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An Ecological Perspective on Pertussis

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2016

Abstract

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by

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Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

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Abstract

In 2012, 48,277 cases of pertussis were diagnosed in the United States. Pertussis, otherwise known as whooping cough, is a highly contagious, often debilitating, sometimes deadly, vaccine-preventable disease with an increasing incidence and death rate in the U.S, which may be due to vaccine exemptions. The purpose of this project was to determine if a relationship exists between immunization policies and immunization exemption rates, immunization exemption rates and pertussis rates, and immunization policies and pertussis rates in each state. Bronfenbrenner's bio-ecological framework was used to guide the project. Publically available data from the Centers for Disease Control and Prevention (CDC), schools of public health, state health departments, and public health officials were retrieved for this cross-sectional, ecological comparison study. Spearman's *r* product-moment correlation coefficient was used to investigate the relationship between the variables. States with lenient vaccine laws had higher exemption rates ($r = .359$, $p < .01$), and states with higher exemption rates had higher pertussis rates ($r = .470$, $p < .01$). Finally, states with lenient vaccine laws had higher pertussis rates ($r = .111$, $p = 0.439$). This project should be added to the literature used to inform and educate the public as well as influence policy makers. As a result of this study, arguments for eliminating non-medical vaccine exemptions should be strengthened. As policies are changed, social change should follow in the form of decreased immunization exemption rates and decreased pertussis rates.

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Dedication

I would like to dedicate this project to all the individuals, past and present, who have succumbed to pertussis and other vaccine preventable diseases. May your loved ones find comfort in knowing your deaths were not in vain as we continue to strive to eradicate these devastating illnesses through research and evidence based practice.

Acknowledgments

I would like to first thank my husband for his never-ending love and support as I pursued my educational dreams. To my children – Thank you for your patience and understanding while I finished my 'homework' all those long evenings. I hope that I have set a good example and that you understand the importance of never giving up on your goals, no matter the trials and hardships life throws at you. To my mother – Thank you for being my rock, my role model, and my mentor. To my preceptors, colleagues and professors – Thank you for your guidance, your support, and your wisdom. Lastly, I would like to give a very special thanks to Dr. Allison Terry. Your encouraging words and patience have meant more than your will ever know. This journey would not have been possible without each and every one of you and I am eternally grateful.

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Section 1: Overview of the Project

Introduction

The Centers for Disease Control and Prevention (CDC) describes pertussis, otherwise known as whooping cough, as a highly contagious, reportable, vaccine-preventable disease caused by the bacterium *bordetella pertussis* (2013b). The CDC has tracked pertussis since 1922 when there were 107,473 cases reported. In 1934, reported cases reached an all time high of 265,269. In the United States (U.S.), pertussis became a vaccine preventable disease in the late 1940s when immunization with the whole cell pertussis (DTP) vaccine became routine. By 1976, the disease had become rare with only 1010 cases reported. However, since that year, reported pertussis cases and associated deaths have steadily risen. In fact, in 2012, the CDC tracked 48,277 cases, making it the highest number reported since 1955. Twenty deaths were directly caused by pertussis as well, making it the only vaccine preventable disease associated with an increasing death rate in the U.S. (CDC, 2013c).

Problem, Purpose, and Research Questions

Pertussis is best prevented with immunization (CDC, 2013b). The near eradication of the disease and subsequent reemergence in the U.S. is a call to action for healthcare professionals. Herd immunity occurs when enough individuals within a society are immunized against a disease so that there is very little opportunity for the disease to spread (Vaccines.gov, 2016). Research consistently shows that in order to protect the general public from vaccine preventable diseases, immunization rates must be unvaryingly high. (Association of State and Territorial Health Officials [ASTHO],

2011). Despite rising pertussis rates and associated deaths since 1998, nonmedical vaccine exemptions for children and adolescents have increased in the United States and at a faster rate than from the previous decade (Caplan, 2012).

The purpose of this project was to explore the correlation between immunization policies, exemption rates, and pertussis rates in each state. Specifically, the investigator sought to accomplish three measurable objectives to determine if a correlation exists: (a) between the lenience of the immunization policy by state with the rate of exemption; (b) between pertussis rate by state and exemption rate; and (c) between pertussis rate by state and the lenience of the immunization requirements for children in public schools. The following research questions were addressed in this study: Do states with more lenient immunization requirements for children in public schools have higher exemption rates than states with stricter immunization requirements? Do states with a higher immunization exemption rate have a higher rate of pertussis? Do states with more lenient immunization requirements for children in public schools have a higher pertussis rate?

Social Significance

Public Health

Pertussis has and continues to be a serious, potentially life-threatening disease, particularly for infants. Approximately half of all infants under the age of one year who contract pertussis are hospitalized and about 1% of those will succumb to the disease (CDC, 2013b). Other serious complications include pneumonia, convulsions, encephalopathy, apnea, and rib fractures (CDC, 2013b). The United States Department of Health and Human Services (HHS), Healthy People 2020 (2013) has established a goal of

increasing the nation's immunization rates and reducing preventable infectious diseases, among which, is pertussis.

Descriptives

According to the CDC (2013c), children less than a year old comprised 4994 of the total cases in 2012 (10.3%, incidence rate [IR] = 126.7). Children between one and six years of age accounted for 8,280 cases (17.2%, IR = 34.1). Children between 7 and 10 had a total of 9,532 cases (19.8%, IR – 58.5). A total of 14,440 cases (29.9%, IR = 38.0) were reported in adolescents and teens between 11 and 19 years of age. Another 10,436 cases (21.6%, IR = 4.5) were reported in adults over age 20. There were 595 cases (1.2%) in which the age was unknown. Infants have the highest mortality rates. While accounting for only 10.8% of reported pertussis cases in 2012, infants less than one year of age accounted for 80% of the deaths attributed to disease (CDC, 2013c).

The state of Wisconsin had the most number of cases and the highest incidence rate of pertussis in the U.S. in 2012 with 6,880 cases reported (IR = 120.2). Vermont and Minnesota had the second and third highest incidence rates at 103.0 and 77.0, respectively. Washington and Minnesota had the second and third highest number of cases at 4,916 and 4,142, respectively (CDC, 2013c).

Vaccine History

The efficacy of the DTP vaccine was evident shortly after its introduction in the mid 1940s when reported pertussis cases fell by 99% over the next three decades in the U.S. (CDC, 2013b). However, concerns about vaccine safety began to surface in the late 1970s and 1980s, specifically related to encephalopathy and seizures. The antivaccine

movement in the U.S. gained momentum in 1982 with the documentary *DTP: Vaccine Roulette,* which aired on network television. The journalist responsible for the documentary set forth a theory linking the DTP vaccine to epilepsy and brain damage, which has since been refuted in numerous studies (Sobel, 2011).

While the documentary aired on national television, parents whose children were injured or died following DTP vaccine established the National Vaccine Information Center ([NVIC], 2014), a national, non-profit organization. According to its website, the organization's goal is to be instrumental in the prevention of vaccine injuries and deaths. They claim to be neither for nor against immunizations. However, their members are strong advocators for individuals' rights to choose whether or not to immunize their children (NVIC, 2014). Many lawsuits were filed nationwide by parents who felt their children were injured by the DTP vaccine. Damages were awarded without scientific evidence, which lead to increased liability and cost to manufacturers and subsequent halting of vaccine production. By 1986, the U.S. saw a vaccine shortage and Congress responded by passing the National Childhood Vaccine Injury Act which requires health care providers to provide vaccine information statements prior to immunizing and to report adverse events following vaccine administration to the Vaccine Adverse Event Reporting System (VAERS). A committee from the Institute of Medicine was appointed to review the adverse events and the National Vaccine Injury Compensation Program was created to compensate children with confirmed injury or death due to vaccine administration (CDC, 2011a).

The U.S. continued to vaccinate at high levels thanks to organizations and practitioners strongly advocating for immunizations and school-entry requirements for DTP coverage. However, on a global level, many developed countries saw a decrease in DTP vaccination thanks to movements against whole-cell pertussis vaccine. Gangarosa et al. (1998) described these antivaccine movements as either active or passive. Active movements were seen in countries where a coordinated media attack was used to promote fear of the DTP vaccine, which lead to wide spread opposition among parents. Passive antivaccine movements were seen in countries where providers, concerned about the safety of the DTP vaccine, simply refused to vaccinate. Gangrosa et al.'s review (1998) assessed the difference in pertussis incidence in countries with antivaccine movements where immunization rates fell and those where immunization rates remained constant through the DTP scare. They found countries with constant high vaccine coverage had pertussis incidence rates 10 to 100 times lower than countries where immunization programs were interrupted or compromised.

In 1996, The Institute of Medicine reported insufficient evidence to determine whether the DTP vaccine increased the overall risk for chronic nervous system dysfunction (CDC, 1996). Nevertheless, the U.S. switched from whole-cell pertussis vaccine to acellular pertussis vaccine in the 1990's amid safety concerns related to the DTP vaccine (Klein, Bartlett, Fireman, Rowhani-Rahbar & Baxter, 2013). The new acellular pertussis vaccine (DTaP) was found to have less adverse effects than the whole cell pertussis vaccine in children less than seven years of age (Zhang, Prietsch, Axelsson, & Halperin, 2012).

As public health officials and practitioners began to put the mind of the public at ease in regards to the safety of vaccines, the second wave of ammunition for the antivaccine movement came about with a study published by *The Lancet* in 1998 linking the MMR vaccine to autism (Wakefield et al., 1998). Over the next decade, scientists and researchers devoted much attention to the proposed link, but study after study proved the authors' claim inaccurate. *The Lancet* officially retracted the article in 2010, but the damage was done. The alleged connection between autism and vaccine sparked a wave of celebrity lead antivaccine hysteria, and the U.S. has seen a continuously rising rate in nonmedical vaccine exemptions as well as rising rates of pertussis and measles since the article was originally published (Caplan, 2012). In response to the nation's rising pertussis rate, the Food and Drug Administration (FDA) licensed a vaccine that added an acellular pertussis booster to the current tetanaus and dipheria vaccine (Td). The tetanus, diptheria, acellular pertussis vaccine (Tdap) is for individuals over 7 years old and has been available since 2005 in the U.S. (National Network for Immunization Information [NNII], 2011).

Financial Implications

Aside from the detrimental health effects, researchers should consider the financial impact of pertussis on society. Vaccines are among the most cost-effective services health care has to offer. In fact, it is estimated that for each birth cohort immunized on schedule, the U.S. saves $9.9 billion dollars in direct health care costs and $33.4 billion dollars in indirect costs (HHS, 2013). According to the CDC, the cost per DTaP vaccine is $15.38 for entities with a CDC contract such as public health

departments. Tdap vaccines are $30.41 (CDC, 2013a). The total estimated cost of the entire pertussis vaccine series including five doses of DTaP during childhood, one dose of Tdap during adolescence, and one dose of Tdap in adulthood is $137.72. The potential cost of contracting pertussis, on the other hand, can be quite expensive. For instance, a study by O'Brien and Caro (2005) looked at the cost of pertussis in an inpatient setting. They found total direct hospital costs ranging from $4,729 per case in children to $9,586 per case in infants. Thus, to completely immunize an individual from birth through adulthood costs about 1.4% of the amount that it costs to treat a hospitalized infant with pertussis. In other words, for the same cost of a single infant hospitalization, 69.6 individuals could receive the entire pertussis immunization series. Wells and Omer (2012) used the state of Iowa to estimate the cost of adding a personal belief exemption to that state's immunization policy. Based on peer reviewed literature and the CDC estimates, the authors projected the addition of the personal belief exemption would cost the state approximately 50% more annually directly related to pertussis.

Effects of Policy

Policy change for public health occurs when the government relies on scientific research to enact laws that will better the health of a population, based on the socio-ecological model (Chappelle & Wooster, 2011). Policies on vaccine requirements and exemptions for children in public schools vary from state to state. Ideally, these policies help combat complacency, which occurs when individuals do not perceive the risk of contracting a vaccine preventable disease as high, and simply neglect to have their children immunized. Vaccine exemptions can be classified as medical or nonmedical. A

medical vaccine exemption is granted for children who have a contraindication to the vaccine, such as an anaphylactic reaction to a previous dose. Nonmedical exemptions are those claimed for religious or personal beliefs. As the number of exemptions rise, herd immunity is diminished, putting the most vulnerable populations (infants, those with weakened immune systems, and those who cannot be vaccinated for medical reasons) at risk. And as research has proven, no vaccine is 100% effective, so even those who were immunized on schedule may be at risk (ASTHO, 2011). Each state's immunization policy should serve as a safety net. They catch those children who were not immunized due to neglect or by accident and also serve as an ultimatum for parents who want their children to attend school outside the home.

Theory

The CDC's Advisory Committee on Immunization Practices (AICP) updates guidelines on immunization schedules every three to five years (CDC, 2011a). The current CDC recommendation for children between 2 months and 6 years of age is five doses of DTaP vaccine. The next booster is recommended at 11-12 years of age with a Tdap (CDC, 2013b). This guideline is based on over half a century of scientific research (CDC, 2011a). With adherence to the current guidelines and evidence from the research, one would expect to see a continuing decline in pertussis rates in the U.S. An explanation for the rise in pertussis on a national level may be the result of multiple factors, and the last decade has seen numerous studies devoted to determining the cause. Some theories include waning immunity to pertussis, public complacency, increasing nonmedical vaccine exemptions, and decreased herd immunity.

Grzywacz and Fuqua (2000) noted the shift in our society's cause of death from infectious disease to chronic illnesses. Immunizations protect our society from potentially fatal, often debilitating infections, yet we continue to struggle with the rising rate of what was once an almost eradicated disease. I used Bronfenbrenner's bio-ecological framework to guide the investigation into this complex social problem. Bronfenbrenner suggested that the individual self, experiences, culture, society, economic situation, and politics influence human behavior (Newworldencyclopedia.org, 2008). His framework, like other ecological perspectives, helps researchers understand how each of these levels is interdependent on the other and interactions between these levels influence the health of individuals and communities (Grzywacz & Fuqua, 2000).

The *bio* aspect of Bronfenbrenner's framework refers to the individual. The *ecological* aspect is broken down into five systems. The *microsystem* consists of the individual's most intimate environment such as their family, friends and work or school environment. The relationships between these elements define the *mesosystem*, such as how a child's home life impacts his or her academic performance at school. The *exosystem* involves places or events that only indirectly affect the individual such as a spouse's work environment. The *macrosystem* involves the individual's culture and might include media, politics, or even the nation's economy. The *chronosystem* includes major events, changes and happenings that have occurred over an individual's life, an example including the loss of a parent or even a terror attack being viewed on television (Newworldencyclopedia.org, 2008).

Bronfenbrenner suggested that social problems arise when one or more of the systems are deficient in its influence among the others (Newworldencyclopedia.org, 2008). Relevant to this study, the social problem is defined as a national rate of pertussis higher than the goals set forth by Healthy People 2020, specifically, to reduce the cases of pertussis among children under one year of age to 2,500 annually and to reduce the cases of pertussis among adolescents aged 11 to 18 years to 2,000 annually (HHS, 2013). This project focused primarily on the macrosystem and exosystem.

Nursing Relevance and Implications for Social Change

Relevant to the Doctor of Nursing Practice (DNP), *The Essentials of Doctoral Education for Advanced Nursing Practice, Essential VII* (2006), focuses on clinical prevention and population health for improving the nation's health. Immunizations fall under the category of clinical prevention in that they promote health and reduce the risk of illness through individual immunity, herd immunity, and finally eradication of vaccine preventable diseases. This project provided me with an opportunity to analyze epidemiological data related to population health.

As leaders in public health promotion, the American Nurses Association (ANA) strongly supports immunization programs and the immunization schedule set forth by the CDC (ANA, 2013). Marcuse (2011) pointed out the movement of responsibility of childhood immunizations from public health clinics to primary care and the challenges primary care providers face when discussing the importance of timely immunizations with parents and caregivers. As advanced practice nurses continue to fill the gap in the need for primary care in the U.S., having the knowledge and expertise to ensure a high

immunization rate among their patient population is vital. It is my hope that the findings of this study will help promote social change resulting in routine immunizations being a default, rather than an option.

Summary

The purpose of this project was to explore the correlation between immunization policies, exemption rates and pertussis rates in each state. The following research questions were addressed in this study: Do states with more lenient immunization requirements for children in public schools have higher exemption rates than states with stricter immunization requirements? Do states with a higher immunization exemption rate have a higher rate of pertussis? Do states with more lenient immunization requirements for children in public schools have a higher pertussis rate?

Pertussis is addressed in Healthy People 2020 (2013) indicating its health and financial impact on a national level. The CDC tracked 48,277 cases of pertussis in 2012, the highest number reported since 1955. Pertussis is best prevented with immunization (CDC, 2013b), but non-medical vaccine exemptions for children and adolescents have increased in the U.S. since 1998, and at a faster rate than from the previous decade (Caplan, 2012). Bronfenbrenner's bio-ecological framework was used to guide this project because it helps determine how human behavior–and resulting social problems–are influenced by individuals, experiences, culture, society, economic situations, and politics (Newworldencyclopedia.org, 2008).

As leaders in public health promotion, the American Nurses Association (ANA) strongly supports immunization programs and the immunization schedule set forth by the

CDC (ANA, 2013). When the social, medical and financial implications are considered, pertussis warrants the attention of all health care professionals, but especially the DNP prepared nurse who has a vested interest in clinical prevention and population health. It is my hope that the findings of this study will help promote social change by influencing future policy makers, resulting in routine immunizations being a default, rather than an option.

Section 2: Review of Scholarly Evidence

Section 1 focused on the current and past rates of pertussis and the impact this disease has on the medical, social, and financial wellbeing of the people in the U.S. The practice problem and its relevance to nursing practice were established. Bronfenbrenner's bio-ecological framework was discussed. Many of the suggested theories for rising pertussis rates fit into the different systems of Bronfenbrenner's framework. Section 2 consists of a literature review with focus on some of the more common theories.

Literature Review

I used the Walden University electronic library to gather relevant articles. Databases included *Cochrane Database of Systematic Reviews*, CINAHL, PubMED, PsycINFO, MEDLINE and Google Scholar. The search terms used were *vaccine exemptions, immunization exemptions, personal belief exemptions, religious exemptions, philosophical exemptions, immunization policy, vaccine policy, pertussis rate, vaccine preventable disease rate,* and *pertussis outbreak*. Fifteen articles were selected from these searches, dated from 2006 to 2014. All articles originated in the U.S.

In 2012, the *Cochrane Library* published a systematic review that assessed the efficacy and safety of the current acellular pertussis vaccine used in the U.S. The authors concluded that the DTaP vaccine is effective and shows less adverse effects than the whole cell pertussis vaccine for the first five doses in children less than 7 years of age. The efficacy of the DTaP vaccine for children who had received three or more doses was

better than for those who received one or two doses (Zhang, Prietsch, Axelsson & Halperin, 2012). This evidence supports the current guidelines by the CDC.

Since the systematic review published in 2012, a large amount of research has focused on the possible reasons for rising rates of pertussis. Glanz et al. (2013) authored a study that backed the current immunization schedule for children 3-36 months of age. They showed a strong association between undervaccination with DTaP vaccine and an increase number of pertussis cases. However, another study by Tartof et al. (2013) showed the longer time interval since the last dose of the five-dose DTaP series, the higher the risk of pertussis. This finding is consistent with the waning immunity theory of acellular pertussis vaccines. In 2012, pertussis was declared an epidemic in the state of Oregon. Liko, Robison, and Cieslak (2014) measured pertussis vaccine effectiveness at 95% for children 15-47 months of age (95% CI, 92%-97%), but only 47% for those 13-16 years old (19%-65%). In their study, unimmunized individuals had a higher rate of pertussis across all age groups, however their findings are again consistent with the waning immunity theory.

Further research by Klein et al. (2013) looked at the risk of pertussis in children 10-17 years of age during the 2010 pertussis outbreak in California. They compared children who received the DTP vaccine and children who received the DTaP vaccine between 1994 and 1999. They found that decreasing the number of DTP vaccine was associated with increased risk of pertussis, indicating the DTaP vaccine is not as effective or long lasting as the DTP vaccine.

When determining whether states that allow personal belief exemptions have a higher number of exemptions, the answer is clear. Omer et al. (2006) confirmed that states that easily grant personal belief exemptions have a higher and increasing number of exemption rates. In 2012, that finding was again confirmed when Omer, Richards, Ward, and Bednarczyk studied the change in immunization rates from 2005-2011 between states that allow philosophical exemptions and states that allow only religious exemptions. They also considered the ease of obtaining the exemption in their study. The addition of a philosophical excuse resulted in exemption rates 2.5 times higher than when only religious exemptions were granted. Additionally, easy to obtain exemptions increased the number of exemptions 2.3 times compared to harder to obtain exemptions.

Haytham et al. (2012) studied the effects of an Arkansas law enacted in 2003 that added a personal belief exemption category to immunization requirements. Their study showed a continuously increasing number in vaccine exemption rates once the law was enacted, however, an upward trend in vaccine preventable disease rates had not been observed. Another study published in 2013 found that states with more lenient exemption laws had a higher number of exemptors, but did not examine the pertussis rate in those states (Blank, Caplan & Constable, 2013). The literature points to a variety of reasons including fear (Berreth, 2012) and lack of knowledge (Dorell, Yankey & Strasser, 2011) as reasons parents choose not to immunize their children.

Literature directly related to the effects of vaccine exemption was also available. Atwell et al. (2013) studied the association between clusters of nonmedical exemptions and clusters of pertussis during the 2010 California outbreak. They found clusters with

high nonmedical exemption rates were 2.5 times more likely to be in a pertussis cluster (odds ratio (OR) = 2.47, 95% confidence interval: 1.10-1.30). In a study by Glanz et al. (2009), the researchers examined the association between parental refusal of pertussis vaccination and the risk of pertussis infection in children. In this case control study, logistic regression was used to estimate odds ratios and 95% confidence intervals. The researchers found that pertussis risk increased by 23 times (OR: 22.8) among vaccine refusers. Feikin et al. (2000) evaluated whether personal belief exemptions from immunizations is associated with risk of measles and pertussis at individual and community levels. The results showed that vaccine exemptors were 22.2 times (95% CI, 15.9-31.1) and 5.9 times (95% CI, 4.8-8.2) more likely to acquire measles and pertussis than vaccinated children. They also found that vaccinated children were at higher risk of contracting measles (relative risk (RR): 1.6; 95% CI, 1.0-2.4) and pertussis (RR: 1.9; 95% CI, 1.7-2.1) when they resided in communities with a high frequency of exemptors (Feikin et al., 2000).

Imdad et al. (2013) studied the association of religious exemptions and risk of pertussis in the state of New York from 2000-2011. They found higher incidence of pertussis in counties with a higher rate of religious exemptions. Omer et al. (2008) examined communities or 'clusters' with a high number of vaccine exemptors in the state of Michigan and found an increased individual as well as community level risk of contracting pertussis when compared to other areas in the state.

When examining whether policy plays a role in the rate of pertussis on a state level, the research is limited and somewhat conflicting. Omer et al. (2006) compared

pertussis incidence with policies of granting personal belief exemptions and the ease at which they are obtained. The authors used multivariate analysis to show that the availability of easy to obtain personal belief exemptions is associated with higher rates of pertussis.

More recently, in a longitudinal study, Yang and Debold (2014) examined nonmedical exemption policies, immunization rates, and annual incidence rates for five vaccine preventable diseases, including pertussis. They concluded that exemption policies and immunization rates did not impact lower-incidence diseases such as hepatitis B, Haemophilus influenzae type B, measles, or mumps. However, pertussis incidence rates were weakly, negatively associated with exemption policy restrictions and DTaP compliance. By the authors' calculation, eliminating the personal belief exemption would result in a 1.4% decline of pertussis (171 cases) annually. They further calculated that a 1% increase in pertussis vaccine compliance across all states would only decrease pertussis cases by 0.04% (5 cases) annually (Yang & Debold, 2014).

The study by Yang and Debold (2014) could give leverage to those opposed to stricter immunization policies that would eliminate or tighten the use of personal belief exemptions. Debold is a PhD RN who happens to be an NVIC board member and volunteers as the Director of Research and Patient Safety. According to its website, Debold's son developed a serious, long-term illness after receiving seven vaccines at a well-baby check up which, in turn, lead to her involvement in vaccine safety research (NVIC, 2014). Despite its limitations and obvious personal bias, the study was published in the *American Journal of Public Health* earlier this year.

Summary

Using primarily the Walden Library, articles were selected for this literature review that focused on recent studies related to the practice problem. One systematic review was found that supported the current pertussis immunization guidelines set forth by the CDC (Zhang et al., 2012). Glanz et al. (2013) also authored a study that supported the current immunization schedule, however, increase pertussis rates were associated with undervaccination (receiving less doses than recommended). The findings of three studies supported the waning immunity theory as a contributor to rising pertussis rates. That is to say, longer amounts of time elapsed from a pertussis booster were associated with higher rates of pertussis. One of those studies had results showing the whole cell pertussis vaccine more effective than the acellular pertussis vaccine during the 2010 pertussis outbreak in California (Klein et al., 2013).

Multiple studies in this literature review confirmed that the availability and ease of obtaining a vaccine exemption were related to increased exemption rates. Additionally, two other common findings emerged from this review in more than one study: Vaccine exemption was associated with increased risk of an individual contracting pertussis, and increased pertussis rates are associated with a high number of exemptors.

Two studies examined the effect of policy on pertussis rates. Omer et al. (2006) found the availability of easy to obtain person belief exemptions to be associated with higher pertussis rates. Yang and Debold (2014), however, found only a weak, negative association between pertussis incidence and DTaP compliance, but no association with any other vaccine preventable diseases. These findings support the need for this project

and further investigation into the effect of vaccine policy on vaccine preventable disease rates.

Section 3: Approach

As described in Section 2, no definitive cause has been determined for the rising rate of pertussis in the U.S. Rather, a variety of contributing variables have been suggested and studied. I sought to determine if state policies on vaccine exemptions contribute to the practice problem. Section 3 details the research method initially proposed, sampling technique, data collection process, data analysis and evaluation.

Research Method and Sample

To determine if the suggested correlations existed, I planned to use a cross-sectional ecological comparison study. Ecological comparison studies seek an association between exposure to a defined variable and the rate of a disease through the use of group analysis, rather than specific case analysis. (Friis & Sellers, 2009, p. 250). Retrieval of existing, previously collected, public data was used for this observational inquiry, thereby eliminating the potential risk to any human subjects (Friis & Sellars, 2009).

The study sample was grouped into people residing in each of the 50 states and the District of Columbia in 2012. The use of secondary data collected by the CDC was utilized to gather information on the number of cases and incidence rates of pertussis in each state. Policies, immunization rates, and exemption rates were researched for each state in schools of public health, state health departments, state policy websites, and direct contact with state public health officials as warranted.

Data Collection

In 2012, all 50 states and the District of Columbia allowed for medical vaccine exemptions. All states except West Virginia and Mississippi allowed for religious

exemptions. An additional 18 states allowed for personal belief exemptions (Johns Hopkins, 2013). Religious and personal belief exemptions were further classified as easy to obtain and hard to obtain. Easy to obtain exemptions are those that require only a parent or guardian signature on a form. Difficult to obtain exemptions are those that require a notary signature on a form from the health department and a letter from a religious or state official (ASTHO, 2011).

In order to establish a lenience level for each state, I used a four-point rank order scale. This type of scale was most appropriate as it allowed for the ordinal data to be sorted, but did not require an established degree of difference between the different ranks. Table 1 is a crude example of the rank order scale I used. As exhibited, states were given a rank between one and four, depending on the vaccine exemptions allowed. A ranking of one indicated a state in which there were no exemptions granted other than those for medical reasons. A ranking of two indicated a state in which medical and religious exemptions were granted, but required an authorized signature from a notary, public health official or healthcare professional. A ranking of three was given to those states that offered medical and religious exemptions without requiring and authorized signature from a notary, public health official or healthcare professional or those that states that allowed medical, religious and personal belief exemptions with a notary, public health official or healthcare provider's signature. And lastly, a state with a rank of four was one in which medical, religious and personal belief exemptions were granted with the signature of a parent or guardian accepted on the exemption form with no further requirements.

Table 1

Vaccine Exemption Lenience Scale

	1	2	3	4
Medical	x			
Religious	x	x		
Religious without signature OR Religious and personal belief with signature	x	x	x	
Religious and personal belief without signature	x	x	x	x

Data Analysis

The study sample is, in fact, representative of the entire population, grouped by state, thereby establishing validity. I examined the timing of policies to eliminate or explain any outside events that may have impacted the findings. Any state with a policy that was unclear or not easily ranked was explained. The definition of the category ranks for each state was also vital to the instrument's reliability. As an example, the state with the highest rate of pertussis in 2012 was Wisconsin. According to the Wisconsin Department of Health Services (2013) website, parents who wished to exempt their child from the mandatory immunizations for entry into public school, needed only sign a form and send it to school with their child. The form was, in fact, available on the website with the option for religious or personal belief exemption to be checked. Wisconsin, therefore, was given a ranking of 4 on the lenience scale.

The first research question was: Do states with more lenient immunization requirements for children in public schools have higher exemption rates than states with stricter immunization requirements? This question was analyzed by determining if an association existed between each state's lenience level and exemption rate. The second research question was: Do states with a higher immunization exemption rate have a higher rate of pertussis? Answering this question involved an examination of the relationship between exemption rate and pertussis rate. The third and final research question was: Do states with more lenient immunization requirements for children in public schools have a higher pertussis rate? To answer this question, the association between each state's pertussis rate and lenience level was examined.

Because I examined the relationship between the named variables rather than establish cause, and because the lenience level was measured on an ordinal scale, Spearman's rank-order correlation was used for data analysis. Spearman's correlation coefficient measures the strength and direction of association between the two variables. The data met criteria for the basic assumptions required for the Spearman's correlation study design. Specifically, there were no nominal variables and there were 51 paired observations. The third assumption, a monotonic relationship between variables, was tested once the data was collected (Laerd Statistics, 2013).

While some ecological studies test an etiologic hypothesis (cause), this project focused only on correlation (Friis & Sellers, 2009). The limitation of ecological fallacy was recognized as the possibility that group findings may not apply to individuals (Friis

& Sellers, 2009). Ecological fallacy was considered during the literature review and research studies are described above to refute this potential limitation.

Evaluation

When applied to the described social problem, Bronfenbrenner's framework showed promise by potentially exposing a substantial way to promote health. I evaluated state level policy outcomes in hopes that the findings may influence future state and federal vaccine exemption policies for children attending public schools. I determined if correlations existed in a three-step approach, based on the objectives discussed previously. The first step was to examine the association between the availability and ease of obtaining the personal belief, or philosophical, exemption and the rate of exemption. The second step was to determine if states with higher exemption rates have higher pertussis rates. Lastly, I determined if a correlation existed between the availability and ease of obtaining a personal belief exemption and the rate of pertussis.

If a correlation existed between lenient immunization requirements and higher rates of pertussis, policy makers may be more inclined to enact stricter laws related to vaccine exemption availability. Using Bronfenbrenner's framework, this project helped reveal how each individual is responsible for promoting and maintaining the health of the larger ecosystem while the larger ecosystem helps guide the choices of the individual to promote health. With stricter policies in place, health care providers would be relieved of the burden of convincing the population to adhere to immunization guidelines. Vaccine policy has the potential to take the burden of choice off of individuals and ensure the

general population is immunized and protected against vaccine preventable diseases like pertussis.

Summary

To examine the correlation between state immunization policies, immunization exemptions and rates of pertussis, I used a cross-sectional ecological comparison study. I used previously collected, pubic data made available by the CDC, schools of public health, state health departments, state policy websites and direct contact with public health officials. The study sample was grouped into 50 states and the District of Columbia.

I classified vaccine exemptions as medical, religious and personal belief. Religious and personal belief exemptions were further classified as easy to obtain and hard to obtain. Depending on the types of exemptions allowed, each state was given a lenience level, based on a four-point rank order scale. Spearman's rank-order correlation was used for data analysis.

I used a three-step approach to determine if the correlations exist. The first step was to examine the association between the availability and ease of obtaining the personal belief exemption and the rate of exemption. The second step was to determine if states with higher exemption rates have higher pertussis rates. The last step was to determine if a correlation existed between the availability and ease of obtaining a personal belief exemption and the rate of pertussis. Evaluating the relationship between state level health policy and vaccine preventable disease rates may impact future state and federal vaccine exemption policies. When applied to the findings, Bronfenbrenner's

framework exposed a substantial way that systems larger than the individual can have an impact on population health.

Section 4: Findings, Discussion, and Implications

As detailed in Section 3, I used a four-point rank order scale to rate the lenience of vaccine exemptions in each state on a level of one to four. Exemption rates were calculated for each state based on an average between the exemption rate between the 2011 – 2012 school year and 2012–2013 school year in each state as reported to the CDC (CDC, 2013d). The project objectives were determined to be realistic and were met as detailed in Section 4.

Summary of Findings

First, using SPSS, I investigated the relationship between the lenience of vaccine exemptions in each state (as measured by the Vaccine Exemption Lenience Scale) and the exemption rate of each state using Spearman's *r* product-moment correlation coefficient. I found a medium, positive correlation between the two variables, $r = .359$, $n = 51$, $p < .01$, with more lenient vaccine exemptions associated with higher exemption rates. Next, I investigated the relationship between the exemption rate in each state and the pertussis rate of each state. Again, I found a medium, positive correlation between the two variables, $r = .470$, $n = 51$, $p < .01$, with higher exemption rates associated with higher rates of pertussis. Finally, I investigated the relationship between the lenience level of vaccine exemptions in each state (as measured by the Vaccine Exemption Lenience Scale) and the pertussis rate of each state using Spearman's *r* product-moment correlation coefficient. I found a weak, positive correlation between the two variables, $r = .111$, $n = 51$, $p = 0.439$, with more lenient vaccine exemptions associated with higher pertussis rates.

Discussion

The first research question was: Do states with more lenient immunization requirements for children in public schools have higher exemption rates than states with stricter immunization requirements? There was a positive correlation between the two variables of medium strength. That is to say, more lenient immunization requirements for children in public schools was associated with higher rates of exemption. These findings are consistent with previous published studies conducted and published between 2005 and 2013, detailed in Section 2, that show personal belief and religious exemptions, as well as the ease of obtaining those exemptions, are associated with higher and increasing exemptions rates.

The second research question was: Do states with higher immunization exemption rates have a higher rate of pertussis? Again, there was a positive correlation between the two variables of medium strength. A higher rate of immunization exemption was associated with a higher rate of pertussis. While this study examined the two variables between states, the findings are again consistent with the studies detailed in Section 2 that examined areas of high exemption rates within states.

The third research question was: Do states with more lenient immunization requirements for children in public schools have a higher pertussis rate? A weak, positive correlation between these two variables was found. More lenient vaccine exemptions were associated with a higher rate of pertussis. The analysis of the relationship between state policy and disease rate was again, consistent with the limited literature available as discussed in Section 2.

The strictest exemption policy was found in the state of Mississippi where only medical exemptions were permitted. In 2012, a physician could request a medical exemption on behalf of a child, and a local health officer could either approve or reject the request (Justia Law, 2015a). In 2012, Mississippi had an immunization exemption rate of 0%, the lowest in the nation (CDC, 2013d) and a pertussis rate of 2.6, the forth lowest in the nation (CDC, 2013c).

The states with the most lenient immunization requirements allowed medical, religious, and philosophical exemptions. The ease of which those exemptions were obtained varied. The least obstacles for exemptions were found in states where a form was available online. A parent or guardian simply checked a box, signed and returned the form to the child's school. Some states required a notary signature. Three states required the signature of a health care professional before the exemption was granted and two states required the parent or guardian undergo an education session on the risks associated with not vaccinating prior to the exemption being granted. Ten states required interaction with the local health department while the others required the exemption request be sent directly to the child's school. Some states required a written affidavit while others had a pregenerated form. Permanent exemptions were offered by some states, while others only offered temporary exemptions and required renewal, usually annually. Interestingly, the highest rates of exemptions were found in Alaska and Oregon at 6.3 and 6.15, respectively (CDC, 2013d). Neither of those states allowed philosophical exemptions in 2012, but both only required the signature of a parent or guardian to obtain

the exemption (CDC, 2011b). Alaska and Oregon had pertussis rates of 48.3 and 23.2 (CDC, 2014d), making them the 9th and 15th highest in the nation.

Considering Bronfenbrenner's bio-ecological framework, the macrosystem, as it relates to this research, includes each state's immunization policy, more specifically, the exemptions allowed in each state and the ease of which those exemptions were obtained. The exemption rate and pertussis rate of each state fall into the exosystem. Bronfenbrenner believed that each level of the bio-ecological framework influences the others and that social problems arise when one or more of the systems are deficient (Newworldencyclopedia.org, 2008). Based on the data analysis, it is possible that at least part of the cause for high pertussis rates in some states is due to deficiency in the macrosystem, or vaccine policies among those states.

Ideally, a policy change in which state legislators make it more difficult to obtain exemptions or eliminate non-medical exemptions would result in a positive change in all of the systems below the Macrosystem. For instance, California's governor recently signed SB-277 into law, which essentially eliminated the personal belief and religious exemptions in that state effective January 1, 2016 (California Legislative Information, 2015). California's pertussis rate reached epidemic proportions in 2010 and 2014 (California Department of Public Health, 2015). If Bronfenbrenner's framework applies, the state of California should see a decrease in immunization exemptions and a sustained decrease in pertussis rates.

Project Strength and Limitations

Strengths

The biggest strength in this ecological comparison study is the groundwork it has laid for future research. The bulk of data needed to investigate how vaccine exemptions relate to disease rates is readily available to anyone with Internet access. Additionally, as the practice problem for this project was defined as a social problem, applying Bronfenbrenner's framework gives the study the added strength of identifying deficiencies in multiple levels within an ecological system. Indeed, it might be acknowledged that state immunization policy may be related to pertussis rates, but other factors, both more individualized and sociologically more complex, are likely involved.

Limitations

States that allow religious exemptions posed a challenge during this project. For most states in this category, there is no filter in place to ensure an exemption is requested based on a genuine religious belief as opposed to a personal belief. This made ranking the state on the lenience scale more difficult and placed a limitation on the strength of the study.

A second limitation of the current study is that the exemption rates used were based only on children entering kindergarten. As detailed in Section 1, adolescents between 11–19 years of age accounted for almost a third of all pertussis cases in 2012 (CDC, 2013c). At that time, the Tdap booster was not mandatory for adolescents in every state; therefore, adolescent exemption rates were not included (Immunization Action Coalition, 2015). It should also be noted that exemptions for each immunization

are not reported separately. It is possible for a parent or guardian to opt out of one vaccine, but agree to another. This could certainly limit the strength of the project.

Finally, the strength of this study was limited by the absence of statistical reliability of the final research question results. The *p* value for this question was noted to be 0.439, outside the limit for statistical reliability. However, based on the results of the first data analysis related to exemption lenience and exemption rate and the second analysis of exemption rate and pertussis rate, I would like to emphasize the illogical approach of outright rejection of the findings, even if they are weak.

Recommendations for Remediation of Limitations in Future Work

Some research devoted to the lack of certainty of religious exemptions being obtained appropriately has been conducted. New Mexico, for instance, allowed medical and religious vaccine exemptions in 2011. A written affidavit from a parent, guardian, or officer of a religious denomination had to be submitted and notarized, but explaining the specific religious practice for the basis of exemption was not required (Justia Law, 2015b). Tang, Selvage, Glaser and Baumbach (2014) conducted a study that same year in which the parent or guardian of children who were granted a legal religious vaccine exemption in New Mexico were surveyed to determine the primary reason for obtaining a religious exemption. Of the families surveyed, only 21.7% reported a religious reason for obtaining a religious exemption while 54.9% reported a philosophical or personal reason (Tang et al., 2014). In 2013, Grabenstein studied the religious teachings of six of the more popular religions of the world and how they apply to vaccines. Of the teachings of

Hinduism, Buddhism, Jainism, Judaism, Christianity, and Islam, Grabenstein determined that very few sects have scriptural or textual bases for refusing immunizations (2013).

To remediate the second limitation in this study, I would recommend further research on the impact of adolescent immunization and exemption rates and how they relate to pertussis rates. One might study the impact of a state implementing the Tdap booster requirement on the state pertussis rate. Another option might be to narrow the focus on the pertussis rates among children in kindergarten through sixth grade when analyzing the exemption rates used in the study.

In order to study the true impact on the exemption of a vaccine and the rate of that particular disease, more research should focus on the individual vaccine exemption rather than lumping exemptors into one broad category. Various types of vaccines are used today to prevent diseases. Live vaccines are those that contain an actual living microbe of an organism, but weakened to the point that it should not cause infection in a person with a healthy immune system (Vaccines.gov, 2015). Live vaccines, such as the MMR are contraindicated in anyone with a severe allergy to a vaccine component, pregnant women and immunosuppressed individuals. DTaP and Tdap vaccines, those that include the acellular pertussis immunization, are inactivated bacterial vaccines. These vaccines do not pose the same risks as live vaccines pose to immunocompromised persons and are, in fact, strongly encouraged. The only contraindications to inactivated vaccines are a severe allergy to a vaccine component and for DTaP or Tdap vaccine, a history of encephalopathy 7 days after a previous vaccine administration without another known cause (CDC, 2015). This information led to yet another uncertainty. The case for any

medical professional granting a DTaP or Tdap exemption should be extremely rare. Some future research should focus on medical exemptions and whether they are being granted for appropriate reasons, particularly for inactivated vaccines.

Lastly, as noted above, the final research question did not meet statistical reliability. For future research, regression analysis could be used to further analyze the relationships among the varying exemption barriers. Learning which barriers (i.e. notary signature, interaction with the health department, education session, etc.) have the greatest impact on vaccine compliance would be valuable information for future policy development.

Implications

Policy

Based on these findings and what is known about herd immunity, this project should give more leverage to individuals seeking to limit immunization exemptions to those granted for only medical reasons. What becomes clear from this project, as well as previously published research, is that immunization exemptions will be obtained if they are available, regardless of if they are classified based on religious or personal belief. With each exemption, herd immunity is diminished and contagious diseases have greater potential to spread.

Practice

Nurses are on the forefront of public health. It is imperative that they remain up to date on the most recent immunization recommendations. This project should be added to the literature that nurses use to inform and educate the public. Research has proven the

effectiveness and appropriateness of the pertussis vaccine schedule. Vaccine policy research can be used by public health nurses to show how policies have helped promote the health of individuals and the public. Additionally, when educating the parent of a child due for immunizations, the findings of this project might be used to encourage parents who live in areas with a high immunization exemption rate to be even more vigilant about keeping children on the recommended vaccine schedule.

Research

As discussed above, there is much research to be done on the cause of resurgence of vaccine preventable diseases such as pertussis. When investigating the role of state public health policy, analyzing the impact any policy change has had on disease rates in the recent past would be beneficial. Tracking disease rate trends before and after immunization policy changes, especially among multiple states, would provide valuable information for policy makers in the future.

Social Change

In order to bring about social change as it relates to this project, one must first start to view immunizations as an obligation of every individual, community and state to public health. Citizens of the U.S. have obligations to society that contribute to the safety and security of the entire nation. Much like laws prohibiting texting while driving, public intoxication, or smoking bans in schools, immunizations should be strictly enforced by policy.

Analysis of Self

The project required to complete the Doctor of Nursing Practice degree has been beneficial to me in numerous ways. I chose the project topic because of simplicity in terms of budgeting, collaboration and lack of risk to human test subjects. As a project developer, I now recognize that collaborating might have forced me to finish in a timelier manner. For future projects, I know I will need to set more concrete deadlines. I had proposed four weeks for data collection and an additional two weeks for data analysis and have spent over a year completing the project. In retrospect, the proposed timeline for these activities could have probably been completed in 3-4 months, but other responsibilities and obligations took precedence. As a nurse practitioner, working in different practice settings, the knowledge gained while completing this project has certainly proven to be beneficial, particularly when addressing patients about immunization compliance. Additionally, I have become a vaccine advocate among colleagues and encourage nurses to set an example by being compliant with annual flu shots and other adult immunizations.

Investigating pertussis and immunization exemptions has expanded my knowledge base of an area in which I was not previously familiar. As a scholar, I find the concept of a non-medical exemption for a mandatory immunization scientifically baffling, and I know I will pick up this topic again in the future, if only to satisfy my innate curiosity and desire to learn. Finally, the amount of professional development achieved through the completion of this project and degree is already starting to be evident. Just recently, I was approached by a physician colleague and asked to be a co-

investigator in an upcoming clinical drug trial. The skill set and expertise this project has given me has opened doors in my professional life that I never anticipated.

Summary and Conclusions

The findings of this project demonstrate positive correlations between each of the variables within the study, exemption lenience, exemption rate and pertussis rate by state. These findings are consistent with the review of literature discussed in Section 2. Considering Bronfenbrenner's bio-ecological framework and based on the data analysis and review of literature, it is logical to say that deficiency in the macrosystem (vaccine policies in each state) could certainly be contributing to the rise of pertussis rates in the U.S.

Despite the outcome of this project, research is still needed to examine the effect of vaccine policy on disease rates. The appropriateness of granting religious exemptions should be explored more thoroughly. The impact of adolescent immunization and exemption rates will need to be determined as well. Attention should be given to individual vaccine exemptions rather than lumping exemptors into one broad category. It is currently unclear if all vaccines or one vaccine is being refused and this information is crucial to determining how exemptions are affecting disease rates. Lastly, focus should be given to the relationship among the varying exemption barriers. Learning which barriers (i.e. notary signature, interaction with the health department, education session, etc.) have the greatest impact on vaccine compliance would be valuable information for future policy development.

The project objectives were met and the findings should have significant implications. What becomes clear from this project, as well as previously published research, is that immunization exemptions will be obtained if they are available, regardless of how they are classified (religious or personal belief). With each exemption, herd immunity is diminished and contagious diseases have greater potential to spread. This project should be added to the literature used to inform and educate the public as well as influence policy makers. Citizens of the U.S. have obligations to society that contribute to the safety and security of the entire nation. Immunizations need to be viewed as an obligation to the health of individuals, communities and states and enforced by health policy.

Section 5: Executive Summary

Project summary

Pertussis, a vaccine preventable disease once close to eradication, still has major public health and financial implications in the U.S. Despite rising pertussis rates and associated deaths, since 1998, nonmedical vaccine exemptions for children and adolescents have increased in the U.S. and at a faster rate than from the previous decade (Caplan, 2012). The purpose of this project was to explore the correlation between immunization policies, exemption rates and pertussis rates in each state.

Background

The CDC has tracked pertussis since 1922 when there were 107,473 cases reported. In 1934, reported cases reached an all-time high of 265,269. In the U.S., pertussis became a vaccine preventable disease in the late 1940's when immunization with the whole cell pertussis (DTP) vaccine became routine. By 1976, the disease had become rare with only 1010 cases reported. However, since that year, reported pertussis cases and associated deaths have steadily risen. In fact, in 2012, the CDC tracked 48,277 cases, making it the highest number reported since 1955. Twenty deaths were directly caused by pertussis as well, making it the only vaccine preventable disease associated with an increasing death rate in the U.S. (CDC, 2013c). An explanation for the rise in pertussis on a national level may be the result of multiple factors, including nonmedical vaccine exemptions. Nonmedical vaccine exemptions have become increasingly popular since the early 1980's when a journalist, without scientific evidence, set forth a theory linking the DTP vaccine to brain damage in a documentary that aired on network

television (Sobel, 2011). Then, in 1998, *The Lancet* published a fraudulent study by Wakefield et al. that linked the MMR vaccine to autism. The study was later retracted, but since it was published, the number of non-medical vaccine exemptions has risen in the U.S., as have pertussis and measles rates (Caplan, 2012).

Social Significance

Pertussis is addressed in Healthy People 2020 (2013), making it a social problem acknowledged on a national level. The guidelines set forth by the CDC for pertussis immunization are based on over half a century of scientific research. Policies on vaccine requirements and allowable exemptions for children in public schools are determined on a state level. Though pertussis can infect individuals of any age, infants less than a year old accounted for 10.8% of the reported cases in 2012 and 80% (18 of 20) of the deaths (CDC, 2013c). Approximately half of the infants who contract pertussis require hospitalization, which can cost thousands of dollars. Immunizations are among the most cost-effective services health care has to offer and pertussis is best prevented with immunization (CDC, 2013b). It is estimated that for each birth cohort immunized on schedule, the U.S. saves $9.9 billion dollars in direct health care costs and $33.4 billion dollars in indirect costs (HHS, 2013).

Literature Review

Databases included *Cochrane Database of Systematic Reviews*, CINAHL, PubMED, PsycINFO, MEDLINE and Google Scholar. The search terms used were *vaccine exemptions, immunization exemptions, personal belief exemptions, religious exemptions, philosophical exemptions, immunization policy, vaccine policy, pertussis*

rate, vaccine preventable disease rate, and *pertussis outbreak*. Review of the literature revealed consistency with the waning immunity theory, under-vaccination, and lack of effectiveness of the DTaP vaccine compared to the DTP vaccine as reasons behind the rise in pertussis rate in the U.S. Additionally, the literature consistently showed that states with nonmedical vaccine exemptions available have higher rates of exemptors. Areas within each state that had a high number of exemptors also had higher pertussis rates. However when examining the effect of allowable exemptions and the ease of which they are obtained on rate of pertussis by state, the literature had conflicting results (Atwell et al., 2013; Berreth, 2012; Blank et al., 2013; Dorrell et al., 2011; Feikin et al., 2000; Glanz et al., 2009; Glanz et al., 2013; Haytham et al., 2012; Imdad et al., 2013; Klein et al., 2013; Liko et al., 2014; Omer et al., 2006; Omer et al., 2008; Omer et al., 2012; Tartof et al., 2013; Yang & Debold, 2014; and Zhang et al., 2012)

Theoretical Framework

I chose Bronfenbrenner's bio-ecological framework to guide the investigation into this project. Bronfenbrenner suggested that the individual self, experiences, culture, society, economic situation, and politics influence human behavior (Newworldencyclopedia.org, 2008). His framework, like other ecological perspectives, help researchers understand how each of these levels is interdependent on the other and interactions between these levels influence the health of individuals and communities (Grzywacz & Fuqua, 2000).

Data Collection and Sampling

Existing, previously collected, public data was used for this observational inquiry. Secondary data collected by the CDC was used to gather information on the number of cases and incidence rates of pertussis in each state. Policies, immunization rates, and exemption rates were researched for each state in schools of public health, state health departments, state policy websites, and direct contact with state public health officials as warranted. The study sample was grouped into 50 states and the District of Columbia, which allowed for group analysis rather than case analysis. Exemption rates used were based on children entering kindergarten. Vaccine exemptions were classified as medical, religious, and personal belief. Religious and personal belief exemptions were further classified as easy to obtain and hard to obtain. Depending on the types of exemptions allowed, each state was given a lenience level, based on a four-point rank order scale.

Research Method and Analysis

To explore the correlations between variables, I used a cross-sectional ecological comparison study. I examined the relationship between variables using Spearman's *r* product-moment correlation coefficient. I used SPSS for all data analysis.

Assumptions and Limitations

The data met criteria for the basic assumptions required for the Spearman's correlation study design. Specifically, there were no nominal variables, there were 51 paired observations, and there was a monotonic relationship between the variables (Laerd Statistics, 2013). Limitations were given forethought as described by Friss and Sellers (2009). I recognized that this project could only establish correlation, rather than cause.

Ecological fallacy was considered throughout the literature review, and research studies were described to refute this potential limitation.

Findings

The first research question addressed in this project was: Do states with more lenient immunization requirements for children in public schools have higher exemption rates than states with stricter immunization requirements? The relationship between the lenience of vaccine exemptions in each state and the exemption rate of each state was investigated and a medium, positive correlation was found, $r = .359$, $n = 51$, $p < .01$, with more lenient vaccine exemptions associated with higher exemption rates. These findings are consistent with previous published studies conducted and published between 2005 and 2013 that show personal belief and religious exemptions, as well as the ease of obtaining those exemptions, are associated with higher and increasing exemptions rates.

The second research question addressed in this project was: Do states with higher immunization exemption rates have a higher rate of pertussis? The relationship between the exemption rate in each state and the pertussis rate of each state was investigated and again, a medium, positive correlation between the two variables was revealed, $r = .470$, $n = 51$, $p < .01$, with higher exemption rates associated with higher rates of pertussis. While this study examined the two variables between states, the findings are again consistent with the studies that examined areas of high exemption rates within states.

The third and final research question addressed in this project was: Do states with more lenient immunization requirements for children in public schools have a higher pertussis rate? The relationship between the lenience level of vaccine exemptions in each

state and the pertussis rate of each state was investigated, and a weak, positive correlation between the two variables was found, $r = .111$, $n = 51$, $p = 0.439$, with more lenient vaccine exemptions associated with higher pertussis rates. The analysis of the relationship between state policy and disease rate was again, consistent with the limited literature available.

Outcomes and Conclusion

Considering Bronfenbrenner's bio-ecological framework, the macrosystem, as it relates to this research, includes each state's immunization policy, more specifically, the exemptions allowed in each state and the ease of which those exemptions were obtained. The exemption rate and pertussis rate of each state fall into the exosystem. Bronfenbrenner believed that each level of the bio-ecological framework influences the others and that social problems arise when one or more of the systems are deficient (Newworldencylcopedia.org, 2008). Based on the data analysis and review of literature, it is logical to say that deficiency in the macrosystem (vaccine policies in each state) could certainly be contributing to the rise of pertussis rates in the U.S. The project objectives were met and the findings should have significant implications. What becomes clear from this project, as well as previously published research, is that immunization exemptions will be used if they are available, regardless of whether they are classified as religious or personal belief. With each exemption, herd immunity is diminished and contagious diseases have greater potential to spread. This project should be added to the literature used to inform and educate the public as well as influence policy makers. Immunizations need to be viewed as an obligation to the health of individuals,

communities and states. Citizens of the U.S. have obligations to society that contribute to the safety and security of the entire nation. Freeing some from the responsibilities held by all is essentially ignoring the science behind over two centuries of vaccine research.

Recommendations for Future Work

Research is still needed to examine the effect of vaccine policy on disease rates. The appropriateness of granting religious exemptions should be explored more thoroughly. The impact of adolescent immunization and exemption rates will need to be determined as well. Attention should be given to individual vaccine exemptions rather than lumping exemptors into one broad category. It is currently unclear if all vaccines or one vaccine is being refused and this information is crucial to determining how exemptions are affecting disease rates. Lastly, focus should be given to the relationship among the varying exemption barriers. Learning which barriers (i.e. notary signature, interaction with the health department, education session, etc.) have the greatest impact on vaccine compliance would be valuable information for future policy development.

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