THE INCIDENCE OF RESPIRATORY INFECTIONS IN MEN WITH CHRONIC RESPIRATORY DISEASE WITH AND WITHOUT DIABETES

by

Marina Elizabeth McCollam, B.S.

A THESIS

Presented to
The Oregon Health Sciences University
School of Nursing
in partial fulfillment
of the requirements for the degree of

Master of Nursing June 11, 1982 APPROVED:

M. Katherine Craptree, M.S., Associate Professor, Thesis
Advisor

Sue Bradley Davidson, R.N., M.S., Assistant Professor, First Reader

Olive Kuni, R.N., B.S., A.N.P., Second Reader

Carol Lindemar, Ph.D., Dean, School of Nursing

This study was supported by traineeships from the United States Public Health Service Grant Numbers 2 ALL NU 00250-05 and 2 ALL NU 00250-06.

ACKNOWLEDGMENTS

My sincere thanks to Kathy Crabtree, my advisor, whose optimism, good spirits and breadth of knowledge made it possible for me to complete this project.

Thanks also to my committee members, Sue Davidson and Olive Kuhl, for their advice and participation.

Thank you, Julie Brown, for showing such patience with my frequent questions.

My heartfelt thanks to Jan Smith for guiding me through the bureaucratic maze.

Finally, a special thanks to my mother and family for their support and patience during my various trials.

TABLE OF CONTENTS

CHAPTER		PAGE
I	INTRODUCTION	1
	Review of the Literature	8 8 9 10
	compromised Adults and Children Summary	18 19 25 28 29
II	METHODS	30
	Subjects and Settings	31 32 33
	Status	34 34 35 36
III	RESULTS AND DISCUSSION	37
	Description of the Sample. Research Question No.1 Incidence of Colds Incidence of Pneumonia Research Question No.2 Poorly Controlled Diabetes and Respiratory Infections Immunization Status and the Incidence of Respiratory Infections Additional Related Findings.	37 41 41 43 45 48 50 51
	General Discussion of Findings	53

TABLE OF CONTENTS

CHAPTER		PAGE
IV	SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS	57
	Summary	57 60 62
	REFERENCES	64
	APPENDICES	72
	Appendix ACover Letter	72 73 74 75 76
	ABSTRACT	78

LIST OF TABLES

PAGE		TABLE
3	Estimated Occurrence of Serious Pneumococcal Disease, United States	1
12	Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)	2
39	Descriptive Characteristics of Men with Chronic Respiratory Disease (N=61)	3
47	A Hierarchial Multiple Regression Examining the Effect of Five Selected Variables on the Number of Colds Subjects Experienced	4
49	A Descriptive Comparison of Poorly Controlled Diabetics, Controlled Diabetics, and Non-diabetics	5
50	Pearson Correlation between Number of Months of Immunization and Respiratory Infections in Men with Chronic Respiratory Disease	6
75	Cold Prevention Measures Described by Subjects	7
77	Other Diseases Noted in Subjects	8

LIST OF FIGURES

FIGURE									PAGE
1	Breakdown	of	Study	Subjects.		٠	•		32

CHAPTER I

Introduction

Pneumonia and influenza are among the leading causes of death in the United States. In an effort to reduce the incidence of morbidity and mortality, pneumococcal vaccine was licensed for use in the United States in November of 1977. Since the introduction of tetradecavalent pneumococcal capsular polysaccharide vaccine, controversy has existed as to the vaccine's effectiveness in certain high-risk groups, as to what constitutes a 'high-risk' group, and as to the vaccine's ability to decrease the over-all incidence of pneumonia nationwide over several years. Diabetics have been designated as a high-risk group.

Despite recent recommendations that diabetics receive pneumococcal immunization, a question existed as to whether or not clinical practitioners were immunizing diabetic clients. Consequently, prior to undertaking the present study, I consulted with several practitioners and reviewed the records of patients treated in a large medical clinic. This survey revealed that pneumococcal vaccine is not widely used for diabetics and those diabetics who were vaccinated often had chronic obstructive pulmonary disease as well as other factors increasing risk of respiratory illness. Consequently, the present study was undertaken to compare the incidence of respiratory infec-

tions in diabetic men with chronic respiratory disease to that of non-diabetic men with chronic respiratory disease. The study examined the effect of diabetes (presence or absence) on the incidence of respiratory infections among men treated at a federal facility for veterans in the Northwest. In order to examine the effect of diabetic status on number of colds, prevention practices, immunization status, severity of respiratory infections, and smoking were statistically controlled using a multiple regression. In addition, the incidence of respiratory infections was correlated with age and immunization status separately.

In the following section, a discussion of morbidity and mortality related to pneumonia and influenza is presented, followed by a description of the prevalence of diabetes mellitus and indications for consideration of diabetes as a pneumococcal pneumonia risk factor. This is followed by a review of the literature on pneumococcal vaccine usage. At the conclusion of the review of literature, the research questions are presented.

Pneumonia is the only remaining infectious disease among the ten leading causes of death in the United States today (U. S. Bureau of the Census, 1979, p. 77). Precise information on the occurrence of pneumococcal disease is not available as it is no longer a reportable disease. The Center for Disease Control (1981, p. 411) provides the following figures:

TABLE 1
ESTIMATED OCCURRENCE OF SERIOUS PNEUMOCOCCAL DISEASE
UNITED STATES

Pneumococcal Disease	Estimated Cases (thousands/Year)	Estimated Incidence*	Case-Fatality Ratio (%)
Pneumonia	150-750	68-260	5-7
Meningitis	1.6-6.2	1.2-2.8	32
Bacteremia	16-55	7-25	20

^{*}Per 100,000 population per year

Nation-wide 2.4/100,000 population deaths and state-wide 2.3/ 100,000 population deaths have been attributed to pneumonia and influenza (U. S. Bureau of Census, 1979, p. 77). Together pneumonia and influenza rate sixth among men and fifth among women in Oregon as a cause of death (Dept. of Human Resources, 1979, p. 38). Pneumonia and influenza are significant causes of death in Oregon and the nation in persons over 45 years old. These statistics indicate that a significant problem of infectious disease persists despite the fact that penicillin (1941) and sulfa drugs (1937) have long been available for the treatment of infections. Those who die from respiratory infections tend to be individuals who are elderly, malnourished, and have multiple chronic diseases; and, therefore, are identified as being at high risk. In light of significant morbidity and mortality from respiratory infections, preventive measures for high-risk individuals are indicated.

In order to decrease the incidence of morality due to pneumonia and as a means of preventing further damage to pulmonary structures, pneumococcal vaccine has been advocated and is indicated for individuals with chronic respiratory disease (Center for Disease Control, 1981, p. 411). A number of distinct respiratory diseases are included under the heading chronic respiratory disease. Chronic respiratory disease refers to several pulmonary diseases and includes asthma, emphysema, bronchitis, and chronic obstructive pulmonary These diseases are responsible for 10.3/ disease (COPD). 1,000 population deaths in the United States (U. S. Bureau of Census, 1979, p. 76) and an appreciably greater number 28.6/100.000 population deaths in Oregon (Dept. of Human Resources, 1979, p. 36). Chronic respiratory disease rates fifth after accidents as a leading cause of death in Oregon and is of particular risk to smokers. Pathological changes associated with smoking include diffuse bronchiolitis, altered bronchiolar epithelium, increased numbers of globet cells, and tenacious intraluminal mucus within the small airways (Bordow, R. A., Stook, E. W., & Moser, K. M., Eds., 1980, p. 228). These changes in small airways (less than 2" in diameter) constitute a potential precursor to the development of chronic respiratory disease (CRD). The inflammation, consolidation, and altered secretions found in pneumonia are a severe threat to individuals whose lungs are already compromised by chronic respiratory disease.

The effectiveness of antibiotic treatment of pneumo-coccal infections has been challenged by Robert Austrian and Jerome Gold (1964, p. 759-776). In a 10 year study of patients admitted to one division of King's County Hospital, Brooklyn, N. Y., they found 2,000 cases of pneumococcal pneumonia and 529 cases of pneumococcal bacteremia (1964, p. 759). The fatality rate for patients was 17 per cent (p. 769) despite antibiotic therapy. One finding of this study was that as age increased, morbidity and mortality from pneumococcal pneumonia increased. Austrian and Gold (1964) also noted that the difference in mortality was four times greater in those with "complicating illnesses" compared to those without. Among the complicating illnesses of importance to this study were bronchial asthma, bronchiectasis, emphysema, and diabetes mellitus.

The inclusion of diabetes mellitus by Austrian and Gold was based on the findings that of the 2,529 individuals with pneumococcal infections, 3 of 18 diabetics died; and, all 3 persons with a diagnosis of diabetic acidosis died (p. 766). Based on the Austrian and Gold study of 1964; diabetes mellitus was linked with the need for pneumococcal vaccination due to the observed severity of the pneumococcal pneumonia when contracted by diabetics. However, the incidence of pneumonia among diabetics and comparison of that incidence to the general population has not been described in the literature.

The diabetic population of the United States is estimated to be 4.2 million or 2% of the total non-institution-alized civilian population (Department of Health, Education, and Welfare, 1977, p. 7-8) with a higher proportion of female diabetics after age 45 (National Institute of Health, 1976, p. 1-12). Across the United States, diabetes is the 6th leading cause of death. Within the State of Oregon, diabetes mellitus is the 10th leading cause of death (11.5/100,000 population) with more women affected than men (Dept. of Human resources, 1979, p. 33). These figures indicate the existence of a large diabetic population. The question remains whether or not diabetics benefit from administration of pneumococcal vaccine.

Polyvalent vaccines of pneumococcal capsular polysaccharides have been shown to prevent type specific pneumococcal infections. There are 83 known types of pneumococci (Danish system of nomenclature). Of these, 14 capsular polysaccharides are responsible for approximately 80% of the pneumonias cultured in the United States today (Broome, Facklam, and Fraser, 1980, p. 119; Lambert, 1980, p. 915). Pneumococcal vaccine that includes 14 of the pneumococcal types most often found in the United States was licensed for use in November, 1977.

Since a sufficient supply of vaccine is now available for use in high risk groups, it is useful to evaluate

the benefits of pneumococcal inoculation among these groups. There is controversy regarding which groups meet the criteria for vaccination. Three criteria used to describe the need for vaccination among high-risk groups are: significant incidence of disease within a specific group, severity of the disease for the group when contracted, and effectiveness of the vaccine for the group. High-risk groups described in the literature include people over fifty years old, those who spleen is absent or abnormal, as well as those who have impaired cardiorespiratory, hepatic, and renal systems and diabetes mellitus (Austrian, 1977, p. 541; Hales and Barrier, 1977, p. 773-774; Center for Disease Control, 1981, p. 441).

To date scant data exist on the efficacy of pneumococcal vaccine in individuals with chronic diseases.

Instead, the vaccine has been studied in relationship
to its ability to prevent pneumonia in well individuals
or raise antibody titers in compromised individuals.

Consequently, there is a need to assess further which
groups are potentially at higher risk than the general
population for pneumococcal infections. It is also necessary to determine the effectiveness of the vaccine in
preventing pneumococcal infections among these groups.

This study examined the incidence of respiratory infections
among diabetic individuals with chronic respiratory disease

compared to non-diabetic individuals with chronic respiratory disease. Clinicians do not routinely immunize diabetics. Therefore, this study examines the effect of diabetes as an additional risk factor among a group of individuals with CRD who might or might not be immunized.

Review of the Literature

The literature review describes clinical studies of pneumococcal vaccine between 1913 and the present. Areas included are: 1. immunologic mechanism, 2. early pneumococcal vaccine investigation, 3. recent pneumococcal vaccine investigations, and 4. pneumococcal vaccination of immunocompromised adults and children. The summary of the literature review includes a comparison of early and recent studies, and discussion of diabetes and chronic respiratory disease as pneumococcal infection risk factors. Immunologic Mechanism

Immunology deals with the ability of one organism to counter the harmful effects of an invading organism through phagocytosis and other processes. An early example of immunological work was the recognition by Edward Jenner in 1798 that cowpox vaccination prevented smallpox. The antigenic action of pneumococcal derivations was demonstrated in the early 1900s by Wadsworth and Brown (1931) based on the earlier research of Heidelberger and Avery (1923). This work led to numerous experiments with varied pneumococcal serotypes involving immunization of popula-

tions considered susceptible to pneumococcal pneumonia. Today, the amount of rise (fold rise) in serum antibody levels after vaccination is considered an index of antibody synthesis after exposure to an antigen. However, the level to which the serum antibody rises may not reflect the degree of protection achieved. For despite the growth in knowledge about antibodies that are the basis of humoral protective mechanism, there are many details yet to be understood. It is unclear at what antibody level immunity is achieved and why, in certain disease conditions, immunity is not achieved after immunization.

Early pneumococcal vaccine investigations

Some of the earliest experiments were those of Sir Almroth Wright (1914) with phylactic and prophylactic inoculations of South African mine recruits using varied doses of pneumococcal vaccine. His research gave no indication for use of pneumococcal vaccine in the therapeutic treatment of pneumonia, but he concluded that doses of 1000 millions pneumococci decreased the incidence of pneumonia and the mortality rate attributed to pneumonia (p. 91).

Field studies by Ekwurzel, Simmon, and Felton (1938) with Civilian Conservation Corp volunteers demonstrated type-specific disease protection among recruits vaccinated with type I and II pneumococcal polysaccharides. MacLeod, Hodges, Heidelberger, and Bernhard (1948) working with

U. S. Armed Forces recruits showed 100% efficacy of immunizations containing the capsular polysaccharides of pneumococcus types I, II, V, and VII. They also demonstrated a 'herd immunity' created by non-immunized soldiers working with immunized soldiers. The incidence of pneumonia was only 17.6% of the expected incidence, based on the occurrence in non-vaccinated soldiers during the previous two years (1948, p. 460).

In research among elderly individuals, Paul Kaufman (1947) demonstrated immunization related protection against pneumonia caused by polyvalent types I, II, and III. Following this early research with prophylactic polyvalent pneumococcal vaccines, there was a period of decreased interest in pneumococcal vaccines as antibiotic treatment became the primary therapy for pneumonia.

Recent pneumococcal vaccine investigations

The investigation of pneumococcal infections by Austrian and Gold (1964) renewed interest in a polyvalent pneumococcal polysaccharide vaccine. This led to further pneumococcal vaccine testing in locations such as Chile, S. A. and West Point, Pennsylvania (Borgono, McLean, Vella, Woodhour, Canepa, Davidson & Hilleman, 1978), Raleigh, North Carolina (Austrian, 1977), and Westoneria, Transvaal, South Africa (Smith, Overholzer, Hayden-Smith, Koornhof, & Hilleman, 1977). These field tests of pneumococcal

vaccine in healthy populations were well tolerated by vaccine recipients and suggested promise in controlling infections caused by pneumococcal organisms through vaccination.

Experiments with pneumococcal vaccine within the past ten years have differed in several respects from earlier experiments. Recent researchers consistently use 12- and 14-valent pneumococcal polysaccharides as the immunizing substance instead of previously used vaccines of only 3 or 4 pneumococcal polysaccharides (see Table 1 1914-1947 vs. 1977-1980). Earlier researchers gauged vaccination effectiveness by the decreased incidence of pneumonia in the inoculated groups while later researchers more often determined effectiveness by increased post vaccination antibody titers (see Table 2 under variable tested). Nearly all the early researchers such as Wright (1914), Ekwurzel et al (1938), and MacLeod et al (1945) examined generally healthy adults, Kaufman (1947) being an exception. More recently researchers such as Beam, Crigler, Goldman, & Schiffman (1980), Giebink, Foker, Kim, & Schiffman (1980), and Friedman, Beyer, Hirsch, & Schiffman (1980) have looked at high-risk groups and children.

Recent clinical studies of pneumococcal vaccine in healthy populations include Weibel, Vella, McLean, Woodhour, Davidson and Hilleman (1977) who used a 12- and

Table 2. Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)

Characteristics		Clinical Studies	
	Wright	Ekwurzel et al	MacLeod et al
Type of Study	series of experiments: non-blind, controls, random and non-random	series of experiments: non-blind, controls, non- random (volunteers)	single-blind, random, controls
Year Published	1914	1938	1945
Subjects Vaccinated (no.)	several 1000s'	29,234	8,586
Control (no.) Characteristics	several 1000s' young miners	41,022 men	8,449 young men
Age Range (years)	not stated	80% under 25 years old	not stated
Polysaccharide	not stated	Types I and II	Types I, II, V and VII
Amount of each polysaccharide	150 million to 250 millions total (polysaccharide type not differentiated)	l mg	30-60 mg
Variables tested Ability to induce antibody Ability to prevent disease Side-effects	no yes no	no yes no	no yes no
Results	decreased incidence of pneumonia among immunized natives	decreased incidence of pneu- monia among immunized	decreased incidence of pneu- nomia among immunized; "herd" immunity to unimmunized

Table 2 (Con't). Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)

Characteristics		Clinical studi	S
	Kaufman	Ammann et al	Riley et al
Type of Study	random, controls, non-blind	non-random, non-blind	double-blind, random, controls
Year Published	1947	1977	1977
Subjects Vaccinated (no.)	5,570	*both groups immunized 77	5,946
Control (no.)	5,153	106	6,012
Characteristics	institutionalized, elderly (New York City Home)	Asplenic and sickle-cell; mainly children	subsistence farmers, more fe- males, New Guinea, rainfall 100" per year
Age Range (years)	40-80+	2–25	all ages
Polysaccharide	Types I, II, and III	1, 3, 6, 14, 18, 19, 23, 51	1, 2, 3, 4, 5, 6, 7, 8, 12, 14, 18, 23, 25, 26
Amount of each polysaccharide	Not stated	50 шд	47 mg
Variables tested Ability to induce antibody Ability to prevent disease Side-effects	yes yes yes	yes yes no	yes yes
Results	increased antibody titers among immunized; less pneu- monia among immunized	increased antibody titers in children with splenic dys- function	84% less pneumonia in immuniz- ed; 44% less mortality in immunized

Table 2 (Con't). Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)

Characteristics		Clinical Studie	S
	Weibel et al	Smith et al	Borgono et al
Types of Study	No control, non-random	double-blind, random, controls	<pre>two experiments: 1. Adults: non-random, non-blind, no con- trols; 2. Children: random, non- blind, no controls</pre>
Year Published	1977	1977	1978
Subjects Vaccinated (no.)	118	1,523	1. 454 adults 2. not stated (children)
Control (no.)	None	3,171	None
Characteristics	Healthy, middle-class, American citizens	young South African novice gold miners	1. healthy volunteers who were drug company employees; 2. heal- thy infants in Santiago, Chile
Age Range (years)	adults and children	young adults	all ages
Polysaccharide	1, 2, 3, 4, 6, 8, 9, 12, 14, 19, 23, 25, 51, 56	1, 2, 3, 4, 6, 8, 9, 12, 25, 51, 56, 73	1, 3, 4, 6, 8, 9, 12, 14, 19, 23, 51, 56
Amount of each polysaccharide	50 mg	50 mg	50 mg (adults) 25 mg (infants)
Variables tested Ability to induce antibody Ability to prevent disease Side-effects	yes no yes	yes yes no	yes yes
Results	increased antibody titers in all subjects	decreased incidence of pneumonia in subjects	increased antibody titers in adults. poor antibody response in children.

Table 2 (Con't). Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)

Characteristics		Clinical Studi	Se
	Siber et al	Mufson et al	Vella et al
Type of Study	controls, non-random, non- blind	single-blind, no controls, random assignment	two studies: no control, selection method not stated
Year Published	1978	1980	1980
Subjects Vaccinated (no.)	53	89	1. 19 adults; 2. 28 children
Control (no.)	10	none	none
Characteristics	immunized-Hodgkin's disease post therapy. Controls- selected from families of the patients or hospital staff	healthy volunteers-medicine & nursing students, medical center employees	employees of Overbrook School for the Blind; children in the Philadelphia area
Age Range (years)	7 to 57	20–55	adults 23-65; children 2-12
Polysaccharide	1, 3, 4, 6, 7, 8, 9, 12, 14, 18, 19, 23	1, 3, 4, 7, 8, 12	not stated
Amount of each polysaccharide	50 mg	50 mg	50 mg
Variables tested: Ability to induce antibody Ability to prevent disease Side-effects	yes no no	yes no yes	yes no yes
Results	impaired antibody response in patients with Hodgkin's disease	increased antibody titers with immunization	increased antibody titers in adults & children (2-12 yrs.)

Table 2 (Con't). Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)

-			
Unaracteristics		Clinical Studies	
	Beam et al	Friedman et al	
Type of Study	controls, non-random, double-blind	controls, non-random	
Year Published	1980	1980	
Subjects Vaccinated (no.)	*both groups given vacc. 40 insulin-dep. diabetics	*both groups given vacc. 8 azotemic,10 renal failure,	
Control (no.)	10 non-diabetics	<pre>5 diabetics (Subjects) # not stated (Control)</pre>	
Characteristics	diabetics, non-diabetics, all men, no history of chronic diseases.	subjects described above; controls were hospital staff or relatives	
Age Range (years)	diabetics-56.5 mean age non-diabetisc-44.5 mean age	age range not stated	
Polysaccharide	1, 2, 3, 4, 6A, 7F, 8, 9N, 12F, 14, 18C, 19F, 23F, 25	not stated	
Amount of each polysaccharide	50 тд	50 mg	
Variables tested Ability to induce antibody Ability to prevent disease Side-effects	yes no yes	yes no no	
Results	increased antibody titers in diabetics similar to non- diabetics	subject and control groups had similar antibody titer increase post vaccina- tion	

Table 2 (Con't). Comparison of Clinical Studies of Polyvalent Pneumococcal Vaccines (1914 to 1980)

Characteristics	Clinical Studies
	Giebink et al
Type of Study	control, non-random
Year Published	1980
Subjects Vaccinated (no.)	*both groups received vaccine 32 splenectomized children
Control (no.)	12 unsplenectomized children
Characteristics	both groups similar economic background, some related
Age Range (years)	5-20 splenectomized 5-15 normal group
Polysaccharide	1, 3, 4, 6A, 7F, 8, 9, 12, 14, 18C, 19, 23 (+) 2, 25
Amount of each polysaccharide	50 mg
Variables Tested Ability to induce antibody Ability to prevent disease Side-effects	yes no no
Results	antibody titer rise <u>less</u> in splenectomized

14-valent pneumococcal capsular polysaccharide with adults and children. Their tests showed significant antibody response among adults and a still significant but lesser response among children. Mufson, Krause, Tarrant, Schiffman and Cano (1980) used a 6-valent pneumococcal vaccine and found increased antibody titers in those receiving pneumococcal vaccine. They also noted a smaller, yet significant rise in antibody titers among those receiving pneumococcal vaccine in conjunction with influenza vaccine. Vella, McLean, Woodhour, Weibel, and Hilleman (1980) also found increased antibody titers following pneumococcal vaccination in adults and children, but the increases in children declined within 21 months. Vella and colleagues (1980) further showed a two-fold or greater amount of antibody in 80% of those vaccinated at least three and one-half years later. Riley, Andrews, Tarr, Pfeiffer, and Challands (1977), vaccinated a group of New Guinea subsistence farmers with known susceptibility to pneumococcal pneumonia and demonstrated increased antibody titers and decreased mortality from pneumococcal infection. Pneumococcal immunization of immunocompromised adults and children

Among immunocompromised groups, a decreased antibody response to pneumococcal vaccine in children with Hodgkin's disease and post splenectomy was demonstrated by Silber, Weitzman, Alsenberg, Weinstein, and Schiffman (1978) and

Giebink, Foker, Kim, and Schiffman (1980). Failure of pneumococcal vaccine has been described also in two children with sickle-cell disease (Ahonkhai, Landesman, Fikrig, Schmalzer, Brown, Cherubin, and Schiffman, 1979) who at the time of immunization discontinued penicillin prophylaxis and subsequently contracted pneumococcal pneumonia. Further, Sumaya, Harbison, and Britton (1980, p. 404-408) reported six cases of pneumococcal vaccinated immunocompromised individuals (mainly Hodgkin's disease) who contracted severe pneumococcal disease with a type contained in the vaccine.

Another study of pneumococcal vaccine in immunocompromised subjects is that of Cosio, Giebink, Le and Schiffman (1981). They judged vaccine success only by its ability to raise antibody titers. Consequently, these researchers concluded that pneumococcal vaccine may be useful in preventing pneumococcal infections among patients on hemodialysis and renal allograft recipients. These studies of immunocompromised groups, though involving small numbers, present sufficient contradictory findings to suggest a need for further study to determine the optimal levels of antibodies in immunocompromised children and adults and to screen for failures, but is beyond the limits of this study.

Summary

Many questions remain relative to vaccine efficacy

in high-risk groups especially diabetics. Recently a question has been raised regarding the efficacy of pneumococcal vaccine in an environment where the bacterial composition changes. A vaccine given no more frequently than every three years with a limited number of serotypes cannot totally protect individuals against naturally occurring local bacterial changes or those due to the individual's movement from one part of the country to another. The previously described studies do not resolve the controversy as to whether all high-risk groups can benefit from pneumococcal vaccination. Whether the use of a vaccine containing 14 pneumococcal serotypes reduces the possibility of contracting pneumonia from 83 different existing pneumococcal serotypes is a related issue. Unresolved issues identified by Kaiser and Schaffner (1974) include the following: "site-to-site (geographical) variations in the recovery of pneumococcal types, geographic and temporal differences in the distribution of types, and the selection pressure associated with the use of a limited number of vaccine types" (p. 404). Selection pressure refers to the need to create a vaccine that responds to the most common infecting organisms at a particular time for a particular area. With vaccines today consisting of 14 out of 83 possible polysaccharide serotypes, there is the danger of increased incidence of infections due to non-vaccine serotypes.

A common factor present in the earlier pneumococcal research done by Wright (1914), Ekwurzel et al (1938), and MacLeod et al (1948) is that the individuals considered susceptible to pneumonia were only recognized as susceptible when these generally healthy individuals from diverse settings were brought into a contained setting. The investigators do not describe hygiene, nutrition, crowding or other environmental living conditions that might have contributed to the increased incidence of pneumococcal pneumonia in the mine company holding areas, Civilian Conservation Corp camps, or military barracks. These investigators did find a reduced incidence of pneumococcal pneumonia in immunized healthy adults.

A sharp contrast is evident between the healthy populations who were field tested to demonstrate the efficacy of pneumococcal vaccine and the population for whom vaccination is recommended today—persons with chronic systemic disorders such as cardiovascular disease, pulmonary disease, diabetes, cirrhosis of the liver, congenital or surgical asplenia, and sickle cell disease (Austrian, 1977, p. 541). As shown in Table 2 current research is addressing suspected high—risk groups and tends to judge the success of pneumococcal vaccine by increased antibody titers. There remains a need for more investigations regarding which groups are highly susceptible to pneumococcal pneumonia, and among those groups whether or not the inci-

dence of infection is reduced following immunization.

There is a scarcity of information in the literature describing the incidence of pneumonia among adult diabetics. Moss (1980) surveyed the literature and concluded that "diabetes is not a valid indication for vaccine..." (p. 2303). His conclusions are based on the understanding that diabetic immune deficiencies such as decreased phagocytosis and mobility of granulocytes during hyperglycemia are corrected by giving insulin. Consequently, there is insufficient evidence that the antibody response to infection in controlled diabetics is any different from that of non-diabetics. In discussing the paucity of literature on pneumonia associated with diabetes, he notes the omission of information describing diabetic control status, presence of other diseases, or bacteriology of the pneumonia.

Moss' conclusion that a diagnosis of diabetes is not sufficient reason to immunize is supported by Albert Sabin (1981, p. 236) for different reasons: 1. pneumonia mortalities in general have declined without the vaccine, and 2. if the vaccine suppresses pneumococcal type infecting organisms that are now prevalent; other, less common, pneumococcal type infecting organisms will emerge. Consequently, the vaccine will be of transient or no value.

In rebuttal Austrian and Winegrad (1980) claim that data are lacking regarding the incidence of pneumococcal

pneumonia and diabetes. Additional support for the use of pneumococcal vaccine by diabetics is claimed on the grounds that diabetics have an antibody titer response to pneumococcal vaccine similar to that of non-diabetics (Beam, et al, 1980; Friedman, et al, 1980). It is assumed here that increased serum antibody titers to a potentially virulent infecting organism provide protection against that organism.

As with diabetes, there is little clinical evidence of susceptibility to pneumococcal pneumonia among people with chronic respiratory disease. There have also been few specific trials of pneumococcal vaccine in groups with chronic respiratory disease. The previously mentioned study by Riley and associates (1977) among a New Guinea population, included a large number of people with acute and chronic respiratory disease secondary to pneumococcal infections. They tested a 14-valent pneumococcal vaccine and reported decreased morbidity and mortality among those vaccinated. Though there has been insufficient testing of pneumococcal vaccine in patients with chronic illnesses, the Center for Disease Control (1981) has included chronic respiratory disease among illnesses that may put patients at greater risk of developing pneumococcal infections or having more severe illness.

Broome, Facklam, and Fraser (1980) with the U. S. Center for Disease Control (CDC) have challenged the idea that

immunocompromised high-risk patients can benefit from pneumococcal vaccination. In order to assess efficacy, they compared patients vaccinated with pneumococcal vaccine with serotypes of 392 isolates from non-vaccinated people. They found similar proportions of infections with vaccine serotypes between the two groups. The estimated immunity provided by pneumococcal vaccine was least in children two to ten years old and persons with preexisting disease. The small number of isolates used in this study resulted in equivocal findings. The study reported by Broome and associates suggests a need for further research regarding which populations might benefit from use of pneumococcal vaccine.

Increased susceptibility to infections among diabetics remains a controversial subject. It has been shown that with mild ketoacidosis the host defense system is compromised in several areas, such as decreased uptake of pathogenic organisms (phagocytosis) and delayed leukocyte migration (chemotaxis). Some of the same researchers who have demonstrated an impaired defense mechanism in poorly controlled diabetics have also demonstrated a normal host defense mechanism in controlled diabetics (Bybee and Rogers, 1964; Bagdade, Root & Bulger, 1974). Further, both Beam and colleagues (1980) and Friedman and colleagues (1980) demonstrated that the diabetic antibody response to pneumococcal capsular polysaccharides was the same as non-dia-

betics. Consequently, diabetes mellitus, without the presence of other possibly complicating factors (i.e., history of respiratory disease, advanced age, use of corticosteroids) appears to be an insufficient indication for pneumococcal vaccination.

There also exists some literature suggesting that pneumococcal pneumonia may not be the most common type found in diabetics (Khurana, Younger & Ryan, 1973; Tillotson & Lerner, 1967). If the organisms producing pneumonia in diabetics tend to be other than pneumococci, then a pneumococcal vaccine would offer little protection.

In conclusion, polyvalent vaccines of pneumococcal capsular polysaccharides have proven effective in preventing pneumococcal infections by related serotypes in healthy populations. Since the relicensure of pneumococcal vaccine in the United States (1977), it has been recommended for use with high-risk groups. However, some questions remain unanswered: 1. Do diabetics constitute a high risk group? 2. What is the incidence of pneumococcal infections among diabetics compared to a normal population? 3. How efficacious is pneumococcal vaccine among diabetics?

4. What types of respiratory infections do diabetics most often develop?

Statement of the Problem

Controversy exists regarding the need for pneumococcal vaccine among diabetics. One view is that diabetes mellitus

is an indication for pneumococcal vaccination, and that diabetics should be "offered the potential protection afforded by pneumococcal vaccine" (Austrian and Winegrad, 1980). The opposing argument is that controlled diabetics in general are not more susceptible to pneumococcal infections than non-diabetics; and consequently, diabetes mellitus is not in itself an indication for pneumococcal vaccination.

Another aspect of whether diabetics benefit from pneumococcal vaccine concerns the need to know the type of respiratory infections experienced by diabetics. This is significant as a polyvalent vaccine offers immunity to a limited number of specific types of pneumococcal pneumonias.

Knowing the type of infections most commonly occurring in diabetics will enable nurses to better advise diabetic clients as to the need for pneumococcal immunization.

The purpose of the study is to describe the number of respiratory infections experienced by diabetic individuals with chronic respiratory disease compared to non-diabetic individuals with chronic respiratory disease. From the review of the literature, diabetes mellitus is thought to affect the occurrence and severity of pneumococcal infections. This study will attempt to describe a population with existing respiratory disease to determine if the presence or absence of diabetes mellitus has any influence on the incidence of respiratory disease. Diabetes

status, control, and duration will be described as well as severity of chronic respiratory disease, pneumococcal and influenza immunization status, smoking history, and self-care practices taken to prevent colds (subsequently referred to as prevention practices).

Diabetics are primarily responsible for making decisions involved in the management of their disease on a day-to-day basis. The nurse serves as a source of information regarding various management problems and advises the diabetic about unfamiliar or unknown health care options. If the nurse is to effectively help the diabetic manage his/her disease, then it benefits both the nurse as the advisor and the diabetic as the recipient of that advice to be aware of the efficacy of pneumococcal vaccine for diabetics.

The question of whether or not diabetes increases the incidence of pneumococcal infection is important, not only because of the desire to avoid the physical damage caused by pneumonia in potential target groups, but because of rising health care costs. If the number of respiratory infections can be reduced, then there would follow a reduction in the money spent for antibiotics, medical and nursing care, respiratory therapy, hospitalization, and other expenses needed to treat pneumonias. Reduced incidence of respiratory infections would also contribute to decreased social costs due to morbidity, absence from work, and loss of income secondary to debilitating infections.

If it can be clarified as to which groups are at high risk for pneumococcal respiratory infections, then low risk groups not requiring immunization can avoid possible reactions such as fever, swelling, erythema, and pain. Though to date reactions have been mild, the need to inflict even temporary discomfort with the use of pneumococcal vaccine must be considered.

Assumptions

This study of respiratory infections in men with chronic respiratory disease with and without diabetes is based on the following assumptions:

- 1. Prevalence of organisms causing pneumococcal pneumonia makes it reasonable to assume that exposure to pneumococcal pneumonia is equal in men with chronic respiratory disease with and without diabetes.
- Individuals with chronic respiratory disease are more susceptible to respiratory infections than individuals without chronic respiratory disease.
- Most respiratory infections are viral, not bacterial, in nature.
- 4. Subjects will return primarily to the Veterans Administration Center for treatment of infections.
- 5. Subjects can remember the number of respiratory infections experienced over the last year.

Research Questions

1. Is there a difference in the number of repiratory in-

- fections (colds and pneumonia) between non-diabetic and diabetic men with chronic respiratory disease?
- When prevention practices, smoking, severity of respiratory disease, and immunization status are controlled, is there a difference in the number of colds experienced by diabetic men with chronic respiratory disease and non-diabetic men with chronic respiratory disease?

CHAPTER II

METHOD

The following sections describe the method of selecting subjects, and the setting in which the study took place.

The method of data collection, the design, and plan for data analysis are also described.

Subjects and Setting

The subjects for this study were selected from a review of patient information cards used in a general medicine clinic. This outpatient clinic is part of a U. S. Veterans Administration (V. A.) Medical Center located in the Northwest.

People potentially eligible for treatment at the V. A. facility include veterans, retired military and their dependents, American Indians, Public Health Service Commission Corp Officers, and active military. The Veterans population tends to be older and contain a larger number of males than the general population. This study consisted of an all male, out-patient population.

Names of 200 patients with chronic respiratory disease who met the pre-determined selection criteria were chosen from among adults treated in the general medicine clinic. The following criteria were used for selecting participants in the study:

 Diagnosis of diabetes mellitus in one-half of the study population for at least one full year prior to study period. Diabetics are identified for the purpose of this study as those presently requiring the use of insulin or hypoglycemic agents, and/or--(a) those with classic symptoms of diabetes and unequivocal hyperglycemia; (b) those with a fasting venous plasma glucose (PG) concentration greater than or equal to 140 mg/dl on more than one occasion; and (c) those with fasting plasma glucose (FPG) above 140 mg/dl, exhibit sustained elevated venous PG values during the oral glucose test (OGTT) (greater than or equal to 200 mg/dl) (National Diabetes Data Group, 1979, p. 1040).

- Documentation of immunization status in the medical records.
- 3. Understands and reads English.
- 4. No history of mental confusion documented in the medical record.
- 5. Male
- 6. Be between the age of 45 and 90 years old.
- 7. Does not reside in an institution (i.e., nursing home, barracks).
- 8. No history of cancer.
- 9. No history of immunosuppressive therapy.
- 10. No history in the past year of anemia.
- 11. No history in the past year of malnourishment.
- 12. No history of splenic dysfunction or asplenia.

 From the 2330 patient information cards examined. 181

men were identified who met the above criteria. Among the 181 patients meeting the criteria, 120 patients were removed or lost from the study for the following reasons:

- 1. Fourteen subjects (9 non-diabetic and 5 diabetic) had expired.
- 2. One subject refused to participate.
- 3. Questionnaires did not reach 14 subjects due to incorrect current addresses despite several attempts to locate their addresses.
- 4. Eighty-two potential subjects failed to return questionnaires.

The final sample consisted of 61 persons including 50 non-diabetics and 11 diabetics. See Figure 1 for breakdown of subjects included in this study.

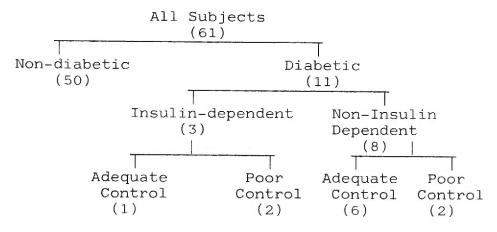


Figure 1. Breakdown of study subjects.

Design and Procedure

This is a descriptive study using a convenience sample. The variables of severity of respiratory disease, number of respiratory infections, diabetes status, and immunization

status were examined in relation to the incidence of respiratory infection among men with chronic respiratory disease with and without diabetes. Information related to the above variables was collected using medical records and mailed questionnaires.

In order to conduct this study, the Associate Chief of Staff for Research was contacted. The proposal was submitted to two Human Subjects Committees for approval. Upon receiving approval from both committees, data collection commenced.

Following selection of the sample, subjects were mailed a cover letter (Appendix A), a consent form (Appendix B), a questionnaire (Appendix C), and a stamped, self-addressed return envelope. They were requested to answer all questions and return the questionnaire at their earliest convenience. The signing and return of the consent form constituted agreement to participate in the study which consisted of completing a mailed questionnaire and review of past medical records. No names appeared on the questionnaire. The questionnaire was coded to facilitate a second mailing. A second copy of the same questionnaire was mailed to those who did not return the original after a period of two weeks. A third mailing followed three weeks after the second. All mailings were sent from and returned to the investigator.

Diabetes Status

This is an ex post facto study and the independent

variable is diabetes status (presence or absence). Diabetes was defined by documented blood glucose levels as described in the subject selection criteria.

Severity of Respiratory Disease, Prevention Practices, Smoking and Immunization Status

In order to investigate the second research question, it was necessary to control for variables that could affect the number of colds. Variables controlled for include pulmonary status, prevention practices, smoking and immunization status. Pulmonary status refers to severity of respiratory disease determined according to the guidelines for ventilatory impairment of Dr. James F. Morris (1976, p. 116). Smoking is measured in pack years. Immunization status is described as months of immunization. Prevention practices (see Table 7, Appendix D) are defined as any type of activities undertaken by the subject to prevent respiratory infections (e.g., avoid crowds). The open-ended question form was used to inquire about these self-care activities. These responses were then grouped into similar categories.

Incidence of respiratory infections

The dependent variables in this study were the number of respiratory infections (colds and pneumonia) identified by the subjects and noted in the medical records in the past year. This information was ascertained by subjects' responses to mailed questionnaires and review of medical

records. For this study, identification by subjects of the number of colds experienced was accepted as the number of colds occurring in the study year. In contrast, subjects' statements about having had pneumonia required verification in the medical records before being accepted for this study. While recalled information is subject to error, it is hoped that phrasing questions simply and not requiring exact information, such as precise dates of respiratory infections, will help subjects to recall the information needed. Self-reports of the number of respiratory infections experienced in the past year were an adequate means of measuring the dependent variable. The questionnaire was used for data collection about the incidence of respiratory infections because these infections are usually viral in nature and medical care frequently is not sought for their treatment. Medical records were used to look for culture and gram stain results denoting infections in which medical care was sought and cultures taken.

Data Collection

Subjects were asked to participate and return a completed questionnaire. By means of the questionnaire, information was obtained regarding the incidence of respiratory infections in the past year, other sources of pneumococcal vaccination, and self-care behavior to avoid respiratory infections.

After completed questionnaires were received, subjects'

records were surveyed for information on age, sex, chronic respiratory disease status (type, duration, severity), vaccination status, number of clinic visits for respiratory infections during the study period and culture and gram stain results (if any). Other data to be collected included: smoking history, other chronic illnesses and conditions, and past exposure to toxic chemicals. See Appendix E for schedule on which data were collected. While patient medical records are not always accurate and complete, they were considered an adequate source of information for this study.

Analysis of Data

The data collected in this study are descriptive in nature. To answer the first research question regarding the difference in incidence of respiratory infections (colds and pneumonia) between diabetics and non-diabetics, t-tests which control for unequal groups were performed. The second research question involving the incidence of colds in diabetics when severity of respiratory disease, smoking, prevention practices, and immunization status were controlled was analyzed using multiple regression.

CHAPTER III

RESULTS AND DISCUSSION

A review of the literature suggested that 1. pneumococcal vaccine is effective in reducing the incidence of pneumonia in healthy high-risk groups, 2. in some groups such as small children and individuals with certain chronic diseases, vaccination is less effective, and 3. diabetes control status influences susceptibility to infection in diabetics. In light of the above, this study examined the incidence of respiratory infections in a group of men with preexisting chronic respiratory disease some of whom were diabetic (N=11) and some of whom were not (N=50).

The next section describes the subjects. This is followed by a comparison of the incidence of colds and pneumonia experienced by diabetics and non-diabetics. Also examined is the effect of diabetes on the number of colds when severity of chronic respiratory disease, preventive measures, smoking, and immunization are controlled. The relationship between pneumococcal and influenza immunization status and the incidence of colds and pneumonia is described. Finally, additional related findings are described and their implications for nursing.

Description of the sample

One hundred and eighty-one men treated at a General Medicine Clinic were sent questionnaires. The first mailing was on November 23, 1981. Those who did not respond

received a second and third mailing on January 4, 1982 and January 23, 1982, respectively. Fourteen potential subjects (9 non-diabetic and 5 diabetic) had died. Another 14 subjects were not reached due to incorrect mailing addresses. As a result, 74 men agreed to participate in the study, 61 non-diabetic and 13 diabetic, reflecting a return rate of 44%. However, the final sample obtained was 61 men, as 13 subjects were lost because their charts were unavailable.

The total return rate was below that expected for a mailed questionnaire (Haberlein and Baumgartner, 1978) despite three mailings. Some possible explanations are that potential respondents failed to find the topic salient or because of the impersonal form of contact. Another possible reason that non-participants may have chosen not to participate is that they considered their condition either too severe or inconsequential.

There also are several reasons for the loss of potential subjects due to inability to locate medical records.

Reasons charts were unavailable include misfiling, unlogged removal of charts to other parts of the facility, transfer of files to other facilities, and lost charts.

A description of the sample is presented in Table 3.

The mean age of subjects was 63 years (ranging from 46 to 85). Using the Occupational Scale of Hollingshead's Two Factor Index of Social Position, the subjects were found to

be largely employed as machine operators and semi-skilled laborers. Only five of the 61 subjects, all non-diabetic, were currently employed. As a group, the non-diabetics were four years younger, and had more severe respiratory disease than the diabetic subjects. The medianduration of diabetes was found to be nine years, ranging from four to 15 years.

TABLE 3

DESCRIPTIVE CHARACTERISTICS OF MEN WITH

CHRONIC RESPIRATORY DISEASE (N=61)

· · · · · · · · · · · · · · · · · · ·			
Characteristics	Non-diabetic N=50	Diabetic N=11	Non-diabetic and diabetic N=61
Age (x years)	63	67	63
Occupation ^a (\bar{x})	6	6	6
Employed (%)	10	0	8
Duration of Diabetes (median years)	NA	9	NA
Duration of Chronic Respiratory Disease (median years) ^b	8	9	8

aOccupation scale from Hollingshead's Two Factor Index of Social Position (Miller, 1977, p. 223-238).

b₂₅ out of 61 values missing from charts. NA = Not applicable

Chronic respiratory disease consisting of chronic bronchitis, asthma, or emphysema alone or in combination were the major forms of respiratory impairment with two exceptions. These two exceptions were subjects with obstructive airway disease secondary to tuberculosis. All subjects had an extensive smoking history averaging 60 pack years which was a conservative estimate. At the time of the study, 72% (7 diabetics, and 37 non-diabetics) were still smoking.

Records of subjects were screened for other chronic illnesses. Two types of conditions, cardiovascular disease and alcohol abuse, were noted as occurring frequently in the sample (see Appendix F, Table 8). Cardiovascular disease occurred with near equal frequency in both diabetic and non-diabetic subjects. However, alcohol abuse occurred two and one-half times more frequently in non-diabetics than diabetics. This finding is discussed later in the chapter.

All 11 diabetic subjects had Type II, maturity onset diabetes. Four of them had poorly controlled diabetes (blood sugar>200 mg/dl) during the year studied, and none of the four were diagnosed as alcoholics. Also, three of the 11 diabetics were insulin dependent. Two of the four poorly controlled diabetics were insulin dependent.

The subjects in this study were 61 older males, largely retired, with more than one major health problem, who are

currently receiving medical care at a veterans facility.

They all have chronic respiratory disease with varying degrees of ventilatory impairment. The diabetic subjects were primarily non-insulin dependent and adequately controlled.

Next, each of the research questions are discussed in relation to the effect of diabetes status (presence or absence) on the number of respiratory infections (colds and/or pneumonia) experienced. Some additional findings are also presented, such as the effect of age on the incidence of colds and pneumonia, and the effect of months of immunization on the incidence of colds and pneumonia. The chapter concludes with a discussion of general findings, relationship of findings to previous research, implications for nursing practice, and limitations of the study.

Research Question No. 1: Is there a difference in the number of respiratory infections between non-diabetic men with chronic respiratory disease and diabetic men with chronic respiratory disease?

Incidence of colds

The overall mean incidence of colds experienced during the year studied for the total sample was 2.5 (range 0-12) with one-third of the subjects having no colds. This was a low incidence of colds in this sample. The mean number of colds experienced by diabetic men was 0.81 (range 0-5) during the year studied. Seven of the eleven diabetics had

no colds. The mean number of colds experienced by non-diabetic men during this study period was 2.6 (range 0-12), with 14 having no colds. The difference in the mean number of colds experienced by non-diabetics compared to diabetics was significant at the .001 level (t=1.26) using a t-test for unequal groups. The explanation for this difference may be related to the greater severity of respiratory disease in the non-diabetics. Also, the increased incidence of alcohol abuse in the non-diabetic subjects may have made this group more susceptible to colds. These results should be considered tentative and suggest the direction for further research.

The mean number of colds experienced by diabetics is below the 1.4 respiratory illnesses estimated for the general population (Knight, 1980, p. 778). The mean number for non-diabetics (2.6) was above the estimate for the general population. The increased number of colds found could be expected in a population with diagnosed chronic respiratory disease. Subjects receiving prophylactic antibiotic therapy (5) continued to have an above average number of colds which may reflect their increased susceptibility as well as the viral etiology of colds which do not respond to antibiotics. The below average number of colds among diabetic men with chronic respiratory disease was unexpected. Part of the difference between diabetics and non-diabetics may artifically reflect the small number of diabetic subjects (N=11).

Another possible explanation is that the diabetic men may have sought medical treatment for respiratory infections more often, thus possibly avoiding repeated infections. However, this did not occur. Only three of the diabetic men sought medical treatment for respiratory infections compared to 21 of the non-diabetic men. Lower incidence of colds could be due also to the fact that seven out of eleven diabetics were in good control. As upper respiratory infections are usually viral in nature and do not require hospitalization, review of the literature revealed no comparison between the incidence of upper respiratory infections in diabetics and the general population.

Incidence of pneumonia

The incidence of pneumonia was examined for a one year period. The overall mean incidence of pneumonia in the total sample was 0.12 (range 0-2). The mean incidence of pneumonia in diabetic men was 0.09 (range 0-1). The mean incidence of pneumonia in non-diabetic men was 0.12 (range 0-2). The difference in the incidence of pneumonia between diabetics and non-diabetics was significant at the .001 level (t=.03). As with the number of colds, the greater incidence of pneumonia in non-diabetics may be attributed to their more severe respiratory disease, and increased incidence of alcohol abuse compared to the diabetic group.

The finding of a low over-all incidence of pneumonia

in the groups studied parallels the low incidence of pneumonia noted in the general population (.0076% derived from the incidence of pneumococcal infections estimated by the Center for Disease Control and a population figure of 220 million) (1981). The low incidence of pneumonia in diabetic men may also have reflected the small number of diabetics included in the sample (N=11). Pneumococcal pneumonia could not be documented on any of the diabetic subjects with pneumonia diagnosed during the year studied. This finding is consistent with the observed low susceptibility of diabetics to pneumococcal pneumonia reported in the literature (Fekety, R., Caldwell, J., Gump, D., Johnson, J. E., Maxson, W., Mulholland, J., and Thoburn, R., 1971; Khurana, R. C., Younger, D., and Ryan, J. R., 1973). Though some subjects were diagnosed as having pneumonia, identification of the infecting organism was not always possible.

Six subjects were treated at the veterans facility for pneumonia in the year studied. Sputum cultures were done on all of them. Four cultures showed no pathogens. Of the two positive cultures, neither of the two were pneumococcal. Subsequent diagnoses noted on the charts of these individuals included "bronchopneumonia, probably pneumonia," "bronchopneumonia," and "pneumonitis."

Etiologic diagnosis of pneumonia is an ongoing problem involving difficulty in interpreting sputum cultures which

is not limited to the facility in which this study took place. Problems in interpreting respiratory infections based on sputum cultures include: 1. specimens that are primarily saliva, 2. taken from the pharynx and not the lower respiratory tract, or 3. lower tract specimens contaminated by upper tract flora. These problems sometimes result in both false-positive and false-negative cultures. Consequently, multiple sources of information are used in diagnosing pneumonia, such as history, physical exam, chest x-ray, and when informative, sputum culture. Pneumonia was defined in this study as a physician's diagnosis which may have been based on some of the above data sources and others not listed.

Research Question No. 2: When prevention practices, smoking, severity of respiratory disease, and immunization status are controlled, is there a difference in the number of colds experienced by diabetic men with chronic respiratory disease and non-diabetic men with chronic respiratory disease?

Adults, as previously mentioned, experience approximately 1.4 upper tract respiratory infections per year which may develop into lower respiratory tract infections. With this in mind, an effort was made to examine the effect of diabetes on the number of colds reported. In order to do this, a hierarchial multiple regression using the Statistical Package for the Social Sciences Regression subprogram

was done by computer. The results are presented in Table The effects of prevention practices, smoking, severity of respiratory disease and immunization status on the incidence of respiratory infections were statistically controlled so that the relationship between diabetes and number of colds could be examined. After accounting for the combined effect of these variables, diabetic status (presence or absence) explained an additional 10 per cent of the variance in the number of colds. The multiple R was noted as being 0.51 which was modest. Finally, beta weights were examined to see which of the variables was the best predictor. this instance, diabetic status was the second best predictor. preceded only by prevention practices. Prevention practices referred to a positive response by the subjects as to whether or not they took measures to prevent colds. See Table 7. Appendix D, for responses given by subjects.

Diabetic status predicted a greater amount of variance than any other single predictor yet it explained only ten per cent of the total variance. Of the beta weights, prevention practices appeared to be a better predictor of the number of colds. Prevention practices were associated with fewer colds. However, other variables not included in the study explained most of the variance. Consequently, all that can be said at this time is that diabetic status influenced the number of colds experienced by these subjects when such variables as prevention practices, smoking, severity of

TABLE 4

A HIERARCHIAL MULTIPLE REGRESSION EXAMINING THE EFFECT OF FIVE SELECTED VARIABLES ON THE NUMBER OF COLDS SUBJECTS EXPERIENCED (N=61)

Variable	Simple r	Multiple R	RZ	Beta	ĮĮ,	Significance
Practices Prevention .	.29	. 29	.08	.41	4.49	.04*
Quantity Smoked	.11	.36	.13	.23	3.63	*60.
Severity of Respiratory Disease	19	.40	.16	21	2.93	*00.
Immunization Status (Influenza or Pneumonia)	.14	. 40	.16	02	2.24	.08
Diabetic Status	22	.51	.26	33	3.17	.02*

* p<.05

respiratory disease, and immunization status were controlled. The multiple regression results tentatively suggest that the presence of diabetes did not predict a higher incidence of respiratory infections.

Initially the effect of blood sugar control on the number of colds was to be examined. This was of interest as poorly controlled diabetes has been indicated in the literature as causing increased infections in diabetics (Perillie, Nolan, and Finch, 1962; Bagdade et al., 1974). Due to the small number of diabetic subjects (11), which included four poorly controlled diabetics, the effect of diabetic control on respiratory infections could not be ascertained. Because statistical analysis is inappropriate, descriptive findings are reported.

Poorly controlled diabetes and respiratory infections

The four subjects with poorly controlled blood sugars (blood sugar>200 mg/dl) had a mean age of 63 years, all had a history of cardiovascular disease, and none had a history of alcohol abuse. The poorly controlled diabetics were younger and had diabetes longer than the controlled diabetics. Two of the four poorly controlled diabetics were insulin dependent. In general, the poorly controlled diabetics resembled the other two groups in age, occupation, and presence of cardiovascular disease.

Poorly controlled diabetics had a higher average number of colds (2.0) than controlled diabetics (0.81), and

less than non-diabetics (2.6). One poorly controlled diabetic experienced one case of pneumonia. Immunization against influenza and pneumonia was equally lacking among controlled, poorly controlled, and non-diabetics.

TABLE 5

A DESCRIPTIVE COMPARISON OF POORLY CONTROLLED DIABETICS

TO CONTROLLED DIABETICS AND NON-DIABETICS

Characteristic	Poorly Controlaled Diabetic	Controlled Diabetic N=7	Non-diabetic N=50
Age (x̄ years)	63	67	63
Occupation	6	6	6
Severity of Respiratory Disease c (\bar{x})	2	2	3
Smoking $(\bar{x} \text{ pack ye})$	ars) 63	65	60
Duration of Diabete (median years)	12	9	NA

^aBlood sugar>200 mg/dl on three occasions during the bstudy year

Occupation Scale from Hollingshead's Two Factor Index of Social Position (Miller, 1977, p. 233-238)

NA=non-applicable

Pulmonary function Test, one-second forced expiratory volume. O=Normal, 1=Mild impairment, 2=Moderate impairment, 3=Severe impairment, 4=Very severe impairment.

Adapted from categories of ventilatory impairment as described by James F. Morris, M.D. (1976, p. 166).

Missing cases were assigned values based upon physician description of ventilatory impairment.

Immunization status and the incidence of respiratory infections

Among the total sample, 43% had received influenza immunization sometime during the study year and 26% had received pneumococcal immunization. There are several reasons for the smaller number of pneumococcal immunizations including the fact that pneumococcal vaccine has not been available as long as influenza vaccine, initial controversy over whether influenza and pneumococcal vaccination could be given safely at the same time, and the better advertising of the availability of influenza vaccine compared to pneumococcal vaccine. Therefore, it is understandable that more subjects had received influenza vaccine than pneumococcal vaccine.

In order to gauge the efficacy of immunization for the study subjects, Pearson correlations were computed. The results are presented in Table 6.

TABLE 6

PEARSON CORRELATIONS BETWEEN NUMBER OF MONTHS OF IMMUNI
ZATION AND RESPIRATORY INFECTIONS IN MEN WITH CRD (N=61)

Respiratory Infections		Pneumonia zation p		f Influenza ization p
Colds	13	.18	11	.22
Pneumonia	.09	.26	.13	.17

These figures show little or no relationship between number of respiratory infections and immunization status. These statistics must be viewed with care due to the small number immunized for either pneumonia or influenza (14 and 24). Though figures in the Table above do not support documentation in the literature of vaccine effectiveness, there is literature (eg., Sabin, 1981) on immunization effectiveness that suggests a possible reason for the lack of correlation. One explanation is that suppression of some infecting organisms by vaccination allows other, previously non-virulent organisms to become dominant. The new organisms are not yet controlled for in vacines and, consequently, vaccination does not provide protection against these organisms.

Another consideration is that subjects were not asked specifically whether they had had the flu during the period studied. Therefore, the incidence of colds may be either higher or lower because some may link colds with influenza and others may have considered them separate infections. This methodological problem could have been circumvented by asking subjects to include influenza under colds if their influenza was accompanied by cold symptoms.

Additional related findings

According to the results of the multiple regression,

prevention practice was the best predictor of the incidence of respiratory infections among the five variables tested. Table 7 in Appendix D describes preventive measures reported by subjects. Staying warm, using over-the-counter drugs, and obtaining flu shots were the most frequent responses. Most subjects did not cite cessation of smoking as a preventive measure taken to reduce the incidence of colds.

It is noteworthy in a population with diagnosed chronic respiratory disease that severity of respiratory disease did not explain more of the variance in number of colds. This may be related to the prevention practices mentioned above as those with more severe disease may have made greater efforts to avoid contracting colds. However, this finding may be also an artifact of the small sample size.

The incidence of alcohol abuse was found to be 41% in the sample. This is significantly higher than the 10% incidence of alcohol abuse estimated for the adult American male population (Dept. of Health, Education and Welfare, 1980, p. 15). Those subjects with diagnosed alcohol abuse (N=25) experienced 66 (\bar{x} =2.64) colds and five (\bar{x} =0.20) cases of pneumonia. Both these figures are slightly higher than those subjects not diagnosed with alcohol abuse (mean number of colds=2.25 and mean incidence

of pneumonia=0.12). However, this difference in number of cases of pneumonia between those diagnosed with alcohol abuse compared to those without was not statistically significant (t=1.55).

General discussion of findings

The results of this study tentatively suggest that diabetics may not have more colds than non-diabetics when such factors as prevention measures, severity of chronic respiratory disease, smoking, and immunization are held constant. Poorly controlled diabetes was associated with increased infections. These findings are inconclusive due to sampling problems. Colds which are sometimes precursors to pneumonia did not occur more frequently in diabetics in this study. The lack of increased colds and pneumonia in diabetics studied fails to support inclusion of diabetes as an indication for pneumococcal vaccination which was noted in the literature (Austrian, 1977; Bean, 1980; Center for Disease Control, 1981). Therefore, in this population, the presence of type II diabetes mellitus does not indicate a need for pneumococcal vaccination. Other risk factors need to be considered when determining necessity of pneumococcal immunization. This finding suggests a need for prospective, longitudinal study to determine common characteristics among diabetic subjects who contract pneumonia.

Generalizability of results are limited for several reasons. The sample was selected according to criteria established to rule out other factors that might affect the incidence of respiratory infections. These criteria and the knowledge that the subjects were older men with a high incidence of alcohol abuse drawn from a veterans outpatient population limit the generalizability of these findings. As the number of diabetic subjects was small and limited to type II diabetics only, this study can address only the influence of diabetic status on respiratory infections in the maturity onset diabetic.

Diabetics, controlled and poorly controlled, with chronic respiratory disease did not have quantitatively more colds and pneumonia than non-diabetics with chronic respiratory disease. This finding may be in error due to the small sample size or problems in the methodology (eg., subjects' difficulty differentiating colds and influenza).

Subject reliability in reporting pneumonia experiences and type of vaccination(s) received was confirmed by reviewing medical records. In this study, two subjects who reported having had pneumonia were found to have had bronchitis instead. Ten subjects indicated that they had received pneumococcal immunization when in fact they had received influenza immunization only; or indicated that the flu shot prevented pneumonia. Two subjects reported wrong diagnoses and did not know the difference

between an upper and lower respiratory tract infection.

This is important as early detection and treatment of pneumonia greatly influences the rate of recovery. The necessity to be able to discriminate between the two infections and vaccinations is discussed under nursing implications.

Though the findings of this exploratory study permit little generalization, the results suggest some nursing implications. A diagnosis of type II diabetes mellitus does not appear to be sufficient indication for pneumococcal vaccination in this type of population. This finding corresponds with comments made by clinical practitioners prior to beginning this study. That is, practitioners need to assess factors other than diagnosed diabetes prior to recommending pneumococcal vaccine to clients. These factors might include age, nutritional status, and respiratory disease.

A clear deficit in patient knowledge about pneumococcal and influenza vaccination was frequently demonstrated in the returned questionnaires. As nursing often
involves care of elderly persons with chronic diseases
who are considered a high-risk group, it is appropriate
that nurses be able to disseminate information to these
clients regarding the nature of the vaccines, the types
of infections that they provide protection against, and

length of protection. For instance, it is important that the recipient of influenza vaccine know that s/he is not being directly protected against pneumonia also. Proper teaching about the type of protection provided by these vaccines provides a better basis of understanding for the patient practicing preventive health care.

Of the variables included in the present study, the best predictor of respiratory infections according to the multiple regression (see Table 5) was prevention practices. That is, those who practiced some kind of prevention had fewer colds than those who did not. This fact emphasizes the need for continued nursing involvement in effective patient education as a means of decreasing the incidence of respiratory infections in potentially high-risk groups. Among the men studied, stopping smoking is a prevention practice in need of emphasizing as 72% continued to smoke despite CRD.

Limitations of sample size and its special characteristics, as previously noted, limit generalizability of results. Consequently, the influence of diabetes on the incidence of respiratory infections, especially pneumonia, has not yet been clearly demonstrated. Further research is indicated and is discussed along with a summary of the study and statement of conclusions in the following chapter.

CHAPTER IV

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Summary

This exploratory descriptive study was undertaken to determine the effect of diabetes on the incidence of respiratory infections in men with chronic respiratory disease. Interest in the subject derived from a discrepancy between recommendations in the literature regarding high-risk groups and the current practice of clinicians. The study sample was drawn from 2,330 veterans receiving care from a general medicine clinic. Questionnaire response rate was 44%. A sample of 11 diabetics and 50 non-diabetics who met the selection criteria listed in the method chapter was obtained. The study determined if any correlation existed between diabetes status and colds experienced when severity of respiratory disease, smoking, prevention practices, and immunization were statistically controlled. study also examined the relative contributions of age, immunization status, and diagnosis of alcoholism to the dependent variable, incidence of colds.

Overall, there was a high (2.4 per person) incidence of respiratory infections, mainly colds, among the study subjects. A higher incidence of colds was found among non-diabetic men with CRD than diabetic men with CRD.

Non-diabetic subjects reported a mean of 2.56 colds during the one year period of study compared to 0.81 for diabetics with CRD. This difference was significant at the .001 level. Similarly, the mean incidence of pneumonia among non-diabetic men with CRD was 0.12 compared to 0.09 for non-diabetics. This difference also was significant at the .001 level. Findings relative to the incidence of respiratory infections in diabetics compared to non-diabetics may be exaggerated due to the small number of diabetic subjects (N=11).

When the number of colds in both groups was examined while controlling for prevention practices, severity of respiratory disease, smoking, and immunization status, diabetes was found to explain 10% of the variance, and the other variables combined explained 16% of the variance. This leaves a substantial amount of the variance in number of colds (74%) unexplained. The contribution of immunization status (influenza or pneumococcal) to the incidence of colds was 2%. Immunization is inadequately represented in these subjects as only 43% had been immunized against influenza for an average of five months; and, an even fewer number, 26%, had been immunized against pneumonia for an average of eight months. The correlation between diabetes status and number of colds (r=-.224) was negative thereby supporting the find-

ing that subjects with diabetes had significantly fewer colds than subjects without diabetes.

While the results of this study are inconclusive due to having a small number of diabetics, non-random sample, and other problems with the method, the results of this study tentatively suggest that respiratory infections are not increased among Type II diabetics. Even the four poorly controlled diabetics whose blood sugars were greater than 200 mg/dl, reported a mean number of 1.5 colds which is less than the mean number of colds for non-diabetics (2.6) and greater than that of controlled diabetics (0.81). Uncontrolled diabetics did have a larger mean incidence of pneumonia (0.25) than either non-diabetics or controlled diabetics, but the small sample size (4 uncontrolled diabetics) raises doubts as to the significance of this finding.

The subjects for this study appear representative of the veterans' population from which the sample was drawn. Besides chronic respiratory disease, 70% of the subjects had concomitant cardiovascular disease and 41% had diagnosed alcohol abuse. The subjects were elderly males with a mean age of 63 years. Their employment had been in semiskilled jobs and as machine operators. Only 8% of the subjects are currently employed. All subjects had an extensive smoking history and the majority still smoke.

On the average, the non-diabetic subjects had severe respira-

tory disease compared to moderate respiratory disease among the diabetic subjects.

Conclusions

As there is little existing literature that examines the incidence of respiratory infections in diabetics compared to non-diabetics, this study is exploratory in nature. It is of interest that in this study diabetics with CRD report fewer colds and pneumonia than non-diabetics with CRD. Numerous researchers, drug manufacturers, and most recently the Center for Disease Control (1982) have suggested that diabetes mellitus is a chronic disease that places one at risk for pneumonia. As mentioned previously, the small sample size and setting in which the study took place precludes generalization of findings. Consequently, these results should be viewed with caution.

These findings suggest that nurses should continue to assess factors other than diabetes status (i.e. age, spleen and liver disease), particularly in controlled diabetics, before recommending use of pneumococcal vaccine. For instance, based on the data, men who abused alcohol had more colds than men who did not. Therefore, diagnosed alcohol abuse may also be a consideration for pneumococcal vaccination. As the guidelines for immunization are not as clear and definitive as desired, there remains a need to examine which groups will benefit most from immunization.

In this study using a Pearson correlation, immunization status was not correlated with number of colds and

pneumonia experienced. There are also a number of instances of vaccine failure reported in the literature (Ahonkhai, et al, 1979; Sumaya, et al, 1980). Therefore, it is important that should the client choose pneumococcal immunization that the nurse continue to provide teaching about preventive measures given non-vaccine recipients. Further, clients need to be made aware of the fact that pneumococcal immunization does not protect them against all forms of pneumonia or other forms of respiratory infection.

Related to client misconceptions about pneumococcal vaccine are misunderstandings about influenza vaccine. Some subjects could not differentiate between those two vaccines and referred to them interchangeably. Nurses in recommending and/or administering these vaccines need to make clients aware of their different purposes, length of efficacy, and side-effects.

Those subjects who reported practicing prevention had fewer colds than those who did not. This finding suggests a need to teach clients that prevention practices may reduce colds. Symptoms of respiratory infections are often quite subtle in early stages. Teaching should include the ability to recognize the signs of infection and intervene appropriately to prevent further respiratory compromise. Teaching is especially appropriate among those subjects who continued smoking despite an already

compromised respiratory status. Nurses in their role of patient educators can influence the number of colds patients experience by teaching and reinforcing knowledge of preventive measures.

Recommendations for further study

Based upon the results of this study, the following recommendations are made for further research:

- 1. To decide scientifically which high-risk groups should be vaccinated, a randomized, prospective, longitudinal study should be conducted to determine the efficacy of influenza and pneumococcal vaccine for different high-risk groups.
- 2. A prospective longitudinal study should be conducted of the response to pneumococcal vaccine among both insulin and non-insulin dependent diabetics with varying degrees of diabetic control.
- 3. A study should be undertaken of the preventive practices most influential in decreasing the incidence of respiratory infections.
- 4. A survey of the ability of patients with chronic respiratory disease to discriminate between the signs and symptoms of colds and pneumonia would be useful to establish the reliability of the self-reporting method used to gather data about colds and pneumonia.

5. Replication of this study with a larger sample representative of the general population is needed.

The need for pneumococcal immunization of diabetics has yet to be clearly demonstrated. Because pneumonia has multiple etiologies, the vaccine's effectiveness over a period of time has been questioned in both high-risk groups and the general population. The vaccine's effectiveness in raising antibody titers to serotypes contained in the vaccine and reducing the incidence of pneumonia for short terms among healthy individuals living or working in high-risk settings has been clearly demonstrated elsewhere. There remains a need for further study regarding recommendations for use of pneumococcal vaccine with diabetics. A profile describing individuals at high-risk for pneumococcal pneumonia and the extent of protection provided by pneumococcal vaccine would be beneficial.

References

- Austrian, Robert & Gold, J. Pneumococcal bacteremia with especial reference to bacteremic pneumococcal pneumonia. Annals of Internal Medicine, 1964, 60, 759-776.
- Austrian, Robert. Prevention of pneumococcal infection by immunization with capsular polysaccharides of streptococcus pneumonias: Current status of polyvalent vaccines. The Journal of Infectious Diseases, August 1977, 136, 538-542.
- Austrian, Robert, Douglas, Robert M., Schiffman, Gerald,
 Coetzee, Albert M., Koornhof, Hendrik J., HaydenSmith, Stanley, & Reid, Robert D. Prevention of
 pneumococcal pneumonia by vaccination. <u>Transactions</u>
 of the Association of American Physicians, May 4, 1976,
 89, 184-194.
- Austrian, Robert. Vaccines of pneumococcal capsular polysaccharides and the prevention of pneumococcal pneumonia, see Roland F. Beers, Jr. and Edward Basset,

 The Role of Immunological Factors in Infectious, Allergic, and Auto-immune Process, New York: Raven

 Press, 1976.
- Austrian, Robert & Winegrad, Albert. Diabetes Mellitus and the pneumococcus. <u>Journal of the American Medical</u>
 Association, Oct. 3, 1980, 244 (14), 1573-1574.

- Bagdade, John D., Root, Richard K., and Bulger, Roger J.

 Impaired leukocyte function in patients with poorly
 controlled diabetes. <u>Diabetes</u>, Jan. 1974, <u>23</u> (1),
 9-15.
- Beam, Thomas, Crigler, Diane, Goldman, Jack K., & Schiffman, Gerald. Antibody response to polyvalent pneumo-coccal polysaccharide Vaccine in diabetics. <u>Journal of the American Medical Association</u>, Dec. 12, 1980, 244 (23), 2622-2624.
- Bordow, Richard A., Stool, Edward W., & Moser, Kenneth M.

 (Eds.). Manual of Clinical Problems in Pulmonary

 Medicine. Boston: Little, Brown, and Co., 1980.
- Borgono, J. Manuel, McLean, Arlene E., Vella, Philip,
 Woodhour, Allen, Canepa, Irma, Davidson, Wallace L.,
 & Hilleman, Maurice. Vaccination and revaccination
 with polyvalent pneumococcal polysaccharide vaccines
 in adults and infants. Proceedings of the Society
 for Experimental Biology and Medicine, 1978, 157,
 148-154.
- Broome, Claire V., Facklam, Richard R., Allen, J. R., & Fraser, D. W. Pneumococcal disease after pneumococcal vaccination. New England Journal of Medicine, September 4, 1980, 303 (10), 549-552.
- Broome, Claire V., Facklam, Richard R., & Fraser, David W.

 Epidemiology of pneumococcal serotypes in the United

 States, 1978-79. The Journal of Infectious Diseases,

- Jan. 1980, 141 (1), 119-123.
- Bybee, J. David and Rogers, David E. The phagocytic activity of polymorphonuclear leukocytes obtained from patients with diabetes mellitus. The Journal of Laboratory and Clinical Medicine, July 1964, 64 (1), 1-13.
- Center for Disease Control. Morbidity and Mortality

 Weekly Report, Aug. 28, 1982, 30 (33), 410-412 and
 417-418.
- Cosio, Fernando G., Giebink, G. Scott, Le, Chap Than, & Schiffman, Gerald. Pneumococcal Vaccination in patients with chronic renal disease and renal allograft recipients. <u>Kidney International</u>, 1981, 20, 254-258.
- Department of Health, Education and Welfare. <u>Diabetes</u>

 <u>Data</u>: <u>Compiled 1977</u>, National Institute of Health,

 DHEW Pub. No. (NIH) 78-1468, 1977.
- Department of Human Resources. <u>Oregon Vital Statistics</u>,

 1979, Oregon State Health Division, Portland, Oregon,
 1979.
- Ekwurzel, G. M., Simmons, J. S., & Felton, Lloyd. Studies on immunizing substances in pneumococci. Public Health Reports, Oct. 21, 1938, 53, Part II, 1877-1893.
- Fekety, R., Caldwell, J., Gump, D., Johnson, J. E., Maxson, W., Mulholland, J., & Thoburn, R. Bacteria, Viruses and mycoplasmas in acute pneumonia in adults.

- American Review of Respiratory Disease, 1975, 104, 499-507.
- Friedman, Eli A., Beyer, Monica M., Hirsch, Sondra, & Schiffman, Gerald. Antibody response to pneumococcal capsular polysaccharides in uremia and diabetes.

 Journal of the American Medical Association, Nov.

 21, 1980, 244 (20), 2310-2311.
- Giebink, G. S., Foker, John E., Kim, Young K., & Schiffman, Gerald. Serum antibody and opsonic responses to vaccination with pneumococcal capsular polysaccharides in normal and splenectomized children. <u>Journal</u> of Infectious Diseases, 1980, 141, 404-412.
- Haleo, Kelly & Barriere, Steven. Polyvalent pneumococcal vaccines: A Review. American Journal of Hospital Pharmacy, June 1979, 36, 773-777.
- Heberlein, Thomas A. and Baumgartner, Robert. Factors affecting response rates to mailed questionnaires:

 a quantative analysis of the published literature.

 American Sociological Review, August 1978, 43 (4), 447-462.
- Heidelberger, M. & Avery, O. T. The soluble specific substance of pneumococcus. Journal of Experimental Medicine, July 1, 1923, 38, 73-79.
- Kaiser, Allen & Schaffner, William. Prospectus: The prevention of bacteremic pneumococcal pneumonia. Journal of American Medical Association, Oct. 21, 1974,

- 230 (3), 404-408.
- Kaufman, Paul. Pneumonia in old age. Archives of Internal
 Medicine, May 1947, 79, 518-529.
- Khurana, R. C., Younger, D., and Ryan, J. R. (Abstract)

 Characteristics of pneumonia in diabetics. Clinical

 Research, 1973, 21, 629.
- Lambert, H. P. Vaccination against pneumococcal disease.

 Archives of Disease in Childhood, 1980, 55, 915-916.
- MacLeod, Colin M., Hodges, Richard G., Heidelberger,

 Michael & Bernhard, William G. Prevention of pneumococcal pneumonia by immunization with specific
 capsular polysaccharides. <u>Journal of Experimental</u>
 Medicine, Dec. 1, 1948, 82 (6), 445-465.
- Miller, Delbert C., Handbook of Research Design and Social

 Measurement. (3rd Ed.), New York: David McKay Co.,

 1977.
- Morris, James F. Spirometry in the evaluation of pulmonary function. <u>The Western Journal of Medicine</u>, August 1976, 125 (2), 110-117.
- Moss, James M. Pneumococcus infection in diabetes mellitus.

 Journal of the American Medical Association, June 13,

- 1980, 243 (22), 2301-2303.
- Mufson, Maurice A., Krause, Helen E., Tarrant, Carl J.,
 Schiffman, Gerald, & Cano, Francis R. Polyvalent
 pneumococcal vaccine given alone and in combination
 with bivalent influenza virus vaccine. Proceedings
 of the Society for Experimental Biology and Medicine,
 April 1980, 103, 498-503.
- National Diabetes Data Group. Classification and diagnosis of diabetes and other categories of glucose intolerance. <u>Diabetes</u>, December 1979, <u>28</u> (12), 1939-1054.
- National Institute of Health, <u>Diabetes Mellitus</u>, DHEW Pub. No. 76-854, 1976.
- Perillie, Pasquale E., Nolan, James P., & Finch, Stuart

 C. Studies of the resistance to infection in diabetes mellitus: Local exudative cellular response.

 Journal of Laboratory and Clinical Medicine, June
 1962, 59 (6), 1008-1015.
- Riley, I. D., Andrews, M., Howard, R., Tarry, P. I.,

 Pfeiffer, M., Challands, P. Immunization with a

 polyvalent pneumococcal vaccine. The Lancet, June
 25, 1977, 1338-1341.
- Sabin, Albert B. Immunization, evaluation of some currently available and prospective Vaccines. <u>Journal</u>
 of the American Medical Association, July 17, 1981,

- 246 (3), 236-241.
- Silber, G. R., Weitzman, Sigmund A., Aisenberg, Alan C.,
 Weinstein, Howard J., & Schiffman, Gerald. Impaired
 antibody response to pneumococcal vaccine after
 treatment for Hodgkin's disease. New England Journal
 of Medicine, Aug. 31, 1978, 299, 442-448.
- Smit, Pieter, Oberholzer, Dennis, Hayden-Smith, Stanley,
 Koornhof, Hendrik & Hilleman, Maurice. Protective
 efficacy of pneumococcal polysaccharide vaccines.

 Journal of the American Medical Association, Dec. 12,
 1977, 238 (24), 2613-2616.
- Sumaya, Ciro Valen, Harbison, Richard W., & Britton,

 Howard. Pneumococcal vaccine failures. American

 Journal of the Disabled Child, Feb. 1981, 135, 155
 158.
- Tilghman, R. Carmichael & Finland, Maxwell. Clinical significance of bacteremia in pneumococcal pneumonia.

 Archives of Internal Medicine, April 1973, 59 (4), 602-619.
- Tillotson, James R., & Lerner, A. Martin. Characteristics of pneumonias caused by escherichia coli. The New England Journal of Medicine, July 20, 1967, 277 (3), 115-122.
- U. S. Bureau of the Census, <u>Statistical Abstracts of the</u>
 United States: 1979. (100th edition, Washington,

- D. C., 1979.
- U. S. Dept. of Health, Education, and Welfare. The

 Alcohol, Drug Abuse, and Mental Health National Data

 Book, DHEW Pub. No. (ADM) 80-938, 1980.
- Valenti, William M., Kenzer, Martin, & Bentley, David W.

 Type-specific pneumococcal respiratory disease
 in the elderly and Chronically ill. American Review
 of Respiratory Disease, Feb. 1978, 117, 233-237.
- Vella, Philip P., McLean, Arlene, Woodhour, Allen F., Weibel, Robert E., & Hilleman, Maurice R. Persistence of pneumococcal antibodies in human subjects following vaccination. <u>Proceedings of the Society</u> <u>for Experimental Biology and Medicine</u>, 1980, <u>164</u>, 435-438.
- Wadsworth, Augustus & Brown, Rachel. Chemical and immunological studies of the pneumococcus. <u>Journal of</u>
 Immunology, September 1931, 21 (3), 245-255.
- Weibel, Robert E., Vella, Philip P., McLean, Arlene A.,
 Woodhour, Allen F., Davidson, Wallace L., & Hilleman, Maurice R. Studies in human subjects of polyvalent pneumococcal vaccine. Proceedings of the Society for Experimental Biology and Medicine, Oct.
 1977, 165, 144-150.
- Wright, Amroth E. Prophylactic inoculation against pneumococcus infections. The Lancet, Jan. 10, 1914, $\underline{1}$, 87-98.

Appendix A: Cover Letter

THE OREGON HEALTH SCIENCES UNIVERSITY

School of Nursing Office of the Associate Dean for Academic Affairs 3181 S.W. Sam Jackson Park Road Portland, Oregon 97201 (503) 225-7893

Date: November 23, 1981

Dear		,

My name is Marina McCollam. I am a nurse working to earn a Master's degree at the Oregon Health Sciences University. I am interested in the subject of respiratory infections (colds, pneumonia) among people with a history of lung problems. As part of earning my degree, I am conducting a study to find out the kind and number of respiratory infections people with lung problems with diabetes have compared to people with lung problems without diabetes.

Your name was one of 200 selected from patients treated at the U.S. Veterans Administration Medical Center, Portland, Oregon. I would appreciate your participation in my study. Your participation is voluntary. Your decision whether or not to participate, will not affect your treatment at the V. A. Medical Center. The information gained by this study will not benefit you directly, but your participation may help others. If you agree to participate, you will be asked to answer some written questions. It should take 15 minutes or less time. Your medical record will be reviewed for the period of November 1, 1980 to October 31, 1981 for information about your medical care related to respiratory infections. A self-addressed, stamped envelope has been enclosed

to return the questionnaire when you are done.

Your name does not appear on the questionnaire, but the questionnaire is coded to allow repeat mailings as necessary. As soon as I have the completed questionnaires, my master list of participants' names and addresses will be destroyed. This will guarantee that your name will not be associated with any answers you give. The information from all participants will be reported in a combined form.

I am willing to answer any questions you have about the study either by phone (503) 254-6180 or by mail.

Thank you for helping me complete this study.

Sincerely,

massa & milallanke!

Marina E. McCollam, RN Graduate Nursing Student

Appendix B: Consent Form

CLINICAL RECORD

Report	no				
	1	or			
Continu	uati	on of	S. F.		
				(Specify type of examination or data)	

(Sign and date)

CONSENT FOR HUMAN REPEARCH PROJECT

(First Name) (Middle Initial) (last lame) agree to participate in the project named "The Incidence of Respiratory Infections in Individuals with and without Diabetes" carried out by marina E. mcSollam, R.M. under the direction of R. hatherine Crabtree, R.M., R. S. The aim of this study is to compare the number of colds and pheumonias experienced by people with lung problems and diabetes to non-diabetic people with lung problems. (ther information of interest to this study include age, occupation, other illnesses, smoking history, immunization status and what you do to prevent respiratory infections.

If you are willing to be involved in this, you will be asked to answer a few written questions that should take 15 minutes or less time. Your medical records will be reviewed to obtain information about active illnesses, age, smoking history, immunisation status, and clinic visits for colds and pneumonia. There is no danger to yourself if you choose to participate in this study. Although you will not directly be rewarded by joining in this study, you may help increase our understanding of the relationable between the number of colds and pneumonias experienced by people with and without diabetes. The information that you give will be handled in a private manner. You will be given a code number to protect your identity.

You may refuse to join in or leave this study at any time without changing your relationship with, or care received at, the U.S. Veterans Administration Redical Center. Theo, you may ask the investigator, Marina E. ReCollam, E.R. any questions that you might have by calling (503) 254-6190.

(continued)

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle, grade; date, hospital or medical facility)

REGISTER NO.

WARD NO.

REPORT ON ____

__ DE CONTINUATION OF .

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11.80 6-8
October 1975 507-106

GPO

CI	INI	CAL	DF	n	חפ
84 L		LUML	n L	uu.	1 L

Report on ______

Continuation of S. F.

(Strike out one line) (Specify type of examination or data)

(Sign and date)

I understar	what is being asked of me and agree to help
	described above.
(Date)	(Participant's Signature)
(Dat∈)	(Witness Signature)

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name-last, first, middle; grade; date; hospital or medical facility)

REGISTER NO.

WARD NO.

REPORT ON ____

___ OF CONTINUATION OF _

STANDARD FORM 507
General Services Administration and Interagency Committee on Medical Records
FPMR 101-11.80 6-8
October 1975 507-106

Appendix C: Mailed Questionnaire

Code N	lo	
Questionnaire		
ackground information)		
cupation		
(Presently employed?	_Yes	No
	YES	NO
Have you had any colds within the past year?		
1a. If yes, how many?		
Have you had pneumonia within the past year?		
2a. If yes, how often?		
Do you tend to have colds every spring or fall (allergy related)?		
(If you had any) Did any of your colds or pneumonia need medical treatment?		
Have you received a shot anytime in the past three years to protect yourself against pneumonia?	Monopolitica	
5a. If yes, where?V.AElsewhere		
when did you receive it?		ible)
Do you do anything to protect yourself from opneumonia?	olds	or
	Questionnaire rections: Place an X in the column that best question and fill in the blank when ackground information) rupation (Presently employed? Have you had any colds within the past year? 1a. If yes, how many? Have you had pneumonia within the past year? 2a. If yes, how often? Do you tend to have colds every spring or fall (allergy related)? (If you had any) Did any of your colds or pneumonia need medical treatment? Have you received a shot anytime in the past three years to protect yourself against pneumonia? 5a. If yes, where? V.A. Elsewhere 5b. If you received a shot to prevent pneumon when did you receive it? Month/Year (if	Questionnaire rections: Place an X in the column that best answe question and fill in the blank where approackground information) requation (Presently employed?

Thank you for your answers to the above questions!

Appendix D: Prevention Practices

TABLE 7 Cold Prevention Measures Described by $\operatorname{Subjects}^{\operatorname{a}}$

Prevention Measure	Non-diabetic N=46	Diabetic N=11	Diabetics and Non-diabetics N=57
None	10	2	12
Nutrition	6	0	6
Antibiotics	1	1	2
Change Climates	1	0	1
Warm clothes, house, etc.	19	3	22
Flu shot	8	2	10
Rest	2	0	2
Stop smoking ^b	2	0	2
Avoid crowds	5	0	5
Over-the-counter medicines	13	1	14
Take prescribed medicines	3	2	5

aFour subjects provided no response.

All subjects smoked at some time and 71% still smoke.

Appendix E: Medical Records Information Data Collection Form

Subject	No.

The Incidence of Respiratory Infections in Men with Chronic Respiratory Disease with and without Diabetes

duration quantity (pack years) Diabetes: typeInsulin DepNon-Insulin dependent duration 3 recent blood sugars: 1. BS, type, date 2. BS, type, date 3. BS, type, date Other active complicating illnesses and conditions: Pneumococcal immunization: Yes No Date of immunization: Yes No Date of immunization: Yes No	
duration Pulmonary Function test results Date Chest x-ray AP Date Smoking hx: duration quantity (pack years) Diabetes: type Insulin Dep. Non-Insulin dependent duration 3 recent blood sugars: 1. BS , type , date 2. BS , type , date 3. BS , type , date 0ther active complicating illnesses and conditions: Pneumococcal immunization: Date of immunization (If immunized) Influenza immunization: Pate of immunization: Tyes No Exposure to toxic chemicals: Yes No	ory disease:
Smoking hx: duration quantity (pack years) Diabetes: type	
duration quantity (pack years) Diabetes: type	AP Date
quantity (pack years) Diabetes: typeInsulin DepNon-Insulin dependent duration 3 recent blood sugars: 1. BS, type, date 2. BS, type, date 3. BS, type, date Other active complicating illnesses and conditions: Pneumococcal immunization: Yes No Date of immunization (If immunized) Influenza immunization: Yes No Date of immunization (if immunized) Exposure to toxic chemicals: Yes No	
typeInsulin DepNon-Insulin dependent duration	ack years)
dependent duration 3 recent blood sugars: 1. BS, type, date 2. BS, type, date 3. BS, type, date Other active complicating illnesses and conditions: Pneumococcal immunization: Yes No Date of immunization (If immunized) Influenza immunization: Yes No Date of immunization (if immunized) Exposure to toxic chemicals: Yes No	
duration 3 recent blood sugars: 1. BS, type, date 2. BS, type, date 3. BS, type, date Other active complicating illnesses and conditions: Pneumococcal immunization: Yes No Date of immunization (If immunized) Influenza immunization: Yes No Date of immunization (if immunized) Exposure to toxic chemicals: Yes No	
1. BS, type, date	dependent
Date of immunization (If immunized) Influenza immunization: Yes No Date of immunization (if immunized) Exposure to toxic chemicals: Yes No	, type, date, type, date
Date of immunization (If immunized) Influenza immunization: Yes No Date of immunization (if immunized) Exposure to toxic chemicals: Yes No	
Date of immunization (if immunized) Exposure to toxic chemicals: Yes No	
joe, madare or exposure	

Number of clinic visits for respiratory infections during study period, if any. (Does not include follow-up visits.)

Type of resp. infection treated 1. 2. 3. 4. 5. 6. 7. 8. 9. 10.

Culture results (if any)	Date
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

Appendix F: Other Diseases Noted in Subjects

TABLE 8
Other Diseases Noted in Subjects

Disease	Diabetic N=11	Non-diabetic N=50	
Cardiovascular	7	36	
Lymphatic, Hematologic	0	1	
ENT	1	4	
Liver, spleen	1	2	
Alcohol Abuse	2	12	

AN ABSTRACT OF THE THESIS OF MARINA E. McCOLLAM

For the Master of Nursing

Date Receiving this Degree: June 11, 1982

Title: The Incidence of Respiratory Infections in Men with
Chronic Respiratory Disease with and without Diabetes

Approved:						
	Μ.	Katherine	Crabtree.	M.S.	Thesis	Advisor

Pneumonia and influenza are the fifth leading cause of death in the United States. Pneumococcal vaccine has been recommended as a means of reducing morbidity and morality due to pneumonia in high-risk groups. Individuals with Diabetes Mellitus are described in the literature as being at high-risk for pneumococcal pneumonia. Controversy exists as to whether or not diabetics are at greater risk than the general population for pneumococcal pneumonia; and, whether or not diabetics would benefit from use of a pneumococcal vaccine. A survey of local practitioners found that pneumococcal vaccine was predominantly given to individuals with chronic respiratory disease (CRD). Few studies have been done on the incidence of respiratory infections (colds and pneumonia) among diabetics. Consequently, this descriptive study examines the incidence of respiratory infections

in men with chronic respiratory disease with and without diabetes.

The incidence of respiratory infections was examined in 61 men (50 non-diabetic and 11 diabetic) with CRD. Data were gathered by means of a mailed questionnaire and medical chart review. Two research questions were explored:

1. Is there a difference in the number of respiratory infections between non-diabetic men with CRD and diabetic men with CRD? and 2. When prevention practices, smoking, severity of respiratory disease, and immunization status are controlled, is there a difference in the number of colds experienced between diabetics with CRD and non-diabetics with CRD?

Two types of analyses were performed to answer these questions. T-tests were used to compare the incidence of respiratory infections in diabetics and non-diabetics. Non-diabetics were found to have a significantly greater number of colds (t=1.26) and pneumonia (t=0.03). A hierarchial multiple regression was used to examine the effect of diabetes status (present or absent) on number of colds, while controlling for prevention practices, severity of respiratory disease, smoking, and immunization status. Diabetes status was found to explain 10% of the variance in number of colds.

Diabetics had a lower incidence of respiratory infections than non-diabetics. This finding requires further in-

vestigation before recommending diabetes as an indication for pneumococcal vaccination. An interesting finding of the study was that the use of cold prevention practices explained 8% of the variance among the variables tested. The findings of this study are exploratory and tentative due to method-ological limitations related to the sample. Therefore, the results are inconclusive but suggest a direction for further research.