provides a statistical measure for the coders to use as a standard and limiting subjective assessment, a kappa of 80% is used to denote agreement (Miles et al., 2013). The Cohen's kappa inter-rater reliability for this study was 84% denoting an agreement.

Results

The results from both the pharmacy schools' academic deans and the pharmacy students indicated that there were several areas discussed by participants, including their knowledge of influenza vaccines in pregnant women, and the role they had to play. Both of these areas were substantially impacted by what they know and their projected practices of interactions with pregnant women.

Review of pharmacy school curricula. This section answered the research questions on what courses and lectures regarding influenza vaccine administration in general and in pregnant

women are provided in the required courses of the accredited schools of pharmacy in Florida. Several themes emerged during the analysis and they include a) course content on immunization, b) course content on immunization in pregnancy, c) compulsory immunization teaching d) compulsory pregnant women immunization teaching e) sufficiency of immunization training, and f) role of a pharmacist.

Demographics. A total of 6 participants from the 6 accredited schools of pharmacy in Florida were interviewed (Table 3), 83% (n=5) of them were female, and 17% (n=1) was male; also 83% (n=5) of them were academic or associate deans, and 17% (n=1), i.e. one person was an associate professor. Fifty percent (n=3) of them had less than or equal to 5 years of associate dean experience, while the other 50% (n=3) had greater than 5 years' experience as an associate dean. The mean age was 45 years (range: 36–55 years). All six academic deans are from accredited schools of pharmacy in Florida. Fifty percent (n=3) of the participants reported they had administered the influenza vaccines in the past, while the other half reported they had never administered vaccines before.

Table 3. Academic Deans Demographics

Characteristics	Number (n=6)	Percentage %
Age		
31-40	2	33
41-50	3	50
51-59	1	17
Gender		
Male	1	17
Female	5	83
Position		
Academic Dean	5	83
Other	1	17
Time in Position		
1-5 years	3	50
>5 years	3	50
Administered Vaccine		
Yes	3	50
No	3	50

Course content on immunization. When asked if their pharmacy schools offered courses that provide content on immunization practices, all the participants (n=6, 100%) reported they offered required courses that covered immunization content and a few (n=2, 33%) reported offering elective courses that contained extra information on immunization.

“That’s a required course, it’s actually part of their first-year milestones, so if they don’t complete that they haven’t necessarily completed their first year of pharmacy school, so we require everyone to do that” AD6

The names of courses that contained immunization content were also provided (Table 2). The course content was explained to include online and in-class modules, course readings, training, and videos on immunization. A common theme among all the respondents (n=6, 100%) was the mention of the use of APhA modules to complement the required teachings and training on immunization, and the role of APhA in the certification of pharmacy students to immunize.

“We also have the students do a certification course through the “American Pharmacists Association” and through that course the students are certified to give immunization. That course is a twenty-hour seminar, also with self-study. So, they will do 12 hours of self-study, and then we have faculty members who are trained and licensed to deliver the course, the seminar portion in xxx University. So, that’s an eight-hour live course, and after finishing the self-course, they would demonstrate their technique, they would get assessed on it, a faculty member will do the assessment and the evaluation and all of that is sent to APhA, and APhA will give the certification to the student”. AD2

“American Pharmaceutical Association has a sort of vocation program for pharmacists to take, and what we did was to embed it in our curriculum and so it is offered to our students in their first year of the program through our public health course.” AD1

“APhA has 12 hours of online content that they have to review, and then they have an 8-hour live session, and at the end of the session they have to administer three vaccines”.

AD6

Majority of the participants (n=5, 83%) reported that the course required for immunization certification was offered in the first year of the pharmacy school curricular, while 17% (n=1) reported it was offered in the second year.

“they get their certificate..., and as part of the skills lab grade they have to submit the requirements to the board of pharmacy to become certified immunizing interns. The reason that we do it in their first year is because they go into the community in their first summer spending four weeks in the community pharmacy during the summer, it is our hope that they will practice immunizing while they are there” AD 6

“The students have to be certified in immunization through the school and through APHA. It is a required course in 1st year. There is an in-class portion of it, and also the online part” AD 4

Table 4. A Typology of Courses that Contain Content on Immunization

Participant	Required Courses	Year Offered	Pregnancy Content
AD1	Foundations of Public Health	PG Y1	NA
AD2	Immunology and Infectious Disease	PG Y2	
	Population Health	PG Y1	Covered
AD3	Applied Patient Care	PG Y1	
	Pharmacotherapeutics III	PG Y3	Covered
AD4	Integrated Pharmacy Application I	PG Y1	
	Integrated Disease Management	PGY2	Covered
AD5	Public health medication safety and disease prevention	PG Y1	Covered
AD6	Professional Practice Skills lab	PG Y1	NA
	Endocrine women and men's health	PG Y2	NA
Participants	Elective Courses	Year Offered	Pregnancy Content
AD3	Vaccine and Immunizations	PG Y2	Covered
AD6	Women's Health	PG Y2	Covered

Course content on immunization in pregnant women. When asked if their schools of pharmacy offered immunization classes that with respect to vaccine (influenza) administration in pregnant women (Table 4), 83% (n=5) indicated that information on vaccine administration was covered in either required (n=4, 67%), or in elective courses (n=2, 33%).

“...and I also teach an elective in women's health and we spend a lot of time talking about pregnancy and disorders in pregnancy. It also covers vaccines, and obviously there are certain vaccines you cannot get in pregnancy. But also, we also re-emphasize the importance of the flu vaccine in pregnancy no matter what trimester the person is at”

AD 6

“they have another required course where they have a couple of hours of lectures that cover it. And all those three different places they learn about pregnancy and vaccines”

AD 3

“Yeah, and in that, all three, the seminar and the two courses. But definitely population health I, that’s a higher-level course, and in the APhA immunization certification course they would go through pregnancy”

AD2

Four of the respondents (67%) mentioned that immunization content specific to pregnant women are covered under “special populations” which include pregnant women, however, two of them mentioned that immunization content is not necessarily focused on pregnant women.

“Not necessarily a focus on pregnant women, the gist of it is about the administration technique, and the different types of vaccines that pharmacists can actually administer, and then there is a special populations discussion, but it is not, you know, like a situation where there is any push to increase administration in pregnant women or anything of that nature” AD1

“It’s broad and covers all the vaccine preventable diseases like influenza, pneumonia, shingles and those sorts of things. There is not necessary a focus just on pregnant women, and it covers other special populations that are immunocompromised, elderly patients, as well as pregnant patients.” AD 6

“For population health, that would teach about pregnancy, different populations, minorities, and so how to immunize, but not just immunization by themselves, they just go through different populations and how to properly treat them for preventive measures.”

AD2

“We teach when vaccines are indicated or contra indicated, what populations should get it and who should not. Just like how we teach about the drugs.” AD4

Compulsory immunization teaching. Regarding making it compulsory for the School of Pharmacy curricula in the U.S. to include content material on immunization, all respondents (n=6, 100%) agree it should be made compulsory.

“I think, at this point because we have the opportunity to make it required, we can definitely do that and not have to justify it..., and we actually got a request from our preceptors to actually make sure the students came either already trained or aware of what that would mean or what their role will be. So, I think all programs should probably do that and make it a requirement. The other thing is I think it is an advantage to students, it gets them very close to feeling like they are pharmacists, and when they get out it is not something that they would have to learn, because they didn't get to do it when they were students and so it's kind of almost like a credential so to speak, so for the schools that aren't doing it, they have that advantage over those students.” AD1

“It's very important, especially with the health risk it prevents and with the requirements that student pharmacists have to have prior to coming to their rotations. Most of the pharmacy schools now, try to ensure that they are certified before they go on rotations.”

AD2

“Most schools already do, a lot has changed in the past few years and Florida is usually one of the last states to do anything, so if we are, I believe almost everyone is.” AD4

Two of the respondents (n=2, 33%) reported that all schools should now be teaching immunization as part of their curriculum in accordance with the ACPE accreditation standards.

“It is part of our standards now. In the required elements of the Doctor in pharmacy curriculum, under the public health curriculum, it says, ‘implementation of activities that advance public health and wellness, as well as provided avenue through which students earn certificates in immunization delivery’ It started in 2016, so everybody should have something in their program that teaches that.” AD6

“I think it should be required; I think it is required. I think it is part of the accreditation documents from ACPE as a topic that has to be covered.” AD 5

Compulsory pregnant women immunization teaching. When asked about making it compulsory for the School of Pharmacy curricula in the U.S. to include content material on immunization specific to pregnant women, all respondents (n=6, 100%) reported pregnancy specific information should be made compulsory. One respondent reported it would be a way for pharmacy students to become advocates for vaccine uptake in this population.

“Very important. Because in one of the suggestions for pregnant women is always to get flu shots, so in our population with our students, with them doing rotations, a lot of them do rotations in women’s health, also they do rotations in the hospital, even in the community just as an advocate for preventive health and we stress that people get their flu shots, so, it is very important they become advocates and do that.” AD2

“Well, yes, I think that, but I think the angles need to change, I think we have some opportunity for some reinforcement where we teach what immunization is and how to do it. And then I think as we talk about how you treat or deal with or provide care to pregnant women, immunization should be a part of that.” AD1

“I feel pretty strongly that content material on immunization regarding pregnant women should be part of it.” AD4

“I think it should also be covered along with the women’s health content, because it is a really important piece, and if we can prevent illness during pregnancy, we have more successful outcomes.” AD6

Sufficiency of immunization training. Regarding the classes/courses and training on immunization being enough to equip students to get certified, all the participants (n=6, 100%) agreed the coursework together with the APhA modules are sufficient to equip and prepare the students to be certified for immunization. Students are required to go through the course and practice a demonstration of vaccine administration technique to earn their certification.

“So, with the course, with the 12 hour of self-study they really go through the background information and kind of reiterate the things that they go through at XXXs curriculum and then being able to demonstrate your technique and get practice before you are certified, then yes, they are equipped to go out and deliver immunizations.” AD2

“Yes, the course for certification follows a very very specific format, which includes the patient assessment process, they are taught to evaluate the patient and they go through these guidelines and steps on what to do.” AD4

One respondent mentioned that students get the certification in school, but to maintain the certification after graduation they need to get more continuing education credit.

“ to get the certificate they have to do a demonstration of actually administering the vaccine, and then that allows them to go to their training sites to participate, but once they get licensed, then they just become responsible for maintaining the certification, and they have to just get more CEs.” AD1

Another participant mentioned that after students get the certification, it will depend on their experience after that to get them more comfortable with administering vaccines, and their subsequent employers to get them more training.

“So, the courses are one thing, they have to practice 3 vaccines that is required for the certificate. The real practice occurs in real life, that is why we want them to be certified before they go into their first year of practice, so that if they would have experienced that. And then, hopefully many of them will work in community pharmacies additionally, so if they are certified they can practice. And then again, they get practice during their fourth year because they do 6 weeks of community pharmacy where they will get additional practice. And then, for most employers, once they get a job, the company requires them to do the training again for them. I mean hopefully with that, just like with

anything, it takes a while to build your comfort. I mean, it is kind of scary the first time with a real person. It is one thing doing it to your classmate who is like 'okay go ahead' but the first time you are doing it with your patient, and nobody is looking over your shoulder, that is a scary thing. We have encouraged them to practice a lot when they are out during the summer.” AD6

Role of pharmacists. When asked about participants' perceptions regarding pharmacists administering influenza vaccines to pregnant women, all academic deans felt that it was something pharmacists could do.

“I honestly think it is a good thing, anything we can do to bring care to pregnant women. But also hope though that pregnant women are getting the health care that they need, if their providers recommend the vaccine, then great get it. But I will want the vaccine to be given with the caveat where following up and making sure she is getting the care for her pregnancy. I know there are controversies giving any kind of medication or drugs to pregnant women.” AD6

Three respondents (50%) mentioned pharmacists being accessible and therefore it would be easier for pregnant women.

“Oh, I think it's a no brainer, you know, the access that we have to the community through community pharmacies is second to none. Right now, they don't have to make an appointment to see us, so we are so accessible, actually the most accessible health care professionals, so I think it's a no brainer that we would join the list of professionals that could give the immunization ...” AD1

“I feel confident, that it is one of the things that pharmacists are certified to do, with pharmacists being so accessible, one of the professions that are on the frontline as far as accessibility, you know someone has to go get an appointment and go to the doctor’s office, it may be an additional cost associated, whereas you can pretty much walk into any retailer or grocery store that has a pharmacy, and the pharmacy would be able to deliver it at that time. So, I think accessibility puts us at an advantage of making sure that a pregnant woman or public is getting the vaccine.” AD2

“I think the number one most important thing to me when it comes to immunization is accessibility, it is always the excuse that I hear from people it was too difficult or they didn’t have the time to receive their vaccine, and I think that is a major barrier. So, with the pharmacists being so easily accessible. I think it is important to make it as easy as possible for a pregnant patient to receive the vaccines that they need.” AD3

One respondent mentioned pharmacists as being qualified to administer vaccines, while another believed there are no controversies or concerns with regards to pharmacists administering the influenza vaccine to pregnant women.

“I believe they are very much qualified regardless of whether the patient is pregnant or not. And it is something they can do and should do.” AD4

“I don’t think there are any controversies with pharmacists, I think when you have pregnant patients, they are more obviously concerned about different procedures that

they are undergoing. I think in general pregnant women getting immunized, I don't see that as a concern with pharmacists doing it." AD5

Generally speaking, all the accredited schools of pharmacy in Florida have content on immunization being taught at their schools, while not all schools may teach immunization in pregnancy-specific content, it may have been covered in other topics. There was agreement across board that pharmacy students get the education and training required to get certified and that pharmacists are equipped and knowledgeable to provide immunization services to the general public and to pregnant women. There were sentiments that pharmacy students must keep practicing immunization and a call for the need for pregnancy-specific immunization content to be incorporated into curriculum.

Pharmacy student focus groups. This section answered the research questions on what pharmacy students learned about influenza vaccine administration in pregnant women in their pharmacy school classes, and their projected practices of influenza vaccine administration to pregnant women after graduation guided by the Theory of Planned Behavior. Each theoretical component was explored during the focus group discussion. In general pharmacy students discussed their knowledge about the influenza vaccine, including where and how the instruction was received. The students also described the individuals, groups or agencies who influence their present and projected future practices. In order to understand their vaccine administration in pregnant women practices, students were asked about situational and internal factors that affect their practices. Finally, pharmacy students discussed any personal experiences with influenza vaccine administration in general and or in pregnant women. The findings are presented below.

Demographics. A total of 18 participants from three of the six accredited schools of

pharmacy in Florida participated in the focus groups (Table 5), 83.3% (n=15) of them were female and 16.7% (n=3) were males. All participants had received instruction on immunization, 83.3% (n=15) mentioned they had received instruction regarding immunization in pregnant women, while 16.7% (n=3) were not sure if they had. All, but one participant was certified to immunize, and none of the participants have provided vaccination to a pregnant woman.

Table 5. Pharmacy Student Focus Group Survey Data

Variable	N	Percent
What is your age range?		
18-30	15	83.3%
31-40	3	16.7%
What gender do you identify as?		
Male	3	16.7%
Female	15	83.3%
Did you take any classes in your Pharm D program which taught you about immunization?		
Yes	18	100%
No	0	0%
Have your pharmacy school classes discussed immunization in pregnant women?		
Yes	15	83.3%
No	0	0%
Not sure	3	16.7%
Are you certified to administer vaccines?		
Yes	17	94.4%
No	1	5.6%
Have you ever administered a vaccine before?		
Yes	9	50%
No	9	50%
Have you ever administered a vaccine to a pregnant woman before?		
Yes	0	0%
No	18	100%

TPB constructs influencing influenza vaccine administration in pregnant women practices. *Knowledge.* The primary purpose of the focus group was to determine how what pharmacy students know and were taught regarding influenza vaccines and its administration especially with respect to pregnant women. Students were generally agreeable about their knowledge of the influenza vaccines, and that resonated across all three schools. Pharmacy

students described four major areas of knowledge: a) knowledge about the mechanism of action, b) knowledge about the types of the vaccine, and c) knowledge about who should get it.

Knowledge about the mechanism of action refers to how the influenza vaccine works in the body.

“As far as the mechanism of action once you administer the vaccine, it is usually administered into the deltoid of muscle intramuscularly, and once that is done the body is able to mount an immune response to the inactivated or the live attenuated vaccine and by mounting that response you then gain immunity to the strains within that vaccine through the formation of antibodies, so that if you are exposed to it again the body is able to defend against it...”

“We all know that there is the live vaccine and there is the inactivated vaccine. Depending on what the patient’s position is, you may not want to give one over the other and there are like different formulations that are better for the younger population and some that are better for the older. There is the trivalent, quadrivalent and all that, they come in different strengths and different amounts.”

Two students mentioned the importance of all individuals getting the vaccines and linked it to the concept of herd immunity.

“Everybody should get it. When they are of age... Well I mean you are not going to give it to like a newborn or something and... I think everybody should get it to protect those who haven’t gotten it, like herd immunity. To stop it from spreading”

“I think of herd immunity and how everyone should be vaccinated on an annual basis”

Students were also knowledgeable about the about the influenza vaccine not causing the influenza illness and were able to discuss correct information about the misconception.

“It takes a couple of weeks to actually have a full effect of the immunization, so if you get sick during those two weeks after having the flu shot, it is not because of the vaccine, but because of the flu virus itself, and you just happen to get it during that time. It is a common misconception. I know that there are different variants of the flu vaccines and every year they come out with a new formulation for it to cover the most common strains after doing research. The trivalent and the quadrivalent are the ones we commonly use.”

“... obviously and there is always a lot of people that are afraid that it is going to give them the flu virus. So, there is still a lot of stigma about that, and I try to tell them it is not true.”

“... it is an opportunity to educate people as well, you are not going to catch the flu from getting the vaccine, you might experience some symptoms, which people are mistaking for the flu, so, I think education and counseling is a good thing for us to do, when we are doing immunizations like that.”

When asked where students learned about influenza vaccines, all students indicated that they had received instruction and information regarding influenza vaccines within the first two

years of their training, in required classes. In addition, others expressed taking some required courses that also contained teaching on immunization. When asked if they remembered receiving instruction with influenza vaccination or immunization in pregnancy-specific content there was a disconnect between what they answered on the demographic survey and during the focus groups. Initially, during the survey, only three participants had previously indicated they were not sure if they had received instruction specific to pregnant women regarding influenza vaccines. However, during the discussion in one school 5 participants either did not remember or were not sure pregnancy-specific content was taught, and one other student from a different school also did not remember. See the excerpt below:

Participant 1: "I personally don't."

Participant 2: "Me neither."

Participant 3: "I remember just a "horror story" being told of like giving the shots to a pregnant woman and then her bleeding - because they have more blood vessels and stuff. So, that's all I remember was like 'Oh, I gave the vaccine and she started bleeding profusely'."

Participant 4: "I remember thinking that pregnant women should get the vaccine, I just don't remember when and where."

Participant 5: "I think it was mentioned but I don't remember details."

“For me, since we had the immunization training quite a while ago, I don’t recall that we discussed pregnant patients too much as far as vaccine administration.”

One student mentioned that during the instruction received regarding influenza vaccination or in pregnancy specific content, it was covered under “special populations”.

“They told us how to go to the CDC and look up and see based on their like... special populations.”

Regarding what the pharmacy students knew about the influenza vaccines and pregnant women, they all agreed the vaccine was safe in pregnant women, so far it is the inactivated vaccine.

“We have the data and the science that it is safe and effective, and it is not going to be harmful as long as it is an inactivated vaccine...”

“One of the biggest things I learned is not to give a pregnant woman a live vaccine because that may transfer to the baby and may cause complications regarding that.”

“In the vaccine elective, where we talked about certain vaccines, you know they will say which ones they do recommend to pregnant women, and which ones you cannot give to pregnant women like live vaccines they can’t get.”

Two students, however, expressed the need for more pregnancy specific training in their

curricular.

“...but I feel like they should be touched on a little bit more in school. Because I feel like we didn't really get enough information for me to be comfortable.”

“...maybe if they included more patient specific populations in the immunization training, the pharmacists may feel more comfortable, especially when they go ahead to get their re-certification hours to learn more about that and why it is okay to do it in certain populations.”

Attitudes. The theme of attitudes reflects the pharmacy student's beliefs regarding providing influenza immunization to pregnant women and the notion that doing so has specific outcomes. Participants were asked about the advantages and disadvantages of providing the influenza vaccine to both the general public and pregnant women, which was expressed as advantages and disadvantages. Across the focus groups, participants believed it was advantageous to the community and pregnant women that pharmacist provides immunization services. Pharmacy students described positive attitudes expressed in the following sub-themes: a) accessibility and b) expertise. Pharmacists are known to be the most accessible healthcare providers, and the participants believed this placed them in a position to provide such services effectively, not just in terms of availability of pharmacies/pharmacists, but also in terms of availability of the influenza vaccine. This sentiment was shared across all focus groups.

“Pharmacists are some of the most accessible health care providers, so even in areas where going to the doctor's office might sound like a trip, there's a possibility that there is a pharmacy that is accessible even closer. So, we are within reach of a lot of people.”

“I agree with XXX I think we are more accessible and given the protocols and the availability of vaccines that pharmacists are now allowed to give. I mean it started out with just influenza and now it is expanding even more and more now. Sometimes doctors’ offices aren’t even carrying certain vaccines anymore, and they say you have to get it at the pharmacy...”

“... pharmacists are easily accessible in the community settings it is a huge advantage for patients to be able to gain access to receiving immunizations. It really opens up as far as the number of immunizations we are able to provide...”

Pharmacists are trained healthcare professionals, and the participants believed they are equipped to provide immunization services and can provide professional assistance to patients.

“Bouncing off of that they have multiple vaccines that they are able to give, so if the patients have questions about the vaccines they can ask the pharmacists and see what they are able to take and what they need to take and maybe discuss their vaccines that they have received...”

“I think we are qualified just in the knowledge that we are providers... Also, we can touch up on things that fall under our scope such as vaccines.”

“I feel like we are qualified, and just like I know what resources I need to go to if I don’t know the information...”

Other subthemes that came up had to do with benefits or ease for the patients.

“It’s less cost if you think about it because they have to make an appointment with their doctor which they have to do a co-pay and then, like, get the vaccine and... it just, it creates less cost for the patient.”

“I work for xxx, and by no way endorsing this, but... we gave a \$10 gift card during the Flu season for people to come in and actually get vaccinated.”

Participants also expressed concerns as to why they may not be in the best position to provide immunization to pregnant women, under the following subthemes: a) Not enough information (as they do not usually have background information on the pregnant women), b) limited knowledge and c) fear of liability. Others expressed concerns about having limited knowledge when it comes to pregnant women and the influenza vaccines, but not everyone shared these sentiments.

“...one disadvantage I think of is, since we are so accessible, we don’t make appointments, we don’t know the patients background health history, generally if the person is not a long time patient or customer of the pharmacy, we are not going to know their story.”

“I agree with..., at xxx we have 6 different questions we use for all vaccines, ...we don’t know the background of the patient as maybe we should”

“We might not have answers to all their questions that they may ask to the doctor, as far as things that might affect the pregnancy. We can talk about like Flu shot, as far as our knowledge at least now as students we are kind of like limited.”

“I think there could possibly be more liability associated with administering vaccines to pregnant women because of adverse effects whether it is related to the vaccine or otherwise could be definitely a liability issue and it could come back to the pharmacist regardless of if they administered it appropriately for that patient. It is just higher risk for the pharmacist’s license”

“I don’t really think there is a disadvantage of providing an inactivated vaccine to a pregnant woman, as long as CDC deems it safe and the patients doctor is aware that they are going to get the vaccine... We have the data and the science that it is safe and effective and it is not going to be harmful as long as it is an inactivated vaccine, so, I don’t see an issue with giving it as long as the physician is aware that the patient is requesting it”

Perceived Control. The theme of perceived control reflects how much the pharmacy students feel that providing immunization or not providing immunization to pregnant women is under their volitional control. Participants were asked about their thoughts and feelings about the facilitators or barriers to providing the influenza vaccine to pregnant women, alongside education and counseling. Participants described healthcare provider recommendation as a facilitator to providing influenza vaccine immunization to pregnant women across all focus groups.

“If they received a note from the doctor, and they speak to their doctor about why it is okay to receive the vaccines from pharmacists and why they should do it, that may make them more likely to”

“I think it would help if they have a recommendation from the physician. For XXX specifically, I know that you can send the vaccine information to the doctor and request it...”

“Would be helpful if the provider can recommend it..., just patient education like in the Doctor’s offices...”

Other facilitators that were mentioned include the use of marketing in the form of posters to inform pregnant women about going to the pharmacists to obtain their influenza vaccines, and also a *provision of incentives to pregnant women.*

Participant 1 “Like posters or something like that”

Participant 2 “Yeah! A poster like ‘hey, you can get it here, but you can also go to your Pharmacist and get it there”

Participant 3 “Incentives too. Like last year was the first time xxx did the whole gift card thing and we had a huge turnout”

When asked about the barriers, pharmacy students expressed various sentiments including lack of a relationship or trust between pregnant women and the pharmacist, lack of awareness by

pregnant women of the safety of the vaccine during pregnancy, lack of time, and lack of education of themselves as pharmacist regarding providing vaccines to pregnant women.

“I think it would depend on your relationship with the patient you know. Like say in the community settings which is where a lot of pharmacists are going to be administering vaccines. If it is just a patient that frequents the store not the pharmacy, it might be hard to kind of convince them of your trust. It is a trusting relationship, like they have that relationship with the doctor. So, they will probably feel safer getting it there.”

“One of the barriers is patients lack of information, they may say I am pregnant why would I get a vaccine that’s going to hurt the baby and they may like keep this information and spread it to others saying, you know, don’t vaccinate when you are pregnant, it is not good for you, that kind of thing.”

“They don’t always think it is safe and sometimes no matter what we tell them, they don’t always believe us.”

“Just based on previous retail experience, I think there is a huge disadvantage in the time constraint that pharmacists have, they have a limited amount of time and usually corporate pharmacy tends to push numbers in terms of goal number of vaccines given per season, usually the flu vaccines specifically. So, the pharmacists feel pressured to meet that number and if they don’t have a pharmacy intern or anybody else to give those vaccines, they have to constantly be leaving the workflow in order to administer vaccine..., it is a pretty time-consuming process.”

“I guess where I am at right now, probably lack of education, we never really focused much on the pregnant women, at least in our education so far. I guess if I was more comfortable and more familiar with administering the flu vaccine or other vaccines to pregnant women and felt really solid in that knowledge.”

“In addition the pharmacists may not feel comfortable administering the vaccine to a pregnant patient even if they are educated about you know, it is okay to, they may still be concerned and maybe not necessarily turn the patient away, but may not inform the patients about getting vaccinated when they are at the pharmacy, they may just not say anything.”

Other themes regarding factors that may affect pharmacy students' volitional control in administering the influenza vaccine to pregnant women include the type of insurance or the community settings (rural, urban) of the pregnant woman. When asked about insurance type, pharmacy students expressed sentiments that insurance type may be a barrier.

“Insurance doesn't always cover it. We have to put in particular codes on the computer and sometimes, depending on the vaccine, and depending on the insurer/insurance coverage, Insurance won't always cover it. They won't cover like a Pharmacist giving it.”

“Yeah, I agree. I got my flu shot and I asked them if they'd take my insurance. I called my Insurance and they told me it has to be administered in a medical office - not the Pharmacy.”

“Some of them will only pay for it at the doctor’s office to be billed like as a service, whereas pharmacists don’t have provider status yet. it really depends on what plan the patient is enrolled in as well. Unfortunately, xxx health insurance doesn’t cover vaccines at the pharmacy, so for us to go get the mandatory flu shot that I have to get, we have to pay out of pocket, so I think that hinders a lot of it. If your insurance only covers it through your doctor, then a lot of patients are not going to get it at the pharmacy.”

When asked about the patient’s location or community settings (rural vs. urban), pharmacy students across all three focus groups believed that in rural areas patients may not be well informed, have transportation, or be able to afford the vaccines.

“You know a lot of people in more rural areas don’t have the knowledge and aren’t educated enough about general health, wellbeing, so they don’t go to the doctor, so I think it kind of stems from that.”

“I think one of the problems with being in a rural setting is that they may be much farther away from their pharmacy or from the doctor and that may lead to some issues in general, like they are not..., they are like ‘oh it is so far away, I am not going to do that’, it is like not worth the trip or anything like that. So, that could be a barrier and they may be scare and nervous or just disregard vaccinations altogether, that may be an issue.”

“I agree, they might also, maybe not have enough access to information regarding vaccination, either through their provider or through basically any other resources they

could obtain in a more urban setting.”

“I think the knowledge definitely is a barrier”

“And access... like having transportation or insurance, being able to afford it”

In summary, the facilitators mentioned include healthcare provider recommendation, posters or advertisements letting pregnant women know they can get the vaccine at the pharmacy, and incentives for the women. Barriers mentioned include pregnant women’s lack of awareness of the pharmacy as a place to obtain vaccines, lack of time, women’s insurance type, women living in rural areas, women’s lack of trust in the pharmacist, and the pharmacists themselves not receiving enough education regarding immunizing pregnant women.

Subjective Norms. The theme of subjective norms refers to the notions of how certain individuals view and approve or disapprove of pharmacists providing immunization services to pregnant women. It also refers to pharmacy students’ engagement in providing influenza vaccines to pregnant women if they feel people close to them think they should. These then motivates the pharmacy students to administer influenza vaccines based on what these individuals think. For the study, the students were asked about the influences of the following individuals on them providing influenza vaccines to pregnant women: a) the CDC, b) the APhA, c) the Florida state statutes, d) physicians, e) pregnant women, and f) their peers.

CDC. When asked about the influence of the CDC, pharmacy students believe it plays a role as a resource for information to keep up with the latest guidelines and changes regarding the influenza vaccine administration.

“I think their role would be to keep the information updated because we are constantly learning so we go to the CDC for updated guidelines for what has changed regarding the vaccine or regarding a special population. I feel like they are the most updated information that we should be able to go to help answer questions that patients may have regarding the vaccine.”

“I actually have the CDC vaccine schedule app on my phone, so even as a student, if I were to be at work and someone should ask for the vaccine, I even looked it up... So, I am expecting that this app is up to date and current with child schedules, adult schedules and special population schedules you know. I am expecting that resource to be on top of the game.”

APhA. When asked about the influence of the APhA, pharmacy students believed it is a key resource through which they obtained their training on immunization and for continuing education, and also expressed the need for the APhA training to focus more on special populations.

“I am not sure as far as re-certification goes, but as far as our previous certification and initial training in APhA..., they could focus more on special populations and it’s probably a time constraint and they can’t address everything which is why they just have us refer to the CDC vaccination schedule. But I think that it certainly could be useful to us to educate us more on those populations, or populations that we will encounter frequently in practice as well as continuing the education like throughout the curriculum.”

“We had a ... during our first year of Pharmacy school, we had an Immunization course given by APHA (which is the American Pharmaceutical Association) and... that’s where we were trained to give vaccinations.”

“I believe that as some of these conferences like APhA conferences, they provide continuing education for pharmacists that provides..., they have like an immunization parcel for that that would kind of give you the updated information that you need, some kind of mini version of what we took our first year at school.”

Florida State Statutes. When asked about the influence of the Florida state law regarding pharmacists providing immunization services under the supervision of a Physician within a framework of an established protocol (Florida, 2018), pharmacy students expressed mixed feelings on how it affects their vaccine administration practices, as they feel it takes away from their autonomy and may not be necessary, as seen in the excerpt below.

Participant 1: “We are a long way from Pharmacists being considered practitioners. We are not even considered practitioners. So, for us to be able to vaccinate, we had to put something in place.”

Participant 2: “It’s a start.”

Participant 3: “It’s a start, yes!”

Participant 4: “I don’t know... I feel like it’s not necessarily like a “bad thing” like in

case of I guess in case of “special cases” or whatever. Then again, it also kind of hinders. To be honest with you, I couldn’t even tell you who xxx, that is my particular store, is contracted with as far as the Physician goes and things like that. I couldn’t even tell you if it’s the same Physician for all xxx stores – you know what I mean? So, it’s just that we have to have it to say there’s a Doctor’s name on it but... why? You know...”

Participant 5: “We’ll get there... eventually.”

Pharmacy students from the other focus groups shared the same sentiment as above, one participant expressed that the arrangement is useful for the pharmacist, and one further expressed how the physician plays a role in determining the type of vaccine manufacturer the pharmacy dispenses.

“The standing order they have one provider that they can use that the prescription is automatically signed by. I have never really had an opinion about, I guess it does kind of put the provider at some risk for liability, but in my experience I have always thought it was very convenient that we have that, and it is very helpful to the pharmacist so, I am sure there are definitely cons to it, but I think it is a useful thing to have for the pharmacist.”

“I think one of the things they do is dictate what manufacturer the vaccines are gotten from or something like that. I just learned that last week, depending on like the doctor that you are practicing under, they actually pick what vaccine or what manufacturer the NDC that you use in your own store. They actually dictate that. But I don’t know if that is a benefit to us, or a disadvantage, because we are sent the vaccine to our store and then we administer it. We know that that is the NDC we have available, so that is the NDC we

are going to use, we don't really know what other ones are available or what other states may use either. So, I think that could be a disadvantage, but nobody, I feel like nobody really talks about it, so we are just kind of like in limbo, we are very unaware about it."

Physicians. When asked about the influence of the physician on pharmacists administering the influenza vaccines to pregnant women, pharmacy students believed if physicians refer pregnant women, they will feel safer coming to the pharmacy for their shots, some believe doctors are already referring patients to go to the pharmacy to receive the influenza vaccine and others expressed the need for communication between pharmacists and doctors.

"Yeah, coming from them (the physician), they (pregnant women) feel more safe doing it at the pharmacy."

"Yeah, I think there is a lot of doctors that are always telling patients like go to your retail pharmacy, go get your vaccines. Honestly, I feel like a lot of Doctors are overwhelmed these days with high patient numbers, so, essentially it is like less work for them, they know that we do it."

"I think as far as we are in communication with each other, it will take some load of the OBGYNs and if they pharmacists have questions to be able to contact whenever, and say 'hey, we are giving this patient this vaccine is that okay with you, and then they proceed in that way. And keeping contact with the patient all in the same loop."

Pregnant Women. When asked about the influence of pregnant women on pharmacists administering the influenza vaccines to them, pharmacy students had all not had prior experience to providing immunization to a pregnant woman. But they expressed that pregnant women may not be comfortable getting their immunizations from the pharmacist, others felt that with proper counseling pregnant women will be comfortable getting their shots from a pharmacist.

“I actually do not have any experience with giving or witnessing the vaccination in pregnant women... But I think they will probably feel a little scared or worried or they may feel like it is in the community, so it is unclear maybe the pharmacist should not do it. If I did it in the doctor’s office, it will be cleaner and be better for me..., you know they may have their different opinions about getting vaccinations in the community.”

“I don’t think I have ever given a pregnant woman a flu shot. The chances are they are probably getting it from their doctor, because I feel like the woman is going to be more in touch with their OBGYN.”

“I would hope they want to come to the pharmacy... I personally wouldn’t know how to approach a pregnant woman who had concerns I would definitely grab my boss who is a Pharmacist and kind of “tag-team” - as I call it – and counsel her and hopefully, with what we explain to her she’d be comfortable getting immunized.”

“I did witness a patient that came up to my counter once, and she asked if she was able to get the flu vaccine, and she seemed like scared and nervous... After speaking with her, the pharmacist gave her the vaccine.”

Peers. When asked about the influence of their peers or other pharmacists on them

administering the influenza vaccines to pregnant women, pharmacy students believed that their colleagues choosing not to provide immunization services to these women, may not affect them personally, but they expressed that when pharmacists do not immunize, it pushes the practice of pharmacy back and pharmacists who do not immunize pregnant women tend to be older, set in their ways and are not interested in broadening their scope of practice.

“I think that pushes us back, because I actually had a pharmacist who told me that she refused to give vaccines when it was first started for like a solid two years. Like patients would come in to ask for the vaccine and she would turn them away. I feel like it makes the patient, probably feel some type of way that a pharmacist with a doctorate is refusing to give the vaccine, so, are all pharmacists capable of giving this vaccine? or what is the reason behind it, I do think that does push us back. And I feel like those pharmacists are set in their ways and they really don't want to expand our scope of practice”

“I kind of understand where those pharmacists will be coming from, they will probably think it is better for the pregnant women to go to their primary care providers or their gynecologist specifically in order to receive that kind of vaccination or treatment. They feel like that is kind of outside their scope”

“I know that the older generation of Pharmacists weren't really too keen – at least some of the pharmacists that I've worked with who've been on the field for twenty plus years... “so, I have to give vaccines now?” It's not something that I think they care to do... But the newer generation of Pharmacists are definitely more on-board for doing

something like that.”

They also expressed that when pharmacists immunize it would increase the number of women receiving the vaccine and will reduce missed opportunities.

“I think it would solidify... because that’s one less person that could give the vaccine so that many more patients are not missed”

Projected future practices. When asked about if they would be willing to administer influenza vaccines to pregnant women, should the opportunity arise, pharmacy students all expressed the same sentiment about their willingness to administer influenza vaccines to pregnant women and most believed it would not feel different from giving a non-pregnant person the vaccine, but may administer I with more caution.

Participant 1: “I would be fine with it.”

Participant 2: “Yeah.”

Participant3: “I would be fine with it too... I personally would probably want to do a little bit more research to make sure that the vaccine that I am giving is safe.”

Participant 4: “But I think we have access to the appropriate resources so that wouldn’t be a problem.”

Participant 5: “Yeah, I would definitely have to consult that resource before I do anything but then as long as it says it is fine, I would have no problem doing it.”

Participant 6: “I would be comfortable. I personally would probably double and triple check myself as far as the vaccine is safe to give.”

Participant 7: “Yeah, as long as there is not any other co-morbidity or anything wrong with that woman’s pregnancy... and same with another patient that might have another co-morbidity – I would want to make sure that everything checks out before giving the vaccine.”

Participant 8: “...but giving it to a pregnant woman, I would just treat them like any other patient.”

Participant 9: “Yeah, pregnant or non-pregnant person, it is the same thing”

Participant 10: “I will feel fine as long as I double check and the pharmacist manager says it is alright, so it will be like just administering the vaccine to any other patient.”

Summary of focus group discussion, main themes and subthemes and a representative quote are seen in table 6 below.

Table 6. Main Themes of Students focus Group Findings and Representative Quotes

Themes	Representative Quote
Knowledge	
Mechanism of action	<i>"...the body is able to mount an immune response to the inactivated or the live attenuated vaccine and by mounting that response you then gain immunity to the strains within that vaccine through the formation of antibodies, so that if you are exposed to it again the body is able to defend against it..."</i>
Types of vaccine	<i>"...there is the live vaccine and there is the inactivated vaccine. Depending on what the patient's position is, you may not want to give one over the other and there are like different formulations that are better for the younger population and some that are better for the older. There is the trivalent, quadrivalent and all that, they come in different strengths and different amounts."</i>
Recommended groups	<i>"Everybody should get it. When they are of age... Well I mean you are not going to give it to like a newborn..."</i>
Misconceptions	<i>"It takes a couple of weeks to actually have a full effect of the immunization, so if you get sick during those two weeks after having the flu shot, it is not because of the vaccine, but because of the flu virus itself, and you just happen to get it during that time. It is a common misconception..."</i>
Instruction on pregnancy vaccine	<i>"I remember thinking that pregnant women should get the vaccine, I just don't remember when and where."</i>
Attitudes	
Access	<i>"...pharmacists are easily accessible in the community settings it is a huge advantage for patients to be able to gain access to receiving immunizations. It really opens up as far as the number of immunizations we are able to provide..."</i>
Experts	<i>"I think we are qualified just in the knowledge that we are providers... Also, we can touch up on things that fall under our scope such as vaccines"</i>
Ease for patients	<i>"It's less cost if you think about it because they have to make an appointment with their doctor which they have to do a co-pay and then, like, get the vaccine and... it just, it creates less cost for the patient."</i>
Limited information	<i>"...we don't know the background of the patient as maybe we should"</i>
Limited knowledge	<i>"... We can talk about like Flu shot, as far as our knowledge at least now as students we are kind of like limited."</i>
Liability	<i>"I think there could possibly be more liability associated with administering vaccines to pregnant women because of adverse effects whether it is related to the vaccine or otherwise could be definitely a liability issue and it could come back to the pharmacist regardless of if they administered it appropriately for that patient. It is just higher risk for the pharmacist's license"</i>
Perceived Control	
Facilitators	
Provider recommendation	<i>"If they received a note from the doctor, and they speak to their doctor about why it is okay to receive the vaccines from pharmacists and why they should do it, that may make them more likely to"</i>
Marketing	<i>"...A poster like 'hey, you can get it here, but you can also go to your Pharmacist and get it there'."</i>
Barriers	

Table 6. Continued

No trust	<i>"...If it is just a patient that frequents the store not the pharmacy, it might be hard to kind of convince them of your trust. It is a trusting relationship, like they have that relationship with the doctor. So, they will probably feel safer getting it there."</i>
No awareness of vaccine safety	<i>"They don't always think it is safe and sometimes no matter what we tell them, they don't always believe us."</i>
No time	<i>"the pharmacists feel pressured to meet that number and if they don't have a pharmacy intern or anybody else to give those vaccines, they have to constantly be leaving the workflow in order to administer vaccine..., it is a pretty time-consuming process."</i>
No education	<i>"I guess where I am at right now, probably lack of education, we never really focused much on the pregnant women, at least in our education so far..."</i>
Community settings	<i>"I think one of the problems with being in a rural setting is that they may be much farther away from their pharmacy or from the doctor and that may lead to some issues in general, like they are not..., they are like 'oh it is so far away, I am not going to do that', it is like not worth the trip or anything like that. So, that could be a barrier and they may be scare and nervous or just disregard vaccinations altogether, that may be an issue."</i>
Insurance	<i>"Insurance doesn't always cover it. We have to put in particular codes on the computer and sometimes, depending on the vaccine, and depending on the insurer/insurance coverage, Insurance won't always cover it. They won't cover like a Pharmacist giving it."</i>
Subjective Norms	
CDC	<i>"I think their role would be to keep the information updated because we are constantly learning so we go to the CDC for updated guidelines for what has changed regarding the vaccine or regarding a special population. I feel like they are the most updated information..."</i>
APhA	<i>"I am not sure as far as re-certification goes, but as far as our previous certification and initial training in APhA..., they could focus more on special populations..."</i>
Florida State	<i>"I don't know... I feel like it's not necessarily like a "bad thing" like in case of I guess in case of "special cases" or whatever. Then again, it also kind of hinders..."</i>
Physicians	<i>"Yeah, coming from them, they (pregnant women) feel more safe doing it at the pharmacy."</i>
Pregnant Women	<i>"...The chances are they are probably getting it from their doctor, because I feel like the woman is going to be more in touch with their OBGYN."</i>
Peers	<i>"I know that the older generation of Pharmacists weren't really too keen – at least some of the pharmacists that I've worked with who've been on the field for twenty plus years... "so, I have to give vaccines now?" It's not something that I think they care to do... But the newer generation of Pharmacists are definitely more on-board for doing something like that."</i>
Projected Practice	<i>"I will feel fine as long as I double check and the pharmacist manager says it is alright, so it will be like just administering the vaccine to any other patient."</i>

Overall, all students responded they were taught about influenza vaccine administration in a required course and called for a need for pregnancy-specific instruction which substantiated

the findings from the Academic Deans curriculum review. The participants across all the focus groups generally expressed positive attitudes about providing immunization services to pregnant women coupled with the belief of being experts in their field and being accessible to increase influenza vaccine uptake in pregnant women, which also substantiated findings from the Academic Dean interviews. Pharmacy students identified attitudes, perceived control factors and subjective norms in their role in administering the influenza vaccine to pregnant women.

Discussion

Connecting the Academic Dean's interview findings with the pharmacy students' focus groups allowed for a better understanding of pharmacy school curricula in Florida. Not only did this study review the immunization with respect to influenza vaccines in pregnant women curricula, but the focus groups provided an insight on how the curriculum is translated to the pharmacy students who received the instruction. The qualitative methods employed in this study best address the issue of cognitive understanding or perceptions of course instruction on immunization in their pharmacy school courses because qualitative research is useful to provide an understanding of human behaviors involving cognition.

The pharmacy school's curriculum review findings showed that among the six accredited schools of pharmacy in Florida, 50% percent of them provided immunization content with respect to pregnant women in their required courses. However, all (100%) six accredited schools provide instruction on immunization as part of the ACPE requirements. All six (100%) Academic Deans reported that pharmacy schools should include compulsory immunization content with a focus on vaccines in pregnant women. Academic Deans reported that the majority of the courses that provide content on immunization are covered under "special populations" which include pregnant women. This finding was substantiated by the information gathered from

the focus groups discussion. Understanding the types of courses that provide instruction regarding immunization on pregnancy to pharmacy students is important to guide educational intervention efforts. In summary the findings from the review of the family school curriculum included the following: a) the accredited schools of pharmacy in Florida, all provide instruction on immunization including influenza vaccine administration in their pharmacy school classes, b) majority of the schools provide immunization instruction with respect to pregnant women, c) pharmacy students are equipped and certified to provide immunization services after receiving instruction and training, and d) there was a call for the need for the integration of pregnancy-specific immunization content to be incorporated into curriculum.

The pharmacy students focus groups provided information on the knowledge of pharmacy students learned about immunization with a focus on influenza vaccine in pregnant women, the types of vaccines, mechanism of action, the recommendations, and misconceptions. The focus group discussions showed an important discrepancy between what the students reported in their surveys and what they reported during the discussion regarding if they received instruction on the administration of influenza vaccines in pregnant women. Initially, only a few students reported not being sure about being taught about it, but during the focus group, additional students shared this sentiment. In addition, students reported they wished they had received more information about influenza vaccine administration to pregnant women. This finding demonstrates that what is taught in pharmacy schools is perceived to be insufficient in equipping pharmacists with the confidence to provide vaccines to pregnant women.

In discussing pharmacy students' attitudes about administering inactivated influenza vaccines to pregnant women, the overall positive attitude assessment is that they believe they are in a good position to provide influenza vaccines to pregnant women as pharmacists are

accessible, are qualified to provide such services, and it may be more cost-effective for pregnant women. Consistent with previous research by Steyer et al (2004), which shows pharmacists are the most accessible health care provider (Steyer et al., 2004). Some have reported that it is cost-effective for pharmacists to administer the influenza vaccine to adults (Grabenstein et al., 1998; Prosser et al., 2008). Pharmacy students also expressed some negative feelings that may interfere with them providing such services such as not having enough background information about the women, fear of liability and as students they feel they might be limited in their knowledge to provide influenza vaccine to pregnant women. Dolan et al (2012), also reported that pharmacists that are certified to immunize had concerns or fear of liability when it came to providing immunization to pregnant women (Dolan et al., 2012).

For the perceived control, pharmacy students reported facilitating factors to provide influenza immunization to pregnant women to include provider recommendation or referral and marketing campaigns. A study by Ding et al (2017), reported that higher rates of influenza vaccine uptake were seen among pregnant women who received a recommendation from their provider compared to those who did not (Ding et al., 2017). Research shows that pharmacists advocating or providing marketing campaigns on vaccines save costs and prevent hospitalization (Grabenstein et al., 1998). In discussing barriers to provide influenza immunization to pregnant women, pharmacy students mentioned pregnant women may not trust the pharmacist and do not believe the vaccine is safe during pregnancy. This is in contrast to a study by Wang et al (2014), which showed that pharmacists are one of the most trustworthy health care providers (Wang et al., 2014). Other barriers include lack of time during work hours, and feelings of not being educated about immunizing pregnant women, type of insurance and the community settings of the women. The study by Dolan et al (2012), also reported that pharmacists believe pregnant

women may not be interested in the vaccine and the patient's insurance may not cover it (Dolan et al., 2012). A study by Murphy et al (2012), reported accessibility of pharmacists administered influenza vaccines to individuals residing in medically underserved areas (Murphy et al., 2012), which was not a sentiment brought up during the focus group discussions.

In discussing the subjective norms, pharmacy students reported that CDC serves as a resource to go to for vaccine information and update and the APhA was viewed as a training resource. The students view these agencies to provide guidelines to make them want to provide influenza vaccines to pregnant women. This is in line with the study by Dolan et al (2012), which reported that one of the reasons pharmacists provide immunization to pregnant women is because it complies with the CDC guidelines (Dolan et al., 2012). However, students expressed the need for training to focus more on special populations such as pregnant women. Students expressed that pregnant women may prefer to get vaccines from their doctors and emphasized the importance of provider referral of pregnant women to the pharmacy. Pharmacy students reported that they felt older pharmacists may not want to immunize pregnant women.

When discussing the Florida state statutes as it relates to the standing order for vaccines, pharmacy students had mixed feelings on how it affects their vaccine administration in pregnant women practices, but still see the relevance of it. This is partly in line with studies that reported that pharmacists providing immunization is facilitated by the standing order (Goode et al., 2007; Steyer et al., 2004; Weitzel, 2000).

Overall, Academic Deans and pharmacy students shared the sentiments that they are equipped to provide immunization services. Despite the call for the need for inclusion of pregnancy focused immunization training, pharmacy students believe that when presented with the opportunity, they will be willing to provide influenza vaccines to pregnant women. This

resonates with studies that assessed pharmacy students and showed they gained self-confidence in administering vaccines, and can boost vaccine uptake rates (Globe, Johnson, Conant, & Frausto, 2004; Turner et al., 2007).

This study had several limitations. Firstly, it composed of qualitative studies with small sample sizes and hence not generalizable. Another limitation of focus groups with respect to the study is that no two students remember or learn the same way, and both the Academic Deans and the student's reports are based on self-report, therefore, perception on instruction may be subjective. However, the focus groups provided a recollection of what students were taught, and correct representation of the instruction they received on influenza vaccine administration in pregnant women.

This study also has several important benefits. Many of the studies regarding pharmacy students and immunization look at students providing immunization in adults, not in special populations including pregnant women. The qualitative nature of this study is important in examining how students perceive what they learn and how they may relate it to their ability as licensed pharmacists in the future. In addition, this study provided an opportunity not to only examine students' perceptions, but also the perceptions of the Academic Deans of pharmacy schools in Florida. Furthermore, this study included the perception of individuals i.e. pharmacists, that are often overlooked when it comes to providing care for pregnant women.

Conclusion

Pharmacists are in a good position and play an important role in tackling the issue of low influenza vaccine uptake among pregnant women rates. Since pharmacists already provide immunization to adults, drawing attention to vaccine administration to pregnant women should

not be an issue. Pharmacy schools and the APhA should include opportunities and strategies in into their PharmD curricula and continuing education and certification training.

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Manuscript 2: The Role of Pharmacists in Administering Inactivated Influenza Vaccines (IIV) to Pregnant Women

Abstract

Background: Influenza vaccine rates in pregnant women continue to remain suboptimal despite the recommendations from healthcare organizations. Although pharmacists can provide immunization services as a result of the standing order by the CDC, relatively few studies have examined the role of the pharmacist in providing immunization services to pregnant women. Despite the feasibility of pharmacists providing these services, few studies have directly considered pharmacists' perspective on how they perceive their role in increasing influenza vaccines among pregnant women. Purpose: This study utilized the Theory of Planned Behavior to explore the inactivated influenza vaccine administration in pregnant women practices among licensed Florida pharmacists. Methods: Semi-structured, in-depth, in-person qualitative interviews were conducted with 18 licensed Florida pharmacists including clinical and retail pharmacists. A thematic comparative analysis was conducted to determine differences in practice. Results: Majority of pharmacists (94%) knew pharmacists could administer influenza vaccines in pregnant women. Participants expressed positive and negative attitudes and identified barriers, facilitators, and subjective norms that influenced their vaccine administration practices among pregnant women. Overall, they believed they were equipped and able to provide influenza immunization to pregnant women. Conclusion: There is a need to strengthen immunization services provided by pharmacists by tailoring them to include pregnant women

specifically.

Introduction

During pregnancy, the immunity of a mother is lowered making her more susceptible to various infections including the influenza virus illness (Mor & Cardenas, 2010). Research has shown an increase of about a four-fold in influenza antibody titers during pregnancy. (Mak, Mangtani, Leese, Watson, & Pfeifer, 2008). In between influenza epidemics, and during influenza pandemics, pregnant women are usually more susceptible to contracting influenza and its subsequent complications such as pneumonia, spontaneous abortions, preterm births, birth defects and fetal loss (Mak et al., 2008; Rasmussen, Jamieson, & Bresee, 2008). Usually, the morbidity from influenza in this population is low, however during the influenza pandemics such as 1918, 1957, 2009 and other influenza outbreaks, there were high death rates in pregnant women (Callaghan, Chu, & Jamieson, 2010; Mak et al., 2008; Thompson et al., 2011).

During the 1918 influenza pandemic in the U.S., 27% of pregnant women died, also in the 1957 pandemic influenza, 20% of influenza-associated deaths occurred in pregnant women (Rasmussen et al., 2008). This increase in mortality during influenza pandemics is a significant cause for concern, thereby placing pregnant women as a priority group for recommending the influenza vaccine (Callaghan et al., 2010; Thompson et al., 2011). The American College of Obstetricians and Gynecologists and Advisory Committee on Immunization Practices (ACIP) from the centers for disease control, recommend that all pregnant women should obtain the influenza vaccine (ACOG, 2004; Fiore et al., 2010; Thompson et al., 2011). Despite the recommendations, inactivated influenza vaccine uptake rate in this population remain suboptimal with about 33% -35% of pregnant women receiving the flu vaccine during the 2016/2017 influenza season (Arnold et al., 2019; CDC, 2017).

In pregnant women reasons for influenza non-vaccination are as a result of determinants such as concerns with safety for their unborn child and themselves; lack of awareness of the “two-fold” benefit of the vaccine; and women in their first or second trimester (Chamberlain et al., 2015; Meharry, Colson, Grizas, Stiller, & Vázquez, 2013; Wheelock et al., 2013). Other barriers to influenza vaccine uptake in this population include access, lack of time, lack of transportation to health care center, and lack of availability of influenza vaccine at providers’ office (Arao, Rosenberg, McWeeney, & Hedberg, 2015; Healy, Rench, Montesinos, Ng, & Swaim, 2015; Meharry et al., 2013). Some of these reasons corroborated among providers include insufficient time during prenatal visits, shortage of vaccines, allergic reaction of women to the vaccine, and their lack of knowledge about the vaccines (Healy et al., 2015; Frew et al., 2018). Providers also reported their personal lack of enthusiasm when recommending the vaccine and insufficient time to explain the benefits of the vaccine during visits, reimbursement challenges (Arao et al., 2015; Clark et al., 2013; Frew et al., 2018).

In the year 2000, the ACIP recommended standing order programs that authorized pharmacists and nurses to administer vaccines to adults (McKibben, Stange, Sneller, Strikas, & Rodewald, 2000). This recommendation followed studies that demonstrated that having nurses and pharmacists administer vaccines improved vaccination rates in adult populations. Implementation of programs such as this helps to take the pressure off physicians and increase adult vaccine coverage (McKibben et al., 2000). Among health care providers, pharmacists are the most accessible, as approximately 250 million individuals make a trip to the pharmacy every week (Steyer et al., 2004). Some of the barriers in inactivated influenza vaccine uptake in pregnant women can be overcome using community pharmacists due to them being accessible and they have more extended hours and days of work (Grabenstein, 1998; Steyer, Ragucci,

Pearson, & Mainous III, 2004). The study by Steyer et al. showed that in states that allowed pharmacists to administer immunization, the vaccine rate increased significantly in adults between the ages of 18-64 years (Steyer et al, 2004).

Studies have demonstrated and assessed the scope or feasibility of pharmacists practice in administering vaccines to adults, it was noted to be facilitated by policies such as the standing order which increased influenza vaccine administration and hence uptake in various states in the U.S. (Goode et al., 2007; Steyer et al., 2004; Weitzel, 2000). Other studies have demonstrated pharmacists' administering influenza vaccines to adults was cost-effective (Grabenstein et al., 1992; Prosser et al., 2008). The study by Grabenstein et al., (1992) reported that pharmacists playing the role of advocates and facilitators through campaigns inadvertently prevent hospitalizations and save costs (Grabenstein et al., 1992). The study by Prosser et al., (2008), reported the cost of vaccination was lower with pharmacists administered vaccines compared to clinics (Prosser et al., 2008). The study by Murphy et al., 2012, noted the accessibility of pharmacists administered influenza vaccines to individuals residing in medically underserved areas emphasizing the unique positions pharmacies might play reducing geographic barriers. Other studies noted that several factors were associated with individuals accepting pharmacies and pharmacists as vaccine administrators, and they include long hours of operation, convenience and easy accessibility (Ernst et al., 1997; Goode et al., 2007; Murphy et al., 2012). A study by Wang et al. (2014), noted that individuals placed pharmacists as the second most trustworthy vaccine administrators among health professionals following doctors. The study also noted that individuals reported that they would be comfortable receiving their influenza shot from pharmacists (Wang et al., 2014).

There are few studies that have qualitatively explored the role pharmacists play in

administering vaccines, especially from the perspective of the pharmacists themselves. Some studies have qualitatively explored the perceptions of the community and other health care personnel on the role pharmacists have played (Blake, Blair, & Couchenour, 2003), but no studies available exploring the pharmacist's perspective. A quantitative study by Dolan et al (2012), assessed pharmacists' knowledge attitudes and practice as it relates to treatment and vaccination of pregnant women during the 2009 influenza virus pandemic. They reported that pharmacists did not believe they had an important role in administering inactivated influenza vaccines to pregnant women (Dolan et al., 2012). The study, however, aims to explore the role pharmacists play in inactivated influenza vaccine administration in pregnant women practice, and this will be carried out qualitatively. This study attempts to fill these gaps by exploring the perceptions of licensed Florida pharmacists about their role in offering and administering inactivated influenza vaccines to pregnant women using the Theory of Planned Behavior (TPB) as a guiding framework.

Methods

Overview. This qualitative research study employed in-depth interviews. The main research question aimed to explore the knowledge, attitudes, social factors, barriers and facilitating conditions that influence IIV in pregnant women administration practices among licensed pharmacists in Florida. The study was approved by the University of South Florida Institutional Review Board (IRB). All records were stored on the USF Box folder and in locked filing cabinets in a locked room at USF. This study was non-invasive and presented minimal risk to human subjects.

Target population & sampling frame. The research aim, to explore the knowledge, attitudes, social factors, barriers and facilitating conditions that influence the influenza vaccine in

pregnant women administration practices among licensed pharmacists, was addressed through in-depth interviews with the licensed pharmacists in the state of Florida. Twenty licensed pharmacists in the state of Florida were chosen as the target population, as most pharmacists work under state and local state board regulations, regardless of the impact of national organizations such as the American Pharmaceutical Association (APhA). The sample size of 20 was used because generally, the sample size for qualitative studies ranges from between 12-60 (Edwards & Holland, 2013). The target the population is pharmacists in Florida who are registered with the Florida Board of Pharmacy.

In-depth interview guide. The interview guide was developed guided by the Theory of Planned Behavior (TPB) to understand the influenza vaccine administration in pregnant women practices among pharmacy students after graduation. Using the TPB, the interview guide asked questions about their knowledge, attitudes, subjective norms, and perceived control regarding administering the influenza vaccines to pregnant women. The interview guide was piloted with a licensed pharmacist who is also an Associate Professor at the USF College of Pharmacy to assess the feasibility, validity, and acceptability of the focus guide. The primary purpose of this pilot test was to assess the feasibility, validity, and acceptability of the interview guide. Qualitative interviews are usually pilot tested with a few interviews among people that have similar characteristics to the population of interest (Hennink, Hutter, & Bailey, 2011).

Sampling plan. Licensed pharmacists were recruited via non-probabilistic stratified purposive sampling for the in-depth interviews. The use of a stratified purposive sampling is to give room for comparison among study participants (Guetterman, 2015; Patton, 1990). In-depth interviews, as opposed to a focus group, were used as they provide an opportunity to explore individual perceptions of decisions regarding influenza administration in pregnant women.

Licensed pharmacists were stratified based on the type of center where they provide services into clinical and community (retail, independent, and others such as floaters who worked both at retail and home infusion and industry). A list of sites where pharmacists work was generated using a convenience sampling method, and the 'gatekeeper' or whoever was in charge at the various sites was contacted to help gain access and recruit participants. Emails and flyers which briefly introduced the study and described how to contact the researcher were sent to licensed pharmacists to recruit study participants.

Pharmacists were eligible for the study if they met the criteria of being a licensed Florida pharmacist. The study used a quota sampling strategy (Bernard & Ryan, 2010). There were two stratified sub-groups for which the adequate sample sizes were aimed to obtain, the participants were stratified by type of pharmacy where they work (clinical/hospital setting or community setting). This stratification provided some variability to the data to assess the impact of the type of pharmacy where pharmacists work on their knowledge, attitudes, subjective norms, and perceived control related to administering the influenza vaccine to pregnant women. The minimum number of pharmacists recruited for the pharmacists who work in a clinical setting was 5, while the minimum recruited for those who worked in community pharmacists was 13. More community pharmacists were recruited as they are known to provide immunization to the community, while fewer clinical pharmacist were recruited as it was unclear if they provided immunization in hospitals, however, their perceptions may provide a different view. This resulted in a total of 18 participants, saturation and redundancy was reached after 16 interviews and two more pharmacists were interviewed to reach a sample size of 18 (Table 7). The interview was piloted with a pharmacist who is also an Assistant Professor at the USF College of Pharmacy.

Table 7. Pharmacy Interview Sampling Strategy

	Certified to Immunize	Not certified to Immunize	Total
Clinical Pharmacist	N=3	N=2	N=5
Community Pharmacist	N=10	N=3	N=13
Total	N=13	N=5	N= 18

Data Analysis.

Data management. To ensure reflexivity through the research process, comprehensive field notes were taken that documented the focus groups and interviews, thoughts on them, and potential causes of bias that may interfere with interpreting results (Miles, Huberman, & Saldana, 2013). The recorded interviews and focus groups were transcribed word for word and were crosschecked for accuracy. Transcriptions did not include participants' names or any other type of identifying information. Once transcriptions were completed, the audio files were deleted to protect participants' confidentiality. A distinctive participant identifying number was used to differentiate each participant. All demographic information and transcripts were uploaded on MAXQDA analysis software, which would be used to analyze and manage data.

Data condensation. An a priori codebook was developed that had themes based on the interviews and focus group guides and the guiding TPB theory. The analysis was carried out concurrently as interviews were being conducted and transcribed, and emergent codes were added to the codebook with revised definitions as needed. The codebook contained the names of the codes, what the code signified (inclusion criteria for applying the code), what it does not signify (exclusion criteria for when no to apply the code), as well as a sample of the type of quote that should be used with the code (Bernard et al., 2016). The codebook development was

an iterative and continuous process, as new themes emerged during analysis. The codebook was imported into the MAXQDA software and was applied to relevant parts of the transcripts. The inductive thematic process, which involves the development of themes from the transcripts, was then employed in the study to analyze interview data to examine conditions and interactions, and determine categories that clustered together (Guest et al., 2011). To identify themes and subthemes, the transcripts were read two times, as well as looking out for repetition, metaphors, and content that was related to the TBP theory that guided the study in the text (Bernard et al., 2016). After themes were selected, the portions of texts that represented the themes were then identified (Bernard et al., 2016).

Data display and analysis. This employed the use of a matrix table in which codes and coded texts were displayed for the purpose of analysis (Miles et al., 2013). Analytic memos were used to note down considerations and anything else that came up during the analytic process (Miles et al., 2013). The analysis was carried out by two independent coders. The primary investigator coded all the transcripts (18) and the second researcher (LB) coded 10% (2) of the transcripts independently to produce an inter-rater reliability measure. Ongoing discussions of codes and themes continued through the analyses process, and discrepancies in the codes were discussed and a decision on the appropriate approach to go forward was determined. A Cohen's kappa provides a statistical measure for the coders to use as a standard and limiting subjective assessment, a kappa of 80% is used to denote agreement (Miles et al., 2013). The Cohen's kappa inter-rater reliability for this study was 84% denoting an agreement.

Results

The overarching purpose of this study was to explore the role of pharmacists in increasing the uptake of influenza vaccines among pregnant women. The results from the study

indicated that there were several areas discussed by participants, including their knowledge of influenza vaccines in pregnant women, and the role they had to play. Both of these areas were substantially impacted by what they know and their day to day interactions with pregnant patients.

Demographics. A total of 18 participants licensed Florida pharmacists were interviewed (Table 8), 50% (n=9) of them were female, and 50% (n=9) was male; 39% (n=7) were aged between 18-30 years, 44% (n=8) were aged between 31-40 years, and 17% (n=3) were aged between 41-56 years. About 72% (n=13) of them were certified to immunize, while 28% (n=5) were not certified to immunize. Seventy-two percent (n=13) worked in community pharmacies, and 28% (n=5) worked in a hospital setting. Twenty-eight percent (n=5) had been practicing for about five years or less, 33% (n=6) had been practicing for 6-10 years, and 39% (n=7) of them had practiced for more than 10 years. About 78% (n=14) had the influenza vaccine in stock where they worked during the past influenza season, and only 6% (n=1) experienced a backorder for the influenza vaccine during the past influenza season.

Table 8. Licensed Florida Pharmacists Demographics

Characteristics	Number	Percentage (%)
Certified to Immunize		
Yes	13	72
No	5	28
Age range		
18-30	7	39
31-40	8	44
>51	3	17
Sex		
Female	9	50
Male	9	50
Years of practice		
0-5	5	28
6-10	6	33
>10	7	39

Table 8. continued

Location of Pharmacy		
Rural	1	06
Urban	12	66
Sub-urban	5	28
Influenza vaccine in stock		
Yes	14	78
No	2	11
Not applicable	2	11
Influenza vaccine back order		
Yes	1	06
No	13	72
Not applicable	4	22
Ever immunized pregnant woman		
Yes	7	39
No	6	33
Not applicable	5	28

Among the pharmacists who worked in the community settings, 77% (n=13) were certified to immunize, and 23% (n=3) were not certified to immunize, also 2 worked at independent pharmacies and were both not certified; and among the pharmacists who worked in the clinical settings 60% (n=3) were certified to immunize, while 40% (n=2) were not certified. Among the clinical pharmacist, 80% (n=4), had the job title of clinical pharmacist, while 20% (n=1), was a clinical operations manager; while among the community pharmacists, 31% (n=4) were pharmacy managers or directors, and 69% (n=9) were staff pharmacists. Among the staff pharmacist were those who also had positions in other types of pharmacies including managed care and industry 44% (n=4).

TPB constructs influencing influenza vaccine administration in pregnant women practices.

Knowledge.

Knowledge about General Influenza Vaccine Administration. Pharmacists' knowledge about the influenza vaccine administration and uptake in the general population and in pregnant

women were assessed using open-ended interview questions. When asked about their general knowledge on influenza vaccines, all (100%) the participants knew about the influenza vaccine and its use to prevent the influenza virus illness. One participant stressed the importance of getting the influenza vaccine regardless of the side effects.

“It is very important that you get it every flu season, it is not going to make you get flu, it is going to prevent it, it is not going to make you sick. Even if you have an egg allergy, you are still able to get the flu vaccine, the incidence of people who actually have a true reaction or true allergy to flu vaccine content is very very minimal, it is rare. And there is another type of vaccine called the “flublok” that we give or recommend for you that will be appropriate if you were concerned about that.”

LP16 (Clinical Pharmacist, certified to immunize)

Another participant emphasized how safe the vaccine is based on the recommendation of governing bodies such as the CDC.

“It’s very safe. There isn’t a whole lot of things that are safer than Flu vaccine. When patients ask me how safe the flu vaccine is, I explain to them that the CDC, the FDA, whatever government agencies..., whatever I think they can understand, says that I can give the Flu vaccine to anybody as young as 6 months of age; if it’s that safe, it’s safe for everybody. The only contraindication to Flu vaccine is if you are allergic to eggs.”

LP 10 (Retail Pharmacist, certified to immunize)

Thirty-nine percent (N = 7) of the participants also mentioned other things they knew about the influenza vaccines such as the recommended age groups and special populations for the vaccines.

“If you are over the age of 6 months you are recommended by the CDC and most of other guidelines to get it. It’s a respiratory virus that can be transmitted. It can cause from mild to severe disease, especially in our high-risk patients need to be vaccinated.”

LP8 (Retail Pharmacist, certified to immunize)

“Everyone should get a flu shot once you are over the age of 6 months, and it should be... I would like guesstimate early august before the temperature changes and all of that.”

LP13 (Retail Pharmacist, certified to immunize)

“The vaccine does not always protect from the virus a 100%, but it provides some sort of protection, immunity. I think it helps especially in pregnancy and other special populations it is something people should get. In general people should get the vaccine even if it is not 100%.”

LP7 (Clinical Pharmacist, certified to immunize)

Other things that were mentioned about the influenza vaccines included: types of influenza vaccines, time to go get the vaccine, and the side effects. When the efficacy of the vaccine was mentioned, all participants said vaccine was never 100% effective against the influenza virus, and it varied from year to year. However, 10% (n=2) felt the vaccines are not effective against the influenza virus disease based on their personal beliefs.

“I would say that I believe it doesn’t really stop you from getting the flu, because sometimes it gives you the symptoms of the flu after you get the flu shot.”

LP17 (Clinical Pharmacist, not certified to immunize)

“I got vaccinated in school and after a day or two I was really sick... It was like I was going to die. So, it was during finals week. I almost failed school, I couldn’t explain why the vaccine I got me sick immediately, ever since, I didn’t take the vaccine.”

LP9 (Retail Pharmacist, certified to immunize)

Also, some participants (10%, N=2) encouraged uptake of the vaccine regardless, as it may still confer some protection.

“In my estimation it is 50-50. It does not hurt to get the vaccine, it does not necessarily mean if you get the vaccine you won’t get the flu, but it does provide some sort of protection, it does not hurt to get it, it is something I will recommend and I will get it myself.”

LP7 (Clinical Pharmacist, certified to immunize)

“I think it can be effective, people have this preconceived notion..., like I hear a lot of people say that it doesn’t even that they got the vaccine, but it still didn’t prevent them from getting the flu. But the thing they might not know about it is that the virus is always creating new genotypes and forms so that it is impossible to have every single type of virus or whatever in a vaccine to protect you from everything that is out there, but it is

going to protect you from the most common ones, or the ones that we have already seen out there.”

LP4 (Clinical Pharmacist, not certified to immunize).

Knowledge about Influenza Vaccine Administration in Pregnant Women. Similar to the general knowledge theme, all (100%) the participants knew about the influenza vaccine and its use to prevent the influenza virus illness in pregnant women. Some of the participants (28% n=5) mentioned the contraindication of live vaccines in pregnant women, and one participant (6%) mentioned the use of the preservative-free influenza vaccine.

“...In most pregnant women the only contraindication usually is the live vaccine, to not administer it to pregnant women, but the inactivated vaccine is safe in women who are pregnant and women who are breastfeeding.”

LP 2 (Retail Pharmacy Director, certified to immunize)

“We are able to immunize pregnant women, but we use the preservative free.”

LP 15 (Retail Director, certified to immunize)

Some of the participants (28%, n=5) mentioned the influenza vaccine can be received at any trimester by pregnant women, while (17%, n=3) mentioned not being sure what trimester was safe for pregnant women to obtain the vaccine.

“Pregnant women can receive the vaccine in any trimester, it is safe for pregnant

women...”

LP 2 (Retail Pharmacy Director, certified to immunize)

“We try to give them flu shot and tetanus shot and I know that they can get it at any time during their pregnancy, so whatever the trimester they are in, as long as they are within the flu season, we try to give it to all of them in our pharmacy setting. We do have the standing order with the doctor so we can administer it. If they are 19 years and older, we can give it to them.”

LP 12 (Retail Pharmacy Director, certified to immunize)

“Not sure the exact time as far as how many weeks or trimester.”

LP 13 (Retail Pharmacist, certified to immunize)

When asked about the benefits of the influenza vaccine during pregnancy, most (72%, n=13) respondents mentioned the vaccine provides ‘dual protection’ for the mom and baby from the influenza illness, keeping them both healthy.

“It is safe in pregnant women. They definitely should receive it, and the vaccine does not affect the child too, so it provides a double coverage to the mom and baby. It is safe and recommended.”

LP 11 (Retail Pharmacist, not certified to immunize)

“...their immune system is weakened when they are pregnant so getting the vaccine would

help them and the baby stay healthy. Also, the baby can't get vaccinated until they are 6 months so if the pregnant mum were to get the vaccine, they would be immune over those first few months after birth."

LP 8 (Retail Pharmacist Director, certified to immunize)

Two participants mentioned additional benefits including providing protection for the community (herd immunity) as part of the benefits of the pregnant women receiving the vaccine.

"I think the biggest thing is protecting the mom and the baby. And for..., not only from each other, but also from the community, that herd immunity."

LP 8 (Retail Pharmacy Director, certified to immunize)

"The benefits of the vaccine in pregnant women, it definitely protects them, the people around them, as well as the baby that they are pregnant with. So, yeah getting the vaccine is very beneficial as the mother whose immune system can be compromised, her organs can be compromised with having a child, it definitely allows them to be more susceptible to the virus, them as well as the baby. So, receiving the can give you more immunity and protect you and the baby and the people you are around."

LP 2 (Retail Pharmacy Director, certified to immunize)

Attitudes. The theme of attitudes reflects the pharmacist's belief regarding providing influenza immunization to pregnant women and the notion that doing so has specific outcomes. Participants were asked about their thoughts and feelings about providing the influenza vaccine to both the general public and pregnant women, which was expressed as advantages and

disadvantages. Across the in-depth interviews' participants believed it was advantageous to the community and pregnant women that pharmacist provide immunization services. Pharmacists described positive attitudes expressed in the following sub-themes: a) accessibility, b) experts, c) increased scope, and d) ease for practices.

Access. Pharmacist believe they are the most accessible health care providers and this sentiment was shared by 78% (n=14) of the participants.

“Pharmacists that work in the community settings are very, they are probably the most accessible healthcare professionals..., I will say they are not the most appropriate, but the easiest professional to reach to get your flu vaccine. They are the one group of professionals where you don't have to make an appointment and things like that.”

LP16 (Clinical Pharmacist, certified to immunize)

“Biggest advantage is accessibility. Can I pick up my medication? sure. Can I get counseled? sure! oh while I am here can I get my flu shot? Sure! So “One stop shop” for majority of all their needs.”

LP 6 (Retail Pharmacist, certified to immunize)

Experts. Pharmacists believe they are experts and knowledgeable, hence, that places them in a great position to provide immunization services to pregnant women. This sentiment was shared by 33% (n=6) of the participants.

“I think that a lot of people lack the knowledge. I think that they feel that the vaccines are going to make them sick. We know a lot; we interact with the CDC a lot so we can

explain to them the importance of it versus the risks of not having it. So, I think that we are just that one extra level of education for them to feel safe about getting the vaccines.”

LP 8 (Retail Pharmacy Director, certified to immunize)

“We are very knowledgeable, and I think it’s just now that our knowledge is starting to come into play, we have been doing this forever...”

LP 6 (Retail Pharmacist, certified to immunize)

Increased scope. Pharmacists expressed that providing influenza immunization services to pregnant women increases the scope of their practice. This sentiment was shared by 39% (n=7) of the participants.

“...it increases our scope of practice as practitioners.”

LP 2 (Retail Pharmacy Director, certified to immunize)

“I also think that it’s a good way for people to see the advancing role of a Pharmacist; that they are not just counting pills, but they have a lot more roles.”

LP 8 (Retail Pharmacy Director, certified to immunize)

Ease for practices and patients. Pharmacists expressed that providing influenza immunization services to pregnant women takes away the burden from physicians and other care providers. It is also more convenient for pregnant women. This sentiment was shared by 39% (n=7) of the participants.

“I think it’s a good thing that Pharmacists are involved now because some patients don’t

have insurance. So, once they think about going to the hospital, getting an appointment, seeing a Doctor and all that it discourages them from wanting to get the vaccine. But, knowing they can walk into a Pharmacy and just get it without waiting in line for too long or setting up an appointment, I think it encourages people at least to want to get vaccinated.”

LP 18 (Independent Pharmacist, not certified to immunize)

“It saves them time and money. More than likely if you are in the pharmacy, just speaking of pharmacies now, most pharmacies have convenience stores, so you are doing shopping there anywhere, to rephrase my earlier statement, it’s a “one stop shop”. No appointments needed, no doctors, just let us know when you want it, and we will take care of it for you”

LP 6 (Retail Pharmacist, certified to immunize)

It helps out some of those strained medical facilities that may be inundated with pregnant women..., I think we, on their end we are a big help to doctors. A lot of doctors’ offices in particular run out of the vaccine very quickly, whereas a lot of the larger chains keep it in stock

LP 2 (Retail Pharmacy Director, certified to immunize)

Participants also expressed concerns as to why they may not be in the best position to provide immunization to pregnant women, under the following subthemes: a) not enough information (as they do not usually have background information on the pregnant women), b)

increased liability and c) lack of education. Others did not share these sentiments and believed there should not be a reason why they would not give a pregnant woman the influenza vaccine. Pharmacists expressed that providing influenza immunization services to pregnant women may not necessarily be disadvantageous to them but would prefer if they had more background information on or access to pregnant women's history. This sentiment was shared by 39% (n=7) of the participants.

“Maybe the pharmacist may not have full comprehensive health history on the patient because the pharmacy system they are not as connected to the hospital system, I am speaking more for community pharmacies now, but like health records like EPIC is becoming more popular, a lot of community pharmacists are starting to use the ambulatory module for EPIC which connects to other hospital records that use EPIC as well. So, as long as the patient is at an institution that can use EPIC or any other like nationwide electronic health record then they should be fine.”

LP16 (Clinical Pharmacist, certified to immunize)

“I think a the main disadvantage that sticks out will be a lack of accessibility to medical history of patients, so again in the community pharmacy they are not privy to pregnant females medical history, so maybe they've had allergy to a component of the vaccine the community pharmacists may not be aware of this information because it lives in the OBGYN or PCPs medical history record. So again, the lack of interphase of medical records, and the lack of familiarity that you know the community pharmacists would not have if a pregnant female presents to the community pharmacy”

LP1 (Clinical Pharmacist, not certified to immunize)

“I don’t think we are at a disadvantage, I mean, because we do not have a continuity of care, it doesn’t really give them an advantage. We can’t see their records; we don’t really know anything else with the full picture of their pregnancy to give them good counselling... Because we do not have a universal healthcare system, we cannot see what we are doing outside of the office.”

LP 11 (Retail Pharmacist, certified to immunize)

Pharmacists expressed that providing influenza immunization services to pregnant women may lead to an increase in liability to them. This sentiment was shared by 50% (n=9) of the participants.

“It probably takes the pharmacist out of his work schedule. There’s room for litigation, as the pharmacists may not be able to respond to potential complications if they arise, though rare. Liability as a result of an inability to respond to complications we cannot anticipate.”

LP 14 (Independent pharmacist, not certified to immunize)

“I think there’s always..., that’s the biggest thing liability, everyone is looking to kind of like get their angle on, like he didn’t ask me this, he didn’t ask me that, oh you know..., I developed GBS when I went to CVS. So, liability I think is the biggest thing.”

LP 3 (Retail Pharmacist, certified to immunize)

One (6%) participant expressed that providing influenza immunization services to pregnant women may be difficult for a pharmacist who is not educated or trained regarding it.

I think the only disadvantage is just the pharmacist him or herself, maybe not feeling confident in their skills or maybe education wise, if they haven't done it in a while, they are not used to doing it so often or not knowing the type of patient that is in front of them, whether vaccine live vs attenuated which is okay you know. Or you know maybe education wise, they might not feel confident, other than that, no.

LP 3 (Retail Pharmacist, certified to immunize)

Others (44%, n=8), believed it would not be disadvantageous to them as pharmacists to provide immunization services to pregnant women.

"No disadvantage, because we are fully educated on immunization as doctors are, and most the patients get are side effects or allergic reactions to the vaccine."

LP17 (Clinical Pharmacist, not certified to immunize)

One participant (6%) however, was not sure pharmacists were allowed to immunize pregnant women.

"I think they have to go get it (influenza vaccine) at their primary physician. I don't think that pharmacists are allowed to do that..., but I am not 100 percent sure."

LP4 (Clinical Pharmacist, not certified to immunize).

Perceived Control. The theme of perceived control reflects how much the pharmacist believes that providing immunization or not providing immunization to pregnant women is under their volitional control. Participants were asked about their thoughts and feelings about the facilitators and barriers to providing the influenza vaccine to pregnant women, alongside

education and counseling. Participants described the need for employing other staff such as pharmacy technicians to assist with workload, so they can focus on immunization services when the need arises. This sentiment was shared by 50% (n=18) of the participants.

“Another thing again is manpower, because a technician can help while you will be able to provide these services. They can take away some of the manual aspect of the work, while you do the clinical aspect of the work.”

LP7 (Clinical Pharmacist, certified to immunize)

“Now if they want to really get the numbers up... take away some of the responsibilities, staff the Pharmacy efficiently so it can actually feel like a health care instead of a fast-food joint where the next... ‘next flu shot, next they are not coming through a trolley...’”

LP9 (Retail Pharmacist, certified to immunize)

Some participants described the need for a physician referral or recommendation immunization services when the need arises. This sentiment was shared by 50% (n=9) of the participants. One participant mentioned that the prescription was not necessary but provided a way for physicians and pharmacists to communicate and helps the patients to follow up. Seen below.

The patients bring their prescriptions for the vaccine, we don't use the prescription, but we use it to see what the vaccine is for. I think patients use it as a way to communicate between the two of us. Because when they tell the patients get this vaccine..., they are not going to remember the details, so they write it down, that helps a lot, cos we can best identify that they need that vaccine, because their doctor said get that vaccine. That is one of the things we have the biggest issue with, when we have to ask, ‘did they tell you to

get the vaccine? have you had this before?’, we do not really have their details, we have ‘Florida shots’ but not everyone uses that.”

LP 13 (Retail Pharmacist, certified to immunize)

“The physician recommending that you get it from the pharmacist, so you can get it at any time, since they are easily accessible. And they have already accessed the patient and they have shown that it is appropriate. It is just like when they say they want a certain medication for the patient and the patient goes to the pharmacy to get it. It could be the same for vaccines.”

LP4 (Clinical Pharmacist, not certified to immunize)

Some others (17%, n=3) believed that physicians may also be a barrier to pregnant women coming to the pharmacy to receive the influenza immunization.

“I think it might present a conflict of financial interest for the physician, it’s like sending your patient away to somewhere else where you will not be able to recoup funds.”

LP16 (Clinical Pharmacist, certified to immunize)

“They can be a barrier, and also a facilitator, in that sometimes they want their patients to stay in the practice and get their vaccines there.”

LP 13 (Retail Pharmacist, certified to immunize)

A few participants (33%, n=6), believed outreaches and campaigns tailored to pregnant women may facilitate pharmacists providing the influenza vaccines to the pregnant women as they will

create awareness.

“There are some promotions that go on every flu season, we do like a blog entry, just like promotional items we have with our preferred pharmacies to encourage customers to get the flu vaccine. It is not targeted to pregnant women specifically but can be.”

LP 5 (Retail Pharmacist, certified to immunize)

I mean when they say “get your flu shot” it’s like a general thing but if they can just put another caption to let pregnant women know cos when you see “get your flu shot” it is just like a generalized thing. So, I mean everything starts from that awareness - let pregnant women know even from the hospitals, commercials though the t.v., everywhere... that it is safe. So... even if the sign is there the pregnant woman might not still take it serious like they are talking to her. So, if there is a lot of awareness, they will feel more comfortable walking in.

LP 18 (Independent Pharmacist, not certified to immunize)

“It would have to be a campaign, and when I say a campaign I mean a campaign from a corporate level and not just a campaign that says “it’s Flu season get your shot” If you really want to be effective with the shots you have to address the fact that these are the barriers that are influencing the pharmacists from giving the shot, once the company says ‘we are going to remove those barriers’, pharmacists will immunize everyone and everybody”

LP 6 (Retail Pharmacy Manager, certified to immunize)

One participant (6%), reported that with support and educations, pharmacists will be more likely

to provide immunization services in pregnant women.

“I think educating them, providing more education around immunizing pregnant women specifically. I think as long as the pharmacists feel like they are supported, they know it is recommended by the CDC then they will be more likely to provide the immunization.”

LP 15 (Retail Pharmacy Director, certified to immunize)

Participants mentioned that when an incentive is provided to the pregnant women to obtain the influenza vaccine, and when it is provided to the pharmacist to provide the vaccine, this can facilitate the provision of the vaccine. This sentiment was mentioned by 28% (n=5) participants.

“We get incentivized on the back end, so it’s more like our “flu goals”. If you have met your goals, and your store is up to par for other things, you can ask for a raise..., we immunized anyone we could find with a pulse, cos we had to meet our goals... But patients also get the incentives, and that is what helps them come to us. I work at xxx typically, and they get a \$10 coupon at xxx.”

LP 13 (Retail Pharmacist, certified to immunize)

When discussing the barriers, pharmacists expressed various sentiments including lack of access to pregnant women and the pharmacist, increased workload, workplace environment, and lack of education of themselves as pharmacists regarding providing vaccines to pregnant women. Other participants (33%, n=6), expressed that not having access to the pregnant women may be a barrier.

“The reality is that a pregnant woman probably..., they are unlikely to come to a pharmacist for their influenza vaccine. It is usually a package in their antenatal care.”

LP 14 (Independent Pharmacist, not certified to immunize)

“Most pregnant women think the doctor has to do it, or they have to go to the clinic. I think the lack of knowledge about using pharmacists is the biggest barrier.”

LP 11 (Retail Pharmacist, certified to immunize)

Seventy-two percent (n=13) of the participants believed that providing immunization services increase their workload.

“Time. That is the biggest thing. Usually, unfortunately when people come to the pharmacy, they are usually here “let me get my medication and go”. Even as pharmacists, the amount of things that are determined of us, we do not have time to sit there and talk to you about your medication, and if we cannot do that about medication, how can we do that about immunization.”

LP 6 (Retail, certified to immunize)

“It is added work for the pharmacist, it is a lot more work. In my experience when I was in retail, in fact one of the reasons why I left retail, it was added work, without help, I don't get help to cover with other things I am supposed to do. On a given day I have 5-10 immunizations, with people waiting for me, doctors call back, counseling sessions. The patient load on the pharmacist is a lot, and now some retail store requires the pharmacist

to give a number of vaccinations in a day or a month, it's your job. It should not be a quota thing for pharmacists to provide such services."

LP7 (Clinical Pharmacist, certified to immunize)

Other participants (11%, n=2) did not feel providing immunization services to pregnant women interrupted or increased their workload.

No, because I know that there are certain pharmacies..., I don't know if technicians actually do that, but you can have your technician set your work flow, set it up. So that way once they identify a patient who needs to be vaccinated, the pharmacist comes in, vaccinates the patient, asks questions, answer questions, counsel the patient, do your 'mtm', it won't take you long, you just have to have that built into your workflow."

LP 3 (Retail Pharmacist, certified to immunize)

A few participants (17%, n=3) shared the sentiment that the pharmacy environment was not in itself conducive to provide immunizations.

"I think the way it used to be, like in the past when pharmacists started immunizing, they had immunization rooms in the pharmacy, a certain area for consultation, they had appointments you would set with the pharmacist for your immunization. Now it has become if you go to checkers or MacDonalD's and you say, I want a flu shot, and the technician types it out, it goes through and literally puts it in the basket, it comes to me, and I am like oh I am doing a vaccine... I do not know your name; I do not know who you

are. I read the form; I do not see any issues giving the vaccine... So, we are just kind of moving around like flies..., honestly, I think our workplace environment is a barrier itself...”

LP 13 (Retail Pharmacist, certified to immunize)

“I think there would be some discomfort, because the pharmacy is not an intimate setting, and pregnancy is very tough. Because of the setting, pharmacies usually have an open concept that would probably prevent them from freely going to get retail immunization, you know, the vaccine. It is not pregnancy friendly”

LP 11 (Retail Pharmacist, certified to immunize)

Other themes regarding factors that may affect pharmacists’ volitional control in administering the influenza vaccine to pregnant women include the type of insurance or community settings (rural, urban) of the pregnant woman. When asked about insurance type, all licensed pharmacists’ expressed sentiments that insurance type may be a barrier or a facilitator depending on the type.

“If they pay for it, we are going to have an increased influx of women wanting to get it; if patients have to pay out of pocket then we have to think about costs. HMOs are going to be the ones that dictate where they go, so those are going to be the ones that probably won’t pay for at the Pharmacy versus telling them they have to go to their Primary Care Physician. For like PPOs and so forth, the patients usually get autonomy and get to pick where they go.”

LP 8 (Retail Pharmacy Director, certified to immunize)

“I am actually taking a class on how insurances work, but I think the biggest thing is just the co-pay, that’s the biggest problem. Anytime you walk into a pharmacy and you are being told that you have to pay forty bucks or sixty bucks or whatever it is, you got your HMO PPO, you will not want do that when you were just at your doctors yesterday, you could have gotten it done there.”

LP 3 (Retail Pharmacist, certified to immunize)

“I have mixed feelings on that. Some of them have provided incentives for that to happen where it is actually cheaper for the Pharmacist to do it than the doctor, so their reimbursement is greater in the stores. But then again, a lot of them don’t believe in preventive care... so then why should I have a rejection on an immunization where it should be automatic preventive care? because they have to think, on the long run, prevention is better than cure right? So, incentivize patients to get vaccinated, lower the co-pays or no co-pays... but Medicare does a good job, there’s no co-pay for Medicare patients.”

LP 9 (Retail Pharmacist, certified to immunize)

“Managed care programs a very good job about it. Pharmacists are given points, saying give the vaccine it’s that time. You give a vaccine. you get a point. It’s a point system you can use on whatever, so we see the benefits of it, and they are trying to make sure that it is promoted to our beneficiaries.”

LP 6 (Retail Pharmacist, certified to immunize)

When asked about patient’s community settings (rural vs. urban), pharmacists’ expressed

sentiments that insurance type may be a barrier or a facilitator depending on the type. When asked about the patient's location or community settings (rural vs. urban), participants shared varied responses. Some of the participants 50% (n=9) believed there was less access to healthcare services in rural areas. However, one participant felt individuals in rural areas may have access to immunization services because of their relationship with their pharmacist.

“Rural is helpful, pharmacists have a relationship with their patients, they are slower paced, you can actually identify them because you know them. You can say, ‘hey Mrs. Cooper we think you should get this vaccine today’, and that is a better way compared to urban where you don’t really have that relationship with your patients who are more in an urban area.”

LP 13 (Retail Pharmacist, certified to immunize)

One participant expressed that there may be issues with access to the vaccine in both areas depending on the barriers they encounter. Others (17%, n=3) believed that barriers to immunization in any region had to do with the patient's culture or socio-demographic characteristics.

“When I think about rural areas, I think about places that have less access to healthcare, less access to providers. I think there are those who might, even if they wanted to get the flu vaccine might not have access just because there might not be a provider nearby that can administer the vaccine to them. So, access would be a barrier in that setting. Now in the urban area I am thinking access to services in addition to a lot of the urban neighborhoods tend to be in lower socioeconomic status, so affordability becomes

something else that we have to think about in that setting. So, where there are free flu clinics where it is subsidized, and people would be more likely to get the vaccine.”

LP 3 (Retail Pharmacist, certified to immunize)

“I think that depends more on the demographics of the area, the patient’s education level, their level of awareness, exposure. We already have a propaganda by people who are against any sort of vaccination, so that’s another thing. It all depends on the demographics, and social standing, education status all those things. I work in a rural area of Florida, and I have seen that health care seeking behavior has to do more with the patients sociodemographic.”

LP7 (Clinical Pharmacist, certified to immunize)

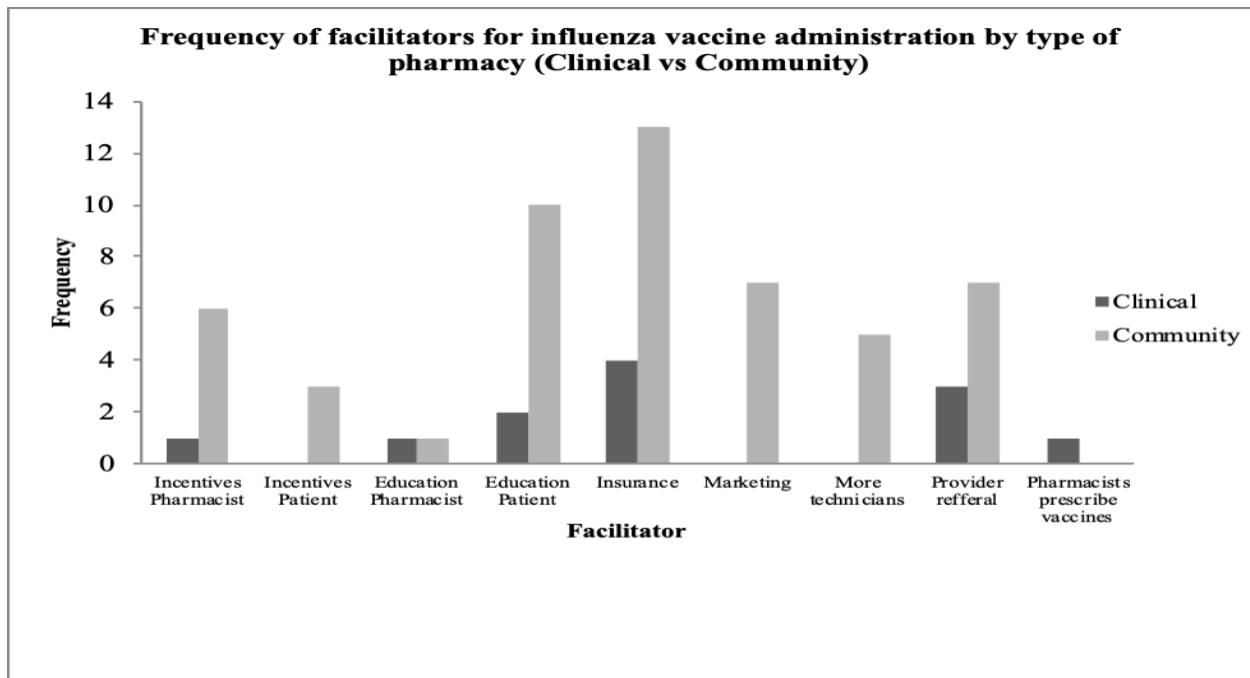


Figure 3. Frequency of facilitators for influenza vaccine administration by type of pharmacy

Subjective Norms. This refers to pharmacist engagement in providing influenza vaccines to pregnant women if they feel people close to them think they should. Which then motivates the pharmacist to administer influenza vaccines based on what these individuals think. For the study, the pharmacists were asked about the influences of the following individuals on them providing influenza vaccines to pregnant women: a) the CDC, b) the APhA, c) the Florida state statutes, d) physicians, e) pregnant women, and f) their peers.

CDC. When asked about the influence of the CDC, licensed pharmacists believe they serve to play the role of quality control and provide the vaccine guidelines regarding administration to pregnant women and the general public.

“CDC has a big influence; they have a lot of information on vaccines that is readily available to everyone. And they make it a little bit easier and more manageable to understand the different types of vaccines and how they should be administered...”

LP4 (Clinical Pharmacist, not certified to immunize)

“I feel like all those guidelines... the APhA, the ACIP, and the CDC... Those are where my recommendations come from. We are required to practice under evidence-based medicine so I can't form my opinion on whether or not they get the shot. I have to go based of those global guidelines.”

LP 8 (Retail Pharmacy Director, certified to immunize)

“... they do a lot of the monitoring, and quality checks and you know quality control just to make sure it is the right vaccine for coverage”

LP 18 (Retail Pharmacist, not certified to immunize)

APhA. When asked about the influence of the APhA, pharmacists (n=4) reported that it is an important resource through which they obtained their training on immunization and for continuing education, and license renewal. Others (n=7) expressed that the APhA acted as an advocate for pharmacists to become immunizers, while a few (n=4), mentioned that the APhA provides information and guidelines regarding immunization in general, but not specific to pregnant women.

“I think that they..., APhA at the national level, and also at the affiliate level, have been very instrumental in getting pharmacists providing care or visibility, so they support pharmacists providing vaccination and have been lobbying for extended roles for pharmacists not just relating to flu vaccine but other vaccines that are out there such as pneumonia and the rest. I know that they really support it from a regulatory standpoint and a regulatory standpoint too.”

LP16 (Clinical Pharmacist, certified to immunize)

“Generally, APhA doesn’t directly affect vaccines for pregnant women, they more so affect clinical practice”.

LP1 (Clinical Pharmacist, not certified to immunize)

“I think APhA gives you the continuing education credits. They have the thing every year where they talk about the flu vaccine, the hits and the misses, all that fun stuff, information.”

LP 13 (Retail Pharmacist, certified to immunize)

Standing order. When asked about the influence of the Florida state law regarding pharmacists providing immunization services under the supervision of a Physician within a framework of an established protocol (Florida, 2018), pharmacists expressed mixed feelings on how it affects their vaccine administration practices. Eight of the participants expressed positive feelings about it. As one participant noted it is a necessary step.

“It has not limited us in any way. My belief is that it was a necessary step in order to achieve future autonomy, because we had to show how we impact immunization rates and how we can do it safely. I don’t think we would have gotten autonomy off the back from a legislative standpoint. we have to earn that.”

LP 15 (Retail Pharmacy Director, certified to immunize)

A few participants (n=3) expressed neutral feelings about the standing order, as it may be redundant. All three participants who expressed this notion were clinical pharmacists.

“ I think I am neutral about it, I don’t work in community pharmacy now but I have worked in community pharmacy before and I know that even though the physicians name is on the standing order as far as the physician in charge for you to give vaccinations. A lot of us that work in community pharmacies have never even seen the physician whose name is on the is on the permission slip. It is a moot point, it is there just to satisfy the regulatory requirement, but the physicians don’t normally do anything, their names are just on a piece of paper. You can be in the pharmacy 10 years and never see that physician one time in your life.”

LP16 (Clinical Pharmacist, certified to immunize)

“I am kind of neutral about it. I mean everything is under the supervision of a doctor, regardless of if it is the influenza vaccine or prescription for any medication.”

LP17 (Clinical Pharmacist, not certified to immunize)

Other (n=6) participants expressed negative feelings about the standing order, and do not believe it is needed.

“Personally, I feel we should be able to administer it even without a standing order from a physician. Maybe in the future it will get to where a pharmacist will be able to prescribe these vaccinations on their own and provide them without a doctors name under it.”

LP 12 (Retail Pharmacy Director, certified to immunize)

“I actually think it is pointless, the physician is just on a piece of paper, because if there was an emergency going on with like you know, vaccine reaction or something like that, I am not going to call the physician, I am going to call 911 to come get the patient. I don't think the physician is necessary.”

LP16 (Clinical Pharmacist, certified to immunize)

The case for independent pharmacists. A few of the participants mentioned why the standing order requiring the physician to sign off on immunization may not be good for independent pharmacies, as it is not as feasible for them to afford a doctor to sign off on them providing immunization services.

“I mean it’s good on paper, it’s hard, because, number one you have to find a physician who will let you sign, if you are not working for like a big corporation right. So, if you are not working for the CVS, the Walgreens, COSTCO or wherever. It’s hard to get a physician.”

LP 3 (Retail Pharmacist, certified to immunize)

“So, we have one physician who oversees everybody, and that is great. Now what if you have an independent pharmacy and there is no physician there, now you have maybe ten people who missed out on vaccinations, you take that and multiply around the country... So, it is very important to recognize the expertise of these pharmacists and give them those additional responsibilities, rather to have them jump through loophole from loophole, because at the end of the day it is the patients that matter”

LP 3 (Retail Pharmacist, certified to immunize)

“Already there is a binding clause, the binding clause is that if I want to provide immunization, then there must be a concurrence to a physician. If the pay is worth it for my pharmacy I will go ahead and go through the paperwork and the concurrence with the physician. If you want to provide immunization services, you need to do that if the cost is worth it. While this has expanded the opportunity for pharmacists to immunize, nothing has really changed for us independents.”

LP 14 (Independent Pharmacist, not certified to Immunize)

Physicians. When asked about the influence of the physician on pharmacists administering the influenza vaccines to pregnant women, all participants believed that physicians play a major role with regards to referring the women and creating awareness that they can get their shots at the pharmacy. One participant mentioned that physicians are key to changing the number of women getting immunized.

“I think if the doctors encourage them to get vaccinated..., I think if they have a secondary provider who is trusted, the doctor allows them to or encourage them to seek their vaccination, that would increase the numbers. Because we know, most essentially the argument is the pharmacy vs the clinic, it is easier, so I think if the physicians refer the patients to the pharmacy, you know, go to your local pharmacy and get vaccinated. If they can encourage that behavior that would be the key to changing the number of pregnant women getting vaccinated.”

LP 12 (Retail Pharmacy Director, certified to immunize)

Peers. When asked about the influence of their peers or other pharmacists on them administering the influenza vaccines to pregnant women, participants were neutral about their colleagues choosing to or not to provide immunization services to these women, one participant, however, talked about how that impacts vaccine uptake in pregnant women.

“I think if a pharmacist has said no to a pregnant woman to administer the vaccine to them, they will probably be scared to go to any other pharmacist and that will have a big influence...”

LPI17 (Clinical Pharmacist, not certified to immunize)

Another participant mentioned that the older pharmacists may not be willing to provide immunization services to pregnant women.

“The older pharmacists won’t do it, they may be like, ‘why are you immunizing pregnant women? We don’t do that here’, they think they are a higher risk a patient group for vaccination.”

LP 13 (Retail Pharmacist, certified to immunize)

Another participant mentioned the importance of a retail pharmacist being capable of providing such services.

“It depends on what industry the pharmacist is working in, if you are a retail pharmacist, you really have no choice, you cannot ignore immunization or that pharmacists won’t have the job, if you cannot. If you are in a hospital you are not required to immunize, in a managed care setting you are also not required to that, so it depends on the pharmacy industry where you work”

LP 7 (Clinical Pharmacist, certified to immunize)

One participant mentioned if more pharmacists were getting certified to immunize, it might spur others up to want to get theirs.

“I mean that will influence me to get my certification and learn more about it. I mean if everyone is doing it, if everyone is providing a service, then I am going to have to try to

transition to that just like when it comes to...,you know, things are advancing so you have to advance with it.”

LP 4 (Clinical Pharmacist, not certified to Immunize)

Pregnant Women. When asked about the influence of the pregnant women on pharmacists administering the influenza vaccines to them, pharmacists expressed that providing influenza immunization services to pregnant women would not be difficult due to the fact that patients trust pharmacists with their health questions. This sentiment was shared by 11% (n=2) of the participants. However, two other participants shared the sentiment that pregnant women may trust a doctor over a pharmacist.

I've always considered us as the first line because, with the patient we... they come to us first and they have that trust-factor with regards to their health questions

LP 9 (Retail Pharmacist, certified to immunize)

“Pregnant women should be comfortable going to the pharmacist for their vaccine, because a lot of people trust the pharmacist’s knowledge of the drug, they trust the pharmacists of drug interactions, there’s a lot of trust in pharmacists in what they provide. As long as they are certified, I don’t think pregnant women will have any reservations getting the vaccine from the pharmacist”

LP7 (Clinical Pharmacist, certified to immunize)

“I think that me just not having an “MD” title. Just not having the faith that I have enough education to Uhm, give it and then if there were a risk to happen that maybe... I just don’t think that Pharmacists are at that level with MDs in most patients’ eyes.”

LP 9 (Retail Pharmacist, certified to immunize)

“Even though the pregnant woman would trust her pharmacist, for the most parts, a lot of pregnant women put a lot of trust in their gynecologist, their doctors such that even if the pharmacists says, they still ask if they can ask their doctors first if it is safe for them. So, a lot of convincing, a lot of convincing...”

LP18 (Independent Pharmacist, not certified to immunize)

Current practices. Among the 11 pharmacists who are currently not providing immunization or have never immunized a pregnant woman before, a few (n=8) reported that they will be willing to provide immunization in the future, while (n=3) reported it was not something they were willing to do.

“I feel like I may be comfortable doing it but then, just like with anything, the fact that you are putting something in somebody’s body... I mean, it comes with the risk itself that you just have to be careful about.”

LP18 (Independent Pharmacist, not certified to immunize)

“No, it is not something I am interested in”

LP14 (Independent Pharmacist, not certified to immunize)

Among those who provide or have provided the vaccine to pregnant women before, one participant mentioned providing the vaccine is a basic skill, while another mentioned the benefit of providing the service, and another participant mentioned it was not their favorite activity.

“I mean, it isn’t brain surgery, or trying to run a catheter through someone’s femoral artery, it is just an IM procedure, it is really not a big deal. Eventually it felt like riding a bike, I just get up, stick the needle and it is done... but you may want to assess the general state of the pregnant woman.”

LP7 (Clinical Pharmacist, certified to immunize)

“I will feel like I am getting two people at once, other than that it is pretty normal.”

LP 12 (Retail Pharmacy Director, certified to immunize)

“Absolutely not! When I first started immunizing pregnant women gave me the most anxiety because they ask you all the questions about like mercury, autism all the things... the lot number, the manufacturer of the vaccine, then it makes you kind of question what you are giving them. And then you are nervous they are going to have a side effect, what they are going to call back and say. So, it gives you pause... Now that I have done so many, it’s like okay, it’s alright. They are not my favorite population to vaccinate.”

LP 3 (Retail Pharmacist, certified to immunize)

Pharmacists in clinical settings regardless of immunization certification status, do not provide immunization in clinics. Clinical pharmacists reported nurses as the individuals responsible for administering immunization in hospitals.

Table 9. Pharmacy Setting Impact on Immunization by Sampling Group

	Certified	Not Certified
Clinical Pharmacist	N=2 “I don’t provide vaccines in the hospital, the nurses are the ones that make the assessment, and they call on me the pharmacist to say we need to provide a vaccine, and then I pull in the patients profile so that the technician will run it to them and they give the vaccine. I really don’t have much contact with patients in that regard” (LP7)	N=3 “I don’t give the vaccines, but I read the policies for vaccine administration for the hospital.” (LP1)
Community Pharmacist	N=10 “So long as it is indicated, as long as it is something that is part of their vaccine schedule or recommended by the CDC and there have been studies for them.” (LP15) “I feel like I am getting two people at once, other than that it is pretty normal.” (LP12) “if the data says its’ good...., no qualms whatsoever.” (LP6)	N=3 cost standpoint (independent) “No, it is not something I am interested in” (LP 14)

Discussion

The primary purpose of conducting these in-depth interviews was to explore the perceptions of licensed Florida pharmacists and their role in administering influenza vaccines to pregnant women. The in-depth interviews provided information about the knowledge, attitudes, perceived behavioral control and subjective norms of pharmacists. It also explored the current and future practices of the pharmacists as regards to administering the influenza vaccines to pregnant women.

In discussing pharmacist’s knowledge about the influenza vaccine generally and it’s benefit to pregnant women, they were conversant with influenza general knowledge including the types, recommendations, efficacy and side effects; and also knowledge specific to pregnant women, such as safety, the type of the vaccine used, and the benefits. However, only about 25% of them mentioned that the influenza vaccines can be received by pregnant women at any

trimester. This is in line with the American College of Obstetricians and Gynecologist (ACOG) recommendation (ACOG, 2018; Fiore et al., 2010; Thompson et al., 2011) that influenza vaccines can be administered at any trimester. About 72% of the pharmacist also reported knowledge of the dual benefit of protection of the mother and infant for the first six months of life (ACOG, 2018; Simonsen & Hayney, 2011).

In understanding pharmacists' attitudes about administering inactivated influenza vaccines to pregnant women, there was an expressed overall sentiment among the participants. In terms of accessibility, 78% expressed that they were the most accessible health care providers, this is consistent in what has been reported in previous studies (Murphy et al., 2012). About a third (33%) of the pharmacists viewed themselves as knowledgeable and therefore experts to provide influenza immunization to pregnant women. Pharmacists also reported that providing such services increased their scope of practice, as seen in the study by Dolan et al (2012), also reported that providing immunization services was seen by pharmacists to expand their scope of practice. In terms of providing ease for patients, research has proven that pharmacists providing immunization services is cost-effective (Grabenstein et al., 1998; Prosser et al., 2008). However, participants expressed negative feelings such as liability and not having enough information on the pregnant women was expressed by participants (Dolan et al., 2012).

In understanding perceived control, pharmacists reported facilitating conditions to provide influenza immunization to pregnant women to include provider recommendation or referral, employing more staff (pharmacy technicians), educating pharmacists and marketing campaigns. Higher influenza vaccine rates are seen among pregnant women who received a recommendation from their provider when compared to those who did not, also pharmacy technicians are known to aid pharmacists to engage in a more effective workflow. Campaigns

and outreaches are also associated with increased immunization rates (Ding et al., 2017; Albanese, Rouse, Schlaifer, & CCP, 2010; Grabenstein et al., 1998). Several barriers were mentioned which include increased workload, no access to pregnant women, pharmacists not perceived as a conducive environment, lack or type of insurance and poor sociodemographic factors of patients. Studies have shown these to be true (Dolan et al., 2012; Murphy et al., 2012; Ballas et al., 2015; SteelFisher et al., 2011). However, not all participants agree that providing immunization to pregnant women will increase workload.

Regarding subjective norms, pharmacists expressed that CDC serves as a quality control resource, and where to get updated vaccine information, the APhA was viewed as a training, certification and continuing education resource. Pharmacists also reported that the APhA served as an advocate, pushing for pharmacists to be immunizers. Studies have shown that pharmacists are fine with providing immunization services if they get information from the required organization (Dolan et al., 2012). In discussing the influence of the Florida standing order statutes, participants reported varied views, some felt it was needed, some felt it was redundant, as they have no physical interactions with the physician signing off on immunization they provide and felt it was not necessary. Since the inception of the standing orders for immunization, vaccine uptake rates have increased (Goode et al., 2007; Steyer et al., 2004; Weitzel, 2000). Participants perceived physicians to play a key role in educating and referring women to pharmacies for immunization (Ding et al., 2017). Additionally, pharmacists expressed that pregnant women would rather go to their OBGYNs than come to them. A study by Wang et al (2014), reported that pharmacists are the most trustworthy health care providers next to physicians (Wang et al., 2014).

Overall, pharmacist expressed sentiments that they are equipped to provide immunization services to pregnant women, 17% however, reported that they were not willing to provide immunization services to these women. Participants also called on the need for the standing order to be reviewed to allow for independent pharmacists to provide immunization services. A study by Burson et al (2016), showed that independent pharmacists were less likely to be certified to provide immunization services (Burson, Bутtenheim, Armstrong & Feemster, 2016). This was also demonstrated in the study, as the two independent pharmacists interviewed were not certified to immunize.

There were several study limitations. Firstly, it was a qualitative study, therefore, it cannot be generalized. Another limitation is there may be social desirability bias from the pharmacists. The pregnant women themselves would not be interviewed on their perceptions on going to the pharmacists to receive the influenza vaccine, also, the study does not include providers such as the OB/GYN, Midwives or family medicine doctors who usually attend to pregnant women, so as to explore their perceptions on pharmacists administering the influenza vaccine to pregnant women.

This study also has several strengths. The qualitative nature of this study is important in explore how licensed pharmacists perceive as their role in providing immunization to pregnant women. In addition, the study was guided by the Theory of Planned Behavior. Furthermore, this study included the perception of pharmacists, who are usually overlooked when it comes to providing care for pregnant women.

Conclusion

Pharmacists play an important role to increase inactivated influenza vaccine immunization rates among pregnant women, inadvertently providing coverage for moms and

infants. Pharmacists have been providing immunization to adults for almost 20 years now and are capable of providing immunization to pregnant women. Systematically implementing pregnant women specific strategies in pharmacists continuing education and training would be an effective intervention.

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Manuscript 3: Community-pharmacist-led Inactivated Influenza Vaccine (IIV) administration in pregnant women in the US

Abstract

Influenza illness continues to cause increased morbidity and sometimes death in pregnant women and their babies. The infection is also associated with a drain on the nation economically.

Although the CDC has placed pregnant women as an at-risk group recommending them for the influenza vaccine, the uptake rate is still lower than the targeted health people 2020 goals.

Traditional prenatal care providers include OBs, family physicians, advance-practice nurses, and certified nurse-midwives; however, pharmacists led influenza immunization services have been documented to increase immunization in adults and other at-risk groups. Pharmacists, specifically community pharmacists are trusted among patients, are an accessible and cost-effective resource and can reach medically underserved individuals. Allowing a task shift in the provision of influenza immunization services from traditional providers of prenatal care to pharmacists will help to increase inactivated influenza vaccine uptake rates among pregnant women. This review aims to suggest the task shifting framework that can equip pharmacists to effectively play the role to administer inactivated influenza vaccines in pregnant women.

Introduction

Seasonal influenza infection in the United States continues to be responsible for hospital visits, hospitalization and mortality due to its related complications such as pneumonia (Nowak, Sheedy, Bursey, Smith, & Basket, 2015). Influenza illness also exacerbates chronic diseases and

cardiopulmonary illnesses which lead to increased mortality (Biggerstaff, Cauchemez, Reed, Gambhir, & Finelli, 2014; Nowak et al., 2015). In its epidemic form, the influenza virus can cause mortality and morbidity in as much as twenty percent of the population in the United States every year, and it results in about three thousand to forty-nine thousand influenza-related deaths (Biggerstaff et al., 2014). The economic cost of seasonal influenza in the United States is estimated to be about \$87 billion annually including direct medical costs of about 10 billion. Missed workdays and loss in productivity account for a bulk of the burden, these emphasize how much influenza illness is a drain on the U.S. economy (Molinari et al., 2007; Nowak et al., 2015).

The Influenza viruses change regularly either through "antigenic drifts," which are minor point mutations or through major "antigenic shifts" (Biggerstaff et al., 2014; Cox & Subbarao, 2000). These antigenic drifts and shifts can cause a new version or strain of the influenza virus to be introduced into the human population of which individuals are not yet immunized against hence, causing epidemics and pandemics (Biggerstaff et al., 2014; Cox & Subbarao, 2000; Treanor, 2004). As a result of these changes, the pattern of new pandemics will be hard to predict (Biggerstaff et al., 2014).

Several groups of individuals are considered as high risk for major influenza illness and mortality, and they include pregnant women, children, adults aged 65 years or older, and individuals who have chronic conditions such as diabetes, obesity, asthma, and immunosuppression, as well as cardiovascular (except hypertension), renal, hepatic, neurologic, and hematologic disease. (Nowak et al., 2015) (CDCs "Pink Book"). During the 2009/2010 flu pandemic, pregnancy was identified to be a risk factor for extreme cases influenza; among women aged 18-29, influenza-pregnancy related deaths occurred in about 16% and

hospitalizations in 29% (Biggerstaff et al., 2014; Memoli, Harvey, Morens, & Taubenberger, 2013).

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) in 1997 added recommending the influenza vaccine for pregnant and breastfeeding women (Arden, Izurieta, Fukuda, Cox, & Schonberger, 1998; CDC, 2003; Fiore et al., 2010). This was added to the influenza vaccine recommendation guideline following a study of the effect of influenza virus infection in pregnant women during seventeen inter-pandemic influenza infection seasons (Arden et al., 1998). It was documented that there is an associated increase in morbidity in pregnant women in their second and third trimesters; it was also concluded that one out of two hospitalizations or admissions in pregnant women could be avoided per 1000 women who get the influenza vaccine (Arden et al., 1998). The influenza vaccine remains the best way to prevent influenza illness among this population (Naleway, Smith, & Mullooly, 2006). The American College of Obstetricians and Gynecologists (ACOG) in 2004 sent out a directive to all its members to use the ACIP recommendation that all pregnant women should receive the inactivated influenza vaccine (ACOG, 2004; Fiore et al., 2010; Thompson et al., 2011). However, inactivated influenza vaccine uptake rates pregnant women have remained lower (figure 4) than the targeted 90% coverage proposed by the healthy people 2020 goals (Lu, Bridges, Euler, & Singleton, 2008; Plans-Rubió, 2012; Whitley & Monto, 2006; Xakellis, 2005).

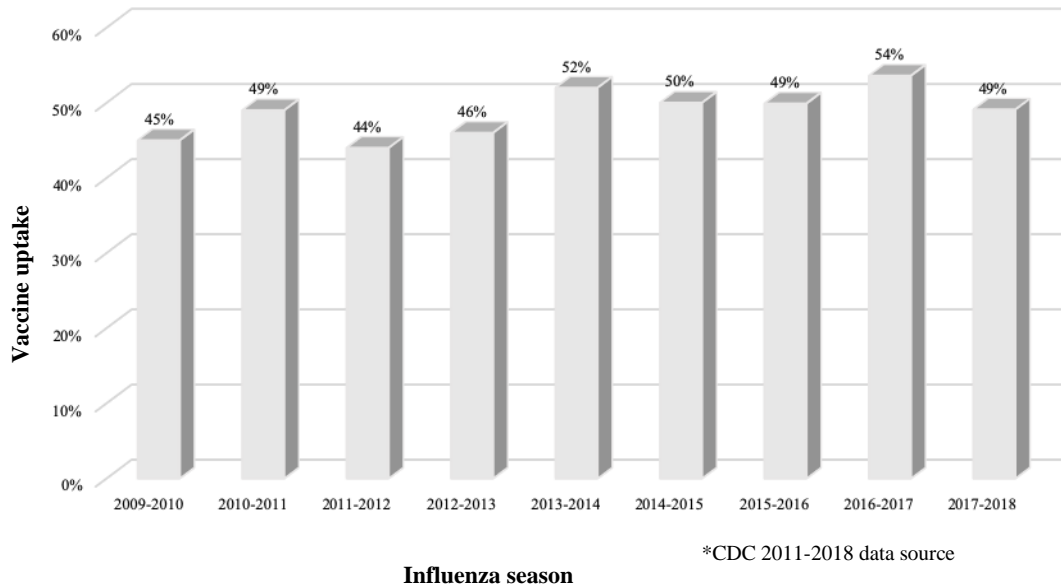


Figure 4: Trends of Influenza vaccine uptake among pregnant women

Several studies have reported barriers and reasons for low inactivated influenza vaccine uptake in pregnant women, such as women being in their first or second trimester of pregnancy, concerns with safety for themselves and their unborn child, and lack of awareness of the “two-fold” benefit of the vaccine (Chamberlain et al., 2015; Meharry, Colson, Grizas, Stiller, & Vázquez, 2013; Wheelock et al., 2013). Other barriers include issues with access, lack of transportation to the health care center, lack of time, distance to care centers, and lack of availability of influenza vaccine at providers’ office (Arao, Rosenberg, McWeeney, & Hedberg, 2015; Healy, Rench, Montesinos, Ng, & Swaim, 2015; Meharry et al., 2013). A study by Healy et al, (2015) reported other reasons from the providers standpoint such as; too little time during hospital visits, women’s allergic reaction to the vaccine, and their own personal lack of knowledge about the vaccines (Healy et al., 2015).

Physicians also reported other barriers including: the pregnant women’s prior beliefs, non-belief in the safety and effectiveness of the inactivated influenza vaccine in pregnant

women, physicians lack of enthusiasm when recommending the vaccine and insufficient time to explain the benefits of the vaccine (Broughton et al., 2009; Arao et al., 2015; O’Leary., et al, 2018). A study by Wallis et al, (2006) reported that obstetric practices had lower inactivated influenza vaccination rates when compared to family physicians (Wallis et al., 2006). Also, larger health (group practices compared to private/solo practices) care centers had lower vaccine recommendation rates (Wallis et al., 2006; O’Leary et al., 2018). Providers also reported not having the vaccine in stock or a shortage in supply and other issues surrounding ordering, tracking, and storing of vaccines (Frew et al., 2018; O’Leary et al., 2018; Clark, Cowan, & Wortley, 2013).

Community Pharmacists as Providers for Influenza Vaccination Services

Since the inception of the Standing Order for Immunization by the ACIP in the year 2000, which authorized pharmacists and nurses to administer vaccines to adults (McKibben, Stange, Sneller, Strikas, & Rodewald, 2000), immunization rates in the general population has improved, and it has helped to take the pressure off physicians (McKibben et al., 2000). Studies have shown the effectiveness of pharmacists providing influenza immunization adults. This has been demonstrated by an increase in influenza immunization rates in adults and high-risk patients (Hagemann et al., 2014; Loughlin et al., 2007; Murphy et al., 2012; Prosser et al., 2008; Singhal & Zhang, 2014; Steyer et al., 2004; Wang et al., 2014; Papastergiou, Folkins, Li, & Zervas, 2014), economical or cost-effective (Grabenstein et al., 1992; Prosser et al., 2008), and effective in providing services to medically underserved areas (Murphy et al., 2012).

In studies that evaluated patients’ experiences and perspectives regarding pharmacy-led immunizations, it was noted that patients reported high levels of acceptance with receiving immunization from pharmacists, this was mostly due to pharmacists being accessible and

convenient (Ernst et al., 1997; Goode & Stanley, 2007; Murphy et al., 2012; Papastergiou, et al., 2014). Patients reported that second to physicians, pharmacists are the second most trustworthy vaccine administrators among health care workers, and they would be comfortable receiving their influenza shot from pharmacists (Wang et al., 2014). The patients also reported that if the pharmacy-led immunization services were not available, they would not have received immunization (Papastergiou, et al., 2014). These findings demonstrate that community pharmacists are able to offer complimentary immunization services to that provided by physicians (Papastergiou, et al., 2014).

Alternative Solution-Task Shifting Framework

The Task Shifting framework was developed to tackle discrepancies and shortages of primary healthcare especially in developing countries (WHO 2018; Aithal & Aithal, 2017). It is defined as a process “that involves extending the scope of practice of existing cadres of health workers to allow for the rational redistribution of tasks among the health workforce in order to make better use of human resources and ease bottlenecks in the service delivery system” (Francesca et al., 2010; Aithal & Aithal, 2017). Task shifting is often used in developing nations to manage the shortage of healthcare professionals, but it has also been used in developed nations (Aithal & Aithal, 2017). Task shifting as demonstrated in the shift from doctors to nurses has been recognized to improve overall health care efficiency and delivery, as nurses who were educated properly were noted to be able to provide about the same level of care as compared to doctors (Maier & Aiken, 2016). Several countries such as the U.S. have adopted task shifting from physicians to other healthcare professionals, especially in patients who are not critically ill and have good health outcomes (Maier & Aiken, 2016).

According to ACOG, during pregnancy, a woman can receive basic level prenatal care

from healthcare providers such as OBs, family physicians, advance-practice nurses, and certified nurse-midwives (American Academy of Pediatrics, & American College of Obstetricians and Gynecologists, 2002). Studies have demonstrated that these providers sometimes experience influenza vaccine shortage, issues with ordering, tracking and storing of the influenza vaccines, experience billing and reimbursement issues and providers not having the time during pregnant women visits (Frew et al., 2018; O’Leary et al., 2018; Clark, Cowan, & Wortley, 2013). Pharmacists have been shown to be educated and trained to provide immunization in adults, they have also been reported to be the first healthcare provider that is questioned on medication advice (Globe, Johnson, Conant, & Frausto, 2004; Turner et al., 2007; Samuel & Einarson, 2011). In order to improve inactivated influenza vaccine rates among pregnant women, task shifting from pregnant women’s prenatal care providers to pharmacists can be applied as an alternative strategy to increase inactivated influenza vaccine uptake rates in pregnant women (figure 5).

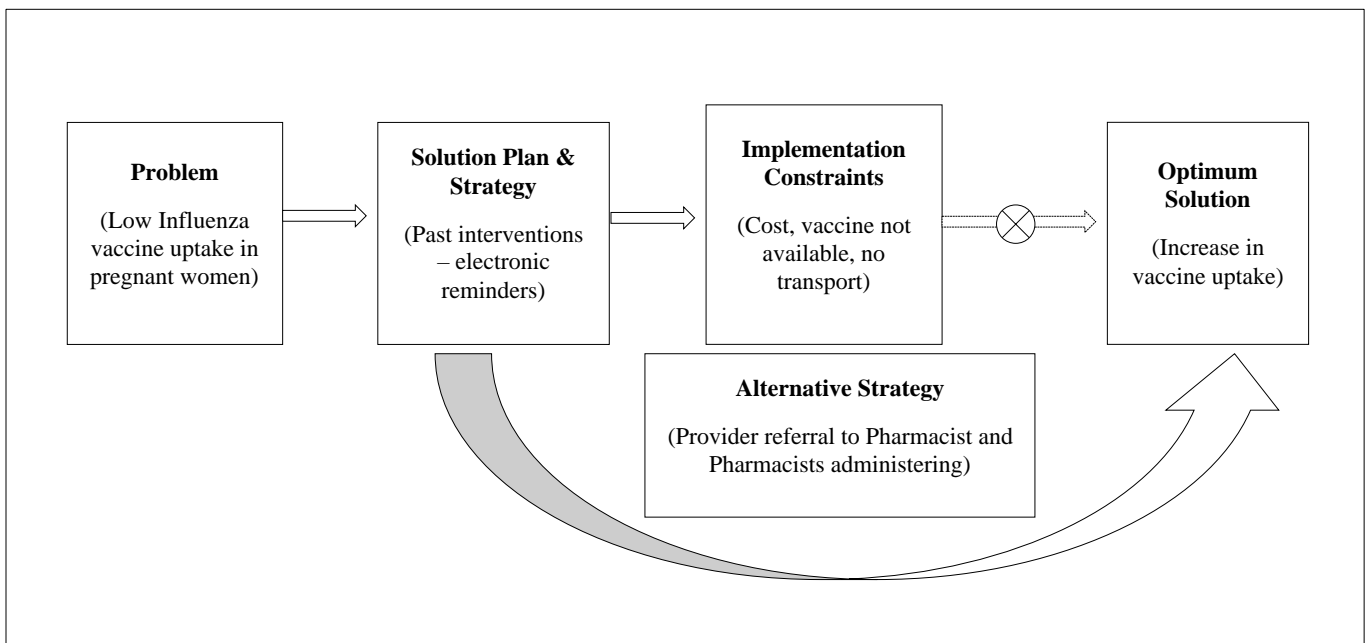


Figure 5. Task Shifting Alternative Strategy to Increase Influenza Vaccine Uptake

Studies have demonstrated some increase in vaccine uptake in pregnant women. Examples are provider-centered interventions providing electronic reminders for providers to (Klatt & Hopp, 2012), and the use of standing orders to provide immunization without a physician's consult (Sherman, Raker, & Phipps, 2012; Wong et al., 2016). Despite over ten years of research on inactivated influenza vaccine uptake among pregnant women, uptake rates remain low. Influenza vaccine uptake rates among pregnant women have remained low over last few years with the highest coverage rate being 53.6% in the 2016/2017 influenza season (Ding et al., 2017), and as of November 2017, influenza vaccine uptake among pregnant women was 35.6% (CDC, 2017). The study by Ding et al (2017), also reported that among the 1893 women surveyed, only 67.3% of women received both influenza vaccine recommendation and offered by their physicians, the uptake or coverage rate among those women was 70.5%. About 12% of the women received influenza vaccine recommendation but no offer, and the vaccine uptake or coverage rate among them was 43.7% (Ding et al., 2017). Among the group of women who receive vaccine recommendation, with the use of standing orders and the implementation of task shift completely to pharmacists may increase influenza vaccination rates in these women (figure1). When traditional prenatal care providers refer pregnant women to pharmacists, this may increase inactivated influenza vaccine uptake in this population.

Conclusion

At-risk patients such as pregnant women, fare alongside the worst hit during influenza epidemics and pandemics, and eventually, become a burden on the health care system and the economy; dictating the need for changes to be made on how influenza immunization is being delivered. In addition, campaigns should target pregnant women to make them aware that they can receive immunization from their pharmacists and that IIV is safe to be administered during

any trimester of pregnancy. Pharmacists are highly skilled healthcare professionals who have also been demonstrated to provide cost-effective care, therefore policies need to be targeted towards equipping them more than they already are to enable them to provide these services as stand-alone providers.

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Conclusions and Recommendations

Introduction

Significance of topic. Exposure to influenza illness can result in dire consequences for the health of the pregnant woman and the development of the fetus, including as pneumonia, spontaneous abortions, preterm births, birth defects and fetal loss (Mak et al., 2008; Rasmussen, Jamieson, & Bresee, 2008). During influenza pandemics and epidemics pregnant women are at a great risk compared to the general population (Rasmussen et al., 2008). This increase in mortality during influenza pandemics is a significant cause for concern, thereby placing pregnant women as a priority group for recommending the influenza vaccine (Callaghan et al., 2010; Thompson et al., 2011). The influenza vaccine is not recommended in infants under 6 months, placing them at a risk for influenza morbidity and mortality. These infants, however, receive immunity from the mother for the first 6 months of life, hence it is important for mothers to receive the vaccines as it provides a two-fold benefit, as it protects the mother and the baby (Simonsen & Hayney, 2011).

Despite over ten years of research on influenza vaccine uptake among pregnant women, uptake rates remain low. Influenza vaccine uptake rates among pregnant women have remained low over last few years with the highest coverage rate being 53.6% in the 2016/2017 influenza season (Ding et al., 2017). The study by Ding et al (2017), also reported that among the 1893 women surveyed, only 67.3% of women received both influenza vaccine recommendation and offer by their physicians, the uptake or coverage rate among those women was 70.5%. About

12% of the women received influenza vaccine recommendation but no offer, and the vaccine uptake or coverage rate among them was 43.7% (Ding et al., 2017). Among the group of women who receive vaccine recommendation, the use of standing orders (which recommends that other health care providers such as pharmacists and nurses be able to assess vaccine status and also administer the vaccine) can help to close the gap of low vaccine uptake (Ding et al., 2017).

Situations where pharmacists have provided immunization services have proven to be beneficial, as there was an increase in vaccine uptake rates, as they provide services that are cost-effective, convenient and accessible to individuals, and serve at-risk populations and can reach individuals that reside in medically underserved communities (Grabenstein et al., 1992; Prosser et al., 2008).

These statistics and trends highlighted the need to explore other avenues through which pregnant women can receive the inactivated influenza vaccine outside their providers' offices. This study sought to fill these gaps in the research. The overall purpose of this study was to explore, in-depth, the perceptions of pharmacists on their role in administering inactivated influenza immunization to pregnant women. Using the Theory of Planned Behavior, this study sought to identify the knowledge, attitudes, perceived control and subjective norms of pharmacists when it comes to administering the influenza vaccines to pregnant women.

In addition, this study examined the pharmacy school curricula, to determine the content on administration of influenza vaccine to pregnant women as taught to pharmacy students. The study also explored the perceptions of pharmacy students on course content, and the projected future practices of pharmacy students as it relates to administration of influenza vaccines to pregnant women. The goal of this study was to create a set of recommendations to pharmacy schools and the department of health regarding a pregnancy immunization content in pharmacy

curriculum and advocate for additional avenues through which pregnant women can obtain the inactivated influenza vaccine through the task shifting strategy.

Overview of Research Design

The study utilized a qualitative research method design which composed of in-depth interviews with licensed pharmacists in the state of Florida, and Academic Deans of the 6 accredited schools of pharmacy in Florida. Focus group sessions were carried out with 3rd and 4th year pharmacy students at the accredited schools of pharmacy in Florida. Participants were recruited through emails (academic deans), and flyers for licensed pharmacists and pharmacy students. All 6 academic deans and 18 licensed pharmacists participated in in-depth interviews, and 3 focus groups with pharmacy students were conducted. Interviews were digitally recorded and transcribed verbatim, and a second coder independently coded the majority of interviews.

Triangulation of findings. Triangulation can be defined as the combination or blending two or greater than two types of data from different sources in the same study. The sources may differ based on theoretical perspectives, the investigators, type of methodological approach used and (Flick, 2004; Patton, 1990; Thurmond, 2001). Triangulation helps to validate a study by testing the consistency of findings to minimize bias, and also gives the researcher a deeper and wider understanding of the research. Triangulation is used to explain, confirm, refute and enrich the data to be combined (Denzin, 2012; Patton, 1990). There are several types of triangulation namely (i) investigator triangulation, (ii) data sources triangulation, (iii) theoretical triangulation, and (iv) methodologic triangulation (Patton, 1990; Thurmond, 2001).

For this study, the data sources triangulation was applied. Data sources triangulation helps to compare different perspectives of different individuals from their different points of view, which leads to an increase in the confidence of the data collected (Patton, 1990). The

findings from the data collected from academic deans of pharmacy schools, pharmacy students and licensed pharmacists in the state of Florida, informed the interpretation of the overall results meaningfully. The findings from the Academic Deans interview and the pharmacy students focus groups elicited that pharmacy students receive training on immunization and are equipped to provide immunization services. It also elicited a lack of pregnancy specific content on immunization in some schools. The interviews with licensed pharmacists also elicited that pharmacists were equipped to and considered themselves experts on providing immunization services, a few of them reported apprehension towards providing immunization to pregnant women.

Conceptual Implications

This study utilized the Theory of Planned Behavior (TPB) framework to understand the influenza vaccine administration practices to pregnant women among pharmacists and pharmacy students. The philosophy of this framework as applied to pharmacists providing influenza vaccines to pregnant women, is that a pharmacist's ability for influenza vaccine administration to pregnant women may vary based on the volitional control, normative beliefs, preconceived notions, perceived difficulty or ease of offering and administering the vaccine to pregnant women. Based on this philosophy, the constructs of the TPB framework include pharmacists having the knowledge about the influenza vaccine in pregnant women; pharmacists having the right attitudes about providing the vaccine to pregnant women; pharmacist understanding and being able to navigate the barriers to providing these services; and the subjective norms that support their role to provide these services are the best predictors of pharmacists providing immunization to pregnant women (Ajzen, 1991).

This study suggests that these constructs are applicable to studying pharmacists and other providers and their intentions to provide a healthcare service, and also have important implications for both interventions and prevention efforts with at risk pregnant women. This is a positive finding in the light of the knowledge that pharmacy schools cover immunization in their curriculum, and some more than others provide content specific to pregnant women, also most pharmacists believe they can play a role in providing influenza vaccines to pregnant women. However, in this study, few schools do not provide immunization content specific to pregnant women, and a few pharmacists had knowledge gaps, and do not believe they have a role to play in administering vaccines to pregnant women, which suggest there is still more work to be done.

Implications for Public Health

This research followed the natural progression of pharmacists from education to subsequent practice. This research offers a distinctive perspective of three different but related datasets. All put together findings show that what students are taught may be associated with what they learn, which inadvertently may be associated with vaccine administration practices in pregnant women which inevitably may be associated with pregnant women access to care. This can be further explained using the vaccine uptake definition as applied to this study; vaccine uptake was defined as a situation where vaccines are available, healthcare providers recommend the vaccine and individuals accept the vaccine (figure 6).

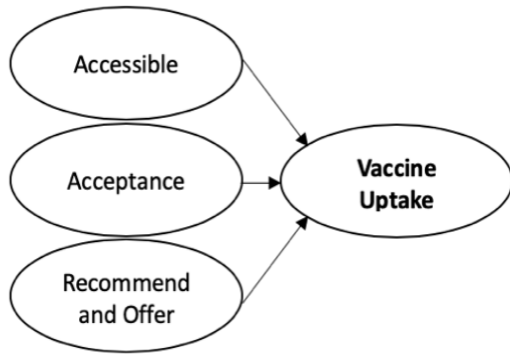


Figure 6: Diagram of modified definition of vaccine uptake as applied to the study.

However, this depiction is significant, in that if all of the elements are not in place, the vaccine uptake may not happen, thereby limiting access to vaccines to those who need it. While this study did not directly assess “acceptance” by the pregnant women, or recommendation by providers, it assessed the ability of the pharmacist to provide counseling and education to pregnant women. Hence, the study model for vaccine uptake demonstrates how there are elements are associated with each other and potentially impact vaccine uptake. Although a multi-pronged approach addressing the pharmacy school curricula, student learning, and pharmacist practice is ideal, an intervention at any point would be beneficial.

Policy implications. Federal implication. In 2012, the National Vaccine Advisory Committee (NVAC) published a report to improve immunization rates in adults. Some of the recommended changes included expanding immunization services offered by pharmacists, increasing immunization by providers that give care to pregnant women, and the inclusion of the Affordable Care Act (ACA) which requires first-dollar provision. Under the ACA non-grandfathered plans will cover some recommended preventive services such as vaccines recommended by the ACA with no cost sharing (Committee, 2014). This allowed for increase in immunization coverage generally. While it is unclear what the American Health Care Act

(AHCA) plans for immunization are, it will be beneficial if the ACA remains implemented to provide coverage for more people.

State implication (Florida). In the year 2000, the ACIP recommended standing order programs (SOPs) which authorize pharmacists and nurses to administer vaccination to adults (McKibben et al., 2000). In the title XXXII of the Florida Statutes, chapter 465, section 189, licensed pharmacists may administer vaccines to adults within the framework of an established protocol (Florida, 2018). To be able to administer vaccines, a pharmacist must have a Florida license and be in good standing, they must complete an immunization certification program, they have to maintain a professional liability insurance of \$200,000 or more, they must obtain a written permission from the owner of the pharmacy, they must report administered vaccines into the immunization information state registry, and lastly, they have to enter into a protocol under a supervising licensed physician (Florida, 2018). The protocol between the licensed physician and pharmacist should include patient specific categories and conditions for which the supervising physician will authorize a pharmacist to administer immunization (Florida, 2018). Authorization of SOPs in states have been seen to increase overall immunization rates (Stewart, Lindley, & Cox, 2016). The SOPs, however, do not specify pregnant women, specification of this group may help increase influenza vaccination. Also, there should be considerations for autonomy for pharmacists to be able to be considered as practitioners, this sentiment was shared by both the licensed pharmacists and pharmacy students.

Implications for research. The proposed study findings do not only add to literature in this field, but it can also spur on future research. Future studies can apply this study to understand pharmacy roles in administering vaccines to other high-risk groups such as people older than 65 and children. The findings can also bring about potential research questions

regarding school curricular review and linking it to practice. Based on the qualitative results of this study, future research could be developed using quantitative methods to reach a wider and more generalizable audience. Future studies can also examine pregnant women's perceptions on seeking health care from pharmacists or going to the pharmacy to receive vaccines during pregnancy, and maybe track vaccine refusals or uptake from pregnant women, to understand if pregnancy women go to the pharmacist and agree to accept the vaccine. Furthermore, future studies can examine physicians/OBGYNs views on pharmacists providing immunization to pregnant women. Another area that can be explored would be to assess the role pharmacists can play in providing other pregnancy required vaccines, to see if there are similarities or differences.

Implications for practice. Although this study was concerned with increasing inactivated influenza vaccine among a specific population, with the utilization of pharmacy services, it has broader implications for public health and for healthcare professionals. For instance, training or education and its translation to clinical practice for healthcare professionals such as doctors, nurses, geneticists, and so on is very important. Successful teaching and its translation to effectual learning and proficient practice and effective policy is essential to better health outcomes in communities. Clinical practice should be driven by research and not personal beliefs or views, also, pharmacists providing influenza immunization should not be diminished due to lack of knowledge. From the pharmacy school curricula review and focus groups, there was an expressed need for pregnant women focused content during immunization classes, there were also shared sentiments by 33% of the students not remembering being taught about vaccine administration in pregnant women. 11% of the licensed pharmacists believed the influenza vaccine caused the influenza illness, and about 40% had ever provided influenza vaccines to pregnant women.

Conclusion

The proposed research has the potential to increase inactivated influenza vaccine uptake in pregnant women. Inactivated influenza vaccine coverage rate continues to remain low in pregnant women, despite ACIP recommendations, interventions on provider recommendation and interventions for pregnant women (Ding et al., 2017). It is important women receive the vaccine during pregnancy as it provides a two-fold benefit of protecting the mother and the unborn infant up until the first few months of life (Naleway et al., 2006). The state of Florida had a 21.6% influenza vaccine coverage among pregnant women during the 2009-2010 influenza season, and it also ranked the lowest among the states studied (Kennedy et al., 2012). The state of Florida would benefit from this research as it hopes to create more opportunities and avenues for pregnant women to receive the inactivated influenza vaccine, by emphasizing the role of pharmacists can play may help increase vaccine uptake. The study explored what is being taught in pharmacy schools, regarding administering influenza vaccine to pregnant women and also how licensed pharmacists are implementing inactivated influenza vaccine administration in pregnant women. Overall, study showed that despite barriers and concerns, pharmacists believe they have a role to play in administering inactivated influenza vaccines to pregnant women.

Strengths and limitations

The proposed study used qualitative methods to explore how the immunization course content is being taught in pharmacy schools in Florida and the experiences of pharmacists in administering specifically influenza vaccines to pregnant women. The qualitative interview and focus group questions were guided by the theory of planned behavior theoretical framework. The study is innovative, and to the best of the researcher's knowledge it has not been conducted elsewhere.

One limitation of this study is that it is a qualitative study, and therefore cannot be generalized to other populations, also, the sample size was small. Another limitation lies with the fact that the pregnant women themselves would not be interviewed on their perceptions on going to the pharmacists to receive the influenza vaccine. Also, the study does not include providers such as the OB/GYN, Midwives or family medicine doctors who usually attend to pregnant women, so as to explore their perceptions on pharmacists administering the influenza vaccine to pregnant women.

Trustworthiness

In qualitative studies the terms that have been used to assess the general validity of qualitative research include rigor, trustworthiness, reliability and specific validity. These terminologies are used to differentiate good quality research from a poor quality one (Elo et al., 2014; Golafshani, 2003). In terms of the criteria for validity and reliability, there is no distinct line dividing quantitative and qualitative content analysis (Elo et al., 2014), rather the qualitative data can be assessed for trustworthiness by applying the following criteria: dependability, credibility, transferability, and confirmability (Elo et al., 2014). Dependability refers to the researcher being cognizant of the changes made by the researchers during the qualitative data analysis process and the degree to which the data changes during that period so as to ensure consistency (Graneheim & Lundman, 2004). For the proposed study an audit trail was used to ensure dependability due to the subjective nature of qualitative data analysis. A detailed notebook was maintained where all the observations of the data collection and analysis process were recorded. During the interview and focus group processes, notes were recorded capturing what participants were more communicative about, and events that may influence the information collected. The notes were uploaded as a memo into the MAXQDA software for the

other coder to also review. Credibility refers to researchers ensuring their study measures the intended focus during the analytic process (Graneheim & Lundman, 2004; Shenton, 2004). For the proposed study, credibility was ensured in the various stages of the data collection process. The interview guides were developed using a theoretical framework and was piloted and pretested with pharmacists for readability. Data was monitored as they were collected, and feedback was elicited from participants after interviews to improve and clarify any issues that came up. Also, during the data collection process, iterative questioning was applied through the use of probes and returning to previous answers raised by participants. Transferability refers to how possible it is to demonstrate that the conclusions and findings of a study can be applied or transferred to other settings or populations (Graneheim & Lundman, 2004; Shenton, 2004). For the study, transferability was ensured by clearly defining the study population and their characteristics and providing in detail the process of the data collection and analysis. Using a theoretical framework, TPB as a guide, to make it more adaptable for other populations. Also, transferability was achieved by providing a rich and robust presentation of the results using the appropriate quotations. Lastly, confirmability which refers to ensuring objectivity in a study (Shenton, 2004). Subjectivity is an issue that arises with qualitative data, especially when creating and apply codes to the transcript text (Guest et al., 2011). For this study, the intercoder agreement was used to increase reliability, and was calculated using the Cohen's Kappa (84%). Also, the audit trail was used to increase transparency and document the processes that were carried out throughout the data collection and analysis period.

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Appendix A: Review of the Literature

Review of Literature 1- Reasons for Low Influenza Vaccine Uptake (Pregnant Women and Provider Perspectives)

Influenza virus overview. The influenza virus is an RNA virus which depending on the annual genetic change and severity of the illness can be grouped as seasonal or pandemic. The influenza virus is transmitted through inhaling aerosols contaminated with the virus (Iwasaki & Pillai, 2014). There are three types namely, A, B and C, of which A and B are known to cause major seasonal outbreaks with associated illnesses and deaths, and A may also cause pandemics (WHO, 2012; Cox & Subbarao, 2000). Influenza epidemics occur yearly all over the world. In the U.S. they cause significant comorbidities and deaths in about 20% of the U.S. population annually (Biggerstaff et al, 2014).

The Influenza viruses change regularly either through "antigenic drifts," which are minor point mutations or through major "antigenic shifts" (Biggerstaff et al., 2014; Cox & Subbarao, 2000). The pandemic strains of the virus which occur every ten to twenty years, are as a result of the "antigenic shift", while the "antigenic drift is responsible for the seasonal strain of the influenza virus (Iwasaki & Pillai, 2014). These antigenic drifts and shifts can cause a new version or strain of the influenza virus to be introduced into the human population of which individuals are not yet immunized against hence, causing epidemics and pandemics (Biggerstaff et al., 2014; Cox & Subbarao, 2000; Treanor, 2004). As a result of these changes, the pattern of new pandemics will be hard to predict (Biggerstaff et al., 2014). The economic cost of seasonal influenza in the United States is estimated to be about \$87 billion annually including direct

medical costs of about \$10 billion. Missed workdays and loss in productivity account for a bulk of the burden; these consequences emphasize how much influenza illness is a drain on the U.S. economy (Molinari et al., 2007; Nowak et al., 2015).

Influenza vaccination guidelines. The Advisory Committee on Immunization Practices (ACIP) recommends that all individuals 6 months or older receive the influenza vaccine, as it remains the most effective way to prevent influenza illness and its comorbidities (Lu et al., 2018). The CDC prioritizes influenza vaccination in several groups of individuals considered high risk or priority, and especially if vaccine shortage occurs. These individuals such as include children aged six months to fifty-nine months, people 50 years and older, pregnant women or women who plan get pregnant during the influenza season, health care personnel, residents of chronic care centers and nursing homes, people aged six months to 18years on long term aspirin treatment who with the influenza illness can develop Reye syndrome, individuals who are Alaskan natives or American Indians, and contacts and caregivers of adults 50 and older and children younger than 5 years, with an important focus on children aged younger than 6 months (CDC, 2016a, 2016b). Other groups of individuals who are also considered as priority or high risk for major influenza illness and mortality, such as individuals who have chronic conditions such as diabetes, obesity and, asthma (Nowak et al., 2015).

Overview of influenza infection in pregnant women. Pregnancy is a unique immunological state, in which the immune system is modulated as a result of placental response and its tropism for specific pathogens and viruses. These affect the pregnant woman's susceptibility to certain infections (Mor & Cardenas, 2010). Research has shown an increase of about a four-fold in influenza antibody titers during pregnancy. (Mak, Mangtani, Leese, Watson, & Pfeifer, 2008). In between influenza epidemics, and during influenza pandemics, pregnant

women are usually more susceptible to contracting influenza and its subsequent complications such as pneumonia, spontaneous abortions, preterm births, birth defects and fetal loss (Mak et al., 2008; Rasmussen, Jamieson, & Bresee, 2008).

Usually the morbidity from influenza in this population is low, however during the influenza pandemics such as 1918, 1957, 2009 and other influenza outbreaks, there were high death rates in pregnant women (Callaghan, Chu, & Jamieson, 2010; Mak et al., 2008; Thompson et al., 2011). During the 1918 influenza pandemic in the U.S., 27% of pregnant women died, also in the 1957 pandemic influenza, 20% of influenza-associated deaths occurred in pregnant women (Rasmussen et al., 2008). This increase in mortality during influenza pandemics is a significant cause for concern, thereby placing pregnant women as a priority group for recommending the influenza vaccine (Callaghan et al., 2010; Thompson et al., 2011). Also, uptake of influenza vaccine during pregnancy has a two-fold benefit, as it protects the mother and the baby for its first few months of life (Simonsen & Hayney, 2011). This protection for the baby is essential, as there is no licensed influenza vaccine for infants under six months of age, and also because, during influenza outbreaks, children experience the highest infection rates (Simonsen & Hayney, 2011).

Reasons for influenza non-vaccination in pregnant women. In order to assess the current reason for influenza non-vaccination in pregnant women in the United States, a systematic literature review was conducted. Articles were systematically selected from a search of PubMed, Web of Science and CINAHL during a date range of January 1st, 1998 to February 8th, 2019. The Search terms were ordered into broad categories of influenza vaccine (e.g., influenza vaccines, [Mesh]) OR influenzavirus vaccines OR flu vaccines OR flu vaccine), prenatal care (e.g., perinatal care"[Mesh] OR perinatal OR pregnancy OR pregnan* [Mesh] OR

preNatal OR antenatal OR antenatal), vaccination refusal (e.g., refuse OR refusal OR uptake OR accept*), and physician (e.g., physicians"[Mesh] OR doctor OR nurse OR midwife). The search strategy for each database used the Boolean term of 'OR' for inclusion of each search term within the broad category, and the Boolean term of 'AND' for inclusion of each broad category. The inclusion criteria for the search were: (1) qualitative and quantitative studies; (2) conducted in English; (3) peer reviewed; (4) Examined the reasons for influenza vaccine refusal or low uptake in pregnant women; (5) conducted post-vaccine recommendation for pregnant women (1998); and (6) conducted in the United States. Studies were excluded if only a published abstract was the full paper was not found.

The initial search of the literature identified 181 studies, and 8 additional studies for gray literature. After removing 28 duplicates, 161 studies remained. Study abstracts were then screened based on the relevance to the topic; this removed 94 studies, and 67 studies were left. Next, the full texts were assessed to determine eligibility based on the inclusion and exclusion criteria. The following articles were removed: 25 for being not related to the study, 5 as they were commentaries, 3 as full texts were not found, 2 for being systematic reviews or meta-analysis, and 1 for being outside of the United States. As a result, 31 articles remained; 26 were quantitative studies and 5 were qualitative.

Description of studies. The study with the earliest date was conducted in 2006, while the most recent were conducted in 2018 (Wallis et al., 2006; Frew et al., 2018; Wootton et al., 2018; O'Leary et al., 2018). The included studies had the following types of samples: 24 studies including pregnant women postpartum women and women of reproductive age (Chamberlain et al., 2015; Eppes et al., 2013; Kharbanda et al., 2011; Gorman et al., 2012; Healy et al., 2015; Ahluwalia et al., 2014; Kharbanda et al., 2013; Meharry et al., 2013; Beel et al., 2013; CDC,

2009; Wootton et al., 2018; Frew et al., 2018; Marsh et al., 2014; Goodman et al., 2015; Chamberlain et al., 2016; Groom et al., 2016; Ballas et al., 2015; Meharry et al., 2014; Drees et al., 2012; Drees et al., 2013; Goldfarb et al., 2011; Ahluwalia et al., 2011; SteelFisher et al., 2011; Howland et al., 2013; Moniz et al., 2013), 7 studies with health care providers (Broughton et al., 2009; O’Leary et al., 2018; Wallis et al., 2006; Frew et al., 2018; Arao et al., 2015; Clark et al., 2013; Moniz et al., 2013) 1 study included both women and providers (Healy et al., 2015), 1 study involved a minority population (African American women), and 11 studies involved national health surveys (SteelFisher et al., 2011; Ahluwalia et al., 2011; Howland et al., 2013; O’Leary et al., 2018; Groom et al., 2016; Wootton et al., 2018; CDC, 2009; Kharbanda et al., 2013; Ahluwalia et al., 2014; Clark et al., 2013; Gorman et al., 2012). Four studies used a theoretical framework (Health Belief Model) (Drees, et al., 2012; Meharry et al., 2014; Gorman et al., 2012; Goodman et al., 2015;), and 2 studies were interventions (Moniz et al., 2013; Meharry et al., 2014). One study assessed both pandemic and seasonal influenza vaccine coverage (Ahluwalia et al, 2014), while the other studies assessed seasonal influenza vaccine coverage. Reasons for influenza non-vaccination, as well as, barriers to influenza vaccination among pregnant women or women of reproductive age were abstracted from each article. These determinants were then explained by levels of the Socioecological framework which is used to understand the different interactive effects of the personal and environmental factors that determine health behavior (McLeroy, Bibeau, Steckler, & Glanz, 1988). It has five levels; namely the intrapersonal, the interpersonal, organizational, community and political (McLeroy et al., 1988). This review summarizes the current state of the reason’s influenza non-vaccination among pregnant women in the United States. From this review of literature, it is evident that the bulk of existing research and interventions has focused on the intrapersonal level and on the

pregnant women. The reasons for low vaccine uptake were similar across all sample locations and sizes.

Reasons for low vaccine uptake. The Social Ecological Model (SEM): This framework is used to understand the different interactive effects of the personal and environmental factors that determine health behavior. It has five levels; namely the intrapersonal, the interpersonal, organizational, community and political (Coreil, 2010). For this literature review, it was used to identify the individual, intrapersonal, organizational and community factors that affect vaccine uptake in pregnant women. Intrapersonal reasons for influenza non-vaccination among pregnant women can be described as demographic characteristics which include; lower vaccine uptake was reported in minority groups such as African Americans (Ahluwalia et al., 2014; Kharbanda et al., 2013; Ballas et al., 2015; Drees et al., 2012; Steelfisher et al., 2011). However, the study by Ballas et al noted higher vaccination uptake in Hispanic women (Ballas et al, 2015). Other groups reported to have low vaccine uptake were women of younger age less than 35 (Groom et al, 2016; Drees et al 2012; Steelfisher et al,2011), women with low income making less than \$35,000 a year (Ballas et al, 2015) less education (Steelfisher et al, 2011) and those reported to live at a distance further away from the clinics (Ballas et al, 2015). A study by Wallis et al (2006), noted lower influenza recommendation in larger obstetric practices when compared to family physicians; while another study by Ballas et al (2015) noted lower vaccine uptake in women seen by family physicians. There were no observed differences between study population recruited from the clinic or community, and also between the smaller samples sizes verses the larger ones.

Barriers such as costs, time, safety concerns, needle phobia, lack of knowledge about vaccines, habits such as not receiving vaccines in the past and women in their first and second

trimester (Beel et al., 2013; Chamberlain et al., 2016; Healy et al., 2015) as reasons for low vaccine uptake which were classified as intrapersonal. Living at a distance further away from the clinics (Ballas et al., 2015), perceived low risk to the influenza infection, feeling that the vaccine is not important and the women not habitually receiving the vaccine were also classified as intrapersonal (Ahluwalia et al., 2014; Drees et al., 2012; Groom et al., 2015; Malik et al., 2016). Pregnant women also reported not perceiving influenza virus infection as a serious illness, doubted the efficacy of the vaccine and reported a lack of awareness of the benefit of the vaccine (Kharbanda et al., 2013; Meharry et al., 2013).

The interpersonal level reasons for low vaccine uptake included patient provider interaction (Ahluwalia et al., 2014; Chamberlain et al., 2015; Drees et al., 2012; Eppes et al., 2013; Gorman, Brewer, Wang, & Chambers, 2012; Healy et al., 2015; Kharbanda et al., 2013), and other reasons such as influence from pregnant women family and friends, pregnant women work commitment and insufficient time during hospital visits (Arao, Rosenberg, McWeeney, & Hedberg, 2015; Meharry et al., 2013). The organizational level reasons for low vaccine uptake had to do with non-availability of vaccine at health care centers (Ahluwalia et al., 2014; Meharry et al., 2013). Community-level determinants of vaccine uptake in this population include transportation issues (Beel et al., 2013; Healy et al., 2015), distance from the clinic and the media (Ballas et al., 2015; Beel et al., 2013).

A reason such as cost can be classified as both intrapersonal and system level; non-availability of vaccine could be viewed as organizational or system level. Studies usually identify reasons situated in intrapersonal, interpersonal, or organizational levels for low influenza vaccine uptake, and do not examine these reasons from a policy or system level (Hershey & Velez, 2009).

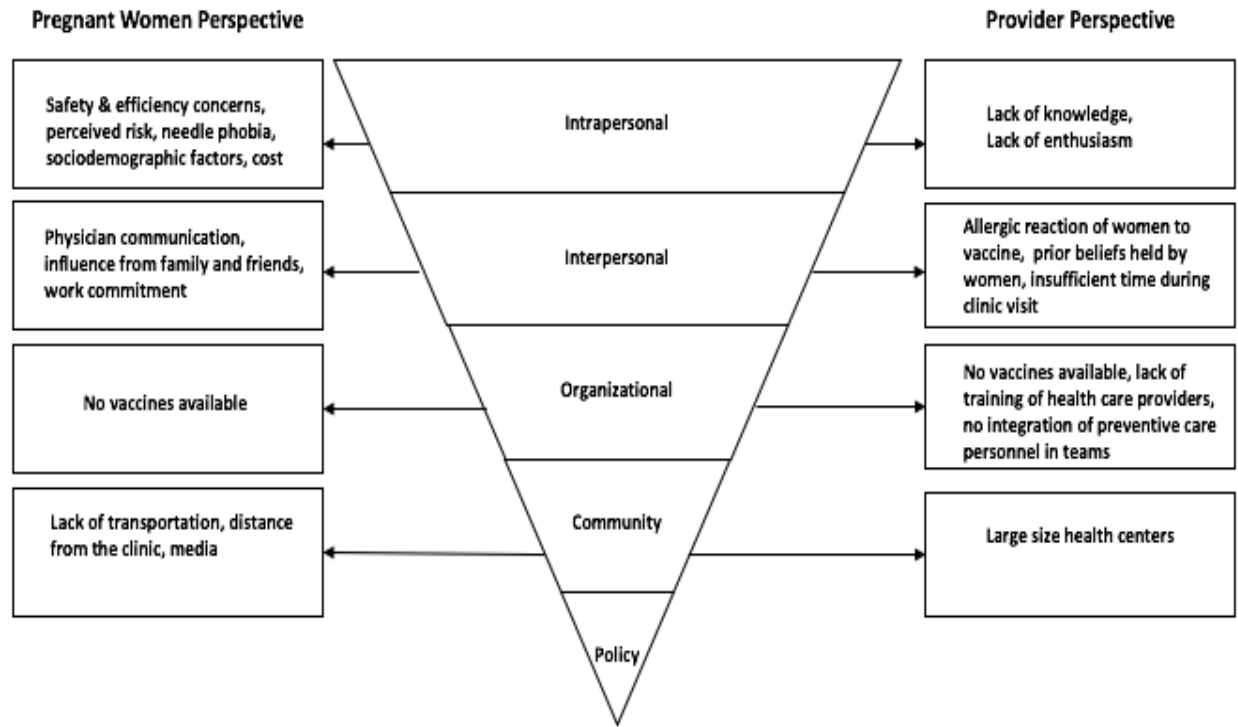


Figure 7. Showing the Differences in the Reasons for Low Influenza Vaccine Uptake

Application of theoretical models. Of the studies included in this review, only one theory was used, which is the Health Belief Model (HBM). HBM suggests that an individual's perceptions or beliefs influence the likelihood that they will take action (e.g., receive the influenza vaccine) (Glanz, Rimer, & Viswanath, 2008). Although five of the studies in the literature review used this model in their studies (Drees et al., 2012; Goodman et al., 2015; Gorman et al., 2012; Meharry et al., 2014; Puchalski, Hollema, & Marshall, 2015), the constructs of the HBM are reflected in many of the other studies and are discussed as follows:

(i) Perceived susceptibility to the influenza virus infection. Women reported that they were not at risk of influenza virus infection, they felt vaccination against influenza is not important, and that they usually do not receive the influenza vaccine (Chamberlain et al., 2011; Kharbanda et al., 2011; Malik et al., 2016; Goodman et al., 2015; Ahluwalia et al., 2011; Drees

et al., 2012; Groom et al., 2016; Eppes et al., 2013). (ii) Perceived severity of the influenza virus infection. Studies included in this review also reported that women felt the influenza virus infection was not a severe illness (Ahluwalia et al., 2011; Drees et al., 2012; Groom et al., 2016; Malik et al., 2016). (iii) Perceived benefits of the influenza vaccine. Women in some of the studies reviewed reported the lack of efficacy of the vaccine (Eppes et al., 2013; Kharbanda et al., 2011; Puchalski et al., 2015). One study also reported a lack of awareness of the benefits if the vaccine for them and the baby (Meharry et al., 2013). (iv) Perceived barriers to influenza vaccine. The review noted various barriers women perceive which stops them from getting the influenza vaccine such as safety concerns for both the mother and the fetus, and fearing they may have a miscarriage or a malformation in the fetus (Chamberlain et al., 2011; Gorman et al., 2012; Kharbanda et al., 2011; Malik et al., 2016; Healy et al., 2015; Alhuwaila et al., 2014; CDC, 2009; Goodman et al., 2015; Meharry et al., 2013; Meharry et al., 201; Drees et al., 2012; Goldfarb et al., 2011; Ahluwalia et al., 2011; Puchalski et al., 2015). Cost, needle phobia, lack of transportation, work commitments, no vaccine available and adverse reaction to the vaccine were also perceived as barriers to vaccine uptake (Healy et al., 2015; Beel et al., 2013; Meharry et al., 2013; Ahluwalia et al., 2011). (iv) Cues to action. In a few of the studies included in this review, it was reported that lack of provider recommendation was a reason for low uptake of influenza vaccine (Chamberlain et al., 2012; Kharbanda et al., 2011; Healy et al., 2015; Kettunen et al., 2010; Drees et al., 2012; Ahluwalia et al., 2011). Health care provider indifference and lack of knowledge about the vaccine were also reported to cause low vaccine uptake (Healy et al., 2015; Meharry et al., 2013).

Pregnant women perspective. Low vaccine uptake was associated with women's concerns regarding safety of influenza vaccine during pregnancy, as they fear it may cause harm

to them and the baby (Chamberlain et al., 2011; Gorman et al., 2012; Kharbanda et al., 2011; Malik et al., 2016; Healy et al., 2015; Alhuwaila et al., 2014; CDC, 2009; Goodman et al., 2015; Meharry et al., 2014; Meharry et al., 2013; Drees et al., 2012; Goldfarb et al., 2011; Ahluwalia et al., 2011; Puchalski et al., 2015). Harm to themselves was expressed in one study as they may come down with influenza after uptake of vaccine (Puchalski et al., 2015). The influenza vaccine not being efficacious and hence not protective was another reason for low vaccine uptake (Eppes et al., 2013; Kharbanda et al., 2011; Puchalski et al., 2015). History of not receiving influenza vaccine ever or normally in the past was also a reason for not accepting the vaccine by the pregnant women (Ahluwalia et al., 2011; Drees et al., 2012; Groom et al., 2016; Malik et al., 2016). Most women also believed that they were not at risk to influenza infection and they usually do not come down with influenza infection, hence did not receive the vaccine (Eppes et al., 2013; Kharbanda et al., 2011; Malik et al., 2016; Goodman et al., 2015). Women were also reported to have noted vaccine cost, insufficient knowledge of vaccine benefit, no transportation, work commitments and needle phobia as other reasons for low vaccine uptake (Healy et al., 2015; Beel et al., 2013).

Some studies reported that lack of provider recommendation was a primary reason for low influenza vaccine uptake (Chamberlain et al., 2012; Kharbanda et al., 2011; Healy et al., 2015; Kettunen et al., 2010; Drees et al., 2012; Ahluwalia et al., 2011), one study reported provider indifference (Meharry et al., 2013), and another study reported lack of health care provider reminder (Gorman et al., 2012). Other reasons such as being in the first or second trimester of pregnancy, not being pregnant during influenza season, and influence of family and friends were also reported (Chamberlain et al., 2016; CDC, 2009; Meharry et al., 2013). Non-availability of the vaccine was also published as a reason for low uptake of the influenza vaccine

(Meharry et al., 2013; Ahluwalia et al., 2011). Women reported lack of knowledge, lack of insufficient information and complete lack of information regarding influenza vaccines also as reasons for not considering taking the vaccine (Eppes et al., 2013; Beel et al., 2013; Kettunen et al., 2010; Meharry et al., 2014; Ahluwalia et al., 2011).

Provider perspective. The study by Healy et al. noted physicians reported that reasons such as too little time during hospital visits, allergic reaction to the vaccine, and their lack of knowledge about the vaccines were the cause of low vaccine uptake in pregnant women (Healy et al., 2015). Physicians also reported that the prior beliefs held by the women, their lack of enthusiasm when recommending the vaccine and insufficient time to explain the benefits of the vaccine during visits are responsible for low influenza vaccine uptake (Arao et al., 2015; O’Leary., et al, 2018). A study by Wallis et al. reported that obstetric practices had lower influenza vaccination rates versus family physicians, and larger health (group practices vs. private/solo practices) care centers had lower vaccine recommendation rates (Wallis et al., 2006; O’Leary et al., 2018). Health care workers also reported a non-belief in the safety and effectiveness of IIV in pregnant women (Broughton et al., 2009). Providers also reported not having the vaccine in stock or a shortage in supply, and other issues surrounding ordering, tracking, and storing of vaccines. (Frew et al., 2018; O’Leary et al., 2018; Clark, Cowan, & Wortley, 2013).

Discussion

Since the ACIP recommendation, influenza vaccine coverage among pregnant women has remained suboptimal. This systemic literature review identified reasons for low uptake of influenza vaccine in this population both from health care provider and pregnant women perspectives. Most pregnant women believe there are harmful outcomes for them and their

babies when they receive the vaccine, or that the vaccine is not effective or efficacious.

Additionally, some pregnant women do not perceive influenza virus infection as severe illness or do not believe they are at risk of the disease. Other concerns reported by women, such as cost, transportation, and non-availability of vaccines were also reasons for low vaccine uptake. The importance of vaccine recommendation by health care providers resonated across most of the studies; thus, continued efforts will be required to ensure health care providers follow the CDC and ACOG recommendation and guidelines. Targeted efforts are also needed for minority populations such as African American population, as they have been reported to have lower influenza vaccine uptake rate (Kharbanda et al., 2013).

Given the results of the review, future research directions may consider formative research with pregnant women-specific intervention. Educating these pregnant women during prenatal visits and addressing logistic concerns such as costs and supply may assist in increasing vaccine uptake. Interventions that targeted pregnant women have been carried out through text message reminders, flyers, workshops, classes and media (Wong, Lok, & Tarrant, 2016). Studies show that education using pamphlets and a "vaccine benefit statement" increases influenza vaccine uptake (Meharry et al., 2014; Wong et al., 2016). However, a study carried out by Moniz et al. (2013) showed no significant increase uptake in influenza vaccines by pregnant women using weekly text messages (Moniz, Hasley, Meyn, & Beigi, 2013).

Provider-centered interventions to increase influenza vaccine uptake among pregnant women usually target reduction of missed opportunities, and they involve the use electronic reminders (Klatt & Hopp, 2012), education, provider feedback and standing orders to administer vaccines without doctors consult. These strategies have been shown to increase influenza vaccine uptake (Sherman, Raker, & Phipps, 2012; Wong et al., 2016). Studies regarding interventions

targeted towards barriers the pregnant women face such as no vaccine available, cost and accessibility have not been described in the literature and should be included in future interventions (Wong et al., 2016).

Conclusion

This review identifies the various reasons for low uptake of IIV in pregnant women from provider and women perspectives in the U.S. Interventions for pregnant women should be targeted to individuals in the lower SES and the African American population with sensitivity to cultural differences. Interventions that address the HBM determinants such as benefits, and barriers should be developed and tested. Interventions for healthcare professionals should target education which may involve courses and seminars; also, implementation of the ACIP and ACOG recommendations at care centers, which may include incentives and packages to encourage providers to recommend, provide and administer influenza vaccines. Other interventions should target organizational and system level determinants of influenza vaccine uptake, such as insurance coverage, availability at care centers and cost reduction.

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Literature Review 2- Pharmacists Administration of Influenza Vaccines in Adults

Introduction

The overall purpose of this literature review is to identify the state of influenza vaccine administration in adults among pharmacists in the U.S. and its impact. Specifically, to examine the studies that have been conducted to date that show the impact on the community of pharmacists administering the influenza vaccines in adults. Additionally, this review will attempt to examine participant characteristics such as urban vs. rural areas, high-risk individuals, race/ethnicity among existing literature reporting on the impact of pharmacist's administration of influenza vaccine in adults.

Results

Description of studies. The study with the earliest date was conducted in 1992, while the most recent was carried out in 2014. Fourteen of the articles reviewed were quantitative studies, and two were qualitative studies. Six of the studies were cross-sectional studies (Bearden & Holt, 2005; Ernst, Chalstrom, Currie, & Sorofman, 1997; Murphy et al., 2012; Singhal & Zhang, 2014; Wang, Munshi, & Hong, 2014; Weitzel, 2000), two of the studies were quasi-experimental (Bourdet, Kelley, Rublein, & Williams, 2003; Steyer et al., 2004), two studies were retrospective, the study by Grabenstein et al, 2009 was a retrospective cohort study (Grabenstein, 2009) and the other a retrospective controlled study (Loughlin, Mortazavi, Garey, Rice, & Birtcher, 2007). Two studies evaluated costs, the study by Prosser et al., 2008 conducted a cost decision model qualitative study (Prosser et al., 2008), and the other conducted a cost analysis model (Grabenstein, Hartzema, Guess, Johnston, & Rittenhouse, 1992). One study was a randomized control trial (Hagemann, Johnson, & Conway, 2014), one was a case report study (Doucette et al., 2012), another a case series study (Goode, Mott, & Stanley, 2007).

Sampling methods for participant recruitment were from community pharmacists, clinics, hospitals, and university campuses. Two of the articles analyzed pooled data from various databases, the study by Singhal et al. 2014 used the health insurance database of patients (Singhal & Zhang, 2014), the study by Grabenstein et al, 2009 used automated pharmacy records and the study by Wang et al, used the Medicare expenditure survey (Wang et al., 2014). All fifteen studies assessed seasonal influenza vaccine coverage. The study with the largest sample size was 71,135,249 million (Wang et al., 2014), and the study with smallest sample size was had 72 people and was a qualitative study (Penfold et al., 2011).

Demographics. Significantly increased influenza vaccine uptake observed among high-risk patients with conditions such as cardiovascular diseases and adults 65 years and older (Ernst et al., 1997; Loughlin et al., 2007; Steyer et al., 2004). Also, influenza vaccine administration by pharmacists was seen to increase coverage among medically underserved individuals (Murphy et al., 2012). In the study by Grabstein et al, 2009, which compared the vaccine administration rates in pharmacies that use nurses to administer vaccine in a single day and pharmacies that allow for daily vaccine administration daily by pharmacists over an influenza season, found the vaccination uptake rates to be significantly higher with pharmacist's administration (Grabenstein, 2009).

Feasibility of pharmacists administering influenza vaccine. Of the studies that assessed the scope of pharmacists practice in administering vaccines to adults, it was noted be facilitated by policy such as the standing order which increased influenza vaccine administration and hence uptake in states (Goode et al., 2007; Steyer et al., 2004; Weitzel, 2000). Several barriers to feasibility were identified such as vaccine purchase which was affected by lack of predictability of vaccine supply, lack of certainty of the demands of the community, and a limit in purchasing

power (Penfold et al., 2011). Another barrier was vaccine delivery which was affected by the complications of managing off-site centers such as schools, the differences in requirements across states for credentialing (Penfold et al., 2011). The last barrier identified involved reimbursement issues (Penfold et al., 2011).

Effectiveness of pharmacists administering influenza vaccine. Fifteen of the studies noted how effective the pharmacist's administration practices of influenza vaccine to adults was, as influenza vaccine uptake rates were increased (Bearden & Holt, 2005; Bourdet et al., 2003; Doucette et al., 2012; Ernst et al., 1997; Goode et al., 2007; Grabenstein, 2009; Hagemann et al., 2014; Loughlin et al., 2007; Murphy et al., 2012; Prosser et al., 2008; Singhal & Zhang, 2014; Steyer et al., 2004; Wang et al., 2014; Weitzel, 2000). Some studies measured the cost-effectiveness of pharmacists administering the vaccine to adults (Grabenstein et al., 1992; Prosser et al., 2008). The study by Grabenstein et al., (1992) reported that pharmacists advocating campaigns inadvertently prevent hospitalizations and save costs (Grabenstein et al., 1992). The study by Prosser et al., (2008), reported the cost of vaccination was lower with pharmacists administered vaccines compared to clinics (Prosser et al., 2008). The study by Murphy et al., 2012, noted the accessibility of pharmacists administered influenza vaccines to individuals residing in medically underserved areas emphasizing the unique positions pharmacies might play reducing geographic barriers (Murphy et al., 2012).

Acceptability of pharmacists administering influenza vaccine. Three studies noted that several factors were associated with individuals accepting pharmacies and pharmacists as vaccine administrators, and they include long hours of operation, convenience and easy accessibility (Ernst et al., 1997; Goode et al., 2007; Murphy et al., 2012). The study by Wang et al. (2014), noted that individuals placed pharmacists as the second most trustworthy vaccine

administrators among health professionals following doctors. The study also noted that individuals reported that they would be comfortable receiving their influenza shot from pharmacists (Wang et al., 2014).

Discussion. Since the inception of the standing order by ACIP for pharmacists to administer vaccines to adults (McKibben et al., 2000), pharmacists have been responsible for administering vaccines to about 30 percent of the population (Kirkdale, Nebout, Megerlin, & Thornley, 2017). The review shows that pharmacists have a unique role in increasing influenza vaccine uptake in the community, as they provide services that are cost-effective, convenient and accessible to individuals, serve at-risk populations and can reach individuals that reside in medically underserved communities. A study by Goad et al, (2013), noted that about 20-30 percent of physicians stocked CDC recommended vaccine (Goad, Taitel, Fensterheim, & Cannon, 2013), nontraditional places where vaccines can be received, such as pharmacies can offer an advantage and provide more vaccine coverage (Goad et al., 2013). To explain factors influencing the state of pharmacists as influenza vaccine administrators the result of the literature review will be further illustrated by dividing the findings to patient factors, provider factors and system factors (figure 8).

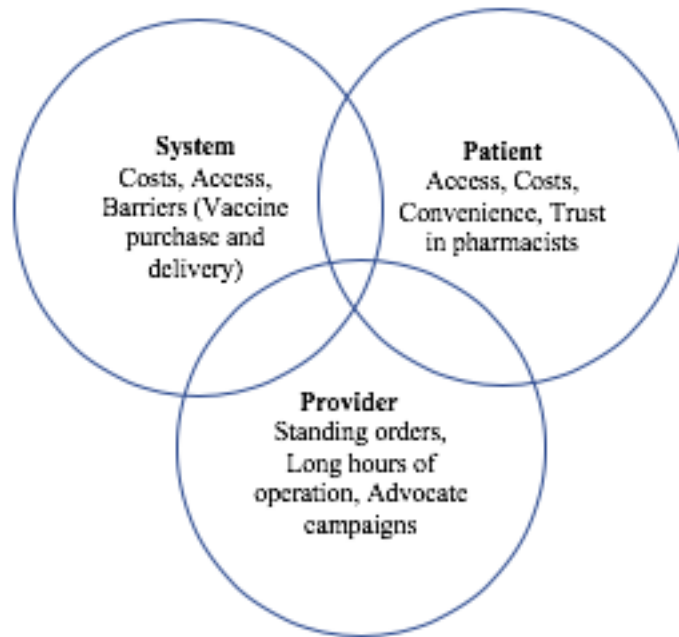


Figure 8. Showing factors influencing the pharmacist’s delivery of influenza vaccine

The review noted systemic factors that affect the delivery of influenza vaccines by pharmacists to individuals to include facilitators such as lower costs and access (Grabenstein et al., 1992; Prosser et al., 2008), and barriers that involve vaccine purchase and delivery (Penfold et al., 2011). The patient-centered factors include accessibility, lower costs, and trust in ability of pharmacists to administer the vaccines (Ernst et al., 1997; Goode et al., 2007; Grabenstein et al., 1992; Murphy et al., 2012; Prosser et al., 2008; Wang et al., 2014). The provider centered factors include the provision of standing orders, the hours of operation of a pharmacy, which could also be system centered, and the advocacy campaigns carried out by pharmacists (Ernst et al., 1997; Goode et al., 2007; McKibben et al., 2000; Murphy et al., 2012; Steyer et al., 2004).

Conclusion

This review identifies the impact of pharmacists administering the influenza vaccine.

Interventions could be targeted towards advocating for at-risk groups such as pregnant women to utilize these services. Interventions can target the vaccine supply and delivery, and the private/public vaccine distribution system. Interventions can also target mandating the standing order for every licensed pharmacist in every state.

Limitations of current research. Several methodological issues have been identified regarding research surrounding the role of pharmacists in administering vaccines. Most of the research involving pharmacists administering vaccines are carried out using nationally representative data such as BFRSS, which has limitations as it uses a general health risk surveillance not specific to pregnant women (Steyer et al., 2004). Furthermore, the BFRSS data did not specify the type of health care provider administering the vaccine (Steyer et al., 2004). Other studies carried out to research the role of pharmacists in administering vaccines, used samples that included high risk group individuals with co-morbidities, children, and the general population (Goad et al., 2013; Kamal, Madhavan, & Maine, 2003; Papastergiou, Folkins, Li, & Zervas, 2014; Steyer et al., 2004; Taitel, Cohen, Duncan, & Pegus, 2011). For the predictor variables, most studies used age, demography and comorbid conditions in relation to the role of pharmacists administering vaccines (Kamal et al., 2003; Steyer et al., 2004; Taitel et al., 2011). Studying the role of pharmacists in administering influenza vaccine to the general population and other high-risk groups, cannot be extrapolated and made generalizable to pregnant women, as they are a unique priority group (Ding et al., 2017).

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Appendix B: Academic Deans Informed Consent Form

Script for Obtaining Verbal Informed Consent for Academic Deans
Information to Consider Before Taking Part in this Research Study

Title: An exploration of the role of pharmacists in increasing influenza vaccine uptake in pregnant women in Florida

Pro # 00038934

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Oluyemisi Falope who is a PH.D. Candidate at the University of South Florida. This person is called the Principal Investigator. She is being guided in this research by Dr. Russel Kirby. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at the University of South Florida. The purpose of the study is to explore the role pharmacists can play in increasing influenza vaccine uptake among pregnant women. This would be carried out by exploring pharmacy school curriculum regarding what is taught regarding influenza vaccine administration to pregnant women.

Participants: You are being asked to take part because you are an academic dean at an accredited school of pharmacy in Florida. We want to ask you about how the course content regarding vaccine administration in pregnant women, with a focus on influenza vaccine is taught at your college. This interview session is expected to last for about 30 minutes. The interview will take place at a location convenient for you (e.g. public place, parks, participant homes), where you will be comfortable. The interview will be audio recorded. This is done so that what you say will be properly captured and not misrepresented.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Your decision to participate or not to participate will not affect your job status, employment record, employee evaluations, or advancement opportunities.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will not be compensated for your participation. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. The only people who will be allowed to see these records are: The Principal Investigator, the advising professor, the research team and the University of South Florida Institutional Review Board (IRB).

If you have any questions, concerns or complaints about this study, call Oluyemisi Falope at XXXXXXXXXXXX .If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Would you like to participate in this study?

Appendix C: Pharmacy Students Informed Consent Form

Script for Obtaining Verbal Informed Consent for Pharmacy Students

Information to Consider Before Taking Part in this Research Study

Title: An exploration of the role of pharmacists in increasing influenza vaccine uptake in pregnant women in Florida

Pro # 00038934

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Oluyemisi Falope who is a PH.D. Candidate at the University of South Florida. This person is called the Principal Investigator. She is being guided in this research by Dr. Russel Kirby. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at the University of South Florida. The purpose of the study is to explore the role pharmacists can play in increasing influenza vaccine uptake among pregnant women. This would be carried out by exploring pharmacy school curriculum regarding what is taught regarding influenza vaccine administration to pregnant women.

Participants: You are being asked to take part because you are a 3rd or 4th year pharmacy student at an accredited school of pharmacy in Florida. We want to ask you about how the course content regarding vaccine administration in pregnant women, with a focus on influenza vaccine is taught at your college. Also, we want to understand your perceptions about administering influenza vaccines in pregnant women. This focus group session is expected to last for about 80 minutes. The focus groups will take place at a location convenient for you (e.g. public place, parks, participant homes), where you will be comfortable. The focus group sessions will be audio recorded. This is done so that what you say will be properly captured and not mis-represented.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Your decision to participate or not to participate will not affect your student status, course grade, recommendations, or access to future courses or training opportunities.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will be compensated with a \$10 Starbucks gift card for your participation. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. The only people who will be allowed to see these records are: The Principal Investigator, the advising professor, the research team and the University of South Florida Institutional Review Board (IRB).

You will be compensated \$10 if you complete the focus group session. If you withdraw for any reason from the study before completion you will be compensated with a \$5 for participating in the study at all.

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind you to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

If you have any questions, concerns or complaints about this study, call Oluyemisi Falope at XXXXXXXXXXX. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Would you like to participate in this study?

Appendix D: Licensed Pharmacists Informed Consent Form

Script for Obtaining Verbal Informed Consent for Pharmacists

Information to Consider Before Taking Part in this Research Study

Title: An exploration of the role of pharmacists in increasing influenza vaccine uptake in pregnant women in Florida

Pro # 00038934

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Oluyemisi Falope who is a PH.D. Candidate at the University of South Florida. This person is called the Principal Investigator. She is being guided in this research by Dr. Russel Kirby. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at the University of South Florida. The purpose of the study is to explore the role pharmacists can play in increasing influenza vaccine uptake among pregnant women. This would be carried out through exploring the perceptions on pharmacists as regards to administering influenza vaccines to pregnant women.

Participants: You are being asked to take part because you are an academic dean at an accredited school of pharmacy in Florida. We want to ask you about how the course content regarding vaccine administration in pregnant women, with a focus on influenza vaccine is taught at your college. This interview session is expected to last for about 60 minutes. The interview will take place at a location convenient for you (e.g. public place, parks, participant homes), where you will be comfortable. The interview will be audio recorded. This is done so that what you say will be properly captured and not misrepresented.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Your decision to participate or not to participate will not affect your job status, employment record, employee evaluations, or advancement opportunities.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will not be compensated for your participation. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records

must keep them confidential. We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. The only people who will be allowed to see these records are: The Principal Investigator, the advising professor, the research team and the University of South Florida Institutional Review Board (IRB).

If you have any questions, concerns or complaints about this study, call Oluyemisi Falope at XXXXXXXXXXXX .If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Would you like to participate in this study?

Appendix E: IRB Approval



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

2/6/2019

Oluyemisi Falope

Community and Family Health

RE: Exempt Certification

IRB#: Pro00038934

Title: An exploration of the role of pharmacists in increasing influenza vaccine uptake in pregnant women in Florida

Dear Ms. Falope:

On 2/5/2019, the Institutional Review Board (IRB) determined that your research meets criteria for exemption from the federal regulations as outlined by 45 CFR 46.104(d):

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

As the principal investigator for this study, it is your responsibility to ensure that this research is conducted as outlined in your application and consistent with the ethical principles outlined in the Belmont Report and with USF HRPP policies and procedures.

Please note, as per USF HRPP Policy, once the exempt determination is made, the application is closed in ARC. This does not limit your ability to conduct the research. Any proposed or anticipated changes to the study design that was previously declared exempt from IRB oversight must be submitted to the IRB as a new study prior to initiation of the change. However, administrative changes, including changes in research personnel, do not warrant an Amendment or new application.

We appreciate your dedication to the ethical conduct of human subjects research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

Kristen Salomon, Ph.D., Chairperson USF Institutional Review Board



Appendix F: Sample Student Recruitment Flyer



Are you a 3rd or 4th year Pharm D. student in Pharmacy School?

Then we need YOU to be part of a research study focus group on influenza vaccine administration in pregnant women with 3rd and 4th year Pharm D. students at the University of Florida.

Who is eligible?

- 3rd and 4th year Pharm D. students

What will I have to do?

- Participate in a focus group discussion with 7 other students.
- Discuss your disciplines influenza immunization course instruction
- Discuss your perception of administering influenza vaccines to pregnant women

How much time will this take?

- Participation will take approximately 30 minutes

Do I get anything for my time?

- Receive a \$10 Starbucks gift certificate and add to scientific knowledge.

When will the group meet?

- Flexible online via zoom or at an agreed location and time
- Dates: 3rd or 4th of June 2019

To participate: Contact Oluyemisi Falope (813) 407-1504 Or email: ofalope@health.usf.edu



IRB number: Pro00038934