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The Effectiveness of Combined Appointments and Influenza Immunization Rates in a Rural WIC Population

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Rural WIC Population

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Abstract

Purpose: The purpose of this descriptive retrospective study was to examine predictors and barriers to influenza immunizations receipt in a low-income WIC population.

Method: A quality improvement project was conducted in October 2010 in which 129 caregivers of children having WIC appointments were randomly assigned to receive (a) influenza immunizations at the time of the WIC visit or (b) educational materials and a later immunization. Caregivers completed a survey about their perceptions of influenza immunizations. Tanahashi's access to care model (1978) was used to identify predictors (acceptability, accessibility, availability, and effectiveness) of influenza immunizations.

Analysis: In analysis of data collected from September to November 2010 the chi-square test was performed to assess the relationship between group assignment and immunization receipt. Logistic regression was used to examine the relationship of the dependent variable, immunization receipt, with the potential variables of acceptability, accessibility, availability, and effectiveness.

Results: Participants who received only the educational materials and an opportunity to receive an immunization at a later date were less than half as likely to get immunized (15.6%) as those who were offered a same day influenza immunization (39.3%). There was a statistically significant association between whether or not influenza immunization was offered at the time of the WIC appointment and the rate of influenza immunization, $\chi^2(1)=7.905$, p=.005. The acceptability scale (Tanahashi's model) was a significant predictor (AOR = 2.261, p = .019) of immunization receipt but items measuring accessibility, availability, and effectiveness were not significant predictors (*p*s all > .16).

Conclusions: These findings suggest that offering immunizations at the time of a WIC

appointment may increase overall rates of childhood immunizations. Further research

with Tanahashi's model is needed.

Key words: Pediatric influenza, Tanahashi access to care, influenza immunizations, access to care, WIC, acceptability of influenza immunization

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Chapter One

This chapter presents the background and significance of the study, statement of the problem, and the purpose of the study. Additionally, the research questions are presented.

Background and Significance

The present system of delivery of care is changing in the context of the Affordable Care Act (Patient Protection and Affordable Care Act, 2010). Traditional methods of practice need to focus on prevention of disease while at the same time being cost effective and responsive to the populations to whom care is being provided. It is requisite that these designs are flexible to allow for differences in the population, changes in the environment, conditions associated with the patient and the providers of nursing. Fragmentation of care is presently an issue creating difficulties in effective delivery of health care. Within the interdisciplinary view of the health care encounter, the patient is the constant factor centered in interdisciplinary care from its inception to completion (Allison & McLaughlin-Renpenning, 1999; IOM, 2010). This is an important consideration when improving delivery of care as often patients are seen by several providers in the context of overall health care.

When evaluating a system of care, it is important to first understand the knowledge of the individual in relation to self and the environment, the factors for life, well-being, and health (Orem, 2001) as well as identify any deficiencies or obstacles in performance/skills/resources needed for self-care/dependent care. If any deficiencies are identified, a self-care or dependent deficit exists (either complete or partial) and involvement by the nurse is required. In this case, dependent-care agency is being examined.

Dependent-care agency's conceptual structure is formed by capabilities of the nurse to exercise operations in knowing and meeting others' therapeutic needs and working with other persons or populations (Orem, 2001). In the case of infants and children, it is important to recognize the needs not only of the infants and children but of the parents and caregivers in providing care for the well-being of the infants and children. In preparation for designing a system of dependent care, it is imperative to assess the knowledge, patterns of behavior, attitudes and beliefs, and identify a usable model for health care delivery. Careful examination of the effectiveness of the present system of care as measured by Tanahashi's (1978) access to care model and implications for changes in future care are proposed here. Orem (1978) cited this planning as an important consideration when developing nursing services to meet the needs of communities.

When discussing best practices in the community and what will be required to meet changing health needs of diverse populations in the future, The Care in the Community report suggested the following challenges be considered when changing health care practices:

- Budgets for public health and community health programs are being cut at a time when these programs are most needed…when greater emphasis is being placed on prevention, wellness, chronic disease management, and moving care into the community.
- Nursing care in the community occurs through partnerships with many other individuals and organizations, and nurses need to take a leadership role in

establishing these vital partnerships. Fostering this type of collaboration could improve the continuum of care between acute and community care settings.

- The delivery of quality nursing care has the potential to provide value across community settings and can be achieved through effective leadership, policy and accountability.

(IOM [Institute of Medicine], 2010)

Significance to Nursing

Understanding the factors related to access to care will assist health care providers in increasing the overall immunization rates of children, not only those in rural areas. Specifically, immunization of children for influenza at the time of other services is likely to increase rates of immunizations overall, thus reducing the number of children not immunized due to problems identified by the access to care model. Furthermore, it is anticipated there will be fewer children falling behind in their recommended immunizations or not receiving routine childhood immunizations.

Nursing has built upon caring as the basis for its many theories and frameworks for practice (Chism, 2013; Kaakinen, Gedaly-Duff, Coehlo, & Harmon-Hanson, 2010; McEwen & Wills, 2014). From the time of Florence Nightingale to the modern-day theorists, caring has been an essential element but conceptualized differently to fit the changing climate of nursing while maintaining the four basic concepts of nursing: individual, environment, health, and nursing. Changes in theories have evolved from nurses' experiences and can be reflective of changes in science, knowledge, political climate and necessity for providing nursing care. Furthermore, these theories provide "a guide for practice and a basis for research" (Chism, 2013, p. 103).

In response to changes in the health care system and the advent of managed care, Allison and McLaughlin-Renpenning (1999, p. 54) postulated, "the concern now is to prioritize services-to provide only those that are essential…the focus of concern or proper object of nursing and the associated variables of concern to nursing and their interrelationships, nursing theory provides…direction". Simply administering nursing services based on prior health care delivery practices is no longer effective. Nurses need to be assertive and take a stronger leadership role in moving nursing forward to meet the demands of the millennium.

Nurses are poised to create interdisciplinary systems in which there is collaboration among providers and services can be provided in one setting as opposed to multiple settings for separate disciplines. This model reflects the efficiency available when nursing is viewed in the context of other disciplines. Nursing is challenged to design systems of delivery by viewing nursing's involvement in a larger context than exclusively providing nursing services.

Nurses are in a unique position, having the opportunity to be an integral part in designing health care systems. Presently, nurses are primarily associated with nursing functions and are intimately familiar with the day-to-day operations of providing health care. Nurses need to ask critical questions of themselves related to the process of knowing and utilizing ethics, aesthetics, empirics, and personal knowledge when designing a health care system.

The Future of Nursing's Care in the Community report IOM (2010) specifically called upon nurses to be full partners in redesigning care, practice to the full extent of their training, and support individuals in improving their health outcomes through

wellness and prevention activities. Successful integration of goals of professional practice and nursing management requires an understanding of nursing as a discipline of knowledge and a science, as well as an understanding of organization theory and economics, for these are foundational to nursing practice (Orem, 1995). Furthermore, the design needs to reflect harmony and integrity for each part of the system as a whole and the relationships among the parts and the whole (Orem), which Tanahashi's (1978) access to care model emphasizes.

Figure 1 demonstrates the interaction among the parts of a nursing health care system and the influencing factors when designing a system. It is important for nurses to recognize the dynamic aspect of these factors as they relate to the nursing paradigm. Conducting formative evaluation throughout use of a system is imperative due to the ever-changing health care environment. For example, changes in legislation affecting medical coverage, availability of care to individuals, and any potential or actual changes in the health of the individual require that the system be reviewed. Nurses are poised as change agents due to their intimate involvement in all aspects of health, the individual, and the environment through nursing care. Due to their education and knowledge, nurses have the expertise to assess the pressing needs and advocate for change.
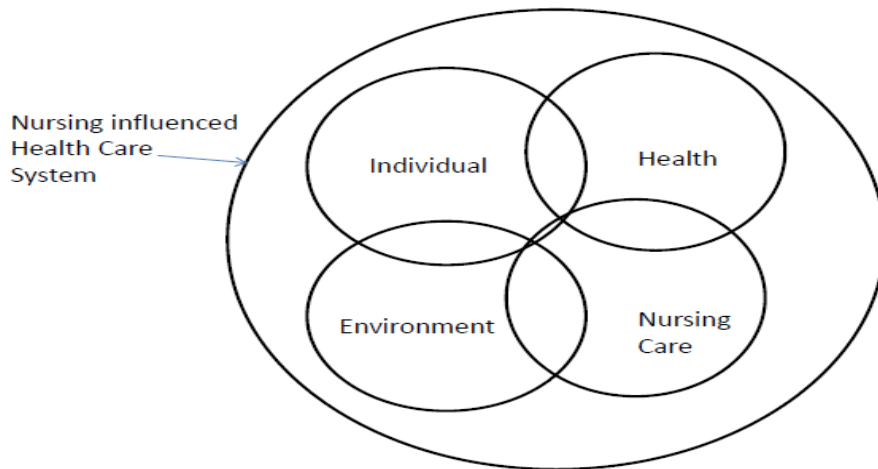
Figure 1. Influences affecting the nursing health care system (Chinn & Kramer)

Nursing needs to retain its focus in relation to individual, environment, health, and nursing while having a broader, stronger influence on access to care through designing systems for delivery of care. Allison and McLaughlin-Renpenning (1999, p. 93) charge nurses to be the leaders in health care by influencing others in setting the tone of the environment. In order to be a competent leader, the nurse needs to excel in the area of nursing knowing, knowing the issues, knowing the population, knowing the current information, and knowing the anticipated needs. Again, this idea is expanded to encompass the individual, health, and environment. Nurses need to be involved in designing systems of care which address health promotion and prevention while reducing fragmentation of care.

Designing nursing systems for patient populations is an obligation of nurses in order to maximize the number of individuals in the population who receive quality, safe, effective nursing care. Many nurses do not see their involvement in designing care as an essential role of their profession because the focus generally revolves around planning for care of individuals or the production of the service. It is their knowing through empirics,

personal knowledge, ethics, and aesthetics that positions them exactly in the process of designing systems.

It is critical that nurses become involved in designing health care delivery systems through research, collaboration, provision of care, and evaluation. Public health seeks to avoid duplication of services provided while ensuring the holes or unmet needs of the population are addressed. Periodic assessments of services are conducted through surveys to identify any unmet needs. The most recent assessments identified access to medical care as an area of concern by the residents of the selected Missouri county (XXXX [name has been deleted in order to de-identify data] County Health Department, 2008, 2012). Barriers to care in this County include: lack of specialists, lack of transportation, lack of acceptability (distrust in the health care providers who provide service), lack of available hours for care, and fragmented care.

Meeting the needs of rural residents is essential for the health and well-being of the population. Nurses are in a unique position to contribute to solutions which address this problem. Identification and access to a health care system that provides linkage among the identified needs of the individual, the environment, health, and nursing care that will improve health care delivery is urgently needed in light of the changes and mandates of the Affordable Care Act.

Significance of the Study

Each year many children are hospitalized or die from influenza-related complications. Wong et al. (2013) compared eight flu seasons, from October 2004 through September 2012 and found that flu-related deaths occur not only in children with underlying health conditions but also healthy children and that most the deaths that

occurred involved children not immunized with an annual flu vaccination. During the 2009 H1N1 pandemic outbreak, the shift away from traditional populations at risk for complications from influenza, those over 65 years of age, to those under 65 years of age (80%) with an estimated years of life lost at three times the number compared to an average flu season (Dawood, et al., 2012). A national longitudinal review of influenza deaths in children under the age of 18 years found 830 children in the United States died from influenza from October, 2004 to September, 2012 with the greatest number of child deaths occurring as a result of the 2009 H1N1 virus (Wong et al., 2013). Of 794 children with known medical history, 43% had no high risk conditions and the median age of these children was seven years of age (Wong et al., 2013).

Immunization of children against infectious agents is one of the most important health interventions of the 20th century (CDC, 1999). Annual influenza immunization has been shown to be the most effective method in preventing influenza infection, and is reflected by the Centers for Disease Control's (CDC) expanded recommendation for influenza immunizations which include all children aged 6 months to 18 years, regardless of high-risk medical conditions (CDC, 2008, 2013; Cox & Subbarao, 1999). Immunizations have eliminated approximately three million influenza related deaths annually and prevented 6.6 million influenza illnesses in the United States alone during the 2012-2013 influenza season (CDC, 2013). The American Academy of Pediatrics (AAP) recommends universal immunizations and recognizes the need for providers to respond to parental refusals of immunization of children in order to increase the number of children immunized (CDC, 2005).

The recommendation for universal influenza immunizations of all children, healthy and those at risk, was implemented during the 2010-2011 influenza season. Since that time, only 40% of children received immunizations during the 2012-2013 season, down from the final estimated rate among children during the 2011-2012 season (CDC, 2013). Despite the known dangers of not immunizing children against influenza, many parents are still not properly vaccinating children less than 18 years of age. During the 2012-2013 flu season, CDC (2013) reported that, to date, the number of influenza-associated pediatric deaths were at 105 for children less than 18 years of age. Of these deaths, it is estimated that 90% occurred in children who had not received an influenza immunization, 60% occurred in children considered high-risk for developing serious complications, and 40% had no recognized risks. The CDC (2013) defined children considered at high risk for influenza complications as those less than 5 years of age with chronic health conditions (lung disorders, heart disease, or a neurologic/neurodevelopmental disorder).

Additionally, it is estimated that immunizing 20% of children against influenza is more beneficial than immunizing 90% of the adult population over 64 years of age (Coleman et.al., 2006), resulting in reduced costs and illness related to influenza. CDC (2013) surmised that the 2012-2013 influenza vaccine was 60% effective in preventing influenza. Halloran and Longini (2006) estimated that less than 5% of school-aged children in the United States (U.S.) are currently vaccinated against influenza. Rather than improving, this trend of non-immunization has continued as more recent statistics support (CDC, 2013). The work of King et al. (2006) found that negative outcomes

related to influenza-like illness were lower in households where children were vaccinated against influenza.

It is important to identify reasons for non-immunization in order to continue reduction and eradication of vaccine preventable childhood diseases. In order to identify methods for maintaining and increasing immunization rates, a review of an influenza program using a model which can identify reasons for non-immunization and bottlenecks in an immunization program is being proposed. It is hypothesized that as a result of implementing a practice that encourages immunization at the time of other health care services, such as a WIC (Women, Infants, and Children) visit, the rate of immunization will increase, resulting in fewer children falling behind in routine childhood immunizations.

Statement of Problem

Immunizations have resulted in reduction or eradication of many childhood diseases. Singleton (2011), indicated for the 2010-2011 influenza season children less than nine years of age had not been properly immunized. Those children between 6 and 11 months of age had the highest rate of immunization with 69% having received their first influenza immunization followed by 33% receiving their second follow up dose. Children two years of age were least likely to have received their first dose (52%) and their second dose (13%). It is difficult to obtain overall influenza immunization rate data specifically for Missouri as detailed data does not appear in the CDC report which is published at the end of each influenza season. However, the Missouri Department of Health and Senior Services does conduct surveillance which identifies the number of laboratory-positive influenza cases and provides trend data. Difficulties reaching children

in rural areas stem from issues related to transportation, lack of providers, access to care, acceptability of care, and use of care. Gale and Lambert's (2006) research of these same issues in rural settings suggested that when addressing differences in rural and urban health care that elements of Accessibility, Availability, and Acceptability of care were crucial when working with the unique issues facing rural populations. In the particular county where this health department is located, the total number of hospitalizations of infants and children related to pneumonia and influenza during 2010- 2013 were 481 individuals, with 2 deaths occurring between 2002-2012 with pneumonia and influenza being the second highest disease/condition (MDHSS, 2015).

Another issue pertinent to administration of influenza immunization is the difference between rural v. urban immunization administration. A review of the differences in rural v. urban areas in the location of influenza vaccine administration revealed that residents of small rural counties were more dependent upon clinical settings than urban residents (Bennett, Pumkam, & Probst, 2011). Bennet et al., 2011 identified that factors affecting influenza immunization rates included socioeconomic factors, health status and conditions, and per capita income of the county, all of which are important when considering access to care and administration of vaccination. Overall immunization rates of children for routine immunizations have improved since 2000, with the rates of disparities between rural and urban dwelling children narrowing between 2000-2008 (Zhao & Luman, 2010). As with Bennet et al.'s findings, rates of immunizations were also affected by sociodemographic and socioeconomic factors. By controlling factors such as income, education, family characteristics and lower education, Zhao and Luman (2010) found that the disparities between groups were reduced.

Additionally, it was found that after controlling other factors, participation and coverage of children requiring immunizations increase among children whose providers participated in the Vaccines for Children (VFC) program (Zhao & Luman, 2010). It should be noted that the clinic at the county health department is a VFC participant.

Despite the known benefits of immunizing children against influenza, there are still identified barriers to obtaining influenza immunizations. Reasons parents do not immunize their children are many: lack of education, reliance on information located on the Internet, anti-vaccination campaigns, pain incurred by the child, poor relationships with the provider, attitudes related to immunization, number of shots a child should receive at one visit, ease with which a parent can get the child to the doctor to get an immunization, access to medical care, and coordination of medical services with financial access (Diekeman, 2005; Nowalk, 2005; Starfield & Shi, 2004).

In the spring of 2010, the CDC changed its recommendations to suggest that all children ages six months or older receive influenza immunization (see Appendix A). There was a need to educate caregivers about this change and increase the number of influenza immunizations to meet these expanded recommendations. Previously, influenza immunizations were only provided during a pre-scheduled immunization appointment. Historically, "no shows" or broken appointments were common and the number of immunizations was low.

In the fall of 2010, in order to meet these new recommendations, influenza immunizations were offered at the time of Women/Infant/ Children (WIC) appointments at the County Health Department as opposed to the prior protocol which required individuals to return at a later date during a scheduled influenza clinic. Family care-giver

surveys were provided as a routine quality improvement project implemented in the WIC department annually, and in 2010 the surveys were expanded to examine facilitators and barriers related to provision of services. These data have remained in a database at the County Health Department; trends based upon this data were identified and analyzed to fulfill state requirements and to complete the community assessment but this data has remained unevaluated and not assessed with an existing framework for the purpose of examining the impact that increased access to immunizations may have had on increased immunization rates.

Purpose of the Study

The purpose of this descriptive retrospective study is to determine the effect of combining WIC and influenza immunization appointments on immunization rates of children six months through five years of age compared to the standard protocol of requiring separate appointments for influenza immunizations. Tanahashi's (1978) model related to access to care will be used to help understand the potential mechanisms of the effect. This process will generate a quality improvement project related to access to care for influenza immunizations in a rural low-income population of children enrolled in a WIC program. Access to care has been identified as a reason why medical care has not been provided and Tanahashi's Access to Care Model (1978) will be used as the framework.

Aim and Hypothesis

It is hypothesized that this model will identify facilitators and barriers to care such as acceptability, accessibility, effectiveness, contact coverage, and availability of

coverage, while identifying bottlenecks in services to parents and caregivers of these children.

As a result of improved access to care, we hypothesize that offering influenza immunizations at the time of a WIC visit will improve the likelihood of children being immunized for influenza as the parents will not have to make a separate appointment and visit to receive influenza immunizations.

The questions this study seeks to answer are:

- How does combining WIC and influenza immunization appointments affect the influenza immunization rate of children six months to five years of age compared to those who received influenza immunizations at a separate appointment?

- What are the identified barriers for pediatric influenza immunizations in a low-income WIC population in a Midwestern community?

The next step in this process was to conduct a review of the literature to better understand access to care in the context of public health, the impact of influenza related morbidity and mortality, the effect of influenza immunizations on influenza related morbidity and mortality, as well as review and critique Tanahashi's model.

Chapter Two: Review of the Literature

When beginning the search for a framework that would best represent access to care in the context of public health, the concept of access to care was examined. A CINAHL, Google Scholar, and PubMed search revealed access to care has been examined and conceptualized by multiple disciplines in an attempt to create a universal definition of the concept. Access to care continues to be an issue relevant to heath care providers. A Google Scholar search using the keyword "access to care" resulted in more than 2 million entries, supporting an ongoing relevancy in improving and identifying methods for access to care. Aday and Andersen's (1974) early review of literature found the concept and measurement of access to care to be ill-defined and sought to conceptualize and operationalize access as well as construct a theoretical framework with empirical indicators of the concept.

This chapter examines the significance of respiratory viruses in children, epidemiology of influenza, transmission of influenza, and influenza vaccines. Access to care and its importance are identified and Tanahashi's model is described. Tanahashi's model is reviewed and critiqued using the Chinn and Kramer (2004) method which examined the theory based upon its concepts, definitions of the concepts, relationships among the concepts, structure, and assumptions; this method also requires reflection related to the clarity, simplicity, generalizability, accessibility, importance, and usefulness of the theory. Barriers to care are also considered.

Background

Influenza is a highly infectious acute viral disease of the respiratory tract that kills about 36,000 people annually and is responsible for more than 200,000 annual

hospitalizations in the United States (American Public Health Association, 2004; Swain & Ransom, 2006). During the 2012-2013 flu season, there were an estimated 31.8 million influenza-associated illnesses, 14.4 million medically attended illnesses in which medical care was sought, and 381,000 hospitalizations in the United States (CDC, 2013). Annually there are an estimated 3.9 million influenza-related deaths worldwide; at least seven documented worldwide pandemics of influenza have occurred in the last two centuries accounting for up to 50 million deaths worldwide (Atkinson, McIntyre, & Wolfe, 2007; World Health Organization (WHO), 2002; Zimmerman, 2007). Of these deaths 105 were children less than 18 years of age residing in the United States (CDC, 2013). This number reduced slightly during the 2013-2014 influenza season to 96 during the 2013-2014 season and 145 during the 2014-2015 season (CDC, 2014, 2015). Despite these statistics, it is estimated that fewer than half of persons in the United States are vaccinated, including those 6 months of age and older (CDC, 2013; Kostova et al., 2013). Therefore, the importance of continued high levels of influenza vaccination is vital for controlling morbidity and mortality.

Respiratory Viruses and Children

Respiratory viruses are a major cause of childhood morbidity and mortality and are responsible for excess hospitalization, medical visits, and antibiotic prescriptions in healthy children. Annually influenza related illnesses lead to more than 25 million physician visits each year, direct medical costs ranging from 1 to 3 billion dollars, and result in the second highest number of hospitalizations for lower respiratory tract infections in children less than 18 years of age (Greenburg & Piedra, 2004; Zimmerman, 2007). Complications from influenza infections include acute otitis media, sinusitis,

bronchitis, pneumonia, and rare episodes of encephalopathy and Reye's syndrome. Experts agree that school-aged children are the primary vectors of influenza epidemics making them optimal targets for immunization to prevent infection in the general population through increasing herd immunity (Greenburg & Piedra, 2004; Zimmerman & Nelson et al., 2001).

Epidemiology

Three types of influenza viruses have been identified, types A, B and C. Type A contains 15 subtypes of which two are associated with widespread epidemics, H1 and H3. Type B is infrequently associated with regional or widespread epidemics, and Type C is associated with sporadic cases and minor localized outbreaks.

Influenza strains A (H3N2) and A (H1N1) and B are most likely to cause infection due to the ability for the virus to evade host immunity (Greenburg & Piedra, 2004). Since 1977, both H1N1 and H3N2 subtypes continue to circulate worldwide (Nelson et al., 2001). Influenza viruses mutate and change through antigenic drifts and antigenic shifts. It is noteworthy that the mutated forms of influenza may be transmitted globally as quickly as in three to six months (APHA, 2004) as was the case for the H1N1 pandemic of 2009-2010. During the 2009-2010 influenza season (April 15, 2009 tho October 2, 2010), the H1N1 pandemic virus caused the greatest number of pediatric deaths (348 reported) while the influenza type "A" virus was responsible for most pediatric deaths (78%) during the 2011-2012 season (CDC, 2013).

Transmission

Transmission of the influenza virus occurs primarily through respiratory droplets that are transferred to the body through hand-to-mouth or hand-to-nose contact in

crowded populations, such as schools and homes and the influenza virus has an incubation period of five to 10 days (APHA, 2004; Atkinson et al., 2007; Nelson et al., 2001). Transmission by pre-school as well as school aged children is a major concern. Due to the immunological naiveté of children, influenza attack rates are highest in this population with reported rates of 14%-40% annually. Children can be infectious for 10 or more days after onset and communicate the infection to those in their environments. Increased rates of infection are seen in families with school aged children (Nelson et al., 2001; Zimmerman, 2007).

Influenza Vaccines

Influenza vaccines have been available for over 60 years (WHO, 2002) and presently provide a 90% protection rate against contracting influenza (Atkinson et al., 2007). Vaccination is the primary mode of influenza prevention and has been estimated to prevent 6.6 million influenza associated illnesses, 3.2 million medically attended illnesses and 79,000 hospitalizations in the United States (CDC, 2013). The efficacy of vaccination depends on the similarity of virus strains in the vaccine to those circulating during the influenza season and the age and immunocompetence of the vaccine recipient (Zimmerman, 2007). Influenza immunization may be accomplished through injection of a vaccine composed of either inactivated virus or live attenuated influenza virus administered annually. The vaccine contains the anticipated influenza strains based on the most recent laboratory and epidemiologic data; strains are selected by the World Health Organization, Centers for Disease Control, and the Food and Drug Administration (Zimmerman, 2007).

Theoretical Framework: Access to Care

Public health seeks to provide health promotion and disease prevention in the most efficient manner while reaching the most number of clients. Understanding the population being served and their needs is part of the underpinnings of public health. In order to identify facilitators and barriers which may affect caregivers' decisions to immunize their children, a model for evaluating access to care was needed. A literature review was conducted and multiple models for health care access were examined. Ultimately Tanahashi's Health Care Access model (1978) was selected and evaluated for its ability to fit, evaluate services provided, and answer the questions this study seeks to answer. A discussion of the selection process and concepts of the model follow.

Access to Care

Aday and Andersen's (1974) early review of literature related to health care access identified two main themes associated with the concept of access: characteristics of the population and characteristics of the delivery system. These themes are still valid and at issue nearly 30 years later as reflected by continued examination of access to care as the subject of multiple research studies. Their framework encompassed the interaction among health policy, characteristics of the health delivery system, characteristics of the population at risk, utilization of health services, and consumer satisfaction. These identified components were further categorized into two indicators of access: process indicators (characteristics of the delivery system and the population at risk) and outcome indicators (utilization and consumer satisfaction) that form the empirical indicators of access (1974).

Furthermore, Aday and Andersen (1974) postulated that understanding the mechanisms for improving access is strengthened by considering the indicators together to evaluate the mechanisms for "improving access to and increasing satisfaction with the health delivery system in the United States." These concepts guided this author's search for a suitable framework. Tanahashi (1978) presented a model of Health Care Access composed of five elements: Availability of care, Accessibility of care, Acceptance of care, Contact (use of care), and Effectiveness of care, which met the criteria set by Aday and Anderson. A critique of this theory was conducted to determine the relevance of this theory in relation to the information being measured in the proposed study.

Access to Care and Evaluation: A Conceptual Model

A review of conceptual models related to evaluation of access to care identified Tanahashi's model as one that examines the entire picture when evaluating health delivery systems with respect to access to care and coverage (Tahashi, 1978). Tanahashi believed health management issues revolved around resource and service allocation and effectiveness of the service and sought to identify and define health service and the successful use of information obtained as a result of evaluating a present health care system. This information would benefit and impact future health care.

Furthermore, Tanahashi (1978) articulated the importance of transforming traditional interventions into successful interventions by examining the factors which influence care such as people's attitudes toward healthcare, supply logistics, facilities, and manpower. Tanahashi (1978) examined the relationships among the target population (those served), service capacity (number that can be served), and service output (actual number served) were examined in relation to potential (service capacity) and actual

coverage (service output) and utilization (ratio between potential and actual coverage) in terms of measurement of coverage and identified five important stages as essential to obtaining a desired and effective health intervention and to define measurements of coverage (see Table 1).

Table 1

Classifications: Measurement of Coverage

Coverage	Definition
Availability	The ratio between the availability of resources which decides the amount of service available to the target population that gives measurement for this stage.
Accessibility	The service must be located within reasonable reach of the people who can reach and use it.
Acceptability	The service needs to be acceptable to the population and influenced by the willingness to use the accessible service.
Contact	The contact between the user and the provider; this is a form of service output.
Effectiveness	The number of people who have received satisfactory care, a reflection of successful contact between the user and the provider.

Tanahashi's (1978) model is hierarchical in nature, reflecting the interaction between health services while recognizing no one single measurement alone reflects access to care (Figure 1). Each measurement is dependent upon the others for evaluation and no one section in itself assesses the effectiveness of access to care. For example,

coverage may be available to the population but that in itself does not constitute effectiveness of the delivery of or access to care. Each level builds upon the other, with the bottom of the model reflecting the most basic level of coverage and the top comprising the most comprehensive and desirable outcome. The jagged operation line reflects this concept and is useful in measuring and evaluating satisfactory performance of the service, i.e. access to care.
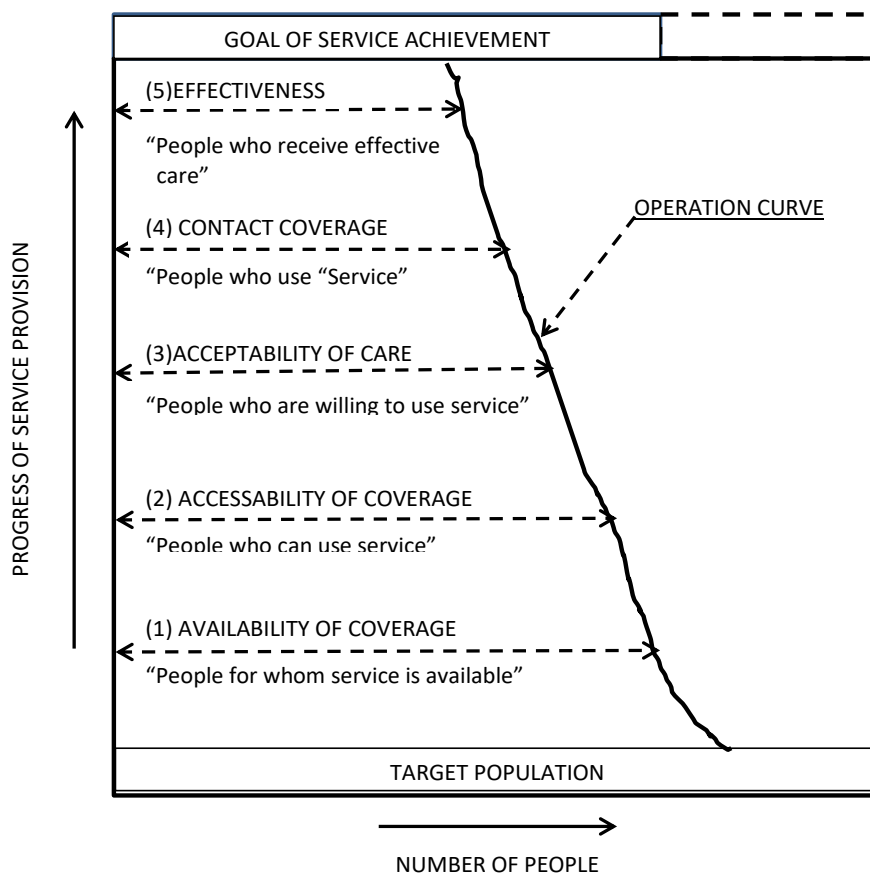
Figure 2. Tanahashi (1978).

In an ideal situation, the operation curve would be a perpendicular line, indicative of an effective match of available services and effectiveness of service throughout the process. Often this is not the case in practice and a method for identification of service

bottlenecks is needed. Utilization of this model allows for the evaluation and identification of service bottlenecks where changes in the system are required. For example, a bottleneck in the first two levels might be indicative of low availability or accessibility of services affecting access to care. Reasons for this bottleneck may be poor allocation of services or supplies or perhaps a lack of appreciation of perceived need by the population. A bottleneck at the effectiveness level may be indicative of poor service. Use of this model allows for examination of each level and provides an opportunity for further reflection and investigation of the identified deficient problem, allowing for understanding of the issue and correction of identified deficiencies.

Tanahashi suggested when developing and implementing coverage evaluation three things are required:

- Information, demographic, epidemiological, and socioeconomic, on the population with which this service is concerned;

- Knowledge of the health problem that the service is intended to deal with and of the activities of the service;

- Ability to gather information on the operation of the service.

(Tanahashi, 1978)

Hongvivatana (1984) validated the concepts of evaluation presented by Tanahashi (1978) and called for the addition of three additional types of health care evaluation: Impact evaluation, effectiveness evaluation, and efficiency or process evaluation. Hongvivatana remarked that previous evaluations focused mainly on efficiency of service provision as opposed to an overall evaluation as Tanahashi suggested.

Since its original presentation in 1978, Tanahashi's model was presented by Hongvivatana in 1984 as a technical publication for the World Health Organization. Thus, the model is often cited as Hongvivatana's Access to Care model and has not been extensively cited in the health literature. Whitener (2000) and Patrick, Stein, Porta, Porter, and Ricketts (1988) utilized the model as their conceptual model in their study on poverty and health services in rural America. Whitener's qualitative research employed the five concepts of the model as groupings for data obtained in interviews. Patrick et al.'s quantitative research loosely applied the five concepts of the model to evaluate services with the intent of policy change.

A database search for use of Tanahashi's (1978) model reflected that the model has been underutilized since its inception. The handful of research studies completed has taken place in foreign countries, primarily in lower middle income countries (Alvarez, 2012; Becart, 2014; Campbell, 2012; Myatt, 2013; UNICEF, 2013). The studies that have utilized this model of care have found it worthy of use and results supported its hypotheses. In more recent years the model has been used more frequently, but not extensively, to examine the midwifery workforce, obtain equitable and effective coverage, identify barriers and boosters of coverage assessment, improve the measurement of coverage programs, discover bottlenecks in coverage and strategies for improvement, and examine coverage assessment (Alvarez, 2012; Becart, 2014; Campbell, 2012; Myatt, 2013; UNICEF, 2013).

Alvarez (2012) used Tanahashi's model to identify and resolve bottlenecks in delivery of care in reaching populations that were previously unreached due to these bottlenecks and barriers as well as to influence decision making processes which would

in turn result in universal treatment of severe acute malnutrition. Alvarez (2012) reported that removing and regularly monitoring the bottlenecks on a regular basis could provide a baseline which could then be utilized to reach optimal coverage which is an important first step toward universal coverage.

Becart (2014) conducted a meta-analysis as part of a coverage assessment project whose purpose was to provide an in-depth analysis of barriers and facilitator to identify common trends in relation to accessing care. After examining more than 78 assessments conducted by the Coverage Monitoring Network and using Tanahashi's (1978) model, socio-cultural factors and quality of care were identified as the primary boosters and barriers influencing care and were the main categories to focus on for improving and continuing access to offered programs.

Myatt (2013) used this model to evaluate coverage in geographical areas to assist with identification of costs, barriers, and needs in order to improve access to coverage. UNICEF (2013) used Tanahashi's (1978) model with the purpose of attaining equitable and effective coverage. Tanahashi's model was adapted for use to examine rural v. urban results and the bottlenecks associated with each population-specific area. This allowed for a comparison of available services and measurement of the equitable distribution of care. As a result of the analysis and use of Tanahashi's (1978) model, critical health system bottlenecks were identified which allowed for future strategic planning to improve access and equitable distribution of care.

While this model has not been well investigated, the completeness of the structure provides not only the components of access to care but allows for evaluation of services provided which in turn will result in effective care. Thus, it is relevant for research which

will test the concepts when examining both access to and effectiveness of care. Evaluation of each component utilizing this model will assist in identifying deficiencies in service provision which can then be examined further in an effort to improve access to care.

Critique of Tanahashi's Theoretical Model

Chinn and Kramer emphasized the importance of theory evaluation and critique as it assists in identifying and specifying the context and situations in which the theory may be used and the purpose of the theory (2011). Additionally, evaluation allows for us to answer questions about the purpose of the theory and the questions it may answer. In this instance, the usefulness of this theory in identifying changes in practice and usefulness to nursing need to be determined. Chinn and Kramer's method involves examining the theory based upon its concepts, definitions of the concepts, relationships among the concepts and its structure and assumptions, and also requires reflection related to its clarity, simplicity, generalizability, accessibility, importance, and usefulness.

Purpose

The purpose of this model is based upon the premises of managing health care services through allocation of services to serve as many people as possible, reach the people it should serve, and effectively meet people's needs (Tanahashi, 1978). Furthermore, Tanashi (1978) postulated it was also necessary to re-examine and clarify the concept of health service coverage by proposing an approach to evaluate the coverage being provided while illustrating uses of coverage information in relation to service management. As a result of examining these factors, it enables health care managers and providers to identify any bottlenecks in service in order to improve service provision. Use

of this model allows providers to predict and evaluate practice in relation to effective and successful access to care.

Concepts and Definitions

The Access to Care model is based upon three primary concepts, health service coverage, measurement of coverage, and evaluation. Health service coverage, as previously discussed, focuses on an interrelationship of factors related to coverage (Tanahashi, 1978). These identified and defined factors are the proportion of the target population who can, have or may receive the potential or actual service/coverage (Tanahasi, 1978). Potential coverage is defined in relationship to service capacity while actual service coverage is related to service output (Tanahashi, 1978). It is important to also consider utilization of coverage which refers only to the service and does not reflect satisfaction with coverage.

Measurement of coverage as used in this theory equate to ways of describing capacity and output of a service (Tanahashi, 1978). Five stages related to coverage that result in health interventions and permit evaluation were further identified by Tanahashi (1978); availability of coverage (the availability of resources, manpower, facilities, medications, etc.), accessibility of coverage (the number of people who can reach and use the service), acceptability of coverage (the service is acceptable to the population), contact coverage (people who use the service), and effectiveness of coverage (people who receive effective care).

Additionally, measurement of coverage is the description, in observable or measureable terms, of the service whose coverage is to be measured. According to Tanahashi, the definition of measurement of service" illustrates the aim and description

of the service, the intended population resources required for the service, expenditures of essential resources required for service, provisions for evaluation, and criteria for satisfactory performance of the service" (Tanahashi, 1978, p. 298).

Evaluation occurs by examining each stage of the model and the target population or service target. Service target (the denominator) or the people for whom the service is intended can be identified and applied to the measurement of service. For example, Tanahashi (1978) discussed using two types of health service: one that meets the intrinsic need of a population and the other type in response to the demand of an individual, for example a vaccination against a specific disease. Measurement of the service relies upon population characteristics that answer the first three questions as well as the ability to measure service output.

Relationships Among Concepts

Tanahashi's (1978) model provided clear illustrations of the relationships among the concepts as each concept builds upon and is intertwined with the next for identifying the goal of service achievement or access to care. These relationships between the measurements of coverage allow for the evaluation of coverage by combining potential coverage (availability, accessibility, and acceptability of coverage) and actual coverage (contact coverage and effectiveness coverage). It is the relationships which assist in identifying bottlenecks in provision which hinder coverage or access to care.

Structure

The structure of this model is based upon a hierarchy of services provided. It is clear and identifies the relationships among the concepts while providing an algorithm for

application. This structure allows for the creation of the theory related to coverage and access to care.

Assumptions

The assumptions of this model are that all five levels must exist satisfactorily in order to evaluate service provision. A breakdown or bottleneck of the services lead to identification of changes needed that will improve coverage resulting in improved access to care. Additionally, it is assumed that the providers of services, whether they be nurses, physicians, or health administrators, can be change agents based upon the evaluation results of this model.

Clarity and Simplicity

The concepts presented in Tanahashi's model are clearly defined in both definition and use. The model is illustrated using clear and specific diagrams which clearly show the correlation and relationship among the concepts. It is clear to those seeking to utilize the model in its discussion and application. The theory is simplistic and allows for application in many disciplines and situations. It can also be used multiculturally and is multidisciplinary, allowing for differences in societal beliefs and norms. This theory contains comprehensive definitions which can be empirically measured.

Generalizability

In the broad sense of generalizability, Tanahashi's (1978) model may be applicable to all situations or programs in which access to care is being examined. However, evaluation of specific services using this theory may not be generalizable due to the uniqueness of each situation being evaluated. It is important to recognize that

cultural differences will influence the individual measurements. For example, what is considered acceptability of services in one culture may not be acceptable to another culture.

Accessibility

In theory, this theory is accessible to many health care providers; it is not well known, however as supported by its limited utilization. With changes related to the Affordable Care Act, this theory has the potential to move to the forefront of evaluation and prove to be a successful indicator of accessible care and coverage.

Importance

As previously mentioned, this theory is extremely important to nursing as well as other providers of services and care. This theory adequately addresses the four metaparadigms of nursing. The person is addressed as those for whom coverage is available and provided. Health is addressed by services offered which result in coverage and health promotional service. Nursing involves provision of care to the population. Environment is addressed by the sum of the five levels of care which encompass the concept of coverage.

Usefulness

Traditional funding and sources of care are changing as a result of the changes in health care delivery which affect services provided to clients in a WIC setting. It is imperative for services provided to meet the five levels of care in order to assure adequate coverage through the provision of services that best meet the needs of the population. Use of Tanahashi's (1978) model allows agencies to evaluate the services provided to determine the level of care provided while identifying bottlenecks. These

bottlenecks need to be addressed in order to improve coverage. This theory provides a specific framework which allows this to occur.

Barriers to Care

An important aspect of providing care is to understand the barriers associated with accessing care related to immunizations. The literature shows that there are common barriers to care. Most common barriers identified by parents are: lack of health insurance, distance to work, parental inability to afford immunizations, scheduling days off from work, child care for other siblings, confusing immunization schedules, too many shots offered at once (Mills, Jadad, Ross, & Wilson, 2005), lack of a medical home (Starfield & Shi, 2004; Taylor et al., 2002), lack of transportation, unknown due dates for next immunizations (Shefer, Mezoff, Caspari, Bolton, & Herrick,1998), lack of mechanism of vaccination (Centers For Disease Control And Prevention, 2011f), poor understanding of the risk of adverse effects, unpleasant staff, parents' intentions to immunize, education levels, understanding of disease process (Daley et al., 2006; Humiston, Lerner, Hepworth, Blythe, & Goepp, 2005; Shefer, Mezoff, Caspari, Bolton, & Herrick, 1998), perceived benefits/risks (Mills, Jadad, Ross, & Wilson, 2005), physician recommendation, and linkage of services (Burns & Zimmerman, 2005; Canavati, Plugge, Suwanjatuporn, Sombatrungjaroen, & Nosten, 2011 Robertson & O'Connor, 2007).

Provider identified barriers are: confusing immunization schedules, lack of information on child's immunization schedule, and perceived parental reluctance to receive immunizations (Udovic et al., 1998). The literature review also identified needs to be addressed by providers in order to improve immunization rates including reduction of missed opportunities, recognition of parents' willingness to immunize, evaluation of

immunizations needed, social marketing, and integration of primary health care into other services and supports (Hambidge et al., 2004; Opel et al., 2009; Udovic et al., 1998; Williamson & Drummond, 2000).

Tanahashi's (1978) model can provide a solid basis for examining the delivery of childhood immunizations in a rural WIC population as well as identifying the potential bottlenecks in coverage provision. Utilizing this model can assist in answering the questions posed earlier by analyzing the present delivery system and identifying methods for improvement in service.

Rationale and Benefits of Combining Services

Availability of care is important when considering service provision as often services provided at the County Health Department are the only sources for immunizations for low-income, uninsured, and underinsured individuals. Uncertainty of locating treatment that is available within a reasonable travel distance was identified in the research of Griswold et al. (2008), Pepper et al. (2008), and Uebelacker et al. (2009). Furthermore, accessibility of care in rural areas can be a determinant as to whether or not an individual receives care (Griswold et al. 2008; Valleley et al. 2007; & Westheimer et al., 2008). By offering combined services, individuals are able to both access their WIC appointments and receive immunizations.

Administering influenza vaccination at times of emergency department (ED) visits has been studied for more than 30 years (Zink, 2008). One of the identified benefits of vaccinating at the time of an ED visit is that patients without a primary care provider who might not otherwise receive an influenza vaccination would receive one (Polis et al., 1987) and 60% of patients surveyed indicated they would receive a vaccination if offered

at the time of the visit. Cohen et al. (2013) found that78% of ED patients offered influenza vaccination at the time of the ED visit received said vaccination. Is it anticipated that offering influenza immunizations at the time of a patient's WIC appointment will have similar results.

The WIC program for Women, Infants, and Children is a Federal program whose purpose is to provide supplemental foods, health care referral, and nutrition education for low-income women who are pregnant or post-partum who may or may not be breastfeeding and for children up to age five (USDA, 2015a). Eligibility for enrollment into this program is based upon income with the maximum income allowance of 185% above poverty (USDA, 2015b). This program is administered through the County Health Department.

Use of Tanahashi's (1978) model when examining the project will provide a framework for evaluation of the practice of providing influenza vaccinations at the time of a patient's WIC appointment which, if successful, can be utilized for delivery of other childhood vaccinations. Evidence has shown that rural residents in small rural counties are more dependent upon clinical settings (Bennett, Pumkam & Probst, 2011) and results of this project will provide evidence supporting the benefits of offering services at the Country Health Department, not limited to influenza immunizations, at the time of service. By implementing changes in the present delivery method of separate appointments, overall the care of residents may improve resulting in improved health.

Chapter Three: Methodology

This chapter describes the research proposed. It will present again the research questions, and summarize the research design, and sample selection for this design, measurement and instrumentation, sample size, allocation to groups, protection of human subjects, and procedure for data collection and analysis.

Research Questions

This study is designed to answer the following research questions:

1. How does combining WIC and influenza immunization appointments affect the immunization rate of children six months to five years of age enrolled in WIC compared to receiving influenza immunizations at a separate appointment?

2. What are the identified barriers for pediatric influenza immunizations in a low-income WIC population in the county served by the County Health Department?

Research Design

The purpose of this descriptive retrospective study is to compare the rate of influenza immunization of children enrolled in the WIC program when immunization is offered at the time of a WIC appointment to the rate of influenza immunization of children enrolled in the WIC program when immunization is offered at a separate immunization appointment. Additionally, we hope to learn how these services can be improved using an access to care model.

In order to analyze and interpret the data collected, a retrospective study design was decided upon. This method was selected as the data were previously collected for reasons other than research, were not pre-planned, and the outcome has already occurred (Hess, 2004; Jansen et al., 2005; LaMorte, 2014; Statsdirect, 2014). Additionally,

retrospective studies are useful in determining whether or not participants actually engaged in the behavior being examined (LaMorte, 2014). Advantages of utilizing a retrospective design are that they take less time to complete, are better for analyzing multiple outcomes, and are less expensive as the data have already been collected. This type of study design was selected due to its fit with existing data collection and the brief intervention already implemented.

Some disadvantages of conducting a retrospectively designed study include the potential for bias, the fact that some statistics cannot be measured, the lack of randomization and blinding when obtaining a sample, the potential for the inability to answer the research questions, and the existence of confounders which may affect the data (LaMorte, 2014; StatsDirect, 2014). In order to better understand how to reduce disadvantages when using a retrospective method methodologies for conducting retrospective research were reviewed (Gearing, Mian, Barber, & Ickowicz, 2006; Hess, 2004). These disadvantages related to use of a retrospective design were recognized and, as a result, are reduced through the proposed analysis plan. Despite being retrospective, this study includes a randomized experiment which serves to counteract some of these disadvantages.

Instrumentation

The County Health Department in this study evaluates its processes and protocols each year to measure quality improvement which is required by the Missouri Department of Health and Senior Services. This health department collects influenza information through a written survey that is completed at the time of each flu clinic visit. Generic surveys (see Appendices B & C) were utilized for influenza clinics open to the general

population for seasonal flu and H1N1 flu from 2009-2010. In 2010 a more detailed and specific survey (see Appendix D) was administered to parents and care-givers of children 6 months through 5 years of age attending the WIC clinic to obtain more detailed information related to this population.

The generic influenza surveys (Appendices B & C) were designed to identify selected demographic data provided by the family member bringing themselves and their families to the clinic. Selected data included initials of the person completing the survey, gender, zip code, age, whether or not the adult and/or their child received immunizations the day of the clinic, highest level of education, and age. Additional questions elicited whether or not the family got flu shots each year, whether the family plans to get a flu shot next year, and if no, why not. An additional series of true/false questions was designed to measure knowledge related to the purpose of the immunization, perceived type of flu covered by the immunization, time between administration and transference of immunity, and attitude related to the importance of influenza immunizations. An open-ended question at the end of the survey provided an opportunity for respondents to add additional comments related to influenza immunizations.

In fall, 2010, in order to assess and improve the quality of services provided and avoid duplication of services at the County Health Department, a quality improvement project was implemented in the WIC Department. Additionally, this project sought to examine how influenza immunization of children 6 months to 5 years of age could be improved overall. The results of this project had the potential to increase immunization rates of other childhood immunizations as well. During the month of October every other WIC family care-givers who came to the County Health Department for any WIC health

care service was given information about the influenza vaccine (see Appendices E & F) and offered the opportunity to receive influenza immunization the day of the visit rather than making an appointment to return at a later date during a scheduled influenza clinic (which was the usual care method).

The 2010 WIC Influenza Immunizations survey (see Appendix C) was developed in order to assess WIC family care-givers. This survey is based upon the prior generic survey associated with influenza immunizations that was completed in 2009 and was again being utilized in the 2010 influenza clinics which were open to the general public. The 2010 WIC Influenza Immunizations survey contained the same generic questions and was expanded from five to 15 questions. The survey was expanded to include detailed information about all the children in the household, rewording of the questions posed in the original survey, and an additional open ended question at the end for comments. Question 1 asked selected demographic data about the WIC family caregiver as well as selected demographic data about each of the children. Questions 2 and 3 asked about past and future annual flu shots for the family and question 4 asked about whether or not the children received regular immunizations other than the flu shot. Questions 2 through 4 also included open ended questions which provided an opportunity for the family care-giver to identify reasons immunization does not occur.

A Likert scale is an ordered scale which measures attitudes by asking people to respond to a series of statements about a topic by using fixed choice responses to measure attitudes or opinions while measuring levels of agreement/disagreement (Bowling, 1997; Burns & Grove, 1997; Likert 1932; McLeod, 2008). Likert scales are commonly used in public health to "assess the public's knowledge and awareness of a public health

campaign" (Losby & Metmore, 2012). Additionally, questionnaires utilizing Likert scale provide ordinal data that can generally be statistically analyzed using t-tests or x^2 methods for determining agreement or disagreement (Information Technology-University of Northern Iowa, 2014). One challenge to utilizing Likert scales is that there may not be a normal probability distribution.

However, in weighing the challenge to the benefits and accepted use of Likert scales for assessing public health issues, this method was determined to be most appropriate for designing Questions 5 through 15. These questions obtained data related to knowledge and beliefs related to flu shots in the areas of protection against the flu, importance of receiving a flu shot, appropriate frequency for receiving a flu shot, ability to receive a flu shot at the time of service for the family care-giver and child(ren), transportation to the appointment for a flu shot, and preference of receiving the flu shot at a WIC appointment or at a general flu clinic. An open-ended question was included for any additional comments the family care-giver wanted to enter. This redesigned survey was created to collect additional information for the health department that would allow for improved services to the WIC population.

Additionally, Tanahashi's (1978) model will be utilized to examine the concepts of accessibility and availability. Data will be obtained from the 2010 WIC survey that was provided to care-givers that brought their children to their WIC appointment. To test accessibility data from questions 6 (Anyone who wants a flu shot can get one) and 13 (Transportation to appointments limits my ability to get flu shots) will be used. To test acceptability data from questions 8 (Flu shots are important), 9 (You need to get a flu shot every year), 11 (If my child could get a flu shot at their WIC appointment today,

they would get one), and 14 (I prefer getting my child's flu shot at the County Health Department instead of my doctor's office) will be examined. We will consider creating summated scales and/or individual items, based on results of reliability analysis.

Setting

The setting for this study is a County Health Department located in a small rural Missouri county which serves a population of approximately 53,860 residents (U.S. Census Bureau, 2014). Services provided by the health department include both adult and child immunizations as well as a WIC program. The County Health Department serves both rural areas and the 15 small cities in the Midwestern community.

The County Health Department is located in the Southern section of the county. The rural county where the County Health Department is located covers approximately 630 square miles. To reach services, the majority of WIC families need to utilize public transportation to reach the County Health Department. It can be assumed that the combination of low income, lack of personal transportation, and distance to travel to the County Health Department can be a challenge for the WIC family care-givers.

Public transportation is provided by The LINC which is available Monday through Friday with one stop in three towns outside of the County Health Department at 6:15am, 6:45am, and 7:00am. The bus arrives at the County Health Department at 7:30am. Final departure time from the County Health Department is 4:30. Residents have to schedule reservations due to limited seating, one day to one month in advance, and complete a rider information sheet. Many residents do not have personal transportation and rely on friends, family, and the limited public transportation services provided. These

limited schedules can be problematic for parents with small children and school-aged children.

There are two pediatricians located in the county and many families go out of county to obtain health care services due to a lack of providers and specialty services. Many of the population of the County are uninsured and 13.7% are at or below the poverty level (U.S. Census Bureau, 2014). The County Health Department provides immunizations to children less than 18 years of age at no charge under the Federal Vaccines for Children (Section 317) program. As a result, many residents come to the health department for WIC and immunization services.

Sample

Participants who completed the survey were the population of family care-givers with WIC appointments during the month of October, 2010. These participants were male or female family caregivers who brought their children aged 6 months through 59 months to a WIC appointment at the County Health Department. All were county residents.

Criteria for inclusion were: a family care-giver with a WIC appointment between October 1st, 2010 and October 31st, 2010, with a child or children aged 6 months to 59 months old, the ability to read and understand English, and not having received an influenza immunization for the child for the 2010 influenza season. Children greater than 59 months old accompanying clients receiving WIC services were eligible for influenza immunizations at the time of service as well. Only children aged 6 months to 59 months are examined for the purpose of this study, however.

Recruitment and Random Assignment

All family caregivers attending WIC at the County Health Department from October1st, 2010 through October 31st, 2010 were given a survey and a copy of the age appropriate CDC Vaccine Information Sheet (see Appendices E & F) at the beginning of their visit by the WIC staff. These family caregivers were instructed to complete and return their survey prior to the conclusion of their visit. At the conclusion of the WIC visit the Maternal Child Health Coordinator/Health Educator was called upon to meet with each WIC client. Each client's survey was assigned a number and every other client was assigned to the intervention group. Those in the intervention group were offered the opportunity to obtain an influenza immunization for the children accompanying them at the time of their visit. Those not offered an immunization that day were offered a separate appointment at a later time when routine immunizations were provided, either that same week or the following week.

This study will use existing data collected by the County Health Department for the quality improvement program related to influenza immunizations. The data used for the sample studied is the database related to the 2010 WIC quality review project. Surveys were provided to these individuals by the County Health Department WIC staff and the Maternal Child Health Coordinator/Health Educator. Data were entered by the Maternal Child Health Coordinator/Health Educator and a student nurse completing her community health clinical into two databases to ensure accuracy of the data entered from the surveys.

Protection of Human Subjects

Institutional Review Board (IRB) approval was obtained from the University of

Missouri-St. Louis and from the County Health Department. The risk to human subjects

as a result of using this database is minimal because all identifiers have been removed.

Procedure for Data Collection and Analysis

Data analysis will consist of two elements. The first will examine the relationship

between the experimental group offered influenza immunizations at the time of the WIC

appointment versus those having to return at a later date for the immunization and rate of

influenza immunization. This analysis will answer the first research question. The

second will allow for the model to be tested in order to answer the second research

question. Data will be retrieved from the County Health Department 2010 WIC Influenza

excel database. The data to be obtained is outlined below:

- Date of birth-Children eligible for participation in WIC may be no older

  than 59 months of age. Data from children born between 2005 and 2010.

- Age of child-children less than six months of age are not eligible for an

  influenza immunization

- Designation as a WIC client-this identifies whether or not the child was in

  WIC, which is a criteria for inclusion in the study.

- Dates of influenza immunizations-these dates are necessary to answer the

  research questions

The information entered has already been de-identified and does not include any

identifiers such as names, addresses, etc. This information will be categorized according

to responses in tabular format. Demographic information will be examined to identify the

care-giver population in general. The percentages of children receiving the influenza immunization at their WIC appointment will be compared to the percentage that received their immunizations at another appointment. When considering the model, potential variables of accessibility and acceptability measured by questions on the WIC survey will be examined and used to demonstrate applicability of this model to predict health care utilization, in this case receiving an influenza shot.

Sample Size and Power

For research question one there will be about 50-70 individuals in each of the two experimental groups for the primary analysis (analysis 1). In an additional analysis, we will compare the 50-70 who were randomly offered immunizations at the WIC visit in October, 2010 to the approximately 200 who attended WIC appointments during the previous year when flu shots were being offered at a separate appointment (2009 and 2010, analysis 2). These data will be analyzed to determine statistical significance between the groups. These data are located in the County Health Department 2010 WIC influenza immunization survey result database.

Chi-square will be calculated to assess the relationship between group assignments (those offered immunizations at the WIC visit vs. those required to make an additional appointment, as usual) and whether they received a flu shot last season (yes or no), in October, 2010. For analysis 2, chi-square will be calculated to assess the relationship between group assignment (those offered immunizations at the WIC visit vs. those required to make an additional appointment, as usual) and whether they received a flu shot in September, October, or November 2010.

To assess statistical power, Cohen's h will be utilized to examine the differences between proportions and determine the effect size. Table 2 provides an overview of the power of detecting an effect for Research Question 1. Alpha was set at 0.05 and an estimated 50-70 participants for each of the two groups were considered for analysis one and an estimated 50-70 participants in the WIC visit flu shot opportunity group and 150-200 in the usual care group for analysis two.

Table 2

Estimated Cohen's h and statistical power of Analyses 1 and 2

Possible proportion getting immunized in usual care group	Possible proportion getting immunized in experimental group	Cohen's h	Statistical power for analysis 1	Statistical power for analysis 2
.40	.50	.20	.19	.27
.25	.35	.22	.23	.32
.25	.40	.32	.42	.58
.25	.45	.42	.60	**.80**
.25	.50	.52	**.80**	.95
.40	.70	~.61	.92	.98

For analysis one, statistical power will be .80 if 25% of those in the usual care group get immunized and 50% of those in the intervention group get immunized. For analysis 2, statistical power will be .80 if 25% of those in the usual care group and 45% of those in the intervention group receive influenza shots, respectively.

To test the model for Research Question 2, logistic regression will be used to examine the relationship of the dependent variable, whether or not the immunization was

received, with the potential variables of accessibility and acceptability in relation to successful contact (i.e., receiving a flu shot).

To assess statistical power for testing Research Question 2, if 35% of the children overall are immunized, there will be .70 power to detect an odds ratio of 1.6 at 1 standard deviation over the mean and .80 power to detect an odds ratio of 1.7 at 1 standard deviation for each of the predictors (acceptability and accessibility, Hsien, 1989).

Chapter Four: Results

Introduction

This chapter presents the study results concerning the effectiveness of offering influenza education and immunization at the time of a child's WIC appointment compared to the practice of usual care which requires a child to return on a different day to obtain the immunization (research question one). This study also sought to obtain an increased understanding of any identified barriers, specifically accessibility and acceptability, of receiving pediatric influenza immunizations at the local health department (research question two).

The data were obtained during a quality improvement project for the county health department in the fall of 2010 and the retrieval of secondary data related to WIC appointments at the county health department from October 1, 2010 through October 31, 2010 retrieved from the Missouri Department of Health and Senior Services. The target population for this study was children enrolled in WIC with dates of birth between January 1, 2005 and December 31, 2010 (up to the age of 59 months) and the care givers that brought these children to their WIC appointments during October 2010. Caregivers that brought children to these WIC appointments were provided with a survey and the CDC's vaccination information sheet (VIS) for the 2010 influenza season.

The purpose of this partly descriptive retrospective and partly experimental study was to determine the effect of combining WIC and influenza immunization appointments on immunization rates of children six months through five years of age compared to the standard protocol of requiring separate appointments for influenza immunizations. Tanahashi's (1978) model related to access to care was used to help understand the

potential mechanisms of the effect. Previous chapters in this dissertation introduced the background, significance, and the conceptual background and methodology. In this chapter, the results of the analyses based on the data will be presented.

This study is designed to answer the following research questions:

How does combining WIC and influenza immunization appointments affect the immunization rate of children six months to five years of age enrolled in WIC compared to receiving influenza immunizations at a separate appointment?

What are the identified barriers for pediatric influenza immunizations in a low-income WIC population in the county served by the County Health Department?

Background

The demographics of the samples used in this project were examined to identify the ages and gender of the children in this project as well as the ages of the caregivers who brought these children to their WIC appointments (Table 3). The ages of the children ranged from 6 months to 59 months, with an average age of 31 months. Of these children, the majority were female (54.2%) compared to males (45.8%). The ages of adult caregivers that brought children for their WIC appointment ranged from 18 years of age to 55 years of age with an average age of 27.42; the overwhelming majority were female (97.6%) compared to males (2.4%). The majority of the caregivers had a high school education or less (71.7%) followed by those with some college (21.1%). The remaining caregivers (7.2%) had a four-year college degree or higher.

Table 3

Variable	Value/Category	Child	Adult
Demographic variables of children and adults			
Gender	% Male	45.8%	2.4%
	% Female	54.2%	97.6%
Age	Minimum	6 months	18 years
	Maximum	59 months	55 years
	Mean	31 months	27.42 years
Education	% HS or less	NA	71.7%
	% Some College	NA	21.1%
	% College Degree	NA	7.2%

We compared the two experimental groups on child and caregiver age and gender. The average age of children not offered influenza immunizations was 32.63 months of age and for children offered immunizations was 29.84 months. The average age of the adult caregiver not offered immunizations was 27.07 years of age and for caregivers offered immunizations it was 27.77 years of age. Two-tailed t-tests were conducted to compare the children's age and caregiver's age between the two groups. The results indicated there was no statistically significant difference in children's age, t (81) =0.72, p=.47 or in the mean age of adult caregivers, t (.80) =0.62, p=.49.

The next comparisons that were conducted were chi-square analyses to compare gender distribution for children and caregivers between the two groups. Results of the chi-square analyses revealed there were no significant differences in gender distribution for either the children χ^2 (1) = 0.01, p=.90 or adults χ^2 (1) = 0.16, p=.69.

Analyses

The first research question examined the association between the experimental group (being offered influenza immunizations at the time of the WIC appointment versus

those having to return at a later date for the immunization) and rate of influenza immunization and whether or not an immunization was received. Of the 129 participants, 45 (34.9%) were randomly chosen to be offered the opportunity to return for the influenza immunization and 84 (65.1%) were offered influenza immunization at the time of the WIC appointment. Overall, 38 (31.0%) received an immunization and 89 (69.0%) did not receive an immunization. When looking at the two groups separately (as shown in Table 4), those that were not offered immunizations at the time of the appointment but only received educational materials related to influenza immunizations were less than half as likely to get immunized (15.6%) as those that were offered a same day influenza immunization (39.3%).

Table 4

Cross tabulation table of immunization offered and received

| | DOI | | |
Flu Shot	Did not get immunized	Did get immunized	Total
Not offered	38	7	45
	84.4%	**15.6%**	100%
Offered at time of visit	51	33	84
	60.7%	**39.3%**	100.0%
Total	89	40	129
	69%	31%	100.0%

Chi square analysis indicated there is a significant association between whether or not influenza immunization was offered at the time of the WIC appointment and the rate of influenza immunization, $\chi^2 (1) =7.905$, p=.005.

The second analysis focused on the testing of the Tanahashi model (1978) in order to answer the second research question which sought to identify barriers to obtaining an influenza immunization. Survey data (n=123) were retrieved from the County Health Department 2010 WIC Influenza excel database. These data were obtained from the caregivers that brought their child to a WIC appointment during the time of the quality improvement project conducted in October, 2010. A binary logistic regression was conducted to determine if there were any significant factors contributing to receiving the influenza immunization. After examining the offered/accepted rate of the immunization, certain participants' data were removed (pregnant mothers without children, children under 6 months of age, and those with missing answers to identified questions), which resulted in the final data set (n=114).

An initial review of the WIC survey data was conducted to determine which of the survey questions closely matched the factors relation to Tanahashi's (1978) model. The questions were categorized to determine potential fit with each of the selected components. Variables considered were the acceptability, accessibility, availability, and effectiveness of services.

Table 5 presents descriptive statistics for the survey questions utilized for the model test. These questions were answered with a 5-point Likert scale with 1=strongly disagree, 2= disagree, 3=neutral, 4=agree, 5=strongly agree

Table 5

Descriptive statistics for survey items

		Statistics			
Item #	Question	Mean	Std. Deviation	% Strongly Agree	% Agree
6	Anyone who wants a flu shot can get one.	3.86	1.07	29.9	45.3
7	Flu vaccines are very effective.	3.38	0.85	8.0	37.2
8	Flu shots are important	3.91	0.83	26.7	41.4
9	You need a flu shot every year	3.77	0.95	24.8	37.6
10	If I could get a flu shot today, I would	3.30	1.16	15.4	35
11	If my child could get a flu shot at their WIC appointment today they would get one	3.39	1.15	17.2	35.3
12	If child could get flu shot at WIC today they would get one, it is convenient	3.55	1.11	20.0	40
13	Transportation limits my ability to get a flu shot	2.13	0.98	2.6	9.4
14	I prefer getting a flu shot at health department	2.89	0.83	2.2	14.7

The highest means and percentages agreeing were for questions 6 and 8. The vast majority of the sample indicated they thought that "anyone who wants a flu shot can get one" (availability) and that "flu shots are important" (acceptability). These responses suggest high levels of perceptions of availability and acceptability. Items number 9 and 12 also have a majority of respondents agreeing and relatively high means. These reflect agreement that "you need a flu shot every year" (acceptability) and "if child could get flu shot at WIC today they would get one" (acceptability) both suggesting high levels of acceptability of influenza immunizations. Furthermore, while the means and percentages were not as high as questions 6-9 and 12, questions 10 "if I could get a flu shot today, I would" (acceptability) and 11 "if my child could get a flu shot and their WIC

appointment today they would get one" (acceptability) also reflected perceived acceptability of influenza immunizations.

The next highest mean and percentage is reflected by the answers to question 7. Just less than half (45.2%) of the sample indicated that "flu vaccines are very effective". This is suggestive of the sample's only moderate belief in the effectiveness of receiving an influenza immunization. The lowest means and percentages for agreeing were for items number 13 and 14. These results suggest that for the majority of the sample, "transportation limits my ability to get a flu shot" (accessibility) and preference for "getting a flu shot at the health department" are not perceived as barriers to receiving a flu shot.

An exploratory factor analysis (Principal Component) was run with orthogonal rotation (25 rotations max) and 1 eigenvalue as the cutoff. Excluding question 5, which was dropped as it was determined it was not a valid indicator of a model variable, three factors were extracted from the questions entered. The rotated component matrix (Table 6) shows the items in the questionnaire associated with each factor. Factor 1 included 8, 9, 10, 11, and 12; factor 2 included questions 13, 14 and 15; factor 3 was comprised of questions 6 and 7. Factor loadings are shown in the component matrix below. Reliability was established for each of the identified potential subscales. Based upon these results, it was determined acceptability was best represented by questions 8,9,10, 11, and 12, and as a summated scale with reliability (Cronbach's alpha) of .84 for the five-item scale. Questions 13, 14, and 15 represent accessibility, with Cronbach's alpha of .59. As a result, these items were not reliable enough to use as a scale. Subsequently (see Table 7), since transportation is believed to be a key barrier to access, question 13 was selected as

being the single best item to represent accessibility of services offered. Question 7 was

selected as the best question to represent effectiveness of the care being offered and

question 14 was chosen as the best to measure availability.

Table 6

Component matrix, ranked, showing different factors and their loadings.

	Component		
	1	2	3
Q11-if flu shot avail today, child would get one	.716	.501	-.068
Q9-need a flu shot every year	.869	-.037	.226
Q12-if child could get flu shot at WIC today they would get one	.613	.470	.003
Q8-flu shots are important	.835	-.068	.226
Q10-if I could get a flu shot today, I would	.688	.264	.067
Q14-I prefer getting a flu shot at health department	.254	.745	-.058
Q13-transportation limits my ability to get a flu shot	-.107	.727	.122
Q15-I prefer getting a flu shot at a flu clinic	.174	.640	.133
Q7-flu shots protect against respiratory flu	.255	.041	.807
Q6-anyone who wants a flu shot can get one	.032	.114	.801

Table 7

WIC survey questions and conceptual relationship to Tanahashi's Access to
Care Model

	Component			
	Acceptability	Accessibility	Availability	Effectiveness
Q6-anyone who wants a flu shot can get one			X	
Q7-flu shots protect me from respiratory flu				X*
Q8-flu shots are important	X			
Q9-you need a flu shot every year	X			
Q10-if I could get a flu shot today, I would	X			
Q11-if my child could get a flu shot at their WIC appointment today they would get one	X			
Q12-if child could get flu shot at WIC today they would get one	X			
Q13-transportation limits my ability to get a flu shot		X*		
Q14-I prefer getting a flu shot at health department			X*	
Q15-I prefer getting a flu shot at a flu clinic		X		

*Indicates the single best measure of the component

The first logistic regression model was conducted to assess the potential

contributors from the model (Table 8). The 5-item acceptability scale and single items to

measure accessibility, availability, and effectiveness were entered into the logistic

regression. A model test was conducted to determine whether the test variables fit the

data well and it was found that the tested set of variables did in fact fit the data well $\chi^2(4)$

=7.440, p=0.114. Additionally, -2 Log likelihood was 117.774. The acceptability scale

was a significant predictor (AOR = 2.261, p = .019) but items measuring effectiveness,

accessibility, and availability (the other variables in the Tanahashi Model) were not

significant predictors (*p*s all greater than .16).

Table 8

Predictor Variables in the Equation

	B	S.E.	Wald	df	Sig.	AOR
Acceptability scale	.816	.348	5.510	1	.019	2.261
Q7-(effectiveness item)	.080	.269	.088	1	.767	1.083
Q13-(accessibility item)	.147	.224	.429	1	.512	1.158
Q14-(availability item)	-.419	.300	1.956	1	.162	.658
Constant	-3.025	1.416	4.565	1		

Demographic variables and whether or not immunization was offered were added

to another logistic regression model to control for potential confounders. Again, the set of

variables entered fit the data well, χ^2 (9) =22.77, p=0.007 with a -2 log likelihood=98.21.

As seen in Table 9, even after controlling for these variables, acceptability was still

significant (AOR = 2.499, p= .016) and items measuring accessibility, effectiveness, and

availability were all still not significant (*ps* > .08). In addition, whether or not a shot the

same day was offered was also significant (AOR = 4.788, p = .007) while adult and child

age and gender were all not significant.

Table 9

Variables in the Equation-including age, gender, and immunization offered

	B	S.E.	Wald	df	Sig.	AOR
Acceptability scale	.916	.380	5.817	1	.016	2.499
Q13 (accessibility item)	.141	.251	.315	1	.574	1.152
Q7 (effectiveness item)	.207	.307	.455	1	.500	1.230
Q14 (availability item)	-.562	.321	3.063	1	.080	.570
Adult age	.062	.054	1.283	1	.257	1.064
Adult gender	-23.856	25268.382	.000	1	.999	.000
Child age	.000	.000	.976	1	.323	1.00
Child gender	.393	.513	.586	1	.444	1.481
Imm. Offered	1.566	.579	7.309	1	.007	4.788
Constant	33.977	50536.764	.000	1		.000

Summary

This chapter discussed the acceptance rate differences and factors that influence acceptance rate of influenza immunization in WIC program. In testing research question 1, it was clearly helpful to offer influenza immunizations the same day as those in that experimental group were more than twice as likely (39.3% vs. 15.6%) to receive an immunization in the next three months than those offered usual care which was to come back for a shot at a future immunization clinic. The test of the Tanahashi Model (1978) for Research Question 2, found that a scale measuring acceptability was a significant predictor of getting a flu shot, while variables measuring accessibility, availability, and effectiveness were not significant predictors. Even after adding demographic variables and whether or not an immunization was offered the same day, the results were the same: acceptability was a significant predictor of receiving an immunization, but availability, effectiveness, and accessibility were not.

CHAPTER 5: Summary, Recommendations, and Conclusions

Introduction

The results and implications of this project will be discussed in this chapter. The interpretation of findings and discussion of the findings in relation to the research questions are presented. Limitations identified while executing the project are examined as well as recommendations to address these limitations. Recommendations for future research related to this project will also be presented.

Interpretation and Discussion of Findings

This project set out to determine the effectiveness of offering influenza education and immunization at the time of a child's WIC appointment compared to the practice of usual care which requires a child to return on a different day to obtain the immunization (research question one). We also hoped to identify barriers, specifically the perceived accessibility acceptability, effectiveness, and availability of receiving pediatric influenza immunizations at the local health department and experiment in a test of Tanahashi's (1978) model.

This project utilized survey data plus retrospective data obtained during a quality improvement project for the county health department in the fall of 2010, secondary data related to WIC appointments at the county health department from October 1, 2010 through October 31, 2010 from the Missouri Department of Health and Senior Services, and influenza immunization records of children enrolled in WIC at the county health department from October 1, 2010 through December 31, 2010.

It is worthy to note that while these data came from a quality improvement project, there was an experimental component. The experiment was related to the test of

Research Question 1. Did the intervention of offering an immunization at the time of a WIC appointment as opposed to usual care of returning to the health department for a separate appointment to receive an influenza immunization affect whether an immunization was received? Research Question one allowed for clearer, causal conclusions than most quality improvement projects.

The target population for this study involved children enrolled in WIC with dates of birth between January 1, 2005 and December 31, 2010 and the care givers that brought these children to their WIC appointments during October 2010. Caregivers that brought children to these WIC appointments were provided with a survey and the CDC's vaccination information sheet (VIS) for the 2010 influenza season.

To address the first research question related to the intervention compared to usual care methods, data were obtained from the health department quality improvement survey and database which tracked whether an immunization was offered or not at the time of the WIC appointment and whether or not the children of these families in WIC between the ages of 6 months and 59 months received an influenza immunization between October 1, 2010 and December 31, 2010. This database included demographics such as age and gender and whether or not the caregiver was offered the opportunity for the children attending the WIC visit to receive a shot at the time of the WIC appointment or to return at a later date, and whether the children in that family received an influenza immunization during the previously specified time period.

Research Question One: How does combining WIC and influenza immunization appointments affect the influenza immunization rate of children six months to five

years of age compared to those who received influenza immunizations at a separate appointment?

Examination of the association between which experimental group children were in and likelihood of receiving an immunization showed that those receiving influenza education materials only at the time of the visit who also required a return visit were less than half as likely to get immunized (15.6%) as those that were offered a same day influenza immunization (39.6%). A chi-square analysis supported a significant association between offering an influenza immunization at the time of the WIC appointment and likelihood of receiving an immunization in the next three months χ^2=7.905, p=.005.

Research Question Two: What are the identified barriers for pediatric influenza immunizations in a low-income WIC population in a Midwestern community?

Research question two sought to test the Tanahashi model in order to identify any factors that helped predict receiving an influenza immunization. Questions from the 2010 WIC quality improvement surveys were matched with Tanahashi's model and the factors analyzed for fit. A reliable five-item acceptability scale and individual items to measure the concepts of accessibility, availability, and effectiveness of services were used as model-related predictors of influenza immunizations.

A logistic regression model was used to identify predictive factors for influenza immunizations and it was found that the scale measuring the acceptability of services was a statistically significant predictor of receiving an immunization. (p=.013), though measures of effectiveness, availability, and accessibility were not significant predictors. An additional logistic regression was conducted in which all model variables were

combined along with potential confounders of demographic variables and the experimental variable (being offered a same day immunization or one at a later appointment). Acceptability of influenza immunizations remained a significant predictor.

Limitations

The results of this project are limited by several factors. The sample examined is small, which can affect the generalizability of the results. A larger sample will have greater statistical power and may yield more statistically significant results. Therefore, additional research with a larger sample is recommended. Additionally, the sample comes from a small rural community health department and examined a limited time period of three months. Influenza immunizations are available through June of each year. Had the project extended to June, percentages receiving immunizations may have increased with unknown impact on the results. A larger sample size may also result in a more reliable assessment of whether offering immunizations at the time of a health care appointment as opposed to scheduling a separate appointment is effective.

Other limitations involve the difference in those that were offered the influenza immunization at the time of the WIC appointment compared to those that were not. A review of those not offered a same day appointment revealed that some of the potential participants left the health department after their WIC appointment. The reasons for this are not clear; it could be that the participants did not have time to remain, were not interested, or the WIC clerk that worked with the clients that day did not refer the client to the immunization nurse. This could have also resulted in non-equivalence of the groups, but at least on the measured demographics there were no significant differences between the groups. Another limit is the quality of the measures. Only acceptability was

measured by a reliable scale while the other model concepts were measured by the single items that appeared to be most conceptually related to the construct. More reliable measures of the other model constructs may have resulted in some of them being significant predictors as well.

While there was no statistical significance for the identified model variable of accessibility, acceptability was a significant predictor of receiving influenza immunizations. This significance was further strengthened by controlling for both offering an immunization at the time of the WIC visit and demographic variables, with acceptability remaining significant. To further reduce barriers to influenza immunizations, the results of this study suggest offering these immunizations at the time of the WIC appointment and further enhancing perceptions of acceptability.

It is important to examine this in the context of access to care. Future research to address the factors identified by the model can help to address bottlenecks in access to care. By creating reliable measures specifically addressing the other four factors in the model-accessibility (ability to use the service), effectiveness (people who receive effective care), contact coverage (people who use care), and availability (people for whom service is available) (Tanahashi, 1978-the results may more accurately reflect the predictors/contributing factors. Tanahashi's (1978) model was not an especially good fit for the data analyzed, as only one variable was a significant predictor of the outcome. It is important to note that there is no way of knowing why we obtained non-significant results from the other four factors. Reasons for this may be that either these are not necessarily strong model predictors of the use of this health service or perhaps the measures used were simply inadequate.

Recommendations

It is recommended that this study be replicated with a stronger design in which the instruments and measures are created to more closely match the other four factors of the model. Again, the results of this quality improvement project contained a research component that lent itself well to the model but specifically designing a study to more closely match the factors measured would be a clearer test of the model and might result in more significant findings.

Utilizing Tanahashi's (1978) model to measure predictors for receipt of influenza immunizations in future studies may strengthen the success of these public health programs by assisting in identifying facilitators and barriers of immunizations and other programs.

Conclusion

Immunizations have resulted in reduction and even eradication of many childhood diseases and influenza immunizations are no exception. Influenza and influenza related complications continue to be a leading cause of illness and mortality worldwide and are preventable through immunization (CDC, 2016a; World Health Organization, 2016). In areas where access to health care is limited, it is important to identify ways to maximize services and care at the time of service. Not only is this cost effective, it ensures care is offered and provided to those populations for whom access to care may be limited, such as rural areas, and developing countries.

The CDC tracks immunization rates of children 19-35 months of age and the rates of children receiving required immunizations of the combined vaccine series (MMR, DTaP, Hep B, Hep A, Rotavirus). They have found immunization rates of required

immunizations range from 64% to 80.2% (CDC, 2015) which, in some areas falls below and exceeds the target rate of 70% required immunizations. Influenza immunization rates of children between 6 months and 17 years within the United States have increased from 43.7% in the 2009-2010 influenza season (when this project was conducted) to 59.3% during the 2014-2015 season (CDC, 2016b). Additionally, it was found during the 2014-2015 influenza season that the group of children (ages 6 months to 17 years) with the lowest rate of influenza immunizations were non-Hispanic white children (56%), which is lower than all other races and lower than the Healthy People 2020 target rate of 70% (USDNNS, 2015). Of all of the children reported as having received influenza immunizations during the 2014-2015 season, only those between the ages of 6 months and 23 months had influenza immunization rates greater than 70% (USDHHS, 2015). Of additional note, there were no differences in influenza vaccination coverage when considering gender (CDC2016b), which was consistent with the results of this study.

Providers need to consider a change in policies to reflect offering immunizations during encounters with children less than 59 months of age. It is important to provide influenza immunization information to parents of children at the inception of the influenza season and counsel parents about the importance of receiving this immunization. Offering immunizations at the time of a WIC visit is beneficial in significantly increasing the rates of influenza immunization of children aged 6 months to 59 months.

If providers do not currently offer immunizations at the time of visits, changes in policies should be made to reflect this practice. When considering these changes, there are both facilitators and barriers to implementing these changes. Barriers to

implementation may be a lack of staff available to administer the influenza immunizations at the time of the WIC visit, resistance to change procedures from the usual care method of immunization, and time constraints related to the length of the visit. These same barriers may also be facilitators for changing practice; facilities experiencing a reduction in funding and staffing may find these changes to be cost effective as multiple visits are not required which saves staffing costs.

There is a benefit to clients as well as there is an increased likelihood that these children will be adequately immunized, there will be increased satisfaction among the clients, and reduced medical costs related to influenza related illnesses. Due to staffing issues and rigidity in conforming to current policies, these changes to practice are unlikely to occur; results from this study will be presented to not only this particular health department but also to the Immunization division of the Missouri Department of Health and Senior Services. Having research to support the efficacy of this intervention will add to the likelihood that these changes will be implemented in health departments or other medical provider offices.

WIC programs provide regular and consistent access to children 6 months to 59 months and there is a unique opportunity to ensure vaccination of this population is offered. Other venues for providers to target to increase the overall rate of immunizations in this population that are not enrolled in WIC would be schools/preschools, emergency rooms, family health fairs, and other places these children are likely to attend. It is also beneficial to provide influenza education to parents of these children. By implementing these practices, barriers which influence immunization of children for influenza may be reduced while increasing the rate of both required and optional childhood immunizations.

Influenza immunization in 2010 was not and is currently still (in 2017) not a mandatory immunization required for children ages 6 months to 59 months of age entering pre-school (CDC, 2016a; Missouri DHSS, 2016). Because the immunizations are not mandatory, they may readily be refused when parents are asked about immunization. This project has shown it beneficial to consider the acceptability of obtaining an influenza immunization and to offer influenza immunizations at the time of a WIC appointment in order to increase the influenza immunization rates of children 6 months to 59 months of age.

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APPENDIX A. Appendix A. CDC Recommended Immunization Schedule for Persons Aged 0 Through 6 Years United States 2010

The recommended immunization schedules for persons aged 0 through 18 years and the catch-up immunization schedule for 2010 have been approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians.

Recommended immunization schedule for persons aged 0 through 6 years --- United States, 2010 (for those who fall behind or start late, see the catch-up schedule [Table])

Vaccine ▼　　　Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB			HepB						
Rotavirus[2]			RV	RV	RV[2]						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	see footnote[3]	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPSV	
Inactivated Poliovirus[6]			IPV	IPV	IPV						IPV
Influenza[7]					Influenza (Yearly)						
Measles, Mumps, Rubella[8]						MMR		see footnote[8]			MMR
Varicella[9]						Varicella		see footnote[9]			Varicella
Hepatitis A[10]						HepA (2 doses)				HepA Series	
Meningococcal[11]										MCV	

Range of recommended ages for all children except certain high-risk groups

Range of recommended ages for certain high-risk groups

Centers for Disease Control and Prevention. Recommended immunization schedules for persons aged 0 through 18 years---United States, 2010. MMWR 2010; 58(51&52).

This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at http://www.vaers.hhs.gov/ or by telephone, 800-822-7967.

1. **Hepatitis B vaccine (HepB).** (Minimum age: birth)
   At birth:
      o   Administer monovalent HepB to all newborns before hospital discharge.

- o If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
- o If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if HBsAg-positive, administer HBIG (no later than age 1 week).

After the birth dose:

- o The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks. The final dose should be administered no earlier than age 24 weeks.
- o Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg 1 to 2 months after completion of at least 3 doses of the HepB series, at age 9 through 18 months (generally at the next well-child visit).
- o Administration of 4 doses of HepB to infants is permissible when a combination vaccine containing HepB is administered after the birth dose. The fourth dose should be administered no earlier than age 24 weeks.
2. **Rotavirus vaccine (RV).** (Minimum age: 6 weeks)
   - o Administer the first dose at age 6 through 14 weeks (maximum age: 14 weeks 6 days). Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - o The maximum age for the final dose in the series is 8 months 0 days
   - o If Rotarix is administered at ages 2 and 4 months, a dose at 6 months is not indicated.
3. **Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).**
   (Minimum age: 6 weeks)
   - o The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
   - o Administer the final dose in the series at age 4 through 6 years.
4. *Haemophilus influenzae* **type b conjugate vaccine (Hib).**
   (Minimum age: 6 weeks)
   - o If PRP-OMP (PedvaxHIB or Comvax [HepB-Hib]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.
   - o TriHiBit (DTaP/Hib) and Hiberix (PRP-T) should not be used for doses at ages 2, 4, or 6 months for the primary series but can be used as the final dose in children aged 12 months through 4 years.
5. **Pneumococcal vaccine.** *(Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])*

- o PCV is recommended for all children aged younger than 5 years. Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- o Administer PPSV 2 or more months after last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. See *MMWR* 1997; 46(No. RR-8).

6. **Inactivated poliovirus vaccine (IPV)** *(Minimum age: 6 weeks)*
   - o The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
   - o If 4 doses are administered prior to age 4 years a fifth dose should be administered at age 4 through 6 years. See *MMWR* 2009; 58(30):829--30.

7. **Influenza vaccine (seasonal).** *(Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])*
   - o Administer annually to children aged 6 months through 18 years.
   - o For healthy children aged 2 through 6 years (i.e., those who do not have underlying medical conditions that predispose them to influenza complications), either LAIV or TIV may be used, except LAIV should not be given to children aged 2 through 4 years who have had wheezing in the past 12 months.
   - o Children receiving TIV should receive 0.25 mL if aged 6 through 35 months or 0.5 mL if aged 3 years or older.
   - o Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.
   - o For recommendations for use of influenza A (H1N1) 2009 monovalent vaccine see MMWR 2009;58(No. RR-10).

8. **Measles, mumps, and rubella vaccine (MMR).** *(Minimum age: 12 months)*
   - o Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.

9. **Varicella vaccine.** *(Minimum age: 12 months)*
   - o Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
   - o For children aged 12 months through 12 years the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.

10. **Hepatitis A vaccine (HepA).** *(Minimum age: 12 months)*
    - o Administer to all children aged 1 year (i.e., aged 12 through 23 months). Administer 2 doses at least 6 months apart.
    - o Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits

- o HepA also is recommended for older children who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.

11. **Meningococcal vaccine.** *(Minimum age: 2 years for meningococcal conjugate vaccine [MCV4] and for meningococcal polysaccharide vaccine [MPSV4])*
    - o Administer MCV4 to children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.
    - o Administer MCV4 to children previously vaccinated with MCV4 or MPSV4 after 3 years if first dose administered at age 2 through 6 years. See *MMWR* 2009; 58:1042--3.

The Recommended Immunization Schedules for Persons Aged 0 through 18 Years are approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (http://www.aap.org/), and the American Academy of Family Physicians (http://www.aafp.org/). Department of Health and Human Services • Centers for Disease Control and Prevention

APPENDIX B. Influenza Survey 2009

2009 H1N1 Flu Clinic

Initials: _____ M/F Zip Code: _____

What is your highest level of education? _____

1. How many people are getting immunized today? (M/F, ages)

2. Do you or does your family get a flu shot each year? If no, why not

3. True/False

_____ It takes 10 days to build immunity after receiving a flu shot.

_____ Anyone who want a flu shot can get one.

_____Flu shots protect me from respiratory flu.

_____Flu shots are important.

_____ You need to get a Flu shot every year.

4. I/my family will get a flu shot again next year. If no, why not?

5. Any comments?

6. Why did you decide to get an H1N1 shot this year?

APPENDIX C. Influenza Survey 2010

<u>2010 Seasonal Flu Clinic</u>

Initials: _____   M/F Zip Code: _____

What's your highest level of education? _____
  1. How many people are getting immunized today? (M/F and age)
  2. Do you or does your family get flu shots each year? If no, why or why not?
  3. T/F

_____ It takes 10 days to build immunity after receiving a flu shot.

_____ Anyone that wants a flu shot can get one.

_____ Flu shots protect me respiratory flu.

_____ Flu shots are important.

_____ You need a flu shot every year.

4. I/my family will get a flu shot again next year. If no, why not.

5. Last year I/my family got (circle all that apply)

H1N1   Seasonal Flu   Where?

6. Comments

APPENDIX D. Survey-Seasonal Flu

2010 WIC Influenza Immunizations

At the County Health Department, we strive to provide the best possible services for our clients. In an effort to improve the quality of our services, we are working on a project that examines influenza immunizations in our WIC department. Your opinion is important to us so please complete our survey in its entirety. Thanks, WIC

1. <u>About You:</u>

Age: _____   Gender (circle one): M   F   Zip code: _____

Relationship to Child: _____Occupation: _____

Highest level of education completed: _____   Are you pregnant at this time? Y   N

<u>About your child/children:</u>

Child 1: Date of Birth: _____   Gender: M   F   Any siblings? Y N

     List any medical conditions: _____

     How many days a week does your child attend day care outside your home?

Child 2: Date of Birth: _____   Gender: M   F   Any siblings? Y N

     List any medical conditions: _____

     How many days a week does your child attend day care outside your home?

Child 3: Date of Birth: _____   Gender: M   F   Any siblings? Y N

     List any medical conditions: _____

     How many days a week does your child attend day care outside your home?

2. Do you or does your family get a flu shot each year? Why or why not?

3. Will you or your family get flu shots again next year? Why or why not?

4. Do you or your child get regular immunizations (not including flu shots)? Why or why not?

Please circle the answer that best describes your answer:

5. It takes 10 days to build immunity after receiving a flu shot.
Strongly disagree   Disagree   Neutral   Agree   Strongly Agree

6. Anyone who wants a flu shot can get one.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

7. Flu shots protect me from respiratory flu.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

8. Flu shots are important.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

9. You need to get a flu shot every year.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

10. If I could receive a flu shot today, I would have gotten one.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

11. If my child could get a flu shot at their WIC appointment today, they would get one.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

12. If I could get a flu shot for my child at their WIC appointment today, it would be convenient.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

13. Transportation to appointments limits my ability to get flu shots.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

14. I prefer getting my child's flu shot at the County Health Department instead of my doctor's office.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

15. I prefer getting my child's flu shot at a flu shot clinic.

Strongly disagree   Disagree Neutral   Agree   Strongly Agree

Comments:

Thank you for your input!

Appendix E. CDC Inactivated Vaccine Influenza Information Sheet 2010-11

INACTIVATED INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2010-11

Many Vaccine Information Statements are available in Spanish and other languages. See http://www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 | Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:
- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Other illnesses can have the same symptoms and are often mistaken for influenza.

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

By getting vaccinated you can protect yourself from influenza and may also avoid spreading influenza to others.

2 | Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, or the "flu shot" is given by injection into the muscle.

2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A "high-dose" inactivated influenza vaccine is available for people 65 years of age and older. Ask your healthcare provider for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year.

The 2010-2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses – influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your healthcare provider for more information.

3 | Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

WHEN

Getting the vaccine as soon as it is available will provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from November through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your healthcare provider.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

4 | Some people should not get inactivated influenza vaccine or should wait

- Tell your healthcare provider if you have any **severe** (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.

- Influenza vaccine virus is grown in eggs. People with a **severe egg allergy** should not get influenza vaccine.

- A severe allergy to any vaccine component is also a reason not to get the vaccine.

- If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

• Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider will help you decide whether the vaccine is recommended for you.

• People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your healthcare provider about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 | What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:
• soreness, redness, or swelling where the shot was given
• hoarseness; sore, red or itchy eyes; cough
• fever   • aches
If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:
• Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.

• In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Ask your healthcare provider for more information.

The safety of vaccines is always being monitored. For more information, visit:
http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html
and
http://www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

6 | What if there is a severe reaction?

What should I look for?
Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
• **Call** a doctor, or get the person to a doctor right away.
• **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
• **Ask** your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **http://www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 | The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at **http://www.hrsa.gov/vaccinecompensation**.

8 | How can I learn more?

• Ask your healthcare provider. They can give you the vaccine package insert or suggest other sources of information.

• Call your local or state health department.

• Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **http://www.cdc.gov/flu**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC

Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (8/10/10)   42 U.S.C. §300aa-26

Appendix F. CDC Live, Intranasal Vaccine Influenza Information Sheet 2010-2011

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2010-11

Vaccine Information Statements are available in Spanish and many other languages. See http://www.immunize.org/vis
Hojas de Informacián Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Other illnesses can have the same symptoms and are often mistaken for influenza.

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Influenza can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

By getting vaccinated you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:
1. **Live, attenuated** influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.
2. **Inactivated** (killed) influenza vaccine, or the "flu shot," is given by injection into the muscle. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year.

The 2010 – 2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses– influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts about a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people **2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below).

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

4 Some people should not receive LAIV

LAIV is not recommended for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- **Adults 50 years of age and older or children from 6 through 23 months of age.** (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women.
- People who have long-term health problems with:
  - heart disease
  - kidney or liver disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). *Close contacts of other people with a weakened immune system (such as those with HIV)* **may** *receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.*
- Children or adolescents on long-term aspirin treatment.

Tell your healthcare provider if you have any severe (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.

  - Influenza vaccine virus is grown in eggs. People with a **severe egg allergy** should not get influenza vaccine.
  - A severe allergy to any vaccine component is also a reason not to get the vaccine.
  - If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider will help you decide whether the vaccine is recommended for you.

Tell your healthcare provider if you have gotten any other vaccines in the past 4 weeks.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your healthcare provider about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 | When should I receive influenza vaccine?

Getting the vaccine as soon as it is available will provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur any time, but most influenza occurs from November through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your healthcare provider.

Influenza vaccine may be given at the same time as other vaccines.

6 | What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:
Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- headache and muscle aches
- abdominal pain or occasional vomiting or diarrhea
- fever
- wheezing

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- cough, chills, tiredness/weakness
- sore throat
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.

- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:
http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html
and
http://www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

7 | What if there is a severe reaction?

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