A Study to Determine the Preliminary Effects of a Theory-Based Intervention (SayNo2Flu) Combined with the Use of Mobile Technology on Parents' Influenza Prevention Beliefs and Behaviors in a Primary Care Setting

by

Patricia Wiseman

A Dissertation Presented in Partial Fulfillment
of the Requirements for the Degree
Doctor of Philosophy

Approved April 2015 by the
Graduate Supervisory Committee

Elizabeth Reifsnider, Chair
Evelyn Cesarotti, Committee Member
Andrew G. Black, Committee Member
Sunny Kim, Committee Member

ARIZONA STATE UNIVERSITY

May 2015

ABSTRACT

This study tested the preliminary effectiveness of a health belief and text messaging intervention for parents of five- to eight-year-old children to determine whether health beliefs and influenza vaccine receipt differ when compared to a text messaging control group. Children are almost four times more likely to be infected with influenza than adults (Belshe Piedra, & Block, 2009), shed the greatest quantities of influenza virus, and have been recognized as vectors for spread of disease (Neuzil, Mellen, Wright, Mitchel, Jr., & Griffin, 2002b). The influenza immunization rate for school-age children is less than 56% (Centers for Disease Control and Prevention [CDC], 2014). Reasons for the low vaccination rate include parents' misperceptions of influenza disease and vaccinations (Bhat-Schelbert et al., 2012; Taylor et al., 2002). There are few theory-based interventions for increasing influenza vaccination rates of school-age children; however, promising results have been found when using the constructs of the health belief model (HBM) (Chen et al., 2011; Coe, Gatewood, Moczygemba, Goode, & Beckner, 2012). Mobile technology using Short Message Service (SMS) text messaging may increase vaccination rates to a greater extent than traditional vaccine reminders (Daley et al., 2002; Grajalva, 2006). Prior to starting this study, only one randomized controlled trial testing text messaging to increase children's influenza vaccination rates was found (Stockwell et al., 2012). In this study, text messaging was effective in promoting behavioral changes leading to a 4% increase in influenza vaccination (27.1% vs. 22.8%, $RR = 1.19$, $p < .001$). This study was a randomized controlled trial using a two-group pre- and posttest experimental design. This study found that a theory-based intervention (SayNo2Flu) guided by the HBM and combined with the use of mobile technology (SMS

text messaging) did change parents' influenza vaccination perceptions. It had an overall increase of 38.1% in Influenza vaccination rates in the intervention group (OR: 4.46, 95% CL, 1.705-11.706, $p < .001$). These results offer some insight into the use of theory-based preventative interventions for parents of young school-age children.

TABLE OF CONTENTS

Page

CHAPTER Page

CHAPTER Page

CHAPTER Page

LIST OF TABLES

LIST OF FIGURES

FIGURE PAGE

CHAPTER 1. INTRODUCTION

This chapter will cover an introduction to the problem followed by the background, problem statement, and the study purpose and rationale. This section will also contain a detailed description of the research questions and hypotheses used for this study while including the study significance, assumptions, and limitations.

Introduction to the Problem

Every year there are 30-60 million individuals infected by influenza virus, many of whom are healthy school-age children. Children are almost four times more likely to be infected with influenza than adults (Belshe Piedra, & Block, 2009), shed the greatest quantities of influenza virus, and have been recognized as vectors for spread of disease (Neuzil, Mellen, Wright, Mitchel, Jr., & Griffin, 2002b). The influenza immunization rate for healthy school-age children is less than 56% (Centers for Disease Control and Prevention [CDC], 2014). These rates are far below the Healthy People 2020 recommendation calling for influenza vaccination of 80% of all children (U.S. Department of health and Human Services, 2010).

Background of the Study

The Advisory Committee on Immunizations Practices (ACIP) advocates that influenza immunization is the most effective method for prevention of illness due to influenza (CDC, 2008). The ACIP is a group of medical and public health experts that develops recommendations on how to use vaccines to prevent and control diseases in the United States. The recommendations stand as public health advice that will lead to a reduction in the incidence of vaccine-preventable diseases and an increase in the safe use of vaccines. This committee was established under Section 222 of the Public Health

Service Act and is governed by the provisions of the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The ACIP has been given statutory roles (CDC, 2014).

In 2008, recommendations for vaccination of children against influenza were revised for all children six months to 18 years of age (Fiore et al., 2008). Nevertheless, the influenza immunization rates for healthy children remain low (CDC, 2014). The literature reveals that prevention of influenza disease in healthy school-age children will decrease the impact of the disease on the more vulnerable in our community: the very young and the elderly (Reichert et al., 2001). Vaccination coverage among school-age children is 50.5% (CDC, 2013). The goal of Healthy People 2020 is to increase immunization rates and reduce infectious disease (U.S. Department of Health and Human Services, 2010). The low vaccination coverage rates amongst children are a pressing concern because children experience the highest rates of influenza and have been recognized as major contributors to the spread of disease especially to those at highest risk (Neuzil et al., 2002b). Today, many vaccine barriers have been addressed such as availability of vaccine (Birmingham et al., 2011), vaccine cost and reimbursement (McInerny, Cull, & Yudkowsky, 2005), and vaccine myths (Daley et al., 2007; Taylor et al., 2002); however, the question remains regarding which immunization intervention would be more effective in raising immunization rates for children.

Burden of disease. Influenza disease is a significant healthcare burden. Estimates project annual medical costs associated with influenza disease at 3 to 5 billion dollars. Medical costs represent hospitalizations and clinic visits. Every year there are more than 50,000 deaths attributed to influenza disease with approximately 36,000 direct deaths and

15,000 indirect deaths (Belshe Piedra, & Block, 2009). Influenza associated pediatric deaths from 2010-2014 range from a low of 35 to a high of 171 pediatric deaths (CDC, 2014).

In addition, there are more than 200,000 hospitalizations attributed to influenza disease, averaging 1,000 per month in every state. Hospitalization rates for children are inversely associated with age, and among school-age children, there are eight to 20 hospital admissions for every 100,000 children. Population-based studies report Influenza infection attack rates ranging from 15% to 42% in preschool and school children during typical outbreaks (Loeb et al., 2010; Neuzil et al., 2002b). Primary care clinics incur a heightened burden during influenza season with each provider experiencing an increase of approximately five clinic visits for every 100 healthy children in their practice (Fiore, Epperson, Perrotta, Bernstein, & Neuzil, 2012). The 2009 H1N1 pandemic underscores the serious nature of influenza among school-age children. During this pandemic, school-age children exceeded their typical hospitalization rates and more than 300 children died during this pandemic (Fiore et al., 2012). Also, during this pandemic, school-age children had higher illness rates (4% to 32%) compared to adults (4% to 10%) (Loeb, 2010), resulting in high absenteeism and causing some schools to temporarily close to prevent further spread of the influenza virus in the community.

Low vaccination rates among school-age children. Vaccines help reduce the number of persons who become infected, decrease the burden of disease, reduce public and private healthcare expenditures, and improve the health of the community (Institute of Medicine, 2003). Influenza vaccination creates a herd immunity, thereby protecting the very young, the elderly, and those who cannot receive the vaccine because of their

medical conditions. Previous vaccination efforts in the United States were focused on populations most at-risk for hospitalization and death, which are the very young and the elderly. Unfortunately, efforts to identify and vaccinate this population have had a marginal impact on the burden of disease. As a result, national efforts are now focused on the 30-60 million infections that occur each year, most of which are among healthy school-age children (Belshe et al., 2009).

During the 2013-2014 influenza season, children's vaccination rates reached 58.9% of *all* children (ranging in age from six months to 17 years), 61.0% among children age five to 12 years, and 46.4% for children who were between 13 and 17 years of age (CDC, 2014). Coverage rates for children vary by race and ethnicity, with vaccination rates of 51.3% for Asians, 47.4% for white only, non-Hispanic, 44.3% among Hispanic, and 41.5% for black only, non-Hispanic (CDC, 2014). The CDC reports every fall the prior season's influenza vaccination rates. An improvement in childhood vaccination rates is an important goal to reduce the overall spread of influenza in the community and to decrease the burden of disease (Belshe et al., 2009). Healthy People 2020 recommendation calls for a vaccination rate of 80% of all children (U.S. Department of Health and Human Services, 2010). Loeb et al. (2010) conducted a cluster randomized control study involving 947 healthy children aged 36 months to 15 years in Canada. They found that an 85% vaccination coverage rate (range 53% to 100%) was able to achieve a 61% indirect protection against influenza among persons in the community who did not receive the study vaccine (Loeb et al., 2010).

Statement of the Problem

Influenza immunization rates for school-age children fall far below the current recommendation; numerous intervention reminder studies have shown modest increases in immunization rates. However, it is not known how a theory-based text messaging educational intervention might impact the current Influenza rate.

Purpose of the Study

The purpose of this study is to test if a theory-based intervention (SayNo2Flu) guided by the health belief model (HBM), combined with the use of mobile technology (Short Message Service [SMS] text messaging) will change parents' influenza vaccination beliefs and behaviors resulting in higher vaccination rates with their children.

Rationale

There are few theory-based interventions for increasing influenza vaccination rates of healthy children, but promising results have been found when using the constructs of the HBM (Chen et al., 2011; Coe, Gatewood, Moczygemba, Goode, & Beckner, 2012). The HBM is a theory designed to predict health behaviors based on the constructs of (a) perceived susceptibility, (b) perceived severity, (c) perceived benefits, (d) perceived barriers, (e) cues to action, and (f) self-efficacy (Sharma & Romas, 2008). No parent studies were found that used both an HBM-guided influenza-related intervention and confirmed receipt of the vaccine. Most studies reviewed either reported the participants' intent to receive the vaccine or relied on self-reports of vaccine receipt (Chen et al., 2011; Marlow, Waller, Evans, & Wardle, 2009; Nexoe, Kragstrup, & Sogard, 1999).

Text messages (SMS) are rapidly becoming a common means of reaching out to diverse patient populations because of the low cost and the ubiquitous nature of mobile phones. The minimal cost and design of the messages makes it possible for educational intervention programs to be easily scaled across a diverse population regardless of age, educational, economic, or ethnic background and maintained for a longer duration, thereby facilitating sustained behavior change (Lau et al., 2013). Numerous studies in the literature have demonstrated that traditional vaccine reminders such as reminder telephone calls, reminder cards, and recall systems do increase vaccination rates short-term (Brigham, Woods, Steltz, Sandora, & Blood, 2012; Esposito et al., 2009). Mobile technology using SMS text messaging may increase vaccination rates to a greater extent than traditional vaccine reminders (Daley et al., 2002; Kharbanda et al., 2010; Stockwell et al., 2012); however, no vaccine reminder studies found were informed by a theoretical framework.

This study used a two-group pre and posttest experimental design to fill a gap in the literature by building upon recommendations of previous studies and determine the preliminary effects of a primary care intervention on parents to promote influenza vaccine receipt among children. For this study, data was collected from a pediatric primary care clinic providing services to low-income, underserved, and special populations. Both the intervention and controls groups were from this pediatric primary care clinic. This study tested the preliminary effectiveness of a six-week HBM-guided intervention (SayNo2Flu) on parental beliefs about influenza vaccination, as compared to the control group. It also compared the differences in parental beliefs of vaccine recipients with non-recipients and confirm the preliminary effects of the SayNo2Flu

program on the receipt of one or more influenza vaccine doses by the end of influenza season.

Research Questions and Hypotheses

Primary research question. Will a six-week HBM-guided intervention (SayNo2Flu) affect parents' beliefs about influenza vaccination?

Sub-question 1. What contributing factors led parents to vaccinate or not vaccinate their child? Are there significant demographic predictors (age, gender, race/ethnicity, education level, marital status, health insurance, income), health variables (child's health status), belief variables, or texting technology?

Sub-question 2. What are the differences in parental beliefs on perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and cues to action when the intervention group is compared to the control group?

Hypotheses.

Hypothesis 1. Parents in the intervention group will have a greater understanding (perception) of the severity and susceptibility of influenza disease when compared to the control group.

Hypothesis 2. Parents in the intervention group will have greater understanding of the benefits of influenza vaccination when compared to the control group.

Hypothesis 3. Parents in the intervention group will experience decreased barriers to vaccination when compared to the control group.

Hypothesis 4. Using text messaging (cues to action) to deliver the education intervention will activate parents' readiness to obtain an influenza vaccination for their child.

Hypothesis 5. Parents in the intervention group will have a significant difference in parental beliefs on self-efficacy when compared to the control group.

Secondary research question. Will the SayNo2Flu program affect the receipt of one or more influenza vaccine doses?

Hypothesis.

Hypothesis 6. Children of parents in the intervention group will have a significant difference in the receipt of 1 or more vaccine doses compared to the control group.

Significance of the Study

This study is *significant and innovative* because there are no published studies evaluating the use of HBM-guided interventions using mobile technology to promote influenza vaccine receipt among parents of school-age children that have been identified. The intervention was designed to be carried out by healthcare providers in a primary care setting. This study may provide further insight into influenza vaccination behaviors of parents and does add to the body of knowledge by providing a comparison of action following a theory-based influenza vaccination educational reminders and non-theory-based health messages.

Influenza vaccination rates for children are rising (CDC, 2014), but coverage levels have not reached national goals. In an era of increasing complexity of immunization schedules, rising expectations about the performance of primary care and demands on healthcare providers, it is important to understand and promote interventions that work in the primary care settings. This sudy used the HBM to guide influenza vaccination interventions using mobile technology to enhance the prevention beliefs and behaviors of parents of healthy children. It addressed previous recommendations that

more studies are urgently needed to (a) target intervention specific to influenza vaccination of children, (b) use a theory-based educational intervention addressing barriers and acceptance of vaccination, (c) include primary care settings, and (d) add to the body of influenza vaccination knowledge using text messaging as a vehicle to deliver the interventions.

This study is the second in a trajectory of research aimed at developing evidence-based interventions for delivery in primary care settings for children with the ultimate goal of improving child influenza vaccination rates and preventing significant healthcare costs and missed schools days that occur as a result of influenza disease.

Assumptions and Limitations

It is assumed that parents participating in this study were honest and did provide complete information regarding their perceptions of influenza disease and influenza vaccination for their child.

The major strength of this study will be its design. It is a randomized controlled two group experimental pre- and posttest design. Institutional Review Board (IRB) approval was secured from both Arizona State University and Scottsdale Health Care. This research is quantitative in nature, providing an analytical look at parent perceptions of influenza disease and vaccination of their child as the outcome measure. However, additional qualitative feedback was also sought to help add to the depth of the data.

The literacy needs of the participants were considered in this study. The pretest and posttest tools were piloted by sample participants for clarity, readability, or literacy level (Wiseman & Records, 2014). The text messages were written at a 7.4-grade reading level (Microsoft, 2015) and reviewed by the primary care clinic's translator. This study

used the HBM to guide the intervention and used a measurement tool specific to the assessment of the HBM constructs. This measurement tool investigated factors in the decision of caregivers to vaccinate their children against influenza disease. The primary outcome variable was dichotomized using Yes (received vaccine) and No (not received). The receipt of vaccine dose(s) was confirmed from the Arizona State Immunization Information System (ASIIS) and/or the child's electronic record.

This study was conducted in a large urban primary care practice whose pediatric daily census is 40-50 children. The majority of the primary care clinic employees are bilingual and proficient in both English and Spanish. The intervention will be delivered in both English and Spanish, depending on the language preference of the parents. The Spanish versions of all study instruments were reviewed and back-tested by the primary care clinic's Spanish translator. The participants were provided a small stipend upon completion. It was the responsibility of the principal investigator (PI) to recruit the sample, explain the purpose of the study, describe the intervention, obtain informed consent, and ensure that the participants' phones could receive a text message.

The educational content of the text messages was developed after an extensive literature review on barriers and facilitators to vaccination. In addition, a pilot text messaging study was conducted to help strengthen and clarify the educational text messaging intervention used in this study (Wiseman & Records, 2014). The results of this pilot study will further be discussed in Chapter 3, as its results led to the development of text messages that were be operationalized in this study.

One of the limitations is that a clinical population was used to recruit participants; therefore, selection bias is a concern. This study may have limited ability to be

generalized to other patient populations because it was conducted in a setting not reflective of diverse populations. A second limitation may be that the participants received a nominal $5.00 gift card as an incentive for their time and participation in the study. This may have had a potential effect on the study results, however the stipend was minimal.

Definitions

Vaccination is the inoculation with a vaccine in order to protect against a particular disease (Vaccination, 2015).

Immunization is the process of inducing immunity to an infectious organism or agent in an individual or animal through vaccination. To immunize is to render immune and to produce immunity in, as by inoculation (Immunization, 2015).

Perception is the way you think about or understand someone or something; the ability to understand or notice something easily; the way that you notice or understand something using one of your senses (Perception, 2015). For the purpose of this paper, perception will is referred to what the parents think or understand about influenza disease and vaccination.

Belief is a feeling of being sure that someone or something exists or that something is true; a feeling that something is good, right, or valuable. It is a feeling of trust in the worth or ability of someone, a state or habit of mind in which trust or confidence is placed in some person or thing (Belief, 2015).

Health belief model is a theory designed to exclusively predict health behaviors based on the constructs of perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy (Sharma & Romas, 2008).

Perceived susceptibility is an individual's assessment of his/her risk of getting the condition. It can be defined as a belief about the chances of experiencing a risk or getting a condition or disease. In this paper, perceived susceptibility refers to the parents' assessment of their child contracting influenza.

Perceived severity is an individual's assessment of the seriousness of the condition, and its potential consequences. It is the belief about how serious a condition is and what its effects are. In this paper, perceived severity refers to the parents' assessment of how serious influenza disease is and the potential consequence for their child.

Perceived barriers are an individual's assessment of the influences that facilitate or discourage adoption of the promoted behavior. It can be defined as a belief about the psychological and tangible costs of an advised action. In this paper, perceived barriers are the parents' assessment of how difficult it is to obtain an influenza vaccination for their child and also their concerns with the vaccine.

Perceived benefits are an individual's assessment of the positive consequences of adopting the behavior. It can be defined as a belief in the efficacy of the advised action to reduce risk or seriousness of threat. In this paper, perceived benefits are the parents' assessment of the positive consequences of obtaining an influenza vaccination for their child.

Cues to action are external influences promoting the adoption of the desired behavior. Cues to action are the link between belief and behavior. In this paper, cues to actions are the healthcare providers' recommendation and the influenza-related text messages. The text message itself is a prompt to the parents to remind them of the need for vaccination.

Perceived self-efficacy is an individual's self-assessment of their ability to successfully adopt the desired behavior. In this paper, perceived self-efficacy is a parent's self-assessment of their ability to obtain an influenza vaccination for their child.

Text messaging is the act of composing and sending brief electronic messages between two or more mobile phones or fixed or portable devices over a phone network. The term originally referred to messages sent using SMS, a text messaging service component of phone, web, or mobile communication systems. SMS text messaging is the simplest and most common type of mobile data service enabling senders to communicate with short messages (approximately 160 characters) between cell phones (CDC, 2011; Irigoyen, Findley, Earle, Stambaugh, & Vaughan, 2000).

Organization of the Remainder of the Study

The remainder of this paper includes a comprehensive literature review comprising Chapter 2. This information will be organized into four primary categories: (a) barriers affecting childhood vaccination rates, (b) intervention studies for raising influenza vaccination rates in children (facilitators), (c) intervention studies using the HBM and influenza vaccination, and (d) intervention studies using mobile text technology and influenza vaccination.

Chapter 3 contains a detailed description of the research methodology used for this study. Chapter 4 contains data collection and analysis. Chapter 5 contains the results, conclusions, and recommendations of this study.

CHAPTER 2. LITERATURE REVIEW

This chapter will provide a comprehensive review of the current literature. It will review the amount of pre-existing literature that has investigated parent vaccine perceptions, beliefs, barriers, and acceptance. However, most of these studies were descriptive studies and some were intervention studies. The descriptive studies described vaccination facilitators and barriers (Chen et al., 2011; Coe et al., 2012; Soyer et al., 2011). The intervention studies evaluated either an educational or vaccine reminder intervention (Bhat-Schelbert et al., 2012; Cheffins, Spillman, Larkins, & Heal, 2011; Fiks, Grundmeiser, Briggs, Localio, & Allessandrini, 2007; Fiks et al., 2009). Influenza vaccination studies have found that perceived effectiveness of the vaccine (Chen et al., 2011; Flood et al., 2010; Norten et al., 2008; Wooten, Lumas, & Barker, 2007) and the healthcare provider recommendations are two of the most consistent predictors of influenza vaccination (Bhat-Schelbert et al., 2012; Cheffins et al., 2011; Gnanasekaran et al., 2006; Soyer et al., 2011; Taylor et al., 2002). Even though both descriptive and intervention studies addressing parental vaccine beliefs were found, no influenza vaccination study was found that was theory-guided, technology-driven, and also confirmed vaccine receipt.

The purpose of this study is to test if a theory-based intervention (SayNo2Flu), guided by the HBM and combined with the use of mobile technology (SMS text messaging), will change parents' influenza vaccination beliefs and behaviors. The HBM guiding this literature review is based on six concepts: (a) perception of severity of influenza disease, (b) perception of susceptibility to influenza disease, (c) perception of vaccination benefits, (d) perception of vaccination barriers, (e) parent self-efficacy for

vaccination, and (f) cues to action. The literature review that follows focuses on each of these six constructs and provides a foundation for the conceptual framework of this study.

Concept of Prevention

There are many facets involved in the definition and the overall concept of prevention. In order to establish the theoretical foundation for this study, this section delves into the definition of vaccination, immunization, perception, and beliefs and a synthesis of the concept of prevention itself.

According to Penrod and Hupcey (2005), serial advancement of a concept depends on the researcher's agenda. However, the process potential is to develop a concept toward a more precise scientific definition that allows the integration into conceptual frameworks that can enhance research or direct practice (Penrod & Hupcey, 2005). The concept of prevention ties to this program of research, which is in community prevention of disease, in particular, influenza prevention in healthy school-age children. Conceptual analysis can help provide an understanding of the methodologies necessary to develop research that will ultimately advance the concept and build theory (Fawcett, 2005). It can also help identify gaps in understanding of the concept.

Healthcare reform will require a fundamental change in healthcare decision-making, delivery, and payment, as now it must be conceptualized and managed based on scientific evidence. According to Magyary, Whitney, and Brown (2006), doctorally prepared clinicians are positioned to proactively shape the 21st century healthcare system and improve health care for all populations. The following section will synthesize the concept of prevention and apply it to the theory guiding this research, which is the HBM.

Synthesis of the concept of prevention. Found in the literature are both ordinary and scientific definitions of the concept of prevention. In 1950, an American healthy lifestyle magazine called *Prevention* began (Prevention Magazine, 2015). Its founder, J. I. Rodale, stated that the word *prevention* included a range of subjects including food, nutrition, workouts, beauty, cooking, and more. The magazine defined prevention as actions people can take to prevent future illnesses (Prevention Magazine, 2015). In the 2013 version of the *Oxford Dictionary*, prevention is defined as the action of stopping something from happening or arising (Prevention,"2013).

This review found two broad categories of prevention emerging. These are the medical definition and public health's definition. In medicine, prevention is defined as medicine or preventive care; it refers to measures taken to prevent diseases or injuries rather than curing them or treating their symptoms (Schneider, 2000). Also, found in the medical definition is the anticipation of needs and hazards, dealing with and avoiding risks, and finally preparation. Disease prevention has its roots in the *medical model*, which means that it uses a negative definition of health as the absence of disease.

Prevention is defined in public and occupational health as (a) the act of going, or state of being, before (Schneider, 2000); (b) anticipation, anticipation of needs, wishes, hazards and risks; hence, precaution, forethought (Maiwald, de Rijk, Guzman, Schonstein, & Yassi, 2010); and (c) the act of preventing or hindering, obstruction of action, access, or approach (Soleimanpour, Geierstanger, Kaller, McCarter, & Brindis, 2010). Public health's focus on prevention is more abstract than medicine's. Its achievements are therefore more difficult to recognize because public health cannot identify people who have been spared from illness by their efforts. Schneider (2000)

describes prevention as protecting and promoting health. Emergency management (disaster management) describes prevention as dealing with and avoiding risks (involves preparing for disaster before it occurs and disaster response) (Schneider, 2000).

Attributes of prevention. The characteristics that appear over and over again within the concept of prevention are to stop, hinder, or prevent illness, disease or injuries, preparation, and/or preventative medicine. All of these help name the occurrence of the prevention phenomenon. Disease prevention has its roots in the medical model, but as prevention evolves, health promotion appears in the literature coinciding with the words of early detection, screening, anticipation, and lifestyle.

Antecedents, preconditions, or precursors of prevention. In both the medical and public health model, disease usually occurred prior to the occurrence of the prevention. With disease came increased awareness and education. In 2010, researcher Tengland discussed prevention involving changing individual beliefs and environmental factors, through increasing opportunities or raising awareness. Disease preventive strategies focus narrowly on a specific disease. If the specific disease is not present, then the aim of prevention strategies is to reduce the risk of developing that disease. Disease prevention often targets certain *risk groups* which are those who have either had the disease or those who run a high risk of developing the disease. The public health definition is mainly concerned with preventing disease in the healthy or at least asymptomatic populations (Tengland, 2010).

Early cancer detection, cardiovascular screening, seatbelts, helmets, anti-smoking campaigns, and preventative vaccines are all examples of positive occurrences within the concept of prevention. In general, prevention includes a wide range of interventions

aimed at reducing risks or threats to health. The three categories of prevention are primary, secondary, and tertiary (Timmreck, 1994).

Primary prevention is the prevention of disease in a susceptible or potentially susceptible population through specific measures aimed at general health promotion efforts. Primary prevention methods are used before the person contracts the disease. It aims to prevent the disease from occurring, thereby reducing the incidence and prevalence of a disease. An example of primary prevention would be vaccination (Timmreck,1994).

Secondary prevention is the effort to decrease the duration of illness, severity of diseases, and disease progression through early diagnosis and prompt intervention. Secondary prevention is used after the disease has occurred, but before the person notices that anything is wrong. The goal of secondary prevention is to find and treat disease early; in many cases, the disease can be cured. An example of this is when a healthcare provider checks for suspicious skin growths (Timmreck, 1994).

Tertiary prevention is the effort to limit the degree of disability and promote rehabilitation and restoration of function in patients/clients with chronic and irreversible diseases. Tertiary prevention targets the person who already has symptoms of the disease. The goals of tertiary prevention are (a) to prevent damage and pain from the disease, and (b) prevent disease progression (World Confederation for Physical Therapy, 2015).

Concept of prevention and how it relates to this research.

In summary, during this literature review, two views emerged of the concept of prevention. These were a medical and public health view. The medical view ties closely with disease prevention and the public health view ties closely with the phenomenon of

prevention as a process that takes action steps to prevent a disease from starting or progressing. In 2006, researcher Satcher stated, "In the United States, more money is spent on treating diseases and their complications than on preventing them in the first place" (p.1010). The response to the current healthcare crisis will require a fundamental change in how healthcare decisions, healthcare delivery, and healthcare reimbursement are conceptualized and managed.

Penrod and Hupcey (2005) stated that, serial advancement of the concept depends on the researcher's agenda, but the potential of the process is to develop a concept toward a more precise scientific definition that permits integration into conceptual frameworks that enhance research or informs or directs practice. (p. 235)

This research views the phenomenon of prevention as a process of action steps to prevent a disease from starting or progressing. Some precursors of prevention are usually the disease or a heightened awareness; this research will address the severity and susceptibility of influenza disease in school-age children. Following through with outcome of prevention is vaccination. For this research study, the medical and public health definitions of prevention are appropriate.

Immunization is one of the most successful public health achievements of the 20th century, and the development of vaccines has allowed smallpox to be eliminated worldwide, and cases of polio, measles, pertussis, and diphtheria are at all-time low (Hitchcock, Marshall, & Middleman, 2007). The standard childhood immunization series prevents approximately 10.5 million cases of infectious illnesses and 33,000 deaths yearly in the United States (Zhou, Santoli, & Messonier, 2005). Vaccination is a great example that highlights the concept of prevention.

Theoretical Framework

The HBM is a theoretical framework used to explain and predict health-related behaviors, particularly for adopting a health-related behavior and assessing health-behavior interventions (see Appendix A). The HBM has two basic assumptions: (a) people do not want to get sick, and (b) people believe specific health actions will prevent them from getting sick. The constructs of the HBM were built upon an individual's perceptions, which are strong predictors as to whether or not they will engage in behavior change (Champion & Skinner, 2008). The HBM is a psychological model that attempts to explain and predict health behaviors. This model focuses on the attitudes and beliefs of individuals and barriers with taking action.

Origins of the Health Belief Model. The original HBM was developed in the 1950s by social psychologists Hochbaum, Kegels, and Rosenstock, working in the U.S. Public Health Service. According to Rosenstock (1974), the HBM was developed during a time when the Public Health Service was focusing on prevention and found that there was a failure of people wanting to participate in screening programs. These factors influenced to a large extent the need to develop a theory that could explain preventive health behavior while addressing disease avoidance.

The background experiences of the social psychologists who participated in the model development possessed a strong philosophical commitment toward theory building, thus wanting to develop an overarching framework of prevention that would collectively address all the individual health concerns. The social psychologists were committed to developing a theory that would include what was required for a person to believe in order to take action (motivate) and prevent disease (Rosenstock, 1974). They

were also committed to understanding what health beliefs a person would need to understand disease in the absence of symptoms. At that time, little research was available to guide the social psychologists.

The development of the model was influenced by the theory of Kurt Lewin, who posited that individuals exist in a life space composed of regions. These regions could be either positively valued, others negatively valued, and some relatively neutral (Rosenstock, 1974). Lewin's theory posited that behavior depends on two variables: (a) the value the individual places on the outcome, and (b) the individual's estimate of how attainable the outcome is (expectancy). This value expectancy theory is a goal-setting theory based on a level of aspiration, in which individuals base future performance on past experience (Sharma & Romas, 2008). It was from the basic assumptions of Lewin's theory that the social psychologists begin the emergence of the constructs of perceived susceptibility, perceived seriousness, perceived benefits, and perceived barriers.

Key constructs of the Health Belief Model. The HBM describes an individual's perceptions for adapting health-related behaviors and can be a guiding framework for researchers and clinicians in developing health behavior interventions. Its basis is in psychological theory and contains primary constructs that predict why people will take action. These constructs represent an individual's core beliefs based on their perceptions of what influences their health behaviors. The key constructs of the HBM are (a) perceived susceptibility, (b) perceived severity, (c) perceived barriers, and (d) perceived benefits. These constructs were proposed as accounting for a person's "readiness to act." An added concept, cues to action, would activate that readiness. In 1988, the concept of

self-efficacy was added to the model to help better fit the challenges people face when trying to change habitual unhealthy behaviors such as smoking, overeating, or a sedentary lifestyle (Glanz, Rimer, & Lewis, 2002). The HBM can be used in the proposed study in the following manner.

Perceived susceptibility. Perceived susceptibility is a parent's belief that their child could contract influenza disease. Previous studies have established that people who had been vaccinated against influenza were more likely to see themselves at higher risk for influenza disease, whereas those who were not vaccinated saw themselves as unlikely to contract influenza disease (Daley et al., 2007; Flood et al., 2010; Norten, Scheifele, Bettinger, & West, 2008; Soyer et al., 2011). However, additional studies have shown that individuals resistant to influenza vaccination are willing to get vaccinated to protect their high-risk family members (Cheney & John, 2013; Norten et al., 2008).

Perceived severity. Perceived severity is a parent's assessment of the seriousness of the influenza disease and its potential consequences. It is the belief about how serious influenza disease is and what its effects are. This construct can specify consequences of risks and conditions. Research on influenza vaccination was mixed when the severity of influenza disease was reviewed. Some studies found that perceived severity alone was not a significant predictor of influenza vaccination (Norten et al, 2008; Nexoe et al., 1999). However, additional studies found perceived severity was a significant predictor of influenza vaccination (Coe et al., 2012; Flood et al., 2010).

Perceived barriers. Perceived barriers are a parents' assessment of the influences that facilitate or discourage adoption of influenza vaccination. Parents who are resistant to vaccination for their child are more likely to report experiencing illness and side

effects from the vaccination (Cheney & John, 2013; Daley et al., 2007; Flood et al., 2010; Gnanasekaran et al., 2006; Taylor et al., 2002). Previous research has also identified knowledge barriers (Baker, Wilson, Nordstrom, & Legwand, 2007; Soyer et al., 2011; Wooten et al., 2007) and vaccine safety concerns (Chen et al., 2011; Cheney & John, 2013; Daley et al., 2007; Flood et al., 2010).

Perceived benefits. Perceived benefits are the parent's assessment of the positive consequences of adopting influenza vaccination for their child. One of the most important benefits is the effectiveness of the vaccination in a given year to reduce the risk of getting influenza disease (Cheney & John, 2013). Several studies have found that perceived effectiveness of the vaccine is one of the most consistent predictors of influenza vaccination (Chen et al., 2011; Flood et al., 2010; Norten et al., 2008; Wooten et al., 2007).

Perceived self-efficacy. Perceived self-efficacy is the parent's self-assessment of their ability to successfully adopt the vaccination for their child. Few studies related to influenza vaccination have looked directly at the role of self-efficacy in vaccine receipt; this may be because vaccination is a simple and time limited behavior that does not require a lifestyle change (Bhat-Schelbert et al., 2012; Champion & Skinner, 2008; Norten et al., 2008).

Cues to action. Cues to action are the parent's external influences promoting the adoption of the desired behavior. This can include information provided by healthcare providers or the community (media) or information sought out by parents. Additional cues for action could be immunization reminder or recall systems by healthcare providers

and personal experiences. These environmental prompts can activate a parent's readiness to seek a vaccination (Cheney & John, 2013).

Health Belief Model hypothesis. The HBM hypothesizes that health-related actions depend upon the simultaneous occurrence of the following four factors. These are: (a) the existence of sufficient motivation to make health issues relevant; (b) the belief that one is susceptible to a serious health problem or illness (perceived threat); (c) the belief that by following a particular health recommendation, the perceived threat is reduced; and (d) at a subjectively-acceptable cost. The prediction of the model is the likelihood that the individual concerned would undertake the recommended health action (preventive or curative).

Health Belief Model applications. In addition to vaccination, the HBM has been applied to a broad range of health behaviors and populations in the literature. This theory was developed mainly to cater to preventative or current health behaviors. It has been used in behavioral research modeling to predict college student health behaviors (Sharma & Romas, 2008) and instrument development such as the AIDS Health Belief Scale (Zagumny & Brady, 1998). It has also been used in in health education for numerous prevention programs such cancer screening (Hajian, Vakilian, Najabadim, Hosseini, & Mirzaei, 2011; Wu, West, Chen, & Hergert, 2006), antihypertensive regimens (Nelson, Stason, & Neutra, 1978; Taylor, 1979), and diabetes programs (Bradley, Gamsu, Knight, Boulton, & Ward, 1986; Bradley et al., 1987).

Some criticisms of the HBM are: (a) when comparing studies, oftentimes different questions are addressed differently in studies to evaluate the same belief, thus making it difficult to compare studies; (b) some perceived barriers are not removable and this

theory does not provide direction on this; (c) some constructs are difficult to test due to the non-specificity of the construct such as perceived susceptibility (Sharma & Romas, 2008); and (d) the model itself cannot inform how an intervention should be structured (Tanner-Smith, 2010).

Relationship of health belief model to the SayNo2Flu intervention. The HBM was chosen as the theoretical perspective to guide the design, implementation, and evaluation of this study because it has been used extensively to study disease and vaccination beliefs and behaviors (Glanz et al., 2002; Janz, Champion, & Strecher, 2006; Painter et al., 2010). The goal of the SayNo2Flu program is to help strengthen the parents' beliefs and behaviors to promote influenza vaccine receipt for their child. It is a targeted influenza vaccination intervention guided by the HBM constructs of (a) perceived severity and susceptibility to influenza disease, (b) perceived barriers to influenza vaccination, (c) perceived benefits of influenza vaccine, (d) self-efficacy, and (e) cues to action. The HBM can help explain parent factors influencing childhood vaccination rates and identify predictors of influenza vaccination in children (see Appendix A).

The goal of the SayNo2Flu program is to provide education on influenza disease (severity, susceptibility) and vaccination (barriers, benefits) to strengthen parent beliefs to promote flu vaccine receipt for their children. Montano and Kasprzyk (2008) stated that incorporating the HBM constructs of this prominent behavior change theory may be appropriate for designing, implementing, and evaluating studies regarding vaccination behaviors (Montano & Kasprzyk, 2008). The ease and timeliness of the SayNo2Flu program guided by the HBM may help strengthen parental beliefs regarding their ability

to promote influenza vaccine receipt for their child while confirming actual vaccine receipt.

The HBM is an appropriate model for this research because it focuses on the attitudes and beliefs of individuals and barriers with taking action. This model can help understand parent factors influencing childhood vaccination rates and identify predictors of influenza vaccination in children. The overarching belief system of parents as related to influenza disease and vaccination of their school-age children will guide authenticity into this research.

Barriers Affecting Childhood Vaccination Rates

A review of the literature identified two distinct areas that affect vaccination rates among healthy children. These are parent characteristics and healthcare provider/system characteristics. Found also during this review was that most studies utilized national immunization recommendation from the American Academy of Pediatrics immunization advisory committee guidelines (ACIP) and the results from the National Immunization Survey (NIS) as a basis for designing their research problem and benchmarking their results. The NIS is a large, ongoing survey of immunization coverage among children in the United States. It has been conducted annually since 1994 by the National Immunization Program and the National Center for Health Statistics, CDC. The NIS is used to obtain national, state, and selected urban area estimates of vaccination coverage rates for children in the United States. The NIS was established to provide an ongoing, consistent data set for analyzing vaccination levels among children in the United States (Fiore et al., 2008).

This section will review four studies that address how parent characteristics such as the mother's literacy level, information needs, information-seeking behavior, maternal age, socioeconomic factors (Baker et al., 2007; Daley et al., 2007; Wooten et al., 2007), and parent's beliefs and myths about vaccines (Daley et al., 2007; Flood et al., 2010) affect vaccination rates.

The first study was by researchers Baker et al. (2007) titled, "Mothers' Knowledge and Information Needs Relating to Childhood Immunizations." The researchers conducted a pilot qualitative study using structured interviews to determine the mothers' literacy level, information needs, and information seeking behavior related to their child's vaccinations. A convenience sample of mothers (n = 30) was recruited at a free urban walk-in immunization clinic in Detroit. The researchers found that (a) the average reading skills were at a seventh to eighth grade level, (b) 70% of mothers' income was $20,000 or less, and (c) 53.8% of mothers did not know the name or purpose of the vaccine their child was receiving. This study points to the importance of developing vaccine interventions for parents that address low health literacy especially noting the high percentage of mothers who did not know the name or the purpose of the vaccine their child had received. If parents are unaware of what the vaccine is for, it is very difficult to understand its effectiveness and value. The proposed study's educational intervention is being delivered via a text message which allows only 160 characters, thus ensuring the simplicity and understanding of the message. This study also highlights the role low socioeconomic status plays in vaccination. The proposed study is taking place in an urban primary care clinic where most of the children receive free vaccines because they live below the poverty level.

The second study reviewed was conducted by researchers Daley et al. (2007) titled, "Misperceptions About Influenza Vaccination Among Parents of Healthy Young Children." A survey was administered to 472 parents from five private pediatric practices in Denver, Colorado. All offices included in the study shared a computerized billing system and participated in a regional immunization registry. In addition, the practices all used the Federal Vaccines for Children (VFC) program to provide free vaccine to Medicaid-insured and uninsured children. The objectives of the study were to (a) describe the knowledge and attitudes of parents of healthy young children towards influenza disease and vaccination, and (b) prospectively identify factors associated with influenza immunization on healthy young children during the 2003-2004 influenza season. This randomized control study administered a survey to assess the knowledge and attitudes of parents (n = 472). Trained interviewers collected survey data by using computer assisted telephone interviewing technology. The HBM and the theory of reasoned action guided the survey development. The conceptual domains of (a) perceived susceptibility to influenza, (b) perceived susceptibility to influenza, (c) perceived risks of vaccination, (d) perceived benefits of vaccination, (e) perceptions of social norms of vaccination, and (f) perceived barriers to vaccination were addressed in the survey questions. The two main study outcomes of the study were (a) parental knowledge and attitudes about influenza and vaccination, and (b) influenza vaccination as documented in either the billing or immunization registry databases.

The researchers found that parental misinformation or inaccurate beliefs about the influenza vaccine for their child were prevalent. Seventy percent of the parents (n = 472) thought influenza vaccine could cause disease, 47% of parents felt their children was

unlikely to contract influenza, and 21% of parents considered the influenza vaccine to be unsafe. In the multivariate analyses, the perception that influenza vaccination was the social norm was positively associated with immunization (OR: 1.32; 95% CI: 1.03-1.69), and parents anticipating immunization barriers were negatively associated with immunization (OR: 0.68, 95% CI: 0.49-0.95). The researchers concluded that parental influenza-related attitudes assessed before the season may be predictive of subsequent vaccination. In addition, educational efforts targeted at parental influenza vaccination attitudes may facilitate higher rates of immunization in this age group (Daley et al., 2007).

In this descriptive study, researchers Daley et al. (2007) used the HBM and did confirm receipt of the influenza vaccination; however, no educational intervention was delivered. This research is very relevant to the proposed study, as the researchers used the HBM to guide the development of their survey questions and concluded that educational efforts targeted at parents prior to the start of the influenza epidemic may facilitate immunization in this age group. The proposed study will be delivered in October and November, thus targeting influenza disease and vaccine education prior to the start of the influenza epidemic.

The third study, Wooten et al (2007) investigated the role of socioeconomic factors in the persistence of racial/ethnic disparities in childhood immunization coverage rates. The specific objectives were: (a) to examine the effects of socioeconomic factors on childhood immunization rates over a five-year period stratified by race/ethnicity, and (b) to assess whether racial/ethnic disparities in immunization can be explained by differences in socioeconomic factors such as maternal education and household income.

The researchers examined up-to-date vaccination records (n = 103,668) over a five-year period and found an overall up-to-date vaccination rate of 78.2%. The NIS data collected in 1999-2003 among children 19-35 months of age were analyzed. The outcome measure used for this analysis is based on the child's up-to-date status for a series of vaccines referred to as the 4:3:1:3 series. The reference to up-to-date vaccination refers to having received the combined 4:3:1:3 series of vaccines by the time of the survey. Further analysis revealed that children who lived above the poverty line had a vaccination rate of (82.32%, OR:1.83, 95% CI: 1.6-2.6), $p < 0.05$), whose mothers had more than a high school education (82.5%, OR: 1.25, 95% CI: 1.1-1.42, $p < 0.05$), and whose mothers were married (80.4%, OR:1.37, 95% CI: 1.20-1.55, $p < 0.05$) at the time of the survey were more likely to be vaccinated. The researchers also found that children who lived below the poverty line (72.7%, OR: 1.10, 95% CI: 0.9-1.3, $p < 0.05$), whose mothers had less education (74.8%, OR: 1.56, 95% CI: 1.4-1.7, $p < 0.05$), or whose mothers were not married (73.5%, 95% CI: 1.8- 2.1, $p < 0.05$) were less likely to be vaccinated (Wooten et al., 2007). The significance of this research to this proposed study is in understanding how poverty, education, and marriage can affect vaccination. This study also highlights the importance of addressing health literacy when developing parental educational intervention and ensuring the simplicity and understanding in the educational message.

The fourth study reviewed was conducted by researchers Flood et al. (2010), titled "Parents' Decision-Making Regarding Vaccinating Their Children Against Influenza: A Web-Based Survey." This study was conducted to explore factors that influence parents' decision regarding influenza vaccination for children two to 12 years of age. The researchers aimed to (a) quantify the factors that influence parents' decision regarding

influenza vaccination, (b) identify an appropriate theoretical model for illustrating the relationship among these factors, and (c) characterize parents by their likelihood of vaccinating their children against influenza. The researchers used a quantitative web-based survey to administer to a sample of parents (n = 500) from an online nationwide panel represented of United States population called Knowledge Network. The parents were divided into three groups based on their current influenza vaccination practices. The three groups consisted of (a) parents who vaccinated their children yearly, (b) parents who did not vaccinate their children, and (c) parents who sometimes vaccinate their child. The parents who vaccinated their children were asked to select drivers of their decision to vaccinate and parents who indicated that they never vaccinate their child were asked to select barriers. The group of parents who sometimes vaccinate their child were asked to select both driver and barriers of their decision to vaccinate.

The researchers used mean agreement ratings to calculate for parental beliefs and perceptions about influenza disease and influenza vaccine and then compared the ratings across the three groups. They found the mean (SD) age was 37.4 (6.82) years, 57.2% were female, and 78.2% were non-Hispanic white. The researchers reported that among those parents (44.2%) who reported they vaccinated their child against influenza every year or sometimes, the major drivers of vaccination were prevention of influenza (95.1%, SD 4.37, $p<0.05$), a doctors' recommendation (89.5%, SD 3.86), and the desire to reduce influenza symptoms (83.3%, SD 4.2, $p<0.05$). Among the parents who reported sometimes or never (55.8%) vaccinating their child against influenza, the most common barriers were the low perceived risk of influenza (46.0%, SD 3.22, $p<0.05$), the perception the vaccine caused influenza (44.0%, SD 3.50), and the vaccine side effects

(36.6%, SD 3.28). Convenience of vaccination was the most important factor among parents (75%, $p<0.05$) with a medium likelihood of vaccination.

A modifying factor found was the parents' belief that the susceptibility and severity of influenza was related to their child's general health status. Overall, all groups found 40.3% (200/496) of parents agreed or strongly agreed that influenza is not that serious for healthy children, and 72.3% (357/496) agreed or strongly agreed that healthy children are less likely to get the flu. The sex of the parent also was associated with perceptions of the threat of influenza. Seventy-two percent of female parents (72.2%, 205/284) versus 60.7% (130/214) generally perceived the threat of influenza to be greater than did male parents.

The researchers identified the HBM as an appropriate theoretical framework for illustrating the factors influencing parents' decision-making about influenza vaccination. The perceived severity (83.0%, SD 4.20,) of and susceptibility to (95.12%, SD 4.37) influenza were positively associated with the likelihood of vaccination. Barriers to vaccination included the risk of adverse effects (36.6%, SD 3.28) and the perceived low risk of influenza (33.7%, SD 2.92). The researchers concluded that increasing the parents' awareness of the threat of influenza and the efficacy and safety of the vaccine, as well as improving the convenience of getting vaccinated may help improve rates of pediatric influenza vaccination. This study is important to the proposed research study because it highlights the need for parental education on the severity and susceptibility of influenza disease. The proposed study will utilize the HBM, in addition to targeting parents of five- to eight-year-olds and addressing the educational needs of influenza disease and vaccination. This study also highlights the convenience of having access to

influenza vaccination, and the proposed study allows parents to drop into the clinic without an appointment or extended wait to receive an influenza vaccination.

Healthcare provider and system characteristics (barriers). There are a number of healthcare provider and system characteristics that affect vaccination rates. Some of these barriers include (a) confusion about national recommendations, (b) a low uptake of strategies known to increase vaccination rates (vaccine reminder-recall systems), and (c) healthcare providers' perceived under-influence on parents (Cheffins et al., 2011; Daley, 2002; Dominguez & Daum, 2005). Healthcare providers also report (a) scheduling difficulty, (b) unpredictability of influenza season length and severity, (c) difficulty estimating amount of vaccine to order, (d) an inadequate supply of vaccine nationally, and (e) the transient period of high demand as barriers to influenza vaccination (Birmingham et al., 2011; Daley et al, 2002). Researchers Bhat-Schelbert et al. (2012) found that identifying children with chronic diseases in practice settings who can benefit from influenza vaccinations has helped providers from being left with unused vaccine supply. The expanded influenza vaccination recommendation now includes all children, making it easier for practices to identify all children and order the appropriate amount of vaccine.

Additional system factors such as low reimbursement rates, protracted credentialing process with insurance plans, and a lack of influenza vaccine mandates for children contribute to low influenza vaccine rates (McInerny et al., 2005). However, more recent research has found that healthcare providers have garnered higher reimbursement rates by advocating for appropriate influenza vaccination reimbursement, acknowledging the seriousness of influenza disease among children, educating parents

about the safety of influenza vaccinations, and supporting national vaccination goals for children (Anderson, 2007; Yoo,2011).

Intervention Studies for Raising Influenza Vaccination Rates in Children

Numerous interventions for overcoming barriers to vaccination for children are well documented in the literature. Early vaccination during back-to-school visits, enhanced availability of walk-in Flu clinics, expanded clinic hours, utilizing year-round scheduling to decrease overcrowding during an epidemic, and healthcare providers' recommendations have all been effective (Bhat-Schelbert et al., 2012; Poehling et al., 2010; Stinchfield, 2008). The use of electronic chart alerts for patients' vaccine reminders and education (Cheffins et al., 2011; Daley et al., 2007; Fiks et al., 2007, 2009; Levy, Ambrose, Oleka, & Lewin, 2009) and improved office processes, such as use of standing orders, written immunization policies, and practice audits have been effective in increasing influenza vaccination rates in primary care settings (Birmingham et al., 2011). In addition, parental influenza disease and vaccine education that addresses vaccine myths have been effective (McInerny et al., 2005; Yoo, 2011). This section will review seven studies that focus on how vaccine reminder systems (three studies) and the healthcare provider recommendation (four studies) positively affect vaccination rates.

Reminder systems. The first study reviewed from researchers Fiks et al. (2007), titled "Impact of Clinical Alerts Within an Electronic Health Record of Routine Clinical Immunizations in an Urban Pediatric Population" was designed to test the effects of immunization alerts on two main outcomes: (a) rates of captured opportunities, and (b) overall immunization rates at two years of age. The researchers questioned if using clinical alerts for routine pediatric vaccinations within an electronic health record (EHR)

would reduce missed vaccine opportunities. They studied a total of 3,217 patients and 35,837office visits that received alerts. There were 1,669 intervention patients (15,928 visits with alerts occurred) and 1,548 control patients (19,909 visits occurred). The child was required to have one visit during the intervention period; both sick and well visits were included in the analysis. The ACIP was the guideline the researchers used for immunization compliance. This was a one-year interventional study with historical controls conducted at four urban primary care centers, and all children younger than 24 months of age were enrolled. From September 2004 to August 2005, an alert appeared in the EHR for the intervention group whenever any patient encounter was opened (office visits and telephone care). For the control group, no vaccine alerts existed; however, healthcare providers were able to review immunization records and make recommendations.

The results from the EMR alert implementation were associated with increases in immunization opportunities from 78.2% to 90.3% at well visits and from 11.3% to 32% at sick visits. There was an overall immunization rate increase of 8%. The researchers found that this EHR-based clinical alert intervention was associated with an increase in captured opportunities for both well and sick visits. The researchers concluded that EMR clinical alerts can be a key strategy in improving immunization rates and ultimately the health of children. The researchers also concluded that this intervention study was effective in increasing influenza vaccinations; however, continued innovative strategies are needed as childhood influenza vaccination rates remain low. The significance of this research to the proposed study is that clinical alerts (reminders) for the healthcare providers prompted them to recommend vaccination to the parent. The proposed research

will send reminders directly from the healthcare provider, prompting parents to have their child vaccinated.

The second study by researchers Fiks et al (2009), titled "Impact of Electronic Health Record-Based Alerts on Influenza Vaccination for Children with Asthma" is from the same researchers as the prior study, except they evaluated the impact of EHR-based alerts on influenza vaccination for children with asthma. The goal was to assess the impact of influenza vaccine clinical alerts on missed opportunities for vaccination and on overall influenza immunization rates for children and adolescents with asthma. The researchers conducted a prospective cluster randomized control trial between October 2006 and March 2007. The intervention sites were the first 20 primary care practices who participate in the Philadelphia Pediatric Research Consortium. This consortium cares for over 235,000 children.

At each intervention site, the EHR-based clinical alerts for influenza vaccine appeared at all office visits for children five years to 19 years of age with asthma. The proportion of captured immunizations opportunities at visits and overall rates of complete vaccination for patients at intervention and control sites were compared with those for the previous year. The study had a greater than 80% power with the ability to detect an 8% difference in the change in rates between the study and the baseline years at the intervention control practice. The study included a total of 23,418 visits and 11,919 children in the intervention group and 21,422 visits and 10,677 children from the prior year in the control group.

The researchers found that 36% (n = 19169) of children were five to nine years of age and privately insured. They also found the overall captured vaccination opportunities

increased from 45.0% to 52.2 % (OR: 4.8, CI: -1.3-9.1, *p*=.23) at the intervention sites and from 44.2% to 48.2% at the control site. This resulted in an increase in influenza vaccination by 4% (OR: 4.8, 95% CI: -1.4-9.1, $p = .23$) at the intervention sites than at the control sites. With standardization for selected covariates (ethnicity, clinical factors, number of office visits), the up-to date vaccination rates increased similarly by 3.4 (OR: 4.8, 95% CI: -1.4-9.1, $p = .23$), a statistically non-significant improvement. When the researchers considered only the urban resident-teaching practices, they found a statistically significant 5.4% increase (OR: 4.8, 95% CI: 1.6-9.7) relative improvement. However, in the multivariate model researchers found the overall improvement in the intervention group was a non-significant change improvement ($p = .23$). The four practices with the greatest increases in rates (> or = 11%) were all in the intervention group as compared to the prior year control sites. The researchers also found that vaccine receipt was more common among children who had been previously vaccinated (OR: 1.63, 95% CI: 1.36-2.00) and received care at well-care office visits (OR: 5.71, 95% CI: 4-26-7.65). The researchers concluded that clinical alerts were associated with only modest improvement in influenza vaccination rates. The importance of this research to the proposed study is that the majority of children studied were five- to nine-year-olds; it highlights that vaccine reminders do work when healthcare providers use them and parents are willing to have their child vaccinated if a healthcare provider recommends it.

The third study reviewed was from researchers Brigham et al. (2012), titled "Randomized Control Trial of an Immunization Recall Intervention for Adolescents." The purpose of the study was to determine if immunization rates could be improved by telephone contact to parents or to the parent and adolescent. The sample was parents (n =

424) of adolescents between the ages of 13-17 years from a Boston tertiary care hospital. The parents were selected if their adolescent was overdue on their immunizations. The participants were randomized into one of three study groups using computer randomization. The two groups were a control group and an intervention parent and/or adolescent group. The study took place from May through July 2010. The parents in the intervention group received a telephone call reminder, and if the parent consented, a telephone reminder call was placed to their adolescent. The control group did not receive any telephone call reminders. The outcome measure was receipt of one or more of three vaccines of interest (meningococcal, varicella, and T-dap) within four weeks after the first phone call attempt had been made to the intervention group. The researchers also examined immunization receipt at one year post-study start.

The researchers found that four weeks after the intervention in the intention to treat group (parents and adolescents contacted), there was a non-significant trend towards increased immunization in both intervention arms (14.4% for parent only, and 14.5% in parent/adolescent as compared with the control group (7.1%). The unadjusted odds of receiving one or more vaccines during the four-week follow-up period were 2.02 times higher (OR: 2.02, 95% CI: 0.89–4.89, $p = .09$) in the parent-only group and 2.22 times higher (OR: 2.2, 95% CI: 1.00–4.94, $p = .05$) in the parent/adolescent group compared with controls. The parent only group had a non-significant trend toward the increased likelihood of receiving an immunization. In the multivariate model, age was the only variable independently associated with immunization (OR: 0.67, 95% CI: 0.48-0.92, $p = .02$), finding older adolescents being less likely to be vaccinated. One year after the intervention, more adolescents had received one or more vaccines, but the trend toward

increased immunization rates in the intervention groups did not persist (35.5% for control, 41.4% for parent only, and 38.4% in parent/adolescent, $p = .59$). However, the results were not significant.

The researchers referred to the as-treated group as those parents and adolescents who were contacted. They found that 79 (56.4%) of the parents in the parent-only group and 70 (50.7%) of the parent/adolescent group were successfully contacted. In total, 270 subjects were not contacted, 119 parents were contacted, and 30 adolescents. Four weeks post-intervention, a post hoc analysis found there was a significantly increased rate of immunization when either the parent only was reached (24.4%) or when both the parent and adolescent were reached (20.0%) as compared to no contact (5.6%, $p < .001$). In the multivariate analysis, the odds of being vaccinated were 5.1 times higher (95% CI: 2.66-10.63, $p < .001$) when the parent only was reached and 4.72 times higher (95% CI: 1.62-13.79, $p = .005$). Similar to the intention to treat group, age was also an independent predictor of being vaccinated.

One year after the intervention, the post-hoc analysis showed a significantly increased rate of immunization when the parent only was reached (51.3%) and when the parent and adolescent were reached (63.3%), as compared to the no contact group (30.0%, $p < .001$). In the multivariate analysis, the odds of being vaccinated were 2.40 times higher (95% CI: 1.51-3.81, $p < .001$) when the parent only was reached and 3.78 times higher (95%, CI: 1.68-8.52, $p = .005$) when both the parent and adolescent were reached, compared to no contact.

The importance of this research to the proposed study is that the reminder was directed to parents and the results indicated that parents will follow through with having

their child vaccinated in the four weeks after the intervention. Vaccination recall interventions have been predominately conducted using telephone or paper. Text messaging is a reminder directed to the parent that can be easily implemented in a primary care office. Text messages are simple, affordable, and can be an effective way to reach the parents for short-term behavior changes.

Healthcare Providers' Recommendation and Parent Education

Primary care pediatric practitioners develop professional and trusting relationships with parents, and this relationship can be leveraged to promote national pediatric recommendations for vaccinations (Cheffins et al., 2011; Gnanasekaran et al., 2006). Young school-age children have regularly scheduled healthcare visits with their primary care providers more often than older children and adolescents (Rand et al., 2007). These routine and frequent visits provide multiple opportunities for healthcare providers to recommend specific health promotion activities. The literature reveals that it is this recommendation from healthcare providers that has a major influence on parental acceptance and receipt of vaccinations for their children.

Four studies reviewed found that the healthcare provider's recommendation is one of the strongest predictors of influenza vaccine receipt (Bhat-Schelbert et al., 2012; Cheffins et al., 2011; Gnanasekaran et al., 2006; Soyer et al., 2011).

The first study, Gnanasekaran et al. (2006), studied parental perspectives on influenza vaccination for children with asthma. The purpose of this study was to (a) identify modifiable factors influencing receipt of influenza vaccination among children with asthma, and (b) evaluate the effect of heightened media attention on vaccination rates. The researchers interviewed parents (n = 500) of children with asthma

about their experiences with and beliefs about influenza vaccination. They randomly selected 500 children from a study population of 2,140 children indentified with asthma in a managed care organization in Massachusetts. Parents of children aged five to 18 years with asthma were randomly assigned to an interview group or control group. The researchers used a telephone survey to obtain information on demographic factors, parental beliefs, and health system factors on receipt of influenza vaccination. The researchers obtained data on influenza vaccination status from computerized medical records.

Bivariate analysis was conducted using Chi-square analysis or the Fisher's exact test for catagorical variables, logistic regression for ordinal and continous variables. The influenza vaccination rate for children with asthma was 43% versus 27% the prior season. The researchers found that children are more likely to be vaccinated if their parent recalled a physician recommendation (OR: 2.6%,95% CI: 1.5-4.4, $p \leq 0.001$), parents believed the vaccine worked (OR: 2.0, 95% CI: 1.4-2.8, $p \leq 0.001$), or expressed little concern about vaccine adverse effects (OR: 1.3, 95% CI: 1.0-1.6, $p \leq 0.001$). The researchers also reported that during the study period, there was a heightened media attention about influenza illness and the vaccine. The findings indicate that a healthcare provider recommendation, parental education about influenza vaccine availability and effectiveness, and beliefs or knowledge of adverse effects were significant factors in a parent's decision to vaccinate (Gnanasskaran et al., 2006). This is revalent to this proposed study because it highlights once again that healthcare provider recommendation and parental education regarding influenza vaccination were significant factors in a parent's decision to vaccinate.

The second study reviewed was conducted by researchers Soyer et al. (2011) titled, "Parental Perspectives on Influenza Vaccination in Children with Asthma." The aim of the study was to identify the demographic factors and asthma-associated characteristics related to vaccination, and caregivers' attitudes and knowledge about influenza disease during the 2007-2008 influenza season. The subjects were caregivers of children with asthma (n = 311) aged six to 18 years. The parents were surveyed using a self-administered questionnaire to obtain information regarding their knowledge about influenza disease, vaccine, and factors influencing vaccination. This survey was used to evaluate parental health behaviors influenced by their perception of personal susceptibility and the severity of influenza. The differences between groups were compared by using the Student's T, Mann-Whitney U test or Chi-square as appropriate. Multivariate logistic regression was used to model the odds of being vaccinated. The researchers found the most important reason cited by parents for deciding on the influenza vaccination for their child was physician recommendation (80.1%). The researchers found the major reasons for declining the vaccination were (a) the caregiver's lack of awareness that the influenza vaccination was a requirement for their child (29.3%), (b) their child was ill at the time of vaccination (20%), and (c) the caregiver did not perceive any benefit from prior vaccination. Logistic regression analysis found that (a) the unvaccinated children had fewer than three physicians visits in the prior year (OR: 1.83, 95% CI: 1.007-3.327, $p = 0.047$), (b) the parents did not agree that influenza vaccination decreases prevalence of asthma attacks (OR: 2.532, 95% CI: 1.331-4.816, $p = 0.005$), and (c) the caregivers did not agree that influenza vaccination decreases school absenteeism (OR: 2.256, 95% CI: 1.172-4.343, $p = 0.015$) (Soyer et al., 2011). The

research is relevant to the proposed study as the results indicate the parents did not perceive any benefits of influenza vaccination. It points to the importance of educating parents on influenza disease and vaccine. This study did highlight once again the importance of a healthcare provider's recommendation for vaccination.

The third study reviewed was by researchers Cheffins et al. (2011), titled "Recommending Vaccination-General Practice Intervention with New Parents." The aim of the study was to describe parental immunization status and examined if parents acted on recommendations for vaccination from physicians based on national influenza recommendations (ACIP). The participants were parents of children aged zero to four years of age from eight general practices (n = 177). It was a pre/posttest experimental design. The intervention was delivered after pretest (self-reported survey) and it consisted of the parent receiving a recommendation for vaccination by their healthcare provider based the current national recommendations for vaccination. The posttest was completed two months post the intervention. The researchers found that physicians made a recommendation to 66.1% (n = 177) of parents which resulted in 53% of parents complying. This resulted in an overall increase in vaccination rates from 33.9% (60/177) to 68.9% (122/177, $p < 0.0001$) (Cheffins et al., 2011). The significance of this research to the proposed study is that it once again highlights the importance of the healthcare providers' recommendation. The healthcare provider recommendation also led to an overall increase in vaccination rates. This study also shows the importance of strengthening parents' perception of the benefits of vaccination.

The fourth study by researchers Bhat-Schelbert et al. (2012) is titled, "Barriers to and Facilitators of Child Influenza Vaccine – Perspectives from Parents, Teens,

Marketing and Healthcare Professionals." In the fall of 2010, researchers conducted eight focus groups (n = l91) of parents, teens, pediatric healthcare staff, and providers to elicit responses that were audiotaped, then transcribed verbatim and coded based on grounded theory methodology. Each focus group had nine to 13 parent participants whose children range from toddlers to college-age. Participants were asked to discuss their past and current experiences with receiving influenza vaccination for their children. The researchers found 10 major themes emerging, which were reported in three emergent domains; these were (a) barriers to child influenza; (b) facilitators of child influenza vaccination; and (c) specific interventions, not strategies, were predictors of vaccination.

The domain of barriers to childhood influenza vaccination fell into three themes. The three domains were further defined as (a) lack of knowledge and misinformation, (b) fear and mistrust of the need for the vaccine, and (c) the vaccine is unnecessary and logistical barriers.

The domain of facilitators of childhood influenza vaccination fell into four themes. These were (a) health promotion and benefits; (b) perceived benefit and trust; (c) better information; and (d) logistical facilitators (convenience of vaccination, office opportunities, and insurance coverage). The domain of strategies for increasing childhood influenza vaccination fell into three themes. These were (a) provider strategies, (b) media and marketing, and (c) teen-specific strategies. Provider strategies were reminder systems, staff education, and educational materials in the waiting room. Media and marketing strategies included television, office displays, posters, and wearable incentives. Teen-specific strategies included web-based resources and communication tools such as social networking and text messaging (Bhat-Schelbert et al., 2012). This study is

important to the proposed study because it assessed parents' past and current experiences with obtaining influenza vaccination for their child. The themes found were consistent with what was found in the literature. The domain of barriers found lack of knowledge and misinformation regarding vaccines and access concerns. The domain of facilitators found benefits of vaccination and convenience of vaccination such as office opportunities. The domain of strategies for increasing childhood influenza vaccination found reminder systems and the use of communication tools such as text messaging. The three domains identified in this study will be addressed in the proposed study.

Review of Studies Using Health Belief Model and Influenza Vaccine

Four studies were reviewed that used the constructs of the HBM to predict preventative behavior. The findings indicate that perceived susceptibility, perceived severity of disease, perceived barriers, and cues to action were significant in affecting behavior change. Of the four studies reviewed, only one study addressed children and influenza vaccination.

The first study by researchers Coe et al. (2012), titled "The Use of the Health Belief Model to Assess Predictors of Intent to Receive the Novel (2009) H1N1 Influenza Vaccine," examined the usefulness of the HBM in assessing the predictors of intent to receive the novel (2009) H1N1 influenza vaccine. The researchers aimed (a) to assess participants' perception of severity, risk, and susceptibility to the novel H1N1 virus or vaccine, vaccine benefits, and barriers, and cues to action; and (b) to identify predictors of participants' intention to receive novel H1N1 vaccine. This cross-sectional study used a convenience sample of adults (n = 664) aged 25-64 years and over at supermarkets in Virginia. The study was conducted over a two-week period during October 2009 utilizing

a 36-item survey. The researchers found that 68% of the participants disagreed with the statement, "They would die from virus," 58.1% of the participants intended to receive the H1N1 influenza vaccination, and 16% to 28% of the participants had received a recommendation for influenza vaccination from their healthcare provider. Physician recommendations (OR = 0.26, 95% CI: 0.11-0.62) and prior season receipt of influenza vaccine (OR: 0.26, 95% CI: 0.24-0.83) were significant predictors of intention to receive H1N1 vaccine. The researchers concluded that HBM educational interventions showed promise in positively impacting vaccination rates. Physician recommendations and 2008 seasonal flu vaccination were significant predictors of intention to receive H1N1 vaccine. The researchers also concluded that it is important to determine whether an educational and HBM-based intervention can be effective when delivered to parents of children (Coe et al., 2012).

The second study by researchers Norten et al. (2008) was titled, "Influenza Vaccination in Paediatric Nurses: Cross-Sectional Study of Coverage, Refusal, and Factors in Acceptance." The researchers questioned if the recommended vaccination rate could be achieved among pediatric nurses using an intensive promotional program. They conducted a multi-component program using best-known practices and analyzed uptake rates from self-administered questionnaires. The researchers referred to best-known strategies as multi-site vaccination clinics, after-hour clinic availability, and disease education. The researchers sought to identify the reasons why nurses refuse influenza vaccine and what were the predictors of future vaccination intent. The survey also included questions regarding their experience with the multi-component program.

The researchers found that a highly promoted influenza vaccination program could achieve adequate vaccine coverage with nurses. The researchers found a difference in predictors between the vaccinated and unvaccinated nurses. A predictor of vaccination amongst the vaccinated nurses was the perceived benefit of protecting themselves or their families from influenza disease (OR: 88.5, 95% CI: 47.05-166.47, p = .05). The unvaccinated nurses felt a perceived lack of personal benefit (OR: 0.18, 95% CI:0.02-1.53, p = .09); they did not need the vaccine. The researchers did find that the program's convenience (OR: 201.11, 95% CI: 99.21-406.19) and previous vaccine receipt (OR: 1.64, 95% CI: 0.42-6.19, p = .05) strongly predicted acceptance of the vaccine. This research has relevance to the proposed study as it highlights the convenience of access to vaccination. The proposed study will take place at a clinic that will allow parents to drop by the clinic without an appointment for influenza vaccine. This study also reinforces the need for education regarding the benefits of vaccination.

The third study by researchers Cheney and John (2013) was titled, "Underutilization of Influenza Vaccine: A Test of the Health Belief Model." The purpose of the focus group discussions was to understand individual attitudes, behaviors, and concerns about influenza vaccination and how practitioners can improve influenza vaccination rates among resistant individuals. The researchers utilized the HBM as a framework for understanding beliefs surrounding the acceptance or resistance to influenza vaccination and to identify intervention points and messaging strategies to increase future vaccination rates. The researchers used a purposive sampling strategy with eight at-risk focus groups (n = 74) who had not received an influenza vaccination during the prior 2006 influenza season. Participants were members of a high-risk group

who had not received an influenza vaccination in the past year. Each participant completed open-ended participant questionnaires, one at the beginning of the focus group discussions and the second following the discussion. At the completion of the focus group, a second questionnaire collected health belief information about influenza. The participants did receive a stipend for participation at the end of the session.

The researchers found that participants who saw influenza as a threat had a 5.4 times the odds of planning to be vaccinated (OR: 5.10, 95% CI: 1.63-16.05, $p = .005$). Those responding positively to cues to action had 12.2 times the odds of planning to be vaccinated (OR: 12.21, 95% CI: 2.91-51.32, $p = .001$). In addition, those responding positively to perceived benefits (OR: 16.29, 95% CI: 4.16-63.78) also responded positively to vaccination. In comparison, resistant individuals did not feel threatened by the flu and they did not respond favorably to cues to action. Perceived threat, perceived benefits, and cues to action were significantly associated with plans to be vaccinated.

The value of this research to the proposed study is that participants identified influenza as a threat; perceived benefits of vaccination and responding positively to cues to action were more likely to be vaccinated. These are three of the constructs from the HBM that will be addressed in the proposed study. This study also highlights the need for influenza disease education.

The third study by researchers Chen et al. (2011) was titled, "Using the HBM to Understand Caregiver Factors Influencing Childhood Influenza Vaccinations." This was the only study found that applied the HBM to examine factors in the decision by caregivers to vaccinate their children for influenza. The purpose of the study was to apply the HBM to investigate factors in the decision by caregivers to vaccinate their children

for influenza. They used a purposive sampling (n = 2,778) of caregivers with children six to 36 months of age participating in vaccination programs using publicly funded vaccine. The researchers administered a three-part self-administered survey (caregiver demographic survey, children's health history, and children's influenza vaccination history). They found that perceived susceptibility (OR: 2.37, 95% CI: 1.53-3.68, $p < .001$) of children to influenza, perceived benefits of vaccination (OR: 4.12, 95% CI: 2.95-5.92, $p < .001$), perceived low barriers to vaccinations (OR: .66, 95% CI: 0.45-0.95, $p < .001$), and cues to action (OR: 2.17, 95% CI: 1.22-3.87, $p = .008$) were predictors of a caregiver's decision to vaccinate. They concluded that their survey results can be used to develop strategies for increasing vaccination rates (Chen et al., 2011).

The results of this study are important to the proposed study because the intervention was guided by the HBM contracts. These study results indicate that addressing the contracts of susceptibility, perceived benefits of vaccination, perceived low barriers of vaccination, and cues to action may have a positive effect on child influenza vaccination.

Mobile Technology

Mobile technology is used for cellular communication. Mobile code division multiple access (CDMA) technology has evolved rapidly over the past few years. A standard mobile device has gone from being no more than a simple two-way pager to being a mobile cellular phone, a navigation device, a web browser, an instant messaging device, a handheld game, and a camera.

There are over 200 million cell phone users in the United States. More than 90% of United States adults subscribe to mobile services, and 72% of users send or receive

text messages. Mobile phone use and ownership is the first technology to reach across demographics and socioeconomic barriers, creating an opportunity to transform the landscape of healthcare delivery (Ahlers-Schmidt et al., 2010). Eighty-seven percent of African Americans and Latinos and 80% of whites own cellular phones. In December 2009, each United States text messaging subscriber averaged 534 messages per month (Smith, 2010). Ninety-five percent of 18- to 29-year-olds and 82% of 30- to 49-year-olds sent or received text messages (Smith, 2010).

Text messaging is becoming a commonly used method of communication and has developed its own niche in United States society. One development is called SMS, a text messaging service component of phone, web, or mobile communication systems. SMS text messaging is the simplest and most common type of mobile data service, enabling senders to communicate with short messages (approximately 160 characters) between cell phones (CDC, 2011). Recent research indicates that interventions delivered by text messages have positive short-term behavioral outcomes. The key advantages of SMS delivery include (a) dialogue initiation, (b) tailoring of content, and (c) interactivity (Fjeldsoe, Marshall, & Miller, 2009). As mobile technologies continue to develop and become more prevalent, so do the possibilities of their use as communication mediums in healthcare interventions (Gibbons et al., 2011).

Text messaging using mobile technology is portable, affordable, and can be an effective way to reach the majority of adults across all socioeconomic levels. In a recent study, 92% of low-income families had cellular telephones; 96% of those were able to receive text messages, and 81% had unlimited plans (Ahlers-Schmidt et al., 2010). In addition, cellular telephone numbers tend to be more stable over a six-month period than

home address or home phone numbers (Ahlers-Schmidt et al., 2010). Mobile technology use is not limited to those of sufficient socioeconomic means any longer. Given the acceptance of mobile technology within minority populations, it can hold great promise in our efforts to address health disparities (Gibbons et al., 2011).

Health Literacy and Mobile Text Technology

Health literacy is a person's capacity to find, understand, and use basic health information and services needed to make appropriate health decisions (Baker et al., 2007). As previously discussed, researchers Baker et al. (2007) found the average reading skills were at seventh to eighth grade level and when people have limited health literacy skills, they have trouble understanding complex health information. There is a need for healthcare providers to find new and better ways to communicate health information to the patient. Large health institutions such as hospitals and insurance plans are increasingly using the internet and other technologies to streamline the delivery of health information and services. The increase in online health information and services challenges users with limited literacy skills or limited experience using the internet. For many of these users, the internet is stressful and overwhelming, even inaccessible (Kutner, Greenberg, Jin, Paulsen, & White, 2006). Although the problem remains largely invisible, millions of Americans have a difficult time reading. According to Kutner et al. (2006), as many as half of United States adults have limited literacy skills.

Mobile text technology can play a significant role in impacting healthcare disparities by making educational messages simple and impactful. On the individual level, it is important to address significant challenges including health literacy, language, integration of evidence-based information, and resources, as well as access to more

complex interventions. And as the emerging evidence suggests, minority populations may have a higher uptake of mobile technology. There is a need to develop messages that can be effectively delivered through mobile devices, but that are also based on sound science. This application could preserve the critical elements of personal interaction, yet reduce or eliminate barriers related to geography, time, or transportation.

With the increasing complexity of health information and healthcare settings, most people need additional information, skills, and supportive relationships to meet their health needs (U.S. Department of Health and Human Services, 2010). Disparities in access to health information, services, and technology can result in lower usage rates of preventative services, less knowledge of chronic disease management, higher rates of hospitalization, and poorer reported health status (Berkman et al., 2004).

Text messages (SMS) are rapidly becoming a means of reaching out to diverse patient populations because of low cost and the ubiquitous nature of mobile phones. The low cost and design of the messages makes it possible for the program to be easily scaled across a diverse population regardless of age, educational, economic, or ethnic background and sustained for a longer duration, thereby facilitating sustained behavior change (Jacobson Vann & Szilagyi, 2005).

Mobile text technologies have the potential to help the underserved communities see the value to connect to their community, providing tools and services that are available to address health education, access, and disease management (Arora, Peters, Agy, & Menchine, 2012). The current documented difference in levels of participation in mobile text technology by persons from low-income populations can provide opportunities for researchers. Mobile text technology has the ability to assist researchers

in delivering focused tailored interventions utilizing health communications that address health literacy and can be expanded to include participation of persons from historically underserved groups (Ahlers-Schmidt et al., 2010).

Review of Intervention Studies Using Text Messaging

Researchers Arora et al. (2012) conducted a prospective proof of concept study to assess satisfaction and preliminary effectiveness of the TExT-MED program. This program was designed to motivate, educate, and empower inner city patients with diabetes. It was a culturally sensitive, low-cost, bilingual, evidence-based, and largely unidirectional text message-based mHealth program requiring only a basic mobile phone to participate.

A consecutive sample of adult patients in the emergency department with diabetes with text messaging-capable phones were enrolled in the study over a seven-day period. Participants received three text messages daily for three weeks in both English and Spanish. The text messages address five domains. These domains are (a) educational/motivational, (b) medication reminders, (c) healthy living challenges, (d) diabetes trivia, and (e) links to free diabetes management tools.

Twenty-three patients with diabetes enrolled and completed the TExT-MED program. In the week prior to the study, 56.5% of participants reported eating fruits and vegetables daily versus 83% after completion of the study; 43.5% reported exercising before versus 74% after; and 74% reported performing foot checks before versus 85% after the completion of the study. Self-efficacy was measured using the Diabetes Empowerment Scale-short form, and participants reported an improvement from 3.9 to 4.2. Scores on the Morisky Medication Adherence Scale improved from 3.5 to 4.75.

Ninety percent of participants indicated they would like to continue the program, and 100% would recommend the program to family or friends. The researchers concluded that their pilot trial of the TeXT-MED program demonstrated increased healthy behaviors, improved self-efficacy and medication adherence, and received excellent satisfaction scores in resource-poor, inner city patients with diabetes (Arora et al., 2012). This research is important to this proposed study because it shows the feasibility and acceptability of a text messaging intervention.

In 2011, a systematic review of text messaging interventions to promote healthy behaviors in pediatric and adolescent populations was conducted by Militello, Kelly, and Melnyk (2012). Researchers reviewed 37 text messaging articles from a comprehensive search. However, only eight articles representing seven studies met the inclusion criteria. The inclusion criteria were (a) the study design was a randomized controlled trial or quasi-experimental; (b) the population served was primarily less than 18 years of age, as well as parent; (c) the intervention included text messaging to impact a health behavior; (d) a health behavior outcome was measured pre/posttests; and (e) the study was published in a peer review journal.

The researchers found the differences between groups was significant in five studies. They concluded their review supports previous literature suggesting that mobile phones are uniquely positioned to bridge gaps in health disparities and reach across demographics. Interventions using SMS may be most effective as a reminder system to support disease management behaviors. Existing recommendations for tailored, interactive, and family-centered support are supported with mobile technology. However,

they did recommend more rigorous, theory-based intervention research using mobile technology is warranted in pediatric and adolescent populations (Militello et al., 2012).

Intervention Studies to Promote Influenza Vaccine Using Mobile Technology

Prior to initiating this study, the literature revealed only one randomized controlled trial testing text messaging in a primary care clinic to increase influenza vaccination rates in children could be found (Stockwell et al., 2012). This study evaluated targeted text message reminders in a randomized controlled trial for 9,213 low-income, urban parents to promote receipt of influenza vaccination. Parents with children aged six months to 18 years who attended one of four community-based clinics during the 2010-2011 influenza season were randomized to a text messaging intervention or a usual care group. The intervention group received five weekly text messages with educational information and influenza vaccine clinic dates. The intervention group had a 27.1% vaccine receipt as compared to 22.8% for the usual care group (RR = 1.19, 95% CI: 1.10-1.28, $p < .001$). Although the overall influenza vaccination rate remained below national goals, the findings provide initial support for the feasibility and acceptability of text messaging interventions implemented in primary care settings (Stockwell et al., 2012). Some limitations of this study were (a) the inability of the study to address parent and clinic barriers to vaccinate, (b) the use of staggered clinic dates to limit overcrowding may have caused missed opportunities to vaccinate, and (c) no theoretical framework was used to guide the intervention.

These limitations were addressed in this study by addressing influenza vaccine barriers with the parent and the clinic. This study site made vaccination convenient. The study site encouraged drop-in vaccinations, where no booked appointments were required

and also hosted an after-hours vaccination program. This should help limit missed vaccination opportunities during the study timeframe. In addition, the HBM will be used to guide this intervention.

In December 2014, the same group of researchers published a follow-up study in to their initial influenza text message reminders study (see above); however, in this study they compared an educational influenza-related text message reminder and a conventional text message reminder. They found a 10.6% (95% CI: 9.7-11.4, $p = .34$) increase in vaccination for participants who received an educational text message versus the conventional text message reminder (Stockwell et al., 2014). This recent study reinforces the importance of simple influenza education to parents.

Conclusions

The purpose of this proposed research study is to develop strategies for the prevention of influenza disease in school-age children. Text messaging may have a significant role in altering parental health beliefs regarding their child's influenza vaccination and may help to increase influenza vaccine coverage. Text messaging can be used for large populations at low cost, especially when linked to immunization registries and EHR systems (Stockwell et al., 2012). SMS text messaging reminders build on prior findings of testing reminder systems for increasing influenza vaccinations and may become the next generation of communication from healthcare provider offices to parents. It may address limitations of prior traditional (mail or telephone) reminder systems, particularly when delivering health information to low-income pediatric populations (Irigoyen et al., 2000; LeBaron, Starnes, & Rask, 2004). Feasibility and acceptability of text messaging has been established in these four studies where the

researchers tested the use of text messaging in reminding parents to complete their children's routine immunizations (Ahlers-Schmidt et al., 2010; Clark, Butchart, Kennedy, & Dombkowski, 2011; Kharbanda et al., 2010; Stockwell et al., 2012). They found that families appear to be interested in text message immunization reminders, particularly those families with unlimited text messaging plans. Text message reminders were effective in increasing routine pediatric vaccinations, although influenza vaccination was not included in these studies.

In 2010, Ahlers-Schmidt et al. also studied what low-income parents from their primary care setting wanted from text message reminders. They found that parents preferred a message containing the child's name, specific immunization information, and physician information.

Text messaging technology is a platform where public health and medical interventions can be delivered. Educational interventions delivered by this technology must be cognizant of the health literacies that patients face. Innovative, theory-based solutions incorporating popular mobile technology may bridge the gaps and reduce disparities in health (Ahlers-Schmidt et al., 2010). Text messaging technology with mobile devices can meet this need as a mechanism to address public health literacy.

There are few theory-based interventions for increasing influenza vaccination rates of school-age children, but promising results have been found when using the constructs of the HBM (Chen et al., 2011; Coe et al., 2012). No studies were found that used both an HBM-guided influenza-related intervention and confirmed receipt of the vaccine. Most studies reviewed either reported the participants' intent to receive the vaccine or relied on self-reports of vaccine receipt.

CHAPTER 3. METHODOLOGY

This chapter provides a brief restatement of the problem followed by a description of the research design and purpose. This section also contains a detailed description of the research methodology used for this study including the specific aims, method, study protocol, setting, sample intervention, data collection, and data analysis.

Restatement of the Problem

Influenza immunization rates for school-age children fall far below the current recommendation; it is not known how a theory-based text messaging educational intervention might impact the current Influenza vaccination rate.

Study Design and Purpose

This study was a randomized controlled trial (RCT) using a two-group pre- and posttest experimental design for the purpose of evaluating the preliminary effects of a theory-based intervention (SayNo2Flu). The two groups consisted of an intervention group and a control group. Participants in both the intervention and control groups received one text message per week for six weeks. The intervention group received the usual clinic care during the study, plus the SayNo2Flu program, which was a series of six weekly HBM-related influenza vaccine text messages (see Table 1). The control group received the usual clinic care during the study, plus a series of six child health-related text messages (see Table 2). Participants were randomly assigned to receive the SayNo2Flu intervention using a computer generated random selection process.

Table 1

Text Messages Based on HBM (intervention group)

HBM Construct	Context	Applied Content	Text	Measurement
Perceived susceptibility HBM flu-related survey: Questions: 1-3	An individual's assessments of their risk of getting the condition.	Flu is contagious; everyone is at risk of getting influenza.	Flu is very contagious and people carry the virus for 5 days before symptoms appear. The best way to protect your child is by getting them vaccinated.	Pretest and Posttest Timing of vaccine receipt.
Perceived severity HBM flu-related survey: Questions: 4-5	An individual's assessment of the seriousness of the condition, and its potential consequences.	Flu causes 50,000 deaths per year and 3-5 billion in healthcare costs. Also, 30-60 million infections that occur each year, most of which are amongst healthy children.	Every year flu causes 30-60 million infections, most of which are healthy children. Even healthy children are at risk if they have not been vaccinated.	Pretest and Posttest Timing of vaccine receipt.
Perceived benefits HBM flu-related survey: Questions: 6-8	An individual's assessment of the positive consequences of adopting the behavior promo.	Children experience the highest rates of influenza, shed the greatest quantities of influenza virus, and have long been recognized as vectors for spread of disease. Stopping the spread will protect many people.	Children easily spread influenza disease. Get your child vaccinated to stop the spread to your family and friends, especially new babies and grandparents.	Pretest and Posttest Timing of vaccine receipt.

Table 1, continued.

HBM Construct	Context	Applied Content	Text	Measurement
Perceived barriers HBM flu-related survey: Questions: 9-14	An individual's assessment of the influences that facilitate or discourage adoption of the promoted behavior.	Parents are concerned about the safety of vaccines and side effects.	Flu vaccine has an excellent safety record and protects millions of children without any side effects. It is a smart way to keep your child healthy.	Pretest and Posttest Timing of vaccine receipt.
Cues to action HBM flu related survey: Question 15-17	External influences promoting the adoption of the desired behavior, may include information provided or sought, reminders by powerful others, persuasive communications, and personal experiences.	Health messaging during the flu season Oct-April (media, text). Healthcare provider's recommendation is one of the strongest predictor of vaccine receipt	The flu can make your child sick enough to miss school or be hospitalized. Your doctor recommends a flu vaccine for your child, it is not too late.	Pretest and Posttest Timing of vaccine receipt.
Perceived self-efficacy HBM flu related survey: Question 18-20	An individual's self-assessment of their ability to successfully adopt the desired behavior.	Ease of vaccination, notifying parents of the availability of clinics.	Getting your child immunized against the flu is easy, with no appointment needed. Just drop by the clinic and have your child vaccinated today.	Pretest and Posttest Timing of vaccine receipt.

Table 2

Health Related-Based Text Messages (control group)

Science-based text message:	
Text 1	Keep regular (yearly) checkups for your child. Children need them even if they are not sick.
Text 2	Give your child a variety of food each day, like meats, milk, vegetables, fruits, eggs, and fish.
Text 3	Keep your kids at school and yourself at work, where you belong. When kids miss school, parents often lose work days to care for them.
Text 4	Remind your kids to wash their hands. Children share close quarters inside schools. They are constantly touching, playing, and sharing with others.
Text 5	Computer and TV take away from being physically active, try to limit your child's screen time to no more than two hours per day.
Text 6	Try to serve your child more whole grains and less added sugar daily.

The purpose was to (a) strengthen parental beliefs about perceived susceptibility to influenza disease, (b) strengthen parental beliefs about perceived benefits of influenza vaccine receipt among children, (c) decrease perceived difficulty in obtaining influenza vaccine, (d) increase healthy vaccination behaviors in parents with children who use a mobile phone, and (e) increase the children's receipt of influenza vaccine.

Specific Aims

Despite supporting evidence, numerous intervention studies have been conducted to raise vaccination rates, but still influenza vaccination rates remain low. Few theory-based intervention studies have been conducted to objectively confirm receipt of influenza vaccination in families with healthy children in a primary care setting. Most

studies reviewed relied on self-reports of vaccine receipt, not confirmation (Chen et al., 2011; Marlow et al., 2009; Nexoe et al., 1999). The primary aims of this study were to:

Aim 1. Test the preliminary effectiveness of a six-week HBM-guided intervention (SayNo2Flu) on parents' (a) perceived susceptibility (risk of getting influenza disease), perceived severity (seriousness of influenza disease), (b) perceived benefits (positive consequences of adopting the desired behavior which is influenza vaccination), (c) perceived barriers (influences that prevent adoption of the influenza vaccination such as side effects, vaccine myths, access), (d) self-efficacy (ability to successfully receive the desired behavior of influenza vaccination), and (e) cues to action (external influences promoting the adoption of the influenza vaccination), as compared to the control group.

Primary research question. Will a six-week HBM-guided intervention (SayNo2Flu) affect parents' beliefs about influenza vaccination?

Sub-question 1. What contributing factors led parents to vaccinate or not vaccinate their child? Are there significant demographic predictors (age, gender, race/ethnicity, education level, marital status, health insurance, income), health variables (child's health status), belief variables, or texting technology?

Sub-question 2. What are the differences in parental beliefs on perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action when the intervention group is compared to the control group?

Hypothesis 1. Parents in the intervention group will have a greater understanding (perception) of the severity and susceptibility of influenza disease when compared to the control group.

Hypothesis 2. Parents in the intervention group will have greater understanding (perception) of the benefits of influenza vaccination when compared to the control group.

Hypothesis 3. Parents in the intervention group will experience decreased barriers to vaccination when compared to the control group.

Hypothesis 4. Using text messaging to deliver the education intervention will activate parents' readiness to obtain an influenza vaccination for their child.

Hypothesis 5. Parents in the intervention group will have a significant difference in parental beliefs on self-efficacy when compared to the control group.

Aim 2. Confirm the preliminary effects of the SayNo2Flu program on the receipt of one or more influenza vaccine doses by the end of influenza season by one endpoint: the end of influenza season as documented in the ASIIS/electronic medical record.

Secondary research question. Will the SayNo2Flu program affect the receipt of one or more influenza vaccine doses?

Hypothesis 6. Children of parents in the intervention group will have a significant difference in the receipt of one or more vaccine doses compared to the control group.

Study Protocol

This section discusses the recruitment and retention process, consent, random assignment, and administration of instruments.

The SayNo2Flu program was designed for parents to promote influenza vaccine receipt among children and sustain influenza immunization behaviors (see Figure 1 & Figure 2). A manualized protocol was used to standardize the intervention. Strict adherence to the protocol was followed. All parent materials were provided in both English and Spanish.

Study Title: A Study to the Preliminary Effects of a Theory-Based Intervention (SayNo2Flu) Guided by the Health Belief Model, Combined with the Use of Mobile Technology on Parents' Influenza Prevention Beliefs and Behaviors in a Primary Care Setting.

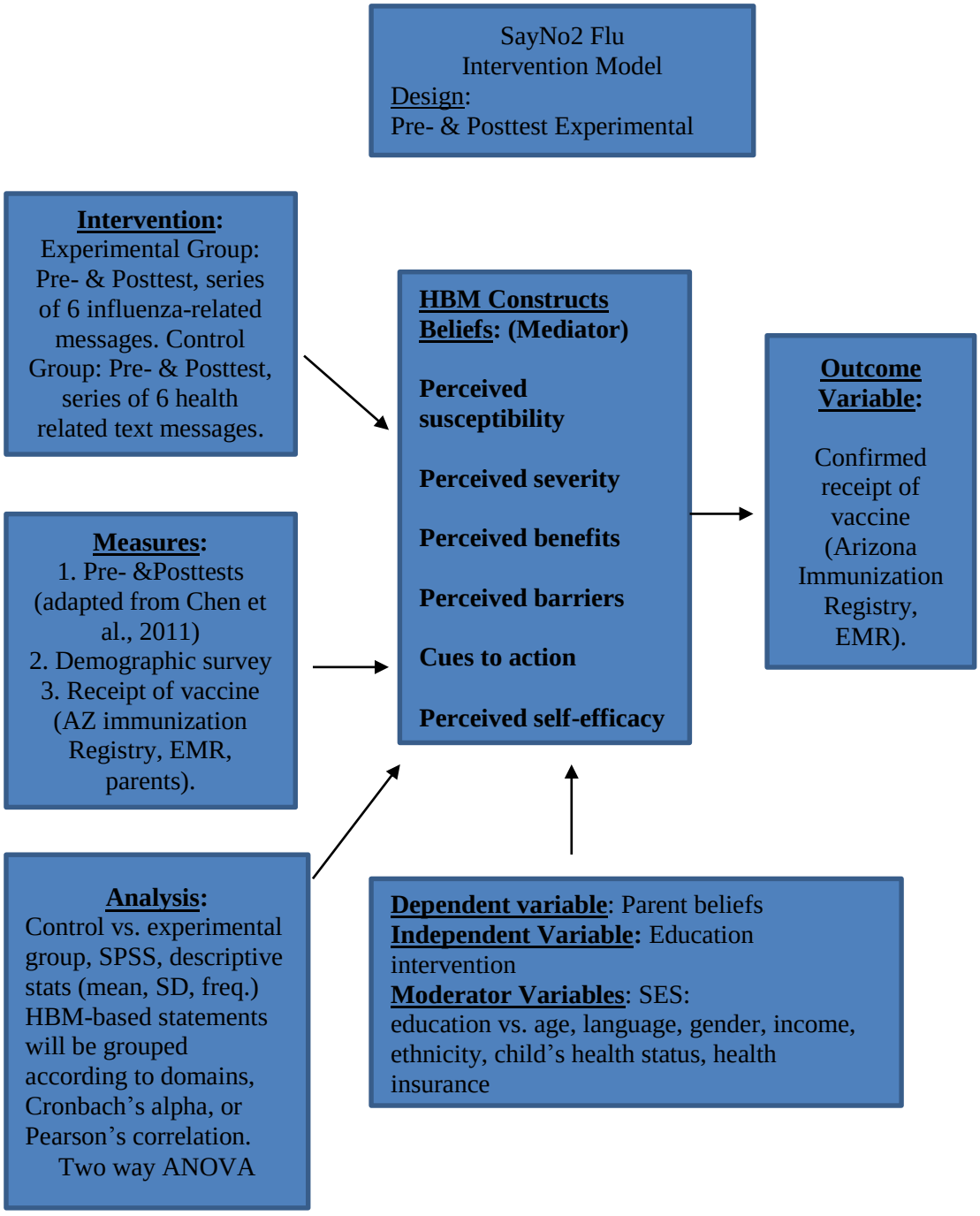


Figure 1. SayNo2Flu intervention model: Concepts and measurements.

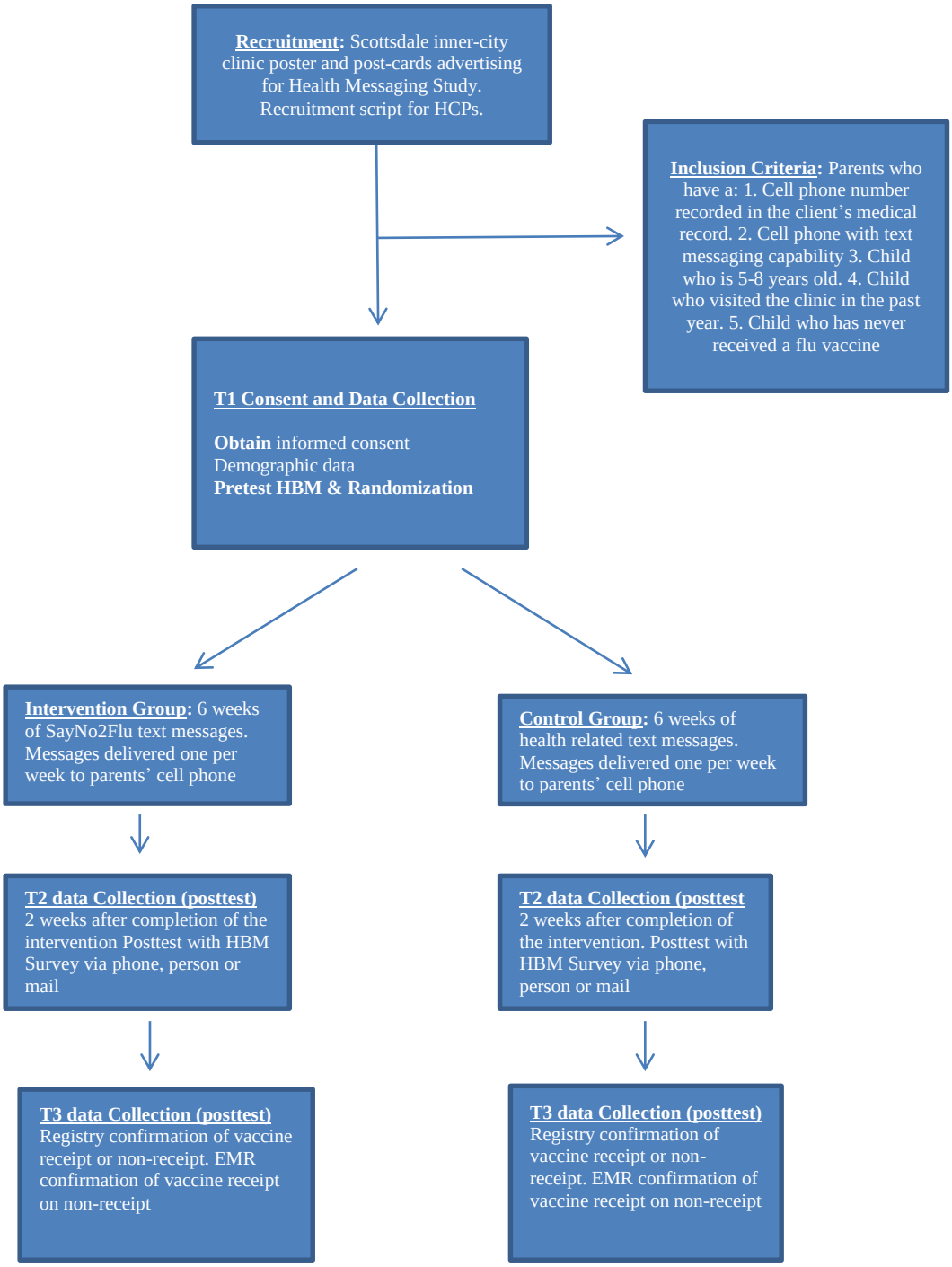


Figure 2. Study flow diagram for the SayNo2Flu theory-based intervention using mobile technology.

Setting

The study intervention was delivered at primary care clinic in Scottsdale, Arizona. This clinic provides primary care services to low-income, underserved and special populations. It is a patient-centered medical home model providing care to >30,000 pediatric patients and families. This clinic serves a primarily Latino and publicly insured population. Of those who visit the clinics, approximately 95% are eligible for free vaccines through the Vaccines for Children Program. The average daily patient census of well-child visits in the five- to eight-year age range sought for this study is 40, providing an ample pool for recruitment. The participants were made aware that the text messages were coming directly from their healthcare providers.

Sample

A convenience sample of 136 parents of children ages five to eight years who were attending the clinic for a well-child visit was used in this study. The sample size was determined to be small as this was a study with the purpose of evaluating the preliminary effects of an HBM-guided mobile-based intervention program on parental perceptions and receipt of influenza vaccine.

Power and sample size considerations. A priori power analysis was conducted via G*Power 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009). To achieve statistical significance ($\alpha = .05$), power ($> .80$), analysis requires 68 participants per group to compare the HBM construct. This study sets as a goal 68 participants per group, for a total of 136 participants. This goal allows for patient @5% attrition (Sackett, Richardson, Rosenberg, & Haynes, 1997).

Inclusion/Exclusion Criteria

Inclusion criteria: parent. To be included in this study, the parent must have (a) had a cellular phone capable of receiving text messages, (b) had a telephone number recorded in the clinic's registration system, (c) be literate in Spanish or English, and (d) provided informed consent. In addition, the parent must have had a child who met the following criteria: (a) between five and eight years of age, (b) visited the clinical sites in the previous 12 months for a wellness or minor illness visit, and (c) no previous receipt of an influenza vaccine.

Exclusion criteria. Parents were excluded from participation if they (a) had a child with a chronic illness or allergy that would preclude the child from receiving an influenza vaccination, and (b) if their child had received an influenza vaccine the prior season. If a parent had more than one child who met the inclusion criteria, the outcome variable was recorded for the oldest child.

Parents of any gender, ethnicity/race, marital status, and socioeconomic status were included, although it was expected that most of the parents would be mothers. Only one parent from each family would participate after completing a screening questionnaire to determine eligibility (see Appendix B). If both parents were present during recruitment, the parents choose whether the father or mother would participate in the study. If the parent had more than one child between the ages of five and eight years, the oldest child was chosen to participate in this study.

Rationale for inclusion and exclusion criteria. Parents of children five to eight years old were included because this age group was added to the 2008 national recommendation and this age requires two doses, four weeks apart, in vaccine-naïve

children (CDC, 2012). Parents of children who had received a previous influenza vaccine were excluded because a predictor of receiving an influenza vaccine is a prior vaccine receipt (*OR: 1.80*, CI: 1.36-2.00 $p < .001$ (Chen et al., 2011; Fiks et al., 2009).

Recruitment/Retention

Recruitment occurred during a three-month period (Nov. 1-Jan. 30). The clinic office provided a poster advertising the SayNo2Flu program. The healthcare providers and the clinic site coordinator (immunization nurse) notified parents of five- to eight-year-old children of the SayNo2Flu program and encouraged participation. The PI contacted only the parents who requested to be contacted. Screening occurred in person. If the participant met the inclusion criteria, the participant was informed of the anticipated time involvement for the study and an initial meeting was scheduled. During the initial meeting, participants were introduced to the program at the primary care clinic in a quiet, private room. The consent was obtained after explanation of the study program (see Appendix C). Each participant received an explanation of the program, reviewed text messaging functionality on their phone, had the ability to opt out, and completed the two-part pretest (Appendix E, demographics, pretest). The cover page of the survey served as the script for this study, providing both the intervention and control group participants with the same instructions relative to completing the survey correctly (see Appendix D).

Free parking or bus fare and light healthy snacks were provided. Parents in both study groups received the usual care from the staff at the study site; this included offering influenza vaccine during the office visit and an outreach automated telephone message in early November to high-risk children. Barriers to participation were minimized through the recognition of the parents' time and effort. Additionally, participants were notified

that fees accrued for the text message portion of the program (i.e., for sent/received messages from the SayNo2Flu program) would be reimbursed at a total rate of $5 ($0.10/text message for an estimated 20-30 messages), which would be included in the compensation for completing the program. Parents were also compensated $5 after completion of baseline (T1) instruments and $5 after completing the posttest (T2). The total parent stipend was $15.00 for this study.

Random Assignment

After a parent completed the screening and informed consent, the PI selected a study assignment packet. Upon opening the assignment packet, the PI entered the parent's data into the Mozeo LLC program and registered the parent to receive the intervention or control text messages. Participants were randomly assigned to receive the SayNo2Flu intervention using a computer generated random selection process using Microsoft Office Excel (Version 2010). The intervention control received randomly grouped text message sequencing, starting with text message number one for the first group.

Instruments

Three instruments were used in this study. All study documents and testing instruments were checked using Microsoft Word (Version 2015) for readability. The study documents and instruments were found to be at a 7.4 reading grade level. Microsoft Word uses Flesch-Kincaid Grade Level test. This test rates text on a United States school grade level. A score of 8.0 means that an eighth grader can read and understand the document (Microsoft, 2015).

The first instrument was a screening tool. This tool has seven questions that screen for the inclusion criteria of the study (see Appendix B).

The second instrument was the Health Beliefs Survey, a two-part pretest and posttest questionnaire (see Appendix E). This survey was developed after an extensive literature search (Chen et al., 2011; Cheney & John, 2013; Coe et al., 2012; Glanz et al., 2002; Gnanasekaran et al., 2006). The first part of the survey collected demographic information on 9 characteristics (parent's age, gender, role, marital status, education, annual income, race, child's age, child health status). Demographics for the child included age and chronic illnesses. The second part of the questionnaire assessed the health beliefs of the parents using a 17-item 5-point Likert scale. The six subscales are based on the HBM: (a) perceived severity (three items), (b) perceived susceptibility (two items), (c) perceived benefits (three items), (d) perceived barriers (six items), (e) cues to action (three items), and (f) self-efficacy (three items). Five response options are available (1 = *strongly disagree* to 5 = *strongly agree*) with higher scores on each subscale indicating higher levels of the construct. The subscale scores were calculated by summing the subscale item response scores for each participant. Prior testing has revealed acceptable alpha reliabilities for the subscales, ranging from 0.74 for perceived benefits to 0.82 for perceived susceptibility, perceived barriers, and cues to action (Chen et al., 2011).

The posttest also included a third part which had an additional four questions that assessed the participant parents' receipt of influenza vaccinations for themselves and their child. There were also two open-ended questions pertaining to the parents' experience in obtaining an influenza vaccination for their child.

Each question in the pre-and posttest questionnaire was directly comparable to that of the other and was also worded in a similar manner. Each of the qualitative questions in the third part of the posttest was also worded in a similar manner.

The third instrument was the parent evaluation of the SayNo2Flu program (see Appendix F). It included both qualitative and quantitative questions that evaluated the study. This included questions regarding the value of information provided, the use of text messaging technology to deliver the information, and any changes to the program. The control group also completed a parent evaluation of the science based text messaging program.

Text Message Content Development

In January 2013, a pilot study was conducted to strengthen the educational content of the text messages. The purpose of this pilot study was to develop and evaluate theoretically-based educational text messages for implementation in a primary care setting influenza vaccination intervention. This section describes the development of theory-based text messages for an influenza vaccination intervention for parents of five- to eight-year-old children that can be implemented in primary care settings.

The development of the text message content was guided by constructs from the HBM. This pilot study was conducted with community pediatric vaccine healthcare providers (n = 8), and parents of five- to eight-year-old children (n = 8) to evaluate the text messages content for clarity, internal consistency, and content validity. The text messages were designed to engage parents in their child's health care (specifically to increase vaccination rates) by altering their health beliefs on influenza vaccination for their child. The intent was to inform rather than just remind. One text message was

generated for each construct to keep parental burden of the number of text messages low. The design of each text message was informed by the evidence in the literature identifying factors important to parents' knowledge, beliefs and behaviors, clinical expertise, and national recommendations regarding influenza vaccinations.

Decisional processes for the development of the theory-based text messages. Several practical decisions were made about the text message intervention. Text messages would be limited to 160 characters due to the capabilities of SMS. The messages were designed to be appropriate to the literacy and language of future study participants, specifically low-income and urban parents.

A three-step process was used for developing the theory-based text messages, beginning with each construct's definition directly taken from the writings on the HBM. That definition was then translated into an applied context (step 2). The applied context was specific to influenza vaccinations and contained information that was clinically relevant for parents to consider or know about influenza or the vaccination. Evidence in the literature and practice expertise guided the selection of content in this translation phase. In the final step of the process (step 3), text messages were crafted from the applied context to fit the requirements of SMS messaging systems with an eye toward the literacy needs of potential recipients. This process resulted in six text messages, one representing each of the constructs of the HBM. See Table 3 for an illustration using one construct, perceived susceptibility.

Table 3

Illustration of 3-Step Process for Developing Theory-Based Text Messages Using the Perceived Susceptibility Construct

Steps	Process	Outcome/Result
1	Write the definition of one construct of the HBM.	Perceived susceptibility is defined as an individual's assessment of his or her risk of getting a particular condition.
2	Form the applied content by taking the construct definition and translating it to influenza-related information.	Flu is contagious; everyone is at risk of getting influenza.
3	Draft a text message of <160 characters reflecting the applied content and making it appropriate for the target population (i.e., urban and low-income parents of five- to eight-year-old children).	The flu is a contagious virus for five days before symptoms appear. The best way to protect your family is by getting everyone over six months of age vaccinated.

The text message design decisions were informed by two recent studies in the literature addressing the use of the HBM and influenza vaccine. The authors of the first study used the HBM to guide their assessment of participants' intent to receive the novel (2009) H1N1 influenza vaccine (Coe et al., 2012). This cross-sectional, descriptive study had a total of 664 adult participants who completed a self-administered questionnaire based on the HBM. The authors found that participants who perceived lower clinical barriers (*OR* = 0.57, 95% CI (0.35-0.93) and cues to action (*OR* = 0.26, 95% CI (0.11-0.62) were more likely to intend to receive the vaccine (58.1%). The researchers concluded that HBM educational interventions showed promise in positively impacting vaccination rates (Coe et al., 2012).

The second study applied the HBM to investigate factors in the decision by adult caregivers to vaccinate their children for influenza (Chen et al., 2011). This study used a cross-sectional design of 2,778 caregivers. The authors found that perceived susceptibility (*OR* = 1.24, 95% CI, 1.10-1.40) of children to influenza, perceived benefits

(*OR* = 3.10, 95% CI, 2.64-3.63) of vaccination, perceived barriers (*OR* = 0.57, 95% CI, 0.48-0.68) to vaccinations, and cues to action (*OR* = 1.19, 95% CI, 1.03-1.37) were predictors of a caregiver's decision to vaccinate. The best predictor was the response that influenza vaccines are safe (*OR* = 4.12, 95% CI, 2.9-5.92). The findings from these studies were used to ensure the content of the text messages included perceived susceptibility, perceived barriers, cues to action, and benefits of influenza disease and vaccination.

Methods

The completed text messages were evaluated in this pilot study using a descriptive design. The purpose of the descriptive design was to obtain an evaluation of the clarity, internal consistency, and content validity of the text messages as related to the HBM from the perspective of individuals with a vested interest in influenza vaccinations. The evaluation steps were important to complete prior to implementing the intervention to increase the likelihood that the text messages would be theory-based, understandable, and relevant to the target population.

IRB approval was received from Arizona State University. The participants were recruited using email recruitment and respondent driven sampling. The required aspects of human subjects' participation were explained in the introductory email and survey instructions, and consent was obtained by survey completion. This was a one-time survey, and individual responses were kept confidential. Two follow-up reminder emails were sent to non-responders.

During the winter of 2013, surveys were electronically distributed to a convenience sample of 24 participants within the pediatric vaccine community. Response

rate for the initial survey distribution was 7/24 (38%). Two reminders were sent to non-responders, two weeks apart, resulting in an overall response rate of 66% (16/24). Evaluations were completed by 16 participants who represented pediatric immunization healthcare providers who were not parents themselves (n = 3), healthcare providers who were also parents of five- to eight-year old children (n = 5), and parents of five- to eight-year-old children (n = 8). The participants included two parent participants with only a high school education who were also low-income, urban parents.

Measurement and Evaluation

Each participant completed a demographic questionnaire, questions pertaining to the vaccine experience, and three investigator-developed questionnaires assessing the clarity, internal consistency, and content validity of each of the six text messages (Imle & Atwood, 1988; Storm, Hausken, & Mikkelsen, 2010). The participants evaluated clarity by assessing whether the text message was clear or unclear. Internal consistency was evaluated by assessing the fit or degree of congruence between each item's applied content and text message. The content validity was evaluated by comparing the theoretical definition, applied content, and the text message for each item for congruence. All questionnaires included an open-ended comment section. These comments informed the revision of the original text messages (see Table 4).

Table 4

Revised Text Messages

	Text Message (Revised)	Applied Content	Definition
1.	Every year flu causes 30-60 million infections, most of which are among healthy	Flu causes 50,000 deaths per year, and 3-5 billion in healthcare cost. Also, 30-60	Perceived susceptibility is defined as an individual's assessment of his or her risk

	children. Even a healthy child is at risk if they have not been vaccinated.	million infections that occur each year, most of which are among healthy children.	of getting a particular condition.
2.	Flu is very contagious and people can carry the virus for five days before symptoms appear. The best way to protect your child is getting them vaccinated.	Flu is contagious; everyone is at risk of getting influenza.	Perceived severity is defined an individual's assessment of the seriousness of the condition, and its potential consequences.
3.	The flu vaccine has an excellent safety record and protects millions of children without any side effects. It is a smart way to keep your child healthy.	Parents are concerned about the safety of vaccines and side effects.	Perceived barriers are defined as an individual's assessment of the influences that facilitate or discourage adoption of the promoted behavior.
4.	Children easily spread influenza disease. Get your child vaccinated to stop the spread to your family and friends, especially new babies and grandparents.	Children experience the highest rates of influenza, shed the greatest quantities of influenza virus, and have long been recognized as vectors for spread of disease. Stopping the spread, will protect many people.	Perceived benefits are defined as an individual's assessment of the positive consequences of adopting the behavior.
5.	The flu can make your children sick enough to miss school or even be hospitalized. Your doctor recommends a flu vaccine for your child, it's not too late.	The flu health messaging during the flu season Oct.-April (media, text). Healthcare providers' recommendation is the one of the strongest predictor of vaccine receipt.	Cues to action are external influences promoting the adoption of the desired behavior, may include information provided or sought, reminders by powerful others, persuasive communications, and personal experiences.
6.	Getting your child immunized against influenza is easy, with no appointment needed. Just drop by the clinic and have your child vaccinated today.	Ease of vaccination, notifying parents of the availability of clinics	Perceived self-efficacy is an individual's self-assessment of ability to successfully adopt the desired behavior

Every survey received was complete with no missing data. Demographic data were analyzed using means and frequency counts. Frequency counts were used to analyze item responses in clarity, internal consistency, and content validity. Inter-rater agreement was assessed using total number of participant responses for each of the validity indicators (16 participants times six text messages = 96 evaluations) and the *Online Kappa Calculator* (Randolph, 2008). Cohen's *kappa* was an appropriate choice for analysis due to the nominal level of the evaluative data and its robustness over percent agreement calculations with agreement by chance taken into consideration. Cohen's *kappa* of $\geq$ 0.70 was considered adequate inter-rater agreement.

Results

Participant characteristics. The pilot study participants ranged in age between 30-56 years (M = 40.12), with the majority of participants female (n = 16, 81.3%). Six of the healthcare professionals provided services to school-age children including influenza vaccinations (75%), and five of the healthcare workers were also parents of five- to eight-year-old children (62.5%). When the healthcare providers were asked to rate personal knowledge about influenza vaccines, four participants (50%) rated themselves as vaccine experts and two of the participants (25%) responded that they knew more than the average person. The four participants who rated themselves as vaccine experts included a physician (key opinion leaders in the vaccine community), a vaccination nurse, and two directors of state-wide immunization coalitions. The healthcare providers were from three southwestern states (Arizona (n=6), Nevada (n=1), California (n=1)). When the parents were asked to rate their personal knowledge about influenza vaccines, seven participants (87.5%) reported that they knew about the same as an average person, and one participant

(12.5%) stated that he/she knew less than the average person. The parent participants reported either a high school education (25%) or higher education (75%). Most parents (88%) reported yearly household incomes of less than $50,000.

Clarity. Participants' evaluated clarity by responding if they found the text message was clear or unclear (see Table 5). The majority of participants evaluated the text messages as clear (85%, 82/96). Text messages 4 and 5 received the lowest clarity ratings. Participants' comments suggested (a) using the word influenza when referring to the virus and vaccine; (b) connecting the different facts in same message; (c) addressing the severity, safety, and spread of disease; (d) prioritizing family before friends in the text; (e) clarifying the timing of season; and (f) providing available flu clinics. Cohen's *kappa* for inter-rater agreement for overall clarity was acceptable at 0.75.

Table 5

Evaluation of the Clarity (Clear/Unclear) of Each Text Message

Text Messages	Clear (n)	Unclear (n)	Comments
1. The flu is a contagious virus for five days before symptoms appear. The best way to protect your family is by getting everyone over six months of age vaccinated.	15	1	1. Might consider saying: People infected with the flu virus, may be contagious up to five days before they show flu symptoms. 2. You would need to write out the five and six since it is under 10. 3. The first piece of information is not connected to the next one.
2. Every year over 20,000 children are hospitalized with the flu. Even a healthy child is at risk if he or she has not been vaccinated.	16	1	1. It is helpful to remind them that healthy individuals can suffer from the flu.
3. Most children safely receive flu vaccines and do not have any side effects. The vaccine	13	3	1. Opening with most parents might scare parents that it is not all, leaves doubt. 2. How is it made?

has an excellent safety record and is made the same way	3. Might also add in that vaccine has been safely used since 1943.

Table 5, continued.

Text Messages	Clear (n)	Unclear (n)	Comments
every year.			4. Sounds defensive (likely in response to "getting the flu from the flu shot." 5. Safety is not clearly defined is it the administration or the vaccine its self?
4. Children easily spread disease. Get your child vaccinated to help stop the spread to their friends and family members, especially new babies and grandparents.	12	4	1. Vaccinated against what? 2. School-age children are the best flu virus vectors and can have up to 40% infection rate. 3. "Disease" vs. "virus" or "illness" sounds like kids have the plague. 4. Even with the vaccine they could have the flu. 5. I would state family before friends as it gives a deeper connection for the average individual and will have them think more about it.
5. The CDC has identified the flu season from November through March. Stop the flu before it hits by getting vaccinated.	12	4	1. We recommend vaccination almost year-round. 2. Does it "stop" it? Or help prevent? 3. Sometimes even with the vaccine they could get sick. 4. The only thing is that it may be confusing to people to list those months when we start vaccinating in August as that gives them the whys to question such as "Why get vaccinated in August instead of waiting until October or November?"
6. Getting your child immunized is easy and no appointment needed. Just drop by the clinic and have your child vaccinated today.	15	1	1. Immunize against what? 2. Best to get flu vaccine as early as possible (Aug-Sept). 3. Caution some only have scheduled flu clinic, otherwise it is an appointment. 4. Short and to the point.

Internal consistency. The participants evaluated the internal consistency (fit) by responding to the degree of congruence between the applied content and the text message content. The majority of evaluations (84%, 81/96 responses) indicated strong internal consistency. Text message 5 received the lowest ratings among the six messages.

Participants' comments suggested (a) including the healthcare providers' recommendation, (b) encouraging vaccine receipt, (c) addressing the severity of disease, and (d) including the availability of flu clinics (see Table 6). Cohen's *kappa* of 0.79 was obtained, exceeding the criterion level of 0.70 for inter-rater agreement.

Table 6

Evaluation of Internal Consistency (Yes/No) for Each Text Message and Applied Content

Text Messages	Applied Content	Yes (n)	No (n)	Comments
1: The flu is a contagious virus for five days before symptoms appear. The best way to protect your family is by getting everyone over six months of age vaccinated.	Flu is contagious; everyone is at risk of getting influenza.	14	2	1. Good
2: Every year over 20,000 children are hospitalized with the flu. Even a healthy child is at risk if he or she has not been vaccinated.	Flu causes 50,000 deaths per year, and 3-5 billion in healthcare cost. Also, 30-60 million infections that occur each year, most of which are among healthy children.	13	3	1. Comment: I do not think it correlates. 2. Content doesn't mention hospitalization.
3: Most children safely receive flu vaccines and do not have any side effects. The vaccine has an excellent safety record and is made the same way every year.	Parents are concerned about the safety of vaccines and side effects.	15	1	1. Yes, consistent but not as closely related as previous texts. 2. Good, but first message doesn't encourage them to get it. 3. I think if you remove the first safety the text message is clear and no meaning is lost in the delivery.

Table 6, continued.

Text Messages	Applied Content	Yes (n)	No (n)	Comments
4: Children easily spread disease. Get your child vaccinated to help stop the spread to their friends and family members, especially new babies and grandparents.	Children experience the highest rates of influenza, shed the greatest quantities of influenza virus, and have long been recognized as vectors for spread of disease. Stopping the spread, will protect many people.	14	2	1. Health care providers are not mentioned in the text. 2. I don't think that the text message makes it clear that children experience the highest rates of influenza.
5: The Centers for Disease Control and Prevention has identified the flu season from November through March. Stop the flu before it hits by getting vaccinated.	Health messaging during the flu season Oct.-April (media, text). Health care providers' recommendation is the one of the strongest predictor of vaccine receipt.	10	6	1. Nothing about docs recommending it. 2. Yes, consistent, but not very informative of where clinics are located and are all clinics drop-in? 3. Don't understand the first message. 4. Message still seems unclear as to the content. 5. Content mentions HCP recommandation. Message does not.
6: Getting your child immunized is easy and no appointment needed. Just drop by the clinic and have your child vaccinated today.	Ease of vaccination, notifying parents of the availability of clinics.	13	3	1. Mention what vaccine is for and check that all clinics need no appointment and are just drop in. 2. Again, double check clinic, hours available may be better. 3. Hope the message has a link for parents…. 4. Which clinic? Is there a number they can call for where to go if they don't know?

Content validity. The content validity was evaluated by participants' assessing the degree to which the construct definition, applied content, and text message content were congruent. The majority of responses (94%, 90/96) indicated that the content of the text messages were congruent with the applied content and theoretical definitions. Participants' suggestions for improvement indicated the need to (a) address susceptibility and severity; (b) increase specificity about which vaccine is referenced; (c) include more information on safety and side effects; (d) consider the negative images from the word *disease*; and (e) include the healthcare providers' recommendation (rather than only the CDC's), timing of season, and when clinics are available (see Table 7). Inter-rater agreement was acceptable for the content validity (Cohen's *kappa* = 0.87).

Table 7

Evaluation of Content Validity (Yes/No) for Text Message

Text Messages	Applied Content	Definition	Yes (n)	No (n)	Comments
1. The flu is a contagious virus for five days before symptoms appear. The best way to protect your family is by getting everyone over six months of age vaccinated.	Flu is contagious; everyone is at risk of getting influenza.	Perceived susceptibility is defined as an individual's assessment of his or her risk of getting a particular condition.	15	1	1. Might consider saying: People infected with the flu virus, may be contagious up to five days before they show flu symptoms. 2. Symptoms can appear five days prior...could vary per individual. 3. Making note that an individual's risk may be higher than another's, however... 4. The section about how children shed viruses really sent a message about risk. 5. The message is clear.

Table 7, continued.

Text Messages	Applied Content	Definition	Yes (n)	No (n)	Comments
2. Every year over 20,000 children are hospitalized with the flu. Even a healthy child is at risk if he or she has not been vaccinated.	Flu causes 50,000 deaths per year, and 3-5 billion in healthcare cost. Also, 30-60 million infections that occur each year, most of which are among healthy children.	Perceived severity is defined an individual's assessment of the seriousness of the condition, and its potential consequences.	16	0	1. Applied content and text are too different although the definition does apply to both. 2. Stating that in typical flu season 100 children die due to flu infection, and more than half were previously healthy children. 3. The message is clear. 4. Include how many of the 20,000 are reported deaths of flu.
3. Most children safely receive flu vaccines and do not have any side effects. The vaccine has an excellent safety record and is made the same way every year.	Parents are concerned about the safety of vaccines and side effects.	Perceived barriers are defined as an individual's assessment of the influences that facilitate or discourage adoption of the promoted behavior.	15	1	1. I would start with flu vaccine is safe with few side effects, has an excellent safety record and is made the same way every year. 2. It all related but I still do think it would be effective marketing to parents. 3. Yes; might also add in that vaccine has been safely used since 1943. 4. To my understanding, even with the vaccine they could get sick with the flu. 5. Remove the first listed safely as it is confusing to the meaning of the text message. 6. Possibly how they have a higher risk of getting the flu than having side effects from the vaccine (if this is so) to compare. 7. May consider sharing that there are more bad effects from unvaccinated kids vs. getting vaccinated and

Table 7, continued.

Text Messages	Applied Content	Definition	Yes (n)	No (n)	Comments
					having a small risk of a reaction to the vaccine. 8. Perhaps statistical evidence…& children's documented side effects.
4. Children easily spread disease. Get your child vaccinated to help stop the spread to their friends and family members, especially new babies and grand-parents.	Children experience the highest rates of influenza, shed the greatest quantities of influenza virus, and have long been recognized as vectors for spread of disease. Stopping the spread, will protect many people.	Perceived benefits are defined as an individual's assessment of the positive consequences of adopting the behavior.	15	1	1. Mention what the vaccine is for? 2. I really think it would be helpful to state that children experience the highest rates of influenza. 3. Again – wording. Instead of disease maybe "virus". Also negative kid image. 4. I would list family before friends as mentioned previously. 5. There doesn't seem to be a clear correlation between the definition and applied content.
5. The CDC has identified the flu season from November through March. Stop the flu before it hits by getting vaccinated.	Health messaging during the flu season Oct.-April (media, text). Healthcare providers' recommend ation is the one of the strongest predictor of vaccine receipt.	Cues to action are external influences promoting the adoption of the desired behavior, may include information provided or sought, reminders by powerful others, persuasive communi-cations, and personal	15	1	1. Pediatricians and the CDC recommend all children get a flu vaccine especially during the peak season from Oct. to March. 2. The text message suggests that waiting till flu season to get vaccinated is acceptable. Should consider rewording to promote late summer flu vaccination. 3. Prevent vs. stop. 4. It's confusing, media set the season Oct.-April, the Centers set Nov.-March. Docs and healthcare providers prevent with a month ahead and a month

Table 7, continued.

Text Messages	Applied Content	Definition	Yes (n)	No (n)	Comments
		experiences.			after. 5. The definition is too high level need to bring it down to 8th grade literacy. Most would not understand cues to action and they can also be internal. Reminders by powerful others is really unclear who the power is from and you do not want to use persuasive in communications being informative is great, but ultimately they need to make the choice and not out of fear of the deliver from someone. 6. Your applied content is inconsistent as you listed previous flu season from Nov.-March in the text message.
6. Getting your child immunized is easy and no appointment needed. Just drop by the clinic and have your child vaccinated today.	Ease of vaccination, notifying parents of the availability of clinics.	Perceived self-efficacy is an individual's self-assessment of ability to successfully adopt the desired behavior.	15	1	1. Mention what vaccine is for. 2. Could offer public health offices, health fairs, and pharmacies…lots of options. 3. Will you be having the family read any of the definitions? If so...make the verbiage much simpler to read and comprehend as they are high level definitions. 4. Just hoping there's a link for parents to locate clinic and hours. 5. It is great if they have free clinics for immunizations because people don't want to take their children to the dr. during the flu season to get vaccinated because they will end up getting sick. So then the child doesn't get vaccinated or some insurances don't cover well visits for kids.

Table 7, continued.

Text Messages	Applied Content	Definition	Yes (n)	No (n)	Comments
					6. Don't see the correlation between ease of appointments and self-efficacy.

Discussion

The theory-based influenza-related text messages were evaluated by participants as clear with valid content and good internal consistency. The themes that arose from the comment sections to help strengthen the content of the text messages were consistent with previously published literature on benefits and barriers to vaccination (Bhat-Schelbert et al., 2012; Ranney et al, 2014; Salmon et al., 2005). The most common themes were (a) vaccine side effects and efficacy, (b) healthcare providers' recommendation, (c) severity of disease, (d) name of vaccine, and (e) availability of flu clinics. The HBM is an appropriate model for vaccination intervention research because its constructs can guide interventions to address the participants' comments/themes that were found in this study. A few comments indicated a preference for a healthcare provider recommendation in addition to or in place of CDC recommendations. This recommendation is consistent with several studies that have found that a healthcare provider's recommendation is one of the strongest predictors of influenza vaccine receipt (Bhat-Schelbert et al., 2012; Cheffins et al., 2011; Gnanasekaran et al., 2006; Soyer et al., 2011; Taylor et al., 2002). Each participant's comments on clarity, internal consistency, and content validity were evaluated, and the text messages were revised for further testing (see Table 4).

Limitations

In this pilot study, there are several limitations that inform the results. Even thought, most of the participants were parents of children within the target age range for the intervention, this sample consisted of participants who were fairly well informed regarding influenza vaccinations. All parent participant had a high school education or higher. The evaluation questions included fixed response questions that were written in English and administered in three southwestern states. These factors, when combined with the small sample of mostly female participants, may have biased the evaluation of the text messages. As such, the results may not be generalized to other populations as further testing may be needed in other diverse populations. Demographic variables were not included that might be important to consider in future investigations that may also impact health literacy, such as race/ethnicity or religion.

Pilot Study Conclusions

The purpose of this pilot study was to develop and evaluate theory-based educational text messages for implementation in a primary care setting influenza vaccination intervention. Participant evaluations suggest that the development methods were successful in creating a theory-based educational intervention that garnered community investment and met the cultural relevance and literacy needs of the priority population. The development of an effective, theory-based educational intervention that will be well received by the priority population is a fundamental step toward achieving increased influenza vaccination rates. The results of this pilot investigation were used to modify and strengthen the educational text messages and made them ready for efficacy testing in this study.

Intervention

Customized text messages for the intervention and control groups were sent using the Mozeo LLC program, a computer to mobile text messaging company that has demonstrated success through such partnerships as College Nannies and GWEC Ministries (Mozeo.com, 2014). Participant confidentiality was secured by Mozeo's privacy policy and the PI.

Participants in the intervention and control groups received one message per week for six weeks. The messages were personalized in English or Spanish, based on the parents' language preference. Study participants were given the option to opt out at any time by texting the word *stop* in response to a text message. The parents were still included in the study results if they chose to opt out from receiving the text messages.

The intervention group received the usual clinic care during the study, plus the SayNo2Flu program, which was a series of six weekly HBM-related influenza vaccine text messages (see Table 1). The control group received the usual clinic care during the study, plus a series of six child health-related text messages (see Table 2).

Participants from both groups completed a posttest within one to two weeks after completion of text messages series. The posttest was administered via phone or in person by the PI. The intervention group's text messages were HBM-guided messages addressing vaccine safety and the seriousness of influenza disease. The messages also informed parents that they did not need an appointment for an influenza vaccination; they could come to the office anytime during office hours (day and evening) between October 2014 and March 2015.

The intervention and control group text messages were delivered weekly (one message per week for six weeks), which is consistent with similar intervention protocols achieving positive effects (Stockwell et al., 2012). Pretest and posttest data collection occurred at baseline (T1) and immediately following (T2) the completion of the six-week intervention (within one-two weeks).

The same questionnaire was used for the pre- and posttest surveys (see Appendix E). Actual receipt of influenza vaccine will be measured at the completion of the influenza season (March 31).

Training

The PI was responsible for all parent training, data collection, informed consent, study enrollment, and confidentiality. All parent participants were provided a brief training on the text message function on their mobile phones during the initial intervention information session. The training was delivered on-site in the study's clinic by the PI. Training was tailored to the parent participants' comfort level with obtaining and reading text messages on their mobile phones. Spanish translators were available to assist with explanations and instructions.

The PI sent a test text message to participants during the initial session to confirm the correct phone number is entered into the system and that the message was delivered and was able to be opened by the participant parent. The PI ensured that all participants were capable of and comfortable using the text messaging feature on their phones prior to the intervention implementation.

Data Collection

Files were established in a locked cabinet in the PI's office for collected measures from all subjects. The participants were assigned an identification number that was used for all instruments, and a master codebook was stored separately both electronically encrypted and hardcopy locked. The coded data collection forms were completed at each measurement time (T1-T2) and were reviewed for missing information. Throughout the data collection process, the PI reviewed measures for missing data and clarified with the participant the reason for missing data. The participants were allowed to complete any missing questions or indicate if they would prefer not to answer the question.

SPSS-22 software was used to analyze the data. The PI entered and verified against raw data forms (hard copy) all data in SPSS-22. The data were protected using computer anti-virus software and hacking protection, password protection for systems and files, and frequent backup and archiving of information. Descriptive statistics of the sample was summarized and reported. Means and standard deviation (SD) for continuous variables was also reported to ensure the quality of the data. In addition, Cronbach's alpha was run on the HBM survey to determine internal consistency and reliability.

The measurement times and intervention implementation were analogous for both the intervention and control group. The pre- and posttest surveys contained no identifiable patient information. The clinic's Spanish translator provided the back translation of all study tools to ensure equability of the meanings. The surveys were also pretested two times with office immunization staff from the clinic for readability, comprehension of instructions, clarity, and for Spanish-back translation. The Spanish

documents were transcribed by a parent of a five-year-old child who was fluent in Spanish (both spoken and written).

Variables and Measures

Table 8 summarizes the demographic, mediating, and outcome variables that were measured using standardized questionnaires and procedures.

Table 8

Measures for Data Collection with Parents of Five- to Eight-Year-Olds

Aim	Construct	Instrument	Data Collection	Cronbach's Alpha
1	Demographics	Demographic Questionnaire	T (0) Baseline	
1	Parent Beliefs: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action (mediating variable)	Pretest HBM Survey Posttest HBM Survey	T1, T2	0.74 – 0.82
2	Vaccine Receipt (outcome variable)	Parent text confirmation AZ Immunization Registry confirmation/EMR	T3	
1	Satisfaction with intervention/text program	Satisfaction survey	T2	

Data Analysis

This section discusses the analysis for Aim 1, which was to test the preliminary effectiveness of a six-week HBM-guided intervention (SayNo2Flu). This analysis (a) compares the difference between the intervention and control groups; and (b) evaluates the constructs of perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and cues to action. The pre- and posttest questionnaire results were coded and analyzed using SPSS-22. Descriptive statistics were used for the demographic data and health belief survey items. Reliability testing was conducted using Cronbach's alpha for the health belief survey items. The HBM-based statements were grouped according to domains of (a) perceived susceptibility to the disease, (b) perceived severity of the disease, (c) perceived benefits to vaccination, (d) perceived barriers to vaccination, (e) cues to action, and (f) vaccine self-efficacy. Cronbach's alpha was calculated to assess for the domain's reliability. Repeated measures ANOVA was performed to determine a statistically significant difference between the intervention and control group at pre- and posttest survey responses independently. To control for potential confounding effects, analysis was adjusted for all significant demographic predictors. The variables of interest to be examined included parent demographic, health, and belief variables. The demographic variables included (a) age, (b) gender, (c) race/ethnicity, (d) highest level of education level, (e) marital status, (f) health insurance, and (g) income. The health variables were the child's health status, and the belief variables included the HBM constructs. The outcome variable included vaccine receipt.

Analysis for Aim 2

This section discusses the analysis for Aim 2, which was to evaluate the preliminary effects of the SayNo2Flu program on the receipt of one or more influenza vaccine doses by the end of influenza season. This aim had one endpoint, vaccine receipt at the end of the influenza season as documented in the child's medical record and/or Arizona Immunization registry called ASIIS. ASIIS is a statewide immunization registry and health care providers are mandated under Arizona Revised Statute (ARS) §36-135 to report all immunizations administered to children from birth to 18 years of age to the state's health department (Arizona Department of Health Services, 2015). Influenza vaccine administration is reported to the ASIIS system during claims processing, which usually occurs weekly. These data are available for immediate viewing, as the credentialed entity has access to the system. The office staff prepared a vaccine receipt data report for all study participants.

The outcome variable was dichotomized using Yes (received vaccine) and No (not received). Hierarchical logistic linear regression using maximum likelihood method was performed to determine the contributing factors of vaccination after six-week intervention and the end of influenza season controlling for variables in the model.

Variables entered for the model were those significant variables based on correlations in each factor of the model framework. Maximum likelihood estimation maximizes the log likelihood to reflect odds in which the observed values of the dependent variable may be predicted from the observed values of the independent variable. The Wald test was used to determine the significance of individual logistic regression coefficients for each independent variable. The odds ratio using a 95% CI for

the dependent variable (child vaccination) was calculated. The overall fit of logistic regression was tested in each step using Hosmer and Lemeshow Chi-square test of goodness of fit. Unstandardized logistic regression coefficients were used to simply estimate parameters and predict the log odds (logit) of the dependent variables in the model. The Cox and Snell and Nagelkerke's R^2 calculations were used to determine the explanatory fit of the modeling.

CHAPTER 4. DATA COLLECTION AND ANALYSIS

This chapter provides a brief restatement of the study design and purpose followed by a detailed description of the data collection and analysis process. The data analysis was based on the aims of the study and also includes a report of the survey results. Comparisons were drawn from the results of the intervention and control groups' perceptions of influenza disease and vaccination for their child. Comparisons were also drawn from the results between the intervention and control group influenza vaccination rates.

Restatement of the Study Design and Purpose

The study design was an RCT using a two-group pre- and posttest experimental design. The purpose of this design was to test if a theory-based intervention (SayNo2Flu) guided by the HBM combined with the use of mobile technology (SMS text messaging) would change parents' influenza vaccination beliefs and behaviors.

The two groups consisted of an intervention group and a control group. The intervention group received Influenza related clinic care during the study and the SayNo2Flu program, which was a series of six weekly HBM-related influenza vaccine text messages (see Table 1). The control group received the usual Influenza related clinic care during the study, plus a series of six child health-related text messages (see Table 2).

Data Collection

De-identified demographic data were gathered to describe the target participants. Data were gathered through three primary means: (a) manually (handwritten) through survey instruments, (b) patients' electronic chart, and (c) ASIIS vaccine registration system. The same pre- and posttest HBM survey was used for both the experimental and

control groups. The two targeted parent groups were enrolled at the Scottsdale primary care satellite clinic sites. The satellite clinic sites were located at two inner city public elementary schools.

Variables and Measures

Table 8 summarizes the demographic, mediating, and outcome variables that were measured using standardized questionnaires and procedures.

Study Protocol

This section discusses the recruitment and retention process, consent, random assignment, and administration of instruments. A manualized protocol was developed to standardize the intervention. Strict adherence to the protocol was followed. All parent materials were provided in both English and Spanish.

Sample

The targeted participants came from a convenience sample of 136 parents of children aged five to eight years old who were patients at the Scottsdale primary care clinic and met inclusion criteria. The inclusion criteria included parents who have (a) a cell phone number recorded in the patient's medical record, (b) a cell phone with text messaging capabilities, (c) a child who is five to eight years of age, (d) a child who visited the clinic in the past year, and (e) a child who has never received an influenza vaccination. The goal was that by targeting this group of parents, they would be able to base their answers on their past and current experiences with vaccinating their child for influenza.

Recruitment/Retention

Recruitment occurred during a three-month period (Oct. 15-Jan. 15, 2015). The participants were introduced to the program and consent was obtained after explanation of the study program. The cover page of the survey served as the script for this study and provided both the intervention and control group participants with the same instructions relative to completing the survey correctly. Parent participants in both study groups received the usual Influenza related clinic care from the staff at the study site; this included being offered influenza vaccination during their office visit and an outreach automated telephone message in early November to parents of high-risk children. Parents were compensated $5 after completion of baseline (T1) instruments and $5 after completing posttest (T2).

Random Assignment

The PI randomly assigned participants to receive the SayNo2Flu intervention using a computer-generated random selection process (Microsoft Excel, Version 2010).

Intervention

Participants in the intervention and control groups received one message per week for six weeks starting in mid-November. The same questionnaire was used for the pre- and posttest surveys (see Appendix E). The pretest was completed at the clinic at the same time as enrollment. The posttest was administered via phone and/or in-person by the PI.

Instruments

As described in Chapter 3, the questionnaires used were primarily derived from several other studies (Chen et al., 2011; Cheney & John, 2013; Coe et al., 2012; Glanz et al., 2002; Gnanasekaran et al., 2006), and modified for the purpose of this research. The

first part of the survey collected demographic information on 18 characteristics (parent's age, gender, role, marital status, education, annual income, and race).

The second part of the questionnaire assessed the health beliefs of the parents using a 17-item Likert scale. There are six subscales based on the HBM: (a) perceived susceptibility (3 items), (b) perceived severity (2 items), (c) perceived benefits (3 items), (d) perceived barriers (6 items), (e) cues to action (3 items), and (f) self-efficacy (3 items). The posttest included a third part which had an additional four questions that assessed the participant parents' experience with influenza vaccinations for themselves and their child. Two of these questions were open-ended. The reason for the open-ended questions was to provide greater detail regarding parent perceptions towards vaccination that were not addressed in the survey (see Appendix E).

Data Collection

The data collection process began mid-November after IRB approvals from Scottsdale Healthcare and Arizona State University were granted. The PI established files in a locked cabinet and the participants were assigned an identification number that was used for all instruments and files. The master codebook was stored both electronically encrypted and hardcopy locked. Throughout the data collection process, the instruments were reviewed by the PI for missing data and clarified with the participant as to the reason for missing data. Quantitative data are presented in a summary format. Qualitative data do not include the identity of the individual comments. Data will be destroyed after two years of retention at the PI's office per the IRB protocols.

Data gathered through the survey were initially placed in a Microsoft Excel (Version 10) spreadsheet and then the quantitative data was moved to SPSS Version 22.0

software to analyze the data. The PI entered and verified against raw data forms (hard copy). The data were protected using computer anti-virus software and hacking protection, password protection for systems and files, and frequent backup and archiving of information. Descriptive statistics were used to determine the mean, median, max, and min for each category: (a) gender, (b) age and race, (c) marital status, and (d) income level. Paired *t*-tests were performed comparing each survey domain to determine statistical significance. The qualitative data from each questionnaire were complied, sorted, and analyzed for common themes using the Miles and Huberman noting patterns and themes methods when drawing and verifying conclusions (Miles & Huberman, 1994).

Of the target sample (n = 136), 100% parents completed the pre-survey and 96% parents (n = 131/136) completed the post-survey. Of the original number of target number of parents for each group (n=68 per group), the post-survey response rate was 98% (n = 67/68) for the experimental group and 94.1% (n = 64/68) for the control group.

Data Analysis

The remainder of Chapter 4 is organized into three data analysis groups: (a) demographic data, (b) quantitative data, and (c) qualitative data. Multiple imputation was used to account for missing data. This method averages the outcomes across multiple imputed data for this analysis. The amount of missing data was found to be random. Initially, frequencies were analyzed looking for missing data. This was then followed by an analysis of descriptive statistics for demographic data and health belief survey items. This was followed by correlations, and highly correlated variables to vaccinations were then further analyzed using paired *t*-tests, Univariate ANOVA, repeated measures

ANOVA, and hierarchical logistic linear regression. Means and SD for all continuous variables were reported to ensure the quality of the data. In addition, Cronbach's alpha was obtained on each HBM survey domain to determine their internal consistency reliability. This analysis was based on the study aims.

Demographic Data

The variables of interest examined were parent demographics and health variables. The demographic variables include (a) age, (b) gender, (c) race/ethnicity, (d) highest level of education level, (e) marital status, (f) health insurance, and (g) family income. The health variable included in the demographic data was the child's health status. The purpose of this information was to present a general picture about the types of parents enrolled in each group.

Table 9

Total Group Demographics

Groups		
Variable	*N*	Percentage
Total # of parents	68	50%
Age		
< than 30	34	25%
< than 40	73	54%
< than 55	11	21%
Medium	35	
Range	24-55	
Gender		
Female	128	94%
Male	8	6%
Ethnicity		
Non-Hispanic white	3	2.5%
Black	1	.5%

Hispanic	132	97%

Table 9, continued.

Groups		
Variable	*N*	Percentage
Language		
English	8	6%
Spanish	128	98%
Legal Guardian		
Father	7	4.5%
Mother	127	94%
Grandmother	2	1.5%
Education		
Elementary	9	7%
High school	102	75%
Some college	16	12%
College/university	5	3.7
Marital status [a]		
Married	93	69%
Single	42	31%
Family Income [b]		
Less than $10,000	63	51%
$10,001-25,000	43	35%
$25,001-$40,000	9	7%
$40,000 and above	8	7%
Child Age		
5 years	27	19%
6 years	32	24%
7 years	35	26%
8 years	42	31%
Child Medical History		
Healthy	111	82%
Asthma/Lung	13	10%
Cardiac	7	6%
Other	5	2%

Note. Missing marital status=1; family income=13

The ethnicity data reflect the population of the area in which the satellite clinics were located. The ratio of female to male parents reflects the current primary care clinic parent trends, where the mother was the most frequent legal guardian. The age may be considered typical for parents of five- to eight-year-old children. If parents had more than one child who were five to eight years of age, the oldest child was included in the study. The total group parents had a high school education or less (78%). Also, 51% of the parents had a total family income less than $10,000. Most of the parents reported their children were healthy (82%).

Bivariate Correlations

Bivariate correlations were conducted to look at the relationships the demographic, health, belief variables and vaccine receipt. Pearson's product coefficient was designed to test the relationships between the interval and continuous level variables. The PI was testing the null hypothesis that no relationship exists between vaccination and demographic, health, or belief variables.

Initially, a scatter plot was checked to assess for violations of assumptions such as linearity and homeoscedastity. The inspection of the scatter plots would also indicate the nature of the relationships between the variables.

Table 10
Pearson's Correlations

Variable		Age	Parent	Ethnicity	Education	Marital Status	Income
Group	Pearson's Correlation	.260**	-1.83**				
	Sig 2-tail	0.002	0.033				
	N	136	136				

Age	Pearson's Correlation	0.260*				
	Sig 2-tail	0.018				
	N	136				
Language	Pearson's Correlation			0.324*		
	Sig 2-tail			0.033		
	N			136		
Gender	Pearson's Correlation	0.407**				
	Sig 2-tail	0				
	N	136				
Marital Status	Pearson's Correlation	-0.215*				0.264**
	Sig 2-tail	0.012				0.003
	N	136				127
Education	Pearson's Correlation		-0.323**			0.199**
	Sig 2-tail		0			0.03
	N		128			119
Income	Pearson's Correlation	-0.278*	-3.00**	0.199**	0.264**	
	Sig 2-tail	0.002	0.001	0.03	0.003	
	N	127	127	119	127	

Correlation is significant at the 0.01 level (2-Tail) **

Correlation is significant at the 0.05 level (2-Tail) *

Numerous variables indicated strong correlations to vaccine receipt. The positive correlations were (a) age, (b) language, (c) gender, (d) educational level, (e) income, (f) pretest susceptibility, (g) pretest benefits and (h) posttest cues to action. The negative correlations were (a) marital status, (b) ethnicity, and (c) parent.

Analysis for Study Aim 1

This section discusses the analysis for Aim 1 which is to test the preliminary effectiveness of a six-week HBM-guided intervention (SayNo2Flu). This analysis
(a) compares the difference between the intervention and control groups; and
(b) evaluates the constructs of perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy.

Primary research question. Will a six-week HBM-guided intervention (SayNo2Flu) affect parents' beliefs about influenza vaccination?

What contributing factors led parents to vaccinate or not vaccinate their child? Are there significant demographic predictors (age, gender, race/ethnicity, education level, marital status, health insurance, income), health variables (health status), belief variables, or texting technology?

Sub-question 2. What are the differences in parental beliefs on perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy when the intervention group is compared to the control group?

Hypothesis 1. Parents in the intervention group will have a greater understanding (perception) of the severity and susceptibility of influenza disease when compared to the control group.

Hypothesis 2. Parents in the intervention group will have greater understanding of the benefits of influenza vaccination when compared to the control group.

Hypothesis 3. Parents in the intervention group will experience decreased barriers to vaccination when compared to the control group.

Hypothesis 4. Using text messaging (cues to action) to deliver the education intervention will activate parents' readiness to obtain an influenza vaccination for their child.

Hypothesis 5. Parents in the intervention group will have a significant difference in parental beliefs on self-efficacy when compared to the control group.

Reliability Testing

Reliability testing was conducted using Cronbach's alpha for health belief survey items. The HBM-based statements were grouped according to domains of (a) perceived susceptibility to the disease, (b) perceived severity of the disease, (c) perceived benefits to vaccination, (d) perceived barriers to vaccination, (e) cues to action, and (f) vaccine self-efficacy. Cronbach's alpha was calculated for the domains and found to be .889 for the HBM pre-test/post-test study instrument.

Table 11

Reliability Scale: Cronbach's Alpha

	Cronbach's Alpha	Mean	Variance	Std. Deviation	n of Items
Total (pretest & posttest)	.88	37.45	48.29	6.80	12
Pretest	.75				6

Posttest	.77				6
Pretest severity	.76	9.79	7.28	2.7	2
Posttest severity	.69	8.04	2.40	1.5	2
Pretest susceptibility	.45	5.35	3.38	1.8	2
Posttest susceptibility	.33	5.45	3.03	1.7	2
Pretest benefits	.71	9.56	5.75	2.4	3
Posttest benefits	.75	10.34	6.54	2.5	3
Pretest barriers	.54	15.32	13.18	3.6	6
Posttest barriers	.63	16.22	16.36	4.0	6
Pretest cue to action	.76	9.63	8.39	2.8	3
Posttest cue to action	.75	11.45	5.02	2.2	3
Pretest self-efficacy	.38	8.85	4.56	2.1	3
Posttest self-efficacy	.41	10.29	3.87	1.9	3

Initially, pooled *t*-tests were conducted to determine if there was a difference in the means between the pretest and the posttest scores for all domains. Paired sample test were conducted to look within subjects. Univariate ANOVA was then conducted to look at the between subjects for the intervention group only. To control for confounding effects, the analysis was adjusted for all significant demographic predictors. The outcome variable was vaccine receipt. The results are shown in Table 13. This was then followed by a repeated measures ANOVA to determine if there was a difference in intervention and control group pretest/posttest scores.

The results of the paired sample *t*-test were conducted to evaluate whether a statistically significant difference existed between the mean pretest and posttest scores after text messaging intervention. Assumption testing indicated no gross violations of assumptions. The results of the paired sample test were significant, indicating there is a significant increase from the pretest and posttest scores. This indicates a rejection of the null hypothesis. As indicated in Table 12, there is a statistically significant difference demonstrated by the data for the primary research question for this study. It was hypothesized there would be a statistically significant difference between the intervention group and the control group. Therefore, the researcher analyzed the pretest and posttest survey questions and determined significant domain groupings of the questions aimed at providing greater detail that could answer the research question and hypothesis. The data indicate that all of the six domain groupings (pretest/posttest) were statistically significant. A deeper analysis of these results will be presented in Chapter 5.

Table 12

Primary Research Questions Group Statistics and t-Test Summary

	Mean	N	Std. Deviation	T	Df	Sig. (2-tailed)	Partial ETa Squared
Pretestseverity – Postestseverity	3.39 3.72	132 132	1.0439 1.1020	-8.81	131	.000	.545
Pretestsuscept – Postestsuscept	2.63 2.66	132 130	1.0264 .85489	-2.34	129	.000	.028
Pretestsbenefits – Postestsbenefits	3.26 3.46	130 130	.78358 .85835	-6.80	129	.000	.057
Pretestsbarriers – Postestsbarriers	2.63 2.63	130 130	.62015 .62088	-6.68	134	.000	.337
Pretestscuestoaction – Postestscuestoaction	3.22 3.57	129 129	.91760 .86922	-6.90	128	.000	.041
Pretestsselfeff – Postestselfefficacy	3.03 3.31	129 129	.74982 .65807	-9.03	128	.000	.131

The *t*-test analysis was followed by univariate ANOVA and then repeated measures ANOVA analysis analyzing between subjects. Initially, for the univariate ANOVA the pretest and posttest variables were transposed to create a difference variable. This variable included the intervention group posttest scores minus the intervention group pretest scores, allowing analysis of the difference between pre- and posttest scores. The fixed factors were the intervention and control groups. The covariates examined were age, gender, ethnicity, education level, and income.

Primary research question. Will a six-week HBM-guided intervention (SayNo2Flu) affect parents' beliefs about influenza vaccination? Yes, this study found that a theory-based intervention (SayNo2Flu) guided by the HBM, combined with the use of mobile technology (SMS text messaging) would change parents' influenza vaccination beliefs.

Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were significant for follow up comparisons for group by time for the domain of perceived severity (F=137.25, p<.001, cues to action *(*F=38.58, p<.001), and perceived self-efficacy *(*F=15.26, p<0.001). The domains of perceived benefits (F=0.252, p<.65) and perceived barriers *(*F=0.117, p<.073) were not significant, however they did indicate an increase in scores (see Figure #3, SPSS Plots). These results will further be discussed in Chapter 5.

Sub-question 1. What contributing factors led parents to vaccinate or not vaccinate their child? Are there significant demographic predictors (age, gender, race/ethnicity, education level, marital status, health insurance, income), and health

variables (child's health status). This study found no significant demographic or health status variables as predictors of influenza vaccination. These results will be discussed in greater detail in conjunction with qualitative data to better determine significance in Chapter 5.

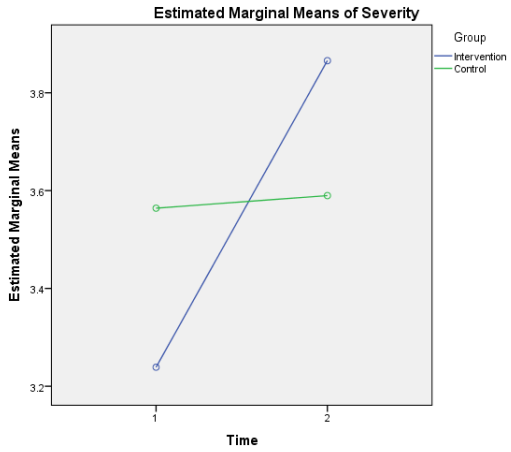
Table 13

Sub-Question 1 Group Statistics and Repeated Measures ANOVA Summary

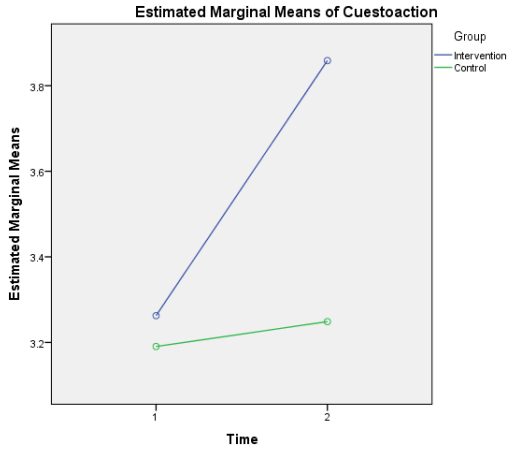
Variable	Time	F	Sig.	Partial Eta
Severity	Time	161.66	0.00	0.926
	Group by time	137.25	0.00	0.514
Susceptibility	Time	3.099	0.81	0.901
	Group by time	.402	0.52	0.011
Benefits	Time	2.588	0.00	0.946
	Group by time	0.190	0.67	0.002
Barriers	Time	46.98	0.00	0.944
	Group by time	0.021	0.88	0.001
Cues to action	Time	57.09	0.00	0.942
	Group by time	38.58	0.00	0.040
Self-efficacy	Time	89.91	0.00	0.954
	Group by time	15.267	0.00	0.001

Figure # 3: Repeated Measures, SPSS Outputs (plots)

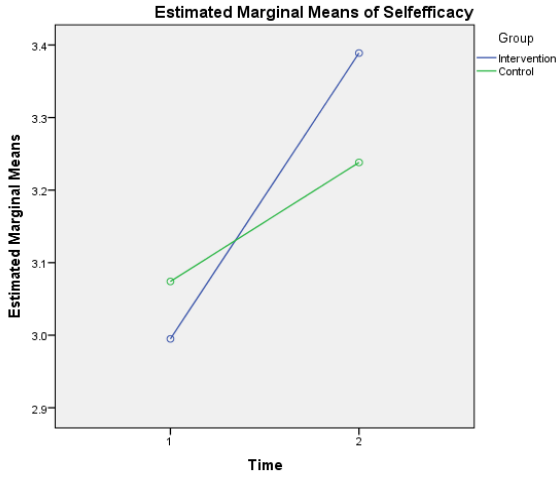
Perceived Severity



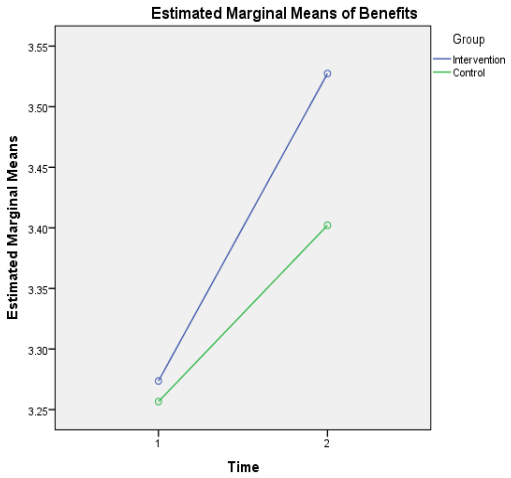
Perceived Cues to Action



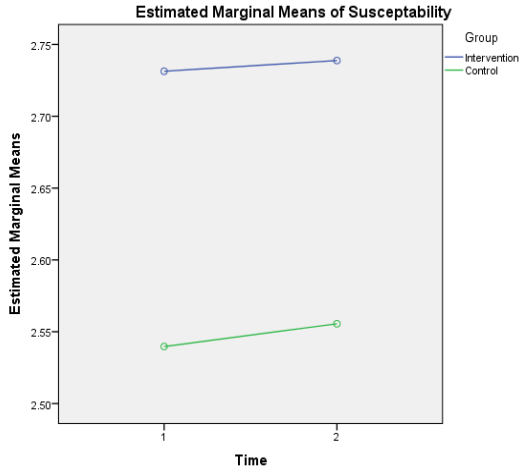
Perceived Self-efficacy



Perceived Benefits



Perceived Susceptibility



Perceived Barriers

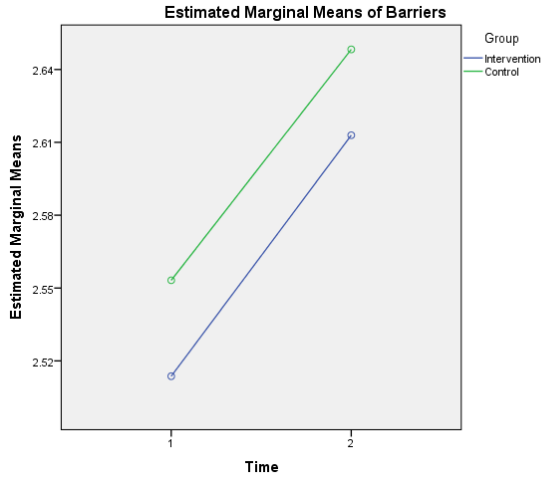


Table 14

Sub-Question 1 Group Statistics and Univariate ANOVA Summary

Variable	df	F	Sig	R2	Alpha
Perceived Severity	1	115.25	.001	.532	0.5
Perceived Benefits	1	6.83	.001	.094	0.5
Cues to Action	1	32.58	.001	.297	0.5

Perceived Self-efficacy	1	13.213	.001	.161	0.5
Perceived Barriers	1	12.26	.083	.082	0.5
Perceived Susceptibility	1	3.71	.056	.165	0.5

Sub-question 2. What are the differences in parental beliefs on perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action when the intervention group is compared to the control group?

Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were significant for follow up comparisons for group by time for the domain of perceived severity (F=137.25, p<.001), cues to action (F=38.58, p<.001), and perceived self-efficacy (F=15.26, p<.001). The domains of perceived benefits (F=0.252, p=.65) and perceived barriers (F=0.117, p=.073) were not significant, however they did indicate an increase in scores. These results will further be discussed in Chapter 5.

Hypothesis 1. Parents in the intervention group will have a greater understanding (perception) of the severity and susceptibility of influenza disease when compared to the control group. Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were significant for follow up comparisons for group by time for the domain of perceived severity (F=137.25, p<.001) only.

Hypothesis 2. Parents in the intervention group will have greater understanding of the benefits of influenza vaccination when compared to the control group. Repeated

measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were not significant for follow up comparisons for group by time for the domain of perceived benefits (F=0.252, p=.65). However, they did indicate an increase in scores.

Hypothesis 3. Parents in the intervention group will experience decreased barriers to vaccination when compared to the control group. Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were not significant for follow up comparisons for group by time for the domain of perceived barriers *(*F=0.117, p=.073), however they did indicate an increase in scores. These results will further be discussed in Chapter 5.

Hypothesis 4. Using text messaging (cues to action) to deliver the education intervention will activate parents' readiness to obtain an influenza vaccination for their child.

Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were significant for follow up comparisons for group by time for the domain of cues to action *(*F=38.58, p<.001).

Hypothesis 5. Parents in the intervention group will have a significant difference in parental beliefs on self-efficacy when compared to the control group.

Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and posttest scores changed over time. The finding were significant for follow up comparisons for group by time for the domain of perceived self-efficacy *(F*=15.26, *p*<0.001).

Analysis of Study Aim 2

This section will discuss the results of the analysis for Aim 2 which is to evaluate the preliminary effects of the SayNo2Flu program on the receipt of one or more influenza vaccine doses by the end of influenza season. This aim has one endpoint, which is at the end of influenza season as documented in the Arizona Immunization Registry/electronic medical record. Here, the outcome variable was dichotomized using Yes (received vaccine) and No (not received). Hierarchical logistic linear regression using maximum likelihood method was performed to determine the contributing factors of vaccination after the six-week intervention and the end of influenza season (March 31, 2015) controlling for variables in the model.

Secondary research question. Will the SayNo2Flu program affect the receipt of one or more influenza vaccine doses? This study found the SayNo2Flu program was significant in affecting the receipt of one or more influenza vaccine doses in the intervention group. This study found 83.5% (n = 56/67) of the intervention group and 45.4% (n = 29/64) of the control group had received an influenza vaccination (OR: 4.46, 95% CI, 1.705-11.706, *p*<.001).

Hypothesis 6. Children of parents in the intervention group will have a significant difference in the receipt of one or more vaccine doses compared to the control group. This study found parents in the intervention group had a difference in the receipt of one

or more vaccine doses compared to the control group (OR: 4.46, 95% CI, 1.705-11.706, $p<.001$).

Variables entered into the model were (a) language, (b) age, (c) gender, (d) ethnicity, (e) marital status, (f) educational level, and (g) family income. Maximum likelihood estimation maximizes the log likelihood to reflect odds which the observed values of the dependent variable may be predicted from the observed values of the independent. The Wald test was then examined to determine the significance of individual logistic regression coefficients for each independent variable. The odds ratio using a 95% CI for the dependent variable (parent perceptions) were evaluated. The overall fit of logistic regression was tested in each step using Hosmer and Lemeshow Chi-square test of goodness of fit. Unstandardized logistic regression coefficients were used to simply estimate parameters and predict the log odds (logit) of the dependent variables in the model. The Cox and Snell and Nagelkerke's R^2 calculations were used to determine the explanatory fit of the modeling. The findings are shown in Table 15.

Table 15

Chi Square

Model	Chi Square	Sig.
Intervention Group	14.43	0.01

Table 16

Predictors of Child Vaccination

	Walds	Df	Sig	OR	95% CI Lower/Upper
Control Group				1	
Intervention Group	12.83	1	0.01	4.46	1.705-11.706
Female	.021	1	.56	1.21	.083-17.83
Ethnicity	.419	1	.51	2.85	.119-68.63
Education	.012	1	.48	1.30	.626-2.777
Income	.208	1	.64	1.18	.571-2.45

The posttest also included four questions that addressed the parents' response to their knowledge of having their child vaccinated and if they were vaccinated (see Appendix E). None of these variables were found significant predictors of vaccination. These findings will further be discussed in Chapter 5.

Qualitative Data Analysis

Along with quantitative data, this study sought to gather qualitative data from the survey participants. Qualitative data was obtained during the post intervention period (T2). This included the administration of the posttest (see Appendix E) and the parent evaluation of the *SayNo2Flu* program (see Appendix F). The last four questions of the posttest HBM survey (see Appendix E) asked four open-ended responses regarding each participant's experience with vaccinating their child. The parent evaluation (see Appendix F) also asked four open-ended questions regarding the parents experience with the SayNo2Flu program. The data received from both instruments were sorted and

analyzed for common themes using the Miles and Huberman tactics to draw and verify conclusions (Miles & Huberman, 1994, p.604). The results of this analysis are presented individually for each question below.

Posttest question 25. What were the reasons to vaccinate your child? Please explain.

Common themes drawn from the participants' survey responses (n=49/131) were to "keep their child from getting sick," "bad flu season," and "might stop pneumonia." Comparing the three sets of responses brought one commonality to the forefront: to prevent their child from contracting influenza. It appeared from the responses that survey respondents' felt the vaccine would prevent illness.

Posttest question 26. Describe your experience with getting your child vaccinated.

Common themes drawn from the participants' survey responses (n=39/131) centered on "easy the doctor's office gave it to us," and "it was free at mall." Common themes drawn from the participants' survey responses centered on availability and access to influenza vaccine was not difficult. Comparing the two sets of responses brought one commonality to the forefront: parents' experience with obtaining influenza vaccine was positive. It appeared from the responses that survey respondents felt that obtaining influenza vaccine was not difficult.

Posttest question 27. What are your reasons for not vaccinating your child? Please explain.

This question received very few responses (n=16/131). Common themes drawn from the participants' survey responses centered on "my child did not need it," "my child

is healthy," "we never get the flu." Comparing the three sets of responses brought one commonality to the forefront: the unawareness of the seriousness of influenza. It appeared from the responses that survey respondents felt their healthy children were not susceptible to influenza disease.

Posttest question 28. What concerns do you have with getting your child vaccinated?

Common themes drawn from the participants' survey responses (n=16/131) centered on "the flu shot could make them sicker," and "nowhere to get it on weekends." Comparing the two sets of responses brought one commonality to the forefront: disease awareness and access are barriers. It appeared from the responses that survey respondents felt it was difficult to obtain the influenza vaccine and were concerned with vaccine side effects.

Intervention Parent evaluation question 1. Please describe what information from the SayNo2Flu program was the most helpful.

Common themes drawn from the intervention group participants' survey responses centered on "the reminder," "sent often so not to forget," "children need it." Comparing the two sets of responses brought one commonality to the forefront: the frequency of reminder and disease seriousness. It appeared from the responses that survey respondents felt the text messages were prompts for vaccination and education was valuable.

Parent evaluation question 2. Which text message did you think helped you decide to have your child vaccinated?

Common themes drawn from the intervention group participants' survey responses centered on "it talked about catching the flu," "call office," child spread," "children need it," and "keeps kids healthy." Comparing the five sets of responses brought one commonality to the forefront: certain key words were triggers. It appeared from the responses that survey respondents felt the text messages were meaningful.

Parent evaluation question 3. Would you recommend the SayNo2Flu text message program to other parents of five- to eight-year-olds?

Common themes drawn from the intervention group participants' survey responses centered on "yes" and "good reminder." Comparing the two sets of responses brought one commonality to the forefront: the text messages were used as reminders. It appeared from the responses that survey respondents felt the text message prompts were good.

Parent evaluation question 4. What would YOU change about the SayNo2Flu program?

There were very few responses to this question. Common themes drawn from the intervention group participants' survey responses centered on "nothing." It appeared from the responses that one commonality was brought to the forefront: parents were not bothered with receiving the text messages. It appeared from the responses that survey respondents felt the program was acceptable.

Parent evaluation question 6. What other type of information would you like to see included in the text?

There were very few responses to this question. Common themes drawn from the intervention group participants' survey responses centered on naming the vaccine. It

appeared from the responses that survey respondents felt that knowing which type of vaccine the reminder was meant for.

Summary

As will be discussed in the next chapter, reliance on quantitative data alone was not enough to fully answer the research questions of this study. Significant values were also drawn from the qualitative responses and the goals of this research were more fully attained.

CHAPTER 5. RESULTS, CONCLUSIONS, AND RECOMMENDATIONS

Chapter 5 contains the results, conclusions, and recommendations of this study. It will evaluate the work produced and address the general implications of the study. This chapter will also make recommendations regarding the validity of this study, to what degree the results answered the research questions, and present recommendations for future studies. The information presented in this study will add to the existing body of knowledge regarding parents' perceptions of influenza disease and vaccination by offering a direct comparison between the intervention group and the control group.

In an era of increasing complexity of immunization schedules, office logistics (e.g., ordering, scheduling, administration, and billing), and rising expectations for quality of primary care, it is important to develop and implement efficacious and effective interventions for primary care settings to increase immunization coverage. Influenza vaccination rates in the United States are far below recommended levels, and researchers have found limited success using traditional vaccine reminders to increase vaccination rates. The recent use of technology as a strategy to increase immunization coverage may provide opportunities to increase school-age children's influenza vaccination rates. As has been found in this study, using text messages to deliver influenza disease and vaccine education can be effective in raising school-age children's influenza vaccination rates.

Restatement of the Problem

The current influenza immunization rate for school-age children is less than 56% (CDC, 2014). This rate falls far below the current recommendation of 80%; numerous intervention reminder studies have shown modest increase in immunization rates. It is

not known how a theory-based text messaging educational intervention might positively impact the rate.

Discussion of the Findings

The literature reviewed and presented within this study provided a refined definition of perception and then discussed the theoretical framework that guided this research. The six constructs of the HBM provided the researchers with the basis for describing the findings presented here. The study targeted parents of five- to eight-year-old children from a Scottsdale Primary Care office. This clinic provides primary care services to low-income, underserved, and special populations. This clinic serve a primarily Latino and publicly insured population. The demographics of this study were reflective of the clinic population. This study found that 77.5% of the parents had a high school education or less. Also, 51% of the parents had a total family annual income less than $10,000 and 82% of parents had a total family annual income less than $25,000. Prior research conducted by Baker et al. (2007) and Wooten et al. (2007) found that the average reading skills were at a seventh- to eighth-grade level and 70% of mothers' income was $20,000 or less.

This study survey tool was developed for a 7.4-grade reading level (Microsoft, 2015). These demographics study results reaffirms the importance of developing vaccine interventions for parents that address low health literacy. Also, this study's educational intervention was delivered via a text message which allows only 160 characters, thus ensuring the simplicity and understanding of the message. This study also took place in an urban primary care clinic where most of the children received free vaccines because

they live below the poverty level. The availability of free vaccines helped remove the barrier of vaccine costs for parents.

Primary Research Question Findings

Primary research question. Will a six-week HBM-guided intervention (SayNo2Flu) affect parents' beliefs about influenza vaccination? This study found that a theory-based intervention (SayNo2Flu) guided by the HBM and combined with the use of mobile technology (SMS text messaging) did change parents' influenza vaccination perceptions. Repeated measures ANOVA (see Table 13) was conducted to determine if the intervention and control group pretest and post test scores changed over time. The finding were significant for follow up comparisons for group by time for the domain of perceived severity (F=137.25, p<.001, cues to action *(*F=38.58, p<.001), and perceived self-efficacy *(*F=15.26, p<0.001). Numerous studies cited in the literature found these constructs to positively affect vaccination rates (Chen et al., 2011; Coe et al., 2012; Marlow et al., 2009; Nexoe et al., 1999). These studies did not use a pretest/posttest experimental design; rather they were assessing participants' beliefs on influenza disease and intent for future vaccination.

The domains of perceived susceptibility (F=0.402, p<.51), perceived benefits (F=0.252, p<.65) and perceived barriers *(*F=0.117, p<.073) were not significant, however the domains of perceived benefits and perceived barriers indicated an increase in scores from pretest to post test (see Figure #3, SPSS Plots).

This study was conducted from November to March and on Jan 5, 2015 there was a heightened awareness in the media of the seriousness of Influenza disease and vaccination. This may account for the post test scores of the control group to be similar

to the intervention group. It was during this time the CDC made an announcement regarding the increase and seriousness of Influenza disease nation-wide. The CDC reported that 43 states experiencing either high or widespread influenza activity. The CDC (2015) also reported that patient doctor visits for influenza-like illness were almost even with the peak of the 2012-2013 season, however this year was much earlier. This report also shared that higher influenza hospitalization rates were seen and another six influenza-associated pediatric deaths were being reported that week, bringing the total number of flu pediatric deaths reported this season to 21 (CDC, 2015). This report also stated that the current influenza vaccine is a mismatch and only 23% effective (CDC, 2015). This information may have impacted the results of this study, as community physicians and the media were sharing this information with parents.

Sub-question 1. The first sub-question was what contributing factors led parents to vaccinate or not vaccinate their child? This study found no significant demographic or health status variables as predictors of influenza vaccination. This result was surprising, as demographic and health variables are well documented in the literature as variables that affect vaccination. Researchers Wooten et al (2007) investigated the role of socioeconomic factors in the persistence of racial/ethnic disparities in childhood immunization coverage rates. They found that children who lived above the poverty line had a vaccination rate of (82.32%, OR:1.83, 95% CI: 1.6-2.6), $p < 0.05$), whose mothers had more than a high school education (82.5%, OR: 1.25, 95% CI: 1.1-1.42, $p < 0.05$), and whose mothers were married (80.4%, OR:1.37, 95% CI: 1.20-1.55, $p < 0.05$) were more likely to be vaccinated. The researchers also found that children who lived below the poverty line (72.7%, OR: 1.10, 95% CI: 0.9-1.3, $p < 0.05$), whose mothers had less

education (74.8%, OR: 1.56, 95% CI: 1.4-1.7, $p < 0.05$), or whose mothers were not married (73.5%, 95% CI: 1.8- 2.1, $p < 0.05$) were less likely to be vaccinated (Wooten et al., 2007). This study was conducted in a low income inner city mostly Hispanic primary care clinic, were most parents' although low income and most had a high school education or less, however they were married. This study found that these factors were not significant predictors of vaccination.

Sub-question 2. The second sub-question was what are the differences in parental beliefs on perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action when the intervention group is compared to the control group? The finding were significant for follow up comparisons for group by time for the domain of perceived severity (F=137.25, p<.001, cues to action *(*F=38.58, p<.001), and perceived self-efficacy *(*F=15.26, p<0.001).

The domains of perceived susceptibility (F=0.402, p<.51), perceived benefits (F=0.252, p<.65) and perceived barriers *(*F=0.117, p<.073) were not significant, however the domains of perceived benefits and perceived barriers indicated an increase in scores from pretest to post test.

Perceived Severity/Perceived Susceptibility

This study found perceived severity of influenza disease significant for the intervention group (F=115.23, p <.001) in changing parents' beliefs regarding influenza disease and vaccination. However, it did not find a significant difference between the groups for the domain of susceptibility (F=0.402, p<.51). This was an un-expected result because numerous studies cited perceived susceptibility as a major predictor of vaccination and the research found was mixed for the perception of severity as a major

predictor of Influenza vaccination (Norten et al, 2008; Nexoe et al., 1999). Researchers also found people who had been vaccinated against influenza were more likely to see themselves at higher risk for influenza disease (Daley et al., 2007; Flood et al., 2010; Norten, Scheifele, Bettinger, & West, 2008; Soyer et al., 2011, Taylor et al, 2002). In prior research both the prevention of influenza and the desire to reduce influenza symptoms were major drivers of vaccination. Researchers have also shown that individuals resistant to influenza vaccination are willing to get vaccinated to protect their high-risk family members (Cheney & John, 2013; Flood et al., 2010;Norten et al., 2008). This points to the understanding of the severity of Influenza disease and the need to protect high risk individuals.

Perceived Benefits and Perceived Barriers

This study found the parental perception of benefits (F=0.252, p<.065) and perception of barriers (F=0.117, p<.073) for group by time were not significant. These study results are not similar to most other studies found in the literature. Numerous studies have cited parental understanding of the benefits of vaccination as one of the most significant predictors of vaccination (Chen et al. 2011; Norten et al. 2008; Cheney and John, 2013; Flood et al.2010), It was during this study, there was heightened media attention towards influenza. On January 5, 2015, the CDC reported that influenza continued to expand its reach in the United States this season, with 43 states experiencing either higher and more widespread influenza activity then the prior year. This report also stated that the current influenza vaccine was a mismatch and only 23% effective (CDC, 2015). This information may have impacted the results of this study, as parents became

aware that the current influenza vaccine may be ineffective, thus impacting their decision to vaccinate.

Cues to Action

In this study, the cues to action domain included the text message as a vehicle to deliver the educational intervention and the healthcare provider's recommendation. Vaccine reminder recall interventions have mostly been telephone or paper. Reminder recall interventions have been well documented in the literature and have had marginal effectiveness. This study found the cues to action domain was significant (F=5.230, p<.02) with the intervention and control group pretest and post test scores changing over time. This study finding were similar to other studies in the literature. Fiks et al. (2009) studied children who were five to 19 years old and found that vaccine reminders do work when healthcare providers use them and recommend vaccinations. They found the intervention group had a 4% (OR: 4.0, 95% CI: 1.4-9.1, p = .23) increase in vaccination rates over the control group, even though the result was not significant. Researchers Chen et al. (2011) also found cues to action (OR: 2.17, 95% CI: 1.22-3.87, p = .008) as a predictor of a caregiver's decision to vaccinate. In addition, researchers Cheney and John (2013) found participants who responded positively to cues to action had 12.2 times the odds of planning to be vaccinated (OR: 12.21, 95% CI: 2.91-51.32), p = .001). This research study has shown that text messaging as a reminder directed to the parent can be easily implemented in a primary care office and was significant.

Self-Efficacy

This study also found self-efficacy domain to be significant (F=15.26, p<0.001). These findings were similar to previously documented literature findings. In 2008,

researchers Norten et al. found that the availability of influenza vaccine (convenience) (OR: 201.11, 95% CI: 99.21-406.19) was a strong predictor of acceptance of vaccine. This research has relevance to this study as it highlights the convenience of access to vaccination. This study took place at a clinic that encouraged parents to drop by the clinic without an appointment for influenza vaccine.

Secondary Research Question Findings

Secondary research question. Will the SayNo2Flu program affect the receipt of one or more influenza vaccine doses?

This study found 83.5% (n = 56/67) of the intervention group and 45.4 % (n = 29/64) of the control group had received an influenza vaccination (OR: 4.46, 95% CI, 1.705-11.706, $p < .001$). An overall increase of 38.1% in vaccination rates in the intervention group. This study found parents in the intervention group had a difference in the receipt of one or more vaccine doses compared to the control group. The control group vaccination rate was found to be less than national rates. These study results are similar to the only study found in the literature prior to the start of this study that used text messaging as a reminder for influenza vaccination. In 2012, researchers Stockwell et al. completed a randomized controlled trial testing text messaging in a primary care clinic to increase influenza vaccination rates in children. They found that the intervention group had a 27.1% vaccine receipt as compared to 22.8% for the usual care group (RR = 1.19, 95% CI: 1.10-1.28, $p < .001$). This study provided initial support for the feasibility and acceptability of text messaging interventions implemented in primary care settings. Some limitations of this study were (a) the inability of the study to address parent and clinic barriers to vaccinate, (b) the use of staggered clinic dates to limit overcrowding may have

caused missed opportunities to vaccinate, and (c) no theoretical framework was used to guide the intervention. These limitations were addressed in this study by attempting to remove influenza vaccine barriers for the parent such as access and cost. The study clinic allowed parents to drop in without an appointment for an influenza vaccine. This study was conducted at a primary care clinic serving primarily low-income, publicly insured children. Also, this study was guided by a theoretical framework.

This same group of researchers (Stockwell et al, 2014) published a follow-up study in December 2014 to their initial influenza text message reminders; however, in this study they compared an educational influenza-related text message reminder and a conventional text message reminder. They found a 10.6% (OR: 10.4, 95% CI: 9.7-11.4, *p* = .34) increase in vaccination for participants who received an educational text message versus the conventional text message reminder (Stockwell et al., 2014). These researchers did find that educational text messages did cause an increase in vaccinations; however, the results are less than what was found in this study. This study found 83.5% (n = 67) of the intervention group and 45.4 % (n = 64) of the control group (OR: 4.46, 95% CI, 1.705-11.706, *P* < .001) had received a vaccination when educational intervention was guided by the constructs of the HBM.

Qualitative Data Findings

The posttest also included four questions that addressed the parents' report of having their child and themselves vaccinated (see Appendix E). This study did not find any of these variables significant predictors of vaccination.

In this qualitative research, a textual analysis (themes) approach was taken because the PI wanted to describe the parent groups' lived experience when deciding to

have their child vaccinated. “Reality is subjective; however, the experience is unique” (Miles & Huberman, 1994, p. 602). The last four questions of the posttest HBM survey asked four open-ended questions regarding each participant’s experience with vaccinating their child (see Appendix E). The intervention group parents also completed a parent evaluation of the SayNo2Flu program (see Appendix F), while the control parents completed a parent evaluation of the science based text program (Appendix G). The intervention group parent evaluation also asked four open-ended questions regarding the parents’ experience with the SayNo2Flu program (see Appendix F). These questions were very insightful as they were similar to what was found in the literature, but at the same time revealed additional parent thoughts regarding immunization.

Posttest question 25. When parents (n = 49/131) were asked their reasons to vaccinate their child for flu, they indicated common themes such as to “keep their child from getting sick,” “bad flu season,” and “might stop pneumonia.” These responses reflect their belief that flu vaccine will prevent illness. These themes/responses are consistent with what was found in the literature as to why a parent would vaccinate their child to prevent illness (Bhat-Schekbert et al, 2012; Soyer et al, 2011).

Posttest question 26. When parents (n = 39/131) were asked to describe their experience with getting their child vaccinated with flu vaccine, common themes drawn from the participants’ survey responses centered on “easy the doctor’s office gave it to us,” and “it was free at mall.” These responses reflect how the clinic encouraged parents to drop in for immunization without an appointment. Both of the satellite clinics were located at an elementary school, thus making it easy for parents to obtain an influenza vaccine. Also, the availability of flu clinics in the community was well publicized. This

also was consistent with what was found in the literature, the availability of Influenza vaccination clinics have decreased barriers to vaccination (Bhat-Schekbert et al, 2012; Soyer et al, 2011).

Posttest question 27. When parents (n = 16/131) were questioned what their reasons were for not vaccinating their child with flu vaccine, some common themes drawn from the participants' survey responses centered on "my child did not need it," "my child is healthy," and "we never get the flu." These responses have been well documented in the literature as parents not viewing their healthy child as susceptible to influenza disease. These themes/responses were consistent with what was found in the literature concerning a parent's misconception of Influenza disease and vaccination (Daley et al.2007; Gnanasekaran et al. 2006).

Posttest question 28. When parents (n = 16/131) were asked what concerns they have with getting their child vaccinated with the flu vaccine, their responses were similar to what was found in the literature. The common themes included "the flu shot could make them sicker," and "nowhere to get it on weekends." These parental responses were similar to what Daley et al. (2007) found. These researchers found that inaccurate beliefs about the influenza vaccine for their children were prevalent. They also thought influenza vaccine could cause disease; their children were unlikely to contract influenza and they considered the influenza vaccine to be unsafe. Parents' misperceptions of influenza disease and vaccinations are often cited in the literature as the reasons for the low vaccination rates (Bhat-Schelbert et al., 2012; Ranney, 2014; Salmon et al., 2005; Taylor et al., 2002). These researchers found that inaccurate beliefs about influenza vaccination were prevalent. They also found that parents felt that influenza vaccination could cause

disease; their children were unlikely to contract influenza and they considered the influenza vaccine to be unsafe. These data point to common barriers previously documented in the literature indicating that parents are still concerned vaccine side effects and access are still barriers to immunization for some parents.

Parent Evaluation Findings

The results from this survey revealed some interesting results. Most parents responded that the information from the SayNo2Flu program was helpful. They felt the text messages were good, with frequent reminders to get their child vaccinated. They also commented that the text messages about influenza disease were the most impactful. It appeared from the responses that survey respondents felt the text messages were prompts for vaccination, and education was valuable. Overall, the participants' survey responses centered on how the text messages "talked about catching the flu," "call office," "child spread," "children need it," and "keeps kids healthy." This study found that these responses brought one commonality to the forefront: certain key words were triggers. These trigger words were used in the intervention group influenza text messages, as these key words/triggers were all based on sound clinical evidence from the literature. It appeared from the responses that participants felt the text messages were meaningful.

The PI did find that three of the intervention group Influenza related text messages allowed for additional words (characters) due to the length of the text messages. These were: (a) text message 2 (perceived severity) had 150 characters; (b) text message 5 (cues to action) had 146 characters; and (c) text message 6 (perceived efficacy) had 147 characters. This allowed the PI to add additional words. The words *Nurse Pat* were added. This resulted in most parents responding back to the PI with a

"thank you" for the reminder. This unexpected response shows that personalizing the text message caused the parents to respond back to the office. This indicates the importance of the text messages coming directly from the healthcare provider and the parents' understanding that this reminder means a vaccine recommendation their child from the healthcare provider. The literature has revealed that a healthcare provider's recommendation is one of the strongest predictors of influenza vaccine receipt (Bhat-Schelbert et al., 2012; Cheffins et al., 2011; Gnanasekaran et al., 2006; Soyer et al., 2011; Taylor et al., 2002). This simple notification from the office directly reinforced the need for vaccination.

When parents (41/67) were asked if they would recommend the SayNo2Flu text message program to other parents of five- to eight-year-olds, the responses were favorable. This result reinforces the acceptability of the text messaging program, similar results was also found in the literature when researchers conducted a systematic review of text messaging and found text messaging as a reminder was feasible and acceptable (Arora et al,2012; Militello, Kelly & Melyk, 2012).

When parents were asked what other type of information they would like to see included in the text, parents responded that adding the name of the vaccine was important. This result indicates the parents' need for knowledge regarding the vaccine and effects.

When parents from the control group (17/64) were asked if they would recommend the science based text message program to other parents of five- to eight-year-olds, the responses were also favorable. This result reinforces the acceptability of

the text messaging program as seen in other studies that evaluated the feasibility and acceptability of text messaging (Arora et al, 2012; Militello, Kelly & Melyk, 2012).

As was seen in these results, reliance on quantitative data alone is not enough to fully answer the research questions of this study. To understand the parents' beliefs regarding Influenza disease and vaccination will help develop educational interventions, however, also understanding parents' lived experience in having their child vaccinated can also shed some valuable insights to inform further research. Significant values were also drawn from the qualitative responses and the goals of this research were more fully attained.

Threats to Validity

This study was a pretest/posttest randomized control experimental design that lends itself to threats to validity. The probing of the questions in the survey can add to the person's knowledge or change their attitude, thus the test becomes part of the intervention. The survey tool used in this study was adapted from numerous studies in the literature with attention to not provide any educational content in the questions regarding influenza disease or vaccination (Chen et al., 2011; Cheney & John, 2013; Coe et al., 2012; Glanz et al., 2002; Gnanasekaran et al., 2006). Care was also taken during the parent recruitment and data collection to ensure no diffusion of the treatment. Parents met with the PI individually at the primary care offices.

However, another threat to validity considered was history. During the study there was heightened media attention towards influenza. On January 5, 2015, the CDC reported that influenza continued to expand its reach in the United States this season, with 43 states experiencing either high or widespread influenza activity, mostly resulting

from circulation of drifted H3N2 viruses. The CDC (2015) also reported that patient visits to doctors for influenza-like illness were almost even with the peak of the 2012-2013 season, the last time H3N2 viruses predominated. This report also shared that higher influenza hospitalization rates seen so far this season are similar to what had been observed during some past H3N2-predominant seasons (CDC, 2015). Additionally, another six influenza-associated pediatric deaths were being reported that week, bringing the total number of flu pediatric deaths reported this season to 21 (CDC, 2015). This report also stated that the current influenza vaccine is a mismatch and only 23% effective (CDC, 2015). This information may have impacted the results of this study, as community physicians and the media were sharing this information with parents.

This study was designed to achieve statistical significance ($\alpha = .05$) and power ($> .80$). This study achieved the goal of 68 participants per group, for a total of 136 participants. This goal allows for patient @5% attrition (Sackett et al., 1997).

Limitations

There are several limitations that inform the results. This was a convenience sample of parents drawn from the primary care clinic population. More than half of the parent participants (77.2%) had a high school education or less. The evaluation questions included fixed response questions that were written in English and Spanish and administered in one primary care practice. These factors, when combined with the small sample of mostly female participants, may have biased the evaluation of the text messages. As such, the results may not be generalized to other populations as further testing may be needed in other diverse populations.

The clinical population was used to recruit participants; therefore selection bias is a concern. This population was low-income, Hispanic, and most had a high school education or less. This study may have limited ability to be generalized to other patient populations because it is being conducted in a setting not reflective of diverse populations.

Another limitation was that the participants were offered a nominal gift card as an incentive for their time and participation in the study. This may have affected the study results.

Practice Implications of a Theory-based Intervention

This theory-based Influenza related educational text messages intervention was effective in raising an overall influenza vaccination rates in children of 5-8 year olds by 38.1% (OR:4.46, 95% CI, 1.705-11.706, $p < .001$). The pilot study conducted to help strengthen the text messages was evaluated by participants as clear with valid Influenza related content and good internal consistency. The participant suggestions were used to improve the content of the text messages that were consistent with previously published literature on barriers to vaccination, such as vaccine side effects and efficacy (Chen et al., 2011; Coe et al., 2009) and these revised text messages were ***operationalized*** in this study. The HBM was an appropriate model for vaccination intervention research because its constructs addressed the participants' concerns that were found in this study, such as disease severity and barriers to vaccination (vaccine safety, side effects, and availability of Flu clinics). Each Health Belief Model construct was represented in one of the six text messages and each construct provided Influenza education that addresses facilitators and barriers of vaccination. The text message (cue to action) was delivered directly from the health care provider office and represented the health care providers' recommendation. This recommendation is consistent with several studies that have found that a health care

provider's recommendation is one of the strongest predictors of Influenza vaccine receipt (Bhat-Schebert et al., 2012; Cheffins et al., 2011; Gnanasekaren et al., 2006; Soyer et al., 2011; Taylor et al., 2002).

To my knowledge there are no Influenza vaccination text messaging intervention studies in the literature that apply the HMB for parents of 5 to 8-year-olds. This Influenza theory based educational text messaging intervention can be easily implemented in a primary care setting.

Theory development

This theory-based Influenza related educational interventional study used text messaging as a vehicle to deliver the educational intervention. This study was designed to motivate, educate, and empower inner city parents to vaccinate their children. It was a culturally sensitive, low cost, bilingual, science-based unidirectional text message-based program that required only a basic mobile phone to participate. This study also was delivered in both English and Spanish via a text message and resulted in increased positive immunization behaviors.

The six constructs of the Health Belief Model were adapted to reflect the finding in the literature that identified facilitators and barriers to vaccine receipt, while also addressing the severity and susceptibility of Influenza disease. The pilot study used a three step process for the theory developed text messages (Wiseman & Records, 2015). This included the construct definition, applied content (translating it to influenza-related information) and then drafting a text message appropriate for the target population. This simple process may be applicable to other theory developed educational text messaging interventions.

This education intervention was well received by the priory population and is a fundamental step toward achieving increased Influenza vaccination rates. The tailored messages were Influenza specific, simple, less than 160 characters, and deliver at a 7th grade reading level.

The intervention itself can be easily implemented in a primary care office. The text messaging program used was HIPPA compliant, required minimal data entry (cellular telephone number), had the ability to send bulk messages and was at a relatively low cost (approximate 3 cents per message). Most electronic medical record systems have a text messaging capabilities (Allscripts, 2015) and currently the Arizona Immunization registry is assessing the ability to add a text message reminder component to its system (Arizona Department of Health Services, 2015). The messages were sent from the health care providers' office providing parents a connection to the office, this resulted in a large number of responses from the parents. The text messaging were not designed nor intended for parents to respond, however the personalization and connection to the provider prompted a response or clarification from the parent. The additional personalization of the messages to the parents with the signature Nurse Pat may have contributed to the parent satisfaction.

The review of the literature provided no theory based reminder studies and of those reminder studies reviewed, vaccination rates showed a modest increase ranging from 4-10.6% (Brigham et al. 2012; Figs et al, 2012; Figs et al, 2007, Stockwell et al, 29012; Stockwell et al, 2014). This study result helps understand the impact of theory guided educational interventions and its affect to promote positive Influenza related behavioral changes.

Recommendations

This research contributes to the knowledge base for theory based influenza vaccination interventions and was distinctive in multiple respects. First, the text messaging intervention is designed to target a unique population of parents of five- to eight-year-old children. Previous influenza interventions have targeted the parents of younger children. Second, to my knowledge there are no influenza vaccination text messaging intervention studies in the literature that apply the HBM for parents of five- to

eight-year-olds. The design of this theory-based text messaging intervention makes it possible for this type of intervention to be easily scaled across a diverse patient population regardless of age, education, economic, or ethnic background. The information gained from this research can be used in future vaccine interventions for raising immunizations rates.

The intervention was designed to be carried out by healthcare providers in a primary care setting with minimal office burden. The series of six messages can be deployed one at a time for a period of six weeks, via mass email. Immunization nurses working in county clinics or primary care practices can easily implement this Influenza intervention with low income parents, at a minimal cost and office staff burden. This researcher suggests that the optimal time for deploying the intervention is in early fall, prior to the start of flu season. This will ensure parents receive Influenza education during a time of heightened media attention to Influenza season and ensure children are vaccinate prior to the epidemic. The flexibility of the clinic staff to encourage parents to drop in for a vaccination without an appointment allowed parents to have a great control over access and increase their perception of self-efficacy.

Implication for Future Research

The goal for this study was to change parents' perceptions of influenza disease and vaccination and ultimately raise vaccination rates. Additional research recommended in support of this overarching goal would include answering the following questions:

1. What other theories can guide educational interventions promoting positive behavioral changes and be delivered in a text message?

2. What additional factors are considered by parents when trying to decide to have their child vaccinated?
3. What is the impact of family members on parents' decision to vaccinate?
4. What types of media do parents value when deciding to have their child vaccinated?
5. What types of social media do parents use when seeking information on vaccines?
6. Would theory-based text messages be applicable to other vaccine-preventable diseases?

Conclusions

The overarching belief system of parents as related to influenza disease and vaccination of their school-age children guided authenticity into this research. This study provides important insights into the factors that affect Influenza vaccination among school-aged children. The goal of the SayNo2Flu program was to provide education on influenza disease (severity, susceptibility) and vaccination (barriers, benefits) to strengthen parent beliefs to promote Influenza vaccine receipt for their children. Montano and Kasprzyk (2008) stated that incorporating the HBM constructs of this prominent behavior change theory may be appropriate for designing, implementing, and evaluating studies regarding vaccination behaviors (Montano & Kasprzyk, 2008). This targeted influenza vaccination intervention guided by the HBM constructs did help further explain parent factors influencing childhood vaccination rates and identified predictors of influenza vaccination in children. The ease and timeliness of the SayNo2Flu program did

strengthen parental beliefs regarding their ability to promote influenza vaccine receipt for their child.

The HBM was an appropriate model for this research and future vaccination research because it focused on the attitudes and beliefs of individuals and barriers with taking action. This study sought to test and compare the parental perceptions towards influenza disease and vaccination. Supporting the goal of this study, analysis was performed to determine what factors may lead parents to have their school-age child vaccinated. Results of the study indicated that there was a statistically significant difference between the perceptions of intervention and control participants. Findings from this study not only confirmed the difference a well thought out theory focused intervention could attain, it also reinforced the role of healthcare providers in encouraging vaccination uptake among this parental group and drawing attention to the impact of health beliefs towards influenza and childhood vaccination. The implementation of this simple educational intervention can be done utilizing a series of customized text messages coming directly from the provider's office. The primary themes that emerged from this study were that the text message was a personalized reminder from the primary care office and the education was valuable, resulting in vaccination.

Participant evaluations suggest that the SayNo2Flu intervention was acceptable and met the cultural relevance and literacy needs of our priority population. This study is *significant and innovative* because no published studies evaluating the use of HBM-guided interventions using mobile technology to promote influenza vaccine receipt among parents of school-age children have been identified. It is this researcher's opinion

that the results of this study can be generalized outside the influenza vaccination and be used for other vaccine-preventable diseases. Not only was the intervention successful in increasing Influenza immunization rates among a vulnerable population, it also tested the Health Belief Model and demonstrated significant difference between intervention and control parents' beliefs about influenza. The effectiveness of the theory-based intervention was shown not only in the positive changes in parents' beliefs, it was shown through significantly increased health behaviors, exactly what the HBM was designed to accomplish. Additionally, as demonstrated in the analysis of the data compared to existing literature, many areas of this study have replicated what was found in the literature. The use of the Health Belief Model is this study resulted in a 38.1% increase in Influenza vaccination rates.

Going forward, more research is needed to further understand the impact of theory guided educational interventions and its effect to promote positive behavioral changes while being delivered in a simple, low cost, culturally and literacy appropriate text message.

References

Ahlers-Schmidt, C. R., Chesser, A., Hart, T., Paschal, A., Nguyen, T., & Wittler, R. R. (2010). Text messaging immunization reminders: Feasibility of implementation with low income parents. *Preventive Medicine, 50*(5-6), 306-307.

Anderson, P. (2007). What is Web 2.0? Ideas, technologies and implications for education. *JISC Technology and Standards Watch*. Retrieved from http://www.webarchive.org.uk/wayback/archive/20140614202026/http://www.jisc.ac.uk/publications/reports/2007/twweb2.aspx

Arizona Department of Health Services. (2015). *Arizona State Immunization Information System (ASIIS)*. Retrieved from http://www.azdhs.gov/phs/asiis/

Arizona Revised Statute (ARS) §36-135. Retrieved from http://www.azleg.state.az.us/ars/36/00135.htm

Arora, S., Peters, A. L., Agy, C., & Menchine, M. (2012). A mobile health intervention for inner city patients with poorly controlled diabetes: Proof-of-concept of the TExT-MED program. *Diabetes Technology Therapy, 14*(6), 492-496.

Baker, L. M., Wilson, F. L., Nordstrom, C. K., & Legwand, C. (2007). Mothers' knowledge and information needs relating to childhood immunizations. *Issues in Comprehensive Pediatric Nursing, 30*(1-2), 39-53.

Becker, M. H. (1974). The health belief model and personal behavior. *Health Education Monographs, 2*, 324-508.

Becker, M. H., Haefner, D. P., Kasl, S. V., Kirscht, J. P., Maiman, L. A., & Rosenstock, I. M. (1977). Selected psychosocial models and correlates of individual health-related behaviours. *Medical Care, 15*, 27-46.

Belief. (2015). In *Merriam-Webster's online dictionary*. Retrieved from http://www.merriam-webster.com/dictionary/belief

Belshe, R. B., Piedra, P. A., & Block, S. L. (2009). *Prevention and control of pediatric influenza.* Retrieved from http://www.healio.com/pediatrics/vaccine-preventable-diseases/news/online/%7Be71da9b6-7edb-4d3b-84c1-994d6607fa40%7D/prevention--control-of-pediatric-influenza

Berkman, N. D., DeWalt, D. A., Pignone, M. P., Sheridan, S. L., Lohr, K. N., Lux, L., . . . Bonito A. J. (2004). *Literacy and health outcomes: Summary* (AHRQ Publication No. 04-E007-1). Rockville, MD: Agency for Healthcare Research and Quality.

Berman, S. (2008). Is our vaccine system at risk for a future financial "meltdown?" *Pediatrics, 122*(6), 1372-1331.

Bhat-Schelbert, K., Lin, C., Matambanadzo, A., Hannibal, K., Nowalk, M., & Zimmerman, R. (2012). Barriers to and facilitators of child influenza vaccine – Perspectives from parents, teens, marketing and healthcare professionals. *Vaccine, 30*(14), 2448-2452.

Birmingham, E., Catallozzi, M., Findley, S. E., Vawdrey, D. K., Kukafka, R., Stockwell, M. S. (2011). FluAlert: A qualitative evaluation of providers' desired characteristics and concerns regarding computerized influenza vaccination alerts. *Preventative Medicine, 52*(3-4), 274-277.

Black, C. L., Wooten, K. G., Yankey, D., & Kolasa, M. (2010). National, state, and local area vaccination coverage among children aged 19-35 months—United States, 2010. *Morbidity & Mortality Weekly Report (MMWR), 60*(34), 1157-1163. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6034a2.htm

Bradley, C., Gamsu, D. S., Knight, G., Boulton, A. J. M., & Ward, J. D. (1986). Predicting risk of diabetic ketoacidosis in patients using continuous subcutaneous insulin infusion. *British Medical Journal, 293,* 242-243.

Bradley, C., Gamsu, D. S., Moses, J. L., Knight, G., Boulton, A. J. M., Drury, J., & Ward, J. D. (1987). The use of diabetes-specific perceived control and health belief measures to predict treatment choice and efficacy in a feasibility study of continuous subcutaneous insulin infusion pumps. *Psychology and Health, 1,* 133-146.

Brigham, K., Woods, E., Steltz, S., Sandora, T., & Blood, E. (2012). Randomized controlled trial of an immunization recall intervention for adolescents. *Pediatrics,* (130), 507.

Burns, N., & Grove, S. (2005). *The practice of nursing research: Conduct, critique and utilization* (5th ed.). Philadelphia: Saunders.

Cellular Telecommunication and Internet Association. (2010). *50 wireless quick facts*. Retrieved from http://www.ctia.org/advocacy/research/index.cfm/AID/10381

Centers for Disease Control and Prevention. (2008). *Recommendations and guidelines*. Retrieved from http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

Centers for Disease Control and Prevention. (2011). Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. *Morbidity & Mortality Weekly Report, 60*(33), 1128-1132.

Centers for Disease Control and Prevention. (2012). Recommended immunization schedules for persons aged 0 through 18 years—United States, 2012. *Morbidity & Mortality Weekly Report, 61*(5), 1-4.

Centers for Disease Control and Prevention. (2013). *Flu vaccination coverage, United States, 2012-13 influenza season.* Available at http://www.cdc.gov/flu/fluvaxview/coverage-1213estimates.htm

Centers for Disease Control and Prevention. (2014). *ACIP vaccination recommendations*. Retrieved from http://www.cdc.gov/vaccines/recs/acip/default.htm

Centers for Disease Control and Prevention. (2015). *CDC: Flu activity expands; severity similar to past H3N2 seasons.* Retrieved from http://www.cdc.gov/flu/news/flu-activity-expands.htm

Champion, V., & Skinner, C. (2008). The health belief model. In K. Glanz, B. Rimer, & K. Viswanath (Eds.), *Health behavior and health education theory, research, and practice* (pp. 45-65). San Francisco, CA: Jossey-Bass.

Cheffins, T., Spillman, M., Larkins, S., & Heal, C. (2011). Recommending vaccination-general practice intervention with new parents. *Australian Family Physicians, 40*(6), 437-439.

Chen, J., Fox, S., & Cantrell, C. (2007). Health disparities and prevention: Racial/ethnic barriers to flu vaccination. *Journal of Communication in Healthcare, 32*(1), 5-20.

Chen, M. F., Wang, R. H., Schneider, J. K., Tsai, C. T., Jiang, D. D., Hung, M. N., & Lin, L. J. (2011). Using the health belief model to understand caregiver factors influencing childhood influenza vaccinations. *Journal of Community Health Nursing, 28*(1), 29-40.

Cheney, M. K., & John, R. (2013). Underutilization of influenza vaccine: A test of the health belief model. *Sage Open*. doi:10.1177/2158244013484732

Clark, S., Butchart, A., Kennedy, A., & Dombkowski, K. (2011). *Parents'* experiences with and preferences for immunization reminder/recall technologies. *Pediatrics, 128,* e1100.

Coe, A. B., Gatewood, S. B. S., Moczygemba, L. R., Goode, J.-V. K. R., & Beckner, J. O. (2012). The use of the health belief model to assess predictors of intent to receive the novel (2009) H1N1 influenza vaccine. *Innovations in Pharmacy, 3*(2), 1-11.

Cowan, A., Winston, C., Davis, M., Wortley, P., & Clark, S. (2006). Influenza vaccination status and influenza-related perspectives and practices among U.S. physicians. *American Journal of Infection Control, 34*, 164-169.

Daley, M., Crane, L., Chandramouli, V., Beaty, B., Barrow, J., Allred, N., . . . Kempe, A. (2007). Misperceptions about influenza vaccination among parents of healthy young children. *Clinical Pediatrics, 46*, 408-417.

Daley, M. F., Steuner, J. F., Braydeb, R. M., Xu, S., Morrison, S., & Kempe, A. (2002). Immunization registry-based recall for a new vaccine. *Ambulatory Pediatrics, 2*(6), 438-443.

Dombkowski, K., Lantz, P., & Freed, G. (2004). Role of health insurance and a usual source of medical care in age-appropriate vaccinations. *American Journal of Public Health*, *94*(6), 960-966.

Dominguez, S. R., & Daum, R. S. (2005). Physician knowledge and perspectives regarding influenza and influenza vaccination. *Human Vaccination, 1*(2), 74-79.

Douville, L., Myers, A., Jackson, M. A., & Lantos, J. D. (2010). Health care worker knowledge, attitudes, and beliefs regarding mandatory influenza vaccination. *Archives of Pediatric and Adolescent Medicine, 164*(1), 33-37.

Esposito, S., Pelucchi, C., Tel, F., Chiarelli, G., Sabatini, C., Semino, M., . . . Principio, N. (2009). Factors conditioning effectiveness of a reminder/recall system to improve influenza vaccination in asthmatic children. *Vaccine, 27*, 633-635.

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods, 41*, 1149-1160.

Fawcett, J. (2005). *Contemporary nursing knowledge* (2nd ed.). Philadelphia, PA: F.A. Davis.

Fiks, A., Grundmeiser, R., Briggs, L., Localio, R., & Alessandrini, E. (2007). Impact of clinical alerts within an electronic health record of routine childhood immunizations in an urban pediatric population. *Pediatrics*, *120*(4), 707-714.

Fiks, A. G., Hunter, K. F., Localio, A. R., Grundmeier, R. W., Bryant-Stephens, T., Luberti, A. A., . . . Alessandrini, E. A. (2009). Impact of electronic health record-based alerts on influenza vaccination for children with asthma. *Pediatrics, 124*(1), 159-169.

Fiore, A. E., Epperson, S., Perrotta, D., Bernstein, H., & Neuzil, K. (2012). Expanding the recommendations for annual influenza vaccination to school-age children in the United States. *Pediatrics, 129*(Suppl. 2), S54-62.

Fiore, A. E., Shay, D. K., Broder, K., Iskander, J. K., Uyeki, T. M., Mootrey, G., . . . Cox, N. S. (2008). Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. *MMWR Recommendations and Reports, 57*(RR-7), 1-60.

Fjeldsoe, B., Marshall, A., & Miller, Y. (2009). Behavior change interventions delivered by mobile telephone short-message service. *American Journal of Preventive Medicine, 36*(2), 165-173.

Flood, E. M., Rousculp, M. D., Ryan, K. J., Beusterien, K. M., Divino, V. M., Toback, S. L., . . . Mahadevia, P. J. (2010). Parents' decision-making regarding vaccinating their children against influenza: A web-based survey. *Clinical Therapies, 32*(8), 1448-1467.

Fox, S. (2011). *The social life of health information,* 2011. Retrieved from http://www.pewinternet.org/Reports/2011/Social-Life-of-Health-Info.aspx

Fox, S., & Duggan, M. (2013). *Health online 2013*. Retrieved from http://www.pewinternet.org/files/old-media/Files/Reports/PIP_HealthOnline.pdf

Grajalva C., Craig, A., Dupont, W., Bulges, C., Iwane, M., Schaffer, W., Edwards, K, Griffen, M. (2006). Estimating Influenza Hospitalization among chldren. *Emerging Infectious Diseases,* 12, p.1-8.

Gibbons, M. C., Fleisher, L., Slamon, R. E., Bass, S., Kandadai, V., & Beck, J. R. (2011). Exploring the potential of Web 2.0 to address health disparities. *Journal of Health Communication, 16*(1), 77-89.

Glanz, K., Rimer, B. K., & Lewis, F. M. (2002). *Health behavior and health education: Theory, research and practice*. San Francisco, CA: Wiley.

Glanz, K., Rimer, B. K., & Viswanath, K. (2009). *Health behavior and health education, theory, research, and practice* (4th ed.). Hoboken, NJ: Wiley.

Gnanasekaran, S. K., Finkelstein, J. A., Hohman, K., O'Brien, M., Kruskal, B., & Liew, T. (2006). Parental perspectives on influenza vaccination among children with asthma. *Public Health Report, 121*(2), 181-188.

Hajian, S., Vakilian, K., Najabadim, K. M., Hosseini, J., & Mirzaei, H. R. (2011). Effects of education based on the health belief model on screening behavior in high risk women for breast cancer, Tehran, Iran. *Asian Pacific Journal of Cancer Prevention, 12,* 49-54.

Health and prevention. (2010). *Prevention Magazine*. Retrieved from http://www.prevention.com/health

Heikkinen, T., Booy, R., Campins, M., Finn, A., Olcén, P., Peltola, H., . . . Weil-Olivier C. (2005). Should healthy children be vaccinated against influenza? A consensus report of the Summits of Independent European Vaccination Experts. *European Journal of Pediatrics, 165*(4), 223-228.

Hitchcock, W., Marshall, G., & Middleman, A. (2007). The 2007 recommended childhood & adolescent immunization schedules: Updates, challenges, and opportunities. *Contemporary Pediatrics, 24*(4), 1-8.

Hochbaum, G. M. (1958). *Public participation in medical screening programs: A socio-psychological study.* Washington, DC: U.S. Department of Health, Education, and Welfare.

Hofman, F., Ferracin, C., Marsh, G., & Dumas, R. (2006). Influenza vaccination of healthcare workers: A literature review of attitudes and beliefs. *Infection, 34*(3), 142-147.

Humiston, S. G., Albertin, C., Schaffer, S., Rand, C., Shone, L. P., Stokley, S., & Szilagyi, P. G. (2009). Healthcare provider attitudes and practices regarding adolescent immunizations: A qualitative study. *Patient Education and Counseling, 75*(1), 121-127.

Imle, M., & Atwood, J. A. (1988). Retaining qualitative validity while gaining quantitative reliability and validity: Development of the Transition to Parenthood Concerns Scale. *Advances in Nursing Science, 11*(1), 61-75.

Immunization. (2015). In *Merriam-Webster's online dictionary*. Retrieved from http://www.merriam-webster.com/dictionary/immunization

Institute of Medicine, Board of Health Care Services. (2003). *Financing vaccines in the 21st century: Assuring access and availability.* Available from http://www.nap .edu/download.php?record_id=10782#

Irigoyen, M. M., Findley, S., Earle, B., Stambaugh, K., & Vaughan, R. (2000). Impact of appointment reminders on vaccination coverage at an urban clinic. *Pediatrics, 106*(October 4), 919-923.

Jacobson Vann, J. C., & Szilagyi, P. (2005). Patient reminder and recall systems to improve immunization rates. *Cochrane Collaboration*. Retrieved from http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003941.pub2/abstract

Janz, N. K., & Becker, M. H. (1984). The health belief model: A decade later. *Health Education Quarterly, 11*, 1-47.

Janz, N. K., Champion, V. L., & Strecher, V. J. (2002). The health belief model. In K. Glanz, B. K. Rimer, & F. M. Lewis (Eds.), *Health behavior and health education: Theory, research, and practice* (pp. 45-66). San Francisco, CA: Jossey-Bass.

Kharbanda, E. O., Stockwell, M. S., Fox, H. W., Andres, R., Lara, M., & Rickert, V. I. (2010). Text message reminders to promote human papillomavirus. *Vaccine, 29,* 2537-2541.

Kietzmann, J. H., Hermkens, K., McCarthy, I. P., & Silvestre, B. S. (2011). Social media? Get serious! Understanding the functional building blocks of social media. *Business Horizons, 54,* 241-251.

Kutner, M., Greenberg, E., Jin, Y., Paulsen, C., & White, S. (2006). *The health literacy of America's adults: Results from the 2003 National Assessment of Adult Literacy* (NCES 2006-483). Washington, DC: I.S. Department of Education, National Center for Education Statistics. Retrieved from http://nces.ed.gov/pubs2006 /2006483_1.pdf

Lau, Y., Brittain, K., Hacking, D., Cassidy, A., Haricharan, H., & Heap, M. (2013). A comparison of two text message-based intervention studies for health promotion in Cape Town, South Africa: The lessons learnt. *Journal of Mobile Technology, 2*(4S), 16. doi:10.7309/jmtm.2.4S.13

LeBaron, C. W., Starnes, D. M., & Rask, K. J. (2004). The impact of reminder-recall interventions on low vaccination coverage in an inner-city population. *Archives of Pediatric & Adolescent Medicine, 158*(3), 255-261.

Levi, B. H. (2007). Addressing parents' concerns about childhood immunizations: A tutorial for primary care providers. *Pediatrics, 120*(1),18-25.

Levy, D., Ambrose, C., Oleka, N., & Lewin, E. (2009). A survey of pediatricians' attitudes regarding influenza immunization in children. *BMC Pediatrics,* 9, 8. doi:10.1186/1471-2431-9-8

Loeb, M.,Russell, M., Moss,L., Fonseca, K., Earn, D., Aoki, F., Horsman, G., Van Caeseele,P., Chokani,K., Babiuk,L., Webby, R., Walter, S. (2010). Effect of influenza vaccination of children on Infection rates in Hutterite communities: a randomized trial. *JAMA,* 10, p. 943-950.

Magyary, D., Whitney, J., & Brown, M. (2006). Advancing practice inquiry: Research foundations of the practice doctorate in nursing. *Nursing Outlook, 5,* 139-149.

Maiwald, K., de Rijk, A., Guzman, J., Schonstein, E., & Yassi, A. (2010). Evaluation of a workplace disability prevention intervention in Canada: Examining differing perceptions of stakeholders. *Journal of Occupational Rehabilitation, 21*(2), 179-189. doi:10.1007/s10926-010-9267-z

Marlow, L. A., Waller, J., Evans, R. E., & Wardle, J. (2009). Predictors of interest in HPV vaccination: A study of British adolescents. *Vaccine, 27*(18), 2483-2488.

McInerny, T. K., Cull, W. L., & Yudkowsky, B. K. (2005). Physician reimbursement levels and adherence to American Academy of Pediatrics well-visit and immunization recommendations. *Pediatrics, 115*(4), 833-838.

Microsoft. (2005). *Test your document's readability*. Retrieved from https://support.office.com/en-au/article/Test-your-documents-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2?ui=en-US&rs=en-AU&ad=AU

Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: A sourcebook of new methods* (2nd ed.). Beverly Hills, CA: Sage.

Militello, L. K., Kelly, S. A., & Melnyk, B. M. (2012). Systematic review of text-messaging interventions to promote healthy behaviors in pediatric and adolescent populations: Implications for clinical practice and research. *Worldview on Evidence Based Nursing, 9*(2), 66-77. doi:10.1111/j.1741-6787.2011.00239.x.

Montano, D. E. (1986). Predicting and understanding influenza vaccination behavior: Alternatives to the health belief model. *Medical Care, 24*, 438-453.

Montano, D. E., & Kasprzyk, D. (2008). *Theory of reasoned action, theory of planned behavior, and the integrated behavioral model.* In K. Glanz, B. Rimer, & K. Viswanath (Eds.), Health behavior and health education: Theory, research, and practice (4th ed., pp. 67-96). San Francisco, CA: Jossey-Bass.

Moore, D. L., Vaudry, W., Scheifele, D. W., Halperin, S. A., Déry, P., Ford-Jones, E., . . . Tam, T. (2006). Surveillance for influenza admissions among children hospitalized in a Canadian immunization monitoring program active centers, 2003-2004. *Pediatrics, 118*(3), e610-e619.

Mozeo.com. (2014). *Mozeo text message marketing*. Retrieved from http://www.mozeo .com/#sms

Nelson, E., Stason, W., & Neutra, R. R. (1978). Impact of patient perceptions on compliance with treatment for hypertension. *Medical Care, 16*, 893-906.

Neuman, B. (1996). The Neuman systems model in research and practice. *Nursing Science Quarterly, 12*, 36-44.

Neuzil, K. M., Hohlbein, C., & Zhu, Y. (2002a). Illness among schoolchildren during influenza season: Effect on school absenteeism, parental absenteeism from work, and secondary illness in families. *Archives of Pediatric Adolescent Medicine, 156*(10), 986-991.

Neuzil, K. M., Mellen, B. G., Wright, P. F., Mitchel, E. F., Jr., & Griffin, M. R. (2002b). The effect of influenza on hospitalizations, outpatient visits, and courses of antibiotics in children. *New England Journal of Medicine, 342*, 225-231.

Nexoe, J., Kragstrup, J., & Sogaard, J. (1999). Decision on influenza vaccination among the elderly: A questionnaire study based on the health belief model and the Multidimensional Locus of Control Theory. *Scandinavian Journal of Primary Health Care, 17*, 105-110.

The Nielsen Company. (2014). *State of the media - The social media report 2012.* Retrieved from http://www.nielsen.com/us/en/insights/reports/2012 /state-of-the-media-the-social-media-report-2012.html

Nigel, M., Graham, J., & Hodges, A. (2014). *"Social media": The complete guide to social media from the Social Media Guys.* Retrieved from https://rucreativebloggingfa13.files.wordpress.com/2013/09/completeguidetosocia lmedia.pdf

Noar, S. M., & Zimmerman, R. S. (2005). Health behavior theory and cumulative knowledge regarding health behaviors: Are we moving in the right direction? *Health Education Research, 20*, 275-290.

Norten, S., Scheifele, D., Bettinger, J., & West, R. (2008). Influenza vaccination in paediatric nurses: Cross-sectional study of coverage, refusal, and factors in acceptance. *Vaccine, 26*(23), 2942-2948.

Painter, J. E., Sales, J. M., Pazol, K., Grimes, T., Wingood, G. M., & DiClemente, R. J. (2010). Development, theoretical framework, and lessons learned from implementation of a school-based influenza vaccination intervention. *Health Promotion & Practice, 11*(Suppl. 3), 42S-52S.

Penrod, J., & Hupcey, J. E. (2005). Concept advancement: Extending science through concept-driven research. *Research and Theory for Nursing Practice: An International Journal, 19*(3), 231-241.

Perception. (2015). In *Merriam-Webster's online dictionary*. Retrieved from http://www.merriam-webster.com/dictionary/perception

Poehling, K. A., Fairbrother, G., Zhu, Y., Donauer, S., Ambrose, S., Edwards, K. M., . . . Szilagyi, P. G. (2010). Practice and child characteristics associated with influenza vaccine uptake in young children. *Pediatrics, 126*, 665-673.

Polifroni, E. C., & Welch, M. (1999). *Perspectives on philosophy of science in nursing: A history and contemporary anthology*. Philadelphia, PA: Lippincott.

Prevention. (2010). *Oxford online dictionary.* Retrieved from http://oxforddictionaries .com/view/entry

Prevention magazine. (2015). Retrieved from http://www.prevention.com/

Rand, C. M., Shone, L. P., Albertin, C., Auinger, P., Klein, J. D., & Szilagyi, P. G. (2007). National health care visit patterns of adolescent vaccines. *Archives of Pediatric & Adolescent Medicine, 161*(3), 252-259.

Ranney,M.L., Choo, E.K., Cunningham, R.M., Sprito,R., Thorsen,M., Mello, M.S., Morton,K. (2014) Acceptibility, Language, and Structure of a Text-message based behavioral intervention for High-Rick Adolcscent Females-A Qualitative Study. *Journal of Adolescent Health* 55, p.33-40.

Randolph, J. J. (2008). *Online kappa calculator*. Retrieved from http://justus.randolph .name/kappa

Reed, P. G., & Shearer, N. B. C. (2009). *Perspectives on nursing theory* (5th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Reichert, T. A., Sugaya, N., Fedson, D. S., Glezen, W. P., Simonsen, L., & Tashiro, M. (2001). The Japanese experience with vaccinating schoolchildren against influenza. *New England Journal of Medicine, 34*(4), 889-896.

Richard, L., Gendron, S., Beaudet, N., Boisvert, N., Sauv, M. S., & Garceau-Brodeur, M. (2010). Health promotion and disease prevention among nurses working in local public health organizations in Montréal, Québec. *Public Health Nursing, 27*(5), 450-458.

Rosenstock, I. M. (1960). What research in motivation suggests for public health. *American Journal of Public Health, 50,* 295-302.

Rosenstock, I. M. (1974). Historical origins of the health belief model. *Health Education Monographs, 2*, 328-335.

Rosenstock, I. M., Strecher, V. J., & Becker, M. H. (1998). Social learning theory and the health belief model. *Health Education Quarterly, 15*(2), 175-183.

Sackett, D., Richardson, W., Rosenberg, W., & Haynes, R (1997). *Evidence-based medicine: How to practice and teach EMB.* New York, NY: Churchill Livingstone.

Salmon, D. A., Moulton, L. H., Omer, S. B., Chace, L. M., Klassen, A., Talebian, P., & Halsey, N. A. (2004). Knowledge, attitudes, and beliefs of school nurses and personnel and associations with nonmedical immunization exemptions. *Pediatrics, 113*(6), e552-559.

Salmon, D. A., Moulton, L. H., Omer, S. B., DeHart, M. P., Stokley, S., & Halsey, N. A. (2005). Factors associated with refusal of childhood vaccines among parents of

school-aged children: A case-control study. *Archives of Pediatric Adolescent Medicine, 159*(5), 470-476.

Satcher, D. (2006). The prevention challenge and opportunity. *Health Affairs, 25*(4), 1009-1011. Retrieved from http://content.healthaffairs.org/content/25/4/1009.full

Savel, T. G., & Foldy, S. (2012). The role of public health informatics in enhancing public health surveillance. *Morbidity & Mortality Weekly Report (MMWR), 61*(03), 20-24.

Schmier, J., James, S. L., Nichol, K., & Mahadevia, P. (2008). Benefits and costs of immunizing children against influenza at school: An economic analysis based on a large-cluster controlled clinical trial. *Health Affairs, 27*(2), 96-104.

Schneider, M. J. (2000). *Introduction to public health*. Gaithersburg, MD: Aspen.

Sharma, M., & Romas, J. A. (2008). *Theoretical foundations of health education and health promotion.* Sudbury, MA: Jones & Bartlett.

Smith, A. (2010). *Mobile access, 2010*. Retrieved from http://www.pewinternet.org /Reports/2010/Mobile-Access-2010.aspx

Smith, P. J., Battaglia, M. P., & Huggins, V. J. (2001). Overview of the sampling design and statistical methods used in the National Immunization Survey. *American Journal of Preventive Medicine, 20*(Suppl. 4), 17-24.

Smith, T., Orleans, T., & Jenkins, D. (2004). Prevention and health promotion: Decades of progress, new challenges, and an emerging agenda. *Health Psychology, 23*(2), 126-131.

Soleimanpour, S., Geierstanger, S. P., Kaller, S., McCarter, V., & Brindis, C. D. (2010). The role of school health centers in health care access and client outcomes. *American Journal of Public Health, 100*(9), 1597-1603.

Soyer, O., Hudaverdiyev, S., Civelek, E., Isik, E., Karabulut, E., Kocabas, C., & Sekerel, B. E. (2011). Parental perspectives on influenza vaccination in children with asthma. *Pediatric Pulmonology, 46*(2), 139-144.

Stinchfield, P. (2008). Practice-proven interventions to increase vaccination rates and broaden the immunization season. *American Journal of Medicine, 121*(78), 11-17.

Stockwell, M., Kharbanda, E., Martinez, R., Vargas, C., Vawdrey, D., & Camargo, S. (2012). Effect of a text messaging intervention on influenza vaccination in an urban, low-income pediatric and adolescent population. *Journal of the American Medical Association (JAMA), 307*(16), 1702-1708.

Stockwell, M. S., Kharbanda, E. O., & Martinez, R. A. (2012). Text4Health: Impact of text message reminder recalls for pediatric and adolescent immunizations. *American Journal of Public Health, 102*(2), e15-e21.

Stockwell, M., Hofstetterm A., DuRivage,N., Barrett, A.,Fernandez, N., Vargas, C., Carmargo, S. (2014). Text Message reminders for Second Dose of Influenza Vaccine: A Randomized Controlled Trial. *Pediatrics,* 135, p: 88-91.

Storm, M., Hausken, K., & Mikkelsen, A. (2010). User involvement in in-patient mental health services: Operationalisation, empirical testing, and validation. *Journal of Clinical Nursing, 19*(13/14), 1897-1907.

Szilagyi, P. G., Schaffer, S., Barth, R., Shone, L. P., Humiston, S. G., & Ambrose, S. (2006). Effect of telephone reminder/recall on adolescent immunization and preventive visits: Results from a randomized clinical trial. *Archives of Pediatric and Adolescent Medicine, 160*(2), 157-163.

Tang, Q., Bin, G., & Hinston, A. (2012). Content contribution for revenue sharing and reputation in social media: A dynamic structural model. *Journal of Management Information Systems,* 29, 41-75.

Tanner-Smith, E. (2010). Evaluating the health belief model: A critical review of studies predicting mammographic and pap screening. *Social Theory and Health, 8*(1), 95-125.

Taylor, I. D. W. (1979). A test of the health belief model in hypertension. In R. B. Haynes, D. W. Taylor, & D. L. Sackett (Eds.), *Compliance in health care.* Baltimore, MD: Johns Hopkins University Press.

Taylor, J., Darden, P., Brooks, D., Hendricks, J. W., Wasserman, R., & Bocian, A. (2002). Association between parents' preferences and perceptions of barriers to vaccination and the immunization status of their children: A study from pediatric research in office settings and the National Medical Association Development. *Public Health Nursing, 26*(1), 79-87.

Tengland, P. (2010). Health promotion or disease prevention: A real difference for public health practice? *Health Care Analysis, 18*(3), 203-221.

Thompson, W. W., Shay, D. W., Weintraub, E., Brammer, L., Cox, N., Anderson, L. J., & Fukuda, K. (2003). Mortality associated with influenza and respiratory syncytial virus in the United States. *JAMA: The Journal of the American Medical Association, 289,* 179-186.

Timmreck, T. (1994). *An introduction to epidemiology*. Boston, MA: Jones and Bartlett.

Ume-Nwagbo, P. N., DeWan, S. A., & Lowry, L. W. (2006). Using the Neuman systems model for best practices. *Nursing Science Quarterly, 19*(1), 31-35.

U.S. Department of Health and Human Services. (2010). *Healthy People 2020*. Retrieved from http://www.healthypeople.gov

Vaccination. (2015). In *Merriam-Webster's online dictionary*. Retrieved from http://www.merriam-webster.com/dictionary/vaccination

Verani, J. R., Irigoyen, M., Chen, S., & Chimkin, F. (2007). Influenza vaccine coverage and missed opportunities among inner-city children aged 6 to 23 months: 2000-2005. *Pediatrics, 119*(3), 580-586.

Wiseman, P., & Records, K. (2014). Using theory to drive influenza related text messaging. *International Journal of e-medicine*. Manuscript accepted for publication.

Wooten, K., Lumas, E., & Barker, L. (2007). Socioeconomic factors and persistent racial disparities in childhood vaccination. *American Journal of Health Behaviors, 31*(4), 434-445.

Wooten, K., Smith, P., Kennedy, A., Gust, D., & Pickering, L. (2006). Association between health care providers' influences on parents who have concerns about vaccine safety and vaccination coverage. *American Journal of Health Behaviors, 26*(3), 235-241.

World Confederation for Physical Therapy. (2015). *Tertiary prevention*. Retrieved from http://www.wcpt.org/node/47998

Wu, T.-Y., West, B., Chen, Y., & Hergert, C. (2006). Health beliefs and practices related to breast cancer screening in Filipino, Chinese and Asian-Indian women. *Cancer Detection and Prevention, 30*, 58-66.

Yoo, B. K. (2011). How to improve influenza vaccination rates in the U.S. *Journal of Preventative Medicine and Public Health, 44*(4), 141-148.

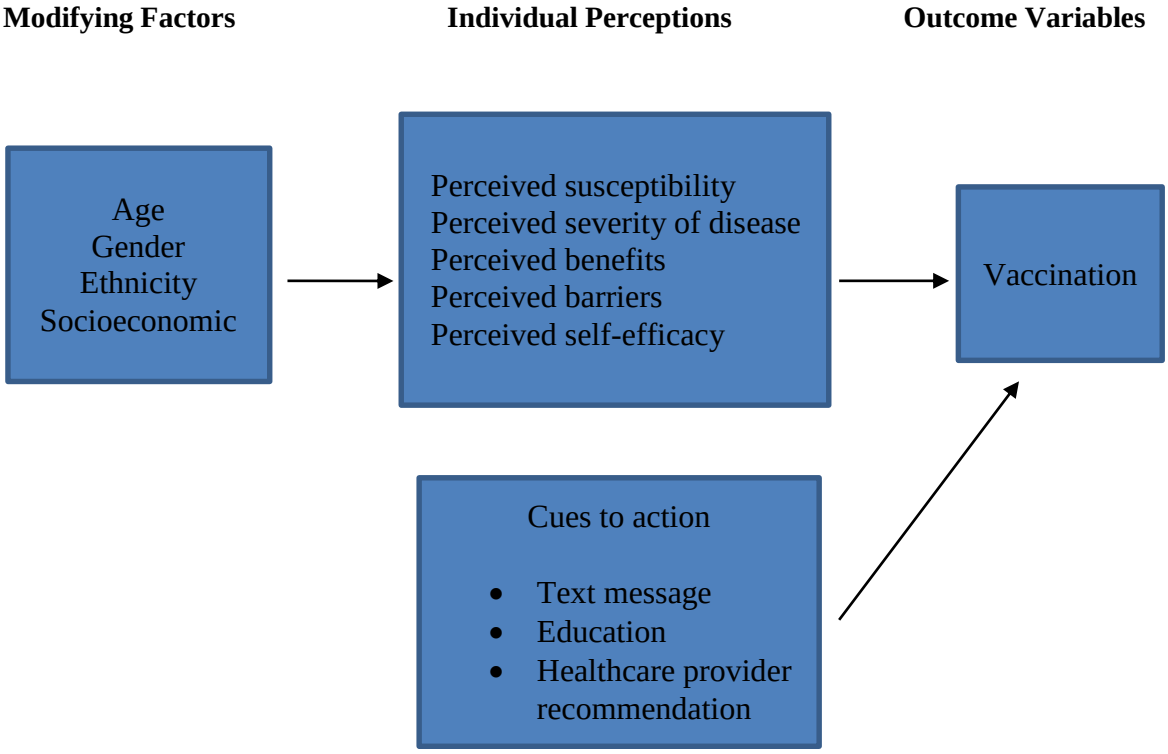
Zagumny, M. J., & Brady, D. M (1998). Development of the AIDS Health Belief Scale (AHBS). *AIDS Education and Prevention, 10*(2),173-179.

Zhou, F., Santoli, J., & Messonier, M. L. (2005). Economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States, 2001. *Archives of Pediatric Adolescent Medicine, 159*, 1136-1144.

APPENDIX A

HEALTH BELIEF MODEL COMPONENTS AND LINKAGES TO THIS STUDY

Health Belief Model Components and Linkages to this Study



APPENDIX B

SAYNO2FLU SCREENING QUESTIONNAIRE

SayNo2Flu Screening Questionnaire

Code Number: _____
Date: _____

1. Do you have a child between the ages of 5-8 years living at home with you?
    a. Yes No

2. Are you, the parent/caregiver, 18 years or older?
    a. Yes No

3. Has your child ever received a flu vaccination?
    a. Yes No

4. Does your child have a chronic illness or allergy that would prevent them from receiving a flu vaccination?
    a. Yes No

5. Do you own/use a mobile, "cell" phone?
    a. Yes No

6. Do you currently use the text message service on your mobile phone?
    a. Yes No

7. Do you feel comfortable using the text message feature on your mobile phone?
    a. Yes No

Thank you!

Di No al Flu cuestinario de admision

Numero de codigo:_____
Fecha:_____

1. Tiene usted un nino entre las edades de 5 a 8 anos de edad viviendo en su casa?
   _____Si _____No

2. Es usted el padre o madre, 18 anos o mayor?
   _____Si _____No

3. Su hijo ha recibido la vacunad de la Influeza antes?
   _____Si _____No

4. Su hijo tiene alguna enfermedad cronica o alergia que le impida recibir la vacuna de la influenza?
   _____Si _____No

5. Tiene usted un telephono celular?
   _____Si _____No

6. Tiene usted servicio de mensage de texto en su telefono celular?
   _____Si _____No

7. Se siente usted seguro o comodo usando mensages de texto en su telefono celular?
   _____Si _____No

Gracias!

APPENDIX C

CONSENT FORM

Arizona State University, Phoenix. Arizona
Sponsor Protocol Number
SHC IRB Number

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	**A study to evaluate the preliminary effects of a theory-based intervention (SayNo2Flu) guided by the Health Belief Model, combined with the use of mobile technology on parent's influenza prevention beliefs and behaviors in a primary care setting**

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done
- What will happen during the study
- Any possible benefits to you
- The possible risks to you
- Other options you could choose instead of being in this study
- How your personal health information will be treated during the study and after the study is over
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

SCOTTSDALE HEALTHCARE
INSTITUTIONAL REVIEW BOARD

Consent to Participate in Research

Protocol Name: SayNo2Flu

Sponsor: Arizona State University

Principal Investigator: Dr. Elizabeth Reifsnider
Co-Investigator: Patricia Wiseman MSN, RN

Contact Name and Telephone:
Dr. Elizabeth Reifsnider
Patricia Wiseman MSN, RN
College of Nursing and Health Innovation
Arizona State University
500 N. 3rd Street
Phoenix, AZ 85004
602-496-1394 (Phone)
623-308-0988 (Phone)
602-496-0873 (Fax)
elizabeth.reifsnider@asu.edu
patricia.wiseman@asu.edu

Introduction

You are invited to consider taking part in this research study because we are conducting research to help promote influenza vaccination in families with children ages 5-8 years old. We are interested in working with parents of school age children to participate in this 6-week program. We will be testing a text message intervention.

The program will involve a series of text messages. At the beginning and end of the six weeks you will meet with a Pediatric Nurse to review how the program and text messages will work. The program will cover information to help you overcome barriers and obtain influenza vaccine for your family.

Participation is voluntary and nonparticipation or withdrawal from the study will not affect your child's treatment or medical care. The decision to take part or not is yours. If you decide to take part, please initial each page, and sign and date the last line of this form.

Background and Purpose of the Study

The proposed study will test the effectiveness of a health belief and text messaging intervention for parents of 5-8 year old children to determine whether

health beliefs and vaccine receipt differ when compared to a text messaging control group.

Total Number of Participants
People in the study are referred to as "participants." **One Hundred (100)** participants will be enrolled at this site.

General Plan of This Study

How your Treatment will be Determined in This Study
You will be assigned to one of two research text messaging intervention groups. A computer will determine which group you will be in through a process that is much like picking a number out of a hat. Neither the researcher nor any of the participants will know who is in which group until the study ends. Your chance of being in any group is one in two. This process is called randomization.

Length of the Study for Each Participant
We expect that you will be in the study for 8 weeks.

Possible Benefits of Participating in the Study
This research has the potential to offer insight for the use of preventative interventions for parents of young school-age children and decrease the burden of influenza disease. Others may benefit in the future from the information we obtain while you are in this study.

Possible Risks or discomforts

- ☐ There is potential for minimal psychological or social discomfort when interacting by text message or completing data instruments in that there may potentially be minimal feelings of discomfort if any of the messages or questions causes you to think about things that may be perceived as unpleasant.

Who Can Participate?
This study is designed for participants who (a) have a cellular telephone number recorded in the clinic's registration system, (b) are literate in English and/or Spanish, and (c) provide informed consent. In addition, the parent must have a child who meets the following criteria: (a) between 5 and 8 years of age, (b) visited 1 of the 2 clinical sites in the previous 12 months for a wellness or minor illness visit, and (c) no previous receipt of an influenza vaccine.

Who Cannot Participate
Participants will be excluded from participation if they (a) do not have a cell phone with text messaging capabilities, (b) have a child with a chronic illness or allergy that would preclude the child from receiving an influenza vaccination.

Participants of any gender, ethnicity/race, marital status, and socioeconomic status will be included, although we expect that most of the parents will be mothers.

Confidentiality of the Data Collected During the Study

Every effort will be made to keep your medical records confidential, as well as other personal information that we gather during this study. Please see the attached "Authorization to Share Protected (personal) Health Information (PHI) in Research."

Whenever data from this study are published, your name will not be used.

Individuals from the Scottsdale Healthcare IRB, Scottsdale Healthcare, and the Arizona State University may look at medical and research records related to this study, both to assure quality control and to analyze data. We will disclose personal information about you to others as required by law.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

The master list linking the participant's ID number to the participant's identifying information will be maintained in a separate locked file cabinet in the PI and/or Co-Investigator's locked office. In addition, signed consent forms will be kept in a separate, locked filing cabinet, and will only be accessible to the PI and Co-Investigator. Access to electronic data will be restricted to the PI and Co-Investigator. Databases will be password protected to guard against unauthorized access. Federally regulated HIPAA guidelines will be followed.

New Findings

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Payments to the Principal Investigator, Institution/Hospital

The principal investigator, Co-Investigator or Clinic for this research are not receiving payment for the time spent completing study.

Payments to You for Participating

Study participants will be paid for participating in this study. Payments will be made as follows: Upon enrolling and completing the first questionnaires, you will receive a $10

gift card to a local grocery store. After completion of the program and completing the last set of questionnaires, you will receive a $20 gift card to a local grocery store. If fees are accrued for the text message portion of the program (i.e., for sent/received messages from the SayNo2Flu program) will be reimbursed at a total rate of $5 ($0.10/text message for an estimated 20-30 messages), which will be included in the compensation for completing the program. No receipts will be required.

Your Rights as a Participant in the Study

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Should you decide to leave the study, the procedure is the following: Notify the PI or Co-Investigator that you do not want to continue. At any stage, you can reply to the text messages to "Stop". Should you decide not to participate or to withdraw, your medical care will not be affected nor will your relations with your physicians, other personnel, and the hospital.

Problems and Questions

Call Patricia Wiseman at **(623) 308-0988** day or night if you have questions about the study or any problems.

Regulatory or Ethical Issues

The Scottsdale Healthcare Institutional Review Board (IRB) has reviewed this document for compliance with federal guidelines, and ethics. *Please note the IRB staff will NOT have information regarding appointment times. You will need to contact the investigator at the number above.* If you have questions about your rights as a research participant, you may call or write: IRB Coordinator or Robert Marlow, MD, Chair, IRB, 9003 E. Shea Blvd., Scottsdale, AZ 85260, 480-323-3071.

Withdrawal by Investigator, Physician, or Sponsor

The investigators, physicians, or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

Participant's Consent

You have read the information provided in this Informed Consent Form (or it was read to you by _____). All of your questions were answered to your satisfaction. You voluntarily agree to participate in this study.

[Upon signing, you will receive a copy of this form, and the original will become part of your medical record.]

Your signature _____ Date _____

Investigator's Statement

I have fully explained this study to the participant. I have discussed the procedures and treatments, the possible risks and benefits, the standard and research aspects of the study, and have answered all of the questions that the participant and the participant's family members have asked.

Signature of Investigator
or Investigator's Designee _____ Date_____

PLEASE NOTE if this study involves the enrollment of children ages 17 and under an Assent form must be developed and included in your submission.

Consent for a Child

As parent or guardian, You authorize _____ (child's name) to become a participant in the study described in this form.

Dr. _____ has explained to you the nature of the study, its purpose, possible risks, and possible benefits and has answered all of your questions to your satisfaction.

Child's date of birth_____

Parent's or Guardian's signature _____ Date _____

Di No al Flu Consentimiento para participar

Consentimiento para participar

Titulo: Di No al Flu

Un estudio para pre-eliminar efectos de una teoria basado en la intervencion (Di No al Flu) guidado por Health Belief Model, combinado con el uso de la tecnologia mobile en padres de familia para prevencion de creencias y habitos en los primeros cuidados establecidos de la influenza.

Fecha:_____

Padres de familia:
Soy un estudiante graduado de la faculta College of Nursing & Health at Arizona State University bajo la direccion de Dr. Elizabeth Reifsnider. Estoy conduciendo un estudio para examiner la efectividad de creencias de salud y la intervencion de mensages de texto para padres de familia con ninos de 5 a 8 anos de edad para determiner si sus creencias de salud y recibir la vacuna difiere cuando lo compara con atentos mensages de texto controlodos en grupo. Los resultados pueden ofrecerle una percepcion de uso de intervenciones preventivas para padres con ninos de edad escolar.

Lo invito a que usted participe en esta evaluacion de mensages de texto. Le ofrezco esta invitacion por que usted es un padre de familia de ninos de 5 a 8 anos de edad.

Son 6 mensages de texto. Cada mensage de texto es similar y puede ser recibido en un telefono celular. El mensage se provera a usted semanalmente por un periodo de 6 semanas. En cualquier momento usted puede decidir que PARE de recibir los mensajes de texto. El proceso de evaluacion toma menos de 30 minutos de su tiempo para completar el pre y examen posterior. Tendra que completar un cuestionario demografico de 10 preguntas.

No incluira un costo por su participacion en el estudio. Cualquier cobro acumulado por los mensaged de texto de este programa (i.e., por enviar/recibir mensages) sera rembolsado a una tarifa total de $5.00 ($0.10/mensage de texto por un estimado de 20-30 mensages). En adicional, usted sera compensado con $5 despues de completar el cuestionario demografico y el pre-examen (T1) instrumento; y $5 despues de completar el examen posterior (T2) instrumento.

Tiene derecho a no contestar ninguna pregunta y de detener su participacion en cualquier momento. Su participacion en este estudio es voluntario. Si usted decide no participar o abandonar el estudio en cualquier momento, no tendra ninguna penalidad. No hay beneficios por participar en este estudio. No hay riesgos por participar en este estudio.

Su respuesta sera individual y confidencial. Los resultados de este estudio podrian ser usados en reportes, presentationes o publicaciones pero su nombre no sera usado. Los resultados solo seran compartidos en grupo.

Si tiene alguna pregunta relativa a este estudio de invetigacion, por favor contacteme al 623-308-0988 (Pat Wiseman, Co Invetigator) . Si tienen alguna pregunta sobre sus derechos como sujeto/participante en esta invetigacion, o si cree usted que esta en riesgo, puede contactar a Chair of the Human Subjects Institutional Review Board, atraves de ASU Office of Research Integrity and Assurance, at (480) 965-6788.

I_____, (apoderado legal) doy consentimiento de participar en **Di No al Flu**

Firma_____Fecha:_____

APPENDIX D

RECRUITMENT SCRIPT

SayNo2Flu

RECRUITMENT SCRIPT

We are conducting a program to help promote influenza vaccination in families with children ages five to eight years old. We are interested in working with parents of school-age children to participate in this six-week program. The program will involve a series of text messages. At the beginning and end of the six weeks you will meet with a pediatric nurse to review how the program and text messages will work. The program will cover information to help you overcome barriers and obtain influenza vaccine for your family.

Participation is voluntary and nonparticipation or withdrawal from the study will not affect your child's treatment or medical care. If you choose to withdraw from this study, the information you have already provided will be kept in a confidential manner, unless you direct otherwise. In appreciation of your time, upon enrolling and completing the first questionnaires, you will receive a $5 gift card to a local grocery store. After completion of the program and completing the last set of questionnaires, you will receive a $5 gift card to a local grocery store.

Di No al Flu

TEXTO DE RECLUTAMIENTO

Estamos conduciendo un programa de ayuda para promover la vacuna de la influenza, en familias con ninos en edades de 5 a 8 anos de edad. Nos interesa trabajar con los padres de familia que tengan hijos con estas edades para participar en un programa de 6 semanas. El programa involucra una serie de mensages de texto. Al principio y al final de las 6 semanas usted se reunira con una Enfermera en Pediatria para revisar como trabajo el programa y mensages de texto. El programa cubrira informacion de ayuda encontra de la influenza y como obterner la vacuna de la influenza para su familia.

Su participacion es voluntaria, si usted decide no participar o abandonar el programa esto no afectara el tratamiento o cuidado medico de su hijo. Si usted decide abandonar el programa la informacion que usted haya proveido se mantendra confidencial, al menos que usted disponga otra cosa. En apreciacion de su tiempo, su participacion y completar los primeros cuestionarios, usted recivira una targeta de regalo de $5. Despues de completar el programa en su totalidad usted recivira una targeta de regalo de $5.

APPENDIX E

HEALTH BELIEF MODEL INFLUENZA-RELATED SURVEY

(PRETEST)

Health Belief Model Influenza-related Survey (Pretest)

Part 1: Demographic Survey

Demographic Survey		
Age		
Gender	Male	Female
Race / Ethnicity	Caucasian	
	African American	
	Hispanic	
	Asian/Pacific Islander	
	Native American	
	Other	
Parent	Father	
	Mother	
	Grandparent	
	Aunt/Uncle	
	Legal Guardian	
Health Insurance	Yes	No
Marital Status	Married	Single
Education Level	Elementary	
	≥ High School	
	Some College	
	≥ College/University	
Estimated Family Annual Income	Less than $10,000	
	$10,001-$25,000	
	$25,000-40,000	
	$40,001-$55,000	
	$55,001-$75,000	
	$75,001 and above	
Health Insurance	Yes	No
Child/Children	Age	
	Age	
	Age	
Child Medical History	Asthma	Yes / No
	Skin or nasal allergy	Yes / No
	Congenital heart disease	Yes / No
	Chronic lung disease	Yes / No
	Other	Yes / No

Encuesta de Mitos y Creencias relacionados con la influenza
Salud Belied Encuesta Modelo

DATOS GENERALES PARA LA ENCUESTA		
Edad		
Genero/ Sexo	Masculino	Femenino
Raza/ Entidad	Blanco Americano	
	Afro Americano	
	Hispano	
	Asicatico/Islas Pacificas	
	Nativo Americano	
	Otro	
Bajo el cuidado de	Papa	
	Mama	
	Abuelos	
	Tio/Tia	
	Guardian Legal	
Estado Marital	Casado	Soltero
Nivel de Educaccion	Primaria	
	Secundaria	
	Preparatoria	
	Universidad	
Ingresos anuales	Menos de 10,000	
	$10,001-$25,000	
	$25,000-40,000	
	$40,001-$55,000	
	$55,001 y mas	
Nino/Ninos	Edad	
	Edad	
	Edad	
Historial Medico del nino	Asma	
	Alergia en la piel o nariz	
	Enfermadades del Corazon al nacer	
	Enfermedad cronica pulmonar	
	Otro	

Health Belief Model Influenza-related Survey (Pretest)
Part 2:

Code Number: _____
Date: _____

Directions: For each of the items below, indicate how strongly you agree or disagree with the statement.

	Items	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Perceived Severity	1. Influenza infection may cause serious health problems.	SD	D	N	A	SA
	2. Influenza with complications is dangerous.	SD	D	N	A	SA
	3. If any of my child/children contracted influenza, the disease could spread to other family members.	SD	D	N	A	SA
Perceived Susceptibility	4. My child/children have a high risk of influenza.	SD	D	N	A	SA
	5. My child/children get sick more easily than other children do.	SD	D	N	A	SA
Perceived Benefits	6. Influenza vaccinations can relieve influenza symptoms and complications.	SD	D	N	A	SA
	7. Influenza vaccinations effectively protect against the flu.	SD	D	N	A	SA
	8. Influenza vaccines are safe for children.	SD	D	N	A	SA
Perceived Barriers	9. I am generally opposed to vaccinations.	SD	D	N	A	SA
	10. Influenza vaccinations have unpleasant side effects.	SD	D	N	A	SA
	11. Influenza vaccinations weaken the natural immune systems.	SD	D	N	A	SA

	Items	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	12. Vaccinations are inconvenient.	SD	D	N	A	SA
	13. Influenza vaccinations are expensive.	SD	D	N	A	SA
	14. I am influenced by negative news about influenza vaccines.	SD	D	N	A	SA
Cues to Action	15. The recommendations in the mass media affect my decision about whether to vaccinate my children for influenza.	SA	A	N	D	SD
	16. My doctor(s)' recommendation affects my decision whether to vaccinate my children for influenza.	SA	A	N	D	SD
	17. My nurse(s)' recommendation affects my decision whether to vaccinate my children for influenza.	SA	A	N	D	SD

(Chen et al., 2011; Coe et al., 2012)

Self-efficacy	18. It was easy to obtain the influenza vaccination for my child.	SA	A	N	D	SD
	19. Vaccinations are convenient to obtain for my child	SA	A	N	D	SD
	20. I believe I can get my child vaccinated.	SA	A	N	D	SD

(Cheney & John, 2013)

Encuesta de Mitos y Creencias relacionados con la influenza
Salud Belied Encuesta Modelo

Instrucciones: Indique en cada pregunta si esta en complete acuerdo, deacuerdo, neutral, desacuerdo o completo desacuerdo.

	Preguntas	Completo Descuerdo	Des acuerdo	Neutral	De acuerdo	Completo Deacuerdo
Perspectiva Severa	1. El contagio de la influenza causa serios problemas de salud.	DSAC	DSA	N	DA	CDA
	2. La influenza con complicacciones es peligrosa.	DSAC	DSA	N	DA	CDA
	3. Si alguno de mis hijos se contagia con la influenza, todos los miembros de mi falmilia podrian contagiarse.	DSAC	DSA	N	DA	CDA
Perspectiva de Vulneravilidad	4. Mi hijo/hija tiene un alto riesgo de contagiarse de la influenza.	DSAC	DSA	N	DA	CDA
	5. Mi hijo/hija se enferma mas facilmente que otros ninos.	DSAC	DSA	N	DA	CDA
Perspectiva de Beneficios	6. La vacuna de la influenza remedia los simptomas y complicaciones.	DSAC	DSA	N	DA	CDA
	7. La vacuna de la influenza es efectiva para proteger en contra del flu.	DSAC	DSA	N	DA	CDA
	8. La vacuna de la influenza es segura para los ninos.	DSAC	DSA	N	DA	CDA

	Preguntas	Completo Descuerdo	Des acuerdo	Neutral	De acuerdo	Completo Deacuerdo
Perspectiva Negativa	9. Completamente me opongo a cualquier vacuna.	DSAC	DSA	N	DA	CDA
	10. La vacuna de la influenza tiene efectos secundarios desagradables.	DSAC	DSA	N	DA	CDA
	11. La vacuna de la influenza despierta nuestro sistema inmunologico natural.	DSCA	DSA	N	DA	CDA
	12. Las vacunas son inconvenientes.	DSCA	DSA	N	DA	CDA
	13. La vacuna de la influenza tienen un costo alto.	DSCA	DSA	N	DA	CDA
	14. Los comentarios negativos a acerca de la vacuna para la influenza han influenciado en mi opinion.	DSCA	DSA	N	DA	CDA
Plan de Accion	15. Las recomendacciones de los medios de comunicacion han influido en mi decision de vacunar a mis hijos de la influenza.	DSCA	DSA	`N	DA	CDA
	16. La recomendacion de mi doctor han me han ayudado para decidir si mis hijos deben vacunarse para la influenza.	DSCA	DSA	N	DA	CDA
	17. La recomendacion de mi enfermera me han ayudado para decidir si mis hijos deben vacunarse para la influenza.	DSCA	DSA	N	DA	CDA

(Chen et al., 2011)

	Preguntas	Completo Descuerdo	Des acuerdo	Neutral	De acuerdo	Completo Deacuerdo
La autoeficacia	18. Era fácil obtener la vacuna contra la gripe para que mi hijo	DSCA	DSA	N	DA	CDA
	19. Vacunas contra la gripe son un conveniente para obtener para mi hijo Vacunas contra la gripe son un inconveniente para obtener para mi hijo.	DSCA	DSA	N	DA	CDA
	20. Creo que puedo hacer que mi niño vacunado con la vacuna de la gripe.	DSCA	DSA	N	DA	CDA

(Cheney & John, 2013)

Health Belief Model Influenza-related Survey (Posttest)
Part 2:

Code Number: _____
Date: _____

Directions: For each of the items below, indicate how strongly you agree or disagree with the statement.

	Items	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Perceived Severity	1. Influenza infection may cause serious health problem.	SD	D	N	A	SA
	2. Influenza with complications is dangerous.	SD	D	N	A	SA
	3. If any of my child/children contracted influenza, the disease could spread to other family members.	SD	D	N	A	SA
Perceived Susceptibility	4. My child/children have a high risk of influenza.	SD	D	N	A	SA
	5. My child/children get sick more easily than other children do.	SD	D	N	A	SA
Perceived Benefits	6. Influenza vaccinations can relieve influenza symptoms and complications.	SD	D	N	A	SA
	7. Influenza vaccinations effectively protect against the flu.	SD	D	N	A	SA
	8. Influenza vaccines are safe for children.	SD	D	N	A	SA
Perceived Barriers	9. I am generally opposed to vaccinations.	SD	D	N	A	SA
	10. Influenza vaccinations have unpleasant side effects.	SD	D	N	A	SA
	11. Influenza vaccinations weaken the natural immune systems.	SD	D	N	A	SA
	12. Vaccinations are inconvenient.	SD	D	N	A	SA

	Items	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	13. Influenza vaccinations are expensive.	SD	D	N	A	SA
	14. I am influenced by negative news about influenza vaccines.	SD	D	N	A	SA
Cues to Action	15. The recommendations in the mass media affect my decision about whether to vaccinate my children for influenza.	SA	A	N	D	SD
	16. My doctor(s)' recommendation affects my decision whether to vaccinate my children for influenza.	SA	A	N	D	SD
	17. My nurse(s)' recommendation affects my decision whether to vaccinate my children for influenza.	SA	A	N	D	SD

(Chen et al., 2011; Coe et al., 2012)

Self-efficacy	18. It was easy to obtain the influenza vaccination for my child.	SA	A	N	D	SD
	19. Vaccinations are convenient to obtain for my child	SA	A	N	D	SD
	20. I believe I can get my child vaccinated.	SA	A	N	D	SD

(Cheney & John, 2013)

Part 3: Health Belief Model Influenza-related Survey (Posttest)

Directions: For this question, please circle Yes or No

21. Did you child receive a flu vaccine this season?	Yes	No
22. Did you receive a flu vaccine this season?	Yes	No
23. Do most of the parents you know take their children for flu shots?	Yes	No
24. Do most of the people important to you think you should give your child a flu shot?	Yes	No

(Daley et al., 2007)

Directions: For these last three questions, please use these open ended questions to describe your experience with vaccinating your child. If you have more than one child, think about experience with vaccinating your child who is between 5 and 8 years of age.

If your child was vaccinated, please respond below:

25. What were your reasons to vaccinate your child? Please explain.

_____

_____

_____

26. Describe your experience with getting your child vaccinated.

_____

_____

If your child was not vaccinated, please answer this question:

27. What were your reasons for not vaccinating your child? Please explain.

_____

_____

28. What concerns do you have with getting your child vaccinated?

_____

Instrucciones: Para esta pregunta, por favor marque Sí o No

	Si	No
21. Su hijo Ocho años de edad reciba una vacuna contra la gripe en esta temporada? Si " Sí " , ¿qué mes?	Si	No
22. Ha recibido una vacuna contra la gripe en esta temporada?	Si	No
23. La mayoría de los padres que conoces llevar a sus hijos por las vacunas contra la gripe?	Si	No
24. Es la mayoría de la gente importante que usted cree que debería darle a su hijo una vacuna contra la gripe?	Si	No

(Daley et al., 2007)

Instrucciones: Para estos últimos cuatro preguntas, por favor, utilice estas preguntas abiertas para describir su experiencia con la vacunación de su hijo. Si usted tiene más de un hijo, piense en la experiencia con la vacunación de su hijo que está entre 5 y 8 años de edad.

25. Cuáles fueron sus razones para vacunar a su hijo para la gripe? Por favor, explique .

_____

_____

_____

26. Describa su experiencia con conseguir su niño vacunado con la vacuna de la gripe.

_____

_____

_____

Si su hijo no ha sido vacunado, por favor responder a esta pregunta:

27. Cuáles fueron sus razones para no vacunar a su hijo con la vacuna contra la gripe? Por favor, explique. _____

_____

_____

28. Qué preocupaciones tiene con conseguir su niño vacunado con la vacuna contra la gripe? _____

_____

_____

APPENDIX F

PARENT EVALUATION OF THE SAYNO2FLU PROGRAM

Parent Evaluation of the SayNo2Flu Program

1. Please describe what information from the SayNo2Flu program was the most helpful.

_____
_____
_____

2. Which text message did you think helped you decide to have your child vaccinated? Please circle:

Text #1:
Test #2:
Text #3:
Text #4:
Text #5:

3. Would you recommend the SayNo2Flu text message program to other parents of five- to eight-year-olds?

A. No B. Yes

Why or why not? _____
_____
_____

4. What would YOU change about the SayNo2Flu program?

_____
_____
_____

5. Did you find the text messages helpful as a reminder to vaccinate your child?

_____
_____
_____

6. What other type of information would you like to see included in the text?
(Please circle all that apply)

a) Child's name
b) Vaccine name
c) Physician name/office name
d) Other _____

Evaluacion de los padres del la Di no al program de gripe

1. Di que encoutrar el informantion do no al programa de gripe util?
A. No B. Si

En caso afirmativo, cual fue until la niebla?

_____
_____
_____

2. Que el mensaje de texto pensaste te ayudo a decidirse a vacunar a su hijo?

Texto #1:
Texto #2:
Texto #3:
Texto #4:
Texto #5:
Texto #6:

3. Recomendarias el decir ningun programa 2 de la gripe a otros padres de ninos de 5-8 anon?
A. No B. Si

Por que o por que not? _____
_____
_____

4. Que cambiarias sobre el decir ningun programa 2 de la gripe?

_____
_____
_____

5. Que encontraste los mensajes de texto util como recordatorio para vacunar a su hijo?

_____
_____
_____

6. Que otro tipo de informacion le gustaria ver?
Por favor marque todo lo que corresponda?
a) El nombre del nino
b) El nombre de la vacuna
c) El nombre del medico

Gracias !