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Walden University

College of Health Sciences

This is to certify that the doctoral study by

Jennifer Gadarowski

has been found to be complete and satisfactory in all respects, and that any and all revisions required by the review committee have been made.

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> > Walden University 2019

Abstract

Advisory Committee on Immunization Practices Recommendations, Socioeconomics,

Demographics, and Influenza Vaccine Uptake

by

Jennifer Christine Gadarowski

MPH, University of South Florida, 2013

BLS, University of Tampa, 2010

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Public Health

Walden University

February 2019

Abstract

Seasonal influenza outbreaks are associated with morbidity and mortality in the United States. Though children are the most susceptible to influenza infection and are most likely to transmit the illness to others, many children are not vaccinated. The purpose of this study was to examine the relationship between seasonal influenza vaccination Advisory Committee on Immunization Practices (ACIP) recommendations, demographic characteristics, socioeconomic factors, and vaccine type among children over 3 consecutive flu seasons. This quantitative cross-sectional study was guided by the social ecology of health model. Secondary data from 3 consecutive flu seasons (2014-2015, 2015-2016, and 2016-2017) provided by the National Health Interview Survey was used for this study. Binary logistic regression and chi-square were used to analyze the data. A relationship between socioeconomic status, demographics (age, race, and family income) and vaccine type (live-attenuated influenza vaccine [LAIV]/inactivated influenza vaccine) was established among U.S. children; those who received LAIV were most likely to be White elementary school age children with a higher family income. Demographic and socioeconomic status was not considered influential in LAIV uptake for race, health insurance status, or family income. ACIP recommendations by age and year had the greatest impact on flu vaccine choice for this sample population. The results of this study can lead to social change by providing information for policy that can increase vaccine uptake, which can result in lower health cost and reduced illness and death rates associated with the flu, especially for those most at risk.

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Dedication

This doctoral study is dedicated to my grandparents, Bob and Carole Lane. Thanks for always encouraging me to follow my dreams and to be a better person. To my mother, Melinda Gordon, for reading me a minimum of thirteen books before bed every night as a child and always encouraging my creativity. To my wonderful husband of 20 years, John Gadarowski, for believing in me even when I did not believe in myself and always supporting my dreams and goal. I also want to dedicate this study to my four children: Trevor, Devon, Athena, and Venus. They have been my motivation, inspiration, and my greatest achievement.

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Section 1: Foundation of the Study and Literature Review

Introduction

In the United States, seasonal influenza outbreaks are associated with morbidity and mortality (Hull & Ambrose, 2011; Weycker et al., 2005; Wilson, Sanchez, Blackwell, Weinstein, & El Amin, 2013). The most effective method for preventing influenza and its complications is annual fall influenza vaccinations (Weycker et al., 2005). Although annual influenza attack rates can be as high as 42% among school-age children (Carpenter et al., 2007), and children are most likely to transmit the illness to others, many children do not receive influenza vaccination. Increasing the number of children immunized against the flu also increases herd immunity by the indirect protection of household and community members (Lind et al., 2014).

The live-attenuated influenza vaccine (LAIV) was developed to address issues associated with production and dissemination of the influenza vaccine for potential influenza pandemics and mass vaccination (Penttinen & Friede, 2016). Production of the inactivated influenza vaccine (IIV) takes time, and administering the vaccine requires basic safety and infection control measures due to its injectable nature. The LAIV option was ideal for mass vaccination of children, especially in a pandemic situation, due to its efficacy, production yield, availability for unanticipated serotypes, and user-friendly application (Penttinen & Friede, 2016). Roughly 30% of children vaccinated for the flu each year receive the LAIV, when available, whereas the other 70% receive the shot (IIV; Kahn, Santibanez, Zhai, & Singleton, 2015). Annual surveillance and vaccine effectiveness research is conducted to improve influenza vaccines, anticipate seasonal virus strains, and track the circulation of influenza in the community (Kelly et al., 2009). Initial studies with comparisons of LAIV and IIV efficacy in young children indicated that LAIV is more effective than IIV for preventing the flu in children 2 to 8 years of age (Belshe et al., 2007). But subsequent studies have had conflicting results with the diminished effectiveness of the LAIV across all circulating influenza virus as opposed to IIV (Caspard et al., 2016; Eick-Cost et al., 2012; Flannery & Chung, 2016).

The topic of this study is the relationship between the Advisory Committee on Immunization Practices (ACIP) flu vaccine recommendations, socioeconomic factors, demographic characteristics, and vaccine type among U.S. children. In addition to the reported inconsistencies in flu vaccine efficacy, annual influenza vaccine recommendations have varied in children 2 to 8 years of age. In 2016, data from four observational studies evaluating influenza vaccine effectiveness in the pediatric population during the 2015-2016 influenza season was presented to the ACIP (Flannery & Chung, 2016). The two studies conducted in the United States showed decreased effectiveness of LAIV compared to IIV (Grohskopf et al., 2016). However, studies in the United Kingdom and Finland showed the statistically significant efficacy of LAIV against all influenza strains ranging from 46% to 58%. These studies show LAIV and IIV effectiveness comparable to vaccine effectiveness in observational studies in prior seasons (Rhorer et al., 2009). Inconsistencies in vaccine recommendations impact vaccine uptake by diminishing the patients' perceived benefits of following these vaccine recommendations (Mueller, Hill, Fontanesi, & Kopald, 2007). For example, studies have shown that parents who delayed and refused vaccine doses were more likely to have vaccine safety concerns and perceive fewer benefits associated with these vaccines (Blyth et al., 2014; Cheney & John, 2013; Smith et al., 2011).

This study is significant because the relationship between influenza vaccination recommendation by the ACIP and vaccine uptake among children is not known, leaving a gap in the literature. The potential positive social change and implications of this study include analysis of factors associated that could impact vaccine choice and help to improve vaccine recommendations and policies. The major sections of this chapter include the problem statement, study purpose, research question, theoretical foundation, nature of the study, literature review, and significance. The chapter will also include discussion of the assumptions, study scope, limitations, and significance of the study.

Problem Statement

The ACIP is a group of public health and medical and medical experts who develop recommendations on vaccine use among the civilian population of the United States for all children 6 months to 18 years of age before the annual influenza season (Hamborsky, Kroger, & Wolfe, 2015). There are two types of influenza vaccines available for children in the United States. These vaccines are either IIV (contains inactivated form of the virus) administered by shot or LAIV (contains a weakened form of the virus) a nasal mist (Flannery & Chung, 2016; Hamborsky, Kroger, & Wolfe, 2015; Kahn et al., 2015). The LAIV has increased in popularity since its introduction in 2003. For flu seasons 2011-2012, 2012-2013, and 2013-2014, over 30% of vaccinated children received the LAIV (Kahn et al., 2015). In 2013 the ACIP recommended preference for LAIV, when available, for children 2 to 8 due to its efficacy compared to the IIV (Centers for Disease Control and Prevention [CDC], 2014). But the subsequent annual influenza efficacy research has indicated a reduction in LAIV efficacy against A/H1N1 in the United States (determined by a few test-negative, small sample size studies), resulting in ACIP no longer recommending the LAIV for any age group for the 2016-2017 flu season, though the LAIV vaccine will still be manufactured and available for use (Grohskopf et al., 2016).

Discontinued recommendation of the LAIV by the ACIP because of reduced vaccine efficacy can reduce vaccination rates among children. According to Healthy People 2020, the ideal influenza vaccination rate of children is at least 70%, though each year actual vaccination rates fall short of the recommended threshold, ranging from 31.1 to 59.3% of children ages 6 months to 17 years of age since 2007 (Peng-jun Lu et al., 2013; Rose et al., 2014). Because the LAIV vaccine was recommended from the 2003-2004 through the 2015-2016 flu seasons, little is known about the relationship between ACIP recommendations to discontinue LAIV recommendations and the impact of influenza vaccine uptake in the pediatric population.

Purpose of the Study

This study was conducted to evaluate the association between seasonal influenza vaccination ACIP recommendations, socioeconomic factors, demographic characteristics, and vaccine type among children over three consecutive flu seasons. LAIV was the recommended choice for children 2-8 during the 2014-2015 flu season, both LAIV and

IIV were equally recommended for the 2015-2016 flu season, and the LAIV recommendation was discontinued for the 2016-2017 season due to studies showing limited efficacy against A/H1N1 (Flannery & Chung, 2016). In addition, multiple socioeconomic and demographic factors can influence vaccine choice including age, race, family income, and health insurance status. The dependent variable for this study was influenza vaccine type (LAIV and IIV) among U.S. children. The independent variables were age, race, family income, health insurance status, and ACIP influenza vaccine recommendation by flu season (2014-2015, 2015-2016, and 2016-2017).

Research Questions and Hypotheses

Research Question 1: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2014-2015?

 H_01 : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2014-2015.

 H_a 1: There is a relationship between age, race, family income, health insurance status, vaccine type (LAIV/IIV) among U.S. children for flu season 2014-2015.

Research Question 2: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2015-2016?

 H_02 : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2015-2016.

 H_a 2: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2015-2016.

Research Question 3: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2016-2017?

 H_0 3: There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2016-2017.

 H_a 3: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2016-2017.

Research Question 4: What was the relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017?

 H_0 4: There is no relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015 (LAIV preferred), 2015-2016 (LAIV & IIV) and 2016-2017 (IIV preferred).

 H_a 4: There is a relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017.

Theoretical Foundation for the Study

Social Ecological Model

The use of ACIP recommendations, demographic characteristics, and socioeconomic status to evaluate influenza vaccine choice is guided by the social

ecological model. Although ACIP recommendations are not mandates, they may influence the availability of vaccines to consumers and their uptake in society. Once individuals have determined the need for the vaccine on a personal level, they look to public opinion and policy for guidance.

The social ecological model identifies multiple factors that influence health behavior including the individual, interpersonal, institutional, community, and policy levels. The intrapersonal level is where health decisions are made based on personal beliefs and knowledge at the individual level. The interpersonal level is focused on social norms, influence in the community, and collective beliefs within a close social network (Kumar et al., 2012). This level consists of peers, general practitioners, family, and friends. The institutional level represents the health care system, medical institutions, and local health care practitioners. At the community level are media, health disparities, and social norms. For example, vaccine uptake increases as more people in the same community get vaccinated (Kumar et al., 2012). At the policy level is regulation, oversight, and governing recommendations.

Variables at each level in the social ecological model are predictors of vaccine uptake (Kumar et al., 2012). In this case, patients have already made a choice to take the vaccine, so uptake was met at the intrapersonal level. For this study, the community and institutional levels of the social ecological model are represented by demographic and socioeconomic status. The policy level of the social ecological model is represented by ACIP recommendations. Although all levels affect vaccine uptake and choice, policies, socioeconomic and demographic factors can directly influence the other levels by altering and influencing the access and desire of flu vaccinations. This is achieved by making certain vaccines unavailable, altering access, reducing their perceived effectiveness, limiting affordability, or indicating a belief of risk associated with their use. For example, the ACIP recommendation to discontinue use of LAIV for the 2016-2017 flu season can negatively influence influenza vaccine uptake. If the underlying cause of LAIV's reduced efficacy is not defined and addressed due to conflicting policy and inconsistent recommendations by governing bodies, local health departments, and family practitioners, the public is left with limited or conflicting information to help guide vaccine choice.

Nature of the Study

This study was a quantitative cross-sectional study with secondary surveillance data provided by the CDC. The nature of this study is focused on ACIP recommendations and socioeconomic status and demographic characteristics regarding how they translate to vaccine choice among children residing in the United States. Secondary publicly available data were used to evaluate vaccine uptake by type among children over three recent flu seasons (2014-2015, 2015-2016, and 2016-2017) with different children sampled each year.

The key study variables include vaccine uptake of LAIV or IIV among U.S. children over three consecutive flu seasons with differing ACIP recommendations in addition to demographic and socioeconomic status defined as age, race, family income, and health insurance. The population for this study includes children (0 to 17 years of age) over three consecutive flu seasons (2014-2015, 2015-2016, and 2016-2017). The

sample population for influenza vaccinations is provided by the National Health Interview Survey (NHIS). The NHIS is a cross-sectional household interview survey conducted continuously throughout each year. Data are collected by the U.S. Census Bureau employees through a personal household interview consisting of four major components: household, family, sample adult, and sample child.

Literature Search Strategy

A search of relevant literature was done in the following databases:

ScienceDirect, Google Scholar, Walden Library, and NIH. Search terms included *liveattenuated influenza vaccine, LAIV, vaccine effectiveness, vaccine efficacy, LAIV, ACIP flu, health belief model vaccinations, child influenza,* and *influenza vaccine*. Peerreviewed articles and CDC reports were chosen to provide the most recent information. Articles focused on side effects or risk associated with the flu vaccine were excluded because they did not relate to the study topic. This initial literature search identified around 87 documents for further review and analysis.

Literature Review

Influenza is primarily transmitted from person to person via airborne-infected droplets that are disseminated when an infected person sneezes or coughs. These infected droplets can be transferred to susceptible persons within 3 feet of the infected individual. Transmission can also occur through direct or indirect contact with contaminated surfaces (Hamborsky et al., 2015). Humans are currently the only reservoir of influenza types B and C, although influenza A viruses infect both humans and animals (Hamborsky et al., 2015). Influenza activity generally peaks from December to March in temperate climates and occurs throughout the year in tropical regions (Deyle, Maher, Hernandez, Basu, & Sugihara, 2016). Adults can transmit influenza for 6 days from 1 day before symptoms appear to the first 5 days of the illness, and children can spread influenza for 10 or more days (Hamborsky et al., 2015). Once infected, the influenza virus penetrates respiratory epithelial cells where replication occurs resulting in the destruction of the host cell (Hamborsky et al., 2015)

The flu is rapidly transmitted in large populations with close contact, especially in the fall and winter months during the traditional academic school year. Seasonal influenza is estimated to impact 10 to 20% of the United States population annually (Hull & Ambrose, 2011). School-age children have the highest influenza transmission and infection rate, ranging from a 10 to 40% attack rate yearly (Wilson et al., 2013). Additionally, according to the CDC (2016), pediatric mortality is highest between 5 and 11 years of age, especially when combined with a secondary bacterial infection. Further, annual influenza attack rates among school-age children, who transmit the infection to others, can be as high as 42% (Carpenter et al., 2007). However, annual fall influenza vaccinations are the most effective method for preventing influenza and its complications (Weycker et al., 2005). The vaccination of children has been shown to reduce the impact of influenza on the communities where they reside, which is important for at-risk populations such as those 65 years of age and older (Wilson et al., 2013). Thus, the World Health Organization recommends a seasonal flu vaccination consisting of a 75% coverage rate for high-risk populations (Longini & Halloran, 2005).

Influenza Vaccine and Advisory Committee on Immunization Practices Recommendations

There are two types of influenza vaccine available for children in the United States. These vaccines are either IIV (administered by shot) or LAIV (a nasal mist) and contain influenza type A(H1N1), type A(H3N2), and type B (Caspard et al., 2016; Hamborsky et al., 2015). The LAIV has increased in popularity since its introduction in 2003. For flu seasons 2011-2012, 2012-2013, and 2013-2014 over 30% of vaccinated children received the LAIV (Kahn et al., 2015). In 2013 the ACIP recommended preference for LAIV, when available, for children 2 through 8 due to its vaccine efficacy compared to the IIV (CDC, 2014). Subsequent annual influenza efficacy research has indicated a reduction in LAIV potency against A/H1N1 in the United States, resulting in ACIP no longer recommending the LAIV for any age group for the 2016-2017 flu season (Robinson, 2016).

The ACIP recommends influenza vaccination for all children 6 months to 18 years of age before the annual influenza season. The CDC identified the average flu season beginning in October each year and extending through March of the following year (Peng-jun Lu et al., 2013). Due to the inconsistent nature of the annual flu season and vaccine uptake, data will be aggregated by month to include 6 months of each year for a total of 12 months. Therefore, the 2014-2015 season was from July 1, 2014, to June 31, 2015, flu season 2015-2016 from July 1, 2015, to June 31, 2016, and season 2016-2017 include July 1, 2016, to June 31, 2017.

Inactivated Influenza Vaccine (IIV)

Influenza vaccination only provides temporary immunity due to antigenic drift which contributes to seasonal outbreaks of the flu virus. For the IIV influenza conferred immunity is less than a year and depends on the individual and circulating flu strains (Hamborsky et al., 2015). Studies show influenza vaccines are effective in protecting about 60 % of healthy people under age 65 years when seasonal strains are closely matched (Tricco et al., 2013). The Influenza vaccine is less effective in populations over 65 years old in preventing illness but may reduce the duration and severity of the illness resulting in reduced influenza-related hospitalization and death (Hamborsky et al., 2015).

Live-Attenuated Influenza Vaccines (LAIV)

LAIV was approved in the United States in 2003. The LAIV and IIV contain the same influenza viruses each season as determined by the World Health Organization annually. LAIV contains cold-adapted, weakened influenza viruses that confer immunity by replication in the nasopharynx (Lanthier et al., 2011). Rather than an injection used for IIV, the LAIV is administered from a single-dose sprayer unit, half of the dose is sprayed into each nostril (MedImmune, 2016). LAIV is approved for use in healthy patients from 2 to 49 years of age (Hamborsky et al., 2015).

Varied Seasonal Efficacy

How well the flu vaccine work depends on multiple factors and can change seasonally. Significant factors contributing to vaccine effectiveness are characteristics of the individuals being vaccinated like age, health status, and time of vaccination during the flu season (Rhorer et al., 2009). In addition, the viruses chosen for the vaccine are most effective when they are similar to the circulating flu viruses in the community (CDC, 2014). Due to these variables determining influenza effectiveness is challenging and requires annual evaluation to determine the most effective means of protecting the population from the flu virus.

Hemagglutinin and neuraminidase are surface antigens located on the influenza virus that can be identified by the immune system if previous exposure has produced the correct antigens (Rhorer et al., 2009; Sultana et al., 2014). The influenza virus alters these surface proteins to escape detection in the host resulting in an illness called antigenic drift. Antigenic drift is a minimal alteration in surface antigens where antibodies from exposure to previous similar strains may provide partial immunity (Hamborsky et al., 2015). Antigenic shift also results in host illness when two influenza viruses share genetic information to produce a new influenza strain unknown to the host immune system. Antigenic shift tends to be more virulent in the population because the virus is completely unknown to the immune system (Hamborsky et al., 2015). Table 1 shows vaccine effectiveness estimates from 2014-2017 (Chung et al., 2016; Flannery & Chung, 2016; Flannery et al., 2017).

Table 1

	2014-	-2015	2015	-2016	2016	-2017
	Adjusted		Adjusted		Adjusted	
Age	VE %	95% CI	VE %	95% CI	VE %	95% CI
6 mo-8 yr	25	(6 to 40)	48	(31 to 61)	61	(49 to 70)
9-17	25	(2 to 42)	64	(44 to 77)	35	(13 to 61)

U.S. Flu Vaccine Effectiveness Estimates for 2014-2017

Note. VE = vaccine efficacy. Adjusted for age, sex, race/ethnicity, self-rated general

health status, days from illness onset to enrollment, and calendar time of illness onset.

Discontinued Live-Attenuated Vaccine and Advisory Committee on Immunization Practices Recommendations

Vaccine recommendations in the United States are developed annually by the Advisory Committee on Immunization Practices. An intranasal cold-adapted, LAIV was first approved for use in the United States in 2003 (Rose et al., 2014). In September 2007, the U.S. Food and Drug Administration expanded the indication for use in individuals 2 to 49 years of age, from the previous 5 to 49 years of age indication (Hamborsky et al., 2015).

In June 2016, data from four observational studies evaluating influenza vaccine effectiveness in the pediatric population during the 2015-2016 influenza season was presented to the ACIP (Flannery & Chung, 2016). The two studies conducted in the U.S. showed decreased effectiveness of LAIV compared to IIV (Grohskopf et al., 2016). For the 2015-2016 U.S. flu season the Influenza Vaccine Effectiveness Network "showed no significant vaccine effectiveness among children aged 2 through 17 years for LAIV for all influenza A and B viruses combined (3%; 95% CI = -49-37) or for influenza A(H1N1) (-21%; 95% CI = -108-30)"(Grohskopf et al., 2016), Studies carried out by MedImmune (LAIV manufacturer), the United Kingdom (35%; 95% CI: -29.9 to 67.5), and Finland (51%; 95% CI: 28 to 66%) showed the statistically significant efficacy of LAIV against all influenza strains (Matrajt, Halloran, & Antia, 2018). These studies showed LAIV and IIV effectiveness comparable to vaccine effectiveness observational studies in prior seasons.

Herd Immunity and Children

Increasing the number of children immunized against the flu also increases herd immunity defined by the indirect protection of household and community members that are unable to receive the vaccine, or that may be at high risk for adverse flu-related outcomes (Lind et al., 2014). Children tend to experience higher attack rates of annual influenza than other populations and gain more complete protection from flu vaccinations making them the ideal target population to slow transmission in the community or reduce incidence among population segments that may be at risk of severe consequences of infection (Fine, Eames, & Heymann, 2011).

High vaccination coverage reduces exposure of unvaccinated persons to infection, resulting in indirect protection in addition to direct protection for the those vaccinated (Glezen, Gaglani, Kozinetz, & Piedra, 2010). The direct effect of immunity reduces infection rates among vaccinated individuals resulting in less infection circulating in the community, less influenza exposure, resulting in herd immunity by indirect means (Fine et al., 2011). Increasing the number of school-age children immunized against the flu also increases herd immunity by the indirect protection of household and community members (Lind et al., 2014).

Uptake in the Community

Annual surveillance and vaccine effectiveness research are conducted to improve influenza vaccines, anticipate seasonal virus strains, and track the circulation of the of influenza in the community (Kelly et al., 2009). Previous clinical trials of LAIV in young children have shown it to be highly effective (Belshe et al., 2007). Initial studies comparing LAIV and IIV efficacy in young children found LAIV to be more effective in preventing the flu in children 2-8 years of age. Subsequent studies have had conflicting results with the diminished effectiveness of the LAIV across all circulation influenza virus as opposed to IIV.

Over half of all flu vaccines in the U.S. are administered to individuals ages 6 months to 17 years old (Peng-jun Lu et al., 2013). Studies addressing flu vaccination barriers cite time off work, cost, and lack of convenience as determining factors in vaccinating school children for the flu. According to the Morbidity and Mortality Weekly Report, the United States vaccination coverage is consistently below the Healthy People 2020 goal of 70 % (Peng-jun Lu et al., 2013).

In addition to the reported inconsistencies in flu vaccine efficacy, annual influenza immunization recommendations have varied in children 2-8 years of age. Inconsistencies in vaccine recommendations can negatively impact vaccine uptake in the community by diminishing the patients perceived benefits of following vaccine recommendations (Mueller, Hill, Fontanesi, & Kopald, 2007). Studies show parents who delayed and refused vaccine doses were more likely to have vaccine safety concerns and perceive fewer benefits associated with these vaccines (Blyth et al., 2014; Cheney & John, 2013; Smith et al., 2011).

Socioeconomic and Demographic Factors

Socioeconomic and demographic factors have the potential to influence the outcome of a study by an indication of a relationship among variables where one does not truly exist. For this study, four variables have been identified as factors that may influence vaccine uptake and choice among children in the United States population. These factors include age, race, family income, and health insurance status.

Age. Age has been identified as a factor that may influence vaccine uptake due to ACIP recommendations. The ACIP recommends influenza vaccination for all children 6 months to 18 years of age before the annual influenza season. While LAIV was approved by the FDA for use in healthy patients from 2 to 49 years of age for previous seasons, ACIP recommendations focused on children ages 2-8 years of age (Hamborsky et al., 2015).

Race. Race has been identified as a factor that may also influence vaccine update due to disparities in vaccine uptake among minorities in the United States. According to Chen (2007), flu vaccine rates among five ethnic groups (White, Latino, African American, Filipino American, and Japanese American) varied significantly. Among all participants who indicated they were concerned about getting the flu, individuals identified as White or African American were more likely to get vaccinated than Latino Americans (Chen, Fox, Cantrell, Stockdale, & Kagawa-Singer, 2007). Latino American were more likely to report access and cost as flu vaccination barriers, and African Americans noted concerns regarding the safety of flu vaccines.

Family income. Family income has been identified as another factor that may also influence vaccine update due to the time and cost associated with vaccination. A study by Cohen (2012), noted more than 10 % of those who were not vaccinated reported prohibitive cost as a reason. Another study indicated low pediatric influenza vaccination-

acceptance rates of 40.8 % in family's whose income was \$40,000 or less annually (Frew, Hixson, Rio, Esteves-Jaramillo, & Omer, 2011).

Health insurance status. Health insurance status has been identified as a covariate due to its potential influence on cost and access barriers associated with vaccination. According to Frew (2011), "children with private insurance were more likely to be up-to-date with immunizations compared with those with public insurance or no insurance although parents without health insurance indicated that they were more likely to vaccinate their children against H1N1 than parents with health insurance."

Definitions

Dependent Variable: Childhood influenza vaccination by type (LAIV or IIV)

Independent Variables: ACIP recommendations by flu seasons (2014-2015, 2015-2016, and 2016-2017). Socioeconomic and demographic factors that may contribute to influenza vaccine type including; age, race, family income, and insurance status.

Advisory Committee on Immunization Practices (ACIP): A group of medical and public health experts that develop recommendations annual influenza vaccination for all persons 6 months of age and older in the United States (Harris et al., 2014).

Attack Rate: is the cumulative incidence of influenza virus infections in a defined population (Jayasundara, Soobiah, Thommes, Tricco, & Chit, 2014).

Assumptions

The following assumptions are made about this study:

• The study sample is representative of the population.

- Secondary information provided by the CDC and WHO is accurate and timely.
- Parent-administered surveys about their child's influenza vaccination status are accurate.

These assumptions are made because the data used for this study is secondary and deviation from these factors cannot be controlled for through study design or primary sampling.

Scope and Delimitations

The focus of this study is influenza vaccination rates of children ages 0 to 17 years of age in the United States; CDC reports for 2014-2015, 2015-2016, and 2016-2017 flu seasons. Studies show vaccination uptake (yes/no) varies among individuals based on socioeconomic and demographic factors (Chen et al., 2007; Frew et al., 2011; Galarce, Minsky, & Viswanath, 2011; Hamborsky et al., 2015). These factors will be evaluated as they may also contribute to flu vaccine uptake by type (IIV/LAIV) in the community. Socioeconomic and demographic status for this study included age, race, family income, and health insurance status.

The delimitations of this study are:

- Three influenza seasons; 2014-2015, 2015-2016, and 2016-2017
- quantitative cross-sectional study
- Including US population
- Includes vaccination rates of children ages 0-17 years old.

An issue of generalization may occur because the secondary data set uses limited variables to define race among participants, where race identification is complex and may not be consistent throughout the U.S. population.

Significance

The potential contribution of this study is to add to current knowledge regarding influenza recommendations and influenza vaccine uptake among children. Most flu vaccine research evaluates the efficacy of the vaccine based on a test-negative design (a variation of the case-control design). Few studies evaluate influenza vaccine uptake by type socioeconomic status, demographic characteristics, and ACIP recommendations. This study aims to assess how socioeconomic and demographic status impacts vaccine uptake for three consecutive flu seasons and how ACIP recommendations influence LAIV uptake among children in the United States over the three most recent flu seasons.

Vaccination uptake is significantly influenced by social and psychological factors, some of which are under-reported and poorly understood (Wheelock, Miraldo, Parand, Vincent, & Sevdalis, 2014). Although structural barriers are known to limit vaccination rates, social and psychological factors may also affect the decision to vaccinate children. Perceptions about flu susceptibility and vaccine effectiveness significantly influence vaccination adoption (Wheelock et al., 2014). Evaluating current procedures and policies could improve patient perceptions and access.

Policies can directly influence the other levels by altering and influencing the access and desire of flu vaccinations by making them unavailable, altering access, reducing their perceived effectiveness, limiting affordability, or indicating belief of risk

associated with their use. The discontinued ACIP recommendation of the LAIV has the potential to negatively influence influenza vaccine uptake in general if the underlying cause of LAIV's reduced efficacy is not defined and addressed due to conflicting policy, and inconsistent recommendations by governing bodies, local health departments, and family practitioners. Improving vaccine recommendations and policy may lead to increased vaccine uptake and result in fewer sick days, reduced suffering, increased productivity, lower health cost and reduced illness and death associated with the flu virus especially for those most at risk.

Section 2: Research Design and Data Collection

Introduction

The purpose of this study was to examine the relationship between seasonal influenza vaccination ACIP recommendations, socioeconomic status, demographic characteristics, and vaccine uptake among children over three consecutive flu seasons. The dependent variable was influenza vaccine type (LAIV and IIV) among U.S. children. The independent variables were ACIP influenza vaccine recommendation by flu season including flu seasons 2014-2015, 2015-2016, and 2016-2017 and socioeconomic-demographic status indicated by age, race, family income, and health insurance status. The major sections of this chapter include research design, methodology, and threats to validity. The chapter will also include discussion of the study population, sampling, operational constructs, and ethical procedures.

Research Design and Rationale

This quantitative cross-sectional study included the NHIS secondary data reported by the CDC for flu seasons 2014-2015, 2015-2016, and 2016-2017 to evaluate the relationship between childhood influenza vaccination rates, ACIP recommendations, socioeconomic factors, and demographic characteristics. This study design allowed for timely analysis of a large dataset and is commonly used to assess policies and their impact on community health. This type of analysis is also used to examine the relationship between exposure and outcome prevalence in a defined population at a single point in time (Oleckno, 2002). The cross-sectional research design also provided advantages in being quick and easy to conduct because the data on selected variables are only collected once. Multiple exposures and outcomes can be measured simultaneously, resulting in the ability to measure prevalence for all variables being studied in a specific population (Oleckno, 2002).

Methodology

Population

The population for this study includes children residing in the United States over three consecutive flu seasons including 2014-2015, 2015-2016, and 2016-2017. The sample population for influenza vaccinations is provided by the NHIS. The NHIS survey is conducted from October through June each year for children 0 to 17 years of age. NHIS data are used to assess annual flu vaccination coverage by age at the national, state, and selected local levels and estimates are based on the parent or guardian reported data (CDC, 2017). Table 2 describes the variables used in this study.

Table 2

Study	Var	iab	les
~~~~			

Variables	Description	Inclusion criteria	Variable type
Dependent	Flu vaccine status	LAIV, IIV	Nominal/Categorical
Independent	ACIP recommendation	Flu seasons 2014-2015, 2015- 2016, and 2016-2017	Nominal/Categorical
	Age	Under a year old to 17 years of age	Nominal/Categorical
	Race	White, Black, Hispanic, Asian, Other	Nominal/Categorical
	Family income	\$0 - \$34,999, \$35,000 - \$74,999, \$75,000 - \$99,999, \$100,000 and over	Nominal/ Categorical/Ordinal

Health insuranc status	e Private, Medicaid and other public, other coverage, uninsured	Nominal/Categorical
Year	2014-2015, 2015-2016, 2016- 2017	Nominal/Categorical

# **Sampling and Sampling Procedures**

Secondary surveillance data provided by the CDC were used in this study based on the NHIS, which is a cross-sectional household interview survey targeting the civilian noninstitutionalized population in the United States (CDC, 2018). The NHIS is conducted as a face-to-face interview, stratified by each U.S. state and the District of Columbia (CDC, 2018). Data are collected continuously throughout the year by The U.C. Census interviewers. The NHIS is conducted using computer-assisted personal interviewing, which guides the interviewer through the questionnaire where the interviewer enters responses into the computer (CDC, 2018). Subsequent survey questions are based on answers to previous questions, and the responses data is automatically saved in the survey data file (CDC, 2018).

For each household with children, a *sample adult* 18 and over and a *sample child* under the age of 17 are randomly chosen to participate in the survey (CDC, 2018). In addition, the NHIS sample design oversamples non-White individuals to make sure all races are represented in the study. Information about the sample child is acquired from an adult residing in the household who is knowledgeable about the child's health (CDC, 2018).
All individual identifying information collected by the NHIS is held confidential and such information is not disclosed or released to anyone for any other purpose without the consent of the respondent (CDC, 2018). The National Center for Health Statistics must adhere to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act (44 U.S.C. 3501 note) to protect the privacy of participants (National Center for Health Statistics, 2015b, 2016b, 2017b).

# Sample Size

According to the NHIS, the sample size can vary from year to year. The publicly released NHIS data files for 2015 contain data for 41,493 households, including 42,288 families, 103,789 persons, and 12,291 children (National Center for Health Statistics, 2015b). Additionally, according to the National Center for Health Statistics,

The 2015 conditional response rate for the Sample Child component was 91.4 %, which was calculated by dividing the number of completed Sample Child interviews (12,291) by the total number of eligible sample children (13,444). The unconditional or final response rate of 63.4 % for the Sample Child segment was calculated by multiplying the conditional rate of 91.4 % by the final family response rate of 69.3 % (National Center for Health Statistics, 2015a, p.16).

Of the 12,291 children surveyed for the 2014-2015 flu season, 5,847 (47.57 %) were vaccinated for the flu (National Center for Health Statistics, 2015a). According to NHIS data, 4,252 (74.79%) received the shot, and 1,369 (24.08%) received the nasal mist (National Center for Health Statistics, 2015a).

The publicly released data files for the 2016 NHIS contain data for 40,220 households containing 40,875 families, 97,169 persons, and 11,107 children (National Center for Health Statistics, 2016b). Additionally,

The conditional response rate for the Sample Child component was 92.3 %. The unconditional or final response rate of 61.9 %, for the Sample Child segment, was calculated by multiplying the conditional rate of 92.3 % by the final family response rate of 67.1 %. (National Center for Health Statistics, 2016b, p. 15).

Of the 11,107 children surveyed for the 2015-2016 flu season, 5,299 (47.70%) were vaccinated for the flu (National Center for Health Statistics, 2016b). According to NHIS data, 4,099 (78.90%) received the shot, and 1,038 (19.98%) received the nasal mist (National Center for Health Statistics, 2016b).

The publicly released data files for the 2017 NHIS contain data for 32,617 households containing 33,157 families, 78,543 persons, and 8,845 children (National Center for Health Statistics, 2017b). Further,

The conditional response rate for the Sample Child component was 92.1 %, which was calculated by dividing the number of completed Sample Child interviews (8,845) by the total number of eligible sample children (9,601). The unconditional or final response rate of 60.6 % for the Sample Child segment was calculated by multiplying the conditional rate of 92.1% by the final family response rate of 65.7% (National Center for Health Statistics, 2017b, p. 15).

Of the 8,845 children surveyed for the 2016-2017 flu season, 4,024 (45.49 %) were vaccinated for the flu (National Center for Health Statistics, 2017b). According to NHIS

data, 3571 (91.24%) received the shot, and 293 (7.49%) received the nasal mist (National Center for Health Statistics, 2017b).

The sample for this study includes 13,347 children ages 0-17 residing in the United States. These cases were chosen based on the data provided; children who did not receive the flu vaccine were excluded from the sample. Additional cases that did not have responses for all independent variables were also excluded.

### **Instrumentation and Operationalization of Constructs**

The NHIS data are used to examine annual influenza coverage of children ages 0 to 17 years of age. Data used for this study are provided by the CDC, are open use, and include all study variables (National Center for Health Statistics, 2015a, 2016a, 2017a).

## **Study Variables**

**Dependent variable.** The dependent variable was influenza vaccination type among children ages 0-17 years of age for each flu season, where IIV is coded as 1, and LAIV coded as 2. Table 3 includes description and coding for the dependent variables. Table 3

Variable name	Description and coding	Variable type	Study code
CSHSPFL1 2014-2015	Was this a shot, or was it a vaccine sprayed in the nose?	nominal	0 Flu shot 1 Flu nasal spray or "LAIV."
CSHSPFL1 2015-2016	Was this a shot, or was it a vaccine sprayed in the nose?	nominal	0 Flu shot 1 Flu nasal spray or "LAIV."
CSHSPFL1 2016-2017	Was this a shot, or was it a vaccine sprayed in the nose?	nominal	0 Flu shot 1 Flu nasal spray or "LAIV."

#### Dependent Variable Descriptions

*Note*. Data Source: NHIS, 2015, 2016, and 2017. Exclude CSHSPFL1 (7 = Refused, 8 = Not ascertained, and 9 = Don't know)

**Independent variables.** Independent variables include year (Research Question 4 only), age, race, family income, and health insurance status (Research Questions 1-3 only). Age was recoded into categorical variables to include children younger than 1 year of age in the analysis. Table 4 includes description and coding for the independent variables.

Table 4

Variable	Description and coding	Variable type	Study code
AGE_P	Age	Nominal	(1) 0-2
(Research			(2) 3-5
Question 1-3)			(3) 6-8
			(4) 9-11
			(5) 12-14
			(6) 15-17
HISCODI3	Race	Nominal	(1) Hispanic
(Research			(2) White
Question 1-3)			(3) Black
			(4) Asian
			(5) All other race groups
INCGRP5	Total combined family	Nominal	(1) \$0 -\$34,999
(Research	income (grouped)		(2) \$35,000 - \$74,999
Question 1-3)			(3) \$75,000 - \$99,999
,			(4) \$100,000 and over
COVER	Health insurance	Nominal	(1) Private
(Research	coverage	1 (01111111	(2) Medicaid and other public
Ouestion 1-3)			(3) Other coverage
(			(4) Uninsured
YEAR	Data year	Nominal	(1) 2015
(Research	Dutu your	i voniniui	(2) 2016
Ouestion 4)			(3) 2017

Independent Variable Descriptions

Note. Data Source: NHIS, 2015, 2016, and 2017.

#### **Data Analysis Plan**

IBM SPSS Statistics version 24 and SAS student edition software packages were used for the statistical analysis of this study. Binary logistic regression was employed to explore the relationship between influenza vaccination type, age, race, family income, and health care status for Research Questions 1-3. Data from three consecutive flu seasons were combined for Research Question 4; cases with missing variables were excluded. Calculations include descriptive statistics on the tested association between ACIP recommendations, vaccine type, and socioeconomic-demographic status. Data for all three consecutive flu seasons were publicly reported by the CDC. The influenza season time periods are based on historical data provided by the CDC.

#### Analysis Plan for Each Research Question

Research Question 1: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015?

 $H_01$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015.

 $H_a$ 1: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015.

The independent variables were age, race, family income, and health insurance status. The dependent variables were vaccine type (LAIV/IIV) for this research question.

These variables are part of the NIS secondary data set provided by the CDC. Descriptive will be utilized to identify outliers and distribution. Binary logistic regression analysis between socioeconomic-demographic status and flu vaccine type for flu season 2014-2015 will be used to test this hypothesis. A P-value < 0.05 indicates rejection of the null hypothesis.

Research Question 2: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016?

 $H_02$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016.

 $H_a$ 2: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016.

The independent variables were age, race, family income, and health insurance status. The dependent variables were vaccine type (LAIV/IIV) for this research question. These variables are part of the NIS secondary data set provided by the CDC. Descriptive will be utilized to identify outliers and distribution. Binary logistic regression analysis between socioeconomic status, demographic characteristics, and flu vaccine type for flu season 2015-2016 will be used to test this hypothesis. A P-value < 0.05 indicates rejection of the null hypothesis.

Research Question 3: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017?

 $H_03$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017.

 $H_a$ 3: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017.

The independent variables were age, race, family income, and health insurance status. The dependent variables were vaccine type (LAIV/IIV) for this research question. These variables are part of the NHIS secondary data set provided by the CDC. Descriptive will be utilized to identify outliers and distribution. Binary logistic regression

analysis between socioeconomic status, demographic characteristics, and flu vaccine type for flu season 2016-2017 will be used to test this hypothesis. A P-value < 0.05 indicates rejection of the null hypothesis.

Research Question 4: What is the relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017?

 $H_0$ 4: There is no relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015 (LAIV preferred), 2015-2016 (LAIV & IIV) and 2016-2017 (IIV preferred).

 $H_a$ 4: There is a relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017.

The independent variable is ACIP recommendations, and the dependent variable is vaccine type. These variables are part of the NHIS secondary data set provided by the CDC. The chi-square test of homogeneity will be used to determine if a difference exists between the binomial proportions of three independent groups (flu season) on a dichotomous dependent variable (vaccine type). This test will be used to determine whether the proportions are statistically significant between groups indicated by flu season. A P-value < 0.05 indicates rejection of the null hypothesis. If there are statistically significant differences in proportions, a post hoc test will determine how these groups differ.

#### **Threats to Validity**

Content validity is defined by the inclusion of all the characteristics of the construct being measured (Frankfort-Nachmias & Nachmias, 2008). Type I sampling error is a false positive while a type II sampling error is a false negative result in hypothesis testing (Oleckno, 2002). Therefore, a type I error detects an association that is not present, and a type II error is failing to identify a positive relationship. Type I sampling error resulting in a false association. P values less than 0.05 are statistically significant and determined by the alpha level (Blair & Taylor, 2008). A substantial sample size increases the chance for statistical significance. Type II sampling error is measured by the

beta level. The smaller the beta level, the higher the statistical power. The beta level is also affected by the sample size, the larger the sample, the less likely for a type II error. Confidence intervals that are narrow suggest the associations are precise (Blair & Taylor, 2008). The survey data for this study provides a large sample size and reduces the risk of Type I or II error.

Reliability is determined by a measurements ability to provide similar results in subsequent tests, calculation of standard deviation can account for the variance in collected data. Standard deviation is used for quantifying the dispersion of a set of data values (Oleckno, 2002). Test results will vary from person to person falling within a bell cover with most cases located near the mean. A small standard deviation indicates that the data points tend to be close to the mean, reflecting increased reliability (Blair & Taylor, 2008). A high standard deviation indicates a lack of consistency with results spread out over a wide range of values. The standard deviation is also used to measure confidence in the statistical conclusions of a study and provide the likelihood of values falling within the same range if the same study is repeated (Blair & Taylor, 2008). Confidence intervals will be reported in the final analysis to show the reliability of study results.

An issue of generalization may occur because the secondary data set uses limited variables to define race among participants, where race identification is complex and may not be consistent throughout the U.S. population. Other factors may influence vaccine uptake beyond those in the scope of this study resulting in a potential type I or II error.

#### The Strengths and Limitations of these Measurements

Cross-sectional quantitative research investigates the relationship between variables in their natural environment rather than a laboratory setting (Polit & Hungler, 1999). This type of investigation often utilizes data from descriptive studies to formulate hypotheses, determine a relationship between variables, and test theories. A Crosssectional study evaluates the nature of relationships that exist and does not infer causality, like traditional experimental studies (Creswell, 2012).

The data from the NHIS survey is cross-sectional, based on an annual sample representing a changing cohort of subjects (CDC, 2015). In this case, the NHIS does not collect information from all subgroup populations omitting institutionalized individuals including military families. This data is secondary, so the health information collected does not include verifiable medical data or laboratory data (Rolnick et al., 2013). Some survey respondents may not be forthcoming about a behavior many consider to be undesirable. It is important to take into account the limitations inherent in self-reported data, including but not limited to reembrace error, reporting bias, incorrect documentation, and loss of cases.

One of the greatest limits to measuring a relationship among variables is the assumption of generalizability (Creswell, 2012). While statistical analysis of data sets may reveal that two variables tend to vary together, it does not mean they actually do. If the data is not representative of the real population, study results could indicate a relationship among variables that does not truly exist in the actual population. There are a number of unknown factors called confounders that can be unaccounted for resulting in a

false perception of a relationship among variables (Oleckno, 2002). In this study, potential confounders will be evaluated to try and control for these factors. Other unknown factors could also contribute to confounding but are not addressed in this study.

## **Ethical Procedures**

No ethical issues were identified in this study. None of the individuals surveyed are identified in the data provided by the CDC. According to the CDC (2017), "Information collected in the National Immunization Surveys is used only for reporting important statistical information about health issues." By law sensitive information like name, address or telephone number about any specific individual are not publicly available, and the CDC abides by these regulations. No efforts will be used to identify cases, only public use data will be used for this study, and all data will be kept on a password protected computer not shared on a network. Institutional review board (IRB) approval will be obtained prior data analysis to confirm that patient privacy is protected.

Section 3: Presentation of the Results and Findings

## Introduction

The purpose of this study was to examine the relationship between seasonal influenza vaccination ACIP recommendations, socioeconomic status, demographic characteristics, and vaccine uptake among children over three consecutive flu seasons. The dependent variable was influenza vaccine type (LAIV and IIV) among U.S. children. The independent variables were ACIP influenza vaccine recommendation by flu season including flu seasons 2014-2015, 2015-2016, and 2016-2017 and socioeconomicdemographic status indicated by age, race, family income, and health insurance status.

Research Question 1: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015?

 $H_01$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015.

 $H_a$ 1: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015

Research Question 2: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016?

 $H_02$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016.

 $H_a$ 2: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016.

Research Question 3: What is the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017?

 $H_0$ 3: There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017.

 $H_a$ 3: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017.

Research Question 4: What is the relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017?

 $H_04$ : There is no relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015 (LAIV preferred), 2015-2016 (LAIV & IIV) and 2016-2017 (IIV preferred).

 $H_a$ 4: There is a relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017.

The major sections of this chapter include data collection and the results of the study. The chapter will also include frequencies, population representation, hypothesis analysis, and a summary of the findings.

#### **Data Collection and Secondary Dataset**

Vaccination rates are documented annually by the CDC, which also involved the ACIP, a group of public health and medical experts who make vaccine recommendations updated annually to reflect continued research and development (Harris et al., 2014). The CDC uses multiple methods to document and surveys vaccination rates for vaccines recommended by the ACIP. In this cross-sectional study, secondary surveillance data provided by the CDC, from the NHIS, were used. The NHIS is a cross-sectional household interview survey targeting the civilian noninstitutionalized population residing in the United States (CDC, 2018). The NHIS is conducted as a face-to-face interview, stratified by each U.S. state and the District of Columbia (CDC, 2018). The U.S. Census Bureau is the data collection agency for the NHIS, and data are collected continuously throughout the year by census interviewers. According to the National Health Survey,

The sampling plan follows a multistage area probability design of clusters of addresses that are located in primary sampling units (PSU's). A PSU consists of a county, a small group of contiguous counties, or a metropolitan statistical area. The NHIS sample is divided into four separate panels, so each panel is a representative sample of the U.S. population. This design feature has a number of advantages, including flexibility for the total sample size.

The NHIS includes the noninstitutionalized civilian population residing in the United States at the time of the interview (National Center for Health Statistics, 2015b, 2016b, 2017b). Individuals excluded from the survey include long-term care facility patients, individuals on active duty with the Armed Forces, incarcerated persons, and U.S. nationals living outside the U.S (National Center for Health Statistics, 2015b, 2016a, 2017b). For the *family core* component, adult members of the household available at interview time are invited to participate. For each household with children, a *sample adult* 18 years of age and over and a *sample child* under the age of 17 is randomly chosen to participate in the survey (CDC, 2018). In addition, the NHIS sample design oversamples non-White individuals to make sure all races are represented in the study. Information about the sample child is acquired from an adult residing in the household who is knowledgeable about the child's health (CDC, 2018).

The NHIS is conducted using computer-assisted personal interviewing (National Center for Health Statistics, 2015b, 2016b, 2017b). The computer-assisted personal interviewing data collection method includes computer software that guides the interviewer through the questionnaire where the interviewer enters responses into the computer (CDC, 2018). Subsequent survey questions are based on answers to previous questions, and the responses data is automatically saved in the survey data file (CDC, 2018).

Participation in the survey is voluntary, and the confidentiality of responses is guaranteed under Section 308(d) of the Public Health Service Act (CDC, n.d.). Additionally, the National Center for Health Statistics must adhere to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act (44 U.S.C. 3501 note) to protect the privacy of participants (National Center for Health Statistics, 2015b, 2016b, 2017b). The annual response rate of NHIS is roughly 70% of the qualified households in the sample (CDC, 2018). All individual identifying information collected by the NHIS is held confidential, and personal information is not disclosed or released to anyone without the consent of the respondent (CDC, 2018).

## **Baseline Descriptive and Demographic Characteristics**

For the 2014-2015 flu season a total of 5,097 children received the flu vaccine, 3,832 (75.2%) received the flu shot, and 1,265 (24.8%) the LAIV. The age range of children in the study was 0-17 years of age. Most participants for this flu season were covered by health insurance (96.8%) either private or public, and only 3.2% were uninsured. The largest ethnic group for this flu season was White individuals at 48.7% of the total population and "All Other Race Groups" was the least at 1.8% of the population. For the 2014-2015 flu season, family income ranged from \$0-100,000+, with the largest population at the lowest and highest income groups. Table 5 includes socioeconomic status and demographic frequencies for the 2014-2015 flu season.

# Table 5

Characteristics	Frequency	Percent	<b>Cumulative Percent</b>
Age			
0-2	860	16.9	16.9
3-5	946	18.6	35.4
6-8	874	17.1	52.6
9-11	818	16.0	68.6
12-14	828	16.2	84.9
15-17	771	15.1	100.0
Total	5097	100.0	
Insurance			
Private	2793	54.8	54.8
Medicaid and Other	2025	39.7	94.5
Public			
Other Coverage	114	2.2	96.8
Uninsured	165	3.2	100
Total	5097	100	
Race			
Hispanic	1480	29.0	29.0
White	2480	48.7	77.7
Black	644	12.6	90.3
Asian	402	7.9	98.2
All Other Race Groups	91	1.8	100
Total	5097	100	
Family Income			
\$0-\$34,999	1623	31.8	31.8
\$35,000-\$74,999	1389	27.3	59.1
\$75,000-\$99,999	592	11.6	70.7
\$100,000 +	1493	29.3	100
Total	5097	100	

2014-2015 Socioeconomic and demographic Frequency Table

Note. Data Source: NHIS, 2015.

For the 2015-2016 flu season a total of 5,676 children received the flu vaccine, 3,766 (66.3%) received the flu shot, and 1,910 (33.7%) LAIV. The age range of children in the study was 0-17 years of age. Most participants for this flu season had health coverage (97.1%) either private or public, and only 2.9% were uninsured. The largest ethnic group for the 2015-2016 flu season was White at 56.7% of the total population, and "All Other Race Groups" was the least at 2.4% of the population. Family income for 2016 ranged from \$0-100,000+, with the largest population at the second lowest and highest income groups. Table 6 includes socioeconomic and demographic frequencies for the 2015-2016 flu season.

# Table 6

Characteristics	Frequency	Percent	Cumulative Percent
Age	-		-
0-2	876	15.4	15.4
3-5	1099	19.4	34.8
6-8	990	17.4	52.2
9-11	917	16.2	68.4
12-14	941	16.6	85.0
15-17	853	15.0	100.0
Total	5676	100.0	
Insurance			
Private	3363	59.2	59.2
Medicaid and Other Public	1961	34.5	93.8
Other Coverage	189	3.3	97.1
Uninsured	163	2.9	100
Total	5676	100	
Race	-		-
Hispanic	1216	21.4	21.4
White	3217	56.7	78.1
Black	679	12.0	90.1
Asian	428	7.5	97.6
All Other Race Groups	136	2.4	100
Total	5676	100	
Family Income	-		-
\$0-\$34,999	1460	25.7	25.7
\$35,000-\$74,999	1503	26.5	52.2
\$75,000-\$99,999	746	13.1	65.3
\$100,000 +	1967	34.7	100
Total	5676	100	

2015-2016 Socioeconomic and Demographic Frequency Table

Note. Data Source: NHIS, 2016.

For the 2016-2017 flu season a total of 3,795 children received the flu vaccine, 3,263 (86.0%) received the flu shot, and 532 (14%) the LAIV. The age range of children in the study was 0-17 years of age. Most participants for this flu season had health coverage (97.3%) either private or public, and only 2.7% were uninsured. The largest ethnic group for the 2016-2017 flu season was White individuals at 56.3% of the total population, and "All Other Race Groups" was the least at 2.1% of the population. Family income for 2017 ranged from \$0-100,000+, with the largest population at the second lowest and highest income groups. Table 7 includes socioeconomic and demographic frequencies for the 2016-2017 flu season.

Table 7

Characteristics	Frequency	Percent	Cumulative Percent
Age		-	
0-2	621	16.4	16.4
3-5	665	17.5	33.9
6-8	677	17.8	51.7
9-11	606	16.0	67.7
12-14	628	16.5	84.2
15-17	598	15.8	100.0
Total	3795	100.0	
Insurance			
Private	2262	59.6	59.6
Medicaid and Other Public	1277	33.6	93.3
Other Coverage	155	4.1	97.3
Uninsured	101	2.7	100
Total	3795	100	
Race	-	-	-
Hispanic	852	22.5	22.5
White	2137	56.3	78.8
Black	437	11.5	90.3
Asian	290	7.6	97.9
All Other Race Groups	79	2.1	100
Total	3795	100	
Family Income	-	-	-
\$0-\$34,999	946	24.9	24.9
\$35,000-\$74,999	969	25.5	50.5
\$75,000-\$99,999	426	11.2	61.7
\$100,000 +	1454	38.3	100
Total	3795	100	

2016-2017 Socioeconomic and Demographic Frequency Table

Note. Data Source: NHIS, 2017.

For all three seasons (2015, 2016, and 2017) a total of 32,243 children ages 0-17 were included in the data set. Of those children, 15,170 (48.6%) children ages 0-17 received the flu vaccine, and 16,052 (51.4%) did not receive the flu vaccine. According to the NHIS survey data, 11,922 (81.5%) received the flu shot, and 2,700 (18.5%) received the flu nasal spray combined over all three flu seasons.

### **Statistical Assumptions**

## **Research Questions 1-3: Binomial Logistic Regression**

The assumptions of a binomial logistic regression provide information on the accuracy of the predictions, test how well the regression model fits the data, determine the variation in the dependent variable explained by the independent variables, and test hypotheses on the regression equation (Laerd Statistics, 2015). The assumptions for this study were:

- Assumption #1: One dependent variable that is dichotomous (LAIV and IIV)
- Assumption #2: One or more independent variables that are measured on either a continuous or nominal scale (age, race, health insurance status, family income).
- Assumption #3: Independence of observations and the categories of the dichotomous dependent variable and all your nominal independent variables should be mutually exclusive and exhaustive. Independence of observations is largely a study design issue rather than something you can test for using SPSS Statistics.

- Assumption #4: A bare minimum of 15 cases per independent variable, although some recommend as high as 50 cases per independent variable.
- Assumption #5: A linear relationship between the continuous independent variables and the logit transformation of the dependent variable. This research question does not include continuous variables, so a linear relationship is not necessary between variables.
- Assumption #6: Data must not show multicollinearity, correlation coefficients and Tolerance/VIF values found no multicollinearity among variables.
- Assumption #7: No significant outliers, high leverage points or highly influential points. No significant outliers were identified.

## **Research Question 4: Chi-Square Test of Homogeneity Statistical Assumptions**

The chi-square test of homogeneity is used to determine if a difference exists between the binomial proportions of three or more independent groups on a dichotomous dependent variable. It will let you determine whether the proportions are statistically significantly different in the different groups. If there are statistically significant differences in proportions, a post hoc test to determine where the differences between these groups lie can be used (Laerd Statistics, 2017).

- Assumption #1: One dependent variable that is measured at the dichotomous level (LAIV/ IIV).
- Assumption #2: One independent variable that is polytomous, Flu vaccine years (2015, 2016, and 2017).

- Assumption #3: Independence of observations, which means that there is no relationship between the observations in each group of the independent variable. Participants for each year were different based on the sampling method identified by the NHIS.
- Assumptions #4: Study type includes random sampling from three or more independent populations. Each year was a different subset of the population.
- Assumptions #5: A sufficiently large sample size so that the approximation to the chi-squared distribution is valid. The sample size includes a total of 13,347 children ages 0-17.

## Results

#### **Data Analysis Research Question 1**

Research Question 1: What was the relationship between age, race, family income, insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015?

 $H_01$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015.

 $H_a$ 1: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015

Analysis of the 2014-2015 flu season. A 2-step procedure was used to assess the relationship of age, race, health insurance status and family income on vaccine uptake (LAIV vs. IIV). The first step used a Pearson's chi-squared cross-tabulation to assess how each independent variable by itself was distributed between vaccine type. This was

used to provide a preliminary look at any potential imbalances across vaccine type. The second step employed binomial logistic regression to assess the impact of the independent variables when evaluated together.

An odds ratio is calculated for each independent variable from the logistic regression model. The odds ratio is a measure of association between an exposure and an outcome (Szumilas, 2010) and the odds that the LAIV vaccine will be given based on a particular characteristic (socioeconomic-demographic status), compared to the odds of the LAIV vaccine being administered in the absence of that characteristic (socioeconomic-demographic status; Szumilas, 2010). This provides the change in the odds for each increase in one unit of the independent variable (Szumilas, 2010). Odds ratios are used to compare the relative odds of the occurrence of the outcome of interest (LAIV), given exposure to the variable of interest (socioeconomic-demographic status).

A 95 % confidence interval (CI) is used to estimate the precision of the odds ratio (Szumilas, 2010). A large CI indicates a low level of precision and a small CI indicates a higher precision of the odds ratio (Szumilas, 2010). Unlike the p-value, the 95 % CI does not report a measure's statistical significance rather the 95 % CI is often used as a proxy for the presence of statistical significance if it does not include the null value of odds ratio = 1 (Szumilas, 2010).

Tables 8-11 show how the socioeconomic and demographic variables are distributed among vaccine recipients their impact on vaccine type. Overall, many more patients received IIV compared to LAIV in the 2014-2015 flu season (75.2% vs. 24.8%). Table 8 shows that the distributions of ages differed by vaccine type. In the IIV group,

the percentage within each age category ranged from a low of 10.9 % (9-11year old) to a high of 15.0 % (ages 0-2 years old) with an average age of 6-8. Within the LAIV group the range of percentages within each age category range from a low of 7.4 % (0-2 years of age) to a high of 24.7 % (6-8 years old) with an average age of 6-8.

Table 8

	Vaccine t		
Age	IIV	LAIV	Total
0-2	767 (20.0%)	93 (7.4%)	860 (16.9%)
3-5	672 (17.5%)	274 (21.7%)	946 (18.6%)
6-8	561 (14.6%)	313 (24.7%)	874 (17.1%)
9-11	557 (14.5%)	261(20.6%)	818 (16.0%)
12-14	628 (16.4%)	200 (15.8%)	828 (16.2%)
15-17	647 (16.9%)	124 (9.8%)	771 (15.1%)
Total	3832 (75.2%)	1265 (24.8%)	5097 (100.0%)

2014-2015 Age and Vaccine Type Frequencies

Note. Data Source: NHIS, 2015.

Table 9 describes insurance coverage by vaccine type. Most participants had some type of insurance coverage (96.3% for IIV, 98.1% for LAIV). More participants receiving IIV had public insurance compared to those receiving LAIV (41.6% vs. 33.9%) while the opposite was true for those having private insurance (52.5% for IIV, 61.8% for LAIV). Table 9

2014-2015 Health Coverage and Vaccine Type Frequencies

	Vaccin		
Health Coverage	IIV	LAIV	Total
Private	2011(52.5%)	782 (61.8%)	2793 (54.8%)
Medicaid and other public	1596 (41.6%)	429 (33.9%)	2025 (39.7%)
Other Coverage	84 (2.2%)	30 (2.4%)	114 (2.2%)
Uninsured	141 (3.7%)	24 (1.9%)	165 (3.2%)
Total	3832 (75.2%)	1265 (24.8%)	5097 (100.0%)

Note. Data Source: NHIS, 2015.

Table 10 describes the distribution of race which differed between vaccine type. Most vaccine recipients were Hispanic (31.2%IIV, 22.6% LAIV) or White (45.7% IIV, 57.5% LAIV).

Table 10

Vaccin		
IIV	LAIV	Total
1194 (31.2%)	286 (22.6%)	1480 (29.0%)
1753 (45.7%)	727 (57.5%)	2480 (48.7%)
500 (13.0%)	144 (11.4%)	644 (12.6%)
314 (8.2%)	88 (7.0%)	402 (7.9%)
71 (1.9%)	20 (1.6%)	91 (1.8%)
3832 (75.2%)	1265 (24.8%)	5097 (100.0%)
	Vaccin IIV 1194 (31.2%) 1753 (45.7%) 500 (13.0%) 314 (8.2%) 71 (1.9%) 3832 (75.2%)	Vaccine typeIIVLAIV1194 (31.2%)286 (22.6%)1753 (45.7%)727 (57.5%)500 (13.0%)144 (11.4%)314 (8.2%)88 (7.0%)71 (1.9%)20 (1.6%)3832 (75.2%)1265 (24.8%)

2014-2015 Race and Vaccine Type Frequencies

Note. Data Source: NHIS, 2015.

Table 11 describes family income. More IIV recipients were in the lowest income group (33.7% vs. 26.2% for LAIV) while more recipients in the LAIV group were in the highest income group (36.5% vs. 26.9% for IIV).

## Table 11

2014-2015 Family Income and Vaccine Type Frequencies

	Vacci	Vaccine type			
Family Income	IIV	LAIV	Total		
\$0 - \$34,999	1292 (33.7%)	331 (26.2%)	1623 (31.8%)		
\$35,000 -\$74,999	1080 (28.2%)	309 (24.4%)	1389 (27.3%)		
\$75,000 -\$99,999	429 (11.2%)	163 (12.9%)	592 (11.6%)		
\$100,000 and over	1031 (26.9%)	462 (36.5%)	1493 (29.3%)		
Total	3832 (75.2%)	1265 (24.8%)	5097 (100.0%)		

Note. Data Source: NHIS, 2015.

Logistic regression was used to describe the data and explain any relationship between vaccine type and the independent variables (covariates). Logistic regression using vaccine type (probability modeled as LAIV) was applied to assess the relationship amongst age group, insurance type, race, family income.

A model containing all 4 covariates was run. Before interpreting the model, the model containing covariates needs to be checked that at least 1 covariate is different from 0 by testing that the global null hypothesis=0. A p-value<0.0001 was obtained allowing for rejection of this null hypothesis. This suggests that at least 1 covariate in the model is different from 0. In addition, a goodness-of-fit statistic, the Hosmer-Lemeshow test, is applied to the resulting model to check that the model is correctly specified, the data do not conflict with the assumptions made by the model. The obtained p-value=0.344 suggests that we cannot reject the hypothesis that the fitted model is correct.

The reduced model was determined a better fit when health insurance status was determined not significant through initial analysis. Table 13 shows the results of the reduced logistic regression analysis used to address Research Question 1. The logistic regression model was statistically significant,  $\chi^2(15) = 315.831$ , p = .000. The Wald test of significance indicated that age (p = .000), race (p = .000), and family income (p = .000) were all statistically significant in relation to LAIV uptake.

# Table 12

							95% CI	for
							Exp(B)	
	В	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Age			198.965	5	.000			
3-5	1.223	.132	85.877	1	.000	3.397	2.623	4.400
6-8	1.542	.131	137.614	1	.000	4.674	3.612	6.047
9-11	1.356	.134	102.453	1	.000	3.882	2.985	5.048
12-14	.967	.138	49.450	1	.000	2.630	2.009	3.444
15-17	.435	.148	8.641	1	.003	1.545	1.156	2.066
Race			30.495	4	.000			
White	.421	.087	23.457	1	.000	1.523	1.285	1.806
Black	.181	.118	2.368	1	.124	1.199	.952	1.509
Asian	027	.145	.036	1	.851	.973	.732	1.293
Other race groups	.196	.268	.535	1	.465	1.217	.719	2.058
Family income			26.992	3	.000			
35,000-74,999	.041	.092	.197	1	.657	1.042	.869	1.249
75,000-99,999	.310	.117	7.001	1	.008	1.363	1.084	1.715
100,000+	.422	.093	20.468	1	.000	1.524	1.270	1.830
Constant	-2.535	.132	369.371	1	.000	.079		

Logistic Regression Reduced Model Flu Season 2014-2015

Note. Data Source: NHIS, 2015. Variable(s) entered on step 1: Age, Health coverage,

Race, Family Income. Comparison groups are age (0-2), Race (Hispanic), Family income

(\$0-34,999), and health coverage (private).

In the full model three of the four covariates are significant (p < 0.05) with only insurance coverage (p = 0.115) not statistically significant. As a result, a reduced model eliminating insurance coverage from the model was run. The Hosmer-Lemeshow statistic from the reduced model was p = 0.393 suggesting a slightly better fit to the data. As a result, inferences are based on this reduced model. The odds ratios are shown in Table 13.

# Table 13

Odds Ratio Estimates and Wald Confidence Intervals				
	Independent Variables	Odds Ratio	95% Confider	nce Limits
Race	White vs. Hispanic	1.523	1.285	1.806
	Black vs. Hispanic	1.199	0.952	1.509
	Asian vs. Hispanic	0.973	0.732	1.293
	All other races vs. Hispanic	1.217	0.719	2.058
	White vs. Black	1.271	1.023	1.579
	White vs. Asian	1.565	1.209	2.027
	White vs. All other races	1.252	0.745	2.105
	Black vs. Asian	1.232	0.900	1.686
	Black vs. All other races	0.985	0.572	1.696
	Asian vs. All other races	0.800	0.454	1.410
Age	3-5 vs. 0-2	3.396	2.622	4.398
	6-8 vs. 0-2	4.673	3.611	6.045
	9-11 vs. 0-2	3.881	2.985	5.047
	12-14 vs. 0-2	2.629	2.008	3.443
	15-17 vs. 0-2	1.545	1.156	2.065
	3-5 vs. 6-8	0.727	0.596	0.887
	3-5 vs. 9-11	0.875	0.712	1.075
	3-5 vs. 12-14	1.292	1.042	1.601
	3-5 vs. 15-17	2.198	1.729	2.795
	6-8 vs 9-11	1.204	0.982	1.477
	6-8 vs 12-14	1.777	1.436	2.199
	6-8 vs 15-17	3.025	2.382	3.841
	9-11 vs 12-14	1.476	1.186	1.837
	9-11 vs 15-17	2.512	1.968	3.207
	12-14 vs 15-17	1.702	1.324	2.189
Family	\$ 35 -74,999 vs. \$ 0-34,999	1.042	0.868	1.249
	\$ 75 -99,999 vs. \$ 0-34,999	1.363	1.084	1.715
Income	\$ 100,000 + vs. \$ 0-34,999	1.524	1.270	1.830
	\$ 35 -74,999 vs. \$ 75 -99,999	0.764	0.609	0.960
	\$ 35 -74,999 vs. \$ 100,000 +	0.683	0.572	0.816
	\$75-99,999 vs. \$100,000 +	0.894	0.719	1.112

2014-2015 Socioeconomic, Demographic, and Vaccine Type Odds Ratios

Note. Data Source: NHIS, 2015.

The highest odds ratios were for children among the 6-8 age group who were 4.673 times more likely to receive the LAIV vaccine than children ages 0-2 and 3.025 times more likely to receive LAIV than children ages 15-17. Children ages 0-2, in which LAIV is not recommended for, were less likely overall to receive LAIV than all other age groups in the study. Children ages 9-11 were also more likely to receive the LAIV vaccine than their peers as they fit into the ACIP age recommendation group.

White children were 1. 565 times more likely to receive the LAIV vaccine than Asian children. In fact, White children were more likely to receive the LAIV vaccine than Black (1.271) and Hispanic (1.523) children as well.

Children with a family income of \$100,000 or more were 1.524 times more likely to receive the LAIV vaccine than those with a family income of \$0- 34,999 annually. Children with a family income of \$75 -99,999 were 1.363 times more likely to receive the LAIV vaccine than those with a family income of \$0- 34,999 annually.

For Research Question 1, we reject the null hypothesis in favor of the alternative hypothesis for race, age, and family income and we fail to reject the null for health insurance coverage. There is a relationship between age, race, family income and vaccine type (LAIV/ IIV) among U.S. children for flu season 2014-2015. Those who received LAIV were most likely to be White elementary school age children with a family income of 75,000+ for the 2014-2015 flu season. Health insurance coverage was very high for this population (96.3% for IIV, 98.1% for LAIV) indicating that the sample of uninsured individuals may have been too low to address a relationship among variables. In addition,

most of the LAIV cases were clustered around the ACIP recommended age of 2-8 years of age considered the preferred flu vaccine type for the 2014-2015 flu season.

#### **Data Analysis Research Question 2**

Research Question 2: What was the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016?

 $H_02$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016.

 $H_a$ 2: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/IIV) among U.S. children for flu season 2015-2016.

Analysis of the 2015-2016 flu season. The same analysis approach as used in Research Question 1 was also used for Research Question 2. Chi-square was used to assess each independent variable by itself, and logistic regression was used to evaluate these variables in a model. Tables 14- 17 show how the socioeconomic and demographic variables are distributed among vaccine recipients their impact on vaccine type. As in 2014-2015, more patients received IIV compared to LAIV in the 2015-2016 flu season (79.8% vs. 20.2%). Table 14 shows that the distributions of ages differed by vaccine type. In the IIV group, the percentage within each age category ranged from a low of 13.7 % (9-11year old) to a high of 18.9 % (ages 0-2 years old) with an average age of 6-8. Within the LAIV group the range of percentages within each age category range from a low of 8.6 % (0-2 years of age) to a high of 23.4 % (6-8 years old) with an average age of 6-8.

## Table 14

	Vaccine		
Age	IIV	LAIV	Total
0-2	712 (18.9%)	82 (8.6%)	794 (16.8%)
3-5	703 (18.7%)	198 (20.7%)	901 (19.1%)
6-8	544 (14.4%)	223 (23.4%)	767 (16.2%)
9-11	517 (13.7%)	200 (20.9%)	717 (15.2%)
12-14	639 (17.0%)	151 (15.8%)	790 (16.7%)
15-17	651 (17.3%)	101 (10.6%)	752 (15.9%)
Total	3766 (79.8%)	955 (20.2%)	4721 (100.0%)
M.C. D.A	NILLIG 20	10	

2015-2016 Age and Vaccine Type Frequencies

Note. Data Source: NHIS, 2016.

Table 15 describes insurance coverage by vaccine type. Most participants had some type of insurance coverage (97.8% for IIV, 99.4% for LAIV). More participants receiving IIV had public insurance compared to those receiving LAIV (35.5% vs. 32.7.0%) and private insurance (58.5% for IIV, 60.7% for LAIV).

#### Table 15

2015-2016 Health Coverage and Vaccine Type Frequencies

	Vaccine			
Health Coverage	IIV	LAIV	Total	
Private	2203 (58.5%)	580 (60.7%)	2783 (58.9%)	
Public	1337 (35.5%)	312 (32.7%)	1649 (34.9%)	
Other coverage	121 (3.2%)	34 (3.6%)	155 (3.3%)	
Uninsured	105 (2.8%)	29 (3.0%)	134 (2.8%)	
Total	3766 (79.8%)	955 (20.2%)	4721 (100.0%)	

Note. Data Source: NHIS, 2016.

Table 16 describes the distribution of race which differed between vaccine type. Most vaccine recipients were either White (54.8% IIV, 60.4% LAIV) or Hispanic (22.2% IIV, 19.9% LAIV).

# Table 16

Vaccine			
IIV	LAIV	Total	
836 (22.2%)	190 (19.9%)	1026 (21.7%)	
2063 (54.8%)	577 (60.4%)	2640 (55.9%)	
459 (12.2%)	110 (11.5%)	569 (12.1%)	
302 (8.0%)	63 (6.6%)	365 (7.7%)	
106 (2.8%)	15 (1.6%)	121 (2.6%)	
3766 (79.8%)	955 (20.2%)	4721 (100.0%)	
	Vaccine IIV 836 (22.2%) 2063 (54.8%) 459 (12.2%) 302 (8.0%) 106 (2.8%) 3766 (79.8%)	Vaccine type   IIV LAIV   836 (22.2%) 190 (19.9%)   2063 (54.8%) 577 (60.4%)   459 (12.2%) 110 (11.5%)   302 (8.0%) 63 (6.6%)   106 (2.8%) 15 (1.6%)   3766 (79.8%) 955 (20.2%)	

2015-2016 Race and Vaccine Type Frequencies

Note. Data Source: NHIS, 2016.

Table 17 describes family income. Family income was similar for both IIV and LAIV recipients. Twenty-six % of children who received the flu vaccine were in the lowest income group (IIV 26.4% and LAIV 24.3%) and 34.4 % were in the highest income group (LAIV 35.9% and 34% for IIV).

Table 17

2015-2016 Family Income and Vaccine Type Frequencies

	Vaccine			
Family Income	IIV	LAIV	Total	
\$0 -\$34,999	996 (26.4%)	232 (24.3%)	1228 (26.0%)	
\$35,000 - \$74,999	991 (26.3%)	256 (26.8%)	1247 (26.4%)	
\$75,000 - \$99,999	498 (13.2%)	124 (13.0%)	622 (13.2%)	
\$100,000 +	1281 (34.0%)	343 (35.9%)	1624 (34.4%)	
Total	3766 (79.8%)	955 (20.2%)	4721 (100.0%)	

Note. Data Source: NHIS, 2016.

Logistic regression was used to describe the data and explain any relationship between vaccine type and the independent variables (covariates). Logistic regression using vaccine type (probability modeled as LAIV) was applied to assess the relationship amongst age group, insurance type, race, family income.

The reduced model was determined a better fit when health insurance status and family income were determined not significant through initial analysis. The logistic regression model was statistically significant,  $\chi^2(15) = 262.482$ , p = .000. The Wald test of significance indicated that age (p = .000) and race (p = .000) were all statistically significant in relation to LAIV uptake. Table 18 shows the results of the logistic regression analysis used to address Research Question 2.

Table 18

							95% CI for Exp(B)	
	В	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Age			220.61	5	.000			
3-5	.894	.107	69.557	1	.000	2.445	1.982	3.017
6-8	1.273	.108	139.332	1	.000	3.571	2.891	4.412
9-11	1.221	.110	124.323	1	.000	3.391	2.736	4.203
12-14	.729	.112	42.687	1	.000	2.073	1.666	2.579
15-17	.295	.118	6.197	1	.013	1.343	1.065	1.694
Race			23.707	4	.000			
White	.228	.073	9.595	1	.002	1.256	1.087	1.450
Black	.058	.105	.303	1	.582	1.059	.863	1.301
Asian	089	.125	.499	1	.480	.915	.716	1.170
Other race groups	462	.219	4.442	1	.035	.630	.410	.968
Constant	911	.053	297.960	1	.000	.402		

Logistic Regression Reduced Model Flu Season 2015-2016

Note. Data Source: NHIS, 2016.

Two of the four covariates are significant (p < 0.05). Insurance coverage (p = 0.652) and family income (p = 0.920) were not statistically significant. Based on this a reduced model eliminating insurance coverage from the model was run. The Hosmer-
# Table 19

	Odds Ratio Estimates and Wald Confidence Intervals						
	Independent Variables	Odds Ratio	95% Confid	dence Limits			
Race	White vs. Hispanic	1.261	1.047	1.517			
	Black vs. Hispanic	1.059	0.813	1.379			
	Asian vs. Hispanic	0.920	0.669	1.265			
	All other races vs. Hispanic	0.627	0.355	1.107			
	White vs. Black	1.191	0.945	1.500			
	White vs. Asian	1.370	1.024	1.833			
	White vs. All other races	2.011	1.156	3.500			
	Black vs. Asian	1.115	0.813	1.627			
	Black vs. All other races	1.689	0.940	3.032			
	Asian vs. All other races	1.468	0.796	2.706			
Age	3-5 vs. 0-2	2.453	1.857	3.239			
-	6-8 vs. 0-2	3.590	2.755	4.737			
	9-11 vs. 0-2	3.398	2.565	4.503			
	12-14 vs. 0-2	2.084	1.559	2.785			
	15-17 vs. 0-2	1.351	0.991	1.843			
	3-5 vs. 6-8	0.683	0.547	0.853			
	3-5 vs. 9-11	0.722	0.575	0.906			
	3-5 vs. 12-14	1.177	0.928	1.493			
	3-5 vs. 15-17	1.815	1.396	2.361			
	6-8 vs 9-11	1.057	0.843	1.325			
	6-8 vs 12-14	1.723	1.360	2.183			
	6-8 vs 15-17	2.657	2.046	3.452			
	9-11 vs 12-14	1.631	1.281	2.076			
	9-11 vs 15-17	2.515	1.928	3.282			
	12-14 vs 15-17	1.542	1.171	2.031			

2015-2016 Demographic characteristics and Vaccine Type Odds Ratios

Note. Data Source: NHIS, 2016.

The highest odds ratios were for children among the 6-8 age group who were 3.590 times more likely to receive the LAIV vaccine than children ages 0-2 and 65% more likely to receive LAIV than children ages 15-17. Children ages 0-2 were less likely overall to receive LAIV than all other age groups in the study. Children ages 9-11 and 12-14 were also more likely to receive the LAIV vaccine than their peers. White children were 1.370 times more likely to receive the LAIV vaccine than Asian children. In fact, White children were more likely to receive the LAIV vaccine than Black (1.191), Hispanic (1.261), and all other race (2.011) children as well. For Research Question 2, the reduced model including race and age provided the best fit. showing there these variables and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016. Those who received LAIV during the 2015-2016 flu season were also most likely to be White elementary school age children.

## **Data Analysis Research Question 3**

Research Question 3: What was the relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017?

 $H_03$ : There is no relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017.

 $H_a$ 3: There is a relationship between age, race, family income, health insurance status, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2016-2017.

Analysis of the 2016-2017 flu season. The same statistical approach was used as was used for Research Question 1 and Research Question 2. Tables 20- 23 show how the

socioeconomic-demographic variables are distributed among vaccine recipients their impact on vaccine type. Overall, many more patients received IIV compared to LAIV in the 2015-2016 flu season (92.5% vs. 7.5%). Table 20 shows that the distributions of ages differed by vaccine type. In the IIV group, the percentage within each age category ranged from a low of 14.8 % (9-11year old) to a high of 18.1 % (ages 3-5years old) with an average age of 6-8. Within the LAIV group the range of percentages within each age category range from a low of 11.3 % (15-17 years of age) to a high of 24.1% (6-8 years old) with an average age of 6-8.

Table 20

2016-2017 Age and Vaccine Type Frequencies

	Vaccine		
Age	IIV	LAIV	Total
0-2	555 (17.0%)	33 (12.4%)	588 (16.7%)
3-5	591(18.1%)	37 (13.9%)	628 (17.8%)
6-8	549 (16.8%)	64 (24.1%)	613 (17.4%)
9-11	484 (14.8%)	61(22.9%)	545 (15.4%)
12-14	546 (16.7%)	41(15.4%)	587 (16.6%)
15-17	538 (16.5%)	30 (11.3%)	568 (16.1%)
Total	3263 (92.5%)	266 (7.5%)	3529 (100.0%)
Note Data S	ource: NHIS 2017	7	

*Note*. Data Source: NHIS, 2017.

Table 21 describes insurance coverage by vaccine type. Most participants had some type of insurance coverage (97.3% for IIV, 97.7% for LAIV). More participants receiving LAIV had public insurance compared to those receiving the Flu shot (35.3% vs. 33.4%) while the opposite was true for those having private insurance (60.0% for IIV, 57.1% for LAIV).

# Table 21

	Vaccine	e type	
Health Coverage	IIV	LAIV	Total
Private	1958 (60.0%)	152 (57.1%)	2110 (59.8%)
Public	1089 (33.4%)	94 (35.3%)	1183 (33.5%)
Other coverage	127 (3.9%)	14 (5.3%)	141(4.0%)
Uninsured	89 (2.7%)	6 (2.3%)	95 (2.7%)
Total	3263 (92.5%)	266 (7.5%)	3529 (100.0%)
Note Data Sources N	1119 2017		

2016-2017 Health Coverage and Vaccine Type Frequencies

Note. Data Source: NHIS, 2017.

Table 22 describes the distribution of race which differed between vaccine type. Most vaccine recipients were Hispanic (22.5%IIV, 22.2% LAIV) or White (56.7% IIV,

53.8% LAIV).

Table 22

2016-2017 Race and Vaccine Type Frequencies

_	Vaccin		
Race	IIV	LAIV	Total
Hispanic	734 (22.5%)	59 (22.2%)	793 (22.5%)
White	1851(56.7%)	143 (53.8%)	1994 (56.5%)
Black	357 (10.9%)	40 (15.0%)	397 (11.2%)
Asian	258 (7.9%)	16 (6.0%)	274 (7.8%)
All other race groups	63 (1.9%)	8 (3.0%)	71(2.0%)
Total	3263 (92.5%)	266 (7.5%)	3529 (100%)

Note. Data Source: NHIS, 2017.

Table 23 describes family income. More IIV recipients were in the highest income group (38.4% vs. 37.6% for LAIV) while more recipients in the LAIV group were in the lowest income group (24.6% vs. 27.1% for IIV).

# Table 23

	Vaccin		
Family Income	IIV LAIV		Total
\$0 - \$34,999	802 (24.6%)	72 (27.1%)	874 (24.8%)
\$35,000 - \$74,999	831 (25.5%)	69 (25.9%)	900 (25.5%)
\$75,000 - \$99,999	376 (11.5%)	25 (9.4%)	401(11.4%)
\$100,000 and over	1254 (38.4%)	100 (37.6%)	1354 (38.4%)
Total	3263 (92.5%)	266 (7.5%)	3529 (100%)
Note Data Source: NL	115 2017		

2016-2017 Family Income and Vaccine Type Frequencies

Note. Data Source: NHIS, 2017.

Logistic regression was used to describe the data and explain any relationship between vaccine type and the independent variables (covariates). Logistic regression using vaccine type (probability modeled as LAIV) was applied to assess the relationship amongst age group, insurance type, race, family income.

Before interpreting the model, the model containing covariates needs to be checked that at least 1 covariate is different from 0 by testing that the global null hypothesis=0. A p-value<0.0001 was obtained allowing for rejection of this null hypothesis. This suggests that at least 1 covariate in the model is different from 0. In addition, a goodness-of-fit statistic, the Hosmer-Lemeshow test, is applied to the resulting model to check that the model is correctly specified, the data do not conflict with the assumptions made by the model. The obtained p-value=0.818 suggests that we cannot reject the hypothesis that the fitted model is correct.

The reduced model was determined a better fit when health insurance status was determined not significant through initial analysis. Table 25 shows the results of the logistic regression analysis used to address Research Question 3. The logistic regression

model was statistically significant,  $\chi^2(15) = 34.831$ , p = .003. The Wald test of significance indicated that age (p = .000) and race (p = .027) were statistically significant in relation to LAIV uptake.

Table 24

Logistic	Regression	Reduced	Model Flu	Season	2016-2017
----------	------------	---------	-----------	--------	-----------

							95% <b>(</b>	CI for
							Exp	(B)
	В	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Age			48.972	5	.000			
3-5	.041	.180	.053	1	.819	1.042	.733	1.482
6-8	.670	.163	16.798	1	.000	1.954	1.418	2.691
9-11	.734	.166	19.685	1	.000	2.084	1.507	2.883
12-14	.220	.176	1.550	1	.213	1.246	.881	1.760
15-17	069	.189	.134	1	.714	.933	.645	1.351
Race			10.942	4	.027			
White	039	.119	.105	1	.745	.962	.762	1.214
Black	.299	.160	3.499	1	.061	1.349	.986	1.846
Asian	280	.213	1.722	1	.189	.756	.497	1.148
Other race groups	.470	.300	2.456	1	.117	1.599	.889	2.878
Constant	-1.774	.077	529.903	1	.000	1.70		

Note. Data Source: NHIS, 2017.

Two of the four covariates are significant (p<0.05). Insurance coverage (p = 0.778) and Family Income (p = 0.761) were not statistically significant. Based on this a reduced model eliminating insurance coverage from the model was run. The Hosmer-Lemeshow statistic from the reduced model was p = 0.170 suggesting a better fit to the data. As a result, inferences are based on this reduced model. Table 25 shows the odds ratios and CIs for the 2016-2017 flu season.

# Table 25

Odds Ratio Estimates and Wald Confidence Intervals					
Independent Variables	Odds Ratio	95% Confi	dence Limits		
White vs. Hispanic	1.777	1.516	2.082		
Black vs. Hispanic	1.216	0.966	1.531		
Asian vs. Hispanic	1.155	0.878	1.520		
all other races vs. Hispanic	1.227	0.727	2.072		
White vs. Black	1.461	1.185	1.800		
White vs. Asian	1.538	1.190	1.989		
White vs. all other races	1.448	0.865	2.423		
Black vs. Asian	1.053	0.775	1.431		
Black vs. all other races	0.991	0.577	1.703		
Asian vs. all other races	0.941	0.537	1.650		
3-5 vs. 0-2	3.386	2.616	4.384		
6-8 vs. 0-2	4.667	3.609	6.035		
9-11 vs. 0-2	3.920	3.017	5.094		
12-14 vs. 0-2	2.676	2.045	3.502		
15-17 vs. 0-2	1.570	1.175	2.097		
3-5 vs. 6-8	0.726	0.595	0.885		
3-5 vs. 9-11	0.864	0.704	1.060		
3-5 vs. 12-14	1.265	1.022	1.567		
3-5 vs. 15-17	2.157	1.698	2.740		
6-8 vs 9-11	1.191	0.971	1.459		
6-8 vs 12-14	1.744	1.410	2.157		
6-8 vs 15-17	2.973	2.343	3.772		
9-11 vs 12-14	1.465	1.178	1.822		
9-11 vs 15-17	2.497	1.958	3.185		
12-14 vs 15-17	1.705	1.326	2.191		

2016-2017 Demographic Characteristics and Vaccine Type Odds Ratios

Note. Data Source: NHIS, 2017.

The highest odds ratios were for children among the 6-8 age group were 4.667 times more likely to receive the LAIV vaccine than children ages 0-2 and 3.920 times more likely to receive LAIV than children ages 9-11. Children ages 3-5 were less likely overall to receive LAIV than children 6-8 years of age. Children ages 0-2 were also more likely to receive the LAIV vaccine than their peers. White children were 1.777 times more likely to receive the LAIV vaccine than Hispanic children. In fact, White children were more likely to receive the LAIV vaccine than Black (1.461) and Asian (1.538) children. For Research Question 3, we reject the null hypothesis in favor of the alternative hypothesis for race and age; we fail to reject the null for health insurance coverage and family income. There is a relationship between age, race, and vaccine type (LAIV/ IIV) among U.S. children for flu season 2015-2016. Those who received LAIV during the 2016-2017 flu season were also most likely to be White elementary school age children.

### **Data Analysis Research Question 4**

Research Question 4: What was the relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017?

H₀4: There is no relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015 (LAIV preferred), 2015-2016 (LAIV & IIV) and 2016-2017 (IIV preferred).

 $H_a$ 4: There is a relationship between influenza vaccine type (LAIV/IIV) of U.S. children and ACIP recommendations indicated by flu seasons 2014-2015, 2015-2016, and 2016-2017.

Analysis of three consecutive flu seasons. Due to lack of efficacy, ACIP did not recommend LAIV for the 2016-2017 flu season. A chi-square test of homogeneity was used to evaluate the relationship between ACIP recommendations by flu season and vaccine uptake (LAIV or IIV) to evaluate the impact of this change in recommendation. Table 26 shows the results by vaccine type. These results showed that IIV was the preferred vaccine for each year regardless of the ACIP recommendation. There was a statistically significant difference between all three independent binomial proportions  $\chi^2(2) = 423.238$ , p = 0.000 indicating that the proportion of patients receiving LAIV and IIV are significantly different. Approximately 75 % of patients received IIV, in 2014-2015, and 2015-2016 and this increased to 92.5 % of patients receiving the vaccine in 2016-2017. This reduction of LAIV use in the 2016-2017 flu season is consistent with ACIP recommendations.

Table 26

Vaccine		Year		
Туре	2014-2015	2015-2016	2016-2017	Total
IIV	$3832_{a}(75.2)$	3766 _b (79.2)	3263 _c (92.5)	10861 (81.4)
LAIV	1265 _a (24.8)	955 _b (20.2)	266 _c (7.5)	2486 (18.6)
Total	5097	4721	3529	13347

Flu Seasons and Vaccine Type Cross-Tabulation Post Hoc Test

Note. Data Source: NHIS, 2015, 2016, 2017.

The next step was to evaluate if, in addition to ACIP recommendations changing, did any of the socioeconomic-demographic status variables also impacted or were they impacted by the change in recommendation. This was achieved by looking at the incidence of LAIV vaccination across the three flu seasons. Table 27 shows the age distribution of for all three Flu seasons for LAIV recipients only. Overall the number of children receiving LAIV in 2016-2017 was smaller than in earlier seasons indicating an impact of the ACIP recommendations. LAIV coverage was consistent across all age groups except the youngest (0-2) for all three years. Children ages 0-2 had a slight increase in LAIV uptake (12.4 %) for the 2016-2017 flu season even though LAIV is not recommended for their age group or the flu season. However, this must be interpreted based on the smaller number of children receiving LAIV in the 2016-2017 season.

Table 27

		Year		
Age	2014-2015	2015-2016	2016-2017	Total
0-2	93 (7.4%)	82 (8.6%)	33 (12.4%)	208 (8.4%)
3-5	274 (21.7%)	198 (20.7%)	37 (13.9%)	509 (20.5%)
6-8	313 (24.7%)	223(23.4%)	64 (24.1%)	600 (24.1%)
9-11	261 (20.6%)	200 (20.9%)	61(22.9%)	522 (21.0%)
12-14	200 (15.8%)	151(15.8%)	41(15.4%)	392(15.8%)
15-17	124 (9.8%)	101(10.6%)	30 (11.3%)	255(10.3%)
Total	1265	955	266	2486

Age Distribution of LAIV Recipients for All Flu Seasons

Note. Data Source: NHIS, 2015, 2016, 2017.

To further evaluate how socioeconomic status and demographic characteristics may influence the differences in LAIV vaccine uptake by year a chi-square test of homogeneity was conducted between flu season (2014-2015, 2015-2016, and 2016-2017) by socioeconomic-demographic status (race, family income, and health insurance status) for LAIV recipients to determine if variations in socioeconomic-demographic status could account for the differences in LAIV uptake between Flu seasons 2014-2015, 2015-2016 and 2016-2017. Table 28 shows the health insurance distribution of for all three Flu seasons for LAIV recipients only. Health insurance coverage among LAIV recipients remained consistent across all three flu seasons. No relationship between year and health coverage was observed (p = 0.087).

Table 28

Health Coverage of LAIV Recipients for All Flu Seasons

Health Coverage	2014-2015	2015-2016	2016-2017	Total
Private	782 (61.8%)	580 (60.7%)	152 (57.1%)	1514 (60.9%)
Medicaid/ Public	429 (33.9%)	312 (32.7%)	94 (35.3%)	835 (33.6%)
Other Coverage	30 (2.4%)	34 (3.6%)	14 (5.3%)	78 (3.1%)
Uninsured	24 (1.9%)	29 (3.0%)	6 (2.3%)	59 (2.4%)
Total	1265	955	266	2486

*Note*. Data Source: NHIS, 2015, 2016, 2017.

Table 29 shows the race distribution of for all three Flu seasons for LAIV recipients only. Race was consistent across all three flu seasons. No relationship between year and race was observed (p = 0.303).

Table 29

Race Distribution of LAIV Recipients for All Flu Seasons

		Year		
Race	2014-2015	2015-2016	2016-2017	Total
Hispanic	286 (22.6%)	190 (19.9%)	59 (22.2%)	535 (21.5%)
White	727 (57.5%)	577 (60.4%)	143 (53.8%)	1447 (58.3%)

Black	144 (11.4%)	110 (11.5%)	40 (15.0%)	294 (11.8%)
Asian	88 (7.0%)	63 (6.6%)	16 (6.0%)	167 (6.7%)
All other race	20 (1.6%)	15 (1.6%)	8 (3.0%)	43 (1.7%)
groups				
Total	1265	955	266	2486

Note. Data Source: NHIS, 2015, 2016, 2017.

Table 30 shows the family income distribution of for all three Flu seasons for LAIV recipients only. Family income was also consistent across all three flu seasons, with a minimal decline in the percent of LAIV recipients in the \$75,000 to \$99,999 family income group from the 2014-2015 flu season (12.9%) to the 2016-2017 flu season (9.4%). No relationship between year and Family income was observed (p = 0.572). Table 30

Family Income of LAIV Recipients for All Flu Seasons

Family Income	2014-2015	2015-2016	2016-2017	Total		
\$0 - \$34,999	331 (26.2%)	232 (24.3%)	72 (27.1%)	635 (25.5%)		
\$35,000 -\$74,999	309 (24.4%)	256 (26.8%)	69 (25.9%)	634 (25.5%)		
\$75,000 -\$99,999	163 (12.9%)	124 (13.0%)	25 (9.4%)	312 (12.6%)		
\$100,000 and over	462 (36.5%)	343 (35.9%)	100 37.6%)	905 (36.4%)		
Total	1265	955	266	2486		
Nota Data Source: NHIS 2015 2016 2017						

*Note*. Data Source: NHIS, 2015, 2016, 2017.

All three flu seasons resulted in significantly different flu vaccine uptake by type consistent with ACIP recommendations. Socioeconomic status and demographic characteristics were not considered influential in LAIV uptake for race, health insurance status, or family income when comparing all three flu seasons. ACIP recommendations by age and year appeared to have the greatest impact on flu vaccine choice for this sample population.

#### **Summary**

The purpose of this study is to examine the relationship between seasonal influenza vaccination ACIP recommendations, socioeconomic status, demographic characteristics, and vaccine uptake among children over three consecutive flu seasons. The dependent variable is influenza vaccine type (LAIV and IIV) among U.S. children. The independent variables are ACIP influenza vaccine recommendation by flu season including flu seasons 2014-2015, 2015-2016, and 2016-2017 and socioeconomic-demographic status indicated by age, race, family income, and health insurance status.

For research questions 1-3 forward, binomial logistic regression was performed to ascertain the effects of age, race, health insurance status, and family income on vaccine uptake by type LAIV or IIV. For research question 4 a chi-square test of homogeneity was used to evaluate the relationship between ACIP recommendations by flu season and vaccine uptake (LAIV or IIV) for all three flu seasons. These results showed that IIV was the preferred vaccine for each year regardless of the ACIP recommendation. To further evaluate how socioeconomic status and demographic characteristics may influence the differences in LAIV vaccine uptake by year a chi-square test of homogeneity was conducted between flu season (2014-2015, 2015-2016, and 2016-2017) by socioeconomic-demographic status (race, family income, and health insurance status) for LAIV recipients.

For the 2014-2015 flu season, a relationship between age, race, family income, and vaccine type (LAIV/ IIV) was established among U.S. children included in this study. Those who received LAIV were most likely to be White elementary school age

children with a family income of 75,000+ for the 2014-2015 flu season. The 2015-2016 and 2016-2017 flu seasons showed a relationship between demographic characteristics (age and race) and vaccine type (LAIV/ IIV) was established among U.S. children included in this study. Those who received LAIV during the 2015-2016 and 2016-2017 flu season were also most likely to be White elementary school age children. All three flu seasons resulted is significantly different flu vaccine uptake by type consistent with ACIP recommendations. Socioeconomic status and demographic characteristics were not considered influential in LAIV uptake for race, health insurance status, or family income. ACIP recommendations by age and year appeared to have the greatest impact on flu vaccine choice for this sample population.

Section 4 will present a summary of key findings, analyzes, interpretation, limitations to generalizability, validity, reliability, recommendations for further research, and implications for positive social change. Section 4: Application to Professional Practice and Implications for Social Change

### Introduction

I examined the relationship between seasonal influenza vaccination ACIP recommendations, socioeconomic status, demographic characteristics, and vaccine uptake among children over three consecutive flu seasons. LAIV was the recommended choice for children 2-8 during the 2014-2015 flu season, both LAIV and IIV were equally recommended for the 2015-2016 flu season, and the LAIV recommendation was discontinued for the 2016-2017 season due to studies showing limited efficacy against A/H1N1 (Flannery & Chung, 2016). In addition, multiple socioeconomic factors and demographic characteristics have the potential to influence vaccine choice. The dependent variable was influenza vaccine type (LAIV and IIV) among U.S. children. The independent variables were ACIP influenza vaccine recommendation by flu season (2014-2015, 2015-2016, and 2016-2017), and socioeconomic-demographic status indicated by age, race, family income, and health insurance status. Secondary surveillance data were taken from the CDC to evaluate vaccine uptake by type among children over three recent flu seasons with different children sampled each year.

For the 2014-2015 flu season, a relationship between age, race, family income, and vaccine type (LAIV/ IIV) was established among U.S. children included in this study. Those who received LAIV were most likely to be White elementary school age children with a family income of 75,000+ for all the flu seasons included in this study. The 2015-2016 and 2016-2017 flu seasons showed a relationship between demographic characteristics (age and race) and vaccine type (LAIV/ IIV). However, socioeconomic-

demographic status was not considered influential in LAIV uptake for race, health insurance status, or family income. Based on the results, ACIP recommendations by age and year had the greatest impact on flu vaccine choice for this sample population.

# **Interpretation of the Findings**

The findings of this study extend the current knowledge about flu vaccine uptake in the community by addressing issues associated with flu vaccine choice. Most flu vaccine research has evaluated the efficacy of the vaccine based on a test-negative design (a variation of the case-control design). Few studies have evaluated influenza vaccine uptake by type, socioeconomic status, demographic characteristics, and ACIP recommendations. Thus, this study adds to current knowledge regarding influenza vaccine uptake among children by identifying socioeconomic factors and demographic characteristics that influence LAIV uptake in the community in addition to the impact of ACIP recommendations on vaccine choice.

Perceptions of safety and efficacy are determining factors regarding seasonal flu vaccination uptake (Galarce et al., 2011). For roughly 50% of flu vaccinated children, parents reported no preference for either IIV or LAIV for both the 2014-2015 and 2015-2016 flu seasons (Santibanez, Kahn, & Bridges, 2018) The percentage who preferred LAIV for 2014-2015 was 22.7%, and for 2015-2016 it was 21.7%, with 70% of those preferring this method citing children's fear of needles (Santibanez et al., 2018). Further, the percentage of parents with a preference for IIV for 2014-2015 was 22.1%, and for 2015-2016 it was 21.7% (Santibanez et al., 2018).

The current study showed that most children who received the LAIV were within the age range recommended by the ACIP of 2-8 across all three flu seasons. In addition, children 6-8 years of age consistently received the LAIV vaccine across all three seasons with an average of 24.1% coverage, though the ACIP recommended no one receive the LAIV vaccine for the 2016-2017 flu season. The American Academy of Pediatrics recommended preference for the IIV vaccine for the 2018-2019 flu season but encourages parents to vaccinate their children for the flu regardless of vaccine type, because receiving the nasal vaccine is better than no vaccine (Munoz, 2018).

Additional findings from this study are that race was indicated as a determining factor for choice between IIV and LAIV for each individual flu season. White children, who were vaccinated for the flu, were more likely to receive LAIV than other races included in this study. This is consistent with a recent study that showed White adult Americans are more likely to receive the flu vaccine than other racial groups, especially those with higher income (Abbas, Kang, Chen, Werre, & Marathe, 2018). This has implications for improving vaccine uptake among adults by,

increasing awareness of the safety, efficacy and need for influenza vaccination, leveraging the practices and principles of commercial and social marketing to improve vaccine trust, confidence and acceptance, and lowering out-of-pocket expenses and covering influenza vaccination costs through health insurance. (Abbas et al., 2018, p.2).

These suggestions are consistent with the results of this study as well.

#### Limitations of the Study

Cross-sectional quantitative research is used to investigate the relationship between variables in their natural environment rather than a laboratory setting (Polit & Hungler, 1999). This type of investigation often involves data from descriptive studies to formulate hypotheses, determine a relationship between variables, and test theories. Cross-sectional studies are used to evaluate the nature of relationships that exist and not infer causality like traditional experimental studies (Creswell, 2012).

The data from the NHIS survey are cross-sectional, based on an annual sample representing a changing cohort of subjects. In this case, the NHIS does not collect information from all subgroup populations, omitting institutionalized individuals including military families. One limitation is that this data are secondary, so the health information collected does not include verifiable medical data or laboratory data (see Rolnick et al., 2013). Some survey respondents may not be forthcoming about a behavior many consider to be undesirable. Therefore, another limitation to this study is the use of self-reported data, which involves setbacks such as reembrace error, reporting bias, incorrect documentation, and loss of cases.

The greatest limit in this study involved measuring a relationship among variables, which is the assumption of generalizability. Although statistical analysis of data sets may reveal that two variables vary together, it does not mean they do. If the data are not representative of the real population, study results could indicate a relationship among variables that does not exist in the actual population. There are several unknown factors called confounders that can be unaccounted for resulting in a false perception of a relationship among variables (Oleckno, 2002). In this study, potential confounders were evaluated to try and control for these factors. However, other unknown factors could have contributed to confounding not addressed in this study.

## Recommendations

Further research is needed to evaluate the relationship among socioeconomic status, demographic characteristics, ACIP recommendations, and Flu vaccine uptake in the Community. While it is important to provide efficacy information to all parties involved in providing flu vaccines to the community, it is also important to determine what factors contribute to uptake especially among children who are most likely to be infected with flu and transmit it to someone else. According to the CDC's FluView Influenza-Associated, pediatric mortality is highest between five and eleven years of age, especially when combined with a secondary bacterial infection (CDC, 2016). School-age children have the highest influenza transmission and infection rate, ranging from a 10-40 % attack rate yearly (Wilson et al., 2013). Over half of all flu vaccines in the U.S. are administered to individuals ages 6 months to 17 years old (Peng-jun Lu et al., 2013). According to the Morbidity and Mortality Weekly Report, the United States vaccination coverage is consistently below the Healthy People 2020 goal of 70 % (Peng-jun Lu et al., 2013).

In addition to the reported inconsistencies in flu vaccine efficacy, annual influenza immunization recommendations have varied in children 2-8 years of age. Inconsistencies in vaccine recommendations can negatively impact vaccine uptake in the community by diminishing the patients perceived benefits of following vaccine recommendations (Mueller, Hill, Fontanesi, & Kopald, 2007). Studies show parents who delayed and refused vaccine doses were more likely to have vaccine safety concerns and perceive fewer benefits associated with these vaccines (Blyth et al., 2014; Cheney & John, 2013; Smith et al., 2011).

#### **Implications for Professional Practice and Social Change**

The discontinued recommendation of LAIV for children in the U.S. has the potential to affect influenza vaccine uptake and community outcomes due to the theory of herd immunity and the transmission rate of illness from child to caregiver. LAIV was developed to address issues associated with production and dissemination of IIV for potential influenza pandemics (Penttinen & Friede, 2016). Production of IIV is timely and administering the vaccine requires basic safety and infection control measures due to its injectable nature. The LAIV option was initially determined to be ideal for mass vaccination of children especially in a pandemic situation due to its superior efficacy, ease of administration, greater production yield, rapid availability for unanticipated serotypes, and user-friendly application (Penttinen & Friede, 2016). Discontinuation of LAIV recommendations has the potential to greatly impact the community by reducing the number of children effectively vaccinated against the flu resulting in an increase of influenza exposure in the community.

Policies can directly influence the other levels by altering and influencing the access and desire of flu vaccinations by making them unavailable, altering access, reducing their perceived effectiveness, limiting affordability, or indicating belief of risk associated with their use. The discontinued ACIP recommendation of the LAIV has the

potential to negatively influence influenza vaccine uptake in general if the underlying cause of LAIV's reduced efficacy is not defined and addressed due to conflicting policy, and inconsistent recommendations by governing bodies, local health departments, and family practitioners. Improving vaccine recommendations and policy may lead to increased vaccine uptake and result in fewer sick days, reduced suffering, increased productivity, lower health cost and reduced illness and death associated with the flu virus especially for those most at risk.

The potential contribution of this study is to add to current knowledge regarding influenza recommendations and influenza vaccine uptake among children. This study found that age and ACIP recommendations influence flu vaccine uptake in the community. Additionally, it was concluded that family income and race might also play a significant part in flu vaccine choice by type. Most flu vaccine research evaluates the efficacy of the vaccine based on a test-negative design. Few studies evaluate influenza vaccine uptake and ACIP recommendations. This study aimed to assess how ACIP recommendations influence influenza vaccination rates among children in the United States over the three most recent flu seasons.

Vaccination uptake is significantly influenced by social and psychological factors, some of which are under-reported and poorly understood (Wheelock, Miraldo, Parand, Vincent, & Sevdalis, 2014). Although structural barriers are known to limit vaccination rates, social and psychological factors can also affect the decision to vaccinate children. Perceptions about flu susceptibility and vaccine effectiveness significantly influence vaccination adoption (Wheelock et al., 2014). Evaluating current procedures and policies could improve patient perceptions and access.

High vaccination coverage reduces exposure of unvaccinated persons to infection, resulting in indirect protection in addition to direct protection for the those vaccinated (Glezen, Gaglani, Kozinetz, & Piedra, 2010). The direct effect of immunity reduces infection rates among vaccinated individuals resulting in less infection circulating in the community, less influenza exposure, resulting in herd immunity by indirect means (Fine et al., 2011). Increasing the number of school-age children immunized against the flu also increases herd immunity by the indirect protection of household and community members (Lind et al., 2014).

### Conclusion

Seasonal influenza outbreaks are associated with considerable morbidity and mortality in the United States (Hull & Ambrose, 2011; Weycker et al., 2005; Wilson et al., 2013). Annual fall influenza vaccinations are the most effective method for preventing influenza and its complications (Weycker et al., 2005). According to the CDC's FluView Influenza-Associated, Pediatric Mortality is highest between five and eleven years of age, especially when combined with a secondary bacterial infection (CDC, 2016). Yet annual influenza attack rates among school-age children, who play a fundamental role in transmitting the infection to others, are as high as 42 % (Carpenter et al., 2007).

The vaccination of children has been shown to reduce the impact of influenza on the communities where they reside, which is of particular importance for at-risk populations such as those 65 years of age and older (Wilson, Sanchez, Blackwell, Weinstein, & El Amin, 2013). Seasonal influenza is estimated to impact 10-20 % of the United States population annually (Hull & Ambrose, 2011). The flu is rapidly transmitted in large populations with close contact, especially in the fall and winter months during the traditional academic school year. School-age children have the highest influenza transmission and infection rate, ranging from a 10 to 40 % attack rate yearly (Wilson et al., 2013). The World Health Organization recommends a seasonal flu vaccination consisting of a 75 % coverage rate for high-risk populations (Longini & Halloran, 2005).

In addition to the reported inconsistencies in Flu vaccine efficacy, annual influenza immunizations recommendations have varied dramatically in children 2-8 years of age. Inconsistencies in vaccine recommendations can negatively impact vaccine uptake in the community by diminishing the patients perceived benefits of following vaccine recommendations (Mueller et al., 2007). Studies show parents who delayed and refused vaccine doses were more likely to have vaccine safety concerns and perceive fewer benefits associated with these vaccines (Blyth et al., 2014; Cheney & John, 2013; Smith et al., 2011).

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