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Nkechinyere Emejuaiwe

Date

THE ROLE OF KNOWLEDGE AND PERCEPTION IN OPTIMIZING VACCINATION
AGAINST INFLUENZA AND PERTUSSIS AMONG ADULTS WITH TYPE 2 DIABETES
MELLITUS IN FORSYTH COUNTY, NC

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Degree to be awarded: M.P.H
Executive MPH

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An abstract of
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MPH program
2015

ABSTRACT

THE ROLE OF KNOWLEDGE AND PERCEPTION IN OPTIMIZING VACCINATION AGAINST INFLUENZA AND PERTUSSIS AMONG ADULTS WITH TYPE 2 DIABETES MELLITUS IN FORSYTH COUNTY, NC

BY

Nkechinyere Emejuaiwe

The development and introduction of vaccines in the 20th century has significantly reduced the burden of several infectious diseases. However, new concerns have risen regarding poor uptake of vaccinations in spite of their proven efficacy. Vulnerable populations include children, the elderly and those with chronic diseases. In particular, the morbidity and mortality associated with diseases affecting the respiratory system such as influenza and pertussis are substantial in those with chronic diseases such as diabetes mellitus. Diabetes mellitus is a growing health problem in the United States associated with economic costs of about \$245 billion each year. It is estimated that 29 million Americans have diabetes and annually 1.9 million adults over the age of 20 are diagnosed with diabetes mellitus.

Abnormal metabolism of glucose in patients with diabetes has a deleterious effect on the immune system. Therefore, this group of patients is more susceptible to infections. Observational studies have shown that vaccination against influenza and administration of the pertussis booster can reduce the risk of hospitalization and death in those with diabetes.

In order to improve vaccination rates, public health professionals need to understand and address the barriers to this preventive strategy. The goal of this research was to determine and understand factors that influence attitudes and behavior of people with diabetes regarding influenza and pertussis vaccination in Forsyth County, North Carolina.

This thesis work implemented a cross-sectional study design with descriptive analysis. Focus group interviews (three in English and one in Spanish) were conducted between May, 2014 and March, 2015 and a total of 18 patients with diabetes participated in the study. An average of 78% of respondents reported regular receipt of the influenza vaccination compared to only 26% who had received the pertussis booster vaccination. The most salient patient-related barriers identified in the study were lack of knowledge, influence of healthcare providers and communication. Results of the current study provide an important opportunity to influence perceptions about vaccinations and ultimately improve health in those with diabetes.

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CHAPTER I: INTRODUCTION

Introduction and Rationale

Influenza and pertussis are highly contagious causes of respiratory illnesses associated with a high morbidity and mortality in people with chronic diseases such as diabetes mellitus. It is estimated that 29 million Americans have diabetes mellitus and annually 1.9 million adults over the age of 20 are diagnosed with the disease (Bluml, Watson, Skelton, Manolakis, & Brock, 2014; Centers for Disease Control and Prevention, 2014). As illustrated in figure 1.1, the incidence and prevalence of diabetes mellitus continues to rise nationally but many affected persons are not receiving the processes of care recommended by the American Diabetes Association.

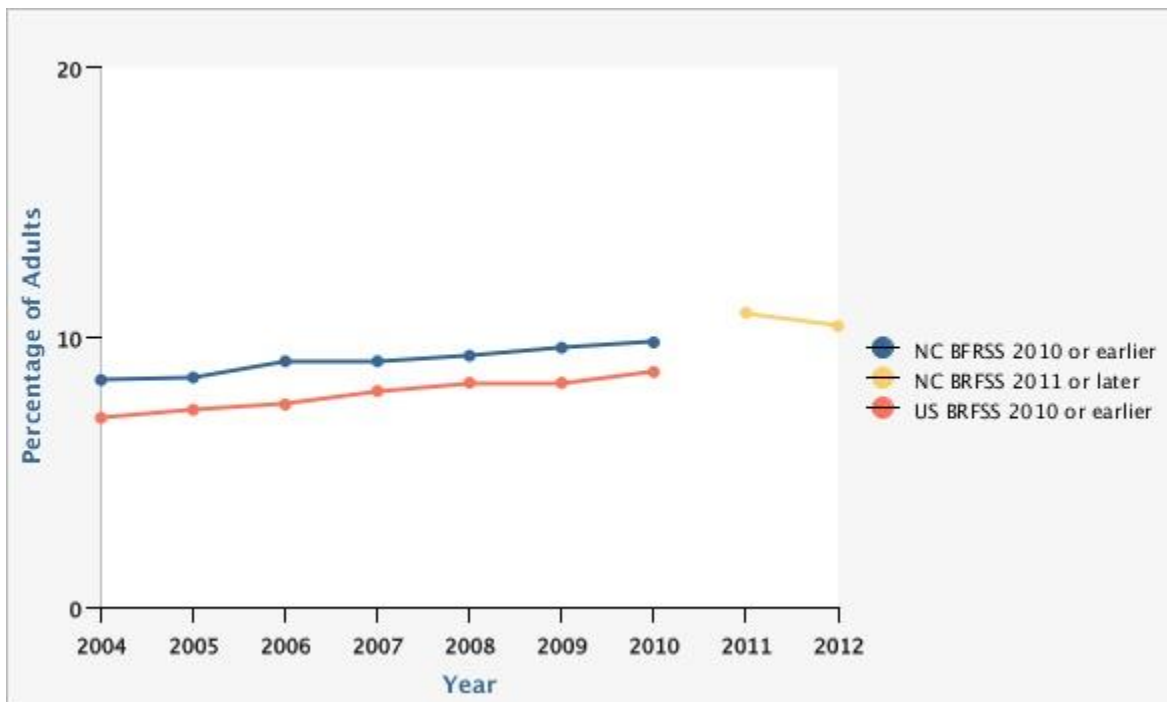


Figure 1.1 Percentage of Adults with Diabetes North Carolina versus United States, 2004-2012

Source: North Carolina Institute of Medicine, 2013

Management of diabetes not only involves prevention of disease progression but also prevention of complications associated with the disease. There is evidence that patients with

diabetes are at increased risk for developing illness related to influenza, six times more likely to be hospitalized and three times more likely to die from complications of influenza when compared to the general population (Smith & Poland, 2000; "Vaccination practices for hepatitis B, influenza, and pneumococcal disease for people with diabetes," 2014). Mortality rates for influenza and pneumonia in the general population of North Carolina between 2008 and 2011 are illustrated in figure 1.2.

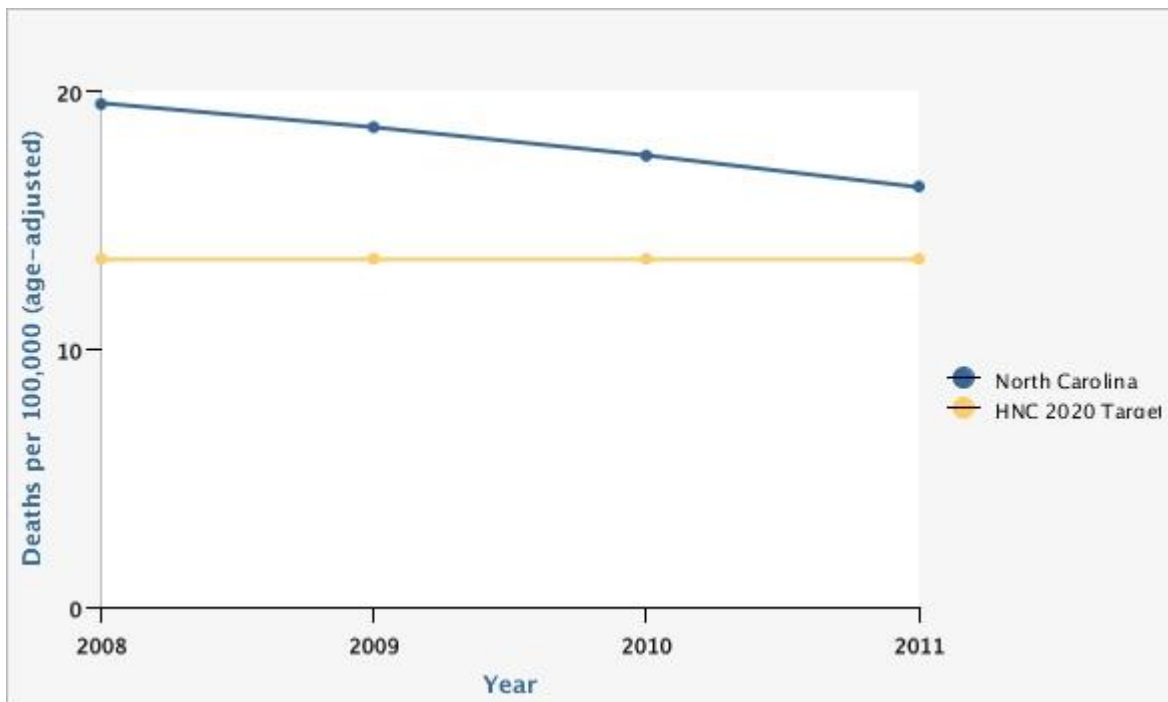


Figure 1.2 Influenza and Pneumonia Mortality Rate North Carolina versus Healthy North Carolina 2020 Target, 2008-2011

Source: North Carolina Institute of Medicine, 2013

Infections may cause hyperglycemia (blood glucose elevation), making blood glucose management in persons with diabetes more difficult ("Vaccination practices for hepatitis B, influenza, and pneumococcal disease for people with diabetes," 2014). Furthermore, hyperglycemia impairs the immune response by depressing neutrophil chemotaxis and adherence to vascular endothelium, phagocytosis, intracellular bactericidal activity, opsonization, and

cell-mediated immunity (Smith & Poland, 2000; Wang et al., 2013). Those at particular risk include individuals with new onset diabetes, elders, African American and Hispanic populations (Morritt Taub, 2006).

According to recent data, the total economic burden of influenza epidemics across all age groups in the United States is estimated to be \$87 billion (Klepser, 2014) while the burden of pertussis among adults 50 and over is \$400 million (McLaughlin, McGinnis, Tan, Mercatante, & Fortuna, 2015). Figure 1.3 depicts the estimated burden of four vaccine preventable diseases (VPDs) in adults in the United States in 2013.

These infectious diseases are preventable and vaccines are amongst the most cost-effective preventive strategies, yet sadly coverage rates remain suboptimal.

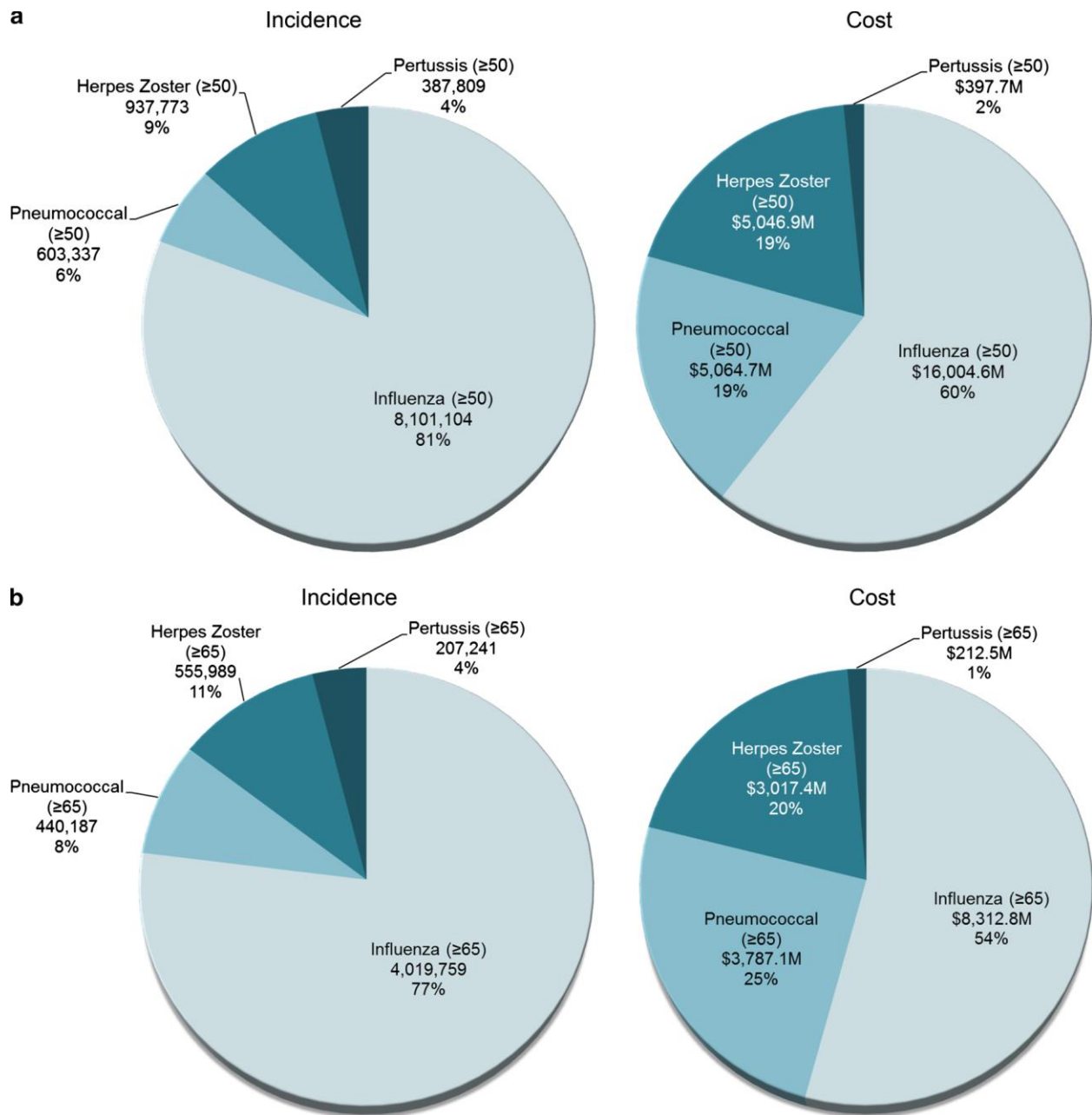


Figure 1.3 Percentage of total estimated number of cases and overall cost of four major adult vaccine-preventable diseases in the United States, 2013 for adults a. 50 years and older; b. 65 years and older

Source: McLaughlin et al., 2015

On a positive note, in general, preventive care services offered to patients with diabetes have improved and this progress can be attributed to multidisciplinary strategies including the provision of care guidelines, education, improved access to care and involvement of healthcare workers at various levels (Satman, Akalin, Cakir, & Altinel, 2013; Sawin, Walder, Bross, & Pogach, 2004). Individuals with diabetes are at increased risk for VPDs and this study aims to understand less-studied patient-related factors that influence vaccination decisions. Overcoming this barrier would play a complementary role in the success of the general care of those with diabetes.

Problem Statement and Statement of Significance

The Centers for Disease Control and Prevention (CDC) recognizes low uptake of routinely recommended adult immunizations as an area of public health practice insufficiently addressed at local, state and national levels (McLaughlin et al., 2015). According to the North Carolina Institute of Medicine and Healthy North Carolina 2020, in 2008 pneumonia and influenza yielded the eighth leading cause of death among North Carolinians, causing approximately 1,750 deaths (North Carolina Institute of Medicine).

According to Forsyth County Health Department, confirmed pertussis cases increased from 6 to 22 between 2011 and 2012 (Fig 1.4). In response to this increase in incidence, North Carolina Department of Health and Human Services and North Carolina Immunization Program provides Tdap vaccine to all persons over the age of 7 years at risk with special emphasis on groups including those with chronic diseases such as diabetes (Forsyth County Department of Public Health, 2012).

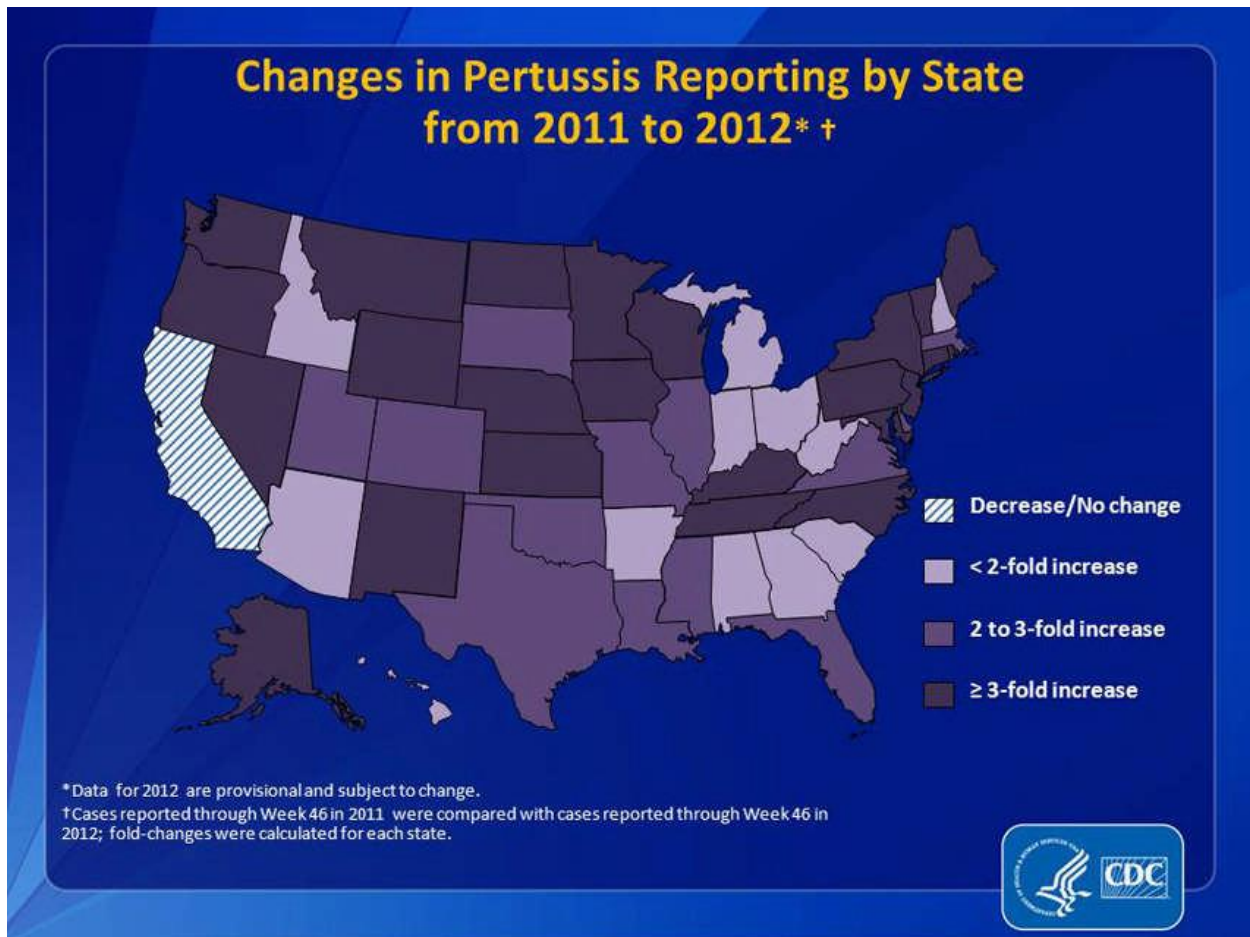


Figure 1.4 Reported Cases of Pertussis by State, 2011-2012

Source: Centers for Disease Control and Prevention, 2015

In spite of this effort, the trend in subsequent years reflects continued increase in pertussis cases reported in North Carolina as seen below in figure 1.5 (Centers for Disease Control and Prevention, 2015b).

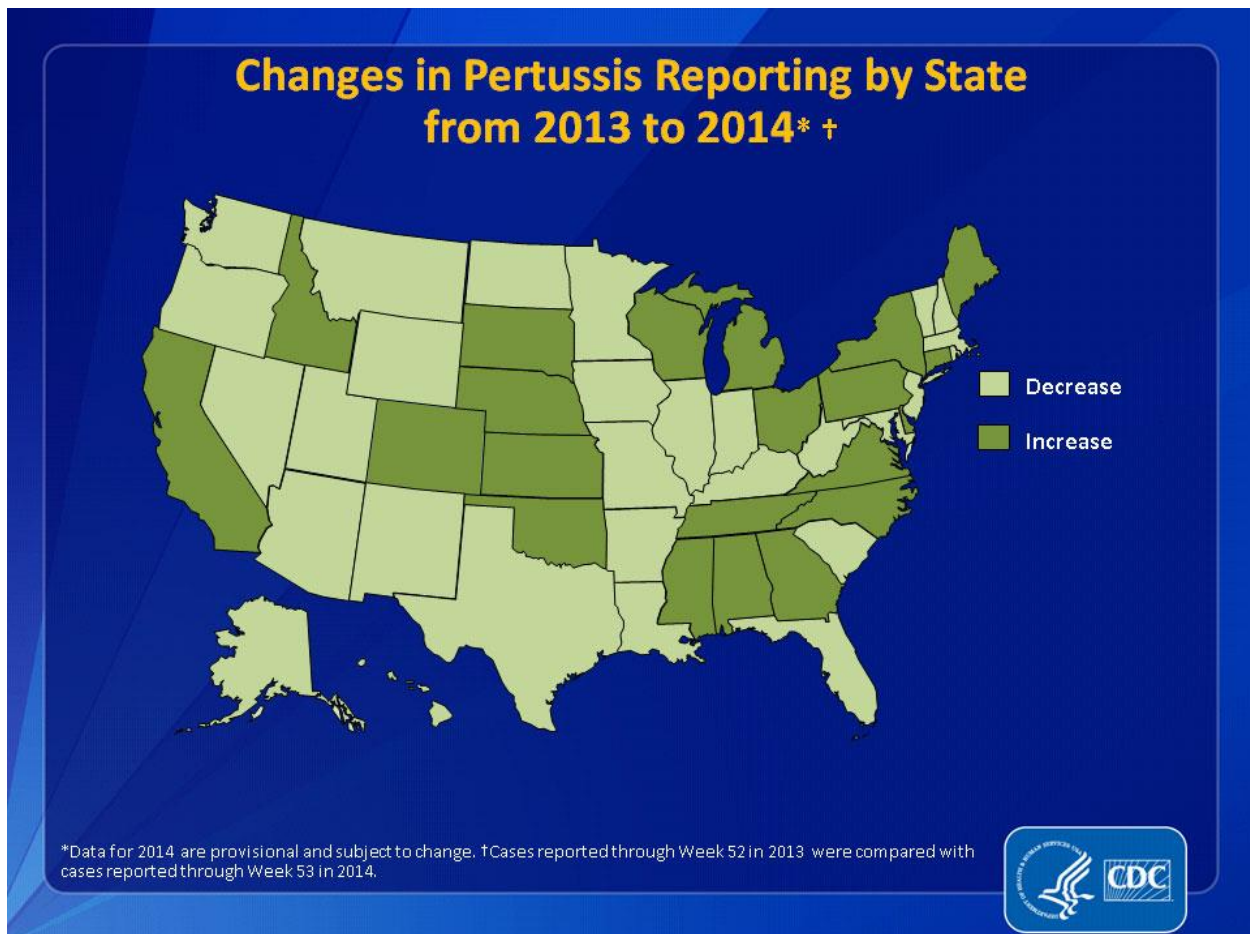


Figure 1.5 Reported Cases of Pertussis by State, 2013-2014

Source: Centers for Disease Control and Prevention, 2015

During the 2010 flu season, it was estimated that only 68.8 % of individuals aged 65 years and older in the general population nationally received the influenza vaccine, falling short of the Healthy People 2010 goal of 90% ("Vaccination practices for hepatitis B, influenza, and pneumococcal disease for people with diabetes," 2014). In 2012, 24.9% of adults younger than 65 and 16.8% of those aged 65 and older nationally reported receiving a dose of the tetanus toxoid, diphtheria toxoid and acellular pertussis (Tdap) vaccine in the preceding 7 years (McLaughlin et al., 2015). Data from a 2011 survey indicated that 60% of adult patients with diabetes reported receiving the influenza vaccination in the preceding year compared to the

national vaccination rate of 42% at the time (Athamneh & Sansgiry, 2014). Although this may appear encouraging, there remains a lot of ground to be covered to reach the Healthy People 2020 goal of 90% for influenza vaccination rate among persons with diabetes. The issue is of such concern that CDC recommends including annual influenza vaccination and a single (booster) dose of the pertussis vaccine as part of regular management for patients with diabetes in an effort to reduce the impact of these diseases (Centers for Disease Control and Prevention, 2015a).

Some have questioned the efficacy of vaccines in patients with diabetes due to the aforementioned effects of hyperglycemia on the immune system. However, due to a predominantly B lymphocyte-driven process, studies show that people with diabetes are able to produce an adequate immunologic response to the influenza and pertussis vaccine (Jimenez-Garcia et al., 2005; Smith & Poland, 2000). In fact, annual vaccination against influenza has been shown to reduce diabetes-related hospitalizations for influenza during epidemics by as much as 79% ("Vaccination practices for hepatitis B, influenza, and pneumococcal disease for people with diabetes," 2014). Although data on vaccination rates against pertussis are sparse, there is some evidence that receipt of influenza vaccination is associated with higher odds of receiving other vaccinations, emphasizing the role of attitude towards vaccination (Jones et al., 2010).

Despite this evidence, the uptake of vaccination remains low and research suggests that barriers exist at the patient, provider and system levels. This study aims to understand patient-level barriers to vaccination against pertussis and influenza in patients with diabetes in Forsyth County, NC.

Hypothesis

Based on the current literature we hypothesized that individualized and system-related factors play a role in the willingness and ability of patients with diabetes to receive influenza and pertussis vaccinations. Table 1.1 delineates our hypothesized key influences.

INDIVIDUAL FACTORS	SYSTEM-RELATED FACTORS
Concern about side effects	Limited access to vaccination resources
Mistrust of the medical care system	Not recommended by healthcare providers
Underestimation of susceptibility to infection	Gap in communication between providers and patients
Lack of knowledge	Distraction by other issues
Resources	

Table 1.1 Hypothesized key influences on patients' willingness to receive vaccines

Theoretical Framework

The conceptual framework for the study is adapted from the Quality Health Outcomes model (Fig 1.6.) which represents a bidirectional relationship between the multiple factors that affect quality of care and a desired outcome (Mitchell, Ferketich, & Jennings, 1998), in this case improved quality of care in people with diabetes, with regard to improved vaccination rates against influenza and pertussis.

It is known that knowledge and attitudes of patients and providers in addition to health system processes and barriers influence vaccination rates (Smith & Poland, 2000)

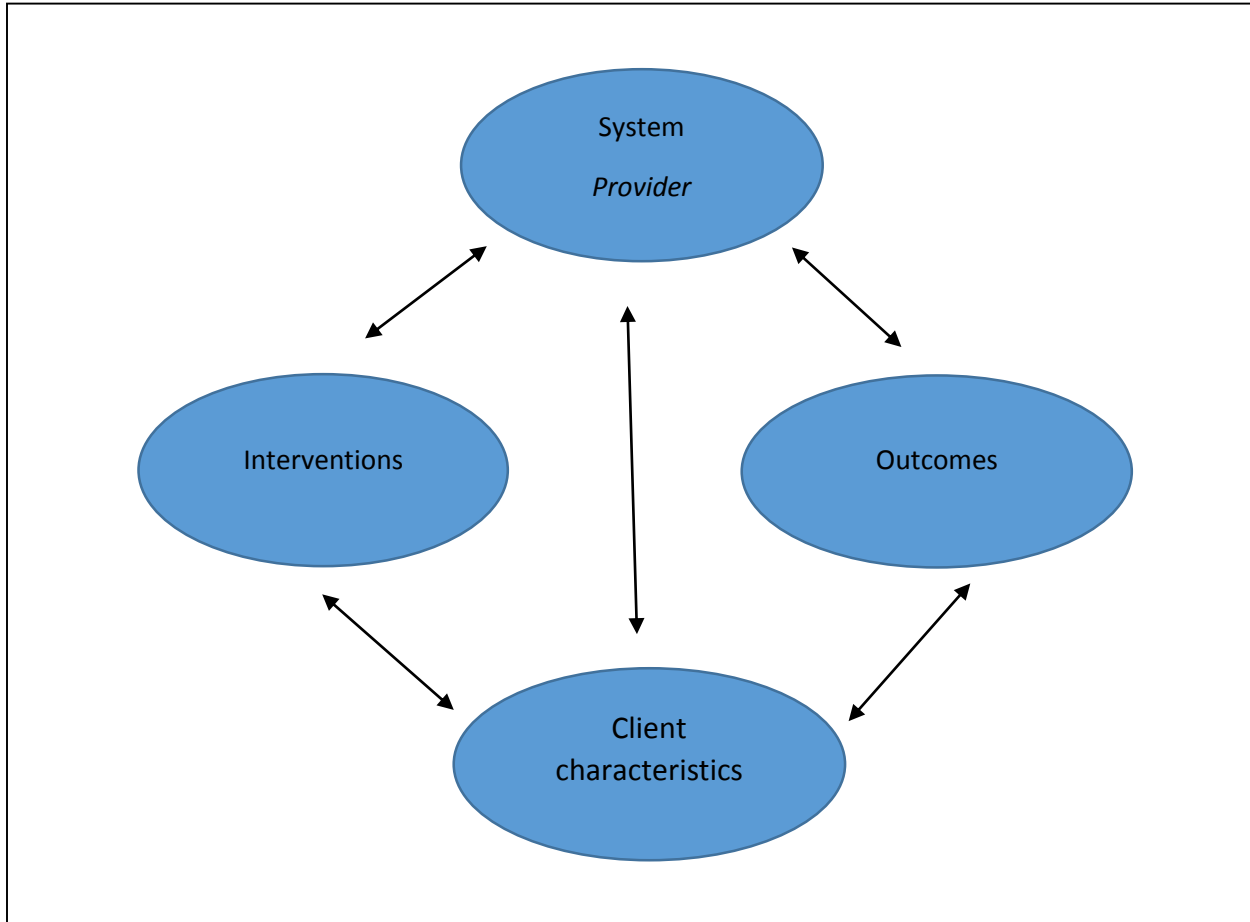


Figure 1.6 the Quality Health Outcomes Model

Source: Mitchell, Ferketich & Jennings, 1998

Purpose Statement

The United States is facing an epidemic of diabetes mellitus and the goal of this study is to identify opportunities to improve the health of the community. The prevalence of diabetes mellitus in the United States increased by 128% between 1998 and 2008 and equally alarming is the estimated \$245 billion annual economic cost associated with the disease (Bluml et al., 2014).

In keeping with the Healthy People 2020 recommendations, to facilitate preventive health efforts, interventions such as vaccinations are essential to a coordinated strategy to promote health. Indeed, the management of diabetes mellitus is multifaceted and includes the prevention of complications such as through obtaining recommended vaccinations.

Research Question

This study will seek to understand the knowledge, beliefs and attitudes of patients diagnosed with type 2 diabetes mellitus about influenza and pertussis and vaccinations against these infections.

Specifically, this study will seek to answer the following questions:

- What is known about the influenza and pertussis vaccine?
- What is known about risk of these infections in people with diabetes?
- What are some factors that influence vaccination uptake?
- How can information about vaccinations be more effectively communicated and disseminated in the community?

Definition of Terms

Behavioral Risk Factor Surveillance System (BRFSS) - is the nation's premier system of health-related telephone surveys that collect state data about United States residents regarding their health-related risk behaviors, chronic health conditions, and use of preventive services.

Healthy North Carolina 2020- is a state health improvement plan developed by the North Carolina Institute of Medicine Prevention Task Force and released in 2011. It prioritizes topics and strategies to improve overall population health (ncphf.org).

Healthy People 2020- is the result of a multi-year process with set science-based, 10-year national objectives for improving the health of all Americans (healthypeople.gov).

The Health Belief Model- a popular theory of health behavior that postulates that health-seeking behavior is influenced by a person's perception of a threat posed by a health problem and the value associated with actions aimed at reducing the threat (currentnursing.com).

CHAPTER II: REVIEW OF THE LITERATURE

Introduction

Ever since the use of a vaccine against small pox by Edward Jenner in 1796, vaccines have become indispensable to the eradication of disease. Major advances have been made not only in the development but also in utilization of vaccines to save lives. Figure 2.1 highlights milestones in vaccine development in the 20th and 21st century. Currently more than 70 vaccines have been licensed for use and in modern day medicine vaccination provides an important, cost-effective strategy to protect against many infectious illnesses (Nabel, 2013).

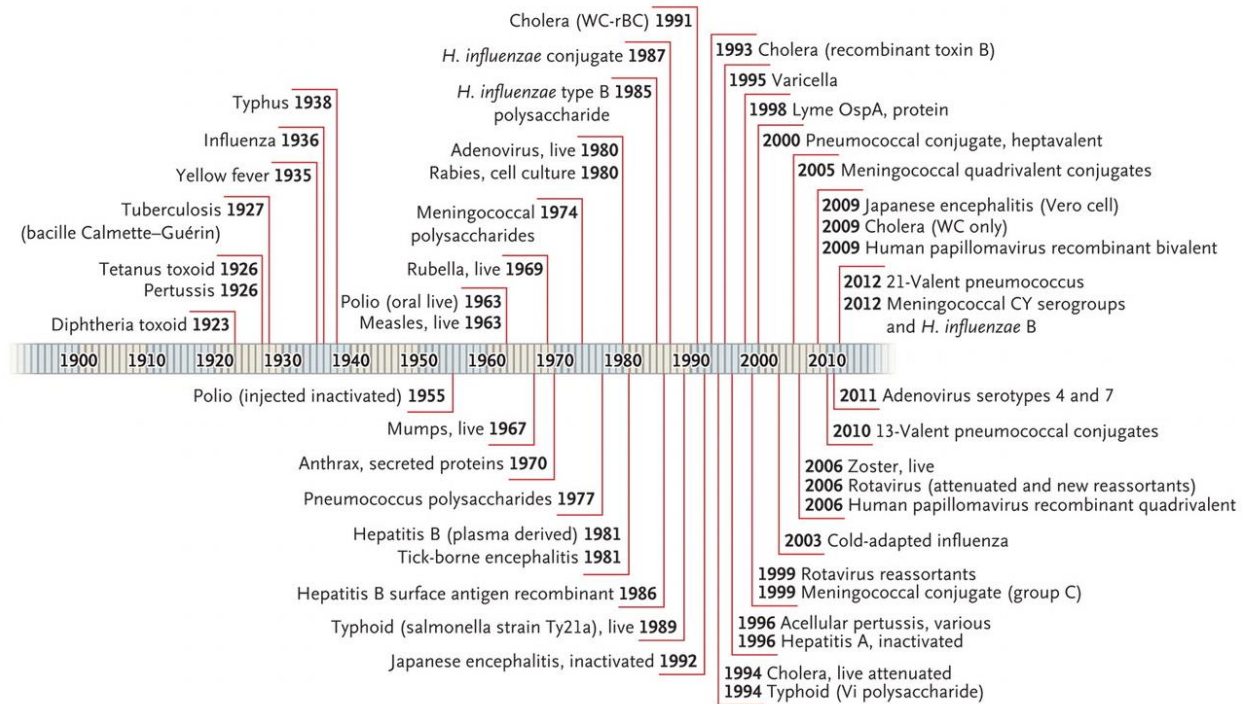


Figure 2.1 Milestones in Vaccine Development

Source: Nabel, 2013

While childhood immunization programs have nearly eliminated many life-threatening illnesses, adult immunization programs have been slow to evolve (McLaughlin et al., 2015). A review of the current, available literature was conducted to better understand the reasons behind

low rates of vaccination uptake in adults. This study focuses on patient knowledge and attitudes in an attempt to understand the uptake of influenza and pertussis vaccination in patients diagnosed with type 2 diabetes mellitus. Therefore, common reasons for vaccine acceptance or refusal and factors that contribute to this decision will be highlighted. A Medline literature search was conducted using the key words vaccination, immunization, influenza, pertussis, knowledge, attitudes, belief and diabetes.

The Role of Knowledge

Knowledge or gaps in knowledge can create barriers to health interventions including preventive measures such as vaccination. In today's increasingly complex environment, patients are faced with multiple external sources of information which, along with individual "internal" knowledge influence healthcare decisions. For example, a study conducted in Singapore involving 307 patients with diabetes revealed that 32% of participants thought that influenza vaccines protect against all strains of influenza while 6% thought a vaccine provides lifelong immunity (Tan, Lim, Teoh, Ong, & Bock, 2010). These proportions, while not enormous, are meaningful due to the inconsistency between knowledge that could form a health decision, and the actual vulnerability to the health risk.

In another study conducted in a primary care setting, healthcare workers received an anonymous self-administered survey and 21 of the 711 respondents whose questionnaires were analyzed reported a diagnosis of diabetes mellitus. Of these, only 47.6% expressed a willingness to accept H1N1 vaccination (Toh, Kannan, Chen, Chng, & Tang, 2012). Interestingly the willingness to be vaccinated against H1N1 was not significantly different between those with and without chronic medical illnesses but those who were willing to accept the seasonal influenza vaccine were more likely to accept the H1N1 vaccine. This might suggest that overcoming barriers to a specific vaccine may positively influence willingness to receive other vaccinations. Indeed, in a random

sample of community residents with diabetes mellitus and residents over the age of 75, a factor significantly associated with influenza vaccine uptake was a history of previous vaccination (Lewis-Parmar & McCann, 2002). Upon further analysis of the healthcare worker survey, the most common reason given for rejecting vaccination was a fear of side effects (Toh et al., 2012). In this case, the knowledge of the study population and their possible exposure to those who may have developed adverse reactions from previous vaccinations negatively influenced their desire to be vaccinated. It is a disturbing finding, considering the risk posed by the spread of infection from healthcare workers to their patients.

The Role of Culture and Race

Culture impacts health not only as it is influenced by socioeconomic status and access to healthcare but also its influence on health practices. National sources indicate that minority populations receive influenza vaccinations at a substantially lower rate than the Caucasian population (Hebert, Frick, Kane, & McBean, 2005). Secondary data analysis from a 2011 Behavioral Risk Factor Surveillance System survey (BRFSS) of patients with diabetes revealed that a significantly lower proportion of African American respondents (50%) compared with Caucasian respondents (61%) reported receiving the influenza vaccination in the preceding year (Athamneh & Sansgiry, 2014). The reasons for this are not entirely clear but perhaps certain practices ingrained within an ethnic group play a contributory role. More than 2 million Native Americans live in the United States and although progress has been made in recent years, this population lags behind the general population for major health status indicators (Buchwald et al., 2000). Chronic diseases such as diabetes mellitus have emerged as leading causes of death and according to Indian Health Service statistics, influenza and pneumonia constitute the sixth leading cause of death among American Indians of all ages (Buchwald et al., 2000). In addition to poor health insurance coverage and provider-based factors such as a limited amount of time

spent with patients, culturally influenced beliefs have been implicated as contributors to missed opportunities for immunization (Buchwald et al., 2000). Black race was noted in one study as a negative predictor for influenza vaccination with lower vaccination rates noted for blacks than their white counterparts even in situations where vaccines were available at no cost (Chi, Reiber, & Neuzil, 2006; Jones et al., 2010). This latter point suggests that factors other than socioeconomics may contribute to racial disparities in vaccination rates.

The Role of Socioeconomic Status and Location of Care

Limitation in access such as a lack of transportation can be indirectly linked to lower income and may account for underutilization of vaccinations (Jones et al., 2010). Higher socioeconomic status and the presence of chronic diseases have been cited as positive predictors for vaccination (Chi et al., 2006). Correlated with this is the influence of location of care on vaccination rates as demonstrated by a cross-sectional population-based study comparing influenza and pneumococcal vaccination rates of veterans to those of non-veterans. In this analysis, a nationwide telephone survey was used to determine self-reported vaccination status of participants aged 65 and older. Influenza vaccination rates were higher for veterans than nonveterans (74% versus 68%, $P < 0.001$) and for Veteran's Healthcare Administration (VA) users than non-VA users (80% versus 72%, $p < 0.001$). Interestingly, diabetes mellitus was more prevalent amongst VA users than non-VA users (Chi et al., 2006). Perhaps the structure of care received at the VA which primarily serves an older population and in which the administration of influenza vaccine is included in a list of recommended health-promoting services, provides an advantage. Indeed, influenza and pneumococcal vaccination rates are included as performance measures and the electronic medical record system utilized at VA health facilities maintains a vaccination history and generates a reminder to providers to administer vaccinations (Chi et al., 2006).

The Role of Gender and Age

Gender and age are factors often speculated to influence healthcare decisions and the utilization of healthcare services. Women and men have different social roles and responsibilities which may impact health behavior and the use of health services. Many studies have shown that women utilize healthcare services at a higher rate than men, and older individuals more than younger people (Carretero, Calderon-Larranaga, Poblador-Plou, & Prados-Torres, 2014). The diseases for which care is sought, the physiologic effects of aging and availability of healthcare coverage for different age groups are variables worth considering in the interpretation of gender and age influences on healthcare decisions. In the case of vaccinations, generalizations about the influence of gender and age cannot be made as there are conflicting reports in the literature. The analysis of one study revealed that males were more likely than females to get vaccinated against H1N1 and influenza; and that vaccination rates increased with age from 27% among those below 25 years to 45% in those 45 years and older (Jimenez-Garcia et al., 2005; Toh et al., 2012). Some other studies have indicated that older age and female sex were positive predictors for vaccination (Chi et al., 2006).

The Role of Provider Recommendation

Provider-patient relationships play an important role in medical compliance and health outcomes. In particular, physician recommendations have been shown to have a positive influence on patients' decision to be vaccinated and studies have reported that information provided by a health professional was a source found to significantly influence vaccine uptake (Jones et al., 2010; Lewis-Parmer & McCann, 2002; Smith & Poland, 2000; Tan et al., 2010). As mentioned earlier, individuals with chronic diseases are at higher risk for infections and although our study focuses on persons with diabetes, patients with end stage renal disease (ESRD) are also at increased risk. The impact of communicating this risk and recommending preventive steps can

often be overlooked by busy providers distracted by other issues. A 2010 survey estimated that only 20% of diabetes educators offered information about or discussed immunizations with people with diabetes ("Vaccination practices for hepatitis B, influenza, and pneumococcal disease for people with diabetes," 2014). Reminder systems have been studied as an effective strategy to improve vaccinations and in the case of patients with ESRD, scheduled dialysis sessions at centers makes access convenient. In a survey of vaccination practices, beliefs and attitudes completed by clinical and administrative staff at several dialysis centers, a majority of the centers "agreed" or "strongly agreed" that vaccinations were safe and important (Bond et al., 2009). 86.8% "agreed" or "strongly agreed" that the influenza vaccine specifically was effective (Bond et al., 2009). Success in the improvement of vaccination rates may therefore be contributed to by diabetes risk education, provision of information about vaccination by healthcare providers and an improvement in access to vaccination.

Other Influences

One's belief that a treatment regimen is effective could to a certain extent affect their response to the treatment (the Health Belief Model). Vaccine uptake may therefore be influenced by a belief that the vaccination is effective in disease prevention (Lewis-Parmar & McCann, 2002). Some individuals have expressed an unwillingness to receive vaccines because of an uncertainty about vaccine effectiveness, a perception of low risk from infection complications and immunity to the infectious agent (Toh et al., 2012). Changing a person's beliefs can be challenging but perhaps sensitive provision of education while respecting expressed beliefs may facilitate a desired modification in those beliefs. For example, traditional and complementary medicine is widely practiced around the world despite limited data on safety and efficacy. Using data from the 2002 National Health Interview Survey (NHIS), the association of complementary and alternative medicine (CAM) assessed behavior of adults and preventive care practices,

including receipt of influenza vaccination (Garrow & Egede, 2006). Initial results of this analysis revealed that diabetic patients who used CAM were more likely to receive influenza vaccination than those who did not (48.9 vs. 44.8%, $P = 0.040$). A plausible explanation for this could be the higher education and socioeconomic advantage noted in the CAM users. However, when adjusted for potential confounding factors, the strength of this association was lost for the influenza vaccination but CAM users were still more likely to receive the pneumonia vaccination (Garrow & Egede, 2006). Patients are often unwilling to discuss the use of complementary treatments with providers for fear of disapproval but an approach void of judgment and with the provision of advice on credible and licensed complementary services may encourage the use of more conventional preventive services such as vaccinations.

Some studies looking into general attitudes regarding vaccination have found that a distrust of the healthcare system and concerns about ethical issues contribute to under immunization. Experiments in the past involved prisoners and orphaned children who were considered less valuable members of society (Bazin, 2001). Additionally, personal preferences including a dislike of needles and objections of a religious nature have also been expressed by some patients. Some believed that to “artificially protect people against an infectious disease was to modify the person’s destiny” (Bazin, 2001; Toh et al., 2012).

The Utilitarian approach of achieving the greatest good for the majority is the premise of vaccination policies, yet the various individual explanations for vaccination unwillingness must be taken into consideration. It is only through understanding healthcare behavior and influences that important changes can be implemented.

Summary of current problem and study relevance

The effectiveness of vaccinations in reducing the morbidity and mortality associated with influenza and pertussis is well established. However several factors contribute to underutilization of this preventive strategy in adult patients. Vaccines are not without risk although arguably the benefits outweigh potential risks. Of particular concern are populations with chronic diseases in whom the effects of infectious illnesses can be devastating. Patients have reported a desire to know more about the safety and effectiveness of vaccines before consenting to vaccination and an increased willingness to receive a recommended vaccination has been noted in attendees of educational programs (Toh et al., 2012). Other proposed strategies include raising awareness about the burden of disease, identifying advocates and engaging key stakeholders in the promotion of vaccination and improving healthcare access. In addition, understanding patient attitudes toward vaccinations can be a key step in influencing these attitudes and ultimately improving vaccination rates.

This research investigated the knowledge and perceptions of patients with type 2 diabetes mellitus in Forsyth County, North Carolina regarding vaccination against influenza and pertussis.

CHAPTER III: METHODOLOGY

Introduction

This study was part of a larger project conducted by the Maya Angelou Center for Health Equity (MACHE) based at the Wake Forest School of Medicine and funded by the National Institute on Minority Health and Health Disparities of the National Institutes of Health. It focused on implementing evidence-based strategies to enhance vaccination rates for influenza and pertussis among patients with diabetes in Forsyth County, North Carolina and was founded on the supposition that understanding and addressing barriers to vaccination could improve rates of this preventive strategy. In this chapter, the methods and procedures used to understand the level of knowledge of patients and assess vaccination barriers will be described. A description of the study population and sample, research design, data analysis, limitations and delimitations will be presented.

Population and Sample

Study participants were adult patients 21 years of age and older with a diagnosis of type 2 diabetes mellitus receiving care at outpatient clinics of Wake Forest Baptist Medical Center health care system. A majority of this population were served in the Downtown Health Plaza (DHP), a facility designed to provide comprehensive primary and preventive health care services affordable and accessible to all citizens of Forsyth County. The patient population consists mostly of individuals of African American ethnicity. In 2010, the DHP had 1820 unique patients with diabetes mellitus; 67% were African American. With a database of more than 6000 adult patients, the DHP has provided a source for recruitment for several clinical studies at Wake Forest Baptist Medical Center.

Research design

A cross-sectional study design was selected as the most appropriate for our descriptive analysis. Previous research on attitudes and perceptions about health care interventions has

utilized a similar design. Although causal inferences may be challenging to make from study results, the cross-sectional design allows the generation of useful hypotheses.

The primary objective of this research was to understand and report factors that influence influenza and pertussis vaccination decisions in a high risk study population - patients with type 2 diabetes mellitus. Appendix A. depicts the logic framework of implemented strategies for this project.

Procedures

A research protocol was developed and submitted for review to the Wake Forest School of Medicine Institutional Review Board (IRB) along with the focus group guide and consent form. In April, 2014, the Wake Forest University institutional review board approved the study. The secondary analysis of interview data for this research study received exemption from further review from the Emory University Institutional Review Board in June, 2015. Documentation of the IRB's exemption letter is included in Appendix B.

Using an electronic health record system, subjects with a diagnostic code for diabetes mellitus (ICD-9 code 250.00) received invitation letters for study participation. An opportunity to decline this invitation was provided by asking uninterested persons to return a prepaid postcard. Prospective participants subsequently received telephone calls with the provision of study-related details.

Focus group interviews (three in English and one in Spanish) were conducted between May, 2014 and March, 2015. On average there were 5 participants in the English language focus groups but only 2 in the Spanish-speaking group. At the beginning of each session, informed verbal and written consent was obtained and hard copies were collected and stored securely. Participants were made aware of the audio recording for transcription purposes and all provided

consent. Participants were also informed that with the exception of data used in the stages of recruitment, the research would not collect, disclose or publish names, addresses, demographic or other identifying data. Participation in the study was completely voluntary; however, each participant was compensated with a \$25 Visa gift card at the end of the interview session.

Instruments

A focus group guide comprised of 10 questions and accompanying probes was developed by the study team. This guide is provided in Appendix C. Questions were based on the study team's review of similar studies in the literature. Most questions were open-ended to probe for expanded information and facilitate discussion among participants. This also allowed the same questions to be asked in all focus groups and enabled consistency.

The focus group guide was submitted to the Wake Forest School of Medicine IRB but validation of this instrument was not conducted prior to its use.

Data Collection and Analysis

Focus group data were transcribed verbatim and each transcript was reviewed by 2 members of the research team independently. A code book was generated from concepts in the literature review and after a preliminary review of all transcripts. The code book is provided in Appendix D. Transcripts were imported into Atlas.ti 7, a software program designed to organize and manage textual qualitative data. Text was cross-coded using a collaborative and iterative process and a consensus was established with an inter-rater reliability of 91%. The data analysis followed a mechanism designed to be descriptive and allowing a segment of text to be attributed to a descriptive code (Miles & Huberman, 1986). After multiple reviews of the data, themes were identified according to the frequency of a concept throughout the interviews. Segments of text were subsequently abstracted by code and analyzed. Comparison of themes across focus groups was made to determine uniqueness or similarities.

This research was intended to provide participant views as well as a description of patterns and themes. Therefore no hypotheses were tested in this study.

Limitations and Delimitations

The study used the ICD-9 code for diabetes mellitus in selecting patients for recruitment and therefore enabled a selection of participants with an accurate diagnosis of diabetes mellitus. This provided an advantage over previous studies that relied on a self-reported diagnosis of diabetes. Although an initial plan involved the recruitment of 8-12 participants per focus group, ultimately the number of participants in each session was small enough to encourage involvement while still enabling a diversity of opinions.

Our study had several limitations including the small sample size of participants receiving care at a single Healthcare system. Selection bias could be introduced and the study findings may not be generalizable to all patients with diabetes mellitus in Forsyth County. Given that Wake Forest Baptist Health, and specifically the Downtown Health Plaza, provides the majority of the primary care services in this area, it was selected as the source from which to recruit study participants.

In addition, our study was subject to nonresponse bias which also has the potential to significantly impact the generalizability of results. Only a small proportion of patients contacted, actually participated in the study. Although reasons for this included unavailability on interview dates, there was no way to determine if respondents differed in meaningful ways from non-respondents.

Another limitation of this research was the absence of an analysis of demographic data. Data on age, gender, ethnicity/race (except in the case of the Spanish speaking focus group), education and household income were not collected or analyzed. In previous studies, age and

ethnicity had been shown to impact vaccination rates and therefore likely also influence perception. A lack of demographic heterogeneity results in under representation of the views of some groups.

Finally, although the same team member conducted all the English focus group interviews, the Spanish group required a Spanish speaking group leader. To facilitate consistency, a standard set of questions was used to guide the focus group interview. However, the structure, phrasing and tenor of questions during an interview process have the propensity to influence respondents and could have introduced interviewer bias in our study.

CHAPTER IV: FINDINGS

Introduction

This chapter presents findings from four focus group interviews conducted between May, 2014 and March, 2015 with patients diagnosed with type 2 diabetes mellitus who reside in Forsyth County, North Carolina. Open-ended research questions facilitated the study goals to determine participant knowledge, attitudes and beliefs regarding influenza and pertussis vaccination. The interview guide is included in the Appendices.

Findings/Results

The frequency of codes was similar in all three English speaking groups supporting consistency in study results across groups. Lower numbers were observed in the Spanish speaking group and this could have been influenced by the low turnout of participants and a different moderator for this interview. Results are illustrated in table 4.1 below where the English focus groups are referenced according to the date of interview as “GRP 1-3” and the Spanish speaking group as “GRP 4”.

CODE	GRP1	GRP2	GRP3	GRP4	TOTALS
Access	2	2	3	1	8
Age	2	2	0	0	4
Communication	3	4	7	1	15
Determination	3	3	2	0	8
Effectiveness	0	1	2	0	3
Employer/School	2	1	1	1	5
Family and Friends	1	1	2	1	5
Fear	3	3	2	2	10
Gender	1	0	0	0	1
Healthcare Provider	5	5	4	0	14
Invincibility	3	2	1	3	9
Knowledge	2	1	4	1	8
Lack of knowledge	8	7	5	2	22
Misconception	2	4	3	0	9
Other	0	1	0	0	1
Personal Preference	2	4	3	0	9
Priority	0	1	0	1	2
Protecting others	3	0	0	0	3
Race	1	0	0	0	1
Religion	1	1	3	0	5
Socioeconomic level	2	2	4	0	8
Transportation	1	3	1	0	5
TOTALS:	47	48	47	13	155

Table 4.1 Frequency of codes in focus groups

Other study findings are organized by the primary research questions as indicated below.

What is known about the influenza and pertussis vaccine?

Respondents appeared to be more knowledgeable about the influenza vaccine than they were about the pertussis vaccine. This knowledge was reflected in the proportion of participants who had received each vaccine. Regular receipt of the influenza vaccination was reported by 100% of respondents in focus group 1, 80% in group 2, 83% in group 3 and 50% in group 4. There were some requests for clarity on what virus strains the seasonal influenza vaccine was

protective against but the majority of participants were aware of the protective effects of this vaccine. In addition, although those who received the influenza vaccine had received the injectable form, participants were not aware that those with chronic diseases such as diabetes (and children), were not eligible for the nasal form of the vaccine.

On the other hand the pertussis booster vaccination had been received by only 20% of the respondents in focus group 1 and 33% in group 3. Most participants were not aware that a single administration of the booster dose was advised in adults and requested more information about pertussis, manifestations of the disease and a distinction from other more familiar respiratory illnesses.

What is known about risk of these infections in people with diabetes?

During focus groups, there was a mixed response to the question about the risk of infections in people with diabetes. One respondent was not aware that people with diabetes could receive the influenza vaccination. However, this was a rare occurrence as most were aware that they required special care as a result of their disease. Impressively, a participant stated “I know that the flu...that you need one every year because the strains change and it’s especially dangerous for people with any chronic illnesses and children and the elderly.”

What are some factors that influence vaccination uptake?

Vaccination influences disclosed in the focus groups are illustrated in figure 4.1. The most salient patient-related barriers identified in the study were lack of knowledge, influence of healthcare providers and communication. Many of the knowledge gaps were with regard to the pertussis vaccination recommendation with statements such as, “This whooping cough thing is really scary. So this is stuff that’s come back around? So now this is affecting older folk?” It appeared that the recommendation for booster shots has been poorly disseminated in some communities as a respondent quite honestly stated “Yeah, I would have turned this one down. If I

was getting my flu shot at the doctor's office and he hit me with the whooping cough, then I would have turned that one down.”

“Healthcare providers” on its own was a factor viewed as important by study participants but it was also strongly linked to knowledge, lack of knowledge and communication. Participants considered providers to play an essential role in educating patients about health risks and in recommending appropriate care. Many respondents cited direction and in some cases persistence of their providers as being the primary reason they received vaccination regularly. Statements below underscored this point:

“I think it should start with their family physician. I think that's really important ‘cause people will listen to their doctor sometimes when they won't listen to other people.”

“I listen to the news and stuff like that but if I want real good, sound advice, I ask my doctor.”

The groups further recommended ways for providers to improve communication about vaccinations such as through the use of pre-recorded telephone reminders, brochures, pamphlets and posters in waiting rooms.

Consistent with commonly reported barriers in the literature, fear and misconception were factors that repeatedly came up in our study groups. Expressed concerns included that taking the flu shot resulted in unacceptable adverse effects or even caused the influenza illness. This latter concern was heavily influenced by family, friends and acquaintances who participants stated had fallen ill with the flu after vaccination. One group member described a family member who “got deathly sick from the flu shot” while another whose wife refuses to get vaccinated stated, “She's dead set against it. I'm for it, she's against it.” Others echoed advice from friends and acquaintances such as, “don't take that shot, you'll be so sick.” While a majority of our focus

group participants received influenza vaccinations regularly and acknowledged that reactions to vaccinations were minor, they admitted that hesitation created by others experiences had the potential to outweigh rational thinking.

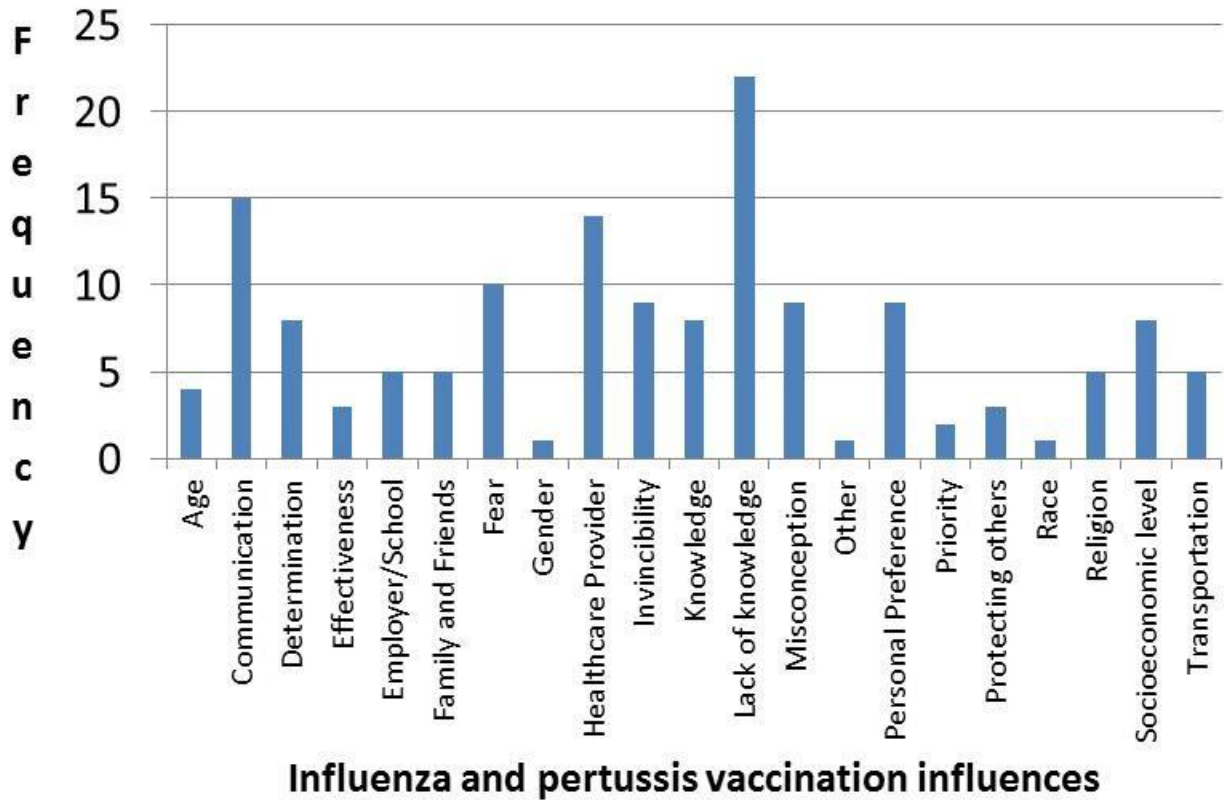


Figure 4.1 Vaccination influences reported by study participants

Due to the nature of the study objectives, text was not mutually exclusive with regard to codes, and text from interviews was coded under more than one theme. Emerging themes were arranged into four families as listed below.

- **Barriers:** Access, Effectiveness, Family and friends, Fear, Lack of knowledge, Priority, Socioeconomic level and Transportation
- **Demographic characteristics:** Age, Gender, Race and Religion

- **Enabling factors:** Communication, Determination, Employer/school, Family and friends, Healthcare provider and Knowledge
- **Personal characteristics:** Determination, Fear, Invincibility, Knowledge, Lack of knowledge, Misconception, Personal preference and Protecting others

For the most part, participants did not question the effectiveness of vaccines in protection against either influenza or pertussis as a reason not to receive vaccination although lack of effectiveness was raised as a potential reason some in the community may decline it. One respondent remarked that an individual who had been vaccinated could still get the flu and this comment was countered by others who pointed out that vaccination reduced the risk of infection and could result in a milder illness than would occur in an unvaccinated individual.

Co-occurring themes of “Access and Socioeconomic level”, “Misconception and Lack of knowledge” and “Misconception and Fear” were less frequent than anticipated.

How can information about vaccinations be more effectively communicated and disseminated in the community?

Participants discussed healthcare workers as credible sources of information: “I think the doctors ought to get out more and speak more on it...If the doctors put more emphasis on it, I think it would help more.” The use of traditional media sources such as radio, television and paper advertising in addition to the internet (social media was not specifically mentioned) were felt to be effective communication mediums. Improving access to information for certain populations could improve communication and enhance vaccination rates. For example, the participants suggested community outreach programs that went “door- to- door” and scheduling educational programs at community centers at an appropriate time (for instance noon for senior citizens) to accommodate target audiences. A participant proposed advertising at convenience

stores to be “attention- grabbing”. Interestingly, collaboration with places of religious worship was advocated as a means for disseminating healthcare information.

Summary

The findings from this study suggest that patients are more likely to receive vaccination against a disease that is well known and for which they perceive great risk. While the majority of study participants received the influenza vaccination regularly, an average of only 26% of respondents had received the pertussis booster vaccination. Another striking finding was the high level of trust placed by patients in their providers in making healthcare decisions. In fact, the primary vaccination influences cited by participants were lack of knowledge, healthcare providers and communication. Chapter five provides additional discussion of these findings as well as recommendations on how they can be used to endorse preventive measures like vaccinations and improve health. It is recognized that these recommendations may not be applicable in all situations.

CHAPTER V: DISCUSSION, IMPLICATIONS AND RECOMMENDATIONS

Introduction

This chapter presents a summary of the study problem, methodology, results, discussion and conclusion. Study findings and comparability to previously published literature will be discussed and implications explored. Finally, recommendations derived from an analysis of study results will be described.

Summary of study

A cross-sectional, qualitative analysis of the knowledge and perceptions regarding influenza and pertussis vaccination in adult patients with a diagnosis of type 2 diabetes mellitus receiving care at outpatient clinics of Wake Forest Baptist Medical Center health care system was conducted. The primary objective was to gain a better understanding of patient-related characteristics as part of a project to improve the health of this unique population.

A total of 18 respondents participated in the focus groups which consisted of three English-speaking sessions and one Spanish-speaking session. A majority of the participants were knowledgeable about influenza and vaccination against influenza and even though some admitted to reservations about the vaccination at some point, most of them receive this vaccine regularly. Less was known about pertussis and the risk of resurgence in adult patients. Participants readily shared their opinions on the subject matter. From the patients' perspective, vaccination influences include patient-dependent factors such as knowledge and misconception but also system-related ones like access and a lack of consistent recommendations from their healthcare providers. Many participants used the interview session as a forum to gain a better understanding of health issues associated with diabetes and obtain clarification on vaccination-related concepts.

Discussion

It is generally accepted in social and behavioral sciences that understanding barriers to health interventions is the key to developing strategies to overcome them. Our study results reflect an important opportunity for improving health through education as well as an opening to influence perceptions about vaccinations.

Participants report lack of knowledge as an important factor in influencing vaccinations and it is unlikely coincidental that both knowledge about influenza and influenza vaccine uptake was higher in the study groups than that about pertussis. In today's world of technology, particularly the internet, patients have access to various external sources of information. Although this technology has many advantages, including speed and convenience, not all information is credible. In all four focus groups, the healthcare provider was mentioned as a valuable and dependable source of health information as well as a key influence in patient-driven health care decisions, including vaccinations. While it cannot be assumed that there was a consensus by every participant, in our study, the influence of healthcare providers was a theme that came up frequently enough during the interviews that it should be considered relevant. This is consistent with other studies in the literature that report a positive influence of providers on patients' decision to be vaccinated and it underscores the importance of involving providers at all levels in efforts to improve vaccination uptake. Practitioners are understandably busy so the issue of vaccination may be overlooked for other health problems considered to be more of a priority. It should be recognized that a majority of respondents in our study indicated that they would comply with recommendations if they came from their providers and attempts should be made to prioritize vaccinations as part of routine care in patients with diabetes. Strategies aimed at simplifying the process of vaccination, including the use of reminder systems, electronic documentation of vaccination status and standing orders that do not require physician pre-

approval, should be encouraged. These relate to the conceptual framework of bidirectional relationships between factors that affect the quality of health care and promote a desired outcome.

While some studies have proposed mistrust of the healthcare system and religion as major influences in patient acceptance of vaccinations, these were not key factors brought up in our focus groups. One explanation could be the evolution of medical care with a resultant increase in transparency between providers and patients. However, one should consider our study setting, which did not provide anonymity, and the influence on nonresponse bias if these were concerns that discouraged some individuals from participating in the study.

Finally, demographic data was not collected or analyzed in this study so comparisons of the role of age, race, gender and socioeconomic factors on the knowledge and perceptions of participants in our study to those of others in the literature cannot be made.

Implications

Progress has been made in increasing the uptake of vaccination against diseases like influenza but some other VPDs like pertussis have not received as much attention. Furthermore, with the rising incidence and prevalence of diabetes mellitus in the United States, the public health implications of VPDs in high risk populations cannot be overlooked. A collaborative effort that includes patient participation is going to be required to improve care in patients with diabetes. The readiness of patients to share their perceptions and to propose communication methods aimed at improving knowledge about vaccinations in those with diabetes indicates that if information is available, patients are willing to listen. Our results on patient-perceived influences on vaccination provide supplementary data to other important strategies such as health education, raising community awareness and improving access. An approach encompassing

these elements supports the Healthy People 2020 goal to increase immunization rates and reduce preventable infectious diseases through clinical and community activities and services (US Department of Health and Human Services, 2014; "Vaccination practices for hepatitis B, influenza, and pneumococcal disease for people with diabetes," 2014)

Recommendations

The results and findings generated from this study provide a foundation for further research. Underutilization of vaccinations is multifactorial and processes that address the barriers associated with poor uptake are needed. The following recommendations are intended to improve study validity and generalizability of conclusions so as to impact healthcare policy and care in a more meaningful manner.

Identify demographic data that are associated with patients' knowledge and perceptions

The collection of this data is recommended as a means of further exploring what factors influence vaccination perceptions and therefore practices. Age, gender and socioeconomic status have been cited as predictors of health resource utilization so obtaining this information could potentially facilitate targeted interventions that increase vaccination uptake.

Longitudinal follow up of study participants

A research design that permits long-term follow up of participants may reveal how attitudes and perceptions change over time, particularly in response to new knowledge acquired by study participants during the focus groups.

Expand study instruments to include surveys

While the focus group setting certainly has its advantages and it was our experience that all participants shared their views without restriction, the incorporation of anonymous surveys may provide additional information. This instrument would need to implement simplicity in design and utilize closed-ended questions to compensate for limitations such as a variation in

literacy level and impaired vision which may affect those with diabetes. Nevertheless, it could facilitate a provision of honest responses and an increase in response rates (reducing nonresponse bias). Surveys may be disseminated in primary care and specialty clinics.

Conduct quantitative research

As mentioned previously, this study is part of a larger project being conducted to enhance vaccination rates against influenza and pertussis. Research analyzing the impact of provider education in-services and electronic health record documentation, and quantifying influenza and pertussis vaccination rates prior to the study and rates in the most recent influenza season is currently in progress. Using logistic regression analyses, with the outcomes being receipt of an influenza vaccination or a Tdap vaccination, and the primary independent variable being time period (pre-intervention and post-intervention), data will be extracted. An additional component of this should include demographic data from which inference on the distributions in vaccination uptake can be made.

Evaluate current communication tools

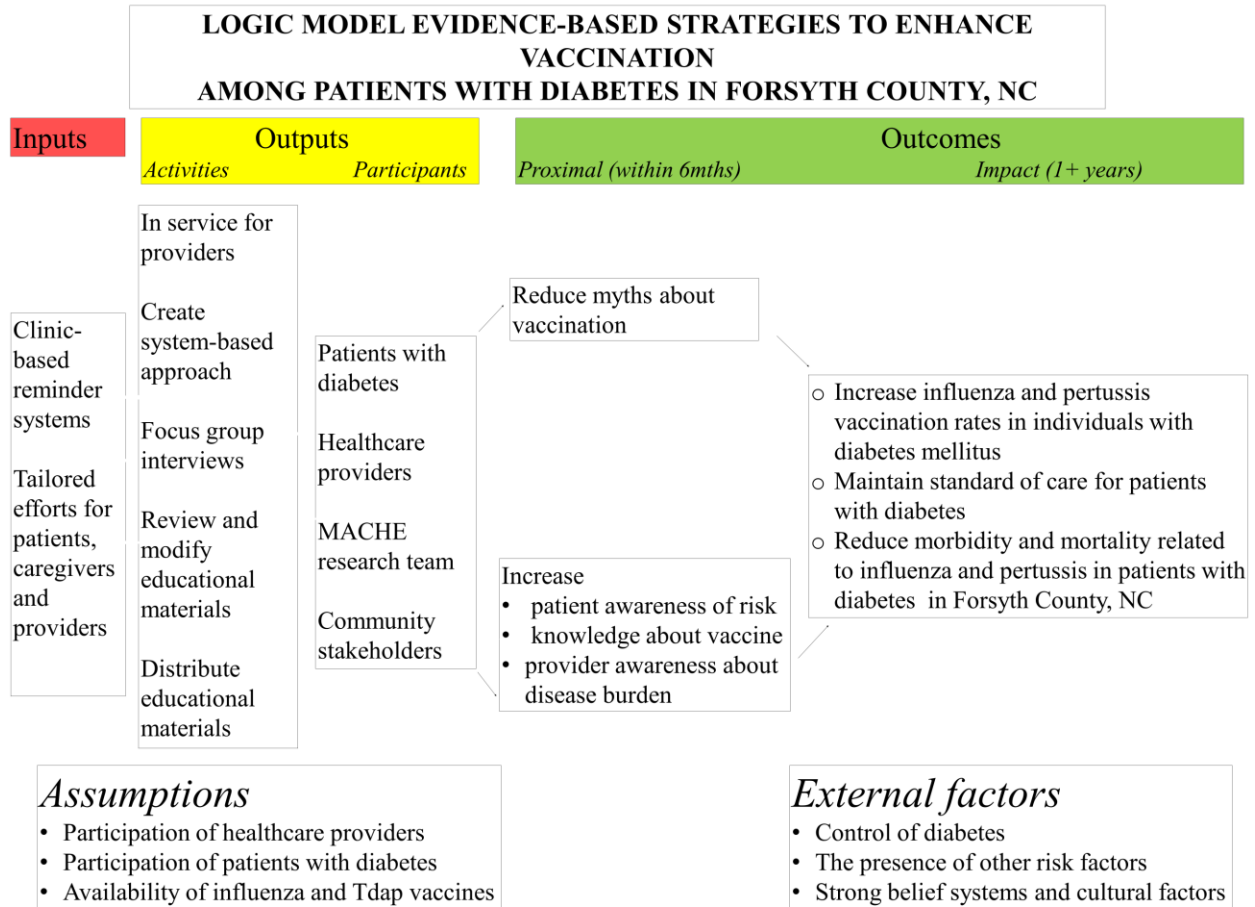
The response and receptiveness of focus group participants to educational materials on influenza and pertussis presented during the interview sessions was collected. This is an important detail because communication can influence the decision to get vaccinated. In particular, knowledge about Pertussis and its resurgence needs to be more widely disseminated. Educational materials should be modified to meet the expressed needs of patients and the feasibility of other proposed communication means explored.

Conclusion

Vaccine preventable diseases remain a major cause of mortality and morbidity especially in patients with chronic diseases such as diabetes mellitus. The incidence and prevalence of diabetes mellitus in North Carolina has exceeded the national average in the past decade and

continues to rise. The economic burden created by this disease and its complications is a major public health dilemma and strategies to improve the health of those affected are continually being sought after. While no health intervention is without risk, those associated with vaccination are relatively negligible when compared to the risk of infectious illnesses. This research illustrates the influence of patient knowledge and perception on vaccination against influenza and pertussis in patients with diabetes. Although conclusions from the results of this study are limited because of the small sample size, data presented in this thesis should provide a foundation for further research. The impact of individual interventions may be difficult to track; however, the overall goal of improving vaccination rates and health in patients with diabetes can be achieved through a combination of strategies.

APPENDIX A



APPENDIX B



EMORY
UNIVERSITY

Institutional Review Board

June 2, 2015
Nkechinyere
Emejuiwe
Emory University Atlanta, GA 30322

RE: Determination: No IRB Review Required

Title: *Qualitative analysis of de-identified interview transcripts from Wake Forest University*

PI: Nkechinyere Emejuaiwe

Dear Nkechi:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definitions of research with “human subjects” or “clinical investigation” as set forth in Emory policies and procedures and federal rules, if applicable. Instead, this is a secondary data analysis study of interviews from a previously conducted study at Wake Forest University. Specifically, you will receive de-identified transcripts of the interviews from the Wake Forest PI. You will have no access to identifying information from the original study, nor will the transcripts provided to you contain any individually identifying information. You will conduct qualitative analysis of the de-identified transcripts to examine if understanding patient knowledge and opinions regarding vaccination could influence rates of vaccination.

Please note that this determination does not mean that you cannot publish the results. If you have questions about this issue, please contact me.

This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Carolyn Sims, MPA
Research Protocol Analyst

Emory University

1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322

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APPENDIX C

Evidence-Based Strategies to Enhance Influenza and Pertussis Vaccination among Patients with Diabetes in Forsyth County, NC

Focus Group Guide

1. What do you know about the flu vaccine?

PROBE: Wanting to determine if participants know that there are various strains of the flu and that the vaccine is given annually

2. Do you typically get a flu shot or nasal spray every season? Why or why not?

PROBE: For those that do, where do they typically get their vaccine? Do they have difficulty finding a time and place to get the vaccine. Do they encourage others to get the vaccine?

PROBE: For those that do not, do they have concerns with side effects or that they think the vaccine causes the flu?

3. Do other members of your family get a regular flu shot?

PROBE: Which family members do and which do not (if any)? Are there different reasons within families for not getting the vaccine?

4. What do you think are some of the barriers that people face in this community in getting a flu shot if they want one?

PROBE: Time that the vaccine is given, location, concerns about side effects, concern that vaccine causes the flu, others

5. Do you think there are a lot of people in your community that are reluctant to get a flu shot?

PROBE: If so, why do you think they feel this way? Are there certain groups of people (men or women, African Americans, whites, Hispanics, other groups) that you feel are more likely to feel this way?

6. Do you think it is true that people with diabetes are at increased risk for getting the flu compared to people without diabetes?

PROBE: Why do you think this way?

7. Do you think it is true that people with diabetes are at increased risk of getting severe disease from the flu compared to people without diabetes?

PROBE: Why do you think this way?

8. What are some of the ways that you get information about your diabetes?

PROBE: Options could include Television/radio, Doctor/health professional, Internet, Friends/family, Others

9. What are some of the ways that you get information about the flu or flu vaccine?

PROBE: Options could include Television/radio, Doctor/health professional, Internet, Friends/family, Others

10. What do you think about _____ (various diabetes/flu materials)? Do you think this would be a good way to educate people with diabetes in your community about their risk for the flu?

- a. If so, what do you like about it?

- b. If not, what do you not like about it? What could be changed to make it more effective?

APPENDIX D

CODE BOOK: INFLUENZA AND PERTUSSIS VACCINATION INFLUENCES

CODE	DEFINITION
ACCESS	Comments about availability of vaccines in multiple convenient locations
AGE	Comments about the influence of age on perceived risk
COMMUNICATION	Role of awareness about influenza or pertussis risk and vaccination through brochures, television advertisements, the internet etc.
DETERMINATION	Desire to lead a healthier lifestyle or stay healthy
EFFECTIVENESS	Comments that question the effectiveness of vaccines
EMPLOYER	Comments about work-place or school mandate for vaccination
FAMILY & FRIENDS	Influence of loved ones, relatives or friends on vaccination
FEAR	Concern about side effects from vaccine
GENDER	Reference to gender influence on decision to receive vaccination
HEALTHCARE PROVIDER	Comments about the influence of healthcare providers
INVINCIBILITY	Reference to reduced vulnerability
KNOWLEDGE	Information about risk of infection in those with diabetes or about benefits of vaccination against pertussis or influenza
LACK OF KNOWLEDGE	Questions that reflect limited knowledge about either influenza or pertussis vaccination or provided as a reason for not getting vaccination
MISCONCEPTION	Belief that getting the vaccine would cause illness
PERSONAL PREFERENCE	Reference to choice and a dislike for injections
PRIORITY	Comments about procrastinating when it comes to vaccination
PROTECTING OTHERS	Concern about the welfare of others
RACE	Any reference to race or ethnicity as influences on decision to receive or refuse vaccination
RELIGION	Reference to personal or community faith or beliefs about vaccination
SOCIOECONOMIC LEVEL	Financial costs as a factor in vaccine interest
TRANSPORTATION	Reference to ability to get to a venue where vaccines are offered

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