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Gaps in Immunization Prevention in the State of Ohio

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Walden University
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Abstract

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MHA, Walden University, 2016

BS, Kent State University, 2014

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

In the United States, the total cost for vaccine preventable diseases was $8.95 billion in 2015. The unvaccinated accounted for 80% of the total costs. This quantitative study was conducted to investigate the success and/or gaps in the implementation of the measles, mumps, and rubella (MMR) vaccine through the Vaccine for Children (VFC) Program by the Ohio Department of Health. General systems theory was chosen as a theoretical framework due to the complicated nature of the healthcare system. Healthcare is a complex system composed of multidisciplinary units that have their own structure and purpose that interact to accomplish the mission and goals of the entire system. The data were obtained from the CDC and originated from telephone surveys conducted by the National Center for Immunization and Respiratory Diseases (NCIRD). A multiple logistic regression analysis was performed to determine the relationship between the VFC Program, the Women, Infants, and Children Program, and the vaccine rates of children 0-35-months old. The analysis revealed that a significant relationship between these variables could not be determined based on the findings. Often the programs designed to improve vaccine rates are not tailored to the needs of every environment or community. It is recommended that immunization program strategies be designed and focused to fit the needs of the community. Organizational partnerships that strive to address the mortality and morbidity issues in infants and children, as well as the disparities their families might suffer, have proven to be more successful in efforts to improve vaccine rates. Strict collection and reporting guidelines for all agencies participating in immunization programs should be a priority which will result in positive social change.

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Dedication

My Grandmother, Tennessee, is responsible for my motivation and commitment to completing my education. She, unfortunately, had no formal education and did not learn to read or write, but she was wise and talented. She was my inspiration and champion, as well as my biggest fan and supporter since the time of my childhood. Special recognition goes to my Mother, who instilled in me a strong work ethic and determination to pursue my dreams. Props go to my Father, who taught me about self-respect and shared many life lessons through short parables. Finally, I dedicate this study to all the little ones 0 to 35-months-old and those not here yet, that they may have a safe and healthy start to life. For they are the future.

Acknowledgments

Thank you to the many family members and friends that often gave encouraging words, and also those that questioned my purpose or made disparaging comments. Yes, nay-sayers encouraged me, too. A special “Thank you” to my chair, Dr. Steve Meigs who was able to “see me” without literally seeing me, and who allowed me to express my opinions and thoughts without condemnation or judgement. He is a great educator who helped me to learn how to think and approach the big issues. Thank you to my Committee members, Dr. Michael Furukawa, Dr. Mary Garbowski, and Dr. Robert Hijazi for without their guidance and support, I could not have completed this journey.

Table of Contents

List of Tables

List of Figures

Section 1: Foundation of the Study and Literature Review

Trust and commitment from the community are critical to the survival of a healthcare organization. Without it, the objectives of the organization cannot be accomplished. Vaccines have unavoidable risk that are exceeded by the benefits they provide in protecting communities from life-threatening diseases. Community and government-based programs are intended to provide interventions that focus on patient education, access, financial incentives, encourage compliance to suggested guidelines and schedules, as well as vaccine alternatives for those who choose not to be immunized. It is the assumption that federally funded programs and access to healthcare would greatly improve immunization rates for all age groups, but there has been limited evidence-based strategies, programs, and research to validate this assumption.

This research study investigated the measles immunization rates for children 0-35 months in the state of Ohio over a seven-year period. The study evaluated how a range of factors affect access in different regions of the state. One of the most difficult challenges for health departments and legislators in the fight against contagious life-threatening vaccine preventable diseases has been tackling the misinformation that is usually found on the internet, and it is this perception of risk that exacerbates the fears of the antivaccine population. This challenge often leads to parents seeking exemption, and/or opting out of immunizations for their children (Ventola, 2016). An even more pressing issue involves poor access to much needed healthcare due to the disparity seen within some communities. Reducing disparity and inequities within communities by ensuring access and quality healthcare at lower costs is also the intended agenda of the Patient

Protection and Affordable Care Act (PPACA). Each healthcare entity must approach the process of providing quality care at an affordable cost on their own terms, based on the needs of their community. Organizational strategies should be customized to adjust to situations affecting public health, such as the economy, surrounding environment, and current policies. There have been many unexpected changes in healthcare and government, which causes confusion and uncertainty. For example, spending in each state fluctuates consistently due to cost of premiums, Medicaid spending, tax credits, and uncompensated care. These fluctuations add to the challenges of providing adequate access to all populations. This quantitative study may help to eliminate some the confusion surrounding the complexity of healthcare programs designed to provide education, reduce medical costs, and improve access, thereby improving immunization rates. The following section is an in-depth view into the problems associated with immunization, the purpose and research questions for the study, history of vaccines and immunization, and the methodology for a reliable analysis of the research study.

Problem Statement

The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) confront issues related to childhood morbidity and mortality due to communicable diseases. Yearly recommendations and guidelines are prepared by both organizations to encourage healthcare providers in their efforts to reduce the incidence of communicable diseases in children and adults (Ventola, 2016). There have been a series of outbreaks of vaccine preventable diseases within the past 5 years, such as the measles and whooping cough, affecting younger children across

the United States. The risks and incidence of death increased during this time for unvaccinated children who contracted these diseases (Daley & Glanz, 2011). According to the World Health Organization (WHO), the high-risk population for vaccine preventable diseases are children under the age of 5 (WHO, 2017). Often, children that are not vaccinated at that age are found in regions of high disparity. The families in regions of high disparity suffer from poor education and low socioeconomic status. It has been the assumption that if families are better educated about the purpose of vaccines and have better access to health resources, then all children would be immunized against life-threatening diseases. In an effort to eradicate disease, federal and state governments set mandates and guidelines, as well as funding, to ensure children have access to the necessary immunizations (US Centers for Medicare & Medicaid Services [CMS], 2018). According to research funded by Merck, a leading manufacturer of vaccines, unvaccinated individuals cost the United States an annual economic burden of over $7 billion. The unvaccinated population accounts for 80% of the total costs of $8.95 billion for vaccine preventable diseases (Keeffe, 2016).

The State of Ohio upholds the federal mandates by improving its immunization programs which are expected to improve access by increasing the number of individuals immunized. The Ohio Department of Health (ODH) administrators also hope the success of these programs would significantly reduce costs that might result from an outbreak of measles, pertussis, and mumps (ODH, 2018). Inadequate immunization, within communities of high disparity in Ohio, is evidence that there are gaps in access and demand attention (Durrheim, 2016). In 1985, CDC data revealed high disparities in

MMR vaccine rates among preschool White children, 64%, and children of other races, 49% (Healio, 2013). Rates vary based on disease type and mode of transmission. Measles is very contagious, and it becomes difficult to protect vulnerable populations if immunization rates are not at safe levels (Oxford Vaccine Group, 2018). In 2001, efforts were developed to improve rates and close the gaps by increasing vaccine rates in preschool White children to 92%, and to 89% for preschool Black children (Healio, 2013). It has been the belief that the implementation of federal health programs designed to improve access to care by providing free vaccines or health insurance to eligible children would improve not only immunization rates, but overall health in children (CMS, 2018).

Presently, there are no research studies in Ohio that investigate the relationship between health insurance status after the implementation of the PPACA and the measles, mumps, and rubella immunization rates in children ages 0-35 months, over time. Access to healthcare is crucial for those communities suffering disparity. Insurance is an important determinant of access to healthcare and provides a sense of protection against poor health and chronic conditions. Federal, state, and local governments have taken initiative to implement policies and create programs to assist the underserved populations who are at risk. Two such programs that were developed to focus on the underserved young children are the Vaccines for Children (VFC) Program, and Women, Infants, and Children (WIC) Program. These programs are available to those families at the poverty level who have very minimal or no insurance, or those who have no income and receive government insurance, such as Medicare, Medicaid, or CHIPS. This research study will

investigate whether the VFC and WIC programs implemented through the Ohio Department of Health have influenced immunization rates in the state of Ohio over a seven-year period.

The CDC recommends the use of program evaluations to detect and resolve any problems. The systematic method of collecting, and analyzing data will ensure accountability, efficiency, and reliability in all areas of program performance and operations (CDC, 2012). Available data can provide information to assist policymakers, healthcare leaders, and agencies in strategy development and the management of effective resolutions.

Purpose of Study

Basic reasons for the resurgence of vaccine preventable diseases once eradicated stem from misinformation, poor access to vaccines, religious beliefs, and lack of knowledge about the benefits of vaccines (CDC, 2001). Present organizations and community programs attempt to address these issues by providing information from evidence-based research. The Vaccines for Children (VFC) program is a government funded program implemented through the ODH, which distributes free vaccines to registered VFC providers in clinics and private physician offices (CDC, 2016a). Despite the many programs and agencies available to tackle the problems of influencing behavior and opinions, and making vaccines accessible to everyone, many children still escape the protection of childhood immunizations (ODH, 2018). Ohio schools are required to report vaccination data on all students entering kindergarten, the seventh grade, the twelfth grade, and any new students upon entrance to a school. This allows for the tracking of

any child born in Ohio, or who has recently become a resident of the state. It was reported in *My Daily Dayton News* that state and private health officials were advocating for more transparency pertaining to school-level immunization data they received from the ODH (Wedell, 2018). The information received by the American Academy of Pediatrics was very different from data shared by the local newspaper. Based on this revelation, it would appear that each school in Ohio collects vaccination information differently. This may result in the data being improperly organized resulting in skepticism regarding reliability (Wedell, 2018). Having the proper strategy in place that sets a standard for collection and reporting is critical for obtaining accurate real-time vaccine rates, as well as, for surveying those children not vaccinated (Woods, 2003).

Poor outcomes, such as low immunization rates and sudden outbreaks, can be indicators that a program or intervention may not be implemented or performing as expected. Problems may arise during the implementation of vaccine programs when the purpose of the program is not communicated effectively, access to facilities are restricted or unavailable to residents, or the program does not address the financial needs of the community. Other issues might stem from the program's framework, data-collection methods, cost effectiveness, and resource issues (Cooper et al., 2002).

The study expanded upon the foundation of previous research with an evaluation framework that was designed to evaluate structure, process, and outcomes. The ODH Immunization program's objective is to improve access, immunization rates, and education (ODH, 2018). The ODH's objective aligns with that of the Federal government, which is to increase available coverage and provide low-cost treatments

through the PPACA and VFC Program. This quantitative research is aimed at determining the effectiveness of the ODH and its implementation of key government funded programs. The ODH Bureau of Infectious Disease (BID) and the Bureau of Maternal, Child & Family Health (BMCFH) are just two of several bureaus, offices, and departments developed to address community health conditions and inequities (ODH, 2020). The BID and BMFCH collaborate closely with providers, hospitals clinics, and local health departments to prevent and control the spread of infectious diseases, reduce infant mortality, and disparities across the state. These entities also support preventative programs through guidance, review, and evaluation of the program goals to improve family health (ODH, 2020). The fundamental components for improving efficiency are access and cost effectiveness of preventative programs. The reduction in the burden of disease, cost of disease, cost for outbreak control, and cost of vaccination is dependent upon the ability of local program administrators to identify the significant effects of interventions and preventative measures (CDC, 2018). The program created to support and improve the health of impoverished families is the WIC program. This study will investigate the affect the WIC program has had on vaccination rates through its efforts to address disparities by providing crucial disease screenings; reducing the risk for malnutrition; and improving the overall quality of life in families, specifically infants and children.

Research Questions and Hypotheses

The research questions for this investigation are:

Research Question 1 (RQ1): What is the relationship between the federal assistance program, Women, Infants, and Children (WIC) and the measles vaccine rates for children 0-35 months in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

$H_0$1:There is no relationship between the federal assistance program WIC and the measles vaccine rates of children ages 0-35 months in Ohio from 2010-2016.

H_a1 - The federal assistance program WIC increased measles vaccine rates of children 0-35 months in Ohio from the year 2010-2016.

Research Question 2 (RQ2): What was the relationship between the Vaccines for Children (VFC) program designed to improve access to the MMR vaccine and the measles vaccination rates for children 0-35 months old in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

$H_0$2 -There is no relationship between the VFC program designed to improve access to the MMR vaccine and measles vaccination rates of children 0-35 months in Ohio during the years of 2010-2016.

H_a2 – The VFC program designed to improve access to the MMR vaccine increased measles vaccination rates of children 0-35 months within Ohio during the years of 2010-2016.

Using a multiple logistic regression analysis determined if there is a relationship between the dependent variable and the independent variables. The dependent variable is the yearly measles vaccine outcomes reported. The independent variables are demographic and socioeconomic characteristics of the target population set with quantitative values.

The federal government's WIC and VFC program are the covariates, or interventions, that may or may not influence immunization outcomes.

Theoretical Foundation for the Study

The theory applicable to evaluating the effectiveness of the monitoring, surveillance, and intervention of various organizations and agencies is the general systems theory. The general systems theory is divided into a subsystems inquiry to cover various areas of study, such as the science, philosophy, and technology of the field being studied (Peters, 2014). The conventional method of evaluating systems, or programs designed to improve outcomes, is to focus on initiatives that bring about change. A system's initiative can be broad and vague requiring a multidisciplinary approach to developing strategies for improvement. An immunization program's initiatives are target-specific and are meant to eliminate barriers pertaining to access, demographics, financial resources, education, or service delivery. To successfully eliminate barriers and close the gaps in immunity, methods of surveillance, detection, and access must become more reliable. Effective strategies must be developed against the most infectious communicable diseases, which also require exceptional immunization coverage. Studies have revealed many factors that have been found to influence immunization rates. An examination of these factors and possible trends or correlations will provide some insight into what factors affect immunization rates in various populations and communities. Population and system characteristics are factors that coincide to influence outcomes. For example, one such factor that was investigated in this study is the socioeconomic status (SES) of the family. By examining and measuring the SES of families, any issues or

inequities in resources that influence informed decision making and access to healthcare were identified. The Institute of Medicine (IOM) has a model intended to eliminate barriers which aids in efforts to address access to health services. The conceptual framework has four levels of intervention that deals with inequality in socioeconomic status. Past researchers have built upon this model to address disparities and barriers relevant to healthcare delivered in the United States (Cooper et al., 2002).

To effectively minimize barriers and increase the number of immunization rates in critical areas of the world, it is necessary to investigate the success and failures of the present services and systems (Durrheim, 2016). The challenge for this research is determining the most appropriate research design and tools that are capable of accurately measuring and analyzing pertinent data. Combining relevant aspects and methodology of previous models can be adapted to present day characteristics of health. Targeting specific populations and narrowing the focus on factors significant to change can provide a clear understanding of any impact made on outcomes. If there is flawed governance within an organization and/or disregard to patient needs, there is an indirect effect on outcomes, which in turn affects quality.

The scientific model that will be applied for this investigation is Andersen's behavioral model of health services use. This model will best identify and examine the pertinent characteristics of the study and all predisposing factors that affect the use of services that relate to decisions about vaccines (Babitsch et al., 2012). The relevant data will be assessed and categorized into a table that can be analyzed for relationships and consistencies. The Andersen's behavioral model of health services use is guided by three

specific dynamics: predisposing factors, enabling factors, and need. Predisposing factors are demographic characteristics such as race, age, and gender or contextual characteristics expressed as culture, social norms, and political views. Enabling factors can influence one's use of medical services and are described as finances, resources, availability, and access to health services. The third dynamic is need, which is based on the way an individual perceives their own state of health and include those experiences that motivates them to seek care. Needs can be driven by environmental factors incurred through accidents, injuries, and crime, or health indicators derived from illness, disease, and disease processes, or death (Babitsch et al., 2012). There have been several modified versions of the model utilized in previous works involving various population types. The approach to this quantitative research will incorporate an expanded version of the Andersen's behavioral model that uses a multiple logistic regression analysis.

The general systems theory tries to explain complex systems consisting of interdependent factors that have a relationship that unifies the system. These relationships result in a portrayal of the natural and social functions of the system. Described as a holistic view, general systems theory examines the relationships between the parts and how it affects the whole. The general systems theory investigates phenomena and the changes that may occur over time. Investigation of complex systems can provide understanding of its complexities, the ability to view the system from different perspectives, and develop laws and principles for controlling the system (Banathy, 1996). The general systems theory is pertinent because human behavior is unpredictable, and regardless of circumstance or similarities between them, each human response is

individual. The Andersen behavioral model targets those individual experiences to give insight into that behavior. The Andersen behavioral model is an adaptive developmental framework for evaluating systems effectiveness. The model was utilized in this study to focus on specific services of the ODH system, the VFC and the WIC program, and the driving mechanisms of the target population that affect outcomes. An adaptation of the model allowed for exploration of multiple variables, their relationships, changes over time, and to assess whether the variables affect a particular phenomenon, which in this case was vaccine outcomes. A limitation of the theory is that all variables were assumed to equally impact the results, however, the degree of impact of each variable will likely vary.

Nature of Study

The Andersen behavioral model of health care utilization was chosen for analysis of this study because it is used to assess factors associated with patient use of healthcare services (Bradley et al., 2002). The presumption is that three specific determinants reflect the possible stages of access and utilization of medical care. Here, it is important to define the concept of access as the dimensions that describe the potential or actual entry into the healthcare delivery system (Bradley et al., 2002). The model describes the determinants of health care utilization as predisposing, enabling, and need factors. Predisposing factors are characteristics that exist before the onset of an illness. These are the factors that create the disposition for seeking services. Enabling factors are those factors that pertain to patients that have the necessary means to use health services. There is a difference between the need for care, which describes the level of illness, and the

actual use of health services. The predisposing and enabling factors alone are not enough to motivate patients to use health services; still, these factors are necessary for the use of health services process. The level of illness the patient is experiencing at that moment is key to motivating them to seek care (Andersen et al., 1983).

According to many researchers, the two main concepts of access pertain to population characteristics, and the characteristics of the delivery system. Others believe outcome measures are also an important element (Bradley et al., 2002). The Andersen model has been expanded by adding psychosocial factors, described as knowledge, attitudes, social norms, or perceived control. The modified Anderson model could then be used to analyze different target populations and identify commonalities associated with long term care. The results can be instrumental in providing an enhanced explanation of the relationships if any exist. This analysis is particularly significant when assessing minority groups and the complex role they have in access to care as well as, how effective specific programs and campaigns are in improving healthcare access (Bradley et al., 2002).

There is limited literature that discusses the affect the ODH Immunization programs have had on possible barriers and vaccine outcomes of the 0-35-month-old population over time. An immunization program's effectiveness for improving access to care can be measured through annual immunization rates. The data collected contains population characteristics that could assist in identifying which populations are at high-risk for suffering poor income, low education levels, and lack of insurance. An investigative analysis determined whether any of this information had an effect on

vaccine rates. Local health departments of the state are responsible for implementing programs to protect and promote public health for the community it services. Each local health department must comply with the minimum or optimal achievable standards of rules to be compensated through state subsidy funds. However, all local health departments are not necessarily equal in the state of Ohio when developing and implementing program strategy. The ODH oversees and supports many immunization programs throughout the state. Immunization information is collected, analyzed, and evaluated by measuring the increasing percentage of children entering kindergarten who are fully vaccinated. The ODH also promotes access to healthcare by measuring the number of families participating in the Medicaid administrative claiming program (Legislative Service Commission, 2017). Previous studies have evaluated a vaccine campaign approach to access and immunization coverage through the measurement of vaccine outcomes (Poehling et al., 2009). This study analyzed the effect of only two programs utilized by the ODH, the VFC and WIC programs, which are designed to address the issues of disease prevention and access to healthcare.

The program quality indicators that were evaluated in this study are identified as access to services and available financial assistance per region. The Ohio annual vaccine rates during a 7-year period were compared and analyzed for trends, patterns, differences, and similarities. The objectives for improvement in the ODH preventative services are expected to reduce costs by improving access to care. The target populations for the outcome measures covered the Ohio metropolitan, rural, urban, and suburban regions. The specific outcome measure and dependent variable for the study is the immunization

rate of the measles, mumps, and rubella vaccine (MMR) given to children 0-to-35-months. The significant independent variables for discussion include socioeconomic status, education, and marital status of the parent(s). An evidence-based discussion about whether the ODH immunization program is or is not effective in improving the vaccine rates for children ages 0-35-months may provide some insight into issues that obstruct a family's access to vaccines.

The information pertinent to analyzing immunization outcomes in the state of Ohio is collected annually, and through reporting systems found in hospitals, clinics, and physician offices providing preventative services. The data contains demographic and/or socioeconomic factors that are relevant to the utilization of health services (ODH, 2017). By using a multiple logistic regression analysis, I sought an accurate description of the various population demographics and the relationship between the given factors and the vaccine outcomes of the target population.

Literature Search Strategy

This literature review focuses on the collection of information relevant to the history and research of vaccines and immunizations. The methods used to assess, analyze, and evaluate data in previous research are reviewed for determining an approach in alignment with this study. The previous research is pertinent to improving global immunization through more effective programs, policies, and access to healthcare. Identifying positive aspects and/or flaws in design can lead to the development of more improved methods. This research study may add to the literature by presenting insight into government funded programs designed for disease prevention and/or vaccine

promotion as possible strategies for closing the gap in efforts to eradicate preventable childhood diseases.

The resources for this literature review originated from evidence-based research articles, journals, and books, including professional, organizational, government and agency websites that focus on immunizations in children. The major search engines utilized were Google Scholar, Bing, PubMed, and Science Direct. Key search terms used for this research were *immunization, childhood preventable vaccines, measles, vaccine programs, vaccine promotion, vaccine history,* and *health department*. The scientific studies and data sources associated with immunization in children were used as guidelines by lawmakers, clinicians, and agencies for health protocol, health reform, decision making, and program initiatives. The historical information gathered for this study are facts written by scholars and researchers beginning in 1973 through 2019. Statistical information and scientific model searches date from 1983 to 2014 covering models and studies pertinent to this research. Literature of current agencies and programs designated to focus on immunization programs and implementation spans from 2013 to 2019.

Literature Review Related to Key Variables and/or Concepts

This literature review contains three categories intended to provide the relevant information needed to examine disease prevention and immunization promotion in infants and children. The first category covers the history of vaccines and the development of the immunization process. The second category discusses various scientific methods used to evaluate and assess systems and programs that were created as

preventative tools. The third category explores the challenges of controlling and eradicating vaccine-preventable diseases and possible solutions. The following section provides context for this research from a historical perspective.

Development of Vaccines

The history of vaccines and immunizations began in the year 1796 with the development of the smallpox vaccine by Dr. E. Jenner. Dr. Jenner's methods for developing the smallpox vaccine became the basis for vaccinology. The issues surrounding the funding and manufacturing of vaccines, vaccine policy and safety, and public fears were prevalent during that time and are the same reasons for today's problems (Stern et al., 2005). By the 1900s, 100 in every 1,000 children would die before their first birthday. This was often due to highly infectious diseases, such as measles (Clayton et al., 2011). History reveals that before the existence of vaccines, the primary causes of infant mortality were the measles, smallpox, pertussis, and diphtheria. In 1757, a Scottish physician named Francis Home was able to demonstrate that the measles was caused by an infectious agent in the blood of his patients (CDC, 2018c).

The distinction between vaccination and immunization must be defined since both are often used interchangeably. The definition of vaccination is the act of administering the immunological agent or the vaccine. The vaccine causes a response from the immune system so that it can recognize the disease-causing bacteria or virus. Immunization is the administration of an immunological agent (vaccine) that will result in adequate immunity (Stern et al., 2005). Immunization is what happens in the body after the vaccine has been administered. Antigens in the immune system records the disease-causing information to

protect the body from future infection. If the vaccine is successful, the antigens cause the release of antibodies, protecting the body from infection, providing the individual immunity (U.S National Library of Medicine, 2019a). Immunological discoveries beginning in the 1800s spanned over a century and initiated praise and funding from private and public sectors. Vaccines were initially regarded as scientific miracles that presidents and aristocrats took as an opportunity to hold mass-vaccination campaigns in their countries. These leaders believed their efforts would have their country viewed as a scientifically developed society that supports the health of its citizens (Stern et al., 2005). The scientific knowledge and research became evidence-based in the early 20th century. Vaccine campaigns became an opportunity for community outreach programs and education about vaccine-preventable diseases and the vaccines used to produce immunity.

Adverse events and their effects during a campaign are taken seriously, have different levels of severity-depending on the individual, and can be life-threatening (WHO, 2019a). Adverse effects can be minimized by proper planning and the steps taken to reduce immunization errors. National Immunization Program (NIP) is a major part of surveillance and monitoring of adverse event following immunization (AEFI). The NIP is particularly critical during detection and investigation of AEFI in the field during a mass vaccination campaign (WHO, 2019b). Efforts in the mid-20th century were successful in bringing certain diseases under control, due to the recommendation of routine vaccines, such as the combined diphtheria, tetanus, and pertussis (DTP) vaccine developed in 1948. The vaccines were developed for diphtheria in 1914, tetanus in 1926, and pertussis in

1938. Large-scale vaccine production in the 1940s made campaigns against childhood preventable diseases possible (The Children's Hospital of Philadelphia, 2019).

As previously mentioned, the smallpox vaccine had been developed in 1796. The smallpox virus had been eradicated in North America and Europe by the mid-20th century, but persisted in Africa, Brazil, and South Asia (U. S. National Library of Medicine, 2019b). In 1968, a global smallpox campaign was led by Dr. D. A. Henderson, who also promoted a campaign to control measles. Initial efforts began in Africa where many challenges hindered the success of immunizing against the smallpox infection. These challenges included hunger and malaria. International collaboration and the advances in technology were major factors that contributed to the success of the smallpox campaign. Thirty-three countries were involved in a campaign to vaccinate infected persons from smallpox. By 1973, five of the 33 countries still had outbreaks of smallpox. The WHO's Global Smallpox Eradication Program took nearly 10 years to accomplish complete eradication around the globe. The smallpox campaign was declared a success in 1977. With this success, smallpox became the first major disease to be eliminated from the globe. Dr. Henderson's efforts led the way for childhood vaccination programs (U. S. National Library of Medicine, 2019b).

Public education begins with the understanding of how vaccines work and the recommended schedule the U.S. Advisory Committee on Immunization Practices (ACIP) developed to protect children from vaccine-preventable diseases. Recommendations are sent to the CDC Director for approval. Once a recommendation has been reviewed and approved by the director and the U.S. Department of Health and Human Services, it

becomes published in the CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR is the official CDC's recommendation for public health (CDC, 2019f). Healthcare providers in the United States are encouraged to follow a schedule prepared by ACIP that is timed to protect children from 14 pathogens by inoculation at the most vulnerable age. The current schedule applies to children younger than 6 years of age. The children are expected to receive as many as 24 immunizations by the time they are 24-months and may receive up to five vaccines during a single doctor's visit. Innovations and advances in technology have reduced the number of inactivated or dead viruses and bacteria used in vaccines and altered bacterial toxins that are known to cause disease and infections.

Newly developed vaccines undergo rigorous testing for safety and effectiveness before approval by the Food and Drug Administration (FDA; Institutes of Medicine [IOM], 2013). The FDA began in 1906, with the introduction of the Pure Food and Drugs Act (also known as the Wiley Act). This law was instituted as a regulatory law that prohibited the interstate manufacture, sale, or transportation of adulterated, misbranded, poisonous, or deleterious foods and drugs (Carpenter, 2016). The next section gives insight into the beginning of vaccine promotion and early vaccine programs.

Early Vaccine Campaigns

Vaccine campaigns and trials began from the introduction of smallpox inoculations in the Americas in 1803 to the success seen with the polio vaccine in the United States in 1955. President Franklin D. Roosevelt founded the March of Dimes in 1938 in an effort to combat the disease polio. The March of Dimes was founded as the

National Foundation for Infantile Paralysis (NFIP) to combat polio. Entertainer Eddie Cantor gave the campaign the name "March of Dimes" to illustrate its national campaign for every person to contribute 10 cents. The campaign was successful in the eradication of polio. Today, the charity raises money to help the March of Dimes fund research and programs. It is a nonprofit organization that is exempt from federal taxation and is focused on assisting moms and their babies to become stronger and healthier. The assistance offered to families can be in the form of vaccines, breathing therapy, newborn screenings, and other health-related ventures (March of Dimes, 2019).

In the decades before 1963 when the measles vaccine was developed, nearly all children got measles by the time they were 15 years of age. It was estimated that at least 3 to 4 million people in the United States were infected annually from measles disease alone. Among the measles cases reported annually, 48,000 people were hospitalized, 1,000 had suffered encephalitis, and an estimated 400 to 500 people died. The measles vaccine was followed by the mumps vaccine in 1967, which lead to the successful development of the rubella vaccine in 1969 (CDC, 2018). These three vaccines, the measles, mumps, and rubella vaccine (MMR) were combined and licensed for use by Merck in 1971. The three diseases are very serious and considered deadly, therefore the vaccines became mandatory in the U. S., and easily distributed when combined. Organizations, such as the WHO and UNICEF (United Nations Children's Fund), began developing global programs in 1974 that focused on vaccinating children in under-developed countries (Stern et al., 2005).

In the beginning, most funding for vaccines came primarily from philanthropic institutions, such as the March of Dimes founded in 1938, the Bill and Melinda Gates Foundation founded in 2000, and the Rockefeller Foundation which was founded in 1913. All three institutions are advocates for humanity and are dedicated to solving the global challenges related to health, research, science, economics, climate change, data, policies, and more (Stern et al., 2005). The next section discusses possible reasons why vaccine campaigns have not been completely successful in eradicating disease around the world.

Protests and Anti Vaccinationists

Protest against vaccines began as early as the 1830s when anti vaccinationists felt the laws for mandatory vaccinations were intrusive. The protesters felt that the new unusual medical practice was supported by charlatans or con artists. The antivaccine groups also received support from other groups who rallied against animal experimentation. The United States Supreme Court responded with the ruling in Jacobs vs. Massachusetts that "the need to protect the public health…outweighed the individual's right to privacy" (Stern et al., 2005, p. 617). The case was argued on December 6, 1904, and decided on February 20, 1905. The case was a citizen's challenge to the state's authority to mandate restrictions on a person's freedom of choice for public health purposes. The court concluded that the "…state may require healthy adults to accept an effective vaccination when an existing epidemic endangers a community's population" (Mariner et al., 2005, p. 583). In 1902 the Board of Health had determined the smallpox disease to be a growing epidemic. The state of Massachusetts had given the city health

boards the authority to require vaccination for public safety. Henning Jacobson refused and refused to have his son vaccinated due to his belief that he previously had an adverse reaction to a vaccine. The Constitutional right to individual liberty is applicable in most cases, except when it is necessary to control an epidemic or "…in particular cases as to justify the interference of the courts to prevent wrong and oppression" (Mariner et al., 2005, p. 583). The court's decision defines the police power of the state in situations when the regulations or standards are so irrational that they will cause more harm than good. Vaccination was considered a reasonable means of controlling the epidemic without committing an "…act in an unreasonable, arbitrary or oppressive manner" (Mariner et al., 2005, p. 583). It is important for public health and constitutional law to evolve as necessary to preserve the trust and respect of the communities to better protect both the health of the public and the personal rights of the individual (Mariner et al., 2005).

The fear of immunization in the nineteenth century was not completely unfounded since the risk of infection from vaccines was very high by today's standards. Most likely, the vaccines produced at that time, would not be an acceptable medical intervention today. Vaccine safety and efficacy have been constant issues for scientists and policymakers. The 1986 National Childhood Vaccine Injury Act (NCVIA) was passed in response to parents' concerns over the possible connection between neurological problems and vaccines (Stern et al., 2005). This led to the FDA, the American Academy of Pediatrics, and the U.S. Public Health Service to reject any vaccines containing

thimerosal which was used in the measles vaccine and thought to be the cause of Autism in children.

Thimerosal is a preservative developed in the 1930s that was previously used in diphtheria, tetanus, pertussis, Hib, and hepatitis B vaccines. Today, it is only used in some influenza vaccines as a preservative. Preservatives are necessary for preventing dangerous bacterial or fungal contamination and are required in multidose vials of vaccines (U. S. Food and Drug Administration [FDA], 2018). The type of mercury found in thimerosal is ethyl mercury. Ethyl mercury is different from the type commonly found in fish, known as methylmercury, and is found to be harmful in large amounts (Public Health Organization, 2019). Scientific studies have shown that Autism, developmental disorders, and other neurological conditions, have no causal connection between vaccines or the additive, thimerosal (Stern et al., 2005). There are more than 25 evidence-based research articles reviewed by U. S. experts, such as the National Academy of Sciences' Institute of Medicine, that refute a possible link between the MMR vaccine and Autism (Immunization Action Coalition, 2017). One study was conducted to investigate the relationship between early exposure to the MMR vaccine that contained thimerosal and the risk of autism spectrum disorder (ASD) onset. The case-controlled study was conducted in Japan due to its highly homogenous population. The results of the study found no evidence that the MMR vaccination containing thimerosal was associated with an increased risk of ASD onset (Uno et al., 2015).

Vaccines are also monitored against contamination to insure they produce immunity and not a serious infection or other adverse effects. Despite the precautions

taken to ensure the safety of vaccines over the years, and the efforts made to improve rates through herd immunity and improved access, there have been shortages of life-saving vaccines and strongly negative public opinions (Stern et al., 2005). The methods and technologies for isolating microorganisms were improved to provide consistency and a high-quality product. Safety guidelines were set to promote efficiency and prevent the risk of adverse events and contamination during production. The theory behind herd immunity is that everyone in a community is immune, even those not vaccinated, because at least 95% of that population has been vaccinated. This is also known as social immunity whereas the majority of the population protects the few (Rey-Jurado et al., 2018). Herd immunity is an attractive way to extend vaccine benefits beyond the target population by giving indirect protection to unvaccinated persons. A large percentage of the population that has been vaccinated becomes immune to the vaccine preventable disease, thereby providing protection for individuals who have not been vaccinated. This type of social immunity was effective in the eradication of smallpox in 1977 and the reduction in the transmission of pertussis in the 1940s (Kim et al., 2011). The anti-vaccinationists increase the risk of a potential outbreak of vaccine preventable diseases when they refuse to have their children and/or themselves immunized against life-threatening diseases. The anti-vaccinationists concerned with the safety and efficacy of vaccines remain a constant force in society, but their presence has resulted in a positive movement towards public education and improved policies (Stern et al., 2005).

A study conducted by Smith et al. in 2004, examined the characteristics of families of children 19-35 months-old in the United States with no vaccination and how

they differed from those children who were under-vaccinated. The study identified patterns in states and counties with high rates of unvaccinated children. Under-vaccinated children were those who had only received partial childhood vaccinations and were considered not fully vaccinated. Unvaccinated children were those who had never received a vaccination, or whose provider reported never giving a vaccine. The researchers found that during the years from 1995-2001 out of a total of 151,720 children, 795 children were not vaccinated. The results revealed that under-vaccinated children tended to be Black, have unmarried younger mothers with no college degree, and who lived in the city at poverty level. The results revealed unvaccinated children tended to be White with mothers who were married, educated with a college degree, and an annual income exceeding $75,000. There is a great contrast between the under vaccinated and unvaccinated children in this study. Annually there were approximately 17,000 unvaccinated children with the majority coming from 10 states across the country. States with philosophical exemptions had much higher rates of unvaccinated children when starting school. Generally, the unvaccinated children lived in the same geographical area increasing the risk for rapid spread of contagious diseases (Smith et al., 2004).

Manufacturers and Pharmaceutical Companies

The role of pharmaceutical companies in legislation pertaining to vaccines is controversial. The industry tends to practice lobbying that is aggressive. There has also been an issue with transparency of the industry's controversial activities in policy making. Pharmaceutical companies that continue to give financial contributions to lawmakers while promoting their agenda risks undermining the prospects for legislation

to foster uptake of new vaccines. This is discussed in a study by Mello, Abiola, and Colgrove (2012) which investigated the role of the Merck & Co. Inc. in the promotion of the Human Papillomavirus Vaccination (HPV) in six states. It was found that in all six states, legislation was adopted to add HPV to each state's vaccine program, but no other policies pertaining to vaccines were adopted. Furthermore, a mandate was added to the law in most of these states that required insurance coverage and the HPV vaccine to be given before school entry. Both requirements had been part of the Merck & Co. Inc. strategy (Mello et al., 2012).

Commercial businesses and private drug companies were the ideal choice to take over vaccine production. Taking production away from government entities into the commercial environment benefitted vaccine promotion in the beginning by providing competition, superior vaccine quality, and lower cost. This idea was soon repudiated when pharmaceutical companies began viewing vaccine production as an economic risk and financial loss due to regulatory barriers placed on the monitoring, sterilization, and quality control in vaccine production (Stern et al., 2005).

Interviews seemed to suggest that the role of the Merck Pharmaceutical company was aa a source providing information to legislative and health department officials (Mello et al., 2012). The company was proactive in its efforts, although its activity was not illegal. Even though these practices were not transparent to the public, it appears that the pharmaceutical industry's influence resulted in successful vaccine mandates. Merck's influence and contribution helped to improve access to vaccines. The participation of pharmaceutical companies in vaccine policies or the offering of vaccines for a committee

seat was viewed as appropriate as long as the company only provided information. Legislators had more of a rapport with the drug industry than it did with the state health departments. The lack of communication with state health officials is the reason for a strong dependence on pharmaceutical input on the part of law-making bodies (Mello et al., 2012).

Offit (2005) revealed that the number of pharmaceutical companies available to develop vaccines had decreased and suggested that this was partially due to the cost of research and testing, and the manufacturing of certain vaccines. Pharmaceutical companies are private businesses that would prefer to manufacture other drugs for a profit rather than increase resources for new vaccines. According to Offit (2005), the attitude and actions of private pharmaceutical companies are founded on a business perspective and not in the interest of health care. To date, there have been no mandates for these companies to manufacture vaccines resulting in shortages of many vaccines. In the past, there was competition for the resources that were needed to develop vaccines, but due to mergers of drug companies, vaccines are in competition for resources with other drugs, and usually, the vaccines lose (Offit, 2005). Unfortunately, the CDC and the U. S. FDA, as well as the pharmaceutical companies are blamed for shortages when they occur. One pharmaceutical company is responsible for manufacturing seven vaccines, and two other companies each manufacture one vaccine. During the period 1967 to 2004, the number of drug manufacturers had decreased from 26 to five. Only the larger, more prominent companies remained after several mergers. The major investors in research and development were Merck, Chiron, GlaxoSmithKline, Wyeth, and Sanofi-Aventis

(Offit, 2005). The factors that influenced the reduction in drug manufacturing companies were found to be low insurance reimbursements, mergers, public participation, regulatory issues, poor infrastructure support, and product liability issues. The manufacturers' remedy to compensate for losses would be to increase the cost of vaccines and decrease the costs to make them (Offit, 2005).

In the 1970s, physicians bought the MMR vaccine for $25 and sold it for $75 to families who paid out of pocket. The high price offset the costs required to purchase, store, administer, and record vaccine information for each child (Offit, 2005). The rise in costs for vaccines caused many physicians to stop providing immunizations. The insurers often reimbursed the physicians poorly, therefore they could not afford the preventive treatments to offer their patients. The vaccine market has since become profitable for pharmaceutical companies and more accessible to target populations. The government purchases more than half of all vaccines for children in the U.S. due to the PPACA mandate that all children receive immunization against childhood preventable diseases at no-out of pocket cost. According to data from the CDC, to fully vaccinate a child with private insurance to the age of 18 would cost $2,192 today compared to $100 in 1986. (Rosenthal, 2014).

In recent years, pharmaceutical companies have been viewed by the public as companies that prioritize profits over patients. The high cost of medication and/or the shortage of vaccines during times of high demand leads the public to believe the pharmaceutical company only services those who are willing and can afford to pay, regardless of the danger or health risk of not having access (Lipworth et al., 2014). If this

were true, it would further increase the risk of young children being susceptible to highly contagious diseases. The recall of new medications and the controversy that vaccines were unsafe have led many to distrust new medications and vaccines. Previous studies revealed that pricing reform for medications might cause drug companies to be less willing to invest in quality research (Lipworth et al., 2014). For instance, if the research for a new drug or vaccine is biased, incomplete, or misleading in any way, or produced unreliable or inappropriate data, and the industry manufactures the resulting drug product, despite warnings or poor test results, public safety is at risk. It would appear that the objectives and or agendas of the pharmaceutical companies, the governments, the public, or even the researchers do not coincide with one another. Either way, the agenda for all stakeholders should be to develop high quality, safe and effective drugs, and vaccines, that are available to everyone (Lipworth et al., 2014). Skepticism and ethical issues would later lead to government policies and regulations for research standards, human testing, and vaccine safety. The next section will discuss the policies created to improve vaccine delivery and the ethical issues that influenced the strategies and decision-making of legislators and health administrators.

Policies and Ethical Issues

Ethics is about making choices that do no harm, are just, and respects the rights of everyone involved. Ethics is not a law, it is not a culturally accepted norm, nor is it a religion or science. However, ethics is based on relevant facts that Government and legislators consider when analyzing complex health issues to determine which option is best for society as a whole. Most issues where a decision must be made has an ethical

dimension. Administrators must make the best decision for a given circumstance that protects and respects the moral rights of others. Ethical decisions made by healthcare administrators have tremendous effect on the health and well-being of others. How a person perceives they are being treated, and how they perceive others to be, determines whether it is possible to build a trustworthy relationship, which is directly relevant to building trustworthy organizations that are accepted by the communities they serve (Markkula Center for Applied Ethics, 2015). Government organizations and the programs they implement are best regarded when they are transparent, treat everyone fairly and equally, and base decisions on ethical principles.

The ethical aspects of the processes in healthcare legislation, that includes not only vaccine safety, but also the activities of the drug industry in policy issues, bring great cause for debate. The CDC is bound by strict ethical guidelines and federal regulations when implementing its role and its strategic plans to accomplish the mission and vision of protecting the American public. The Public Health Ethics Unit, in collaboration with the CDC Public Health Ethics Committee (PHEC) is responsible for developing the CDC's health ethics infrastructure. This includes creating an environment and culture that supports and develops ethical practices. The guidelines are considered the foundation for the government health agency when conducting health-related services (CDC, 2017). The Public Health Law Program (PHLP) was established by the director of the CDC, Jeffrey Koplan in 2000, to develop tools associated with the law to assist practitioners and policymakers in improving public health (CDC, 2018d). The practitioners and policymakers are part of state, tribal, local, and territorial (STLT) public

health departments. The PHLP, the STLT departments, and other pertinent authorities: identify law priorities; analyze legal preparedness; research laws; and prepare documents and reports related to public health (CDC, 2018d).

The 14 General Principles of ethical conduct were issued as an Executive Order by the former President, G.W. Bush for all branches of government. As standards towards ethical behavior for the CDC organization, it begins with requiring its members as public servants, to be loyal to the constitution, ethical principles, and laws above personal gain. As public employees, CDC members are held to a higher standard and must retain the trust of the public. CDC members must be fair, objective, and impartial to all parties and individuals providing equal opportunity regardless of race, color, creed, religion, age, handicap, or national origin. Members are prohibited in participating in activities of financial conflict and are obligated to disclose corruption, abuse, fraud, and waste of resources promptly to the appropriate officials (CDC, 2009).

The act of preferring one company's agenda over another can lead to different outcomes when developing policies. The role of pharmaceutical companies presents many challenges and opportunities. Through lobbying and campaign contributions these powerful companies can influence the policymaking process. The policies affected are the regulations for medical research, and the safety, costs, and manufacture of medications and vaccines (Offit, 2005).

The PPACA is a healthcare policy that is funded $10 billion by the government to support efforts to improve public health through the Prevention and Public Health Fund (CMS, 2019). The health fund was designed to help create an infrastructure necessary for

the prevention and detection of disease and to manage chronic conditions. The act also supports efforts to expand and strengthen the primary care workforce. The implementation of the PPACA in 2010 was a major step towards ensuring all American citizens would have access to quality affordable healthcare. The law has three primary goals: expand access to health insurance; protect patients against arbitrary actions by insurance companies; reduce costs (CMS, 2019).

The State of New York passed a public health law in 2008 mandating all health care providers to document new and past immunization records of children 0-18 years electronically to the New York State Immunization Information System (NYSIIS). The law was passed due to too many missed vaccines, follow-up vaccines, and inaccurate record reporting. The system is important for identifying high risk populations and addressing the barriers associated with vaccine completeness (Suryadevara et al., 2013). In 2011, the meaningful use initiative required healthcare providers to increase the "meaningful" use of Electronic Health Record (EHR) systems and establish a connection with an Immunization Information System (IIS) to receive EHR-MU incentives (CDC, 2016b). Government agencies and programs were created to address the barriers associated with poor vaccine uptake in high-risk populations.

Agencies and Programs

The federal government through its agencies and advisory committees have a major role in making vaccines one of the leading public health interventions. The important steps to ensure the success of its programs include: improving coverage through strategy development; monitoring vaccine safety and impact vaccine purchase;

the development and testing of vaccine antigens; the evaluation of clinical and manufacturing data that leads to licensure; the formulation of recommendations; and the compensation for individuals injured by vaccine adverse reactions (Schwartz et al., 2001). The infrastructure necessary to accomplish successful immunization of a population involves government agencies, state and local immunization programs, the biotechnology industry, and individual vaccine providers (Schwartz et al., 2001).

The Immunization Action Coalition is an organization in collaboration with the CDC, that distributes vaccine information and recommendations to healthcare professionals and the public. The Chief Strategy Officer (CSO) of the Immunization Action Coalition discussed the impact of the Affordable Care Act (ACA) on Medicare, access to immunizations, and effect on complimentary immunizers, such as pharmacists, public health clinics, and school-based clinics. According to research by the CSO, the ACA was intended to improve on access and not necessarily improve payments to providers. It was shown that hospitals that paid 100% for outpatient preventative services under Medicare Part B showed improved access to immunizations (Tan, 2015).

The Community Preventative Services Task Force (CPSTF) was established by the Department of Health and Human Services in 1996 and promotes a fact sheet of summarized information in the form of a community guide. The organization consist of a non-federal independent panel of health prevention experts who are appointed by the CDC. The CDC also provides scientific, technical, and administrative support to the CPSTF (CDC, 2020a). The Community Guide is evidence-based findings and recommendations for preventative resources and services (The Community Guide, 2017).

Intervention strategies can be adapted based on community needs by local health departments and immunization agencies for improvement of vaccine rates. The CPSTF recommendations are divided into three categories, where each category list interventions that can be implemented by the Department of Health and Human Services at the community level. The categories are:

A. Enhancing access to vaccination services (which list four strategies).

B. Increasing community demand for vaccinations (which list four strategies).

C. Provider or system-based interventions (which list five strategies) (The Community Guide, 2017).

The strategies or recommendations in the same category or among the three separate categories can be implemented in combination to address the issues of the community. Individual strategies have not been proven to be effective alone (The Community Guide, 2017).

An example of the Community Guide's use was a project in Illinois to increase vaccination rates, particularly to vulnerable populations. The Champaign County Community Health Plan was devised using the fact sheet to develop a portrait of the health assets and needs of the residents. Illinois state law required every local health department to participate in the Illinois Project for Local Assessment of Needs (IPLAN). A local health authority in Champaign, Illinois in collaboration with the Carle Family Medicine Residency Program provided immunizations for all children covered by Medicaid and accepts the insured and underinsured families for a small fee. Population

estimates, and demographic reports revealed significant health threats related to unvaccinated populations with little or no access to clinics. The project focused on ways to improve access for those areas at risk by implementing a combination of strategies adapted to the needs of the community (Community Health Improvement Plan, 2017). Poor or no access to clinics or other healthcare resources means no access to critical vaccine information, alternate financial resources, and/or life-saving immunizations.

A study in Duval County, Florida implemented quality improvement strategies in combination with several recommendations found in The Community Guide. There was great concern for the risk of increased outbreaks of vaccine preventable diseases because of falling vaccine rates that began before 2009. Low vaccination rates had been seen in children under the age of two in the urban area of Jacksonville, Florida. The Duval County Health Department devised a plan that included interventions adapted for healthcare systems and community-based system. The vaccine rates for the county increased to the target goal within one year (The Community Guide (The Community Guide, 2017).

Dombkowski, Lantz, and Freed (2004) evaluated the risk factors associated with the delay in children receiving vital vaccines at the recommended age. The researchers conducted a rare investigation into the effects of risk factors and immunization. It was found that there is an association between the demographics and health status of the child. Program strategies must not only address vaccine access, vaccine acceptance, and vaccine rate improvement, but successful vaccine outcomes rely on effective communication and education with families for good follow-up care. Therefore, future

research is necessary to address the evidence gaps related to the effectiveness, sustainability, and adaptability of policies and interventions when implemented in various population demographic and socioeconomic environments.

Centers for Disease Control and Prevention (CDC)

The CDC is a government organization that works around the clock to protect the American public from diseases and disease threats that can negatively affect or ultimately destroy human life. The organization is one of the major components that functions under the U. S. Department of Health and Human Services (CDC, 2019d). The types of threats the CDC is concerned with, whether abroad or in the United States (U.S.), involve the health, safety, or security of the American population. Regardless, if the illness occurred due to human error or as a deliberate assault; being preventable or a curable disease; beginning suddenly or suffered for an extended period, the CDC inputs countermeasures to fight disease processes, educate the public, and support communities in their efforts (CDC, 2019d). The job of the CDC begins immediately when notified of such threats. The role of the CDC includes detecting and responding to new and emerging health threats; tackling the biggest health problems causing death and disability for Americans; putting science and advanced technology into action to prevent disease; promoting healthy and safe behaviors, communities, and environment; developing leaders and training the public health workforce, including disease detectives; taking the health pulse of our nation (CDC, 2019c). These efforts are accomplished through the collection of high-quality scientific data and resources, as well as the most highly trained professionals to make the best decisions in public health (CDC, 2019c).

U.S. Food and Drug Administration (FDA)

The FDA is responsible for regulating, licensing, and overseeing the safety, potency, purity, and effectiveness of vaccines issued in the U.S. Currently, the U.S. has the safest and secure system for developing vaccines and the safest and most effective supply in history. FDA scientists in the Center for Biologics Evaluation and Research (CBER) conduct mission-related programs and provide a scientific base for effective regulatory review of biological products. These include research into vaccines, allergens, blood, gene and cellular therapy. Studies are conducted with adult volunteers, that evaluate all measures for safe use of vaccines for children, before being approved by the FDA (CDC, 2013). These evaluations occur after clinical trials are implemented in three phases, and the results are reviewed by the FDA to ensure the use of the highest ethical standards, and quality of scientific testing available (Food and Drug Administration, 2012).

U. S. Department of Health and Human Services (Centers for Medicare & Medicaid Services)

The Department of Health and Human Services (DHHS) awarded $1.25 billion to states willing to participate in the expanded Medicaid program that protects against public health emergencies as well as promote wellness and prevent disease. There are a set of 10 categories of health services insurance plans covered under the PPACA (CMS, 2019). A variety of plans are available through the Health Insurance Marketplace intended to give patients a choice at a cost they can afford. The preventative services are free when delivered by a doctor or another provider listed in the plan's network. The care

you receive to prevent illnesses or diseases is known as preventive care which also includes counseling to prevent health problems. To help children and their families stay healthy, preventative care services are provided at no cost. Preventive care, such as screenings and immunizations are services that can reduce the risk of future chronic illnesses and thereby reduce the potential cost of care. Insurance plans must cover vital preventive services, like those previously mentioned, and counseling services, with no cost-sharing under the new health care reform (CMS, 2019).

The PPACA provisions were vital to millions of American families receiving access to healthcare through the extension of insurance coverage, also known as Medicaid expansion. Since its implementation, 37 states have adopted the Medicaid expansion option in the law and 14 states have opted out. Studies have shown that public access has increased substantially where Medicaid expansion occurred, and there is evidence that the act has significantly reduced health disparities in ethnic and racial groups (Glied et al., 2017). Medicaid expansion was intended as a step to insure coverage for everyone across the U. S. The June 2012 Supreme Court ruling made it optional for states to expand their Medicaid programs, but by opting out, the nonparticipating 14 states left many vulnerable individuals without health coverage or a feasible option. Medicaid eligibility under the PPACA would be extended to most low-income individuals with incomes at or below 138 percent of poverty, which is $17,236 for an individual in 2019. The PPACA also provides a premium tax credit for Marketplace coverage intended as an option for covering people with moderate incomes. All adults that do not have children, or those having incomes above Medicaid eligibility limits or

below the lower limit for Marketplace premium tax credits, fall into a “coverage gap.” As a result, states that do not expand Medicaid deprive 2.5 million uninsured individuals of behavioral health services, prescription drugs, rehabilitative services as well as, medical and long-term services (Garfield et al., 2019).

Children's Health Insurance Program (CHIP)

The Children’s Health Insurance Program is insurance jointly funded by the state and federal government to eligible children through Medicaid or a separate CHIP program. The program was signed into law in 1997 and is one of six Centers operating within the Centers of Medicare and Medicaid Services, which is an agency of the Department of Health and Human Services (HHS) (CMS, 2021). The program is administered by each state according to federal requirements. The insurance is available to families of low income who do not qualify for Medicaid and cannot afford private insurance. The Center for Medicare and Medicaid Services give broad guidelines for states to modify the program as they choose using three criteria:

1. Medicaid expansion
2. Separate Child Health Insurance Program
3. Combination of the two approaches (CMS, 2021).

Women, Infants, and Children (WIC)

The Women, Infants, and Children program is a supplemental nutritional program established in 1972 that serves to provide support and health maintenance to low-income families. These families include mothers who are pregnant, breastfeeding, or post-partum, or have children under the age of five (United States Department of Agriculture [USDA],

2016). The WIC program is partnered with other government health programs to promote a holistic approach to the well-being of the child. The program gives educational support to the families on the importance of nutrition, as well as immunization screening and referrals (USDA, 2016). The Child Nutrition and WIC Reauthorization Act of 1989 (P.L. 101-147), "required that all WIC State agencies enter into cost-containment contracts for the purchase of infant formula used in WIC… reducing the income criteria for participants into the program" and "established adjunct income eligibility for Food Stamp, Medicaid, and Aid to Families with Dependent Children (AFDC) recipients" (Economic Research Service/USDA, pgs. 8-10, 2001). WIC is considered a gateway to healthcare and social services through its coordination and referrals to other healthcare and social service providers (Economic Research Service/USDA, 2001).

National Institutes of Health (NIH)

The NIH is the major agency that traces back to 1798 responsible for the education of public health and the advancement of biomedical research. It is now part of the United States Department of Health and Human Services that provides the funding for biomedical research. Its main focus is on improving health quality through promotion and prevention. The NIH responds to legislation that adjusts NIH's programs to meet the constantly changing needs in research. The NIH reauthorization process enables the agency to respond strategically during a time when medical research consistently demands innovations and increased interdisciplinary efforts (National Institutes of Health [NIH], 2019)

The State and Local Department of Health

The State Department of Health is a government agency whose mission is to develop laws, regulations, and policies to improve health and quality of life. The State Department of Health is in the unique position to collect, analyze and draw conclusions about local data gathered through assessment. The local health department focuses on issues related to the general health of the community in which it services and is considered to be the frontline of public health. There is a state health department for every state and territory in the U. S. to service its communities. Examples of services provided by local health departments are to oversee water and sewage systems, waste disposal, sanitation of restaurants, and communicable disease control. The state of Ohio Department of Health multidisciplinary team is composed of the Chief of Staff, the Medical Director, the General Counsel, senior management, and supervisors who are committed to protecting and improving the health of Ohioans. The state health departments are responsible for protecting the health of citizens at the national level (Ohio Department of Health, 2019).

Vaccines for Children

The Vaccines for Children (VFC) Program is the largest federally funded purchaser of vaccines which has caused a decrease of purchasing in the private market (Ohio Department of Health, 2014). The private market consists primarily of private health organizations and insurance companies. Health maintenance organizations (HMOs) traditionally emphasized preventive services and would provide immunization as a basic covered benefit. Preferred provider organizations (PPOs) and indemnity

insurance companies have always had a more limited immunization coverage. The decline in private insurance for immunization coverage is probably due to the high cost of certain vaccines, and the omission of patient cost sharing in the form of deductibles and copayments (IOM, 2003). The VFC program was implemented in 2014 by state Department of Health Immunization Programs across the country and provides free vaccines to public and private health care providers. The provider agrees to enroll and immunize eligible children who visit their practice or clinic. The free vaccine program was developed by the Omnibus Budget Reconciliation Act of 1993 to improve access to vaccines and reduce costs. The vaccines, including those recommended by the Advisory Committee on Immunization Practices (ACIP) for infants and children, protect babies, children, and adolescents from 16 diseases (ODH, 2014). Children eligible to participate in the program must be under 18 years of age and meet one of four criteria: 1) The child must be covered by a state Medicaid program. 2) The child has no health coverage or medical insurance. 3) The child is a Native American Indian or Native Alaskan of Indian descent as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603). 4) The child has health insurance that does not cover the cost of vaccines, or has a limit or cap on vaccines, or has insurance that only covers certain vaccines (CDC, 2014). The federal government offers free vaccines to eligible children. The VFC Program covers all vaccines included in the immunization schedules which are purchased and distributed by the CDC and is critical to providing access to healthcare resources for this population (CDC, 2014).

Advisory Committee on Immunization Practices

The Advisory Committee on Immunization Practices (ACIP) is a committee made up of a group of public health and medical experts within the CDC (Ahmed, 2013). The committee provides advice and guidance on effective control of vaccine-preventable diseases to the Director of the CDC and the Secretary of the Department of Health and Human Services (HHS). The ACIP develops recommendations on how to use vaccines to control diseases in the United States. There are seven mandatory vaccines required by all 50 states that children must have to attend school. However, 47 of the 50 states allow for exemptions based on religious or philosophical beliefs. The CDC recommends vaccines that are developed using a detailed evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (CDC, 2019f). The primary factors utilized during recommendation development are type or quality of evidence, the balance of benefits and harms, health economic analyses, and the values and preferences of the people affected (Ahmed, 2013).

Conclusion

The previous discussion provides the history of vaccine development and production as well as, the individuals and groups responsible for the steps that led to present-day immunology. Researchers throughout the years have investigated the origins of vaccines, the first campaigns in disease prevention, and how research, technology, and policies changed from 1796 to 2019. Since the administration of the first vaccine, advocates for preventative medicine of this type were faced with challenges that dealt with safety, funding, costs, accountability, and the moral compass of those involved with

vaccine research and development. The concerns in the beginning were not without merit, and many clinical trials and testing would be necessary to build evidence-based research. Despite the many successes, including the eradication of life-threatening diseases in significant regions of the world, century-old challenges persist.

There are a few issues involving the manufacture of vaccines that should be examined for justification and possible solutions to problems. The pertinent information to future research about immunizations access, safety, and availability is the brief assessment of the recent financial history of vaccine manufacturing, an explanation of the role of the pharmaceutical industry, and their connection with the government, private agencies, and the healthcare industry. It is well understood that vaccines are used only several times in a lifetime and that many drugs are used often or every day. Therefore, the market for vaccines is much less lucrative than the market for drugs. Drug companies will compete to make similar drug products, but there is no competition in making vaccines. Strategies must be developed to motivate and encourage drug manufacturers to produce life-saving vaccines.

The approach to improving immunization delivery and rates is challenging and requires governments, organizations, and agencies to collaborate to develop effective strategies, policies, and programs. Cultural influence, policies, economics, and environmental factors vary from country to country and even state to state. Each region demands an approach specifically tailored to the needs of its community for a vaccine program or campaign to be successful. The next section evaluates the designs, methods,

research tools, and types of data utilized by researchers to investigate variables associated with access to vaccine.

Research Methodology and Frameworks

It is important to understand the distinction between different methods of research to determine the framework the researcher must choose for analyses and the type of data pertinent to the research questions. This study will be based on quantitative data, which can be measured through statistical and comparative analysis. The results of any study should be clear and objective. Qualitative studies contain descriptive information usually collected through interviews and observations. Qualitative studies are in-depth studies that focus on the "why" when a phenomenon occurs (Vock et. al., 2011). It is critical to obtain datasets pertinent to population characteristics, delivery of services, and other health indicators to accurately measure access to medical care. Often, subjective, or descriptive information will be given quantitative value to measure the relationships between an at-risk population and the access behavior when seeking medical care (Bradley et al., 2002). This section of the literature review will examine different types of research relative to this study to better comprehend the different approaches for collecting and analyzing data, choosing the best model fit, and interpreting the results.

Scientific Methods and Tools

The scientific method has been a fundamental and systematic process for testing a hypothesis since the 18th century. It is a logical approach to finding answers to naturally occurring phenomena. Choosing the correct scientific tools for data collection and analysis is imperative when developing the research framework and design. The complete

process must be fair and unbiased to result in reliable and valid evidence-based research (Waljee et al., 2014).

There are significant differences between traditional explanatory research and prediction research. Explanatory research uses statistical methods and test causal hypothesis. Predictive research also utilizes statistical methods, that is not based on a theoretical construct, but may incorporate data mining techniques (Waljee et al., 2014). The perfect model fit for this research should be adaptable for future studies, as new valid and/or conflicting data emerges.

Bayesian Model

Developing a predictive model can be useful when using large data and is an effective way of identifying which populations are at risk or need an intervention. This type of research is intended to predict future outcomes based on patterns within a set of variables (Waljee, et al., 2014). A model can be uncertain in its predictions, and unfortunately, calculations for some statistical models do not estimate for uncertainty. In the Bayesian model, parameters are established and used to update the probability for a hypothesis, as more information becomes available. What happens when researchers fail to account for model uncertainty when it is used to estimate the global burden of disease? Uncertainty in the model sample variability, structure, and any potential covariates may inevitably lead to a potential for error in calculations (Tipping, 2004). According to Waljee, Higgins, and Singal (2014), “When assessing model performance, it is important to remember that explanatory models are judged based on strength of associations,

whereas predictive models are judged solely based on their ability to make accurate predictions" (p. 2).

The Bayesian model has the mathematical framework for explaining the reasons for uncertainty in meta-analysis and meta-regression models. The WHO compared 76 studies from around the world to estimate the number of child deaths from a particularly dangerous disease using the Bayesian model. The disease caused a common symptom of many illnesses, diarrhea (Vock et al., 2011). The data and previous estimations were computed by multiplying each country's total number of deaths caused by diarrhea by the estimation of reported deaths. The results from every country were then added together. A meta-regression model and a random-effects meta-analysis was used to analyze the estimates, whereas the data was stratified to reduce in-between study variability. The results from the different models were averaged using the Bayesian model, which showed an increase in the estimated number of deaths. This increase changed the confidence interval from 105,000 to 198,000 deaths (Vock et al., 2011). These parameters represent all uncertainty in the models, which includes the uncertainty of the inputs and outputs. The researcher is confident that the results lie within these parameters and these parameters become his best estimate based on the available data. The parameters described in the Bayesian inference are treated as random variables in the models that affect the observed data. The researcher then concludes by analyzing the posterior distribution over these random variables given the observed data. Bayesian ideas have impacted machine learning which is the scientific study of algorithms and statistical models that computer systems use without direction. Over a period of more than 20 years,

it has become quite popular because of the flexibility it provides in structuring models for any type of data based on real-world situations (Tipping, 2004).

McNemar Test and the Standard 2-Proportion Comparison

Suryadevara, Bonville, Ferraioli, and Domachowske (2013) utilized two research tools, the McNemar test and the standard 2-proportion comparison in their study of the effect of adequate resources and education on vaccine rates. The McNemar test compares the proportions for two correlated dichotomous variables. The standard 2-proportion comparison tests the inequality of two proportions. The aim was to compare coverage rates for 2011 with coverage rates nine months later in 2012 (Suryadevara et al., 2013).

The analysis determined statistically significant differences in vaccine rates when testing matched or independent data. Vaccine rates for 28% of children (416 of 1477) were complete, but this number included the annual influenza vaccine. Excluding the influenza from the analysis resulted in the number of vaccine outcomes in children completely vaccinated increasing to 70% (1034 of 1477). Comparisons were made for different age groups up to 18 years, as well. Vaccine rates improved over a nine-month period due to the increased number of children given the influenza vaccine. The surveys conducted during the campaign revealed that 97% of parents supported the recommended immunization schedule and believed them to be safe. Racial disparities related to resources and education were evident. The largest improvement in vaccine rates was seen in the 0-3 cohort, which increased from 156 to 256 of 392 children total with a 95% confidence interval [CI] (21.2–29.8) completion rate (Suryadevara et al., 2013).

Data and Variables

In 1912, all U.S. healthcare providers and laboratories were required to report all diagnosed cases of measles. Each year for the first decade of reporting, an average of 6,000 measles-related deaths were reported (CDC, 2018c). A 2018 report by the CDC reviewed data and statistics on the major leading vaccine-preventable diseases that have been transmitted from country to country by infected travelers. The report reflects data and cases that support the positive influence of vaccines and the dangers of not being vaccinated.

Methods and processes utilized by WHO and the United Nations Children's Fund (UNICEF) for estimating immunization rates are based on government reports and data that are supported with additional information from local experts, regional and national staff, and national immunization system managers (Burton, et al., 2009). The studies were analyzed to estimate national coverage and delivery of vaccines. The authors examined the trends and measurement of immunizations and how they can be used to develop strategies to control and eradicate preventable diseases, and monitor programs on the local, regional, and national levels. The results are also used to assess the need for new vaccines, as well as identify areas that require additional focus and resources. Data is collected from various countries from service providers and surveys, then clustered, analyzed, and reported on an annual basis to the WHO and UNICEF. Estimates of national immunization coverage are published and used: to determine where resources will be allocated; for the development of immunization policy, and to support vaccines. The method for analysis did not include statistical or mathematical models, instead

estimates of administrative data, which report the number of vaccinations, and household surveys, the most common source, were collected from designated countries. Three survey sources included the: Expanded Programme on Immunization (EPI) cluster survey; the Demographic and Health Survey (DHS); and the UNICEF Multiple Indicators Cluster Survey MICS). The EPI is a simple survey tool for immunizations, whereas the MICS and the DHS are more complex and extensive surveys. The latter two surveys are more precise, expensive, and difficult to administer (Shaw, 2017).

Mello, Abiola, and Colgrove (2012) took great caution to ensure the sample population in their qualitative study was diverse politically and demographically, as well as, in terms of immunization policy. A purposive sample of 10 informants from each state represented the number of interviews it takes to reach thematic saturation. Other considerations for each state, were ethnicity, vaccine laws and mandates, and purchasing policies. The study involved 73 individuals semi-structured face-to-face and telephone interviews (51 solo and nine groups), lasting up to 60 minutes. There were at least 10 interviewees from each state and nine from multiple states or the national level. The guide for questioning was approved by the national policymaker's organizations. The transcripts were coded using the NVIVO Version 8 software package. The media reports were used as support of background information (Shaw, 2017).

A grey literature review that investigated immunization coverage levels and trends, showed limitations in the reporting of the data, and ultimately, referred to estimates for all immunizations (Burton, et al., 2009). In this study, the data and information collected from each country were reviewed for that specific country and was

not borrowed from other countries. Generalizations were usually made for similar countries referring to demographics and other dimensions, such as income, geographical characteristics, and population size, but were not correlated in this study. Estimates were made from the source data only. The quality of the estimation is determined by the quality of the available data, which was measured as surveys and administrative reports, but these methods can still be subject to biases. Yet, there are no consistent and complete multiple ways of measuring the vaccine time series of an entire population (Shaw, 2017).

Gaps in Access and Interventions

Inequality and poor access to the necessary resources for improving health has had a negative impact on the quality of health and health outcomes of many populations (Crocker-Buque et al., 2017). Multicomponent interventions have been developed to address the needs of individuals and families based on ethnicity/culture, socioeconomic status, and geographic location. There is compelling evidence that some interventions may not target inequalities or the cultural needs of a population leaving a whole section of the population exposed to the risk of potentially life-threatening diseases (Crocker-Buque et al., 2017). The collaborative efforts of stakeholders in filling the gaps through successful programs is imperative for improving the quality of life for the deprived populations, thereby improving the quality of life for all. Healthcare administrators with the assistance of governments, agencies, researchers, and other stakeholders must consistently identify and assess a situation, develop effective strategies, and make decisions based on dire circumstances, and unpredictable events.

Barriers

The Institute of Medicine learned that despite 90% of children entering kindergarten having received the most recommended vaccines, there were still gaps in the communication between providers and parents about vaccine safety. Some parents felt the vaccine schedule was too congested. The parents wanted the vaccines to be given over an extended period of time. Despite the well-documented benefits of vaccines, many others feared potential side effects whether they were scientifically linked to vaccines or not. When a few parents choose not to have their children immunized, the potential result is the outbreak of highly contagious diseases (Stratton et al., 2011).

Research reveals that the number of children immunized at age 19 to 35 months old, who were uninsured or covered by Medicaid, was lower when compared to private insurance-covered children. In the U. S. today, up to 32.9% of this cohort live below the poverty level resulting in lower vaccine coverage (Rey-Jurado et al., 2018). A collaborative effort by Suryadevara et al. (2013), was designed as an intervention study that would determine whether adequate resources and education affected vaccine coverage rates. The belief has been that lack of education and access to medical coverage in poverty-stricken communities would increase the risk of disease outbreaks and serious health concerns (Suryadevara et al., 2013).

In 2011, the researchers focused on obstacles that might influence vaccine delivery and determined vaccine outcomes by analyzing surveys, demographic data, and immunization records of children 19 to 35 months of age. The target population was resource-poor families with incomes based on the 150% federal poverty guidelines in

Onondaga County New York. The researchers also considered vital information from similar studies that concluded certain community-based programs, in collaboration with community and state services, was detrimental to the success of immunization programs. The local health department and the Salvation Army, the largest community-based organization (CBO) in the area for this study, implemented a charity program that serviced members of the target population. The participants were individuals who would register and access the charity event. This occurred over 12 days in 10 separate community sites (Suryadevara et al., 2013).

Parents of young children were asked to participate in a 10-minute survey about vaccine concerns, while the providers gave education on the importance of vaccines and immunization schedules. At the time of each interview, records for each eligible child whose parent participated were accessed and reviewed for vaccine completeness or delay. Recommendations were given at the time of the interview with a copy of the child's immunization record. The total target population results were 1,531 children from 630 families. The primary co-variants were age, sex, single-parent homes, and medical insurance coverage. The results revealed that 96% of families were insured, but few parents would consent to children being vaccinated during the interview, despite their eligibility for several different vaccines (Suryadevara et al., 2013).

Interventions

IMMUNIZATION-basics Project

At the request of the Strategic Advisory Group of Experts (SAGE) in 2009, a quantitative study utilizing secondary data was conducted in the form of a grey literature

review. The study was based on the IMMUNIZATION-basics Project, which was funded by the U.S. Agency for International Development, and served to provide information on the epidemiology of unimmunized children (Shaw, 2017). Further investigation was expected to identify which child had an incomplete series (including boosters), and why. Two other groups participating were: the Swiss Tropical Institute, who analyzed surveys and multi-cluster surveys pertinent to health and demographics; and the CDC also analyzed peer-reviewed literature. The WHO examined the information to determine the influence sex and gender have on vaccinations (Shaw, 2017).

At least 126 relevant documents were identified and analyzed from the global grey literature collected from TechNet and CORE Group websites. These websites contain case studies, reports, and experiences submitted by health care providers and medical professionals from all over the world. The approach was to include documents based on the date it was written, the type of studies (journal articles, project reports, and reports from international organizations), the scope (national, sub-national, district, or smaller), projects by region, and countries with the most projects. A requirement of the information reviewed was that it pertained to the routine immunization services provided for young children in poor to middle-income countries. The countries included would describe immunization activities since 1980, and report vaccine information that was collected consistently. The documentations were mostly formatted in English, French, and Spanish and were formally published, photocopied from personal files, and journal articles. The peer-reviewed articles were omitted (Shaw, 2017).

A format was developed by two reviewers that reviewed summaries and counted the number of programs for vaccines. A qualitative analysis of case studies was implemented, then the reviewers in an agreement with experts at the CDC used the Classification of Factors Affecting Receipt of Vaccines to classify the facts into main clusters, consisting of: Parental Attitudes/Knowledge; Immunization Systems; Family Characteristics; and Communication and Information. The results revealed nine major causal factors and major risk factors identified as reasons for the under-vaccination of children living in under-developed countries. The reasons were related to access to immunization services, and parental knowledge and attitudes (Shaw, 2017).

Global Vaccine Action Plan

Dr. D. Durrheim discusses the new opportunity presented after the successes seen in the eradication of measles in countries such as Brazil, in his article, *Measles elimination —Using outbreaks to identify and close immunity gaps* (Durrheim, 2016). This means, according to the WHO expert advisory committee, that it is biologically, operationally, and technologically possible to globally eradicate measles. The Global Vaccine Action Plan (GVAP) will be the framework for eradicating measles and rubella in six target regions of the world by the year 2020. The GVAP is supported by 194 Member States of the World Health Assembly (Durrheim, 2016).

The measles virus was the most contagious infectious communicable disease known to mankind for many years. It is crucial to the health and well-being of all children the disease is brought under control. To achieve the appropriate level of immunity, 95% of each birth cohort in each community in every country (minus small

remote islands) must be vaccinated. This is known as herd immunity which makes it possible to fill immunity gaps in subpopulations. Due to poor records of vaccine coverage, there is no guaranteed method for detecting gaps in immunity for subpopulations or age cohorts vulnerable to measles outbreak. Evidence of the importance and urgency for identifying and defining vulnerable populations was seen in the measles outbreak in the Amish community in Ohio (Gastañaduy et al., 2016). It may be possible to identify subpopulations and age cohorts through demographic characteristics, including ethnic, social, cultural, and religious descriptors, that can help target this population accurately. These groups can sometimes be elusive and at a higher risk for infection which means they require special tools for identification. More creative ways and effective tools for detecting members of subpopulations who travel to other countries are needed to address the challenges presented when the destination area is not adequately immunized (Durrheim, 2016).

A study evaluating the impact access to information has on the acceptance of vaccines have shown that despite efforts to inform and educate the public, doubt about vaccines still persist among many parents (Handy et al., 2017). Participants reported that although they relied on healthcare providers for information, they did not receive sufficient communication from the healthcare providers. The study was conducted in three countries outside the United States and revealed that trust in the government and healthcare system varied between each country. There was also variation in the acceptance of vaccines which indicates there should be further studies that utilize data specific to the needs of that country (Handy et al., 2017). This analogy can be applied to

any region and population size to determine which factors can be used as leverage to influence vaccine acceptance.

National Institute for Health and Care Excellence (NICE)

A systemic review by Crocker-Buque, Edelstein, and Mounier-Jack (2017) was conducted using cohort, ecological, or intervention studies. The review was written as an update to a 2009 review that evaluated inequalities in vaccine uptake in children and young adults up to 19 years of age. It was an evaluation of how to reduce inequalities by utilizing new effective vaccine technologies and programs. The 2009 study was conducted by the National Institute for Health and Care Excellence (NICE) which included a review of cost-effectiveness, specifically in high-income countries, as well as vaccine efficacy of various interventions. The updated study was necessary due to the development of new interventions and innovations and how they might relate to the inequalities in different populations under the age of 19 years (Crocker-Buque et al., 2017).

The authors used the same methodology as NICE in the updated version, and in alignment with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA). PRISMA focuses on reporting of reviews evaluating randomized trials and can be used as a basis for reporting systematic reviews, such as evaluations of interventions. PRISMA aims to improve the reporting of systematic reviews and meta-analyses (Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA], 2015). Most studies were collected from the United States with a few from

the United Kingdom, Canada, and Australia. There were no studies in European countries possibly due to restrictions such as language or data availability.

The framework for the study was set as a time series and pre-and-post trails based on a total of 41 studies: 17 randomized control trials (RCT); 20 quasi-experimental studies; and four ecological and observational cohort studies. The authors define "uptake" and "coverage" because they were used interchangeably throughout the studies. The word "uptake" is defined as the eligible portion of the population that received vaccination during a specific time period. The word "coverage" describes the portion of eligible population that was vaccinated regardless of time. The interventions were complex due to variations in delivery, or the resulting impact on different outcomes (Crocker-Buque et al., 2017).

There were five intervention types for a total of 41 separate interventions. These included: reminder call systems; outreach programs; computer-based interventions; prompts for healthcare workers; and multicomponent complex interventions. The categories for outcomes were based on the intervention types and the different age groups requiring specific vaccines. The overall results did not include outcomes based on inequalities, and the authors were not able to find any research related to media use (such as text messages as reminders) in vaccine uptake to reduce inequalities (Crocker-Buque et al., 2017).

Other limitations to the study were that vaccine hesitancy was not addressed in the surveys, nor was the cost-effectiveness of interventions. The authors concluded that although some technologies have not yet been evaluated, locally designed

multicomponent interventions showed evidence of being effective in ethnically diverse deprived urban populations. The authors also concluded that in well developed countries with high incomes there are a significant number of differences pertaining to gender, vaccine uptake and socioeconomic status, ethnic background, religion, and geographical location (Crocker-Buque et al., 2017).

The IOM conducted more than 60 vaccine safety studies in 40 years that included an extensive review of the immunization schedule. There has been no proof that not receiving vaccinations on-time would cause major safety issues. The IOM study concluded that even though not receiving vaccines on-time was not harmful, following the recommended vaccine schedule is strongly linked to the prevention of vaccine-preventable diseases (IOM, 2013).

The research study based on socioeconomic status, belief, gender, location, and ethnicity by Crocker-Buque et al. (2017), focused on the inequalities among groups, and the effectiveness of the interventions implemented to address them. There were separate studies on vaccine hesitancy. Neither study type measured vaccine uptake nor outcome. The researchers recommended interventions to increase community demand, increase community access, and increase provider delivery of screening services. These interventions are better known as multicomponent interventions that have been defined by the Community Preventative Services Task Force and proven to be effective in urban, ethnically diverse, deprived populations. Further studies are needed that target ethnic groups and those with specific religious beliefs that directly affect decisions on vaccines (Crocker-Buque et al., 2017).

Vaccines are biological agents, which makes them more difficult to manufacture than many other drugs. The suggested solutions for addressing manufacturing issues are to offer financial incentives to pharmaceutical companies to encourage vaccine production to maintain an adequate supply of high-quality vaccines. Research and development (R & D) results in better techniques, innovative technologies, and new and improved drugs. Pharmaceutical companies need to qualify for tax credits offered by the internal revenue, as an incentive to research and manufacture vaccines (Offit, 2005).

Program Partnerships

Government programs and services that work in partnership to address disparities and the health needs of the community benefit from funding through the PPACA. The partnerships between the VFC, WIC, and local immunization programs are an example of encouraged collaborations that have a strong impact on the health outcomes of mother and child. The WIC program's primary focus is nutrition, but it's screening services increase the likelihood of children participating in the program being vaccinated. There are approximately seven million mothers participating in the WIC Program each month (National WIC Association, 2018). The US Census Bureau for Administrative Records Research and Applications (CARRA) oversees an ongoing research project that integrates census and state government data of undercounted children, particularly minorities under the age of five years. The project links data from the Administrative Records, the American Community Survey, and third-party sources such as Medicaid and the Department of Urban Housing and Development. It is then utilized in identifying the

different characteristics between children under 5 years being reported and those not being reported (Fernandez et al., 2018)

The data collected from the American Community Survey and WIC administrative records are measured to identify and evaluate populations: eligible for WIC benefits; eligible and participate in the program; and eligible, but do not participate in the program. Demographic and economic information of each population characteristics is studied for trends over time that can be used to improve program effectiveness and efficiency. The WIC Management Information Systems (MIS), designed to support frontline WIC services, collects vast amounts of data that cannot be easily retrieved or analyzed by the research community. This is partially due to non-standardized definitions and data collection procedures that vary from state to state which makes variable comparisons difficult. A priority of the WIC program is the maintenance of high-quality data that can one day be attainable to community researchers for surveillance. monitoring, planning, and evaluating the program's effectiveness and efficiency (National WIC Association, 2018).

The VFC program provided free vaccines to eligible children through a network of 61 grantees and 44,000 enrolled providers in 2010. The success of the program resulted in approximately 82 million vaccine doses administered to an estimated 40 million children. The cost for protection against life-threatening diseases in that year was $3.6 billion. VFC providers are expected to meet certain criteria in vaccine management to become an eligible provider of the free vaccines (Department of Health and Human Services, 2012). The U.S. Department of Health and Human Services Office of the

Inspector General (OIG) conducted a study using CDC data to determine vaccine management by participating VFC providers. A sample of 45 VFC providers taken from five grantees, and who had ordered the highest volume of vaccines, were visited at their clinical locations. These clinical sites were observed for their management and oversight practices of vaccines. The primary vaccine requirements of concern included vaccine inventory, documentation, and storage management. The investigation found that 76% of the 45 providers had stored the VFC vaccines at the wrong temperature for at least five hours. Expired vaccines had been stored with non-expired vaccines by 13 of the providers, increasing the risk of administering a less effective vaccine. Also, providers had fallen short of the required vaccine management, documentation, and oversight practices. The CDC requirements for VFC management are vital to the safety and efficacy of the program as they are intended to reduce the risk of abuse, waste, and fraud (Department of Health and Human Services, 2012). This study highlights the importance of utilizing a system's approach to evaluating all aspects of a program. The participants involved in the manufacture, distribution, management of medication, and healthcare services for vaccines must adhere to strict guidelines and regulations to not only reduce waste, but also prevent harm and mistrust in the community. Administering ineffective vaccines would require notifying patients that they must be re-vaccinated, which might produce doubt and fear about the safety of vaccines. Such errors could negatively impact the outcome of an immunization program.

Conclusion

The primary goal of all immunization programs and interventions is the prevention and/or eradication of disease. Insight into issues that affect utilization, improvements in technology, development of effective strategies, and changes in policy are all major concepts to address the gaps in immunization. Durrheim (2016) suggests a sensitive means for detecting gaps in immunity. The initial problems lie in the collection of the data. The accuracy, completeness, and timeliness of the data representing a community is critical for developing valid and reliable immunity profiles for populations. The data must be collected in a careful consistent way using a process of standardized definitions and protocols. Highly contagious diseases like the measles expose gaps in immunity when there are outbreaks in subpopulations. These setbacks can be looked at as an opportunity to develop new tools and techniques for detecting and servicing vulnerable populations.

The United States is a culture with layers upon layers of subcultures that primarily have common ideals and beliefs about quality of health, but many subgroups express their beliefs differently based on ethnicity, culture, or experience. This is true for many populations around the world. The task of developing a solution for closing immunity gaps in a complex and diverse society is daunting and requires a stable, reliable, and adaptable approach (Andersen, 1973).

The well-known barriers that prevent access and delivery of successful immunization coverage include poverty, poor education, lack of resources, and misconceptions. Evidence shows that the one common denominator in most all studies on

vaccine prevention is the impact socioeconomic status has on vaccine rates. Yet, the interventions that most programs create to improve rates do not adequately target inequalities. It is even more difficult to address vaccine hesitancy, as this challenge relates to personal beliefs and attitudes that influence decision making and behavior (Andersen, 1973).

The United States spends more on health care than any other industrialized nation in the world. It is unfortunate that the quality of health care in the U.S. is not at the forefront when compared to many other countries. Most problems are associated with healthcare costs and access related to resources and primary care providers. Most health plans under the PPACA are expected to cover a set of preventive services, like shots and screening tests, at no cost to the patient. Government agencies, health organizations and services, health providers and community stakeholders must be committed to the improvement of healthcare services. The U.S. has a complex healthcare system that is unpredictable, characteristically dynamic, nonlinear, and has a complicated framework. Those involved in policymaking should keep this in mind when developing guidelines and regulations.

Definition of Key Terms

Access: Access to health services means "the timely use of personal health services to achieve the best health outcomes"(IOM, 1993, p. 219). Access requires three distinct steps: entering the health care system (usually through insurance coverage); accessing a location where needed health care services are provided (geographic availability); finding

a health care provider whom the patient trusts and can communicate with (personal relationship) (National Healthcare Quality Report, 2013).

Andersen model: The Andersen model developed by Ronald M. Andersen and is a conceptual model that describes the factors that influence the use of health services. Usage of health services (including inpatient care, physician visits, dental care etc.) is determined by three dynamics: predisposing factors, enabling factors, and need. Predisposing factors can be characteristics such as race, age, and health. Predisposing factors reflect the individuals' propensity to use health services, enabling factors are the resources that may facilitate access to services, and the need factors represent potential needs of health services use, such as self-perceived health, chronic conditions, and restricted activity (Andersen, 1995).

Anti vaccinationists: The anti vaccinationists (sometimes known as "anti-vaxxers") which include parents, politicians, religious leaders, and more, are strongly opposed to vaccination, particularly childhood vaccination. At its core, the anti-vaccination movement argues that vaccines are unnecessary, ineffective, or dangerous (Blume, 2006).

Barriers: Barriers to health services include inadequate or no insurance coverage. Poor access to services includes disability status, geographic region, demographics language spoken, socioeconomic status, and the high cost of care. The ability to access care affects health care utilization, which includes whether it is available, timely and convenient, and/or affordable- (Department of Health and Human Services, 2019).

Cohort: A cohort is a group of individuals having a statistical factor (such as age or class membership) in common in a demographic study and refers to people who are

approximately the same age. When researchers conduct different types of studies (for example, developmental/cross sectional studies), they use cohorts to see how people of different ages compare on some topic at one point in time (Merriam-Webster Dictionary, 2019b).

Community-based programs: The Steps to a Healthier US (now Healthy Communities program) is a Centers for Disease Control and Prevention (CDC) initiative that provides funding to communities to identify and improve policies and environmental factors influencing health to reduce the burden of obesity and other chronic diseases, and to encourage people to become more physically active, eat a healthy diet, and not use tobacco (Trust for America's Health, 2009).

Community-based Organizations (CBO): The CBO is a public or private nonprofit organization of demonstrated effectiveness that-(A) is representative of a community or significant segments of a community; and (B) provides educational or related services to individuals in the community. The CBO nonprofit groups work at a local level to improve life for residents. The focus is to build equality across society in all streams - health care, environment, quality of education, access to technology, access to spaces and information for the disabled, to name but a few (U S Legal, 2019).

Comprehensive Clinic Assessment Software Application (CoCASA): COCASA is a tool for assessing immunization coverage and practices within a provider clinic, or any other environment where immunizations are provided. CoCASA has immunization data entry and Immunization Information System (IIS) data import capabilities. After immunization data is entered or imported into CoCASA, data analysis capabilities can be

utilized for coverage assessment purposes providing a variety of different reports that can be utilized to pinpoint areas of strength and areas requiring improvement for an individual immunization provider. CoCASA generates reports of childhood adolescent vaccine coverage, invalid doses, missed opportunities, and more (CDC, 2019a).

Diphtheria: Diphtheria is an infection caused by the bacterium Corynebacterium diphtheriae. Diphtheria causes a thick covering in the back of the throat. It can lead to difficulty breathing, heart failure, paralysis, and even death. CDC recommends vaccines for infants, children, teens, and adults to prevent diphtheria (CDC, 2018a).

Evidence-based research: Evidence-based research is the information used to make informed decisions about patient health care, which is based on sound research, not opinion. Several valid, reputable studies from published articles in medical journals must be researched (or in electronic form) for data, results, and conclusions (University of Rhode Island, 2015).

Federal poverty guidelines: The Federal Poverty Level (FPL), or the "poverty line" is an economic measure that is used to decide whether the income level of an individual or family qualifies them for certain federal benefits and programs. The FPL is the set minimum amount of income that a family needs for food, clothing, transportation, shelter, and other necessities. U.S. Federal Poverty Guidelines are used to determine financial eligibility for certain federal programs. To calculate percentage of poverty level, divide income by the poverty guideline and multiply by 100 (Kenton, 2019)

Health Immunization Information System (IIS): Immunization information systems (IIS) are computerized databases that record all vaccine doses administered by providers

participating in the program. These databases are confidential and population-based in each geopolitical area. The IIS can provide consolidated immunization histories at the point of care wherein providers determine appropriate client vaccinations. The IIS provides aggregate data at the population level for use in surveillance and program operations. The CDC surveys jurisdictions through an annual self-administered IIS Annual Report (IISAR) to monitor progress of program goals (CDC, 2019e).

Immunization: A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation (CDC, 2018b).

Immunization program: A national immunization program (NIP) is the organizational component of Ministries of Health charged with preventing disease, disability, and death from vaccine-preventable diseases in children and adults. A NIP is a government program that operates within the framework of overall health policy. The national immunization program is used interchangeably with the Expanded Programme on Immunization (EPI) that originally focused on preventing vaccine-preventable diseases in children (WHO, 2019c).

Immunization registry: The immunization registry is a confidential, population-based, computerized information system that attempts to collect vaccination data about all persons within a geographic area. It consolidates the immunization records from multiple sources for each person living in its jurisdiction (The Free Dictionary, 2019).

Measles: Measles is a very contagious respiratory infection. In fact, nine out of 10 people who are not vaccinated for measles will get it if they are near an infected person. It causes

a total-body skin rash and flu-like symptoms. People with measles can spread the disease from four days before the rash starts until about four days after that. They are most contagious while they have a fever, runny nose, and cough. Measles (also called rubeola) is caused by a virus, so there is no specific medical treatment for it. A measles infection can last for several weeks. Symptoms usually start 7–14 days after someone is exposed to the virus. The virus must run its course. (The Nemours Foundation, 2019).

Measles, mumps, and rubella (MMR): M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against measles (rubeola), mumps, and rubella (German measles). Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older (Merck Sharp & Dohme Corporation, 1971).

Multicomponent interventions: Multicomponent interventions are a combination of two or more intervention approaches that have been reviewed by the Community Preventive Services Task Force (CPSTF). Combinations are selected from eleven possible individual approaches that are separated into three strategies: increasing community demand, increasing community access, and increasing provider delivery of screening services. Multicomponent interventions to increase cancer screening may be coordinated through healthcare systems, delivered in community settings, or both (The Community Guide, 2019).

Mumps: Mumps is a contagious disease that is caused by a virus. It typically starts with a few days of fever, headache, muscle aches, tiredness, and loss of appetite. Then most people will have swelling of their salivary glands. This is what causes the puffy cheeks and a tender, swollen jaw (CDC, 2019b).

Rubella: Rubella is a highly contagious viral disease that comes from the nose and throat of an infected person. Once the virus becomes airborne, it spreads through droplets or mist on a surface or another person. Rubella can cause mild symptoms of low fever, joint pain, swollen glands, and a fine red rash in most children and adults. Pregnant women in their first trimester of pregnancy can have severe complications. These include severe birth defects or death of the fetus (Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, & Allied Health, 2003).

Socioeconomic status: Socioeconomic status is the social standing or class of an individual or group. It is often measured as a combination of education, income, and occupation. Examinations of socioeconomic status often reveal inequities in access to resources, plus issues related to privilege, power, and control (American Psychological Association, 2019).

Vaccination: The act of introducing a vaccine into the body to produce immunity to a specific disease (CDC, 2018b).

Vaccine: A medication that stimulates a person's immune system to produce an immune response to a specific disease, resulting in the person being protected the from that disease. Vaccines can be administered through needle injections, by mouth, or sprayed into the nose (CDC, 2018b).

Vaccine campaign: A vaccine campaign is a focused effort for promoting childhood and adult immunizations; explaining the basics of vaccines, including the safety of immunizations, why they are important, who should get them and possible side effects. Highlighting the dangers of communicable diseases and effectively improving people's perceptions of immunization (Crawford, 2018).

Vaccine coverage: Vaccine coverage is the information used to identify areas and groups with lower vaccination coverage so public health departments, health care partners, and schools can take action to help improve vaccination coverage and protect everyone from vaccine-preventable diseases (CDC, 2016c).

Vaccine hesitancy: Vaccine refusal is an unwillingness to allow oneself or a family member to be immunized against a preventable contagious disease, such as measles, mumps, rubella, or chickenpox. It occurs most often in people who fear adverse effects from vaccination, in people who have religious or philosophical objections to vaccination, and in people who have had allergies to a component of a vaccine. Vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccination services (Medical Dictionary, 2009).

Vaccine uptake: Vaccine uptake is the act of being vaccinated. A range of factors influence whether a person is vaccinated or not. The Increasing Vaccination Model states that what people think and feel, and social influences will affect motivation to vaccinate. Practical factors affect the ability to act on the motivation and get vaccinated (WHO, 2019d).

Assumptions

The major assumption for this study is that immunization programs implemented by the ODH have had a strong impact on immunization rates by providing education and accessible resources to its communities statewide. Vaccine mandates are set by state health departments to ensure the maximum number of children will be vaccinated. Still, many individuals have philosophical or religious beliefs that conflict with the idea of immunization. It appears that behavioral determinants are the unpredictable factors that drive a parent's decision whether to have their child vaccinated. Parents who refuse to vaccinate may feel their rights are being infringed upon when mandates require their child must be vaccinated. This issue can occur if the public is at risk of succumbing to a highly contagious disease, and to protect the public from the vaccine preventable disease, state regulations override an individual's right.

The assumption that data collected from physician offices, clinics, and other medical facilities that give immunizations is up to date, and includes all children in the community it represents, can be misleading. There is no standard data collection process in the state of Ohio. This means the collection process of immunization information varies from county to county resulting in a possible underestimation or overestimation of the actual population being vaccinated. Until the implementation of EHR systems throughout the state are completed, and a more consistent data collection and reporting methods are developed, secondary data from federal and state agencies are the best resources for research.

Scope and Delimitations

In the U.S., the resurgence of the life-threatening disease, measles, has become a matter of major concern for high-risk populations. Families of poor education and low socioeconomic status living in areas of high disparity, are the most vulnerable, according to studies. The immunization programs provide free vaccines and education to families in need. The belief was that the vaccine preventable disease was eradicated because the gaps had successfully been filled pertaining to access, availability of resources, and education. The vaccine for measles is required to be given to children under the age of five years, identifying this age as the critical point for prevention to avert unnecessary suffering or death (CDC, 2019b).

This quantitative study focuses on children 0-35 months in the state of Ohio. Annual measles immunization rates are measured and compared over a seven-year period. The predisposing factors that include marital status, socioeconomic status, and insurance status are considered as possible influencers of decision making when seeking and receiving care. This study investigated whether the immunization program implemented by the Ohio Department of Health had an effect on the vaccination rates by making available the necessary resources and health services. The inquiry analyzed the annual vaccine rates of the target population during the seven-year timeframe before and after the implementation of the PPACA to determine the program's effectiveness in servicing the local community and surrounding areas. The PPACA, a policy intended to improve access to healthcare, was made available to families who previously had little to no financial options for adequate care before 2010. Many families gained access to

medical care in the state of Ohio through various programs and insurance options (specifically Medicaid expansion) after the regulatory overhaul and expansion of health coverage. Many families with children under the age of 5 and who qualified to receive Medicaid due to the expansion could take advantage of WIC services, as well. A 7-year comparison analysis was conducted to determine which subpopulations had poor coverage outcomes, which can be an indicator of poor performance by the ODH Immunization Program in some areas. It was hoped that the study would also identify possible changes in certain community characteristics over time that affect coverage.

The limitations to the study exclude certain populations and pertinent information that require a qualitative analysis. The population for the study is limited by age, whereas the decision to be vaccinated is directly dependent upon the parent. There are limitations to the study that pertain to the health status of the child before and after being vaccinated. The data information collected did not reveal whether any children contracted the measles virus, thus deeming it not necessary to vaccinate in such cases. Data relating to individual ODH regional operations, which include management, and day to day distribution of resources and services, was unavailable for this study. The data did not identify areas of high disparity, but the analysis did reveal whether relationships between the variables affected immunization rates. Therefore, performance is determined by outcomes or yearly vaccine rates, which is determined by yearly vaccine rates in alignment with the 0-35-month cohort population growth.

The scientific method utilized for this quantitative study can be adapted to any state, community, or combination of states for a multiple regression and comparison

analysis. The researcher can formulate a hypothesis based on observations and measurable data related to the conditions and problems of the region and/or programs being evaluated. All variables should be specific to the region and population of interest.

Significance, Summary, and Conclusions

The ODH immunization prevention program is designed to promote health access and education to protect vulnerable populations from the threat of disease (ODH, 2018). There is limited literature describing the affects the ODH Immunization Program has had on the 0-35-month cohort and the barriers that the program is designed to address. This study investigated whether the social and personal characteristics of families with infants increase or decrease measles vaccine rates in Ohio. There is the possibility that ineffective communication, poor access to facilities and the financial resources of families are influential factors that can lead to the failure of an immunization program. The prevention of health crisis or pandemic from a life-threatening disease saves lives and limits the number of undue medical occurrences, thereby reducing the economic burden in healthcare. The measles is a vaccine-preventable disease once eradicated in the U.S (CDC, 2018c). Herd immunity is no longer effective in some communities. The resurgence of the disease in Ohio suggests that many populations in Ohio communities may not have access to immunization programs (either geographically or financially) or may be misinformed or uneducated to the benefits of being vaccinated.

Researchers are needed to investigate complex scientific processes and health issues. Complicated science also needs a facilitator to explain and discuss the findings to initiate collaboration and support for a global movement towards successful universal

health programs. The collection of data in healthcare must be consistent and subjected to guidelines that promote validity and reliability for safety, education, and training, as well as for improvement in operations and delivery. It is important to comprehend the method and collection of data for more efficient and reliable data-sharing and transparency between agencies. A standardized method of collecting data is necessary for tracking and monitoring all vaccinated and unvaccinated individuals residing in the state. EHR systems are an effective way of collecting and sharing massive amounts of information to improve health programs and practices. Adequate data is also critical for building evidence-based research. The information collected is vital for preventative programs in their efforts to eradicate vaccine-preventable diseases.

Research of the measles vaccine coverage in various communities might reveal possible gaps in the ODH efforts for addressing low literacy and accessibility in communities of disparity. Ohio expanded Medicaid under the PPACA policy to allow residents of the state to enroll in the Medicaid program year-round and qualified healthcare plans (QHP) which are offered through open enrollment in the Ohio insurance exchange or marketplace. The QHP is also the federal marketplace website known as Healthcare.gov. (Qualified Health Plan, 2020). By participating in the VFC and WIC Programs, Medicaid providers can give free vaccines to all eligible children they service (CDC, 2016). The state mandates for increasing vaccine coverage are also expected to be effective interventions for improving vaccine rates. Still, the recent measles outbreaks in 31states, including Ohio, are indicators that researchers and stakeholders must remain

diligent in their fight against deadly diseases that affect the most vulnerable populations (CDC, 2019g).

The Andersen Model was chosen as the basis for the research design to investigate the relevant characteristics of the population and predisposing factors that affect use of services. The data was analyzed for trends and consistencies using a logistic regression analysis. The findings provide information for the improvement of services and policy. The next section will discuss the design and methodology for this study in detail.

Section 2: Research Design and Data Collection

This research study was designed to investigate the effectiveness of the Ohio Department of Health Immunization Program by assessing the measles vaccine coverage across the state in the 0–35-month cohort beginning in 2010 through 2016. The time period is crucial in relation to the implementation of the PPACA of 2010 and is meant to provide a clear picture of success, failure, or improvement in the ODH efforts to increase access to healthcare across the state. After implementation of the policy, key programs were created or modified to address the needs of populations lacking economic stability, insurance, or education, as well as placing high priority on those at risk for a potential health crisis. This mission centered around preventative care is not only important to the health and safety of the public, but critical to keeping the cost of care at a minimal.

The measles virus causes an extremely contagious respiratory infection that can become fatal in infants and children who have not been treated with the measles, mumps, and rubella (MMR) vaccine. The disease, once eradicated in the United States, has had a resurgence that threatens the lives of populations with little to no access to quality healthcare. A recent factor that contributes to the health crisis is due to the increased number of parents that delay or refuse to have their children vaccinated because of religious, philosophical, or cultural reasons. However, some parents may not agree to vaccinate because of misinformation, poor education, socioeconomic status, or medical reasons. Issues surrounding vaccine refusal affects herd immunity by decreasing the number of individuals immunized necessary to keep the unimmunized protected. According to the Ohio Department of Health and Human Services, the necessary

percentage of immunized individuals to achieve adequate protection against the measles virus is 95% of a community. In this case scenario, an effective immunization rate is ultimately achieved due to reduced symptoms in the population, as well as a decreased disease rate. The more individuals immunized reduces the risk of those not immunized being exposed to the lethal pathogen (Ventola, 2016).

The development and implementation of vaccines by government agencies have been the most effective strategies against life-threatening childhood diseases. Vaccines are the safest, most extensively studied, and most effective preventative medicine introduced in the 20th century. Health threats such as measles, mumps, and rubella can be eliminated when vaccines are readily available, and families have adequate access to resources. It is estimated that due to the recommended childhood immunizations, there is a $70 billion savings in healthcare (Ventola, 2016).

Government organizations and agencies, with the assistance of community programs are dedicated to creating and implementing services that address the needs of all populations. The technological support of EHR systems for data collection, and scientific studies aimed at providing evidence-based research is critical to addressing the issues surrounding immunization. The mission of the ODH Immunization Program is to increase immunization coverage for the entire population and ensure equity of access regardless of geographic or financial barriers. Recent and frequent outbreaks of the measles virus indicate gaps in the efforts made by these organizations and agencies. It is imperative that the problem and cause is identified, and a feasible strategy is developed to

rectify the issue. Considering the highly contagious and lethal nature of the disease, time is of the essence.

This study was intended to determine the effectiveness of Ohio agencies designated to provide education, financial support, and access to the MMR vaccine. The analysis discovered patterns and trends in the data to suggest a possible lack of support or an increased support in certain areas. The first approach to evaluating effectiveness is an adaptation of the Andersen model by utilizing a logistic regression analysis to identify which populations and population characteristics are relevant to a family's ability to access care. Based on outcomes of the number of vaccines given over time, and the evaluation of areas having access to immunization programs, a picture should emerge revealing which populations are at risk. The next section will provide details of specific variables, how and where data is collected, and the design constructs for analyzing pertinent information. This section also identifies possible threats to validity and discusses the precautions necessary to maintain ethical procedures to produce an objective and authentic statistical analysis.

Research Design and Rationale

The pertinent factors for inquiry are specific characteristics of the families with children in the Ohio valley. The dependent variable of the study is the vaccine rates of the 0–35-month cohort for the metropolitan/micropolitan regions of the state. The state of Ohio is equally proportioned into regions based on the population density of certain areas. Annual surveys are conducted to collect health and insurance related information to assist with analyzing access to healthcare coverage. Quality data is utilized to identify

emerging health problems, monitor trends, and develop and oversee public health programs and policies. The independent variables for this study consist of demographic statistics for families of the 0–35-month cohort. The mediating or intervening variables are the WIC program, chosen as a proxy for insurance status, and the VFC program. The independent covariates are race, income, education, employment, and marital status of the parents. The research examined Ohio immunization rates and statistical data related to family demographics per year over a 7-year period, then analyzed the factors that affect access. The study lacked enough information to identify populations at risk of a measles outbreak. Reliable data could expose areas with low vaccine rates, or areas under the recommended 95% coverage to establish herd immunity (CDC, 2019h). A comparison analysis was conducted for similarities, patterns, and trends over the 7-year period.

The vaccine rates in the target population can be further described as the number of children who received the measles vaccine, either through the VFC program or other means afforded to their families. The VFC program is federally funded and typically awarded to low-income families or Medicaid recipients. The independent covariates or demographic information chosen for the study were measured characteristics that are specific to the population of each region. The availability of an immunization program that provides free vaccines to eligible children was expected to show some value and/or influence on vaccine rates. The independent variables were analyzed for a relationship that affects the number of vaccines given at any point and time during the 7-year period. The time period of the data for this analysis is crucial in that the vaccine rates being measured begin with the year 2010, after the implementation of the PPACA, and

continue through 2016. The timeframe of the data gave sufficient insight into any influence the ODH Immunization program has had on access to immunization.

As previously discussed, the analysis for this study was an adapted version of the Andersen behavioral model using a multivariate logistic regression analysis to identify and compare patterns or similarities within the data. The research questions ask:

RQ1: What is the relationship between the federal assistance program WIC and the measles vaccine rates for children 0-35-months old in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

RQ2: What was the relationship between VFC program designed to improve access to the MMR vaccine and the measles vaccination rates for children 0-35-months old in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

The Andersen model identifies characteristics that influence the use of medical services, such as the level of education, access to resources, and financial status. The model describes three dynamics that influence a parent to make the decision to seek health services: predisposing factors (race, age, gender, culture), enabling factors (finances, resources, availability, and access), and need (based on patient health or environmental factors). The “need” in this study is described as the necessity for disease prevention, in light of the resurgence of the measles.

The research questions for this analysis ask if there is a relationship between vaccine rates and characteristics meant to remove barriers or influence health decisions. The study also investigated whether there was a relationship between the immunization program and vaccine outcomes. The Andersen model allows the researcher to analyze

and evaluate all pertinent factors to determine if a relationship exists. The adaptability of the model can target specific populations and allows for the addition of more than two variables for a comparison analysis. The Andersen model takes a holistic approach to explain complex phenomena.

Methodology

Population

The study explored challenges the ODH faces when implementing its immunization program to vulnerable populations to improve access and vaccine rates. This is a quantitative study that investigated the variables relevant to the vaccine outcomes of a sample population of the 0–35-month cohort in Ohio. There has been a slight fluctuation in this number over time depending on the region. This study was intended to identify the characteristics of at-risk populations to improve access to vaccines and produce evidence-based information for more practical and successful interventions.

Sampling and Sampling Procedures

The sample population wherein data for the study were drawn represent approximately 11.5 million people in 88 counties of the state of Ohio (United States Census Bureau, 2018). The sub-population, or the sample population, was derived from state and local estimates of vaccine coverage in Ohio based on information obtained from surveys conducted by the National Center for Immunization and Respiratory Diseases (NCIRD) of the CDC. Authorization for conducting these surveys derived from the United States Public Health Act of 1944, which granted the federal government authority

to prevent the introduction and transmission of contagious diseases from other countries through the collection of health statistics, research, and initiation of quarantines (CDC, 2019e). The policy held the United States Public Health Service accountable for preventing the spread of communicable diseases into and within the country's borders (Public Health Service, 1944).

An adequate representation of all population groups is necessary to produce results that will be beneficial when devising methods for system evaluation or monitoring and operation analysis. The detailed state data was originally collected from Ohio Impact Statewide Immunization Information System (ImpactSIIS), which stores demographic, socioeconomic, and immunization records on all Ohio populations. The information is stored and utilized by authorized users to track and edit patient information and by the ODH for monitoring and surveillance. The state measures its progress towards eradicating vaccine-preventable diseases by tracking vaccine rates in children 0-35-months. Data regarding family insurance status information and participation in the VFC program are also collected in surveys and interviews, then encrypted for patient protection. The Ohio Department of Medicaid increased its efforts to collect population-level health and health systems data specific to Ohio's Medicaid and Medicaid eligible populations which are critical to assess the potential impact of the PPACA.

The ODH Methodology Standard is designed to protect the personal or confidential health information that is utilized for public disclosure. Those providers that collect this information are responsible for following guidelines and regulations to ensure confidentiality. The disclosure limitation standard set by the ODH is beneficial in that it

allows data to be used by program approved users and prevents the misuse of data. The vaccine information collected by the Ohio Immunization registry is also monitored by the Department of Health and Human Services, National Center for Health Statistics and the CDC for public safety purposes based on the Public Health Service Act of 1944, Section 306 (Public Health Service, 1944).

The data for this study was derived from surveys conducted by the CDC's National Center for Immunization and Respiratory Diseases (NCIRD). The National Immunization Surveys were collected from all 50 states and territories of the United States of America. The surveys were designed to "check" vaccination coverage of children and teenagers after an outbreak of the once eradicated measles in the 1990s. Only information for the state of Ohio was acquired for this analysis. The number of surveys conducted in Ohio from 2010-2016 ranged from 357-443, annually, and was calculated based on the estimated area of residence for that particular year (CDC, 2015). Multiple independently pooled samples of the NIS annual surveys from 2010-2016 were collected and tested for variability. The total number of random sample surveys from Ohio for the years 2010-2016 were combined into a larger "pool" of surveys. Sample pooling results in a numerical statistical sample of the population that represents all apparent variations in the population, as well as the average characteristics of the total population (Deming, 2018). This method was allowed for a more precise estimate of the population characteristics when obtaining results of individual comparison analysis. The core concept in a quantitative analysis is based on determining the variance or inconsistencies in relation to normal occurrences. Variance is calculated to determine

how randomly a variable or characteristic occurs in the population. Variance can show how strong of a relationship each variable has with each other. A parameter is set where the probability of a certain population characteristic will fall between the parameter values. This is known as the confidence interval (CI) and should reveal the true values that represent the population characteristics when repeated over time (Deming, 2018).

Instrumentation and Operationalization of Constructs

The authorized data obtained from the National Immunization Surveys (NIS) contain identifying characteristics and measurable data collected from participating households across the United States for the years 2010-2016. The telephone interviews were conducted with an authorized parent or guardian of the child in question. The CDC states that the data is used for statistical purposes only and that no personal information is released. After receiving consent to notify the child's healthcare provider, a questionnaire was mailed to acquire adequate vaccination information for each child in the household. Possible ethical issues may pertain to appropriate use of data. Maintaining ethical standards in transfer and utilization of information is a priority and was addressed when accessing the data. Patient privacy was not an issue, as personal information was not disclosed in the data necessary for this study.

The questionnaire for the NIS consists of demographic, socioeconomic, and geographic information. There were also questions that were intended to obtain detailed information about vaccination status and health insurance access. The original intent was to investigate the relationship between insurance status and its effect on vaccine rates. The WIC program was used as a proxy for insurance status because there was not

sufficient data to perform an analysis using the insurance status of the child. The question to determine insurance status of the child asked what type of insurance and several options were listed and numbered as: 1 = Medicaid, 2 = state government healthcare assistance, 3 = private insurance, and 4 = self-pay/no insurance. If this information were available in the data, it would be key to determining which families have the financial support or insurance needed to gain access to vaccines, those families receiving government assistance, and families with no financial means for medical care. The detailed responses for categorical variables allow for insight into the influences that may affect the use of health services. WIC participation was utilized as a substitute for Medicaid recipients who were also eligible for free vaccines.

The demographic information is listed as age, sex, race, marital status, educational level, household income, and employment status. The variables age, sex, and employment status were not used in this study. The telephone surveys collected information from an adult in the household on either a landline or cellular phone. Children ages 19 to 35 months for each data collection year were born between January and July of the previous year. The dataset has adult and child codes for the variables pertinent to this study. The following section describes the variables and the value system that were utilized for analysis.

The NIS contains a substantial amount of information for assessing up-to-date status and age-appropriate immunization. The NIS is also the only data source to provide comparable vaccination data across states and local regions in the United States. The data collected contains a series of questions that illicit answers that are given as a numerical

value: 1= “Yes,” 2= “No,” 98= “DK” for Don’t know, 99= “RF” for refused/no response/missing values, or a specific answer was given to a question requiring more detailed information. The variables listed from the immunization history questionnaire generally do not have specific missing value codes. The adult respondent or responsible party for the child were asked the county where they live and their relationship to the child, which was matched to an answer list and corresponding number.

The independent variables race, educational level, and income level list categorical responses pertinent to this study. Previous studies have shown that ethnic and racial disparities continue to exist in education and in healthcare. After the state of Ohio adopted Medicaid expansion under the PPACA, new health programs were developed, and the number of insurance options increased to include an underserved population. It is important to know whether the family has health insurance or not, or what is the family’s income level, but also if they receive medical assistance, since there are certain criteria that makes a child eligible for free vaccines. It is important to know that not all insurances cover the cost of vaccines. The independent variable, marital status has a binary value. Marital and educational status are all variables that typically effect the financial dynamics of the family. All factors examined in this study have the propensity for increasing or decreasing access to healthcare, whether in combination or as a single influence that affects one’s decision to seek care or to gain access to care. The following paragraph explains the codes that will be utilized in this study.

The education level of the respondent is given a categorical value from one to four listed as: no high school diploma, high school graduate, some college, college

degree, respectively. The respondent is asked the number of children <12 months, and/or 1-3 years in the home. For the purposes of this study, information is listed for each age group. Demographic and immunization information is completed for each child, and the respondent and the child are given an identification number. The question for race is listed and numbered as: 1= White/non-Hispanic, 2= Black/non-Hispanic, 3= Hispanic, 4= Other non-Hispanic, and 5= Multiracial. Marital status is given binary values as: 1= Married, or 2= Not married. The living arrangements of different families are influenced by their culture and life events, and must be investigated to determine its impact, if any, on healthcare utilization.

The respondent was asked to provide information for vaccines appropriate for the child's age, and specifically if the child received the MMR vaccine. It is recommended by the Advisory Committee on Immunization Practice (ACIP) that the critical point of prevention for the measles vaccine is to give it to children 0-35 months. The vaccine is generally given as the MMR vaccine. The answer corresponds with the value for yes, no, DK, or RF, as previously noted. Information regarding free vaccines through the VFC program is given by the respondent, or permission is given to contact the participating provider when collecting the data. The question asks if the child qualifies for the free vaccine and the answer is given a binary value as 1= yes, or 2= no. This information was utilized in the study to determine who was eligible for the free vaccines compared to the number of children who actually received the measles vaccine (Table 1).

The variables for this quantitative study can be described as data that when observed or measured can reveal changes that can be explained. The dependent variable

has a discrete value in which the frequency of occurrence in the sample population is evaluated for each region from 2010 to 2016. The observed numbers for any year are expected to coincide with the population numbers revealing a 95% or above coverage of the cohort population. A comparison study of annual outcomes and population characteristics reveals which sub-population(s), if any, fall short of the expected goals of the ODH Immunization Program in any given year. The population(s) revealing low coverage are identified and examined more closely for trends or patterns by further investigation of the independent variables.

The nominal or independent variables which are descriptive and used for comparison analysis are race, education, income level, marital status, and WIC participation. First, an individual comparison analysis of the variables was conducted to provide a clear picture of the diverse groups within the population and determine their significance in relation to the families of the 0–35-month cohort. The results were measured and analyzed for significance. The results provide a baseline for determining which variables have bearing on vaccine rates. Then two or more independent variables were analyzed in combination to evaluate how much change occurred, if any, in vaccine rates. An example would be the combination of the two variables, education, and marital status, of all families with a child or children under 35 months, and the effects both variables have on the number of vaccines given per year. If after analysis, the number of children vaccinated increased, then it could be said that the two variables have more influence together, than separately for that year. Participation in the WIC program represents a portion of children receiving Medicaid, and who were eligible to receive the

measles vaccine through the VFC program. Even though the results do not represent all the children eligible for the VFC program via Medicaid, the findings can determine if the program's screening practices and partnerships with immunization programs are effective in improving vaccine rates. This is based on Medicaid as an insurance intended to improve access to vaccines by being available to underserved populations. The intent is to measure the relationship between the variables by determining if one variable influences the other. This type of analysis was completed for each year, as family conditions may change for different populations over time. Changes can be due to reasons associated with economics or environment, for example. The presence of the VFC program, is a preventative intervention and primary quality indicator, and is expected to be available for underprivileged children to improve access to vaccines. Finally, income, for families that allowed their children to be immunized, was analyzed as a continuous numerical variable, and evaluated for significance and/or influence on the number of vaccine rates annually.

A combination of evidence-based interventions and resources have shown improvement in vaccination rates at the community level (The Community Guide, 2017). The ODH's implementation of the VFC Program after the introduction of the PPACA is a collaborative effort to address the shortcomings in preventative measures against life-threatening vaccine preventable diseases. A Pearson Correlation was utilized to test the individual characteristics of the 0–35-month-old populations, such as race and insurance status, or race and vaccine rates over time to reveal any inconsistencies. The aim was to identify and track trends that tend to be disproportionate in certain populations.

Inconsistencies between populations might suggest the program should be adapted to meet the needs of the community that is suffering insufficient access. The data variables for comparison are vaccine rates and children participating in the WIC and VFC programs, as well as the sociodemographic factors: parent education, marital status, income level, and race. The independent variables were examined for potential multicollinearity and to identify the factors associated with the under immunization of populations. The Spearman Correlation analysis was utilized when examining any ordinal independent variables, such as the educational or income level of the parent. This analysis was intended to identify those regions where the Department of Health and Human Services might find it necessary to increase the number of strategies to improve vaccine rates. The linking of immunization health services, like the National WIC Association and the Academy of Pediatrics for example, that focus on the infant/child population, are strategically positioned by the Department of Health and Human Services to address immunization efforts. These partnerships are an adjunct to other immunization services provided by the state of Ohio. As previously mentioned, children eligible for Medicaid are also eligible for the WIC program. The WIC Program partners with other health organizations and services in coordinating efforts to improve immunization levels in children, thus WIC was added as an independent variable.

An example of an influential trend may be an increase or decrease in Medicaid enrollment in a specific population group of the 0–35-month-old children over time. Then a Pearson Correlation analysis was used to determine whether this trend affects annual vaccine rates. The analysis is measuring for influence and not necessarily how much of

an impact the variables have had on annual vaccine rates over time. The increase in Medicaid enrollment simultaneously with an increase in vaccine rates might suggest the program has had a positive effect in that region of the state, since Medicaid enrollment is synonymous with access to free vaccines. Tables and figures are used to illustrate the relationships between all variables.

Data Analysis Plan

The software used for analyzing the data for this research study is the Statistical Package for the Social Sciences (SPSS). The statistical analysis allowed for an impact evaluation on the accessibility and use of vaccines. The methods used for this analysis were intended to improve the way immunization programs are assessed.

RQ 1: What is the relationship between the federal assistance program WIC and the measles vaccine rates for children 0-35 months old in Ohio from 2010-2016, adjusting for race and socioeconomic status?

$H_0$1: There is no relationship between the federal assistance program WIC and vaccine rates of children ages 0-35 months old in Ohio from 2010-2016.

H_a2: The federal assistance program WIC increased vaccine rates of children 0-35 months old in Ohio from the year 2010-2016.

RQ 2: What was the relationship between the VFC program designed to improve access to the MMR vaccine and the measles vaccination rates for children 0-35 months old in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

$H_0$2:There is no relationship between the VFC program designed to improve access to the MMR vaccine and the measles vaccination rates of children 0-35 months old in Ohio during the years of 2010-2016.

H_a2:The VFC program designed to improve access to the MMR vaccine increased vaccination rates of children 0-35-months old in Ohio during the years of 2010-2016.

The null hypothesis for a study using a multiple logistic regression analysis suggest there is no relationship between the dependent variable and the independent variables. The outcomes which are described as the vaccine rates for each region are assumed to be random and occur only by chance. From this type of analysis, an equation can be developed that will best predict the change effect, if any, to the dependent variable by the independent variables. Since the multiple logistic regression does not assume that the variables are normally distributed, the resulting P value is used only as a guideline to develop an equation that includes any independent t variable that has a significant relationship with the dependent variable. This means the P value is not used to measure the strength of the relationship between the dependent and independent variable, but as a determinant of which variables are best suited in the analysis. The results are compared for patterns and similarities that occur during each year. Charts, graphs, and tables were constructed to reveal correlations between variables and illustrate which populations have been significantly affected by the independent variables. In other words, illustrations allow for a visual description of each sample population to be observed based on the relationship between the dependent variable and each independent variable.

The vaccine rates for the sample population are tabulated and compared from 2010 to 2016 for measured variations. The years 2010-2016 were evaluated for changes observed after the implementation of the PPACA, which expanded Medicaid. All sub-population results during the seven-year period were evaluated for characteristic variations that had some impact on the outcomes. Specifically, financial and insurance characteristics that effect access to resources, whether singularly or in combination with other variables. This was accomplished by using a cross-sectional regression analysis of the secondary data for each sample population for each year. The observations were used to describe the cause and effect of the variables on vaccine rates, and describe the relative risk associated with those regions that have experienced poor results.

The quality indicators for a successful immunization program were defined and listed as access to services, which include the availability of the VFC program, clinical and educational services, and financial assistance. The availability of these services and partner programs and services are vital for parents' informed decision-making as to whether their child should be vaccinated or not. The quality indicators were compared during final analysis to determine if access is lacking in an at-risk population. The completed analysis did identify an at-risk population, and which determinants might influence the effectiveness of the ODH Immunization programs for the sample population representing the state of Ohio.

Threats to Validity

It is the intent of this researcher to reduce threats to validity by choosing a large enough random sample of the population. It is important that the analysis compares

different groups with varying characteristics related to their health environment and the resources available to the region. The differences and/or commonalities established can reveal motivators or potential influences that effect outcomes. A threat that may be difficult to overcome is related to the activities of anti vaccinationists in their efforts against immunization. Another threat of similar circumstance relates to personal beliefs, religion, or social norms of particular populations that do not accept the concept of immunization. Researchers must keep in mind that outcomes in healthcare are often influenced by social interactions, which include patient/physician relationships, and are not necessarily the result of interventions and demographics.

The number of young children accounted for in each county through medical and school records is uploaded into the local and state databases. Immunization records for these children are used for monitoring and surveillance of life-threatening diseases. Determining which population is at risk and developing interventions greatly depends on data that includes as many characteristics as necessary to identify the root of the problem. The lack of, or minimalization of identifying factors of the population threatens the validity of the results. Too few identifying characteristics or the omission of pertinent information during an analysis can result in misleading conclusions. The analysis is only as good as the sample size and data input. If the data is not reliable or does not represent the entire population adequately, then the analysis will show bias. Adequate and relevant data is also critical to successfully producing a valid and reliable research study. Researcher bias can occur if significance is distorted where no pattern or trend exists in the data and despite this revelation, the researcher misinterprets the results by concluding

there is a relationship. Therefore, caution is taken to ensure that the methods and analysis of comparison and correlation are the appropriate fit for the study, and that inferences made accurately explains the variability of all results.

Ethical Procedures

In accordance with the Federal Department of Agriculture regulations, Institutional Review Board (IRB) approval is necessary to proceed with research involving human subjects. The committee is designated to protect the rights of research participants and ensure informed consent has been acquired before the research study can begin. Approval of the Proposal by the IRB allows the researcher to proceed with the study, including data collection and analysis. Ethical procedures encompass the moral responsibility to protect the privacy of participants and is intended to maintain the integrity and authenticity of the research. This is accomplished by ensuring researchers follow a code of conduct that promotes the protection and appropriate use of data, accountability for errors, and objectivity with the use of information. In this study, permission was obtained from the appropriate administrative departments in the ODH for access to secondary data containing quantitative and characteristic information only. Large volumes of public health data are stored in the Ohio Public Health Information Warehouse. The information in this warehouse is collected from two main sources, the U.S. Bureau of Census and the ODH documents, that include reports from hospitals, clinics, physician offices, and other external sources. Researchers may obtain raw data from the ODH or CDC by formal request. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is a federal law that prevents any violation of

patient rights to privacy pertaining to personal identifiers and medical information without that person's consent. The medical professional or researcher when collecting patient information must request permission from that patient for use of health information for purposes of study which is obtained by written consent at the point of care, or before surveys are given. The raw data is encrypted for patient privacy by state and federal agencies. There is no personal contact or knowledge of participants when accessing the secondary data from these agencies. The potential risk associated with ethical procedures for this study is related to data transfer from server to server. The data was transferred and saved to a USB flash drive that was used on a private computer system protected by Norton Security. For extra precaution, the system was not connected to the internet or other external systems during analysis. The computer system is equipped with the SPSS and Excel programs and was purchased specifically for the purpose of this study. All raw data was handled according to agency regulations and researcher guidelines. All necessary steps and precautions were rendered to prevent illegal acquisition or hacking of the data during transfer and personal use by this researcher.

Summary

The framework for this study is a statistical approach to determine the effectiveness of the ODH Immunization Program's mission to provide equity of access to the MMR vaccine. A regression analysis was expected to reveal variables or indicators that demonstrate whether or not immunization services are adequate in improving access to vaccines over time. The analysis was expected to show which factors are most relevant

and any relationships that might give insight on improving access. The methodology for evaluating the performance of a health delivery system is complicated and requires a review of many operational components. Access to such information is limited for this study and would not necessarily correlate with the factors that influence a parent's decision to vaccinate their child. Therefore, this study focused on simple variables that are applicable across all populations, and are easily monitored, collected, and measured for impact.

Section 3: Presentation of the Results and Findings

Socioeconomic status, education, and access to healthcare have a profound effect on the livelihood of families no matter where they live. The financial status and education of families directly influence the health status of each family member and the family's ability to seek medical care when necessary. Taking preventative measures at an early age to reduce the risk of contracting a highly contagious life-threatening vaccine preventable disease, such as measles, greatly reduce the probability of a resurgence of the disease and promote the eradication of the disease. Early prevention also aids in the reduction of medical costs for treating preventable diseases that develop into serious conditions (CDC, 2020b). The most vulnerable high-risk populations for measles anywhere in the world are infants and children 0-35-months-old. This age is the primary level of prevention for promoting optimal health. Immunization at this age prevents needless suffering, injury, and death.

The immunization programs implemented by health organizations are designed to improve access to vaccines through available resources, education, and financial assistance. The implementation of the ODH Immunization Program has made it possible for families experiencing low income and disparity to receive vaccines at little or no cost through the PPACA and the VFC program. With the resurgence of the once eradicated measles disease, questions arise as to whether the ODH Immunization Program has successfully addressed the issues plaguing many communities across the state. This research asks:

Research Question 1 (RQ1): What is the relationship between the federal assistance program, Women, Infants, and Children (WIC) and the measles vaccine rates for children 0-35 months in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

$H_0$1:There is no relationship between the federal assistance program WIC and the measles vaccine rates of children ages 0-35 months in Ohio from 2010-2016.

H_a1 - The federal assistance program WIC increased measles vaccine rates of children 0-35 months in Ohio from the year 2010-2016.

Research Question 2 (RQ2): What was the relationship between the Vaccines for Children (VFC) program designed to improve access to the MMR vaccine and the measles vaccination rates for children 0-35 months old in Ohio from 2010 to 2016, adjusting for race and socioeconomic status?

$H_0$2 -There is no relationship between the VFC program designed to improve access to the MMR vaccine and measles vaccination rates of children 0-35 months in Ohio during the years of 2010-2016.

H_a2 – The VFC program designed to improve access to the MMR vaccine increased measles vaccination rates of children 0-35 months within Ohio during the years of 2010-2016.

The presumption is that the insurance status of families and/or the VFC program may influence the vaccine rates in children 0-35-months-old in the state of Ohio in a positive way. This quantitative study was an attempt to find the answers to those questions.

This section describes the data and collection process used to conduct a multiple logistic regression analysis and a Pearson Correlation analysis to test the study assumptions and ultimately answer the research questions. The variables associated with disparity in the 0-35-month-old cohort in Ohio, the intervening factors, and the vaccine rates were assessed and measured for relationships and correlation among the variables over a seven-year period. A comparison study was conducted testing the effect the independent variables have on the vaccine rates of the 0-35-month-old cohort and the findings of these analyses are discussed and evaluated for relevance.

Data Collection and Secondary Data Set

The CDC sets regulations and guidelines for data collection, as well as coordinating and collaborating with all health organizations on data collection standards, data use and sharing, and patient confidentiality. The state and local immunization registries and health management systems provide data support and are committed to improving data quality and promoting data use. The data obtained from the CDC for this research study was easily accessed through the CDC website and originated from telephone surveys conducted by the National Center for Immunization and Respiratory Diseases (NCIRD). The NIS-Child data is an estimation of annual vaccine coverage of infants and children across the United States. The NCIRD collected information from families with children of the targeted age. The survey was given to a qualified guardian for the child. Demographic and health information consisting of vaccine series and actual doses administered to the child was obtained from the guardian and/or child's healthcare provider via mail in survey, only after guardian consent was given.

The secondary data used for this study consist of surveys for children 0-35-months for the years 2010-2016 in the state of Ohio. The Council of American Survey Research Organizations (CASRO 1982) defines the standard approach for measuring response rates in telephone surveys. Some children received vaccines from more than one provider, therefore the number of questionnaires mailed to providers exceeds the number of completed interviews for children with consent. A User Guide is available for each year surveys given and provides information pertaining to data collection and response rates.

The original intent for collecting the datasets was to import data directly into the SPSS program, but this proved to be quite challenging. Instead, a Stata program was used to import and prep the data. Data from the seven datasets spanning the survey years of 2010 to 2016 were downloaded from the NIS data repository into R Studio. The Stata software allows for multiple datasets to be put into memory where the data can be accessed, linked, and create new datasets without changing the original dataset. The new datasets called “frames” can be used interactively. Standardized R input statements were also downloaded, and this code was run over the datasets to properly label, code, and process the data files, which were then exported in .csv format for further analysis in STATA 15.1. The seven data files were merged into one comprehensive dataset representing the timeframe between 2010-2016 and responses from all locations other than Ohio were deleted. Ten variables from the NIS dataset were used for this analysis (Table 1). State and adequate provider data were used to limit the study sample to the appropriate responses. Only residents of Ohio and children with adequate provider data,

and thus adequate outcome data, were included in this study. Independent variables used included race/ethnicity, family income, maternal education, maternal marital status, receipt of WIC benefits, and whether providers ordered vaccine from state or local health departments through the VFC program.

Table 1

Variables from National Immunization Survey Dataset Used for Analysis

Original Variable Name	Variable name used in analysis	Description	Modifications from original	Type of variable	# of Categories	Responses
---	id	Unique identifier for each survey response	Generated	Continuous/ numeric	N/A	---
YEAR	year	Year of survey	N/A	Continuous/ numeric	N/A	2010-2016
STATE	state	State of residence	Limited to Ohio	Categorical	1	Ohio
OPDAT	adeq_prov_ data	Child has adequate provider data (used to define study sample)	N/A	Binary	2	1=Yes 0=No
RACEETHK	race_eth	Race and ethnicity (combined) of child	N/A	Categorical	4	1=Hispanic 2= Non-Hispanic White 3= Non-Hispanic Black 4=Non-Hispanic Other + Multiple Race
INCQ298A	fam_income2	Family income	"Don't know" and "refused" set as missing	Categorical	12	1=$0-7,500 2=$7,501-10,000 3=$10,001-17,500 4=$17,501-20,000 5=$20,001-25,000 6=$25,001-30,000 7=$30,001-35,000 8=$35,001-40,000 9=$40,001-50,000 10=$50,001-60,000

Original Variable Name	Variable name used in analysis	Description	Modifications from original	Type of variable	# of Categories	Responses
EDUC1	mat edu	Education level of mother	N/A	Categorical	4	11=$60,001-75,000 12=$75,001+ 1=Less than 12 years 2=12 years 3=More than 12 years, non-college grad 4=College grad
MARITAL2	mat_married	Marital status of mother	N/A	Binary	2	1=Married 0=Not married
INS_STAT_I*	hlth_insur	Insurance status of child	N/A	Categorical	4	1=Private 2=Medicaid 3=Other insurance 4=Uninsured
CWIC_01	wic_ever2	Child ever received WIC benefits	"Never heard of WIC" and "Don't know" set as missing	Binary	2	1=Yes 0=No
VFC_ORDER	vfc2	Providers order vaccines from state/local health dept	Combined original categories into binary variable	Binary	2	1=All or some order from VFC 0=No providers order from VFC
P_UTDMMX	utd_mmr	Child is up to date with MMR vaccine	N/A	Binary	2	1=Yes 0=No

Note. *Missing data (n=2,615; 92%). Excluded and used CWIC_01 as proxy variable.

Variables

When assessing the data for variables necessary for the study, it was found that there were multiple combinations to describe race and ethnicity. The categorization variables for race are: 1= race; 2= ethnicity; or 3= race/ethnicity. The category variable, race/ethnicity, was chosen for this study since it defines and includes all backgrounds. There were multiple variables listed for income as: 1= income to poverty ratio (I-P ratio), 2= poverty status, and 3= family income. Family income was chosen because it has more monetary categories and can be easily used to define and interpret the family

socioeconomic status (Table 1). Employment status for the child's parents was unavailable for analysis.

Financial resources for health care are available for those families at the poverty level and is provided through the state and federal governments. The missing data for health insurance posed a problem for identifying those children who qualify for the free vaccines offered through the VFC program. The largest category of children eligible for the VFC program are Medicaid-enrolled children according to the CDC (CDC, 2016). The Medicaid program varies from state to state, but each state must file a Medicaid State plan amendment to cover its Pediatric Immunization Program. This is the only way the state may receive Federal funds to operate its Medicaid program and to receive free vaccines from the VFC program. A monthly income of $1,784 or less, or annual income of $21,404 or less, qualifies a child for Children's Medicaid (CDC, 2016). Thus, those children that receive Medicaid are also eligible to receive free vaccines through the VFC program.

The variable, child ever received WIC benefits, was used in this analysis instead of insurance status because of an extreme number of missing data (92%) for the insurance status variable. The NIS Survey listed the insurance status variable as having four categories that include, 1= Private, 2= Medicaid, 3= Other insurance, and 4= Uninsured (Table 1). Eligibility requirements for WIC, includes families with an income at or below an income level or standard set by the state agency. WIC participants can also be determined income-eligible automatically based on participation in certain programs, such as Medicaid. The income standard must be between 100 percent of the federal

poverty guidelines (issued each year by the DHHS) but cannot be more than 185 percent of the federal poverty income guidelines (the same as Medicaid) (US Department of Agriculture [USDA], 2016). The variable is a binary variable with the response; 1= Yes, or 2= No, when answering whether the child had ever participated in the WIC program (Table 1). The linking of other immunization programs and services with the WIC program has previously shown significant improvement in immunization coverage of infants and young children participating in the WIC program (US Department of Agriculture [USDA], 2016). WIC played a crucial role during the measles epidemic in the 1990s in helping to increase measles vaccination rates among WIC participants (US Department of Agriculture [USDA], 2016). WIC holds a unique position in providing access to the high-risk 0-35-month-old population who are most in need of immunizations. This is accomplished when parents bring infant/child immunization records per request to WIC appointments so that the staff can screen vaccine records as part of the WIC certification process. The role of the WIC Program is to screen for unvaccinated children, inform the parents, then give a referral for an immunization appointment (US Department of Agriculture [USDA], 2016).

When assessing which variable to use pertaining to the vaccination question, it was found that there are an excessive number of variations to describe what type of measles vaccine the child might have received. This is because the measles vaccine can be administered as the MMR vaccine, the measles vaccine alone, or in combination with other vaccines. This research study is concerned with the MMR vaccine, so this variable was chosen for analysis. One dose is recommended for children less than 35 months of

age; therefore “up to date” status indicates that the child received one dose of MMR vaccine. The dependent variable, vaccine rates, in this analysis is defined as the “up to date” MMR vaccine status of children under the age of 35 months (Table 1).

Analysis

The sample of children with adequate provider data were compared to children with inadequate provider data to determine whether there were any significant differences between the populations that might limit the generalizability of results. Further descriptive analysis of the study sample (i.e., children with adequate provider data) by year are presented using frequencies and proportions. The Pearson’s chi-squared test ($\chi 2$) was used to determine if there were any significant differences in demographic characteristics by year or by vaccination status, and whether vaccination coverage differed annually. Differences in vaccination status by demographic characteristic were also analyzed for each year, where the proportion of children vaccinated were plotted using a series of line graphs.

To assess research question 1 (RQ1), a bivariate analysis between the receipt of WIC benefits and vaccination status was performed using Pearson’s chi-squared test. This test was followed by a multiple logistic regression analysis where vaccination status was the dependent variable and receipt of WIC benefits, race, and family income (a measure of socioeconomic status) were the independent variables. A similar analysis was conducted for RQ2 where participation in the VFC program was compared to vaccination status using multiple logistic regression. Additional ad hoc analyses were performed as

needed (i.e., Spearman's correlation) to further explore or explain results of the regression models.

Results

Descriptive Statistics

Between 2010-2016, the target population resulted in 2,836 children residing in Ohio being surveyed through the National Immunization Survey (NIS). Adequate provider data, or the provider-reported vaccination data, were required to assess and confirm vaccination coverage of the 0-35-month-old cohort. In total, 1,739 (61.3%) children met this criterion and had data pertaining to the MMR vaccine. Demographic characteristics of the 0-35-month-old children and their families is presented in *Table 2*. The table also displays the recorded provider data status and compares families having adequate recorded data to those without adequate recorded data using Pearson's chi-squared test ($\chi 2$).

Table 2

Demographic Characteristics of Children and Families by Provider Data Status.

	Total *N* (%)	Adequate Provider Data *N*	Adequate Provider Data %	Inadequate Provider Data *N*	Inadequate Provider Data %	*P* value
Race/Ethnicity						.15
Hispanic	194	110	6.3	84	7.7	
Non-Hispanic White	2,025	1,266	72.8	759	69.2	
Non-Hispanic Black	333	191	11.0	142	12.9	
Non-Hispanic Other or Multiple Race	284	172	9.9	112	10.2	
Family Income						.50
$0-7,500	160 (5.6)	107	6.1	53	4.8	
$7,501-10,000	135 (4.8)	83	4.8	52	4.7	
$10,001-17,500	171 (6.0)	115	6.6	56	5.1	
$17,501-20,000	109 (3.8)	66	3.8	43	3.9	
$20,001-25,000	117 (4.1)	73	4.2	44	4.0	
$25,001-30,000	127 (4.5)	81	4.7	46	4.2	
$30,001-35,000	83 (2.9)	50	2.9	33	3.0	
$35,001-40,000	124 (4.4)	73	4.2	51	4.6	
$40,001-50,000	203 (7.2)	124	7.1	79	7.2	
$50,001-60,000	149 (5.2)	96	5.5	53	4.8	
$60,001-75,000	275 (9.7)	155	8.9	120	10.9	
$75,001+	951 (33.5)	612	35.2	339	30.9	
Don’t know	98 (3.5)	57	3.3	41	3.7	

	Total *N* (%)	Adequate Provider Data *N*	Adequate Provider Data %	Inadequate Provider Data *N*	Inadequate Provider Data %	*P* value
Refused	134 (4.7)	47	2.7	87	7.9	
Maternal education						.12
Less than 12 years	274 (9.7)	178	10.2	96	8.7	
12 years	547 (19.3)	332	19.1	215	19.6	
More than 12 years, non-college graduate	760 (26.8)	442	25.4	318	29.0	
College graduate	1,255 (44.2)	787	45.3	468	42.7	
Maternal marital status						.01
Married	1,942 (68.5)	1,221	70.2	721	65.7	
Not married	894	518	29.8	376	34.3	
Ever received WIC benefits						.97
Yes	1,249 (44.0)	768	44.2	481	43.8	
No	1,571 (55.4)	965	55.5	606	55.2	
Never heard of WIC	6 (0.2)	3	0.2	3	0.3	
Don't know	10 (0.3)	3	0.2	7	0.6	
Year of Survey*						<.00
2010	357	243	68.1	114	31.9	
2011	394	284	72.1	110	27.9	
2012	418	292	69.9	126	30.1	
2013	420	249	59.3	171	40.7	
2014	386	231	59.8	155	40.2	
2015	418	219	52.4	199	47.6	
2016	443	221	49.9	222	50.1	

Note. *Using % of row total instead of column totals.

Among the 1,739 children included in the final study sample, almost three-quarters (n = 1,266, or 72.8%) were Non-Hispanic White and had mothers who were married (n = 1,221, or 70.2%). More than one-third (n = 612, or 37.4%) had a family

income of greater than $75,000. Most mothers (n = 1,561, or 89.8%) had at least a high school diploma or equivalent degree, and approximately half of that group (n = 787, or 45.3%) had a college degree. Slightly more than half of children (n = 965, or 55.5%) had received WIC benefits at some point in their lives. Demographic characteristics, as well as the vaccination status of children by year of survey is displayed in *Table 3*.

Table 3

Demographic Characteristics and Vaccination Status of Children by Year of Survey, 2010-2016

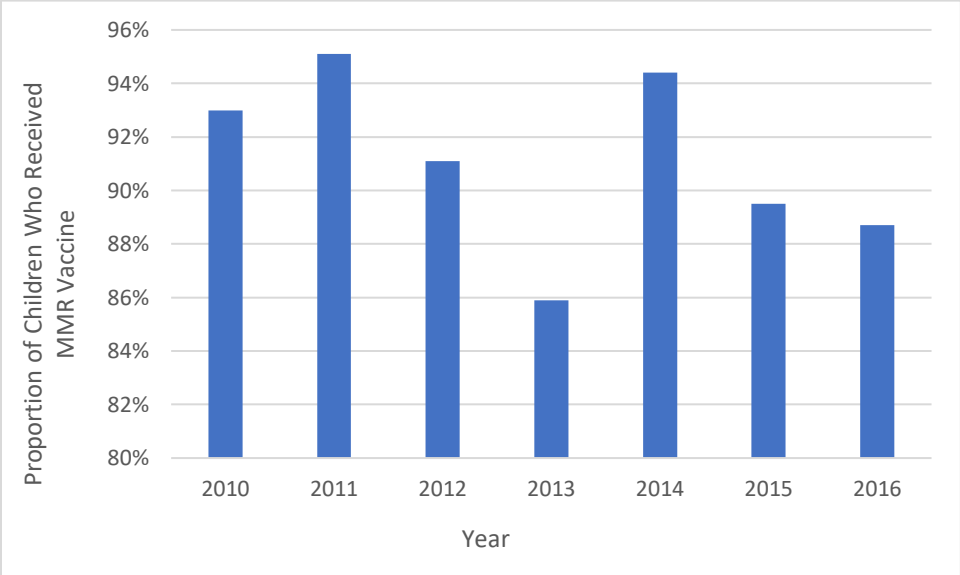
	2010	2011	2012	2013	2014	2015	2016	*P* value
Race/Ethnicity								< .00
Hispanic	14 (3.9)	17 (4.3)	32 (7.7)	37 (8.8)	25 (6.5)	22 (5.3)	47 (10.6)	
Non-Hispanic White	296 (82.9)	305 (77.4)	282 (67.5)	286 (68.1)	288 (74.8)	287 (68.7)	281 (63.4)	
Non-Hispanic Black	22 (6.2)	43 (10.9)	57 (13.6)	63 (15.0)	33 (8.5)	55 (13.2)	60 (13.5)	
Non-Hispanic Other or Multiple Race	25 (7.0)	29 (7.4)	47 (11.2)	34 (8.1)	40 (10.4)	54 (12.9)	55 (12.4)	
Family Income								.15
$0-7,500	9 (2.7)	27 (7.5)	32 (8.4)	29 (7.5)	17 (4.8)	23 (6.0)	23 (5.6)	
$7,501-10,000	12 (3.7)	18 (5.0)	22 (5.7)	24 (6.2)	19 (5.3)	23 (6.0)	17 (4.2)	
$10,001-17,500	16 (4.9)	26 (7.3)	29 (7.6)	27 (7.0)	21 (5.9)	28 (7.3)	24 (5.9)	
$17,501-20,000	12 (3.7)	14 (3.9)	17 (4.4)	21 (5.4)	10 (2.8)	12 (3.1)	23 (5.6)	
$20,001-25,000	12 (3.7)	16 (4.5)	23 (6.0)	19 (4.9)	15 (4.2)	13 (3.4)	19 (4.7)	
$25,001-30,000	12 (3.7)	15 (4.5)	21 (5.5)	23 (5.9)	18 (5.1)	14 (3.6)	23 (5.6)	
$30,001-35,000	11 (3.4)	12 (3.3)	10 (2.6)	14 (3.6)	8 (2.2)	14 (3.6)	14 (3.4)	
$35,001-40,000	18 (5.5)	19 (5.3)	17 (4.4)	23 (5.9)	18 (5.1)	11 (2.9)	18 (4.4)	
$40,001-50,000	26 (7.9)	20 (5.6)	21 (5.5)	28 (7.2)	29 (8.1)	37 (9.6)	42 (10.3)	
$50,001-60,000	21 (6.4)	22 (6.1)	26 (6.8)	24 (6.2)	16 (4.5)	17 (4.4)	23 (5.6)	
$60,001-75,000	52 (15.9)	40 (11.2)	34 (8.9)	37 (9.5)	45 (12.6)	39 (10.1)	28 (6.9)	
$75,001+	126 (38.5)	128 (35.7)	131 (34.2)	119 (30.7)	140 (39.3)	154 (40.0)	153 (37.6)	
Maternal education								.60
Less than 12 years	24 (6.7)	42 (10.7)	42 (10.0)	49 (11.7)	40 (10.4)	38 (9.1)	39 (8.8)	
12 years	67 (18.8)	68 (17.3)	79 (18.9)	88 (20.9)	67 (17.4)	79 (18.9)	99 (22.3)	

	2010	2011	2012	2013	2014	2015	2016	*P* value
More than 12 years, non-college graduate	98 (27.4)	110 (27.9)	111 (26.6)	118 (28.1)	108 (28.0)	108 (25.8)	107 (24.1)	
College graduate	168 (47.1)	174 (44.2)	186 (44.5)	165 (39.3)	171 (44.3)	193 (46.2)	198 (44.7)	
Maternal marital status								< .00
Married	270 (75.6)	284 (72.1)	284 (67.9)	264 (62.9)	283 (73.3)	278 (66.5)	279 (63.0)	
Not married	87 (24.4)	110 (27.9)	134 (32.1)	156 (37.1)	103 (26.7)	140 (33.5)	164 (37.0)	
Ever received WIC benefits								.15
Yes	137 (38.5)	175 (44.4)	186 (44.8)	203 (48.3)	160 (41.7)	188 (45.2)	200 (46.0)	
No	219 (61.5)	219 (55.6)	229 (55.2)	217 (51.7)	224 (58.3)	228 (54.8)	235 (54.0)	
Child's providers ordered vaccines from state/local health departments								.27
All or some providers	191 (87.2)	238 (86.9)	213 (82.6)	199 (84.0)	181 (85.4)	161 (84.7)	161 (90.7)	
None	28 (12.8)	36 (13.1)	45 (17.4)	38 (16.0)	31 (14.6)	29 (15.3)	16 (9.0)	
Child received MMR vaccine								.00
Yes	227 (93.0)	270 (95.1)	266 (91.1)	214 (85.9)	218 (94.4)	196 (89.5)	196 (88.7)	
No	17 (7.0)	14 (4.9)	26 (8.9)	35 (14.1)	13 (5.6)	23 (10.5)	25 (11.3)	

No significant differences were observed in family income, maternal education level, the receipt of WIC benefits, or whether the child's provider ordered vaccines through the VFC program. However, the proportion of Non-Hispanic White children vaccinated decreased over time while all other race/ethnicity groups increased ($\chi 2 = 71.2$, $p < .00$), and a greater proportion of mothers were unmarried in the later years of the study period ($\chi 2 = 28.2$, $p < .00$) (*see Table 3*). The proportion of children who received the MMR vaccine ranged from 85.9% to 95.1% and differed significantly by year ($\chi 2 = 20.3$, $p = .00$) (Figure 1). Herd immunity among children was only reached in 2011. In no other year did the proportion vaccinated reach the 95% threshold needed for herd immunity in measles (Figure 1).

Figure 1

Proportion of Children Who Received MMR Vaccine by Year



Bivariate Analysis

When performing individual bivariate analysis between demographic characteristics and vaccination status, the only significant factor was maternal education level (*Table 4*). As mothers received more formal education, the proportion of child vaccinations increased ($\chi 2 = 18.9$, $p < .00$). Interestingly, no individual subset of the study population reached 95% herd immunity over the combined seven-year period. Year to year variations in vaccination coverage was examined for statistical significance among demographic characteristics (Figures 2-5). Variations in maternal education (2015, see Figure 4), maternal marital status (2014, see Figure 5), and receipt of WIC benefits (2015, see Figure 6) were observed and were found to hold some statistical significance.

Table 4

Demographic Characteristics by Vaccination Status of Child

	Vaccinated	Not Vaccinated	*P* value
Race/Ethnicity			.62
Hispanic	103 (93.6)	7 (6.4)	
Non-Hispanic White	1,158 (91.4)	109 (8.6)	
Non-Hispanic Black	172 (90.0)	19 (9.9)	
Non-Hispanic Other or Multiple Race	154 (89.5)	18 (10.5)	
Family Income			.09
$0-7,500	94 (87.8)	13 (12.1)	
$7,501-10,000	74 (89.2)	9 (10.8)	
$10,001-17,500	103 (89.6)	12 (10.4)	
$17,501-20,000	58 (87.9)	8 (12.1)	
$20,001-25,000	64 (87.7)	9 (12.3)	
$25,001-30,000	69 (85.2)	12 (14.8)	
$30,001-35,000	46 (92.0)	4 (8.0)	
$35,001-40,000	66 (90.4)	7 (9.6)	
$40,001-50,000	108 (87.1)	16 (12.9)	
$50,001-60,000	91 (94.8)	5 (5.2)	
$60,001-75,000	144 (92.3)	12 (7.7)	
$75,001+	574 (92.3)	38 (6.2)	
Maternal education			< .00
Less than 12 years	151 (84.8)	27 (15.2)	
12 years	297 (89.5)	35 (10.5)	
More than 12 years, non-college graduate	398 (90.0)	44 (9.9)	
College graduate	741 (94.0)	47 (6.0)	
Maternal marital status			.17
Married	1,122 (91.8)	100 (8.2)	
Not married	465 (89.8)	53 (10.2)	
Ever received WIC benefits			.05
Yes	689 (89.7)	79 (10.3)	
No	892 (92.3)	74 (7.7)	
Child's providers ordered vaccines from state/local health departments			.35
All or some providers	1,249 (92.9)	95 (7.1)	
None	211 (94.6)	12 (5.4)	

Figure 2.

Year-to-Year Variations in Vaccination. Coverage by Demographic Characteristic of Child and Family.

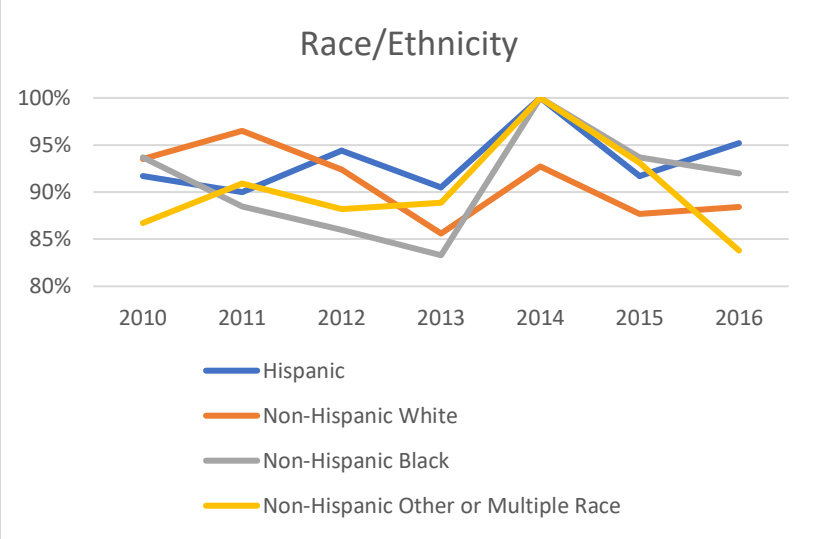


Figure 3.

Year-to-Year Variations in Vaccination Coverage by Demographic Characteristic of Child and Family Income.

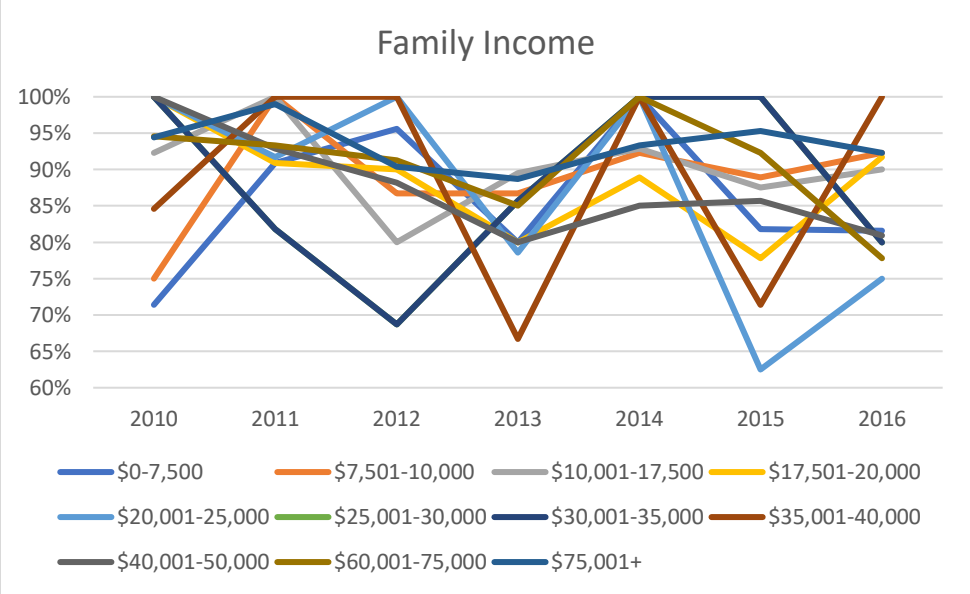


Figure 4.

Year to Year Variation in Vaccination Coverage by Demographic Characteristic of Maternal Education.

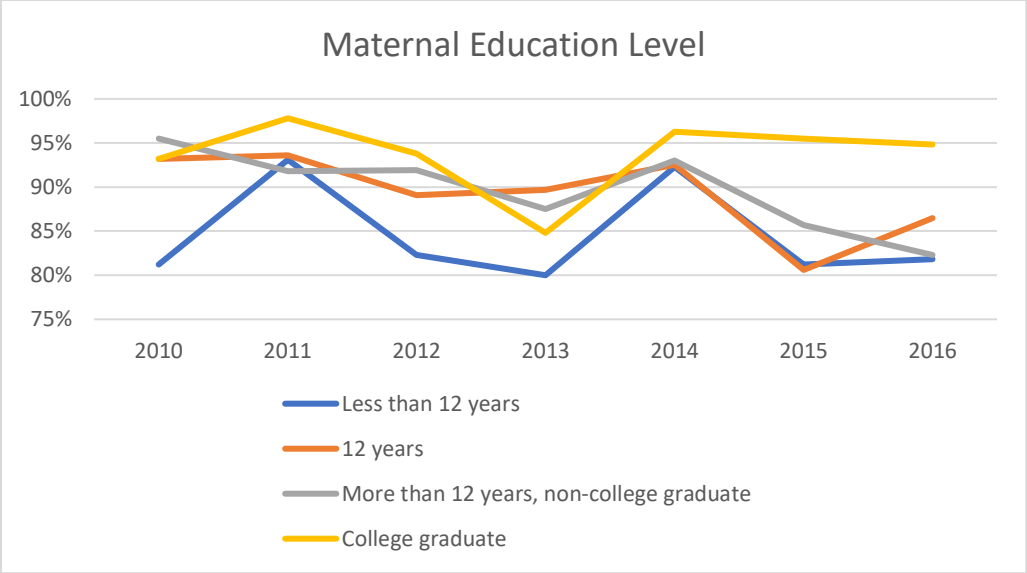
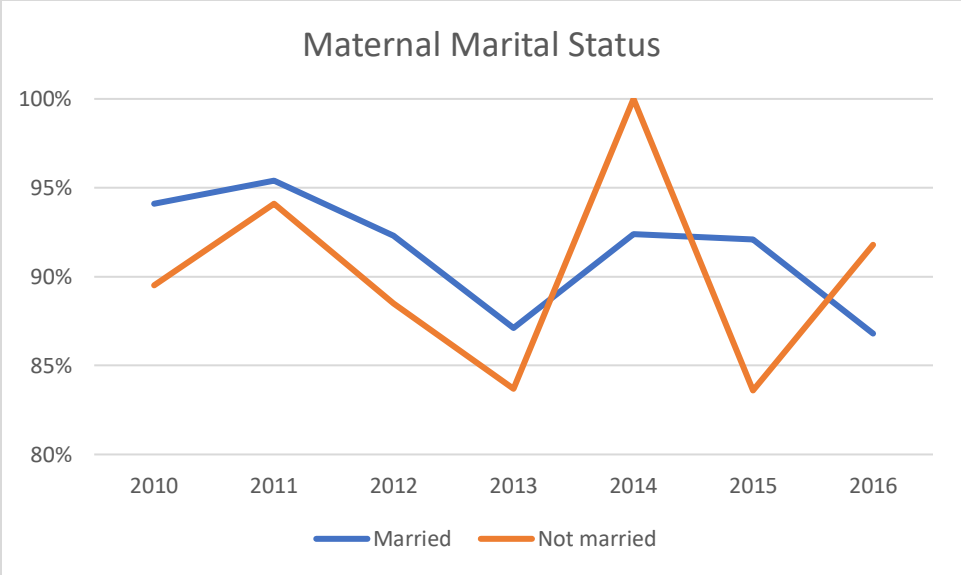


Figure 5.

Year-to-Year Variations in Vaccination Coverage by Demographic Characteristic Maternal Marital Status.



Multiple Logistic Regression Analysis-Research Question 1

To determine whether race and socioeconomic status as measured by family vaccination status among children (RQ1), multiple logistic regression was used. In the basic model where only the receipt of WIC benefits was included as an independent variable, receipt of WIC (*Table 5*) significantly increased the odds of vaccination by 40%, whereas odds ratio (OR) = 1.40, 95% CI [1.01 – 1.95], p = .04. The odds ratio or unadjusted OR means that no other factor is being tested for influence of the outcome, but this is not realistic. There may be many factors that associate with the dependent variable and that is why it is necessary to test other factors and "adjust" the model. The adjusted odds ratio considers the effect each variable may have when additional variables are included in the analysis. With the inclusion of race and family income in the model,

the receipt of WIC lost significance, resulting in the adjusted odds ratio of aOR) = 1.07, 95% CI [0.64 – 1.77], p = .80. Race/ethnicity was not a significant predictor of vaccination status (*Table 5*) however, family income was shown to be a significant predictor, resulting in aOR = 1.06, 95% CI [1.00 – 1.14], p = .04. With every categorical increase in family income (e.g., from $0-7,500 to $7,501-10,000), the odds of a child having received the MMR vaccine increased by 6%. Overall, this model was statistically better than a null model, or one without any predictors (p = .04). Therefore, we fail to reject the null hypothesis that there is no relationship between the receipt of WIC benefits and MMR vaccination status among children after controlling for race and socioeconomic status (*Table 5, Figure 6*). Under this analysis the researcher was unable to provide clear evidence for the alternative hypothesis.

Table 5

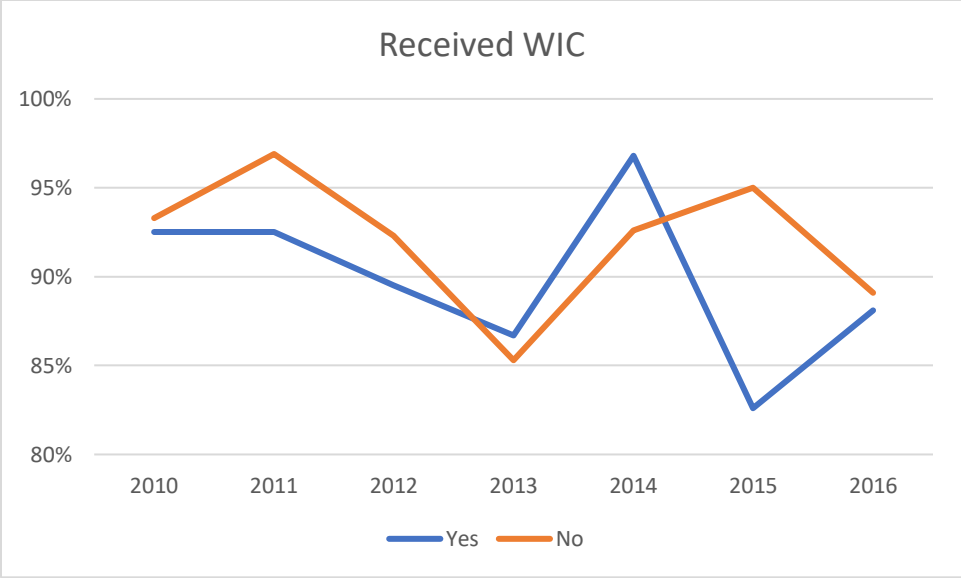
Logistic Regression Statistics Describing Receipt of WIC Benefits and MMR Vaccination Status of Children

	Odds Ratio	Std Error	Z	*P* value	95% CI
Basic Model					
Received WIC	1.40	0.23	2.03	.04	1.01 – 1.95
Constant	6.17	1.62	6.92	.00	3.68 – 10.35
Multivariate Model*					
Received WIC	1.07	0.28	.25	.80	0.64 – 1.77
Hispanic	1.58	0.65	1.11	.26	0.70 – 3.55
Non-Hispanic Black	1.13	0.32	0.43	.67	0.64 – 1.97
Non-Hispanic Other or Multiple Race	0.88	0.25	-0.43	.66	0.51 – 1.53
Family income	1.07	0.03	2.03	.04	1.00 – 1.14
Constant	5.31	1.61	5.52	.00	2.94 – 9.62

Note. *Non-Hispanic White was used as the comparison group.

Figure 6.

Year-to-Year Variations in Vaccination Coverage by Demographic Characteristic of Child and Family Receiving WIC Benefits.



Post hoc Analysis 1

In bivariate analysis, the only variable with a significant association to vaccination status was maternal education level (*Figure 3*). Maternal education and family income were found to be strongly correlated with one another ($r = 0.63$, $p < .00$). A post-hoc regression model that included maternal education as a covariate supported this finding, where family income became non-significant (aOR = 1.03, 95% CI [0.96 – 1.10], p = .40). Maternal education was statistically significant, whereas the aOR = 1.37, 95% CI [1.11 – 1.68], p = .00. It is important to note that maternal education was also significantly associated with receipt of WIC ($\chi 2 = 1000$, p = .00), due to mothers with higher levels of education less often having reported ever receiving WIC benefits.

Multiple Logistic Regression Analysis-Research Question 2

RQ2 explores the relationship between the VFC program and measles vaccination status among the 0-35-month-old cohort. Using provider orders of vaccines through the VFC program to estimate use of the VFC program, a second set of multiple logistic regression models were conducted. In the basic model where only VFC participation was included as an independent variable, it was not a significant predictor of vaccination status (OR = 0.75, 95% CI [0.40 – 1.39], p = .36) (*Table 6, Figure 7*).

Table 6

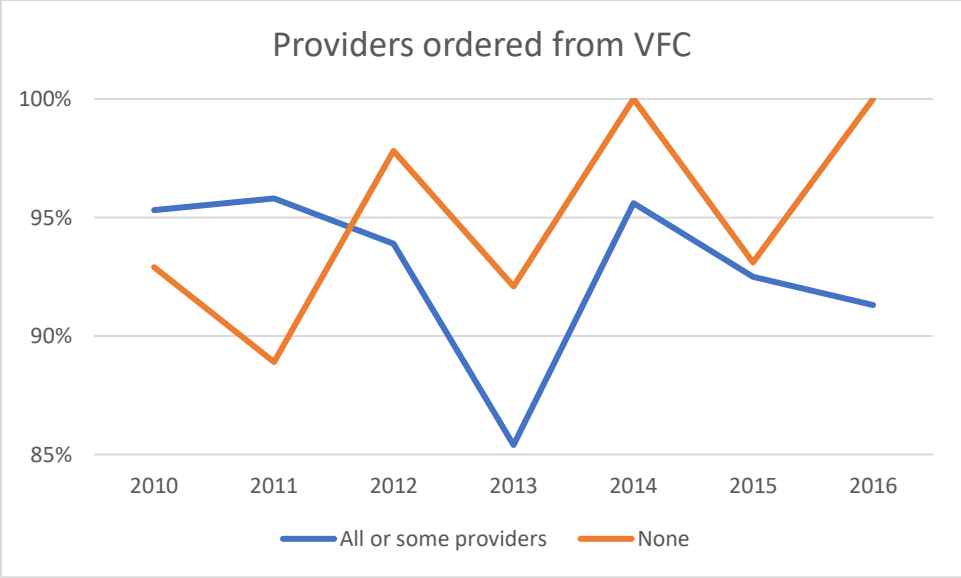
Logistic Regression Statistics Describing Participation in the VFC Program and MMR Vaccination Status of Children

	Odds Ratio	Std Error	Z	*P* value	95% CI
Basic Model					
VFC participation	0.75	0.23	-0.92	.36	0.40 – 1.39
*Constant	17.58	5.22	9.66	.00	9.83 – 31.46
Multivariate Model*					
VFC participation	0.96	0.31	-0.13	.90	0.51 – 1.81
Hispanic	2.80	1.70	1.70	.09	0.85 – 9.20
Non-Hispanic Black	1.17	0.39	0.48	.63	0.61 – 2.25
Non-Hispanic Other or Multiple Race	1.30	0.48	0.71	.48	0.63 – 2.68
Family income	1.11	0.03	3.84	.00	1.05 – 1.17
*Constant	5.68	2.28	4.33	.00	2.59 – 12.47

Note. *Non-Hispanic White was used as the comparison group.

Figure 7.

Year-to-Year Variations in Vaccination Coverage by Demographic Characteristic of Child and Family.



After including race/ethnicity and family income in the model, VFC participation and race/ethnicity were not significant, although family income was again a significant predictor of vaccination status (aOR = 1.11, 95% CI [1.05 – 1.17], p < .00). With every categorical increase in family income, the odds of a child having received the MMR vaccine increased by 11%. This model was statistically significant in predicting vaccination status (p = .00). Thus, we fail to reject the null hypothesis that there is no relationship between provider participation in the VFC program and MMR vaccination status among children 0-35-months-old.

Post hoc Analysis 2

The post-hoc inclusion of maternal education did not significantly alter the results of the regression model. Family income remained a significant predictor and maternal

education was found to be insignificant. Maternal education and VFC participation of providers were significantly associated ($\chi 2 = 44.95$, $p < .00$). As maternal education increased, the participation of providers decreased, although much less dramatically than observed among the receipt of WIC benefits.

Summary

RQ1 analysis is an investigation to identify and predict whether any relationship might exist between vaccine rates and health insurance status of the families in Ohio, represented by the WIC program for Medicaid and low-income families, adjusting for race and socioeconomic status. When evaluating the income levels of all families with adequate provider data it is revealed that at approximately 23% of families fall within the poverty guidelines described by the Department of Health and Human Services, and of all families that have inadequate provider data at least 21% have low income. Over 80% of Ohio providers participated in vaccine programs. The WIC program as a variable identifies a small portion of the target population that qualifies for Medicaid, as well as the free vaccines provided through the VFC program. The use of WIC as a proxy for insurance status when compared to vaccine rates revealed a definite positive correlation when tested alone, but when other factors were considered, WIC no longer held as strong an impact. WIC became less significant when race and income factors were added to the multi-logistic regression model. The socioeconomic and demographic factors that play into the receipt of WIC seem to be more important for vaccination status. The results revealed that there is a larger population with adequate financial resources that improved access to the measles vaccine, thereby improving vaccine rates disproportionately.

RQ2 analysis attempts to identify and predict whether the VFC Program in Ohio has had any influence on vaccine rates, adjusting for race and socioeconomic status. The Pearson Chi-square test measured the type of relationship that might exist between the provider participation in the VFC Program and vaccine rates, as well as the strength of that relationship. The results concluded there was no significant correlation to suggest that the participation of providers in the program would affect vaccine rates in any way. On the other hand, the multivariate model revealed that the only factor that consistently show a correlation with vaccine rates is income status. The next section will discuss and interpret the findings, limitations, and make recommendations for future research.

Section 4: Application to Professional Practice and Implications for Social Change

According to the WHO, the high-risk population for vaccine preventable diseases are children under the age of 5 (WHO, 2017). Often, children that are not vaccinated at that age are found in regions of high disparity. The families in regions of high disparity suffer from poor education and low socioeconomic status. It has been the assumption that if families are better educated about the purpose of vaccines and have better access to health resources, then there would be an increase in the number of children immunized against life-threatening diseases (American Academy of Pediatrics, 2021). To eradicate disease, federal and state governments set mandates and guidelines, as well as funding, to ensure children have access to the necessary immunizations (CMS, 2018). The unvaccinated population accounts for 80% of the total costs of $8.95 billion for vaccine preventable diseases (Keeffe, 2016). Basic reasons for the resurgence of vaccine preventable diseases once eradicated stem from misinformation, poor access to vaccines, religious beliefs, and lack of knowledge about the benefits of vaccines (CDC, 2001). Despite the many programs and agencies available to tackle the problems of influencing behavior and opinions, and making vaccines accessible to everyone, many children still escape the protection of childhood immunizations (ODH, 2018).

Interpretation of the Findings

During the 7-year period, the number of participants in the survey gradually increased while the number of adequate providers providing information decreased. The data revealed that the more educated the mother, the greater the likelihood of there being adequate provider data. After the introduction of the PPACA in 2010, the data reveals

that from 2011 to 2016 the number of 0-35-month-old children vaccinated fluctuated in all races, but not equally. The results for the non-Hispanic Black children show a 4-year period of a steady decrease in vaccine coverage until 2013 when the numbers were at the lowest level. Vaccine coverage plummeted in all races during 2013 then had a sharp increase for all races in 2014.

The analyses conducted for this study consisted of a multiple logistic regression analysis and Pearson Chi-square analysis to determine if a relationship existed between the dependent variable-vaccine rates, the covariates-WIC and the VFC, and the independent variables- demographic and socioeconomic characteristics of the 0-35-month-old cohort in Ohio. The data was assessed for relevance, patterns, trends, and inconsistencies. The analysis for the research study resulted in a failure to reject the null hypotheses for both RQ1 and RQ2.

Despite not having sufficient evidence to fail to reject the null for both hypotheses, the data shows enough discrepancy to suggest a portion of the population may not be accurately portrayed. The measles vaccine, as well as other healthcare resources, are being accessed disproportionately. WIC is not a direct financial resource for families suffering financial hardship and does not guarantee a participating child will be vaccinated. This does not mean that WIC is not a valuable resource to assist in the access of the measles vaccine. The WIC program targets young children and specifically the 0-35-month-olds who are at the poverty level or receive financial assistance through Medicaid, which subsequently represents a small group of eligible recipients who may

receive free vaccines. It should be noted that the WIC program is not necessarily utilized by all families receiving Medicaid or who are at the poverty level.

In 2014, a measles outbreak occurred in the state of Ohio resulting in the highest recorded number of measles cases in the United States for that year. The measles outbreak in an Ohio Amish community resulted in 383 infections from March 2014 through July 2014. There were nine Ohio counties affected which accounted for almost two-thirds of the country's total measles cases (Gastañaduy et al., 2016). Maternal education showed improvement during this time, but this does not necessarily mean increased coverage of the measles vaccine was a consequence of education alone. A campaign was initiated to prevent the spread by isolating the affected Amish community which accounted for approximately 99% of the measles cases. The number of measles cases in the state were reduced further when 10,000 vaccines were administered to the general public (Gastañaduy et al., 2016).

The idea that provider participation in the VFC program would somehow improve vaccine rates or get vaccines into children has not been proven by this analysis. The decrease in adequate provider data over time raises the questions as to why this is occurring. Missing data and/or insufficient and inaccurate reporting affects efficacy of service delivery, the quality of care, and subsequently trust in the healthcare profession. The calculations in this study do not give an explanation as to why parents may or may not choose to have their child vaccinated. Insight into what motivates a parent’s decision might well be education and economics according to the data. Further analysis is necessary to determine what other factors may have a significant role in influencing

vaccine rates. The analysis show that the programs designed to improve vaccine rates will need to develop more tailor-made strategies to target specific subpopulation.

Limitations of the Study

The limitations in the study begin with the fact that all populations may not have been adequately represented. This is based on the missing data pertaining to the health insurance status of the families and the data becoming less complete as time progressed. This yields a potential loss of relevant and completed data needed to correctly identify at risk populations, and to determine what intervention methods may be useful in improving access to the measles vaccine. This analysis provided some insight into which variables show an association with the outcome of vaccine rates for the years 2010-2016.

Performing a multiple logistic regression analysis and bivariate analyses reduced the risk of false positive results. There was no data for employment status which might have been beneficial in identifying families with no insurance or income. Further limitations may be due to the inability to associate participants to the region or locality of the state in which they live. The study would have benefited from access to zip codes that could be grouped into regions in the state. This would assist in identifying areas of inequity where subpopulations and communities might need access to programs, resources, the measles, and other life-saving vaccines. Many subpopulations are made up of diverse groups, live in the metropolitan and urban areas, and require assessment for social-cultural tools necessary to improve community health. The unavailability of certain pertinent variables limited the research in providing a more comprehensive picture of vaccine coverage across the state of Ohio. Families and providers must ensure

demographic, financial, insurance, and health information is completely and accurately reported to provide quality data that will result in reliable and valid research studies representing all populations.

Recommendations

Improve Infrastructure

The services that health systems provide can lead to improvements in immunization programs and health outcomes. The findings for this research study are intended to: positively impact efforts to improve research strategies and design for increasing vaccination coverage; decrease morbidity and mortality; improve efficacy in service delivery, as well as increase equity throughout communities. The integrity of a study relies on the attributes of the data obtained for analysis. Emphasis is placed on the data being accurate, relevant, and a good representation of the population being studied. In this study there was an increasing lack of reporting by providers over time that resulted in a substantial amount of missing data related to health insurance and employment. To address this issue, I recommend that responsible entities implement strict guidelines for participating agencies when collecting and reporting immunization data for all populations. The data collection and reporting process should be timely and standardized for assessment and data sharing capabilities.

Because of limited information associated with the employment and insurance status of families, these aspects were excluded from this analysis. An analysis of these factors could have been useful in measuring estimates for use of immunization service. Despite this information being collected by public and government entities that assess

and review health status, insurance information, and gaps in the health system, there has not been extensive research in the capacity of financial resources of the family in relation to immunization utilization in children 0-35 months in the state of Ohio. This is clearly an indication of the need for a wide range of measured quality data that further describes and/or represents certain population groups and how they access healthcare. The inclusion of as many descriptive factors into a survey can assist in providing evidence-based conclusions for a parent's decision to vaccinate their child. Physicians are the most compelling figures when it comes to influencing parents to have their child vaccinated. They must be consistent when educating parents about vaccine safety and the importance of having their child vaccinated. I recommend all physician offices, clinics, hospitals, schools, and public health departments participating in an immunization program be required to report complete and consistent child vaccine, demographic, and insurance information to the Ohio Immunization Registry system. This information can be assessed and utilized in research for planning and developing strategies to address poor access and inequities. All participating organizations should be required to educate families on age-related recommended vaccines and send reminders for future vaccines. Immunization programs with a mission that focuses on providing financial resources benefit from data containing all aspects of the family's available income for healthcare, including insurance status. Financial and insurance data results in strategies and interventions to improve access.

Future Research

The population in the state of Ohio is growing and becoming more diverse. With the growing population comes unpredictable changes in economic resources and health policies (Kaiser Family Foundation, 2014). Situational changes in the family dynamic, such as unemployment or death, can negatively affect the financial resources of the family, thereby affecting the family's quality of health. I recommend future studies explore the social and economic changes in various regions of the state and identify the location of subpopulations suffering from disparity. Having this information could help determine if an immunization program and health resources exist in the area, and if so, identify what strategies may be lacking to address the issues in that community.

Best Practices

The changes experienced by Ohio families have become even more complicated during recent events caused by the Covid-19 pandemic. The spread of a new highly contagious disease that resulted in 59,000+ hospitalizations, 19,000+ deaths, and 1+ million total cases in the state of Ohio over the span of one year validated the necessity for this type of research (USA Facts, 2021). The strategies implemented by immunization programs across the state were put to the test. It has been discovered that certain populations, especially those suffering great disparity are negatively impacted in all aspects of health care. This results in a consistent inequity of services provided to these populations in Ohio (Ohio Department of Health, 2021). It became clear during the year 2020 that social determinants of health, racism, discrimination, misinformation, and lack of education are factors that can lead to high morbidity and mortality rates not only in

Ohio, but across the United States and worldwide (Biggers, 2020). It is recommended that cultural awareness and sensitivity training that addresses racism and discrimination be added to all healthcare organizations, curricula, and continuing education programs. This will help ensure efforts to devise strategies and methods for data collection and research analysis will be unbiased and more inclusive. The disparity suffered by various subpopulations and the discriminatory practices in healthcare experienced by minorities are barriers to healthcare that can no longer be ignored. The first step to eliminating barriers is to acknowledge the problem and take steps to correct it. The best way to identify what barriers prevents access to care in a region is to ask the patient who lives there. Federal, state, and local governments must invest in low-income areas to provide transportation, better housing, improve education, and access to primary care facilities. Existing healthcare organizations and clinics should collaborate and develop partnerships and strategies to address transportation, financial, social, and cultural barriers that hinder access in regions suffering disparity. Health professionals, clinicians, and healthcare organizations must build trust and a rapport with patients by being transparent, attentive, honest, and acknowledging concerns.

Implications for Professional Practice and Social Change

Professional Practice

The efforts of healthcare professionals must include tools and processes utilized in data collection that result in successful monitoring, planning, and implementation of strategies that improve vaccine rates. Policies and programs developed through evidence-based research can result in an immediate, efficient, and effective response to life

threatening situations. Proven interventions that reduce morbidity and mortality rates increase public awareness and demand for vaccinations. The VFC program reduces the incidence of morbidity or mortality through immunization. Whereas the goal of the WIC program is to decrease the incidence of illness and death by reducing malnutrition in impoverished mothers and children. One of the WIC program's missions is to partner with other services and programs to assist in the health and well-being of mother and child. Screening for the recommended childhood immunizations and giving referrals is the way the WIC program aids in the effort to improve vaccine rates among children under the age of 5. Diversity within communities dictate that different services are required and rendered to the various populations. Communication and collaboration among existing services and programs can prove to be more successful together than alone when servicing the community. Partnerships between health organizations are seen as more effective in preventative measures when coordinating to promote similar goals, such as screenings and referrals.

It must be emphasized that to improve access to healthcare and vaccine rates it is important for the healthcare professional to collect information from families that is relevant, accurate, timely, and unbiased. Public health departments and health organizations must comply with immunization policies and recommendations to deliver the full treatment benefit of immunization programs. An immunization program can only accomplish what it is designed to accomplish, and it is only as effective as the effort placed on assessment, implementation, and delivery of life-saving vaccines to the intended population.

Positive Social Change

The United States healthcare system has many obvious implications for upgrading health systems and changing how healthcare services are delivered and maintained. Since health guidelines, regulations, and policies begin with evidence-based research, it stands to reason that reliable data is necessary to improve health operations and health service delivery. Preventative healthcare practices reduce cost of care and risks of acquiring life-threatening diseases, especially at the beginning of life. Presently the best form of prevention available against most contagious diseases are vaccines. Vaccines have been given to most of the population for over 50 years, but the fact remains that lack of education, misinformation and doubt causes fear of vaccines. This implication coupled with the lack of access and financial resources can lead to disease outbreaks and devastation. The same reasons for not receiving or accepting a vaccine have continued to perpetrate over time, which highlights the need for interventions that focus on vaccine education, and the under-served communities that are high risk for poor health outcomes.

There is no mandate to report to the ODH's immunization registry. Although, the ODH's immunization registry accepts all vaccines recommended by the Advisory Committee for Immunization Practices. There is a great need for the development of methods for evaluating the progress and success of a program, as well as creating intervention strategies that are adaptable to the needs of the community. All future immunization program strategies executed in clinical care settings must be created to be more inclusive and overseen by an immunization advocate that ensures compliance and transparency in all activities. Compliance advocates might oversee resources and

inventory, vaccine records and prompts, staff education, patient education and concerns, including translators. This type of adjustment in implementation of a vaccine program can address inequities in practice as well as alleviate patient fears and mistrust when interacting with physicians and clinical staff.

Conclusion

Imagine a world where disease is no longer a threat. A large number of people in the population worldwide must be vaccinated to act as a buffer or safety net for those individuals not able to be immunized. It is imperative that all societies work together to accomplish the goal of eradicating life-threatening diseases. The measles virus was once the most contagious disease in the world with the capability of causing death, but it is no match to the damage caused by Covid-19 in the year 2020. The world has witnessed that there is no community or society secure from a catastrophic event resulting from a deadly disease. Healthcare Administrators must continue to develop strategies and interventions to improve vaccine delivery and rates. Healthcare organizations and programs must be accessible and designed to service its community appropriately. Governments and heads of state must make an effort to collaborate and work together to prevent a crisis like a measles epidemic or the Covid-19 Pandemic from ever reoccurring.

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