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A COMPARISON OF IMMUNIZATION ADHERENCE RATES FOR INDIGENT AND NON-INDIGENT 2-YEAR-OLDS

By

C. CAROL MCCORMICK

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The members of the Committee approve the thesis of C. Carol McCormick defended on March 17, 2004.

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Jeanne Flannery
Professor Directing Thesis

_____

Sandra Faria
Committee Member

_____

Denise Tucker
Committee Member

Approved:

_____

Jeanne Flannery, Director of Graduate Studies, School of Nursing

_____

Katherine P. Mason, Dean, School of Nursing

The Office of Graduate Studies has verified and approved the above named committee members.

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ABSTRACT

This Study compared immunization adherence rates and demographic characteristics of 288 indigent and non-indigent 2-year-old children in Leon and surrounding Counties in North Florida. The hypothesis of the study was that indigence is not a primary influence of immunization non-adherence in this population. Providing data to validate the hypothesis is important in order to target strategies to improve immunization adherence to the correct population.

The study validated the hypothesis by showing that non-indigent children are significantly less adherent than indigent children. It also demonstrated that focusing efforts on female, urban dwelling, first-born, children of married, employed mothers would reach the largest group of non-adherent 2-year-olds.

Pender's Health Promotion and Revised Health Promotion Models (Pender, 1997) were used as the conceptual framework for the study. These works help to explain the disease prevention and health promotion behaviors of individuals. In this study, the parents' behaviors in seeking immunizations for their children were the focus. As indicated by the data, indigent parents more frequently overcome barriers to immunization.

CHAPTER 1
INTRODUCTION

Immunizations have proven to be one of the most cost-effective and successful public health initiatives of the last century, and are credited with being a major contributor to our increased life expectancy (Gellin, Maibach, & Marcuse, 2000). However, this country continues to struggle with the problems of under-immunization and periodic resurgences of vaccine-preventable illnesses (Evers, 2000). Florida Health officials have recognized the need to identify and target interventions toward geographic areas with populations at high risk for under-immunization (A.R. Neasman, personal communication, September 7, 2001). Correctly identifying those areas and populations is a key factor to increasing immunization rates. Research has shown that under-immunized children are likely to be indigent and members of ethnic and racial minorities (Findley, Irigoyen, & Schulman, 1999; Moore, Fenlon, & Hepworth, 1996; Wood & Halfon, 1996). While attention is often focused on indigent and minority children when efforts are made to increase immunization rates, this study focuses on other risk factors and attempts to show that they may be just as, or even more influential in affecting immunization rates.

In 1998, the findings of the National Immunization Survey conducted by the Centers for Disease Control (CDC) indicated that less than 80% of 2-year-old children had all

of the recommended immunizations for their age (Centers for Disease Control and Prevention, 1999). Children less than 2 years of age are the most susceptible to infectious diseases. However, there are no formal legislative mandates requiring complete immunizations at this age when children are most vulnerable to the devastating consequences of vaccine preventable diseases (West & Koop, 2000). With the National goal's being 90% of children having the recommended immunizations by age 2 (Yawn, Xia, Edmonson, Jacobson, & Jacobsen, 2000), much work remains to be done.

In Florida, for the year 1999-2000, the immunization levels for 2-year-olds ranged from 83.6% for children classified as "high-risk" to 88.2% for the non-high-risk group (State of Florida, Department of Health, 2000). For the 2000-2001 year, the rates for the high-risk group decreased to 82.15, while the non-high-risk group rose to 90.4% (State of Florida, Department of Health, 2001). The numbers for the high-risk group continued to decrease, to 79.7%, for the 2001-02 year, while the non-high-risk group increased to 90.8 (State of Florida, Department of Health, 2002). The children in the high-risk group included those whose mothers met one or more of the following criteria: less than a 12^{th} grade education; less than 20 years old; had three or more children; were unmarried; prenatal care started after the second trimester (State of Florida, Department of Health, 2002). Although the immunization levels in Florida are greater than the National averages (Centers for Disease Control and Prevention, 1999; State of Florida, Department of Health, 2001), State Health officials continue to work for improvement.

In the last several years, the number of recommended immunizations for 2-year-olds has increased from eight to

20 or 21 (depending on the brand of vaccine used), and the type of vaccine used has also changed. For example, inactivated poliovirus vaccine by injection rather than the oral vaccine is now the standard. So, in addition to more vaccines, all of them are now administered by injection. Progress is being made with marketing combination vaccines in order to reduce the number of injections, but these products are not universally available (Consumer Reports Online, 2001). There is concern that the increased number of injections is a factor in some parents' reluctance to, and/or procrastination in, having their children immunized (Swingle, 2000).

There is also concern that the tremendous success of immunizations in eliminating many of the threats of serious infectious diseases in young children may actually decrease parents' understanding of the importance of vaccines. Because many of today's young parents have never had personal experience with vaccine-preventable illnesses, they may have more fear of the vaccines than of the illnesses they prevent (Gellin, Maibach, & Marcuse, 2000). Childhood immunization is a safe and effective way to prevent many infectious diseases and their consequences. Immunizations have important financial benefits and improve children's quality of life. Examples of quality and cost-benefit issues include: One in 19 children who get mumps may develop meningitis or encephalitis; a child with chicken pox misses 8 or 9 days of school, which results in parents missing work; of 100 people infected with diptheria, 5-10 will die; 3 of 10 people who get tetanus die; half of the children who get pertussis have to be hospitalized (National Committee for Quality Assurance, 2001).

In considering the many factors that can and do influence immunization rates, careful attention must be focused on the underlying cultural aspects of care-seeking behaviors. It may be too easy to attribute the lack of immunization adherence to indigence (Findley, Irigoyen, & Schulman, 1999; Moore, Fenlon, & Hepworth, 1996; Wood & Halfon, 1996), rather than looking at the myriad of factors that may be involved.

Statement of the Problem

The availability of immunizations in this country is virtually universal. Cost is no longer a major factor since the inception of the Vaccine for Children Program, which provides free vaccine to children whose parents do not have insurance coverage or other means to pay for vaccine. Many studies and initiatives have focused on vaccine availability, access, and parental compliance, and have resulted in many innovative programs to increase the number of children receiving complete and timely vaccinations (Evers, 2000; Strobino, Prislin, & Dyer, 1999; Wilson, 2000; Yawn, Xia, Edmondson, Jacobson & Jacobsen, 2000). Yet, children continue to contract vaccine-preventable illnesses because they, and others with whom they come in contact, are not fully immunized. In addition, there is a direct correlation between childhood immunization rates and the adequacy of pediatric health care in general. Under-immunized children typically have fewer preventive health care visits, making them less likely to be screened for developmental problems, anemia, sensory deficits, and signs of chronic medical conditions and special needs (Hillman et al., 1999).

The on-going public education campaigns, special clinics and other efforts to increase the availability of and access to immunizations have, no doubt, increased the numbers of immunized children. However, as reported by the Florida Department of Health (2001), over 14% of Florida's children remain unprotected and at risk for serious, debilitating, costly and potentially lethal illnesses. This is unacceptable.

Special efforts to improve immunization adherence are typically directed to neighborhoods that include a high population of indigent children. These efforts usually include immunization clinics in locations such as housing projects, certain schools, and community centers. There is little evidence to demonstrate the effectiveness of such 1-day immunization events (The National Vaccine Advisory Committee, 1999). Data to show that non-indigent populations comprise a large percentage of the under-immunized children should result in redirection of these efforts and thereby improve immunization rates in the community.

Significance of the Problem

Efforts to increase the numbers of immunized children consume a large amount of public health resources. Factors influencing immunization programs include cutbacks in federal funding for county health department immunization programs (A. R. Neasman, personal communication, September 7, 2001), and the addition of new immunization requirements for school entry (Florida Statutes, 2002). Given the National economic climate, if resources allocated for public and child health programs decrease, it is

increasingly important to concentrate efforts on programs and populations that will render the greatest return in increasing the rates of childhood immunization and decreasing the incidence of vaccine-preventable illnesses. Knowledge of the risk factors for inadequate immunization must be included in strategies to increase rates.

Although health officials in Florida consider the effects of many cultural influences on the immunization status of children (State of Florida, Department of Health, 2001), there may be other factors that are not considered. To a large degree, immunizations are only available during the usual workweek, Monday through Friday. Yet, many parents, due to work and other obligations, have difficulty accessing non-urgent care during those times (Evers, 2000). Frequently, new mothers return to work at about the same time that the first series of immunizations is due. Because they have often just been on extended leave from their jobs, obtaining time off for well care and immunizations may be difficult. Another frequent concern is that in addition to time off to obtain the immunizations, the child may become ill after obtaining the vaccine causing the need for more time off (Wilson, 2000). Few, if any, evening or weekend well child and/or immunization clinics are available and, if they are, there are still many competing demands like cooking, washing, and child-care for siblings (Wilson, 2000). According to the Census Bureau, 55% of mothers with children younger than a year of age were working in 2000. Although this is a 4% decrease from 1998, the recent downturn in the economy may result in reversal of the trend (Cohn, 2001). With the large number of working mothers and the decreasing number of two- parent families (McKim, 2001), this problem will intensify. The mothers in

these categories are not necessarily indigent. Other obstacles, not related to the family's economic status, often include competing priorities, inconvenient locations of clinics, missed opportunities, and lack of appointment reminders (Houseman, Butterfoss, Morrow, & Rosenthal, 1997).

It is possible that the redirection of some of the efforts to increase immunizations may result in significantly greater numbers of protected children. Efforts must not only be focused on indigent children, most of whom are now in Medicaid managed care programs with excellent access to care, but the children of middle class, working families as well. This may well be the cultural group that includes a significant number of under-immunized children. If one initiative or cultural consideration that prevents a single death from varicella, meningitis, measles or any vaccine-preventable illness in a child can be identified, the effort is worthwhile.

The role of nurses as leaders in the effort to immunize children is well documented. As the level of health care providers with the largest numbers and as the first health care provider with whom parents and children come in contact, nurses are vital to the immunization effort (American Nurses' Association, 1994). Nurses must continue their leadership roles in the effective and efficient delivery of vaccine to children. All nurses, and especially Advanced Practice Nurses, must continue efforts in the education of parents and of other vaccine providers regarding the schedule of vaccinations and the necessity for on-time, complete immunization of all children. And, they must collaborate with public health agencies, schools, social service programs, and others in the development of

innovative strategies to eliminate barriers and to develop policies and programs to assure that all children are immunized.

Purpose of the Study

The purpose of this study is to compare the rate of adherence to recommended vaccine schedules between indigent and non-indigent 2-year-old children in a selected geographic section of North Florida. Data are needed to show the degree to which non-indigent children contribute to immunization non-adherence. The study will also identify cultural influences which may affect immunization rates.

Research Questions

The following research questions will direct this study:

1. What are the demographic characteristics of the children from which data will be obtained for this study?
2. Are there differences in immunization adherence for indigent and non-indigent 2-year-old children in North Florida?

Hypothesis

Indigence is not a primary influence of immunization non-adherence for 2-year-olds in North Florida. Therefore, strategies to improve immunization adherence in this area should be directed to populations other than, or in

addition to, the indigent, in order to reach the largest number of children in need of immunizations.

Operational Definitions

Some of the terms utilized in this study have definitions unique to this effort. Those definitions are provided in the following section.

Indigent: For the purpose of this study, children who receive Medicaid benefits under Title XIV or XXI of the Social Security Act, as determined by verification of their identification number as active in the Florida Medicaid Management Information System are considered indigent.

Non-indigent: Children who are not listed in the Florida Medicaid Management Information System as current or previous recipients of Medicaid benefits.

Immunization adherence: Documentation in the child's medical record that all of the vaccines and doses recommended by the Advisory Committee on Immunization Practices, that are also later required for school entry, for children who are 2 years old, have been received, including Hepatitis B (three doses); Diphtheria, Tetanus, Pertussis (four doses); Haemophilus Influenza type B (three or four doses, depending upon the type of vaccine utilized); Inactivated Polio (three doses); Measles, Mumps, Rubella (one dose); Varicella (one dose).

Two-year-old: A child who has reached the second birthday, but has not reached the third, as documented by the Birth Certificate or hospital birth record found in the child's medical record.

Demographic characteristics: For this study, these will include gender, race, Medicaid coverage or none (as

the test for indigence), urban (the two most highly populated cities, Tallahassee and Perry) or rural (all other towns and locations in Leon, Wakulla, Gadsden, Jefferson, Madison, Taylor, and Liberty Counties) domain, number of siblings and birth order, the mother's marital status, and whether or not she is employed outside the home.

Conceptual Framework

Nola Pender's (1996) Health Promotion Model was used to guide this study. Pender identified three areas for consideration: Individual characteristics and experiences, including prior related behavior and personal factors such as biological, psychological, and sociocultural issues; behavior-specific cognitions and affect, which include perceived benefits, perceived barriers, perceived self-efficacy, activity-related affect, interpersonal influences, norms, support and models, and situational influences such as options, demand, and aesthetics; and behavioral outcomes including commitment to a plan of action and health-promoting behavior (Pender, 1996).

This model is well suited for a study of immunization adherence rates for 2-year-olds and cultural influences affecting the rates. Although the model was designed for use with adults and this study focuses on children, it is the action of adults, namely the parents/care-givers of children, that directly affect immunization adherence. Pender (1996) advocated nursing intervention to reduce barriers to health care and overcome cultural influences that restrict access to care. She encouraged empowerment of individuals to value health and the benefits of health-

promoting behaviors to such an extent that they are willing to overcome barriers to healthy behavior.

The Health Promotion Model should be used as a guide to new directions in health care. Dr. Pender pointed out that health care reform is, in actuality, a paradigm shift to health promotion and that health promotion and prevention must be central to the development of health care for the future (Pender, 1999). Using this model to guide a study of immunization adherence is an example of the practical use of a research model in the development of strategies to improve health-promoting behaviors. While the study cannot incorporate all aspects of the model, interpersonal influences and immediate competing demands will be targeted as keys to immunization adherence.

Assumptions

For the purposes of this study, the following assumptions are presented:

1. All parents want their children protected from preventable illnesses.
2. Cost of the vaccine and/or administration of vaccine are not barriers to immunization adherence in Leon and surrounding Counties.
3. Health care providers have the ability to help reduce the number of children who get ill from vaccine-preventable illnesses with interventions to change the behavior of their parents or caregivers.

Limitations

Many of the communities in North Florida are well known as predominantly managed care communities. The vast majority of the population that has private health insurance is served by Health Maintenance Organizations (HMOs), one of which has over 200,000 members (Capital Health Plan, 2002). The indigent population is also served either by Medicaid HMOs or Medicaid's own managed care option known as MediPass (State of Florida, Medicaid Options, 2001). With so much of the population covered by managed care and/or case managed entities, this study could only be generalized to communities with similar numbers of managed care participants.

Summary

Immunizations are one of the most valuable services available for health promotion and illness prevention in young children. Yet, many children remain under-immunized and susceptible to serious, potentially lethal illnesses (Cotter et al., 2000; Evers, 2000). Children must depend on their parents/caregivers to make obtaining immunizations a priority. In many areas, a large percentage of the under-immunized population is made up of indigent children (Findley, Irigoyen & Schulman, 1999; Szilagyi et al., 2000). This study, using Pender's (1996) Health Promotion Model as a guide, seeks to show that non-indigent children, as a result of other cultural influences, play a significant role in the problem of immunization non-adherence in this area.

Chapter 2 provides a review of literature related to immunization adherence and research supportive of the use of Pender's (1996) Health Promotion Model as a framework for this study. It also provides an overview of the diseases for which immunization is required for 2-year-old children.

CHAPTER 2
REVIEW OF LITERATURE

This chapter provides a theoretical review of Nola Pender's (1996) Health Promotion Model as it relates to parents' obtaining immunizations for their children. It also provides a review of research studies utilizing theoretical concepts included in, and/or similar to, those in Pender's model. Additionally, a review of adherence as a concept and the variables influencing it, and a discussion of diseases for which immunization has been mandated are presented. Studies utilizing other conceptual frameworks, reports of unique immunization needs and practices, studies pertaining to adherence to medical regimens, and barriers to care are also presented in order to describe fully the body of knowledge related to the research questions.

Theory

Pender's Models

The Health Promotion Model published by Pender in 1987 and her Revised Health Promotion Model published in 1996 (Pender, 1996) help to explain the disease prevention and health promotion behaviors of individuals. The Health Promotion Model (HPM) provides a framework for personalizing immunization adherence practices. Pender's

(1996) behavior-specific cognitions can be identified in studies of immunization adherence and reasons for non-adherence. These same behaviors can be applied to parents' behavior in seeking preventive services, including immunizations, for their children. The effect of indigence on these behaviors is examined by this study.

The HPM identifies and explains six behavior-specific cognitions and affects in the promotion of behavior change:

1. Perceived benefits of the action result in a mental image of positive consequences.
2. Perceived barriers to actions are real or imagined obstacles that reduce the commitment to a plan of action.
3. Perceived self-efficacy is the process of deciding one's ability to perform a certain task with a certain level of expertise.
4. Activity related affect is the subjective feeling one gets prior to, during and after a behavior.
5. Interpersonal influences are the effects of the attitudes and beliefs of other people.
6. Situational influences are the effects of considering options available and the features of the surroundings that affect a behavior (Neely, 2000).

Identifying the roles these factors play in parents' decisions regarding obtaining immunizations for their children can lend insight into adherence with recommended vaccines and schedules. An example of the perceived benefits of the action resulting in a mental image of positive consequences is described by Gellin, Maibach, and Marcuse (2000) when respondents to their telephone survey spoke about immunizations keeping their healthy children from getting diseases from children who are not immunized.

Real and imagined obstacles reduce parents' ability to obtain immunizations for their children as described by Evers (2000), Wilson (2000), and Yawn et al., (2000). All describe issues such as transportation, competing tasks, past experiences, and the need for reminders as such obstacles.

Perceived self-efficacy in obtaining immunizations was indirectly included in the study by Evers (2000) in obtaining respondent's feelings regarding their responsibility to keep their children healthy. Parents who do not obtain needed immunizations were thought by other parents to be lazy and irresponsible. The same study described parents feeling positive and good about themselves when they did get their children immunized (Evers, 2000).

Interpersonal influences that affect immunization adherence include religious beliefs, negative past experiences, and inaccurate information. An example of such misinformation is parents thinking that if the child has any illness, immunization should be withheld until the child is completely well (Wilson, 2000).

Situational influences, including the barriers described previously, can be overcome by developing optional methods of service delivery. These may include instituting recall and reminder programs, providing incentives and rewards, and creating other means of changing negative influences into positive outcomes (Hillman et al., 1999; Houseman et al., 1997; Yawn et al., 2000).

Immunization Preventable Diseases

Vaccines have drastically reduced the mortality and morbidity from infectious diseases in the last century. Prior to 1925 when vaccines for diphtheria and pertussis were introduced, the yearly incidence for each in this country exceeded 200,000 cases (West & Koop, 2000).

Diphtheria. First described by Hippocrates in the 5th Century B.C., diphtheria is an acute, toxin-mediated infection caused by the organism Corynebacterium diphtheriae. The most common site of infection is the nasopharynx and the onset is indistinguishable from that of the common cold. The toxin produced by the organism affects cellular protein synthesis, which causes local tissue destruction and membrane formation. Absorption of the toxin into the bloodstream results in distribution to other tissues and may cause major complications such as myocarditis, neuritis, and thrombocytopenia. The fatality rate for diphtheria is 5% to 10%, with higher rates, up to 20% in persons less than 5 and greater than 40 years old. Death usually results from airway obstruction (Centers for Disease Control and Prevention, 2000).

Pertussis. This is a highly communicable, vaccine preventable illness that manifests in children with paroxysmal spasms of severe coughing. Caused by the gram-negative coccobacillus, Bordetella pertussis, the disease results in high morbidity and mortality. In the U.S. the incidence is increasing and it now affects 5000 to 7000 people a year, with 5-10 deaths per year, usually in unvaccinated children (Centers for Disease Control and Prevention, 2000).

Tetanus. This disease, caused by the bacterium Clostridium tetani, is rare in this country due to the high

immunization rate. Although very common in the soil, the bacteria are quickly killed by exposure to oxygen. However, wounds that are not open to the air, like puncture wounds, provide a suitable environment for the bacteria. The bacteria produce a toxin that spreads through the blood stream and causes severe muscle spasms, paralysis, and frequently, death (Centers for Disease Control and Prevention, 1997).

Poliomyelitis. Polio has been evident for over 3,000 years and was one of the most feared diseases of the first half of the 20th Century (Sass, 1996). Polio is transmitted by fecal-oral spread, attacking the nervous system and often leading to paralysis. In the early 1950's there were over 20,000 cases annually. Vaccination was started in 1955 and the number of cases fell to about 3,000 in 1960 and to only about 10 by 1979 (Centers for Disease Control and Prevention, 2000). There has not been a naturally occurring case in the United States for over 20 years, but it remains common in other countries where many people are not vaccinated. There were cases in the U.S., however, that were associated with vaccine virus. This lead to the recommendation that live virus immunization be discontinued. Currently, all routine immunization in this country is accomplished using killed polio vaccine (Centers for Disease Control and Prevention, 2000).

Measles. Measles is highly contagious, with an infected person's releasing the organism in the air by coughing or sneezing, and a susceptible person's inhaling it. Symptoms include fever, cough, conjunctivitis, and a red-brown, splotchy rash. Measles can lead to pneumonia or encephalitis, permanent disability, or death (Centers for Disease Control and Prevention, 1997).

Mumps. This acute, viral infection causes fever, and swelling and tenderness of the salivary glands, usually the parotid. The sublingual and submaxillary glands may also be involved (Centers for Disease Control and Prevention, 2002). Before mumps vaccine was licensed in 1967, there were over 200,000 cases a year, mostly in children. Now there are about 1500 reported cases a year, mostly in young adults. Complications are rare, but potentially serious, including orchiitis, pancreatitis, encephalitis, inflammation of the ovaries and hearing loss (Mayo Clinic, 2000).

Rubella. Also known as German measles or three-day-measles, rubella is a highly contagious viral illness causing fever, swollen lymph nodes and a rash that starts on the face and spreads to the torso, then arms and legs. While not serious in children, infection in pregnant women during the first 3 months of the pregnancy, can be devastating to the fetus causing heart damage, blindness, deafness, mental retardation, miscarriage, or stillbirth (Centers for Disease Control and Prevention, 1997).

Hepatitis B. This is a viral illness that can cause acute symptoms including fatigue, loss of appetite, vomiting, diarrhea, and jaundice. In its chronic form, cirrhosis, liver cancer, and death may result. In this country, about 1.25 million people have chronic hepatitis B infection, with approximately 80,000 new cases a year, mostly in young adults. Chronic hepatitis results in 4,000 to 5,000 deaths a year (Centers for Disease Control and Prevention, 2001).

Haemophilus Influenzae, Serotype B Disease. Commonly known as Hib, this illness can present as meningitis, cellulitis, pneumonia, and/or sepsis. The illness is spread

by direct contact with respiratory droplets from a carrier. Since the introduction and widespread use of Hib vaccine in the early 1990's, the rate of disease in children less than 5 years of age has declined by more than 95%(Centers for Disease Control and Prevention, 2000).

Varicella. Commonly known as chicken pox, varicella is a highly contagious, viral disease caused by varicella zoster, a member of the herpes family. Prior to use of the vaccine, there were approximately 4 million cases each year in the United States, resulting in 10,000 hospitalizations and 100 deaths. Ninety percent of the infections, two-thirds of the hospitalizations, and almost half of the deaths occur in children. Varicella in children is one of the greatest risk factors for severe, invasive, group A streptoccal disease. Spread either by direct contact with the fluid in the pox blisters or by airborne droplets, the incubation period is 7 to 21 days. If started early, antiviral treatment can help to reduce the symptoms and the length of the illness. Otherwise, treatment of the symptoms is usually recommended (Pediatrics, 2000).

Adherence

The concept of adherence has been investigated in the context of the Health Belief Model (HBM). The HBM has three broad concepts: General health motivation; perception of the amount of threat imposed by a specific disease; and, perception of the effectiveness of a specific behavior in reducing the threat. Therefore, someone who is positively motivated toward health, perceives a disease as a threat, and a particular behavior, such as immunization, as threat-reducing, is more likely to engage in that behavior than someone who lacks any one of these beliefs (Mirotznik,

Ginzler, Zagon, & Baptiste, 1998). An individual must also have a psychological state of readiness for action before undertaking a recommended health action. It must be perceived that the individual, in this case the child, is susceptible, and the threat is severe and unmodified by barriers and other factors to the extent that the parent is motivated to act (Redeker, 1988). The concept of adherence is also affected by numerous other factors including knowledge of the need for the action or behavior, such as immunizations, past experiences, competing activities, cost, and transportation (Wilson, 2000).

Immunization Requirements

West and Koop (2000) pointed out that there are no formal legislative mandates requiring complete immunizations by the age of 2, thereby leaving children vulnerable to the potentially devastating effects of these preventable illnesses. Although there are no federal laws requiring immunizations, Salmon et al. (1999) indicated that the U.S. Supreme Court consistently upholds the constitutionality of state immunization laws and that most states still allow some exemptions for religious and philosophical reasons. These exemptions also contribute to placing children at risk for vaccine-preventable diseases.

In Florida, in order to enter public or private school, grades kindergarten through 12, children must be immunized against diphtheria, tetanus, and pertussis (DTaP)- 5 doses; polio- 4 doses; measles, mumps, and rubella (MMR)- 2 doses; haemophilus influenzae (Hib)- 3 or 4 (depending on the brand of vaccine used); hepatitis B- 3 doses; varicella- 1 dose, unless medical documentation of having had the disease is provided (Florida Department of Health, Bureau

of Immunizations, 2001). Each district school board and the governing body of private schools must keep proof on file of each child's immunizations. Children whose parents provide written objection to immunization based on religious practices or beliefs are exempt, as are those for whom immunization is not medically indicated, as certified by a licensed physician (Florida Statutes, 2002). The laws governing vaccine requirements for school entry do not apply to children who are home-schooled.

Immunization Rates

A National Immunization Survey conducted by the Centers for Disease Control and Prevention in 1998 found that less than 80% of 2-year-old children had received all recommended vaccines (Centers for Disease Control and Prevention, 1999). A more detailed list of rates, by vaccine, estimates that 83.3% of children are fully vaccinated against diphtheria, tetanus and pertussis (DPT); 59.4% against chicken pox; 93.5% against H Influenza B; 88.1% against Hepatitis B; 91.5% against measles, mumps and rubella (MMR); and 89.6 % against polio (Consumer Reports Online, 2001).

Immunization rates by vaccine type for 2-year olds in Florida for the year 2000-2001 were: 87.9% for DPT, 75.5 % for chicken pox, 96.7% for H influenza B, 95.2% for Hepatitis B, 95.2% for MMR, and 93.6% for polio (State of Florida, Department of Health, 2001). In 2002, the coverage for the basic series of vaccines in Florida (4 DTP/DTaP, 3 polio, and 1 MMR) for 2-year olds was 85.3 percent. Adding 3 Hib and 3 Hepatitis B, the coverage rate drops to 82.6 percent (State of Florida, Department of Health, 2002). Although the rates for the individual vaccines are much

higher, the rates for the basic series are disappointing. It should be noted that the rates are based on a sample of 1,291 randomly selected 2-year old children in 12 counties. The success of vaccine coverage in Florida is attributed the efforts of county health departments and private health care providers, including HMOs, who now administer 75% of the childhood immunizations. Local immunization coalitions and other community partners, including Lions Clubs, who are very active in the effort, are recognized in the success of Florida's immunization program (State of Florida, Department of Health, 2002).

Stokley, Rodewald, & Maes (2001) reported that the measurement of immunization rates is affected to a large degree by mobility of the population and the lack of a coordinated immunization tracking system. Because many indigent children receive immunizations at various clinics and other medical facilities, the rates reported for this population may be inaccurately low. Perrin et al. (2000) reported that the key issue in immunization assessment methodology is defining the patient population. In Florida, the majority of children now receive vaccines through private providers and HMO's. There is no reporting requirement for these providers. The providers that participate in the Vaccine for Children Program provide aggregate numbers of immunizations given. Statewide immunization rates are computed using sampling techniques rather than data reported for all children by all providers. While the data are assumed to be representative of the actual populations, it is possible that the true immunization rate for indigent children is negatively affected by their mobility and the frequency with which they change medical providers.

Effects of Poverty and Other Sociodemographics

In reviewing the literature on the topic of adherence rates for immunizations, it was quickly evident that the vast majority of the published studies show poverty and a lower overall socioeconomic status to place children at risk for immunization non-adherence. Santoli, Szilagyi, and Rodewald (1998) identified five factors strongly linked to low immunization rates: socioeconomic factors including poverty and cost; starting vaccinations late; a lack of patient and provider awareness of the need for more information; provider practices such as missed opportunities and failure to track needed immunizations and remind parents when they are due; and, office or clinic factors like long waits and inconvenient hours.

Yawn et al. (2000) spoke to family characteristics that have been associated with lower immunization rates in 2-year-olds. These include large family size, less formal parental education, lower socioeconomic status, being nonwhite, single parent families, receiving public health department services, and inadequate insurance. This study, however, found many serious barriers to immunization adherence in a non-indigent population as well. These findings support the assumption that factors other than indigence play a significant role in immunization non-adherence. Examples of these factors are inconvenience, fear of reactions, sick child delays, and not knowing the recommended schedule of immunizations. Parents commonly suggested the need for a recall system and for a unified immunization schedule.

Several reports indicated that sociodemographic characteristics are linked to immunization status. Prislin, Dyer, Blakely, and Johnson (1998) concluded that children's

immunizations are affected primarily by their parents' beliefs, attitudes, and perception of control over immunizations. This conclusion is not consistent with the findings of Strobino, Hughart, & Guyer (1999) which indicate that while sociodemographics are closely associated with immunization status, there is little relationship between parents' attitudes and immunization status. However, Gellin, Maibach, and Marcuse (2000) indicated that parents frequently have an attitude of indifference. Since vaccines have greatly reduced the threat of many serious childhood illnesses, parents may now undervalue immunizations. The diseases prevented by vaccines no longer serve as a reminder of the importance of childhood immunization (Gellin, Maibach, & Marcuse, 2000).

The National Immunization Survey conducted in 1998 by the Centers for Disease Control indicated that less than 80% of individuals who are the most susceptible to vaccine-preventable diseases, children under the age of 2, are fully immunized (Centers for Disease Control and Prevention, 1999). Data from the Florida Department of Health (2001) documented better over-all immunization rates than the national rates. Their report divides the 2-year-old population into high risk and non-high risk categories. The factors that constitute high risk include maternal age, education, marital status, trimester of initiation of prenatal care, and the number of children in the family. Economic variables were not included. In the report, the high-risk population had an over-all immunization rate of 82.1% compared to 90.4% for the non-high-risk group. It should be noted, however, that data from a large private health maintenance organization in North Florida, which has a low percentage of high-risk patients, documented a rate

of 67.34% of fully immunized 2-year-olds in their population, for the year 2001, compared to the national HMO average in 2000 of 47.56% (Capital Health Plan, 2001).

Research

Pender's Model

Using Pender's (1996) Model as a framework for studying immunization practices, the behavior specific cognitions she identified can be seen in studies that examine perceived benefits of, and barriers to, immunization. The qualitative study by Evers (2000) included these cognitions. Caregivers sampled (*N*=13), using focus-group interviews, reported that immunizations "keep our children healthy" and protect them from some common childhood illnesses. Barriers reported in the study included long waiting times at clinics and conflicts with clinic hours and work or school. Despite the small sample in the study, interesting commonalities emerged among the four focus groups in response to the same open-ended questions asked of each group. None of the caregivers mentioned cost or transportation as barriers to obtaining immunizations. They did include less commonly voiced barriers such as caregiver laziness and lack of responsibility for the well-being of their children.

Houseman, Butterfoss, Morrow, and Rosenthal (1997) in another qualitative, focus-group study of public, military and private sector mothers (*N*=41) also reported long waits as a barrier, in addition to concerns about immunization safety and side effects, difficulty reaching the clinic or doctor's office for appointments, and problems with child care, and transportation. This study also included

questions to elicit information regarding caregivers' feeling of self-efficacy, another of Pender's cognitions. The respondents reported the perception that health care providers were insensitive in communicating with young, inexperienced, and/or poor mothers. The study concluded that obtaining optimal, on-time immunizations is a complex task that requires planning and resources. To achieve maximum success, the health care system must identify and remove barriers, and assist caregivers to maximize opportunities.

Findings in other studies, including that by Gellin, Maibach, and Marcuse (2000) would lead to questions about parents' self-efficacy when they (25%) reported fears that children's immune systems may be weakened by too many immunizations. This nationally representative telephone survey of 1600 parents also reported that a substantial minority of respondents (23%) believed that children get more immunizations than are good for them. Although most of the parents surveyed understood the importance of immunization and supported them (86.9%), many (19 to 25%) had misconceptions that could erode confidence in their safety. The study concluded that more education is needed to address common misconceptions and ensure informed decisions regarding immunizations. It further reported that parents see physicians and nurses as the most important source of information about immunizations, further documenting the importance of the role of health care providers in reducing this barrier to immunization. Data from this study can be very useful in helping providers and public health officials design strategies to better meet the needs of communities and children relative to immunization provision.

Yawn, Xia, Edmonson, Jacobson, and Jacobsen (2000) reported that fear of reactions to vaccines was the biggest barrier to obtaining immunizations. They also listed long waits as a problem. The population-based, case-control designed study included 332 cases and 1,053 controls, all parents of under-immunized and fully immunized children, under 20 months of age. It is note-worthy that in multivariable analysis, there were two significant family demographics associated with under-immunization: income and self-payment. More under-immunized children had a household income (19.4% vs. 7.9%) of less than $20,000. In the study, conducted in a relatively affluent Midwestern community, 47% of the parents reported some barriers to immunization series completion, although less than 3% were considered major barriers. Identification of barriers, as indicated by this study, may provide useful information on strategies to overcome them.

Interpersonal and situational influences on health promotion, specifically those related to immunization adherence, have been examined in numerous studies. Rodewalk et al. (1995), in a historical cohort study of 1,178 children, aged 12 to 30 months, found that 34% were under-immunized at 12 months of age. Compared to fully immunized children, the under-immunized group made 47% fewer preventive health visits and were at greater risk for delayed screening for anemia (38%), lead (69%), and tuberculosis (76%). They also had 50% more missed appointments. The researchers concluded that under-immunization is a strong indicator of inadequate health supervision in this population. The study makes a strong case against uncoupling immunizations and primary care.

Another type of situational influence was examined by Wilson (2000). Because rural areas usually have fewer sources of health care, higher rates of poverty, and a generally poorer health status, it would seem logical that the children would have lower immunization rates. However, Wilson reported on data that indicated comparable immunization rates between rural and urban children. In his study, a grounded theory, qualitative analysis of data obtained from 12 subjects (parents), Wilson identified other situational influences that contributed to under-immunization, including negative past experiences with immunizations, such as adverse reactions, and competing tasks which included work schedules and other causes of lack of time to obtain immunizations. The study also concluded that maintaining a strong relationship between parents and health care providers and providing accurate and timely information are key components to improved immunization adherence.

The aspects of the Health Promotion Model described by these studies clearly indicate the applicability of the use of this model in studying immunization adherence and comparison of adherence between indigent and non-indigent children.

Immunization Preventable Diseases

The study by Gellen, Maibach, and Marcuse (2000), cited previously, asked respondents to rate the severity of vaccine-preventable diseases. Meningitis from H Influenza B, polio, and hepatitis B were rated the most serious, with pertussis and measles being considered somewhat less serious and varicella perceived as the least serious. Parents also considered varicella the most likely disease

for their children to catch if they were not immunized. In the study, 87% agreed that immunization is extremely important in keeping children well. However, 25% believed that too many immunizations may actually weaken a child's immune system and 23% thought that children get more immunizations than are good for them. The study provides valuable insight into parents' misconceptions regarding immunizations and the on-going need for education.

Adherence

Irigoyen, Findley, Earle, Stambaugh, and Vaughan (2000) found that reminding parents that vaccinations are due is an effective strategy for increasing vaccination coverage. In their study of 1,273 children, ages 4 through 18 months, patients were assigned to 1 of 4 groups: a control group who received no intervention (n = 346); a group that received post card reminders (n = 314); a group that received telephone call reminders (n = 307); or, a group that got both a post card and a telephone call (n = 306). The primary outcome variables were kept-appointment rate and vaccination coverage. Children assigned to the reminder groups were significantly more likely to keep appointments than controls (13.7% higher), with children who received both a post card and a telephone call being 2.3 times more likely to keep appointments than the controls (95% *CI* = 1.4, 3.7). The reminders were also significantly effective in increasing vaccination coverage for the subgroup of children who were not up-to-date at baseline. The study showed that appointment reminders are a sensible and cost-effective way to increase kept-appointment rates, thereby reaching and vaccinating children who are not up-to-date. Children who kept their appointments were more than twice

as likely to be immunized fully for their age. For children who were not up-to-date at baseline, the postcard and the telephone reminders tripled their immunization coverage rate compared to controls (*OR* = 2.9, *CI* = 1.1, 8.0). The study by Wilson (2000) corroborates the importance of immunization reminders, with 58% of the mothers in that study admitting to confusion about the immunization schedule and depending on reminders to know when immunizations are needed.

Immunization Rates

Determination of immunization rates must include specific criteria for inclusion in any evaluation of the rate for a specific population. In a study by Perrin et al. (2000), an assessment of immunization rates in 10 pediatric practices was conducted using four methods of defining the denominator of active patients. The assessments were done using the Clinic Assessment Software Application (CASA) to determine the number of records to be assessed in each practice, based on the size of the practice. A total of 1,823 patients' charts were reviewed, 641 from high-Medicaid practices and 1,182 from low-Medicaid practices.

For all practice types (high- and low-Medicaid), the mean immunization rate was 83%. The rate in the high-Medicaid group was 71.8%, with the low-Medicaid group being 87.8%. The immunization rates were significantly higher in practices that frequently purge inactive patients. In the high-Medicaid practices, 61% of the patients were considered active, compared to 83% in the low-Medicaid groups. The study also concluded that immunization rates reported by County Health Departments and other providers with no means of adjusting for patients who leave the area

or obtain care through alternate providers, understandably, demonstrate lower immunization rates when analyzing aggregate data.

Stokely, Rodewald and Maes (2001), in a study that analyzed data from the 1995 National Immunization Provider Record Check Study, reviewed 1,352 records of children 19 to 35 months of age. From an immunization history questionnaire mailed to and completed by parents, 1,352 (65%) had provider immunization data. A total of 304 (22%) children went to more than one provider for immunizations. Sensitivity, specificity, and predictive value analysis of the most recent provider was performed to determine if the ability to identify under-immunized children varied by provider type. They found that among children with more than one immunization provider, the records of the most recent provider were wrong 23% of the time, indicating that completely vaccinated children were in need of additional immunizations. The study affirmed that scattered immunization records significantly reduce clinicians' ability to determine the immunization status of their patients, potentially resulting in both over- and under-immunization. Analysis of the study indicates that a significant number of fully immunized children (150,000) are thought to be under-immunized. Numbers of this proportion could significantly impact immunization rate data throughout the country.

Effects of Poverty and Other Sociodemogrphics

Many studies have examined the effects of poverty and other sociodemographics on childhood immunization. Moore, Fenlon, and Hepworth (1996) in a study of 566 mother/infant dyads which included interview and immunization record

review, compared Mexican-American (n = 274) and white, non-Hispanic (n = 292), Medicaid-sponsored 1-year-olds. Comparisons were made between the two groups using the chi-square test. Correlations and multiple regressions were used to determine relationships between variables such as maternal age (χ^2 = 2.309; df = 5; p = 0805), number of siblings (χ^2 = 32.999; df = 2; $p \leq .001$), maternal education (χ^2 = 42.376; df = 3; $p \leq .001$), marital status (χ^2 =12.575; df = 2; p = .002), employment status (χ^2 =8.343; df = 1; p = .004), travel time (χ^2 = 17.277; df = 4; p = .002), and the infant's health status and immunization level. Most of the infants, 90.1%, were considered by their mothers to be in good or excellent health. The other 9.9% thought their babies were in fair or poor health. The mean number of children in the white, non-Hispanic families was 2.33, while the Mexican-American families averaged 3.14 children. More of the white, non-Hispanic infants received the basic series of immunizations by 1 year of age (74%) than the Mexican-American children (58%). Other variables that correlated with higher completion of the basic series were younger maternal age and higher maternal education levels.

The results of this study are comparable to the results of the analysis by the State of Florida, Department of Health (2002) of the immunization status of 2-year-old children by high-risk characteristics. Higher maternal education was an indicator for higher immunization rates, with 89% whose mothers completed grade 12 fully immunized, compared to 78.2% fully immunized whose mothers did not finish high school. Children with more siblings also had lower immunization rates in Florida. Of those with no siblings, 88% were fully immunized compared to 68% who had

three or more siblings. Greater maternal age, however, in Florida, correlates to higher immunization rates with 87.9% of children whose mothers were over 30 being fully immunized and 76.4% whose mothers were less than 20 having all recommended shots.

Summary

A review of the theoretical and research implications of Pender's (1996) Revised Health Promotion Model, with its six behavior-specific cognitions and affects in the promotion of behavior change, support its appropriateness as a framework for this study. Identifying and analyzing the roles these factors play in parents' decisions regarding immunizing their children provide insight into immunization adherence.

Vaccines to provide immunization against the 9 diseases, which are currently recommended for children, age 2 and below, have significantly reduced morbidity and mortality for the diseases Centers for Disease Control and Prevention, 2000). Yet, there is no formal legislative mandate that all children be immunized by age 2. The literature clearly indicates that many children are not adequately immunized (Evers, 2000; Gellin, Maibach, & Marcuse, 2000; Houseman et al., 1997; Irigoyen et al., 2000; Rodewalk et al., 1995) and that many factors contribute to immunization non-adherence, including the methods by which immunization rates are calculated (Perrin et al., 2000). While studies have found that poverty is a factor (Findley, Irigoyen & Schulman, 1999; Hillman et al., 1999), other studies indicated that factors not related to income were as, or more, problematic (Houseman et al.,

1997; Wilson, 2000; Yawn et al., 2000). Data produced by the State of Florida, Department of Health (2002), compared to data published by a large, private HMO (Capital Health Plan, 2001), clearly indicated that the HMO group, which is not impoverished, has a lower rate of fully immunized 2-year-olds, than the state average. This study further examines and will ultimately add to the body of knowledge regarding factors related to immunization adherence.

Chapter 3 describes the methodology used for this study. It also presents the design, setting, sample size, protection of human subjects, instruments, data collection, and data analysis procedures utilized.

CHAPTER 3
METHODOLOGY

This chapter describes the methodology applied to the study. The design, setting, sample, protection of human subjects, instrumentation, data collection, and data analysis procedures are discussed.

Design

The study consisted of an ex-post-facto, retrospective review of the immunization records of 2-year-old children in Leon and surrounding counties in North Florida. The independent variable of indigence or non-indigence was expected to affect the dependent variable of immunization adherence.

The Research Questions examined are: (1) What were the demographic characteristics of children from which data was obtained for this study? (2) Are there differences in immunization adherence for indigent and non-indigent 2-year-old children in North Florida?

Setting

The immunization records of 2-year-old children from seven doctors' offices were examined. A variety of office

locations were utilized in order to reach a cross section of the geographic locations of the children's residences.

Sample

A random sample of 2-year-old patients' immunization records was reviewed. An equal number of records of indigent and non-indigent children, based on receipt of Medicaid benefits, were included. Given that the assumptions specified in the Data Analysis are credible for the populations of interest and the researcher's having set alpha at .05, power (1-β) at .80, and a moderate effect, a minimally adequate sample size was determined to be 144 records each of indigent and non-indigent children (288 total; Cohen, 1988). Every effort was made to keep the sample sizes equal in order to prevent reductions in power.

Protection of Human Subjects

The study was conducted following approval by the Florida State University Institutional Review Board (Appendix A). In conducting the record review, patient confidentiality was protected, to the extent allowed by law, at all times. The children's names were not recorded. Their immunization records were copied by staff working in the individual doctor's offices and given to the researcher with no identifying information other than a number, which was assigned by the staff. Other demographic information, including the child's date of birth (to verify the age), sex, race, family size and composition, birth order, Medicaid status, mother's marital and work status, and

urban versus rural domain likewise, contained no information that could be linked to a specific child. Consent forms were not required since the records were anonymous. Appendix B contains a letter from the President of the Tallahassee Pediatric Foundation whose member physicians agreed to allow their staff to provide anonymous immunization records to the researcher.

When the staff from each office obtained a representative number of indigent and non-indigent records, the records were sealed in a manila envelope and placed in a designated location for pick-up by the Tallahassee Pediatric Foundation courier who delivered the sealed envelopes to the researcher. The records will be retained, by the researcher, in a secured file cabinet, until the research project is complete, at which time they will be destroyed by shredding.

Instruments

A tool, constructed by the researcher, was available for use in recording immunization and demographic information (See Appendix C). It contained the date of birth of each child whose record was reviewed as well as an indicator of the Medicaid eligibility status. Since Medicaid eligibility changes frequently, only children who were on Medicaid continuously from the month of birth through the month of their second birthday were considered indigent. Children who were never on Medicaid were considered non-indigent. It was necessary for office staff to consult Florida Medicaid, using the point-of-sale device in their office, such as Envoy or MediFax, to obtain this information.

The review tool also included the list of recommended immunizations that should be obtained by children who have reached age 2, and a space for the date of receipt of the vaccine. Children who received all of the immunizations, at the appropriate time intervals, were considered fully immunized and therefore, adherent. In lieu of the review tool, staff could also provide a copy of the child's immunization record, with no name, an example of which is Appendix D, on which they also recorded the other needed information.

Procedure

Following IRB approval, and the approval of the physicians in the offices to be utilized, the offices were contacted and one nurse, medical assistant, or practice manager in each office was identified who obtained the data. The individual, to whom compensation of up to $50.00 was offered, was provided detailed instructions as to how to obtain a random sample of 25, 2-year-old patients who were indigent/Medicaid recipients and 25, 2-year-old children who were not indigent, as determined by their payment status. Non-indigent children could have indemnity insurance coverage such as Blue Cross/Blue Shield, United Health Care, Aetna, etc., an HMO such as Capital Health Plan or Vista Health Plan (formerly Healthplan Southeast), or could be on self-pay status.

To obtain the random sample, staff was asked to prepare a computer-generated list of all of their patients who were 2 years old. Based on a coin flip, they selected either the first patient on the list if the coin landed on heads, or the second patient on the list if landed on tails. The

sample was then drawn, starting with either the first name or the second name, and selecting every third name on the list thereafter, until they had 25 each who were on Medicaid and not on Medicaid. The physicians' office staff then completed the record review tool or copied the immunization record of the 2-year-old children included in the random samples, and recorded the patients' insurance information, specifically whether they were on Medicaid or private insurance. For purposes of the study, in order to be considered indigent, the child had to have been covered by Medicaid since birth. If a copy of the record was provided in lieu of the review tool, staff recorded the same demographic and family constellation data as requested on the tool.

Data Analysis

Research Question 1 (What are the demographic Characteristics of children from which data will be obtained for this study?) was examined by using and presenting descriptive statistics including central location measures, dispersion measures, and displays of frequency such as graphs, charts, plots, etc. Both the arithmetic mean and the median are provided to describe the central location of the data for variables that are measured on at least an interval scale. The median is the more representative central location measure since, under conditions of asymmetry, it is unaffected by extreme scores in a data set(Thorndike & Dinnel, 2001).

To describe the general dispersion of scores from the mean, variance and standard deviation are provided. Again, because a scale of measurement that is at least interval is

needed for meaningful interpretation of these statistics, the investigator only presents these summaries when that condition is reasonably defensible.

For Research Question 2 (Are there differences in immunization adherence for indigent and non-indigent 2-year-old children in North Florida?) the primary analytical and inferential aspect of the inquiry is the need for a statistical inference regarding the difference, if any, in immunization adherence rates for indigent and non-indigent 2-year-old children in Leon and surrounding Counties. Since the children in the study are either be up-to-date or not with regard to immunizations, the data are dichotomous. The primary independent variable of indigence or non-indigence is also dichotomous, based on the patients' either being on Medicaid or not on Medicaid. Therefore, data are considered nominal in scale. This research question was addressed through the use of two analogous, independent sample techniques, the traditional Chi-square test for a 2 X 2 contingency table with a correction for continuity, and the Fisher Exact test (Conover, 1971). Although these two techniques make the same assumptions (the observations both within and between the samples are independent; the four cells in the contingency table are mutually exclusive and exhaustive; the underlying nature of the dependent variable is continuous; the samples are drawn randomly) and test the same null hypothesis, the first test gives an approximate *p* value and the second provides an exact *p* value for the statistical outcome. While both were determined for comparison purposes, the conclusions of the study result from the *p* value provided by the Fisher Exact procedure.

The null hypothesis (H_o) is that there is no difference in immunization adherence for indigent and non-indigent 2-

year-olds in Leon and surrounding Counties. Another way to state the null is that the two samples are selected from the same population. The alternate hypothesis (H_a) is that there is a difference in the immunization adherence rates for these groups of children. This can also be stated that the two samples are drawn from two different populations.

Summary

This chapter described the methodology applied to the study, which compared immunization adherence rates of indigent 2-year-old children to those of non-indigent 2-year-old children. The design of the study is described, as are the setting, sample size determination, protection of human subjects information, instruments, procedure, and data analysis. The ex-post-facto, retrospective review of randomly chosen immunization records from doctors' offices in Leon and surrounding Counties was described. The sample of 144 each indigent and non-indigent children's records are included and analyzed using descriptive statistics and two independent sample techniques. The null and the alternate hypotheses are described. Analysis of the data will be presented in Chapter 4.

CHAPTER 4
DATA ANALYSIS

This Chapter presents the statistical findings of the study. Data describe the demographic characteristics of the sampled population (Research Question 1) and address the answer to Research Question 2, determining if there are differences in immunization adherence for indigent and non-indigent 2-year-old children in Leon and surrounding Counties of North Florida.

Demographic Description of the Sample

The randomly selected immunization records of 288 2-year-old children residing seven counties, in both urban, 77% (n = 221), and rural, 26% (n = 66), settings were reviewed. Children who resided in the two most highly populated communities were considered to be urban dwellers, while those with addresses outside of those communities were considered rural. The gender of the children was almost evenly divided with 146 males and 141 females. The racial mix was 51.7% Black, 43.4% White and 4.9% other. Although this mix is not representative of the racial mix of the State (approximately 15% Black, 78% White and 7% Other, according to census data from 2000), the type of sample, with approximately half being indigent, skews the racial mix. Currently according to Medicaid data,

approximately half of the Medicaid population is a racial minority.

An attempt was made to determine the number of siblings and the birth order of each child in order to analyze the possible correlation between immunization adherence and those factors. Some of the physicians' records did not list siblings, making the information difficult to obtain. As a result, those data elements are missing for 12 children.

Table 1 presents the number of siblings of each child whose record was examined.

Table 1

Number of Siblings

Siblings	Frequency	Percent	Valid Percent*
0	120	41.7	43.5
1	93	32.3	33.7
2	46	16.0	16.7
3	13	4.5	4.7
4	4	1.4	1.4
Total	276	95.8	100.0
Data Missing	12	4.2	
Total	288	100.0	

(*Valid Percent excludes records with the data element missing.)

Of the children's records (*n* = 276) from which information regarding siblings could be obtained, 43.5% (*n* = 120) had no siblings, while 66.5% (*n* = 156) had from 1 to 4 brothers and/or sisters. Ninety percent of the 2-year-old children (*n* = 120) with no siblings, and 92.5% of those with 1 sibling (*n* = 93) had all of their immunizations. As the number of siblings increased to 2, 3, and 4, the number

fully immunized decreased to 87% (*n* = 46), 69.2% (*n* = 13), and 50% (*n* = 4) respectively, leading to the conclusion that the families with multiple children who were sampled were less adherent with immunizations.

Table 2 shows the birth order, within his or her family, of each child whose record was reviewed.

Table 2

Birth Order

Order	Frequency	Percent	Valid Percent*
First	148	54.4	53.6
2nd	79	27.4	38.6
3rd	39	13.5	14.1
4th	6	2.1	2.2
5th	4	1.4	1.4
Total	276	95.8	100.0
Missing Data	12	4.2	
Total	288	100.0	

(*Valid percent excludes records with the data element missing.)

Of the first-born children whose records were sampled, 91.2% (*n* = 148) were fully immunized. In the second-born group, 89.9% (*n* = 79) were completely adherent, with the percentage for third-, forth- and fifth-born registering 84.6% (*n* = 39), 66.7% (*n* = 6), and 50% (*n* = 4), respectively. The data, therefore, indicate that immunization adherence decreased as the order of birth increased.

The determination of marital status of the parents of the children whose records were examined was also difficult. If the mother and father had the same last name,

it was assumed that they were married. Other factors such as parents' addresses and telephone numbers, and personal knowledge of the families by the staff in the doctors' offices who were engaged to obtain the data, were utilized to validate this factor. Of those that could be determined (n = 277), the sample was almost evenly divided between children whose parents were married, 50.2% (n = 139) and those who were not, 49.8% (n = 138).

It was also difficult to determine the mothers' employment status. Staff members used as research assistants were instructed to consider them employed if there was a work telephone number listed in the record. Again, personal knowledge of the children and their parents by the individuals used to extract the data was helpful in obtaining the information for 278 of the children and revealed that 61.2% (n = 170) were employed, while 38.8 % (n = 108) were not.

The number of indigent (n = 145) and non-indigent (n = 143) children in the sample was virtually even. The children with Medicaid, therefore considered indigent, comprised 49.7%, while 50.3% had private health care coverage, making them considered non-indigent.

Results

The study examined a total of 288 immunization records of 2-year-old children to determine if they were fully immunized for 10 specific diseases: Diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, haemophilus influenzae, and varicella. Due to the common use of combination vaccines to administer diphtheria, tetanus and acellular pertussis (DTaP), and measles, mumps,

and rubella (MMR), a total of 6 different single or combination vaccines was tabulated. Other common abbreviations for the vaccines include "Hib" for haemophilus influenzae, "Hep B" for hepatitis B, and "V'vax" for varicella.

To be considered fully immunized, the records had to contain documentation of four doses of DTaP, three doses each of Hib, Hep B, and polio, and one dose each of MMR and V'vax. While it is known that some brands of Hib vaccine require four doses, and others require only three, it was not always possible to determine which type was used. Therefore, children with documentation of at least 3 doses were, for the purposes of this study, considered fully immunized.

The total number of children in the study who received all of the required vaccines was 254 or 88.2%. Of the 34 children who were not fully immunized, 41% (n = 14) had missed more than one dose of vaccine. Table 3 shows the frequency and percentage of children who were immunized for each vaccine:

Table 3

Number and % Immunized By Vaccine Type

Vaccine	Yes(n)	Percentage	No(n)	Percentage
DTaP	270	93.8	18	6.2
Hib	283	98.3	5	1.7
Polio	277	96.2	11	3.8
Hep B	282	97.9	6	2.1
MMR	283	99.3	2	0.7
V'Vax	280	97.2	8	2.8

DTaP accounted for the largest number of missed doses. This is not unexpected since it was one of the vaccines in critically short supply during the National shortage in 2001-2002, and again in 2003 (Borenstein, 2003). During that time, the recommendation of the Centers for Disease Control and Prevention was to omit the 4th, "booster" dose of DTaP. When the shortage subsided, pediatricians were advised to recall all of the children who missed the dose. Some may have elected to wait until the next regularly scheduled well-care visit. It is known that many children do not obtain preventive services between the completion of the basic immunization series at age 18 months to 2 years and the pre-school boosters at age 4 to 5 years (Yu et al., 2002). It is likely, therefore that some children may not have had well care and may not have gotten the omitted dose of DTaP.

The next largest number of missed doses was polio vaccine. The 3rd polio immunization is frequently given at the same time as the 4th DTaP. The possible omission the 4th DTaP may have affected the number of missed doses of polio vaccine (Centers for Disease Control and Prevention, 2002).

Varicella (V'Vax) is not currently one of the vaccines included in the usual 2-year-old adherence studies by the State Health Program (State of Florida, Department of Health, 2002). It has only recently been required for school entry (Florida Statutes, 2002). This, and the conception of many parents that it is a benign and an expected childhood illness (Baby Center, 2004), may have contributed to non-adherence.

The success of immunization with the MMR vaccine may be because it requires a single dose, given after one year of

age. A "booster" dose is now required at school entry (Florida Statutes, 2002).

The children who were adherent (*n* = 254), who were also indigent (*n* = 137) accounted for 53.9% of the total number of adherent records. Children who were not indigent made up 46.1% (*n* = 117) of the total. To determine the statistical significance, if any, between immunization adherence for indigent and non-indigent children, the Fisher Exact Test was used. The exact *p* value for indigence and adherence was *p* = .001, a significant difference from Alpha, which was set at .05, leading to the conclusion that the sample data was sufficient for the claim that indigence and immunization adherence are not independent of each other. The null hypothesis, there is no difference in immunization adherence between indigent and non-indigent children, must be rejected.

Table 4 provides a comparison of adherent indigent and non-indigent children and the exact *p* value for each specific type of vaccine.

Table 4

Number of Adherent Indigent and Non-indigent By Vaccine Type

Vaccine	DTaP	HIB	Polio	Hep B	MMR	V'Vax
Indigent	141	143	144	145	144	143
Non-indigent	129	140	133	137	142	137
p value	.015	.683	.005	.014	1.0	.171

Given this tabulated information, the comparison of adherence between indigent and non-indigent children, using the Fisher Exact Test, is statistically significant for DTaP, polio, Hep B, and V'vax. The adherence rate for HIB

vaccine may be inaccurate due to the different brands of vaccine requiring different numbers of doses. Since it was not always possible to determine the brand of vaccine used, children with at least three doses were counted as adherent. The difference between indigent and non-indigent adherence for HIB was too low to determine significance. Since only two children failed to receive MMR, one being indigent and one non-indigent, there was not sufficient evidence to form any assumption regarding indigent versus non-indigent adherence.

Other Results

Other information regarding the sample is of interest. Females comprised 58.8% (*n* = 20) of the children who were non-adherent and 82.4% (*n* = 28) were urban dwellers. Children with no siblings accounted for 38.7% (*n* = 12) of the non-adherent group, while 22.6% (*n* = 7) had one sibling, 19.4% (*n* = 6) had two siblings, 12.9% (*n* = 4) had three siblings, and 6.5% (*n* = 2) had four siblings. More first-born children (41.9%; *n* = 13) were non-adherent, with those who were born second comprising 25.8% (*n* = 8) and those who were third equaling 19.4% (*n* = 6). Children who were the 4^{th} or 5^{th} born each accounted for 6.5% (*n* = 2) of the total. More of the adherent children (*n = 126)* were from non-intact families (51.6%) whose mothers (*n* = 170) worked.

Conclusions

The following conclusions are drawn from analysis of the data:

1. White females comprise the largest number of 2-year olds who are not fully immunized.
2. Most of the 2-year-olds who were not fully immunized are first-born with no siblings and are from urban dwelling, intact families, with working mothers.
3. More indigent 2-year-olds are fully immunized than non-indigent.
4. DTaP Vaccine accounted for the greatest number of missed doses, with Polio ranking second.

Summary

This chapter provided the statistical findings to describe demographic information regarding the sample studied and to determine if there are differences in immunization adherence between indigent and non-indigent 2-year-old children who reside in Leon and surrounding Counties in North Florida. In the sample studied, non-indigent children were significantly more non-adherent than indigent children. A discussion of factors that could have had an effect on the outcome of the study will be presented in Chapter 5.

CHAPTER 5
DISCUSSION

The value of immunizations to the public health of this and future generations is rarely disputed. However, the number of fully immunized children in this country, this state, and this area is far from optimal and it is declining. Historically, studies of immunization adherence have focused on barriers and missed opportunities. One barrier often targeted as a reason for low adherence is indigence (Evers, 2000; Findley, Irigoyen, & Schulman, 1999; Prislin, Dyer, Blakeky, & Johnson, 1998). This study was designed to look again at indigent and non-indigent 2-year-old children to determine if indigence is a factor in immunization adherence in North Florida. The data from the study show that a number of non-indigent children are not fully immunized, and they significantly exceed the number of indigent, non-immunized children.

This chapter will discuss the findings of the study and possible trends related to them. It will relate the findings to both supportive and differing literature and tie the results of the study to the conceptual framework used as a guide for the research. Limitations will be presented and reviewed. The relationships of assumptions to the outcomes of the study will be examined, as will recommendations for future research. Implications of the

study for nursing practice, including advanced practice, administration, and education, will also be presented.

Findings

The results of this study, that indigent 2-year-old children have greater rates of immunization adherence than non-indigent 2-year olds in Leon and the surrounding counties, were not unexpected, given the resources available for immunizing children in the area. Medicaid managed-care programs, including MediPass and Medicaid HMO's, offer indigent children a medical home and preventive care. One of the MediPass Programs, the Tallahassee Pediatric Foundation Primary Care Program, implemented in the area 20 years ago, mainstreams indigent children into the private sector of care, and, with the addition of a vital nurse case management component, is likely to have had a major impact on immunization rates for indigent children (Tallahassee Pediatric Foundation, 2003). This trend is expected to continue unless the resources to fund the Program are seriously reduced or eliminated.

Relationship to Literature

The literature reviewed for this study contained numerous findings and opinions regarding the effect of socioeconomic status on immunization adherence. Some studies cite indigence as a barrier to immunization adherence (Santoli, Szilagyi, & Rodewald, 1998; Yawn et al., 2000), while others report greater concern with factors such as parental attitudes and beliefs (Houseman, Butterfoss, Morrow, & Rosenthal, 1997; Prislin, Dyer,

Blakley, & Johnson, 1998). Another concern is parent's undervaluing immunization because they no longer see the terrible consequences of the diseases prevented by vaccines (Gellin, Maibach, & Marcuse, 2000). The findings of this study clearly correlate with the studies that cited barriers other than indigence as the cause for under-immunization.

Conceptual Framework

Using concepts from Pender's (1996) model as a guide for this study was useful in determining the scope of the data elements needed to draw conclusions about the population and their parents. The effect of indigence on parents seeking immunizations for their children is tied to the behavior-specific cognitions identified by Pender (1996). Since over 88% of all children whose records were reviewed were fully immunized, most parents apparently perceived that immunizations have positive consequences and are beneficial for their children. These positive feelings may have led to the parents' feeling good about themselves as they overcame negative interpersonal influences, such as bad past experiences, inaccurate information, and numerous barriers and hardships making immunization adherence difficult. Real, or imagined, obstacles to immunization adherence may be linked to family income, transportation issues, working mothers with many competing demands, and other family dynamics (Santoli, Szilagyi,& Rodewald, 1998; Yawn et al., 2000). In this area, as evidenced by this study, the health promotion behavior of low-income families, specifically in obtaining immunizations for their

children, significantly exceeds that of non-indigent parents.

The hypothesis of this study, that indigence is not a primary influence on immunization non-adherence for 2-year-olds in Leon and surrounding Counties, was supported by this study. Pender (1996) advocated nursing intervention to reduce barriers to health care and overcome cultural influences that restrict access to care. She encouraged empowerment of individuals to value health and the benefits of health-promoting behaviors to such an extent that they are willing to overcome barriers to healthy behaviors. In Leon and surrounding Counties, many indigent children have the benefit of a nurse-case managed, Medicaid-managed care program, that helps to reduce barriers and to empower parents to obtain health care, including immunizations, for their children. Although the usual barriers to immunization exist, in Leon and the surrounding Counties, they seem to have a greater effect on the non-indigent population than on the indigent.

As shown by the data, over 61% of the mothers of children whose immunization records were reviewed were employed. This is likely a major barrier to immunization adherence in this area since the availability of immunizations often conflicts with work hours. If Pender's Health Promotion Model were used as a guide to new directions in health care, with prevention the central concept in the development of health care models for the future, making immunizations more accessible with evening and weekend clinics would quickly eliminate this barrier.

Other aspects of Pender's model were utilized in determining key data elements obtained in the study. Assessing elements such as urban versus rural dwelling,

maternal marital status, number of siblings, and birth order, targeted interpersonal influences and immediate competing demands. These are key components of Pender's model and provided insight into the characteristics of the population studied and their families.

The results of the study regarding some of the barriers and interpersonal influences seem incongruous. For example, although the majority of the children's parents were married, more children whose parents were married were non-adherent. Although the correlation between those who were married and unmarried was not statistically significant (p = .137), this apparent lack of spousal support for obtaining immunizations could likely be explained by the fact that the majority of the mothers, and presumably the fathers, work.

Another unexpected finding was that more non-adherent children reside in urban areas. Logistically, it would seem that immunization adherence would be more difficult for children residing in rural areas. The fact that parents often commute to the urban locations for work and for day care for their children, it is likely that they also commute for medical care. This assumption is validated by the fact that there are few pediatric medical care providers in the rural areas. It is possible that having to expend more effort to obtain immunizations makes the availability of the care more appreciated by the non-urban parents, resulting in greater adherence. Conversely, those who have the service readily available and who have to expend little effort to obtain immunizations may undervalue their worth and underutilize the services.

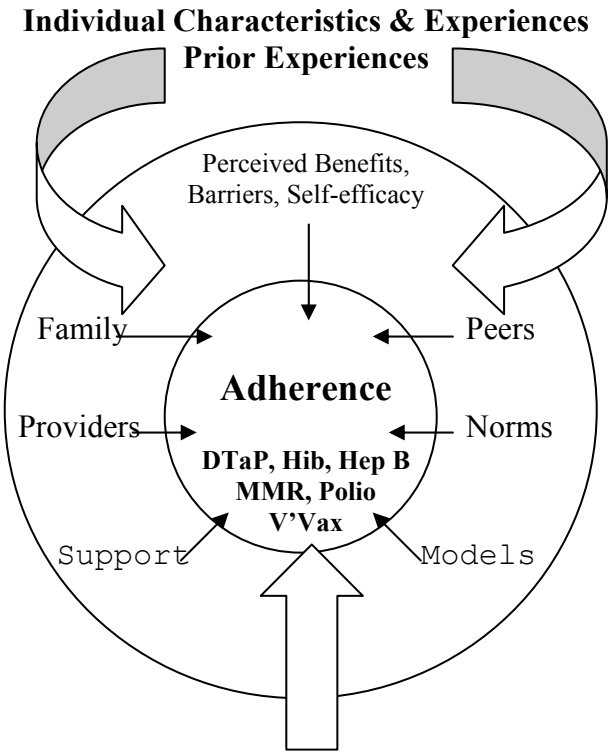
The influence of the number of siblings and birth order of the children whose records were reviewed is also

interesting. Children with higher numbers of siblings were less adherent and those who were the second, third, forth, or fifth child born in the family were progressively less adherent. These findings may indicate that parents become less concerned with immunization as the size of the family increases. However, they could also validate that larger families result in more competing demands for parents' time, making immunization adherence a lower priority.

The use of Pender's (1996) model as the framework for this study provided good points of reference for examining immunization adherence. With adherence as the target, Figure 1, Target: Immunization Adherence, depicts the influence of individual characteristics and experiences, including prior experiences, on perceived benefits, barriers, and self-efficacy. It shows that the influence of family and other support systems, providers, peers, role models and the norms of the community have an effect on reaching the ultimate goal of adherence. It also shows that competing demands affect all levels of activity in route to attaining the target, immunization adherence.

Relating the behavior-specific cognitions, as well as interpersonal and situational influences, on health promotion, described by Pender, to parents' actions in obtaining immunizations for their children worked well and provided interesting supportive information. The data indicate that efforts to increase immunization adherence in Leon and surrounding Counties focused on non-indigent, female, urban dwelling, later-born children, with married, employed mothers, would potentially render the greatest impact.

Target: Immunization Adherence



Immediate Competing Demands:

Work
Siblings
Spouse
Extended Family
Transportation
House-keeping
Meals
Shopping
Budgeting
Etc.

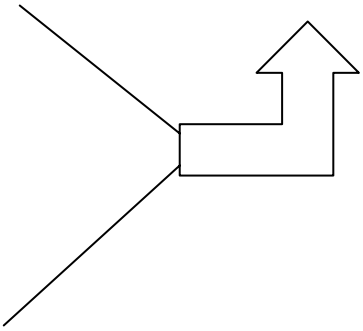


Figure 1 Target: Immunization Adherence

Assumptions

The assumptions presented in Chapter 1 were neither supported nor unsupported by this study. The argument could be made that the first assumption, all parents want their children protected from preventable illnesses, was unsupported, given the number of children shown by the study to be non-adherent with immunization recommendations. However, it is not possible to state that non-adherence correlates to parents' wanting their children to contract illnesses. Rather, barriers and competing demands may outweigh the risk of illness, sadly forcing parents to gamble with their children's health and well-being.

An unstated assumption of the study was that there would be an adequate supply of vaccine available for all children seeking immunizations. Unfortunately, this is no longer a valid assumption. In recent years there have been critical shortages of DTaP, MMR, Hib, Varivax and Hepatitis B vaccines, resulting in children's missing doses (Keep Kids Healthy, 2003), and creating an unanticipated limitation to the study.

Limitations

In addition to the limitation stated in Chapter 1, there were several others that presented during the course of the study. When initially conceived, it was anticipated that children's medical and immunization records would be personally reviewed by the researcher in the doctors' offices. Concern over recently enforced Health Insurance Portability and Accountability Act (HIPAA) restrictions on access to protected health information forced a change in

the method of obtaining the immunization information. Staff in the doctors' offices was retained to obtain the information, making timeliness of the receipt of the data uncontrollable. While most were sensitive to the needs of the researcher's timeline, the addition of a major influenza outbreak delayed data collection in some offices and made it not possible in others.

There is no standard form or format for recording immunizations in doctors' offices. Even within the offices, multiple formats are used, and almost all of the records are hand-written, making reviewing and recording the data very arduous. However, the reliability of the data collected is thought to be very high. None of the offices used the tracking form developed for this study, opting instead to provide copies of immunization records. Having copies of the actual records placed responsibility for recording the data solely on the researcher, leaving no concern for the possibility of the doctors' staff making errors.

The Florida Department of Health is piloting a statewide immunization registry, Florida SHOTS (State Health Online Tracking System), which will eventually be made available to all primary care providers. Providing incentives to private practitioners and mandating the use of the system by all public entities that provide immunizations could go a long way in standardizing vaccine records and improving adherence data.

In the three largest offices, which include a total of 10 pediatricians, the practice managers personally took responsibility for drawing the samples in the manner prescribed by the researcher, and extracting the immunization records. The long-term working relationship

and mutual professional respect between the researcher and these individuals lead to assurance that the samples were randomly drawn and the information provided was as accurate as possible, thus eliminating a possible limitation. The records drawn from those three offices represented 63.5% of the entire sample.

Not all of the children's records contained all of the demographic data elements being sought, making the data unobtainable. However, given the sample size, it is not likely that the number of missing data elements would have significantly affected the outcome of the demographic information being sought.

The geographic area within which this study was conducted is heavily penetrated by health maintenance organizations and other managed care options for both the indigent and the non-indigent population. A state-contracted, nurse case-managed, private practice-based, primary care program for indigent children has been operating in the area for 20 years and serves over 8200 children. Generalizing this study to areas without this type of service for indigent children would not likely yield the same results.

Vaccine shortages and the necessity of postponing doses of vaccine resulted in delay of this study until the major shortage was over. And, it is likely that the shortage did affect the outcome of the study in that one of the vaccines most frequently missing in non-adherent children's records was DTaP. During the shortage, the 4th, "booster" dose of DTaP was withheld and it is possible that dose was not obtained when the shortage ended.

Implications for Nursing

The implications for nursing that result from this study include the need to place renewed emphasis on barriers to immunizations that affect not just indigent, but non-indigent families as well. Nurses working in public health and private sector primary care settings must focus on ways to make vaccines readily available to the children of working parents. In this community, like many others, efforts to increase vaccine adherence frequently target low-income neighborhoods. Targeting children of all income levels by challenging local health care providers, including the HMO's, to offer evening and weekend access to immunizations would likely improve adherence.

Clinical Expert/Advanced Practitioner

Advanced practice nurses, working as clinical experts in pediatric offices, must take the lead to redefine the norm in the provision of pediatric well and preventive services and make the care available at times that will accommodate working parents. Most of the private pediatric practices have Saturday hours, but only for "sick" visits. The pediatric nurse practitioners working in those offices must advocate for expanding the scope of services available on Saturdays to include immunizations. The office-based clinical experts also must address the reduction of missed opportunities to immunize children in their practices by keeping abreast of the most current recommendations regarding contraindications to immunizations. All nurses working in primary care settings must work to assure that opportunities to immunize children are maximized by

reviewing immunization records at all primary care visits, and immunizing children at every opportunity rather than just during scheduled well care visits.

Nurse leaders must also take the lead in lobbying for both State and Federal statutory changes and needed funds to close gaps in current immunization regulations, particularly in the area of exceptions to immunization requirements for school and day care entry. There must be funding for staff to monitor student's records and issue appropriate warnings and reprimands to institutions allowing entry of under-immunized children. There also must be funding for parent educational materials and staff time to implement educational efforts.

Administration

Nurse administrators have the duty and responsibility for development and implementation of practice standards for many of the public and private entities that provide childhood immunizations. Although case management to help ensure adherence to immunization recommendations works, it has a price tag that some think is too high (Rand Health, 1998). Program administrators must assess the cost-benefit of case management or other strategies to increase immunization adherence, such as appointment reminders, after-hours clinics, etc. Comparing the costs of prospective initiatives to that of morbidity, disability, lost parental work time and, therefore, income, and even death due to vaccine-preventable illnesses may yield data to show that the cost is not too high.

Education

Nurse educators are key participants in the effort to improve immunization adherence. Nursing curricula at both the undergraduate and graduate levels must include emphasis on all preventive care, starting with well child services and immunizations. Teaching nurses to recognize barriers to immunization and strategies to ameliorate them are paramount to increasing adherence. Teaching the principles of immunology and ways to translate the immune response produced by vaccines to parents, in terms they can understand, will address one of the major barriers, parental misunderstanding of how vaccines work (Yawn et al., 2000), and encourage them to have their children immunized.

Continuing education aimed at office nurses and pediatric nurse practitioners regarding vaccine recommendations and strategies for overcoming barriers is needed. Vaccine manufacturers invest large amounts of money in professional education programs and materials. They are forced to compete for nurses' and physicians' time in order to give them the resources they have available. Making the information and continuing education offerings available at convenient times and in appealing locations will likely result in greater utilization.

Recommendations for Future Research

This study supports the hypothesis that efforts to increase immunization adherence in North Florida should focus on non-indigent children. However, it is not likely that the results of one study will convince policy-makers

to change their strategies for reaching children who are not adequately immunized.

During the 1997-98 school year, local health officials conducted an informal, retrospective study of immunization records of school children in Tallahassee to determine their immunization status on their second birthday. The immunization rates were highest in the schools in the affluent, north side of town, and decreased concomitantly as the location of the schools moved south, to the less affluent areas. Using the information from that study, Health Department and Immunization Coalition members have focused attention on the South side of town, holding special immunization clinics in those neighborhoods, with little participation by the residents (A. Waltz & J. Westaway, personal communication, February 13, 2004). A formal, retrospective study, conducted by Department of Health Immunization Program Nurses, utilizing randomly selected day care and school immunization records from various locations in North Florida, to determine immunization adherence of children on their second birthday may help to validate the findings of this study. Replication of this study at a time further removed from the vaccine shortage may also add validity to the results.

Summary

A comparison of immunization records of indigent and non-indigent 2-year-old children residing in North Florida revealed that non-indigent children were significantly less adherent. Health-promotion behaviors and efforts to overcome barriers by the parents of non-indigent children

must be improved through education and interventions to make immunizations more readily available. Health care providers, including advanced practice nurses, administrators, and educators have a role in achieving this goal.

Children do not get a choice in the parents who receive them. The priorities of most parents include the best interests of their children, but competing demands for parental time, energy, and resources may delay or derail children's needs, especially those that are not crisis-oriented. Fortunately, the failure to obtain immunizations in a timely manner does not frequently result in a crisis. But, if and when it does, children suffer needless pain, disability, and even death. The efficacy of immunizations is scientifically proven and well documented. Vaccines are available to all children, regardless of parents' insurance status or ability to pay. Accepting excuses and allowing children to remain unprotected from vaccine-preventable illnesses must stop. Children deserve nothing less.

APPENDIX A

HUMAN SUBJECTS COMMITTEE APPROVAL

Florida State
UNIVERSITY

Office of the Vice President
For Research
Tallahassee, Florida 32306-2763
(850) 644-8673 · FAX (850) 644-4392

APPROVAL MEMORANDUM

Human Subjects Committee

Date: 10/13/2003

Carol McCormick
708 Lupine Lane
Tallahassee, FL 32308

Dept.: **Nursing**

From: **David Quadagno, Chair** DQ|ph

Re: **Use of Human Subjects in Research**
A Comparison of Immunization Adherence Rates for Indigent and Non-Indigent 2-Year-Olds

The forms that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Secretary, the Chair, and two members of the Human Subjects Committee. Your project is determined to be exempt per 45 CFR § 46.101(b) 4 and has been approved by an accelerated review process.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals, which may be required.

If the project has not been completed by **10/13/2005** you must request renewed approval for continuation of the project.

You are advised that any change in protocol in this project must be approved by resubmission of the project to the Committee for approval. Also, the principal investigator must promptly report, in writing, any unexpected problems causing risks to research subjects or others.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols of such investigations as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Protection from Research Risks. The Assurance Number is IRB00000446.

Cc: Jeanne Flannery
HSC No. 2003.524

APPENDIX B

TALLAHASSEE PEDIATRIC FOUNDATION PRESIDENT'S LETTER

THE TALLAHASSEE PEDIATRIC FOUNDATION, INC.
A CORPORATION NOT-FOR-PROFIT
1126-A LEE AVENUE
TALLAHASSEE, FLORIDA 32303
TELEPHONE (850) 488-7935

PRESIDENT
LARRY C. DEEB, M.D.

VICE PRESIDENT
MARY E. SEAY, M.D.

SECRETARY-TREASURER
LOUIS B. ST. PETERY, M.D.

ADMINISTRATOR/NURSING DIRECTOR
C. CAROL McCORMICK, R.N.

September 10, 2003

To Whom It May Concern:

The physician members of the Tallahassee Pediatric Foundation, Inc., are fully supportive of the research project proposed by C. Carol McCormick, RN, in partial fulfillment of the requirements of the Master's in Nursing degree at Florida State University, and have agreed to allow staff in their offices to provide immunization and demographic data for the study. In order to maintain patient confidentiality, the information provided will contain no names or other identifying information.

Sincerely,

Larry C. Deeb, M.D.
President

APPENDIX C

IMMUNIZATION ADHERENCE TOOL

				Immunization Adherence						
NUM/DOB	SEX/RACE	MED/UB-RL	SIBS/ODR	MAR/WORK	DTaP	HIB	POLIO	HEP B	MMR	V'VAX
									XXXXXXXX	XXXXXXXX
									XXXXXXXX	XXXXXXXX
NUM/DOB							XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
									XXXXXXXX	XXXXXXXX
									XXXXXXXX	XXXXXXXX
NUM/DOB							XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
									XXXXXXXX	XXXXXXXX
									XXXXXXXX	XXXXXXXX
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APPENDIX D

EXAMPLE OF IMMUNIZATION RECORD

Vaccine Administration Record for Children and Teens

Patient name: _____

Birthdate: _____

Chart number: _____

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS§	Date given§	
Hepatitis B† (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)			IM						
			IM						
			IM						
			IM						
Diphtheria, Tetanus, Pertussis† (e.g, DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
***Haemophilus influenzae* type b**† (e.g., Hib, Hib-HepB, DTaP-Hib)			IM						
			IM						
			IM						
			IM						
Polio† (e.g, IPV, DTaP-HepB-IPV)			IM•SC						
			IM•SC						
			IM•SC						
			IM•SC						
Pneumococcal conjugate (PCV)			IM						
			IM						
			IM						
			IM						
Measles, Mumps, Rubella (MMR)			SC						
			SC						
Varicella (Var)			SC						
			SC						
Hepatitis A** (HepA)			IM						
			IM						
Influenza** (Flu)			IM						
			IM						
			IM						
			IM						
			IM						
Other**									
Other**									

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), *not* the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

www.immunize.org/catg.d/p2022b.pdf • Item #P2022 (4/03)

Immunization Action Coalition • 1573 Selby Avenue • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org

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BIOGRAPHICAL SKETCH

C. Carol McCormick was born in New Orleans, April 3, 1950, and was raised in Apalachicola, Florida. She graduated from Chapman High School and received her Bachelors of Science Degree in Nursing from Florida State University in 1972. Her career has been devoted to Pediatric Nursing primarily in community health settings. In 1984, she developed the Tallahassee Pediatric Foundation (TPF) Primary Care Program as a pilot, nurse case-managed, private sector based, medical home model for indigent children. The Program, which is contracted through the Department of Health, Children's Medical Services, now serves over 8200 children, and has been replicated in many other areas of the state.

She looks forward to finishing her career at TPF, resuming hobbies like fishing and fly tying and spending more time at the beach with her family and new grand-niece, the most beautiful baby in the world, Emily.