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ADEQUACY OF IMMUNIZATION FOR RURAL CHILDREN
THROUGH AGE TWO YEARS

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ADEQUACY OF IMMUNIZATION FOR RURAL CHILDREN THROUGH AGE TWO YEARS

By

Barbara A. McNamara

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ABSTRACT

ADEQUACY OF IMMUNIZATION FOR RURAL CHILDREN THROUGH AGE TWO YEARS

By

Barbara A. McNamara

This study investigated the level of adequacy of immunizations in a rural county health department. The Starfield model provided the framework for this retrospective review. Analysis of the data included three levels for adequacy of care: complete, adequate, and inadequate.

The major finding of this study was a vaccination coverage rate of 89.4% nearly meeting the national goal of at least ninety percent of children fully immunized through age two. Additional findings were 64.4% of children started immunization on time, 32.9% received complete care, 56.5% adequate care and 10.6% inadequate care. The advanced practice nurse can use these findings to improve the childhood immunization rate through clinical application, education and dissemination of current research to health care providers, and periodic assessment of clinic immunization rates.

Further research needs to study the health of rural children and the association between poverty and under vaccination to target interventions and improve coverage.

ACKNOWLEDGMENTS

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INTRODUCTION

Immunization, one of the most fundamental of preventive services, is efficacious, cost effective and an essential component of comprehensive well child care. Direct and indirect savings to society range from $29.10 for every dollar spent on DTP vaccination to $2.00 saved for each Hepatitis B immunization (Orenstein, 1997).

Children in the United States receive vaccinations against ten diseases from birth until school entry. The current schedule of immunizations recommended by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) includes diphtheria, tetanus, pertussis (DTP), Haemophilus B influenza (Hib), polio, mumps, measles, rubella (MMR), hepatitis B (HBV), and varicella. Approximately five visits are required during the first two years of life to adequately immunize children. During this period, children are most susceptible to the morbidity and mortality associated with vaccine-preventable diseases.

An important relationship exists between immunization and the use of other medical services. State laws enacted in 1979 require complete immunization for school entry, but

immunization rates among younger children signal the overall adequacy of well child care. Well-child care is an integral part of family-focused preventive and primary care. Although limited, data consistently indicate a preventive health care deficit exists in rural America (Harris & Leininger, 1993). Several characteristics associated with lower levels of preventive care are more predominant among rural clients when compared with urban clients. Rural clients tend to be poorer, less educated, less well insured, and have access problems related to lack of transportation and greater distances to care (Harris & Leininger, 1993; Slifkin, Clark, Strandhoy, & Konrad, 1997). In addition, their communities are often designated as health care personnel shortage areas. Not surprisingly, recent evidence identifies rural residents as a population at greater risk for many types of injuries, disease, and disability than urban residents (Goeppinger, 1993; Knollmueller, 1994).

Also of concern is the trend for primary care physicians, according to Hueston, Meade, and Mainous (1992), to increasingly curtail the practice of offering childhood immunizations in their office due to liability issues, cost of vaccines and inconvenience. Discontinuation of childhood immunizations is more common among rural practitioners. Discontinuity of care and referral to county health departments may cause children, especially those living in rural areas, to miss or delay recommended vaccinations.

As part of a national health strategy focusing on disease prevention and health promotion, Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention (U.S. Department of Health, Education and Welfare (DHEW), 1979) established broad goals for improving the health of Americans by the year 2000. Immunization of children was identified as an objective. Healthy People 2000: National Health Promotion and Disease Prevention Objectives (U.S. Department of Health and Human Services, 1992) established as an objective the completion of the basic immunization series of at least 90% of American children by age two years. The Healthy People 2000 Review, 1995-1996 (National Center for Health Statistics, 1996) revised the wording of the objective to reflect completion of the basic immunization series through age 2 (35 months) rather than by age 2 (24 months). This revision reflects changes in data sources on immunization coverage that have occurred resulting in the measurement of immunization levels among preschool children 19-35 months old.

The development and widespread use of vaccines has been vital in reducing the incidence of infectious diseases, especially childhood diseases during the past half century. Reported cases of measles in the United States decreased by 95% within 5 years of vaccine licensure (Markowitz, Preblud, & Orenstein, 1989) and pertussis decreased to one hundredth of the prevaccination levels just 10 years after beginning routine immunization (Cherry, Baraff, & Hewlett, 1989).

The marked decrease in the incidence of vaccine-preventable diseases is associated with immunization rates of 95 per cent or more in school-age children (Hinman, 1988). These immunization rates are the direct result of enactment and enforcement of school immunization laws in each state.

Unfortunately, there is no mechanism such as a nationwide registry that tracks immunizations to achieve similar rates among preschoolers and thus extend the decreases in disease burden and mortality to this younger age group. The measles resurgence that occurred in 1989 was attributed primarily to a failure to vaccinate preschool-aged children early in their second year of life (National Vaccine Advisory Committee, 1991). In 1993, 5,793 cases of pertussis were reported among preschool-aged children; 68 per cent of these children were less than one-year of age (CDC, 1994a). Only 55% of 2 year olds (19 to 35 months) have received the basic immunization series (four DTP, three polio, and one MMR; 4:3:1) according to data from the 1992 National Health Interview Survey (CDC, 1994c). In 1994, Michigan had the lowest immunization rate of all 50 states. Only 61% of Michigan two-year-olds were fully immunized, while nationally 75% of children ages nineteen through thirty-five months had up-to-date immunizations (Bouffard, 1995). Despite this significant increase overall nationwide, the 1995 National Immunization Survey documented coverage rates for the 4 DTP, 3 polio, 1 measles containing

vaccine series (4:3:1) varied as much as 23 percentage points between the highest state and the lowest state. A variance of 25 percentage points in vaccination coverage rates occurred between the highest city and the lowest city (Orenstein, 1997). Based on data collected by the National Immunization Survey from July 1996 to June 1997, Michigan's vaccination coverage rate has improved and is no longer the lowest in the United States. For the 4:3:1 series, the vaccination coverage rate in Michigan is 76% and for the 4:3:1:3 series (4 DTP, 3 or more doses of Hib, 1 MMR, and 3 polio) it is 73% among two year olds (CDC, 1998).

Despite the increase in vaccine coverage rates, the United States is far from achieving the goal of at least 90 percent of American children completing the basic immunization series through the age two. Fortunately, the measles epidemics of 1989-1991 have resulted in renewed national focus on achieving the elusive immunization goal established in 1979.

Statement of the Problem

Despite the proven efficacy and cost-effectiveness of vaccines and the existence of many national immunization programs, nearly one million two-year-olds are not fully immunized. More than 20% of American children two years of age are not fully protected against all preventable childhood diseases (CDC, 1997a). Vaccination coverage levels consistently remain below the goal of at least 90 percent of American children completing the basic

immunization series through age two established by Healthy People 2000 Review, 1995-1996 (National Center for Health Statistics, 1996). Although the vaccination coverage rate in Michigan has significantly increased from 61% in 1994 (Bouffard, 1995) to 73% according to the National Immunization Survey data collected from July 1996 through June 1997, it continues to fall short of the national goal (CDC, 1998).

Multiple barriers to obtaining and receiving immunizations may be grouped into three main categories: parental barriers, provider barriers, and systems barriers (Grover, 1996). Parental barriers are identified as financial, lack of knowledge regarding immunizations and concern about adverse effects (Grover, 1996; Kimmel, Madlon-Kay, Burns, & Admire, 1996). Provider barriers include missed opportunities to vaccinate. A missed opportunity to vaccinate occurs when a child who needs immunization seeks health care and either receives no immunizations or fewer than needed. Missed opportunities occur in two ways:

1. the child does not receive immunization because of a condition inaccurately perceived by the provider as a contraindication or all indicated vaccinations are not administered simultaneously, and
2. a child needing immunization, but seeking other health care services, is not immunized because the immunization status is not reviewed or the 6 vaccination is not administered (Orenstein, Atkinson,

Mason, & Bernier, 1990; Salsberry, Nickel, & Mitch, 1995).

In a study conducted by Salsberry, Nickel and Mitch (1994), parents rated missed opportunity as the fourth greatest barrier out of 17, behind cost, lack of insurance, and office wait too long. Providers rated missed opportunity as the third greatest barrier to immunization, behind parents forgetting the immunizations or not knowing when they are due.

Systems barriers include economics, limited clinic hours, inaccessible clinic locations, insufficient clinic staff, financial screening, and requirements for appointments, physical examination, and enrollment in comprehensive care well-baby clinics (Grover, 1996; Orenstein et al., 1990; National Vaccine Advisory Committee, 1991). These barriers may discourage parents from obtaining immunization services for their children.

Study Purpose and Research Questions

The purpose of this study was to examine the adequacy of immunization of rural children through thirty-five months of age receiving immunizations at a local county health department. This study was patterned after Ambrose (1995) and Jurcich (1996) and addressed the questions:

1. What percentage of children from a local health department in rural northern Michigan obtain complete care, adequate care, or inadequate care with respect to all immunizations through age two years as recommended

by the Advisory Committee on Immunization Practices (ACIP)?

2. For each series of immunizations, what percentage of children received complete care, adequate care, and inadequate care?
3. What patterns of immunization are evident for those children receiving adequate or inadequate care with respect to initiation of immunizations and the spacing of those immunizations through age two years?
4. For the subset of children who received complete care for the immunizations recommended to be given at two months, what is the percentage of complete, adequate, and inadequate care for subsequent immunizations?

Theoretical Framework

The Starfield Model

The variables in this study were derived from Starfield's model for assessing primary care (Starfield, 1992). This model provides a framework for measuring and evaluating the attainment of primary care by examining the structure and process of a health services system and the influence exerted on the outcome of care.

Starfield (1992) acknowledged genetic structure, social and physical environment, individual behaviors and health services as factors which interact to determine the health status of individuals and populations. The health services system, although a less important determinant of health, reflects the contribution of primary care.

Each health services system has three main components: structure, process and outcome that are the principal elements in the Starfield model (Figure 1). The fourth component, the social and physical environment, interacts with the previously mentioned components to influence the desired health status and outcome of care.

Structure, as a variable, is defined as the resources necessary to provide services and consists of nine components. These nine components are: 1) personnel; 2) facilities and equipment; 3) management and amenities and governance of services; 4) range of services; 5) organization of services; 6) mechanisms for providing continuity of care; 7) mechanisms for providing access to care; 8) arrangements for financing; and 9) population eligibility.

The processes of a health service system are composed of two elements. The first element represents the activities of the health care professional in the provision of care. These activities include problem recognition, diagnosis, treatment, and reassessment of the problem. The second element consists of activities of the individual or population in the receipt of care. These activities include utilization, acceptance, satisfaction, understanding and participation with the health care provided.

Outcome of care is the effect or impact that the structure and processes of the health services system have

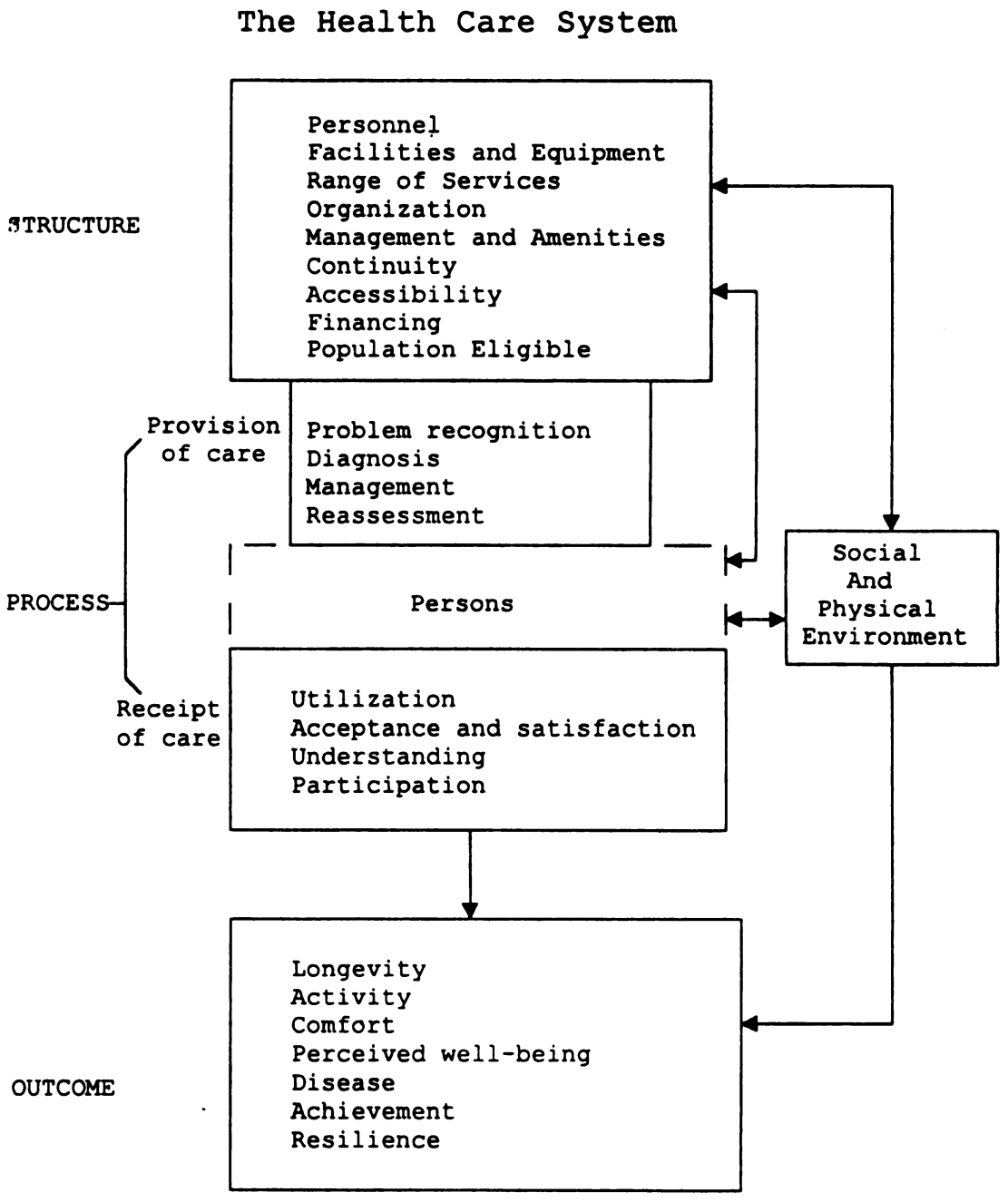

Figure 1. Starfield Model: A Basis for Evaluating Primary Care (Starfield, 1992).

on the health status of an individual or population. Starfield (1992) identified seven components of health status: longevity, activity, comfort, perceived well being, disease, achievement and resilience.

The social and physical environments represent aspects of the individual's and the health services system's culture, society and environment that influence the structure, process and outcome.

Application of the Starfield Model to Study

The conceptual definitions in this study were patterned after those of Ambrose (1995) and Jurcich (1996). The main variable from Starfield's model used in this study was outcome, as shown in Figure 2. Variables interacting with and influencing the outcome were structure, process, and social and physical environment.

Structure. Structure is defined as the resources necessary for a health services system to provide care. The structural components in this study were the facilities, equipment and the nurses administering immunizations as well as the immunization records for selected subjects who obtained vaccinations at a local health department in rural northern Michigan. At each clinic visit, parents are asked if their child has received any immunizations at another site, such as a private health care office, since the last visit. If parents are unable to provide documentation of additional immunizations, a telephone call is made to the

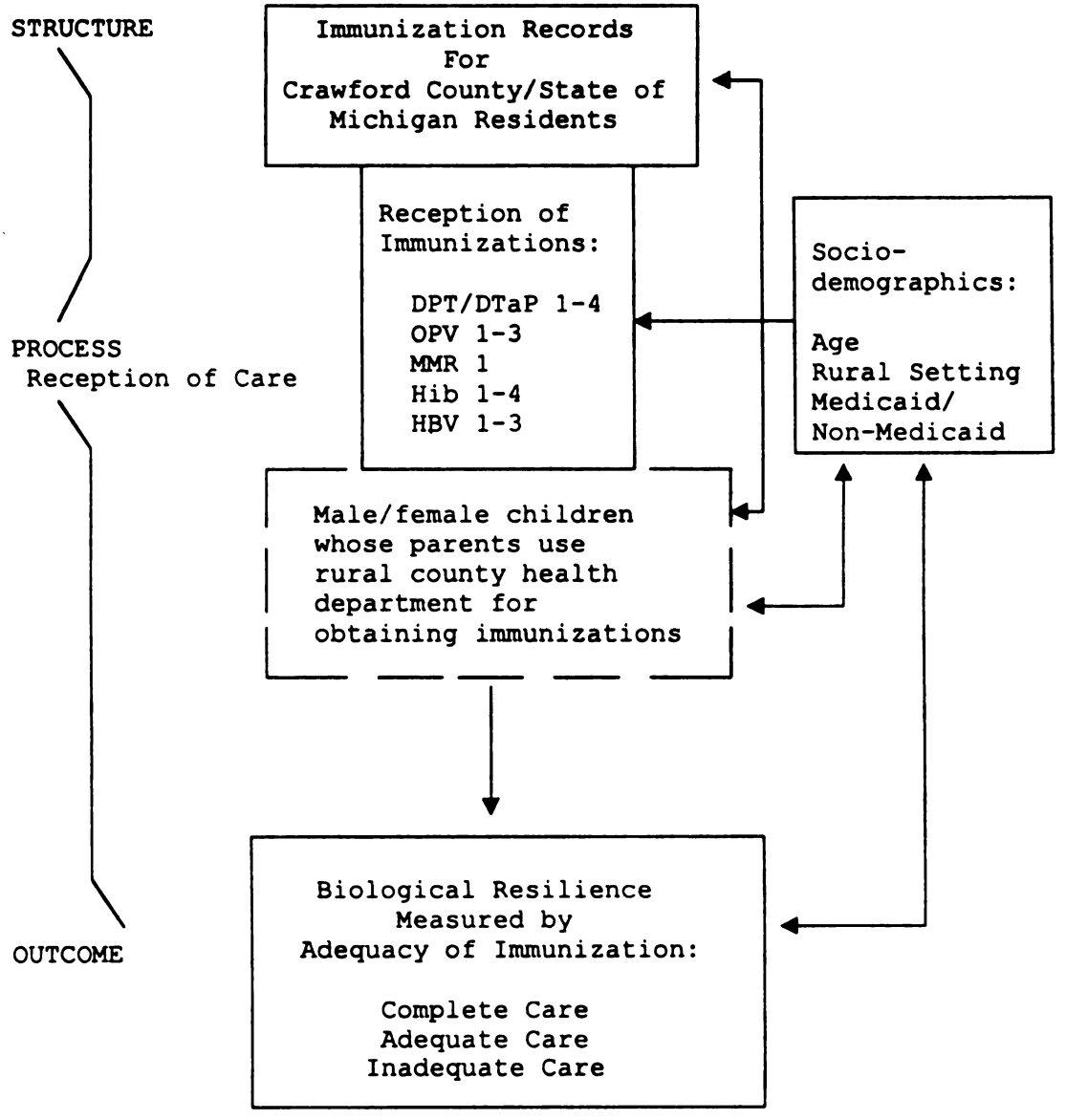

Figure 2. Adequacy of care through immunization for children age two years utilizing the public health system. Adapted from the Starfield Model (Ambrose, 1995; Starfield, 1992).

site where the immunizations were given to gain the information. The additional immunizations are entered into the computer at the health department and asterisked to denote they were obtained elsewhere.

Process. Process refers to obtainment of vaccinations by the children (Figure 2). The parents or their designated representative are also included in the process as they are instrumental in determining when, where, and if the child becomes vaccinated. In this study, the process was limited to whether vaccinations were or were not obtained. Factors such as missed opportunities, barriers and facilitators to obtaining vaccinations, and the health seeking behaviors taken by parents and children to receive vaccinations were not addressed although they are a part of the process and have an impact on the outcome.

Social and Physical Environment. Components of the social and physical environment selected for this study were age, sex, and insurance status. The defined service area of health providers in Crawford County is federally designated as rural. In rural areas, insufficient primary medical care and public health services, increased rates of poverty, and barriers such as transportation difficulties may inhibit access to vaccinations and basic health care services (Steiner, Lowery, Siegel, Barton, & Goodspeed, 1996). Each of these components influences the structure, process and outcome elements of the Starfield model. The structure element is influenced by the community or population

eligible to receive the services provided by the health services system. The health services system should be knowledgeable regarding the sociographic and demographic characteristics of the community or population in order to maximize its potential. These characteristics also affect the process element, receipt of vaccinations and the outcome component, adequacy of vaccination.

Outcome. Outcome of care, also viewed as the impact on health status, is affected by the structure of the health system and the processes of care. Starfield (1992) conceptualized immunizations under resilience, one of the seven components of health status. She defined biological resilience as the state of being appropriately immunized against preventable diseases. Within this study, the outcome of care was defined as the measurable adequacy of immunization for the sample: complete care, adequate care, and inadequate care (Figure 2).

Care was defined as complete when the child received all vaccinations recommended by the ACIP at the prescribed time through age two. Care was defined as adequate when the child received all immunizations through age two but not at the recommended times. Care was defined as inadequate when the child had not received all recommended vaccinations through age two.

Review of Literature

The effectiveness of preventive health care, especially immunizations, is well-documented (Orenstein et al., 1990).

Pruitt, Kline, and Kovaz (1995) focused on identifying barriers to childhood immunization in a rural population. In this study, 109 parents of infants and toddlers identified as inadequately immunized or at risk for delayed immunizations were interviewed. The number of children in the family, the mother's age and the father's employment correlated significantly with immunization delays. These findings were consistent with other studies that found young parental age, large family size, low socioeconomic status, use of public clinics as the source of immunization, lack of prenatal care, and late start of the immunization series to be risk factors for poor or delayed immunization (Orenstein et al., 1990; Robinson, Sepe, & Lin, 1993).

The primary reason identified by parents living in a rural setting for delayed immunization was illness although the Center for Disease Control and Prevention (CDC, 1989, 1994b) has recommended that children with minor illnesses accompanied by fevers less than 38 degrees Centigrade receive immunizations. Significant confusion existed about when immunizations were due, reflecting the many changes in immunizations over the last few years. Inconvenient clinic hours, waiting time and cost of immunizations were also identified as barriers (Pruitt et al., 1995).

Hueston, Meade, and Mainous (1992) assessed the immunization utilization practices of 200 rural and urban primary care physicians in Kentucky. The study noted that urban and rural pediatricians were more likely to offer

immunizations to children in their practice, as were urban family physicians and general practitioners. Rural family physicians and general practitioners were less likely than rural pediatricians to offer immunizations in their practice. Sixty nine percent of urban physicians and 83% of rural physicians stated they refer some patients to other locations for routine immunization, usually the public health department. Patient cost was the most common reason for referral. The authors suggest therefore that rural children may experience more missed opportunities for immunization since rural children are more likely to receive care from family physicians or general practitioners (McManus & Newacheck, 1989) and many must make an additional visit to the public health department for immunization.

Mainous and Hueston (1993) also investigated factors influencing the use of primary care physicians and public health departments for childhood immunization in urban and rural areas. They utilized a telephone survey of adults from 97 households with children under the age of 5 living in the home for data collection. This study found that individuals who received childhood immunizations at the health department were more likely to be at or below the poverty threshold and live in a rural area than those individuals who received immunizations at a primary care physician's office. These factors, which influence the selection of the public health department for childhood

immunizations, may be associated with higher risks for vaccine preventable childhood diseases (Hutchins, Escolan, Markowitz, Hawkins, Kimbler, Morgan, Preblud, & Orenstein, 1989).

A retrospective review exploring the adequacy of immunization for children two years of age who received their immunizations at an urban/suburban county health department found unacceptably low levels of immunizations. Only 65% of the children began immunizations on time, no one received all immunizations as recommended by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Practice, and only 45% received all immunizations by age two years (Ambrose, 1995). A similar study conducted by Jurcich (1996) also revealed unacceptably low immunization rates. Sixty percent of the children began immunizations on time, 6.9% received immunizations as recommended, and only 28.7% received all immunizations by age two.

Critique of Literature

Although approximately 27% of the population of the United States lives in rural areas (Shreffler, 1996), literature, data and research regarding rural health, health services utilization and financing is very limited. Few articles dedicated to either the overall health status of rural children, immunization delivery or adequacy of immunizations could be located. This study, although generalization is limited, will provide additional

information regarding the adequacy of immunizations in rural areas.

Methods

Research Design

Modeled after Ambrose (1995) and Jurcich (1996), this study was a retrospective review of immunization records. It was a nonexperimental study using descriptive data to investigate vaccination coverage levels of children through the age of two whom received immunizations at a rural county health department. Computerized vaccination records were utilized to obtain the data. To obtain results for this study, nominal and ordinal levels of measurement were applied to the data.

Sample

This study used a randomly selected sample of 85 immunization records obtained from the local county health department Vaccination Automated Control System (VACS) database. Using a table of random numbers, sample cases were randomly selected from 171 immunization records meeting the following inclusion criteria:

1. Birth dates from January 1, 1994 through April 30,1995.
2. All records of children vaccinated at the local county health department were eligible.

Crawford County is composed of a homogenous rural population of 12,471 residents. The 1996 unemployment rate of 7.1% was higher than the annual Michigan unemployment average of 4.7% (Grayling Regional Chamber of Commerce,

1997). According to the Kids Count in Michigan 1996 Data Book, 32.2% of young children ages 0 to 4 years live in poverty as compared to the state average of 26.6%.

Setting

The setting used was the District Health Department No. 10 clinic located in Crawford County. This site was selected because it is a central site for immunizations in Crawford County and services a significant proportion of the children in the county.

Operational Definition of Variables

Ambrose (1995) developed the definition for adequacy of care and operationalized it as follows using three levels: complete care, adequate care, and inadequate care.

Adequacy of Care. Adequacy of care was defined as the number of immunizations the child had received and the intervals at which they received them in relation to the recommended immunization schedule. The childhood immunization schedule approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Practice (AAFP)(CDC, 1995) was used in this study as the standard of care (Figure 3). The shaded bars in Figure 3 indicate that the specific vaccination is recommended within that time period. For example, the fourth DTP is recommended between ages 12 months and 18 months and DtaP can be administered starting at 15 months.

Oral poliovirus vaccine was administered to the

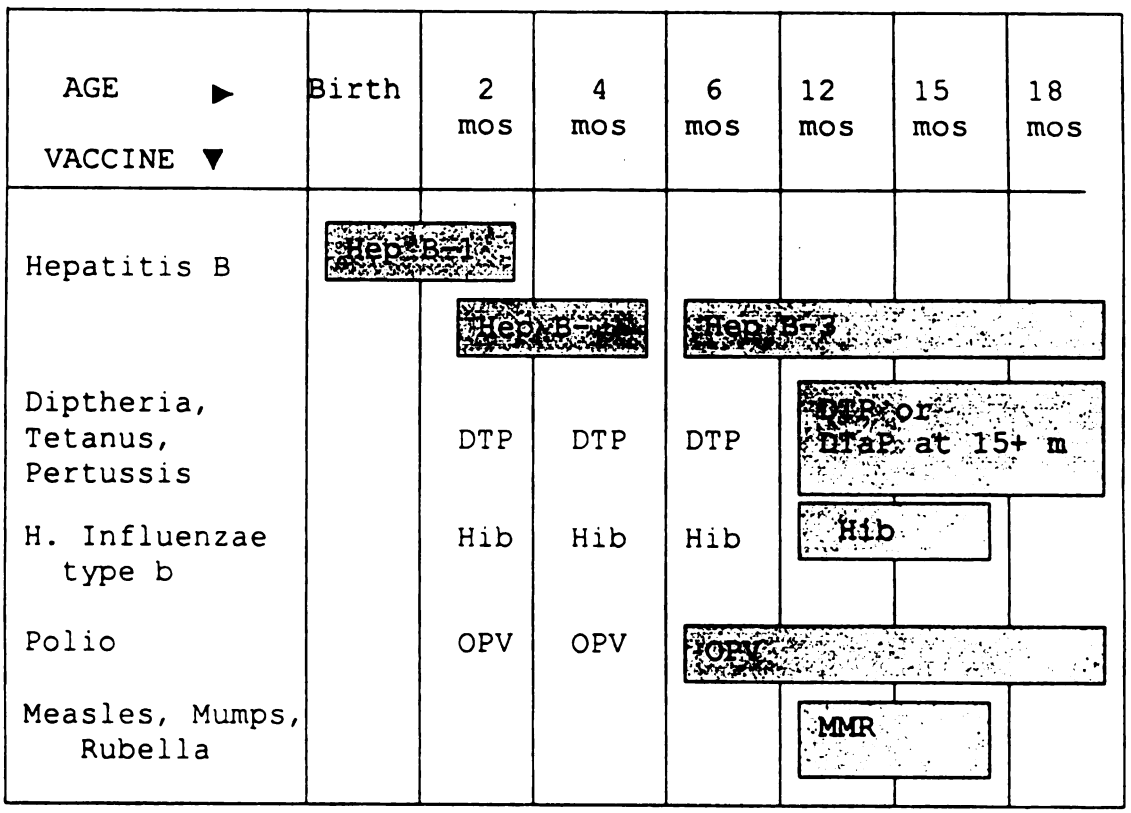

Figure 3. Recommended childhood immunization schedule from the ACIP, AAP, and AAFP. Adapted from CDC (1995).

children in this study. A total of one dose of inactivated poliovirus vaccine (IPV) was administered parenterally. In January 1997, the Advisory Committee on Immunization Practices (ACIP) recommended a sequential parenteral-oral vaccine schedule aimed at reducing the rate of vaccine-associated paralytic poliomyelitis (CDC, 1997b). All the subjects had either started or completed the OPV series prior to this recommendation. Varicella vaccination was not

studied because it was not administered at the health department during this period.

The variable, adequacy of care, was operationalized with three levels: 1) Complete Care—4 DPT immunizations, 3 OPV immunizations, 1 MMR, and 3 or more doses of Hib (4:3:1:3 series) and 3 Hepatitis B vaccinations received through age two (35 months) and correctly spaced within 30 days of the ACIP recommended schedule; 2) Adequate Care—All immunizations received through age two years, but not properly spaced within 30 days of the recommended ACIP time frame; and 3) Inadequate Care—Less than all of the recommended immunizations completed through two years of age.

The adequacy of care levels for the 4:3:1:3 series and the Hepatitis B series will be reported separately to allow comparison with data from the National Immunization Survey.

Parameters for each immunization variable were defined employing three levels: 1) obtained on time and properly spaced; 2) obtained through age two years, but not properly spaced; 3) not obtained through age two years. This was done to allow analysis of each series of immunization to determine if any differences existed between individual immunizations within a series and also between each series of immunizations.

Proper Spacing of Doses. Criteria for properly spaced doses were based on the recommended childhood immunization schedule plus or minus 30 days (Figure 3) along with the

minimum age for initial vaccination and minimum interval between vaccine doses (Figure 4). When information on the month and year of vaccination were available but not the date, the 15th was designated as the date (Zell et al., 1994).

Immunization records at District Health Department No. 10 are updated with the dates of immunizations given at other facilities if the information can be verified by the provider over the telephone or in writing. Any immunization for which there were no data was deemed not obtained and reflected as inadequate care. This assumed the later immunizations would not have been given without evidence of prior immunization; however, later immunizations may have been obtained at another source of health care and not reported to the local health department. No conclusions regarding the proper spacing of immunizations could be made in these cases.

Data Collection Procedure

Immunization records of the children who received immunizations at a local health department in rural northern Michigan with birth dates between January 1, 1994 through April 30, 1995 were obtained from the VACS computer database. These records also contained the date of birth, sex, and limited insurance data. Insurance data other than Medicaid was not routinely collected on immunization clients. Therefore, it was impossible to determine the insurance status of the non-Medicaid population.

Vaccine	Minimum age first dose	Minimum interval dose 1 to 2	Minimum interval dose 2 to 3	Minimum interval dose 3 to 4
DTP (DT)	6 weeks	4 weeks	4 weeks	6 months
Combined DTP/Hib	6 weeks	1 month	1 month	6 months
DTaP	15 months			6 months
Hib (primary series				
HbOC	6 weeks	1 month	1 month	2 months + age 12 mos
PRP-T	6 weeks	1 month	1 month	2 months + age 12 mos
PRP-OMP	6 weeks	1 month	2 months + age 12 mos	
OPV	6 weeks	6 weeks	6 weeks	
MMR	12 months	1 month		
Hepatitis B	birth	1 month	2 months + age 4 mos	

Figure 4. Minimum age for initial vaccination and minimum interval between vaccine doses, by type (CDC, 1995).

The immunization records were used as the instrument for data collection. Each record was sequentially numbered starting with one.

Statistical Analysis of Data

Data analysis was done using the SPSS statistical analysis software. Frequency and percentage were used as appropriate to describe the study results.

Analysis of data included the following:

1. **Percent of records sampled that indicated complete, adequate, and inadequate care for all immunizations received through age two (Research Question 1).**
2. **Percent of records sampled that indicated complete care, adequate care, and inadequate care for each**

immunization series (i.e. DTP/DTaP) the children received through age two (Research Question 2).

3. Percent of records sampled that indicated adequate care and inadequate care in the proper spacing for all immunizations (Research Question 3).
4. Mean number of days from date of birth to date of starting immunizations for those children who received adequate and inadequate care (Research Question 3).
5. Percent of records sampled that indicated complete care, adequate care, and inadequate care for the subsequent immunizations if the first set at age two months was complete (Research Question 4).

Study Limitations

There are three limitations to this study. First, the sample utilized was from a public health department clinic in a rural setting and may not be representative of the general population of the county and state. Data were limited to children receiving immunizations at a local county health department in rural northern Michigan. The immunization status of children who receive immunizations from a public health department clinic may differ from children who receive their immunizations in the private sector and, in general, from the immunization status of the county and state population. Therefore, discussion of the results of this study must be limited to children who receive immunizations from a health department in a similar county and may not be generalized to the overall population

of the county and state. Second, system, parental and provider barriers to immunizing these children were not available, therefore, conclusions regarding potential influences on vaccination coverage levels are beyond the scope of this study. Third, data were obtained solely from health department computer records. No effort was made to fill in missing data or verify records of immunizations received from other providers that were entered by the health department staff. This was beyond the scope of the study.

Study Assumptions

The assumptions identified by Ambrose (1995) were used for this study:

1. Immunizations against vaccine-preventable childhood diseases are reasonably safe and efficacious.
2. The immunization schedule recommended by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Practice is a valid standard for the prevention of some childhood diseases.
3. High vaccination coverage levels in the general population benefit those immunized and the overall population in the United States by decreasing the risks of morbidity and mortality.
4. Subsequent immunizations in a series would not have been given without evidence of prior immunization.

5. The data recorded at the local county health department were accurate.

Protection of Human Rights

The rights of the individuals whose immunization records were utilized in this study were protected in accordance with the guidelines developed by the University Committee on Research involving Human Subjects (UCRIHS) at Michigan State University. Approval of this committee was obtained prior to gathering the data (See Appendix A).

Permission was also obtained from the District Health Department No.10 Medical Director to collect data (See Appendix B). No data were used that could identify individuals in the study and no identifying data was removed from the clinic site. Once the immunization records were obtained they were sequentially assigned numbers beginning with one. All data were entered into the SPSS database by this investigator. No identifying variables were entered into the SPSS data bank. Confidentiality was maintained.

Results

Description of Sample

The sample consisted of 85 immunization records from a local county health department in rural northern Michigan. As illustrated in Table 1, the majority of the sample were male (58.8%) and the remaining female (41.2%).

The years of birth included in this study were 1994 and 1995. The majority of the sample (83.5%) was from 1994 due

Table 1.

Demographics of Sample

Characteristics	Frequency	Percent
Gender:		
Male	50	58.8
Female	35	41.2
Insurance		
Medicaid	50	58.8
None/Other	35	41.2
Gender and Insurance		
Male and Medicaid	25	50.0
Female and Medicaid	25	50.0

to the exclusion criteria for birth dates from January 1, 1994 through April 30, 1995. The sample was fairly evenly distributed throughout the months. May 1994 contained the lowest number of immunization records with one (1.2%) and August 1994 and September 1994 contained the most, each containing eleven records (12.9%). The only insurance information listed on the immunization records was Medicaid. Fifty children (58.8%) were designated as Medicaid recipients. The remaining children had either private or no insurance.

Answers to Research Questions

The research questions presented in this study were based on the concern that children are inadequately immunized during the first few years of their life; a time when they are most susceptible to the morbidity and

mortality associated with vaccine preventable diseases. The outcome in this study was measured by the level of care received with respect to the immunizations received through two years of age: complete, adequate, or inadequate care.

Question 1. What percentage of children from the local county health department in rural northern Michigan obtained complete care, adequate care, or inadequate care with respect to all immunizations through age two years as recommended by the ACIP, AAP, and AAFP?

The percentage of children receiving complete care for the 4:3:1:3 series was 32.9% (n=28); adequate care, 56.5% (n=48); and inadequate care 10.6% (n=9)(Not listed in a table). This sample obtained an adequate immunization coverage level of 56.5% and when combined with the complete care results, the percentage of children receiving all immunizations through age two increased to 89.4%.

The overall vaccination coverage level for the Hepatitis B Vaccine series was 90.6% with 51.8% of the children receiving complete care and 38.8% adequate care.

The overall vaccination coverage level for Hib as a series of 3 or more vaccinations was 93.2%. If the Hib series data had been analyzed as a series of 4 vaccinations as was done by Jurcich (1996), the overall vaccination coverage level would have declined to 81.2%. A series of three or more doses provides herd immunity therefore the National Immunization Survey data reflects 3 or more Hib doses as acceptable vaccination coverage.

Question 2. For each series of immunizations, what percentage of children received complete care, adequate care, and inadequate care?

For each series of immunizations, the percentage of children who received complete, adequate, and inadequate care is listed in Table 2. The percentages of complete care ranged from 38.8% (n=33) for the DTP series to 76.4% (n=65) for the MMR vaccination. The level of adequate care ranged from 21.2% (n=18) for the MMR vaccination to 51.8% (n=44) for both the DTP and the Hib series.

Ninety-four percent of the sample received the OPV series as either complete care (45.9%) or adequate care (48.2%). Ninety percent of the sample received the HBV series as either complete care (51.8%) or adequate care (38.8%).

The majority of children received the recommended number of immunizations as either complete or adequate care in all series through age two. The DTP and HBV series shared the lowest percentage (90.6%).

Question 3. What patterns of immunizations are evident for those children receiving adequate or inadequate care with respect to initiation of immunization and the spacing of those immunizations through age two years?

Table 3 reports the findings for each individual immunization. The following patterns were noted for DTP, Hib, OPV, and HBV where more than one vaccination is recommended to complete the series. First, the vaccination

Table 2.

Adequacy of Care for Each Immunization Series (N=85)

Immunization Series	Adequacy of Care	Frequecy	Percent
DTP	Complete	33	38.8
	Adequate	44	51.8
	Inadequate	8	9.4
Hib	Complete	36	42.4
(3 or more doses)	Adequate	44	51.8
	Inadequate	5	5.9
OPV	Complete	39	45.9
	Adequate	41	48.2
	Inadequate	5	5.9
MMR	Complete	65	76.4
	Adequate	18	21.2
	Inadequate	2	2.4
HBV	Complete	44	51.8
	Adequate	33	38.8
	Inadequate	8	9.4

Table 3.
Adequacy Level for Individual Immunizations (n=85)

Immunization	Adequacy Level	Frequency	Percent
DTP1	Complete	56	65.9
	Adequate	29	34.1
	Inadequate	0	0.0
	Missing	0	0.0
DTP2	Complete	42	49.4
	Adequate	41	48.2
	Inadequate	0	0.0
	Missing	2	2.4
DPT3	Complete	37	43.5
	Adequate	44	51.8
	Inadequate	1	1.2
	Missing	3	3.5
DPT4	Complete	60	70.6
	Adequate	17	20.5
	Inadequate	2	2.4
	Missing	6	7.1

Table 3 (cont.)

Immunization	Adequacy Level	Frequency	Percent
Hib1	Complete	54	63.5
	Adequate	31	36.5
	Inadequate	0	0.0
	Missing	0	0.0
Hib2	Complete	41	48.2
	Adequate	42	49.4
	Inadequate	0	0.0
	Missing	2	2.4
Hib3	Complete	37	43.5
	Adequate	43	50.6
	Inadequate	2	2.4
	Missing	3	3.5
Hib4	Complete	43	50.6
	Adequate	27	31.8
	Inadequate	1	1.2
	Missing	14	16.5
OPV1	Complete	56	65.9
	Adequate	29	34.1
	Inadequate	0	0.0
	Missing	0	0.0
OPV2	Complete	43	50.6
	Adequate	40	47.1
	Inadequate	0	0.0
	Missing	2	2.4
OPV3	Complete	60	70.6
	Adequate	20	23.5
	Inadequate	2	2.4
	Missing	3	3.5
MMR	Complete	65	76.5
	Adequate	18	21.2
	Inadequate	1	1.2
	Missing	1	1.2
HBV1	Complete	54	63.5
	Adequate	29	34.1
	Inadequate	1	1.2
	Missing	1	1.2
HBV2	Complete	46	54.1
	Adequate	33	38.8
	Inadequate	3	3.5
	Missing	3	3.5
HBV3	Complete	65	76.5
	Adequate	12	14.1
	Inadequate	4	4.7
	Missing	4	4.7

coverage rate ranged from 63.5% to 65% for DTP1, Hib1, OPV1, and HBV1 vaccinations and was 76.5% for the MMR vaccination as received according to the recommended schedule. Secondly, with subsequent immunizations (i.e., DTP2, DTP3, Hib2, Hib3, OPV2 and HBV2) coverage rates successively declined. The decline for vaccinations received according to the recommended schedule was the least between Hib2 and Hib3 (4.7%) and was greatest between DTP1 and DTP2 (16.5%). However, those immunizations with an extended range of recommended age for vaccination (i.e. DTP4, Hib4, OPV3, and HBV3) showed an increase in coverage rates for immunizations obtained according to the recommended schedule. The most dramatic increase was 27.1% between DTP3 and DTP4. The smallest increase (7.1%) was between Hib3 and Hib4. The data consistently demonstrate an increase in the receipt of vaccination at the adequate level of care through two years when immunizations are not received according to the recommended schedule and vice versa.

Interestingly, when the percentages for each of the individual immunizations received according to ACIP recommendations and through two years of age are added, there is a successive decline in coverage level throughout each series. The decline throughout the series is greatest for the Hib vaccination. Vaccination for Hib1 is 100% and decreases to 82.4% with Hib4. The vaccination series experiencing the least decline in coverage level is OPV that begins at 100% and declines to 94.1% with OPV3. Also, the

percentage of missing data increases with each subsequent immunization.

Children with Medicaid listed as their insurance were two and one half times less likely (20.0% versus 51.4%) to receive the 4:3:1:3 series as complete care in accordance with ACIP recommendations than children not on Medicaid. Those on Medicaid were twice as likely to receive the 4:3:1:3 immunization series as adequate care. The percentage of children receiving inadequate care for the 4:3:1:3 series in both groups was similar (10.0 versus 11.4%).

Table 4 reports the mean number of days for children to receive the initial set of immunizations and the resulting level of adequacy of care achieved for all recommended series of immunizations. For the children receiving their initial set of immunizations according to ACIP guidelines (n=55), 28 received complete care (50.9%), 27 received adequate care (49.1%), and no one received inadequate care for all recommended series of immunizations. For children receiving the initial set of immunizations later than ACIP recommendations (n=30), 21 children (70.0%) received adequate care and 9 children (30.0%) received inadequate care for all recommended series of immunizations. These results do not wholly support that the continued morbidity and mortality of vaccine preventable diseases is due, in part, to a failure to immunize children at an early age resulting in inadequate immunity to childhood disease.

Table 4.

Adequacy Level for All Immunizations with Respect to Initiation of Initial Set of Immunizations

Initiation of Immunizations	Mean Number of Days	Adequacy of Care Complete	Adequate	Inadequate
Initial set received by all subjects (n=85)	98.9 days	32.9% n=28	56.5% n=48	10.6% n=9
Initial set received at 2 months per ACIP guideline (n=55)	68.5 days	50.9% n=28	49.1% n=27	0.0% n=0
Initial set received later than ACIP recommendation of 2 months (n=30)	154.7 days	0.0% n=0	70.0% n=21	30.0% n=9

Question 4. For the subset of children who received complete care for the series of immunizations recommended at two months of age (first set), what is the percentage of complete, adequate, and inadequate care for subsequent immunizations?

Fifty-five children (50.9%) in the sample received complete care for the first DTP, Hib, OPV, and HBV according to the recommended schedule. Table 5 lists the percentages for the level of adequacy for each series and for all immunizations through age two for the subsets of children

Table 5.

Adequacy Level for the Subset of Children who Received Complete Care for the First Set of Immunizations

Immunization Series	Adequacy Level	First Set at 2 months (N=55)		First Set at > 2 months (N=30)	
		n	%	n	%
All Series (except HBV)	Complete	28	50.9	0	0.0
	Adequate	27	49.1	21	70.0
	Inadequate	0	0.0	9	30.0
DTP	Complete	33	60.0	0	0.0
	Adequate	22	40.0	22	73.3
	Inadequate	0	0.0	8	26.7
Hib	Complete	36	65.5	0	0.0
	Adequate	19	34.5	25	83.3
	Inadequate	0	0.0	5	16.7
OPV	Complete	39	70.9	0	0.0
	Adequate	16	29.1	25	83.3
	Inadequate	0	0.0	5	16.7
MMR	Complete	48	87.3	17	56.7
	Adequate	7	12.7	11	36.7
	Inadequate	0	0.0	2	6.7
HBV	Complete	42	76.4	2	6.7
	Adequate	11	20.0	22	73.3
	Inadequate	2	3.6	6	20.0

who received the first set of immunizations according to the recommended schedule and those who received the first set after two months of age.

Twenty-eight (50.9%) of the children receiving complete care for the first set of immunizations continued to receive immunizations for all series according to the recommended

schedule. Of the remaining children in this subset, twenty-seven (49.1%) received subsequent immunizations for all series through two years of age and no one failed to complete all series. The only immunization series that reflected adequate care was HBV.

All the children (n=55) who received the first set of immunizations per the recommended schedule had completed all series through age two. Only 70.0% of the children (n=21) who received the first set of immunizations after two months completed all series of immunizations through age two. Overall, children who started immunizations per the recommended schedule were more likely to have received complete or adequate care through two years of age.

Discussion

The major finding of this study was that the overall immunization coverage in this sample of clients from a county health department in rural northern Michigan for the 4:3:1:3 series (4 DTP, 3 Hib, 1 MMR, and 3 Polio) was 89.4%). This result is near the national goal of greater than or equal to 90% of two -year old children achieving series complete coverage for all recommended vaccines. If Hib4 was included in the measurement as was done by Jurcich (1996), the overall immunization rates drops substantially to 81.2%, a decline of 8.2%. The Hepatitis B series immunization level in the same population was 90.6%, far exceeding the national goal of 70%.

The percentage of children in this study achieving series complete coverage (complete and adequate care) for all recommended vaccines was higher than reported by the CDC (1998) in the National Immunization Survey (NIS) for the state of Michigan (73%) and the city of Detroit (63%). Data for each county are not reported by the NIS. The results of the current study can not be readily compared with others in the literature due to multiple differences in the sample other than the NIS done for the state of Michigan (CDC, 1998).

The Ambrose (1995) and Jurcich (1996) studies using health department records are similar to this research. The research by Ambrose revealed 45% of children up to age two years received adequate care and 55% received inadequate care for the 4:3:1 series (4 DTP, 3 Polio, and 1 MMR). These were the recommended immunizations for that time. The study by Jurcich showed 6.9% of the children received complete care, 28.7% received adequate care and 64.4% received inadequate care for the 4:4:1:3 series (4 DTP, 4 Hib, 1 MMR, and 3 Polio) of immunizations recommended by the ACIP. The immunization coverage level for receiving all recommended immunizations by age two was only 35.6%.

Many reasons can be identified for the results of this study. The National Immunization Survey for the period April to December 1994 found only 61% of children age 19 to 35 months in Michigan were fully immunized (4:3:1 series). This result was significantly lower than the national rate

of 75% fully immunized. Michigan had the lowest immunization coverage rate of all 50 states for 1994. This distinction attracted the attention of media, professional organizations, and state and federal funding. Increased services by the Michigan Department of Public Health at the local level which included educational programs, assessments of immunization levels and consultative services were also forthcoming (Bouffard, 1995).

This increased focus on childhood immunizations has led to a significant improvement from 61% to 73% in Michigan's immunization coverage among two-year-old children. Unless multiple factors continue to be addressed, increased immunization rates will be temporary.

A major factor, which may have also affected the results of this study, is the inability to track the immunization status of children. A number of children receiving inadequate care had missing data that could have been due to the child receiving vaccinations from another health care provider. No effort was made to fill in missing data. These children may have been fully immunized but, within this study, there was no provision for validating this possibility. Therefore all records were included in the study.

An immunization tracking system, called the Michigan Childhood Immunization Registry (MCIR), is being established statewide and will contain birth records for all children born in Michigan on or after January 1, 1994. This record

keeping system, for children who receive immunizations in Michigan, will allow authorized users to receive up-to-date immunization information and submit new data as it becomes available. Participation in the MCIR is mandatory and state law requires that health care providers submit immunization records to the registry unless a parent or guardian objects (Smith, 1998). Use of this system will facilitate tracking of the immunization status of children under the age of twenty years and eliminate the problem of missing data for childhood immunizations received in Michigan. When functional, the MCIR should improve the completeness of records and ability to accurately assess the immunization status of children in Crawford County and throughout the state.

In this study, 56.5% received adequate care and 10.6% received inadequate care. Barriers to immunizing children are well documented in the literature and include cost, failure of insurance to cover immunizations, missed opportunities, number of vaccinations, limited access to health care and inadequate public awareness (Gamertsfelder, Zimmerman, & DeSensi, 1994; Hinman, 1991; Salsberry, Nickels, & Mitch, 1994). Barriers to complete care may also be due to health care provider practices such as missed immunization opportunities, overly cautious interpretation of vaccine contraindications and lack of administration of simultaneous vaccines (Gamertsfelder et al., 1994).

Barriers specific to this rural population in Crawford County which may result in inadequate or delayed immunization are low socioeconomic status and limited access to health care, especially the availability of health care providers who administer immunizations and transportation to these sites. The health department is one of the few sites in the county administering childhood vaccinations. Immunization at the health department requires a separate visit and additional time to obtain well-child care at a primary care provider's office. These additional visits, in addition to access problems, could result in a decreased level of immunization coverage.

The rates for complete and adequate care for each individual series of immunizations, excluding MMR, vary slightly. This may be due to similar recommended schedules for each series. The DTP, Hib (3 or more doses), and OPV have higher percentages of adequate care than complete care. The HBV series and MMR reflect the opposite. The MMR is a single vaccination recommended for administration at 12 to 15 months of age. It is often given at 12 months, a common age for a well child visit and to receive other recommended vaccinations. The first dose of HBV is usually given at birth in Crawford County, the second and third doses are recommended for administration at 2 and 12 months respectively. The recommended schedule for the MMR and HBV vaccines coincides with the recommended time frame for

administering additional childhood vaccines which may account for the higher rate of complete care.

One half of the children who received their first set of immunizations according to the recommended schedule at two months had complete care for all recommended immunizations. This number (n=28) represents one-third of the entire sample. Timely receipt of the initial doses of vaccines recommended to be administered at two months of age was associated with a higher level of vaccination coverage. In this study, of the 55 children who received the initial immunizations at two months, 50.9% received complete care and 49.1% received adequate care. This finding is consistent with existing research.

Rapid changes in vaccine recommendations have resulted from the development of new vaccines, changes in the epidemiology of vaccine preventable diseases, and other scientific findings (Peter, 1992). The recommended childhood immunization schedule continues to increase in complexity with the recent additions of varicella and rotavirus vaccines. With the increased number and type of vaccinations, it is imperative that children begin and continue to receive immunizations as recommended to ensure high levels of vaccination coverage.

Discussion of Results within the Theoretical Framework

The findings of this research support the theoretical framework adapted from Starfield (1992) for evaluating the structure of the health system and processes of primary care

and the resulting outcome or effect on health status. Starfield (1992) conceptualized biological resilience, one of the components of health status, as the state of being appropriately immunized against preventable diseases. A level of immunization (89.4%) which provides herd immunity reflects that the health status of two-year-old children in Crawford County is not compromised by the risk of contracting vaccine-preventable diseases.

Implications for Advanced Practice Nurses in Primary Care

The purpose of this study was to determine the adequacy of immunization for children through age two years who received their immunizations at a public health department. The main findings in this study include 1) immunization rates slightly below the national goal of 90%; and 2) higher rates of complete and adequate care associated with starting immunizations on time according to the recommended schedule.

Eighty thousand four hundred of Michigan's toddlers remain inadequately immunized and at risk of contracting vaccine preventable diseases and succumbing to the inherent morbidity, mortality and potential disability (Michigan League for Human Services, 1998). The advanced practice nurse (APN) in primary care can have a positive impact on improving immunization coverage and overall child health through clinical, educational and research avenues.

As a clinician, the APN should routinely identify children with risk factors for delayed immunizations such as large family size, low socioeconomic status, single parent

status, young parental age, and low educational level of either parent (Bates, Fitzgerald, Dittus, & Wolinsky, 1994; Bobo, Gale, Thapa, & Wassilak, 1993). Studies have shown that poverty is significantly associated with failure to complete immunizations while the other risk factors correlate with delayed initiations of the immunization series and failure to immunize according to the recommended schedule (Bates et al., 1994). Once identified, these children and their parents can be the focus of continuing intense efforts to achieve adequate immunization and improve other aspects of preventive care and health promotion.

Ideally, parental education on childhood immunization should be initiated prenatally by the APN or in collaboration with the prenatal care provider. Parents should be informed of the benefits, risks, and adverse effects of each vaccine and given a copy of the recommended immunization schedule. Reinforcing the importance of initiating and receiving subsequent immunizations on time for all children along with scheduling an appointment for the next recommended immunization may help to maintain and further improve levels of immunization coverage. Lack of knowledge regarding the importance of vaccines has been identified as the most important barrier to immunizations (Kimmel et al., 1996).

Many newborn infants in Michigan receive the first Hepatitis B vaccination in the hospital prior to discharge presenting an additional opportunity for the APN and parents

to discuss care of the infant including immunizations and well child visits. Knowledge of the importance of on time immunizations and the risks of morbidity and mortality due to under vaccination would allow the parents to make informed decisions regarding illness prevention practices for their child. To facilitate educating parents, the APN should establish an ongoing relationship of trust in which to assess parental beliefs and attitudes regarding immunization and address parental concerns.

In addition to educating parents, community education and participation may help improve parental awareness of the need for timely childhood vaccination. The APN can disseminate information through parenting classes, infant and child day care settings, prenatal classes and church groups such as the health ministry. Organizations such as the Kiwanis Club or food establishments such as McDonald's can be approached to provide incentives for immunization such as story books or food coupons.

The APN should review a child's immunization status at every appointment not only well child visits and vaccinate as indicated. The scheduling of programs such as the Women, Infants, and Children (WIC) Program in conjunction with an immunization clinic would increase accessibility and improve vaccination coverage levels in this population. At District Health Department No. 10, the immunization status of all children seen during the WIC clinic is assessed and vaccinations are given as indicated. These practices work

to eliminate missed opportunities and ensure the child is adequately immunized.

Periodic audit of pediatric client records is another tool the APN can use to monitor and improve childhood immunization rates. These audits serve to verify compliance with receipt of recommended immunizations, identifies the immunization coverage rate within the practice and reinforces the importance of immunizations to physicians and primary care staff. If all vaccine doses for which a child is eligible have not been administered, a recall system, such as a mailed reminder, should be initiated. A mailed reminder is cost effective and can serve to increase the immunizations received and influence immunization seeking behavior in families whose children do not have up-to-date immunizations (Young, Halpin, Johnson, Irvin, & Marks, 1980). Once MCIR is completely operational, the audit process should be easier and more accurate since it will include data from public and private health care providers.

Education of physicians and other health care professionals, in addition to parents and the community, can also increase immunization levels among children. The Standards for Pediatric Immunization Practices recommended that providers receive education on current immunization recommendations. The APN can educate the primary care providers and clinic staff about current immunization research and practices. Education would include inservices regarding changes in the recommended immunization schedule,

current standards of immunization practices, true contraindications to vaccine administration and the importance of simultaneous administration of multiple vaccine injections to decrease missed opportunities.

An equally important role for the APN, in addition to clinician, researcher and educator is as an advocate. The APN can disseminate information and research findings, both positive and negative that impact vaccination coverage levels, and seek policy changes, legislation and funding to improve the status of childhood immunization.

Recommendations for Future Research

This study revealed several areas for further research. Currently research regarding rural health and the assessment of childhood immunization status and child well being is limited. Further development of research in this area would allow specific subgroups to be targeted and interventions developed to improve overall vaccination coverage levels. Another area for research is the relationship between poverty and under vaccination. Additionally, assessment of vaccination coverage rates and concurrent assessment of perceived parental and provider barriers to immunization should receive further research. Many parents are concerned about the number of injections their children receive when vaccines are administered simultaneously. The ACIP recommendation of a sequential parenteral-oral poliovirus vaccine schedule further increases the number of injections. Future research should investigate whether parental concerns

regarding multiple injections impacts the implementation of this recent recommendation. Controversy regarding the safety of whole-cell pertussis vaccines has also raised parental concern. This concern prompted the development of acellular pertussis vaccines which are less likely to cause adverse effects. Research is indicated to determine if parental concern regarding the safety of the pertussis vaccine has changed. Further study in these areas could help the APN, health care professionals and other governmental agencies understand how and why many children do not receive immunizations according to the recommended schedule.

Recommendations for Formal Education

Immunizations are a vital part of comprehensive well child care, and vaccination coverage levels of children are an indicator of the quality of preventive health services (Grover, 1996). Undergraduate and graduate nursing programs, with the event of managed care and the emphasis on controlling health care costs, must emphasize the importance of health promotion and preventive health services. Immunizations, as one focus, require initial in-depth instruction and frequent updating throughout nursing programs due to rapid changes in vaccine technology and the ACIP schedule for immunization. Students must become thoroughly knowledgeable regarding the ACIP schedule for and contraindications to vaccine administration. They must also develop an awareness of opportunities to vaccinate infants

and children regardless of the clinical setting and for educating parents, caregivers, and the community about the importance of and need for immunizations. As missed opportunities to vaccinate decrease due to the efforts of nurses at all levels, vaccination coverage levels will continue to improve and eventually will surpass the goal set by Healthy People 2000.

Summary

This research assessed the adequacy of immunization status for children through two years of age. The levels of complete, adequate, and inadequate care were evaluated for a sample of records of children receiving immunizations at a local county health department in rural northern Michigan. The level of complete care in this study was 32.9%, adequate care 56.5%, and inadequate care 10.6%. The findings of this study do not support the findings of other studies that current immunization levels fail substantially below the Healthy People 2000 goal of at least ninety-percent of two year-old children completing the basic immunization series. Specifically, this study identified that children who received their first set of vaccinations at age two months as recommended were more likely to complete all immunizations through age two years than the children who received their first set of immunizations at a later date than recommended.

The findings of this study will assist the APN in monitoring and improving the vaccination coverage rates for

children through the age of two through the roles of clinician, educator, researcher and advocate. Maintaining and increasing current vaccination coverage rates is vital to further decrease the morbidity, mortality and potential disability associated with vaccine preventable diseases.

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APPENDIX A

UCRIHS Approval

MICHIGAN STATE
UNIVERSITY

May 14, 1998

TO: Linda Spence
A230 Life Sciences

RE: IRB#: 98-284
TITLE: ADEQUACY OF IMMUNIZATION FOR RURAL CHILDREN THROUGH AGE TWO YEARS
REVISION REQUESTED: N/A
CATEGORY: 1-E
APPROVAL DATE: 05/13/98

The University Committee on Research Involving Human Subjects'(UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed above.

RENEWAL: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES: Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

Sincerely,

David E. Wright, Ph.D
UCRIHS Chair

DEW:bed

cc: Barbara A. McNamara

OFFICE OF
RESEARCH
AND
GRADUATE
STUDIES

University Committee on
Research Involving
Human Subjects
(UCRIHS)

Michigan State University
246 Administration Building
East Lansing, Michigan
48824-1046

517/355-2180
FAX: 517/432-1171

APPENDIX B

District Health Department No. 10 Approval