THE RELATIONSHIP OF SICKNESS IMPACT PROFILE SCORES TO OUTPATIENT TREATMENT COMPLIANCE

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DEDICATION

To my parents.

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ABSTRACT

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Patient noncompliance to prescribed therapeutic regimen is a significant problem hindering the provision of optimally effective health care. This study examines the problem of noncompliance and offers a potentially predictive tool for practical use by the medical community. The sample for this study was a group of 50 Chronic Obstructive Pulmonary Disease outpatients who were participating in a nationwide Division of Lung Disease (DLD) study of respiratory therapies. Upon inclusion into the DLD study, each participant was evaluated by a team of physicians and was given a psychological test composed of 12 subcategories, the Sickness Impact Profile (SIP). This test is a scaled measure of patient-perceived illness impact in terms of dysfunction or disruption of daily activities. It was asserted that those who perceived themselves more ill would be more compliant to prescribed treatment.

The treatment in the DLD study required each patient to take 20 minutes daily respiratory therapy in the home. Average daily time-use calculations were recorded at the

end of a five month period. These figures were statistically related to the previously mentioned SIP scores. There was no significant relationship between the total SIP score and subsequent compliance or noncompliance to the treatment regimen. However, two subcategory scores were used to accurately predict compliance in 74% of the participants.

It was the conclusion of the investigator that selected subcategory scores of the SIP could be used as predictors of patient compliance for this sample.

DEDICATION

To my parents.

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CHAPTER 1

INTRODUCTION

Since the advent of preventive medicine, one of the primary goals of health care providers has been to encourage a more independent and self-motivated consumer of health care services. Programs have emerged using innovative treatment and medication regimes requiring informed cooperation and participation of those receiving the prescribed care. Examination of such programs reveals a recurring problem with the lack of consumer compliance to stipulated plans of home therapy. Several variables such as age, sex, race, education, and socioeconomic status have been positively related to influencing patient compliance. This study, while addressing the above mentioned variables, attempted to relate compliance with the patient's perception of the impact of his illness. Through the use of a psychological test, the Sickness Impact Profile (SIP) (Pollard, Bobbitt, Bergner, Martin, & Gibson, 1976; Appendix A), the degree of patient-perceived dysfunction attributed to illness was established. It was further asserted that this type of information could provide a

guide for more individualized and optimally more feasible planning and management of home health therapy regimes.

This study examined a group of chronically ill lung disease outpatients. These outpatients were part of a large, ongoing study conducted by the Division of Lung Diseases (DLD) in Washington, D.C. Each participant underwent a battery of physiological and psychological tests including the SIP upon entrance into the DLD study; each participant agreed to a standardized daily home therapy program.

Statement of the Research Problem

The following problem was explored:

What is the relationship between the study participants' Sickness Impact Profile scores and their five-month compliance to a prescribed home treatment regimen?

Research Justification

Noncompliance has been observed in the treatment and management of a wide variety of diseases. Blackwell (1972) found that complete failure to adhere to medication and/or treatment prescriptions occurred in 25% to 50% of all outpatients. The failure of patients to comply to recommended home therapy may render many preventive, therapeutic, or rehabilitative regimens ineffective. Therefore, the exploration of a potentially predictive tool of compliance, such

as the SIP, was believed to be an invaluable addition to the patient profile, enhancing effective patient management. For example, various health care professionals, including the physician, the nurse, the physical therapist, and others, could utilize the additional patient data gleaned from the SIP to structure more appropriate care plans and patient teaching activities. In discharge planning the SIP could be useful in identifying those patients most capable of adhering to the prescribed treatment regimens, as well as those who may require additional medical follow-up.

The examination of the relationship of the SIP scores and patient compliance was viewed as imperative for modern health care providers in all inpatient and outpatient settings. It was believed that the ultimate goal of preparing a more independently compliant health care consumer could be a predictable and feasible process, particularly if research can confirm the advantageous use of instruments such as the SIP.

Conceptual Framework

The conceptual framework of the study was derived from the Health Belief Model set forth by Rosenstock (1966). This model attempts to explain the complexities involved in understanding the health behavior of individuals (Appendix B).

According to the model, the individual is viewed as a composite of social, demographic, personal, and cultural factors. All of these factors influence individual health beliefs which, in turn, influence health behavior. Stemming from this multifaceted view of the individual, the model asserts that there are four immediate determinants of health behavior: (1) susceptibility, the degree to which poor health is anticipated; (2) seriousness, the degree of severity perceived to be associated with poor health; (3) benefits/costs, the ratio of positive to negative results of the health behavior; and (4) cue to action, a stimulus for triggering health behavior (Bauman, 1980). Although all these determinants contribute to health behavior, this study focused upon the aspect of seriousness, as defined by the SIP score. It was believed that the exploration of the patient's perception of the severity of his disease in terms of dysfunction in his activities of daily living was positively related to his health behavior, i.e., his compliance to home therapy. Becker (1974) reinforced this hypothesized positive correlation and asserted that "one may conclude that the Health Belief Model's component 'perceived severity' should be included as a basic element of a sociobehavioral model of compliance" (p. 82). The Health Belief Model, therefore, was viewed as exemplifying

a value-expectancy approach to health behavior, particularly compliance, while the SIP was utilized as an instrument with which to operationally define behavioral dysfunction and sick role behavior. With these constructs as a basis the subsequent hypotheses were created.

Assumptions

The following assumptions were recognized in association with this study:

1. Each study participant met the inclusion criteria as outlined by the DLD in Appendix C.
2. Each study participant was instructed as to appropriate machine care and use.
3. There was no accountable difference in the use of the IPPB or CN machines due to the fact that machine care and prescribed home therapy using either machine was identical.
4. The time measurement technique was accurate for use in research calculations.
5. The administration of the SIP test was instituted by trained personnel in an unbiased manner.
6. The Health Belief Model component "perceived severity" was applicable to the chronically ill.
7. Study participants perceived some degree of illness impact upon their lives.

Research Hypotheses

The primary hypothesis of this study was:

H_1: There is a significant positive relationship between individual study participant's compliance (average daily machine-measured treatment readings) and the study participant's perception of disease severity (SIP scores).

Additionally, sub-hypotheses included:

H_2: There is a significant relationship between age and compliance.

H_3: There is a significant relationship between sex and compliance.

H_4: There is a significant relationship between each SIP subcategory score and compliance.

Definition of Terms

For the purposes of this study, the following terms were defined:

1. Compliance--The participant's average daily treatment time of 20 minutes per day, as measured by the time meter on the participant's Intermittent Positive Pressure Breathing (IPPB) machine or the Compressor Nebulizer (CN) machine in his/her home.
2. Machine measured readings--Machine-measured readings were the average times in minutes per day that each

individual study participant activated the electric time meter on the IPPB or CN machine by turning on the machine. The readings were averaged over the first five months of home therapy as stipulated in the ongoing DLD study.

3. Sickness Impact Profile (SIP)--The Sickness Impact Profile was a verbal interviewer-administered test given to each study participant upon his/her inclusion in the DLD study. The SIP is composed of 12 subcategories of items, each of which describes dysfunction in an area of living or a type of activity. Listed below are brief definitions of each subcategory topic area and selected items to illustrate the composition of that subcategory.

   Emotional behavior--Subcategory items involved or related to feelings and sensations, e.g., I laugh and cry suddenly for no reason.

   Body care--Subcategory items involved or related to personal hygiene and self-care, e.g., I dress myself, but do so very slowly.

   Home management--Subcategory items involved or related to household affairs, e.g., I am doing less of the regular daily work around the house than I usually do.

   Mobility--Subcategory items involved or related to movement or confinement, e.g., I stay within one room.

Social interest--Subcategory items involved or related to personal interactions and social behaviors, e.g., I am going out less to visit people.

Ambulation--Subcategory items involved or related to locomotion, e.g., I am walking shorter distances.

Communication--Subcategory items involved or related to verbal expression, e.g., I often lose control of my voice when I talk.

Work--Subcategory items involved or related to occupational activities, e.g., I am not working at all.

Recreation and pastimes--Subcategory items involved or related to leisure activities, e.g., I am going out for entertainment less often.

Alertness behavior--Subcategory items involved or related to orientation and awareness, e.g., I sometimes behave as if I am confused or disoriented to time and place. Sometimes I am unaware of the year.

Eating--Subcategory items involved or related to nutritional practices, e.g., I am eating no food at all. I am fed intravenously.

Sleeping--Subcategory items involved or related to rest, e.g., I lie down to rest more often during the day (Bergner, Bobbitt, Pollard, Martin, & Gilson, 1976).

The total score for the SIP was utilized as the overall indicator of that participant's perception of disease

severity. Subsequently, each subcategory score was examined for its relationship to compliance.

4. Trained personnel--Study personnel included nurses, respiratory therapists, and technicians hired by the DLD and trained by the DLD in standardization of testing procedures and techniques.

Limitations

The following limitations were recognized in association with this study:

1. Each participant's awareness of his/her inclusion in a research study may have influenced his/her compliance.
2. It cannot be ascertained whether study participants actually used the IPPB or CN machines for treatment, or if the time meter was simply activated without use.
3. The accuracy of the time measurement may have included a negligible amount of error because, although instructed to note the metered machine time, the participant may have used an alternate time piece to monitor his/her treatment. However, it should be noted that monthly checks of the time meters are routinely conducted by DLD researchers.
4. The administration of the SIP may not be instituted by the same personnel for each participant in the study.

5. The stage of disease process may have progressed in the five month observation period and may have affected the participant's physical ability to adhere to the home treatment regimen.
6. Generalizability of the results is confined to the study sample.

Summary

The goal of this study was to enhance the management and treatment of health care consumers with chronic lung disease. This can be more effectively achieved by assessing the consumer's perception of the severity of the diagnosed disease. By understanding and perhaps "closing the gap" between patient-perceived and clinician-perceived extent of illness, more appropriate therapy regimens with higher levels of compliance will evolve. The results of this study may fortify this claim and open a new realm of knwoledge from which more complete and satisfying health care can be instituted.

Chapter 2 presents a comprehensive review of the literature. A discussion of the methodology of the study is found in Chapter 3. Chapter 4 contains an analysis of data, and a summary of the entire study. Conclusions derived from the analysis of data are presented in Chapter 5.

CHAPTER 2

REVIEW OF THE LITERATURE

Noncompliance with medical regimens drastically curtails the benefits patients may obtain from treatment, increases health care costs, and provides considerable frustration for health care professionals. The magnitude of this problem is evident when one reviews current studies noting an across-the-board noncompliance rate of at least 50% (Davis, 1968). The pervasiveness of this dilemma is particularly notable in those who experience chronic illness. That is, those persons with impairments or deviations from normal which have at least one of the following characteristics: (1) are permanent, (2) leave residual disability, (3) are caused by nonreversible pathological alteration, (4) require special training of the patient for rehabilitation, (5) may be expected to require a long period of supervision, observation, or care (Mayo, 1956, p. 10). Although exact numbers with respect to this problem are not known, Davis (1968) stated:

> We estimate that only one third of chronically ill patients adhere correctly to their regimens, one third are noncompliant because they adhere to a misunderstood regimen, and another one third are knowingly noncompliant. (p. xiii)

In this chapter an overview of the development and progression of Chronic Obstructive Pulmonary Disease (COPD) is presented as well as a summary of the complex treatment and medication regimens prescribed for these patients. Using the most current literature, factors associated with compliance are examined specifically as they relate to the chronically ill. A summary highlighting the overall problem of patient noncompliance concludes the chapter.

Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is a widely accepted term describing a functional category in which there is a chronic obstruction of bronchial airflow. Asthma, chronic bronchitis, and pulmonary emphysema are the primary disease states producing this condition; however bronchiectasis, pulmonary tuberculosis and silicosis may contribute alone or jointly to the development and progression of COPD (Miller & Keane, 1978).

COPD, the sixth leading cause of death in the United States, kills some 19.5 per 100,000 population annually (American Lung Association, 1978). Hospital admissions for exacerbations of COPD are surpassed only by those admitted for cardiovascular complaints (Miller & Keane, 1978). Thus, one can imagine the exorbitant health care costs incurred by having this disease.

Various factors have been related positively to the development and progression of COPD. The increase in the consumption of cigarettes parallels the rising mortality rates associated with COPD, and thus far data support a cause and effect relationship between smoking and this chronic illness. Other factors such as industrial pollution, allergens, genetic predispositions, and chronic infections have been implicated in the development of COPD (Streider, 1976).

The progression of COPD is insidious. By the time symptoms become evident irreparable lung damage already has occurred. Initially the victim experiences easy fatigua-bility, dypsnea on exertion, shortness of breath, and chronic mild cough. As the disease progresses, symptoms are more pronounced. Periods of severe exacerbations followed by remissions are not uncommon, and complications are frequent and numerous. Involvement of all respiratory structures and consequent impairment of all pulmonary circulatory function often lead to hypoxemia and the most severe complication, respiratory arrest (Streider, 1976).

Pathologically, COPD causes an irreversible change in the structure of the bronchi and bronchioles in the lung. Mucosa become swollen and mucus glands hypertrophy; hence the removal of mucus is hindered. The destruction of cilia is common and the blockage of airways occurs due to large

mucus plugs. Deep in the lung, the walls of the alveoli are broken down causing large nonfunctioning air spaces and the enlargement of surviving alveoli. A resultant loss of capillaries serving the alveoli decreases the diffusion of gases and the exchange of carbon dioxide and oxygen. Pulmonary circulation is affected, which in turn increases the workload of the right side of the heart. Lung elasticity also is impaired severely (Miller & Keane, 1978).

Diagnostically, the COPD patient may exhibit hyperinflation of the chest with audible ronchi, rales, and wheezes. Blood gas analysis may indicate the poor exchange of gases across the alveolar walls. Chest X rays and fluoroscopy usually confirm the diagnosis of COPD. Once the diagnosis is clear, a rigorous life-long treatment and medication regimen is prescribed (Miller & Keane, 1978).

Treatment Regimen for COPD

The treatment of COPD is primarily aimed at restoration, if possible, and maintenance of existing lung function. A time-consuming, complex daily treatment and/or medication regimen is prescribed routinely for each person. Relief of symptoms and the institution of rehabilitative planning result in improved health status.

Initially, each COPD patient is tested by using several physiological measurements. Pulmonary function

tests and blood gas determinants as well as exercise tolerance tests are a part of the patient assessment. All tests are repeated at varying prescribed intervals throughout each year in order to follow the progression of the disease. These tests can be exhausting and emotionally taxing for the patient, but their necessity cannot be ignored. Modifications in treatment and/or medications are based on test results and patient feedback (Division of Lung Diseases, 1979).

Changes affecting diet, exercise, and daily activities are required by the COPD patient as well as the daily treatment regimen using specific respiratory assistance machines. Additional extensive training to enhance breathing capacities is advocated and taught by most health care providers. A complex daily medication regimen requiring intense patient education and cooperation are necessary to reach the desired improved health status (Strieder, 1976).

In short, the COPD patient must lead a restricted and highly disciplined life. He or she must truly believe that the prescribed treatment and/or medication recommendations are beneficial in the improvement of his/her disease. Religious adherence to the complex therapy must become a part of everyday life.

The Problem of Patient Noncompliance

The gap between the therapy that is prescribed for the patient and the actual therapy which the patient self-administers is frequently vast. Unfortunately, health care professionals generally do not recognize the scope of the noncompliance problem (Cohen, 1979). Several studies, such as the one conducted by Caron and Roth (1968), demonstrated that physicians grossly overestimate patient compliance to therapy, and further, that no evidence was found that physicians were able to discriminate good from poor compliance. In Caron and Roth's study, 27 resident physicians estimated the compliance of patients with peptic ulcer disease to self-administered antacid therapy. Of the 27 physicians, 22 overestimated their patients' compliance; and when further tested, the physicians were unable to distinguish patients who were identified as complying on good, fair, or poor levels.

Even when noncompliance is recognized correctly, the traditional responses of members of the health care team have been inadequate. For instance, Davis (1966) found that 67% of physicians attributed noncompliance to the "uncooperative personality" of the patient, whereas only 26% perceived that the physician may have had some responsibility for patient nonadherence to the regimen. Of the

physicians interviewed by Davis, 40% believed that the patient's inability to understand recommendations was a major deterent to compliant behavior.

The problem of patient noncompliance is a complicated one, with the responsibility for its occurrence attributed in part to the actions of both the patient and the health care professionals. Whomever is to "blame," a feasible solution must be found or developed through research in order to make therapy effective.

It is the purpose of the following section to explore factors related to patient compliance in hopes that a more in-depth understanding of this phenomenon will lead to the identification of, and more appropriate management of, non-compliant health behavior.

Determinants of Patient Compliance to Therapeutic Regimen

Hundreds of investigations attempting to discover and understand the determinants associated with compliant health behavior have been instituted over the past 15 years. Several factors have been related, at least in part, to some aspect of patient compliance. However, no one factor or group of factors has been found to predict or explain this complex facet of human behavior. Herewith a discussion of relevant studies exemplifying one or more significant determinants of patient compliance is presented.

Knowledge

It seems logical to speculate that a reasonable explanation for patient noncompliance may be found in the misunderstanding of, or lack of knowledge about, various aspects of the prescribed therapeutic regimen. Unfortunately, data regarding patient knowledge and subsequent compliance are inconsistent and nondirectional. For example, Bergman and Werner (1963) studied a group of children placed on a 10-day course of penicillin to eradicate streptococcal infections. It was found that 90% of the children's families knew that the medication was penicillin, 80% possessed adequate knowledge of the diagnosis, and 95% correctly indicated directions for giving the drug. Despite this high degree of factual knowledge, only 45% of the children received their recommended dosage by the third day of the regimen. By the sixth day compliance had fallen to 30% and by the ninth day only 18% of those studied were receiving their medication. Werner and Bergman concluded: "We can only state that our patients did not stop taking the drug through ignorance" (p. 1338).

These results typify those found by Podell (1975) in his review of the compliance of hypertensive patients to a medical regimen. He stated:

> At least a dozen studies show a positive association between patient knowledge and compliance. On the

> other hand, at least two dozen studies show no such relationship. (p. 36)

Further demonstration of the skepticism exhibited in the above quote by Podell was obtained by Sackett, Haynes, Gibson, Taylor, Robert, and Johnson (1978) in a study of the role of increased patient knowledge and subsequent medication compliance. It was determined that patient knowledge at intake was not associated with medication compliance. In Sackett et al.'s (1978) research, a group that was given intense instruction showed more knowledge than the control group. The instructed subjects, however, demonstrated no higher level of compliance. On resolving this conflict in logic, Cohen (1979) offered:

> One approach to reconciling these seemingly conflicting results is to view knowledge about certain details of the regimen as essential for correct compliance, but also to recognize that such information is rarely sufficient to produce adequate patient cooperation; and to look at other variables that may be associated with communication of better information to the patient. (p. 3)

A study yielding credence to the first part of Cohen's statement was done by Tagliacozzo (1970). Compliance to follow-up visits by chronically ill outpatients was examined and disease knowledge was tested. The conclusion of the study was twofold: (1) for individuals who are motivated to comply, but suffer from ignorance, the provision of information may be beneficial; and (2) for those individuals who are knowledgeable, but not motivated to comply, the

provision of additional information about the medical regimen is unlikely to improve compliance.

Exploration of other factors which are related to the communication of information to patients was researched in 1973 by McKenney. Of 50 hypertension outpatients, 25 were given 30 minutes of medication instruction monthly by the pharmacist, in conjunction with their routine medical follow-up. During the period of study compliance rose by 54% in the instructed group. It was found, however, that six months after the end of the study period the compliance rate of the experimental group dropped to that of the pre-intervention level. It was suggested by McKenney that the surge in the compliance rates during the study was attributed to the motivating influence of the pharmacist's extra attention rather than the acquisition of additional knowledge.

From the numerous studies that have been conducted one may conclude that adequate knowledge of the medical regimen is necessary to insure correct compliance and subsequently to gain the desired improved health status. Instruction regarding those aspects of treatment that are imperative for the success of therapy must be clearly and emphatically conveyed to the patient so that those who are ignorant, yet motivated, will in fact benefit from the prescribed treatment or medication. In general, knowledge

alone does not guarantee compliance, however, when in conjunction with other positive factors such as motivation and increased patient awareness (discussed later), the level of adherence to therapy can be improved.

Demographic Characteristics

Easily identifiable demographic, social and personal characteristics such as age, sex, race, religion, ethnic group, occupation, income, and marital status have been studied with respect to patient compliance. The multiplicity of findings resulting from this research have been either not predictive of compliance or mutually contradictory. For instance, in Sackett and Haynes' (1976) annotated bibliography on patient compliance, a review of 192 investigations exploring various demographic characteristics indicated a total of 43 positive correlations between such variables and compliance, 4 studies with negative results, and 145 studies in which no significant relationship between the demography and compliance was obtained. The only factor consistently related to both noncompliance (and medication errors) was that of extremes of age. It has been speculated that this relationship was upheld because at one extreme, children refuse foul-tasting medications, and at the other extreme, the elderly are often victims of self-neglect or forgetfulness (Cohen, 1979).

Interestingly, personality and compliance were studied by Roth, Caron, and Hsi (1970) with no correlation obtained. This finding contradicts the results of the compliance study by Davis (1966) demonstrating that most physicians attribute noncompliance to the "uncooperative personality" of the patient.

It appears that noncompliance is a common problem among patients of all demographic, personality, and social types. Furthermore, one cannot generalize the results of the various studies because of the specificity of the therapies, populations studied, and research methodologies used. Several limitations need consideration when exploring the sociodemographic aspects of the compliance problem. First, even if one variable or characteristic is found to be related to compliance or noncompliance, it could not possibly account for the entire phenomenon. Second, due to the enduring quality of the demographic characteristics (i.e., sex, age, religion, and so forth), few opportunities for interventions to improve compliance are possible. Third, the positive correlations between certain characteristics and compliance do not account for those persons who may possess one or more adverse characteristics and still comply with therapy. And finally, these demographic variables alone do not present a unified explanation of differential compliance (Cohen, 1979).

While demography, social and personal characteristics should be included in an encompassing study of compliance, these factors can only aid in categorizing or identifying populations who may be at risk of not complying to therapy. More total research including a wide span of variables is necessary in order to get a true idea of the total patient and his/her potential compliant or noncompliant behaviors.

Motivational and Attitudinal Characteristics

The subjective perceptions of the individual and his subsequent adherence or nonadherence to therapeutic regimens has been scrutinized by several notable sociologists and psychologists (i.e., Kasl & Cobb, 1966; Kosa & Robertson, 1969; Suchman, 1970; Rosenstock, 1966). From their research, models to explain health behavior have been developed and used by the professional community with respect to predicting and managing patient compliance. Though each model offers a different approach, different orientation, or different set of concepts relative to compliance, only one, the Health Belief Model (Rosenstock, 1974; Appendix B), offers a unified, multifactorial approach toward analyzing the problem.

The Health Belief Model links together the demography, resources, and motivational and attitudinal characteristics

of the patient to formulate an accurate idea of the individual's utilization of health care services and/or therapies. Developmentally, the model's basic core dimensions have been derived from psychological and behavioral theory such as that of Lewin, Dembo, Festinger, and Sears (1944). The resultant value-expectancy approach as presented in the concepts of this model has been proven effective in predicting compliance in various types of studies with differing patient populations (Cohen, 1979). Thus, due to the versatility and encompassing nature of the Health Belief Model, it was used as the conceptual framework for this research and as a guide for organizing this behavioral section of the literature review. The following is an examination and discussion of pertinent studies regarding patient motivations and attitudes affecting subsequent patient compliance.

Patient Perceived Susceptibility

Many studies recently have shown positive correlations between a patient's subjective estimate of his/her vulnerability to illness and his/her compliance with prescribed regimen. Several screening programs such as those for cervical and breast cancer, tuberculosis, heart disease, and dental caries (Cohen, 1979) have comprised the bulk of this type of compliance research. Further research, however,

regarding vulnerability and medication compliance was conducted by Heinzelman (1962). The study examined resusceptibility after a diagnosis previously had been made. A group of college students with a history of rheumatic fever was given a long-term course of penicillin prophylactically. Those students who had higher subjective estimates of the possibility of disease recurrence proved to be more compliant. Similarly, studies by Elling, Whittemore, and Green (1960) and Becker, Drachman, and Kirscht (1972b) demonstrated higher compliance to clinic appointments by mothers who perceived their children more susceptible to recurrence of otitis media.

Research points to the idea that perceived susceptibility plays an important role in compliance with preventive and/or prophylactic therapy in varying types of patient populations. The belief that one, or one's child, is, in fact, capable of becoming a victim of disease or susceptible to a recurrence of a previously diagnosed condition, is supported by Rosenstock (1975) and elaborated upon as a component of the Health Belief Model. However, perceptions of susceptibility, in and of themselves, are not predictive of patient compliance to recommended therapy. Several other emotional and psychological factors have been implicated in the examination of adherence or nonadherence to self-administered health prescriptions.

Patient-Perceived Severity

Medical estimates of severity of illness do not predict accurately patient compliance (Davis, 1968). However, it has been shown that patient-perceived severity and preventive health behavior are positively related. In a study by Campbell (1971) preventive health measures were effectively employed by men with a high risk of developing heart disease. Their perceptions regarding the severity of the disease positively influenced their compliance to recommended diet, medication, and exercise regimens.

There has been no such positive correlation found between perceived severity and participation in disease screening programs. In fact, it has been hypothesized by Janis and Feshback (1953), Becker and Maiman (1975), and Leventhal (1965) that for asymptomatic individuals, very low levels of perceived severity are not sufficiently motivating, and very high levels are inhibiting or immobilizing. Both extremes are associated with a low likelihood of taking preventive (disease screening) health action.

Studies examining compliance to medications and patient-perceived severity of illness have consistently yielded positive correlative results (Becker, Radius, Rosenstock, Drachman, Schuberth, & Teets, 1978). Unlike preventive care, prescribed regimen suggests that the patient is either experiencing symptoms or has experienced

them in the past (as in the case of rheumatic fever prophylaxis). The presence, therefore, of symptoms may produce a realistic effect for the patient fortifying the perceptions of severity associated with the disease and thereby motivating him/her to comply to recommendations.

Perceptions of Benefits/Costs

Patients believing in the validity or benefit of the prescribed treatment have been shown to be more compliant to the regimen (Kirscht & Rosenstock, 1977). This positive relationship holds true for preventive health measures such as screening programs for cervical cancer, tuberculosis, and dental caries (Cohen, 1979). The examination of the actual belief of the patient regarding the benefits of the prescribed regimen is of the utmost importance when the efficacy of the therapy is in question. The consensus between the health care provider and the patient with respect to medication and/or treatment modalities is a necessary facet of the physician-patient relationship.

"Costs" associated with prescribed regimen such as side effects, monetary expense, and social inconvenience, have been negatively related to compliance. For instance, in a study by Rosenstock and Derryberry (1959) examining poliomyelitis vaccines, it was found that regardless of the level of patient concern, he or she would not obtain

the recommended innoculation if there were some question as to the vaccine's safety.

Generally speaking, the patient must perceive the benefits of the regimen as being significantly more substantial than the "costs." Maintenance of homeostasis is a primary goal of all human beings and the weighing of activities toward that goal is a natural predictable process.

Characteristics of the Regimen

Certain characteristics of the regimen have been consistent predictors of patient compliance. By and large, the duration of the therapy has been negatively related to compliance by several researchers (Bergman & Werner, 1963; Charney, 1967; Smith, 1976). Other factors such as cost, side effects, and the degree of behavioral change required by the patient, have been associated with lesser degrees of compliance. As Haynes (1976) stated:

> A steep gradient has been demonstrated in which compliance exhibited by patients who must acquire new habits, such as taking medication, is much greater than that exhibited by those who must alter old behaviors, such as dietary or vocational habits, which exceeds, in turn, that of those who must break personal habits, such as smoking or drinking, or nonmedical use of drugs. (p. 31)

This relationship to the degree of behavioral change required by the patient may be associated with the decrease

in compliance that accompanies increasingly more complicated prescribed therapies (Haynes, 1976).

In summary, the various characteristics of the regimen can affect patient compliance. Investigations suggest that regimens which require more intense behavioral changes reduce compliance, as do more complicated prescriptions and the continuation of therapy over time.

Patient-Provider Interaction

The relationship established between the patient and the health care provider can be a positive or a negative factor influencing compliance. Problems of communication with respect to specific aspects of therapy can confuse and undermine the best efforts of a compliant patient. Thus an optimal level of patient-provider interaction is imperative.

Several factors associated with the contemporary patient-physician relationship have been identified as negatively affecting compliance. Physician impersonality and the brevity of encounters consistently were identified in destroying the patient's will to adhere to prescribed therapy (Coe & Wessen, 1965). On the other hand, continuity of care, when good rapport is present, is positively related to compliance. For instance, if a satisfying relationship with one health care provider has been established, compliance increases with the continuation of care by that

individual (Becker, Drachman, & Kirscht, 1972a). Furthermore, it has been found that increased patient cooperation was obtained when outpatient visits were increased, home visits were added, and positive feedback regarding compliant behavior was expressed (Haynes, 1976).

The establishment and maintenance of a mutually expressive patient-provider relationship is an integral part of the total care of the patient and is necessary to enhance compliance (Becker et al., 1972a).

Summary

Research findings reviewed indicate an ever-growing problem with improper administration and/or nonadherence with prescribed treatment modalities. The realization of this problem, and the health professionals' ability to recognize its occurrence, has been a slow, but gradually developing process. The solution to the problem has not yet been found, however, several positive correlations have been identified with respect to compliance: (1) adequate patient knowledge of regimen; (2) patient perceptions of susceptibility or resusceptibility; (3) patient perceptions of severity of illness; (4) patient perception of benefits gleaned from therapy; and (5) effective patient-provider interaction. These factors work jointly or alone in influencing proper patient adherence to prescribed therapy.

On the other hand, various factors have been found to hinder the compliant behavior of patients, such as: (1) duration of regimen (i.e., those with chronic conditions); (2) complexity of treatment and/or medication prescriptions; (3) patient ignorance associated with actual self-administration of therapy; (4) extremes of age; (5) low patient perception of susceptibility to illness; (6) low patient perception of severity of illness; (7) "costs" or liabilities of therapy outweighing the benefits; and (8) poor patient-provider relationship. Once again these factors may work alone or conjointly in the determination of patient compliance.

Only partial answers to the perplexing problem of patient compliance have been elaborated upon in this review of the literature. Furthermore, no one particular study has produced a tool or mechanism with which to predict accurately patient compliance. Thus, research exploring various methodologies and instruments with which to gain a more complete understanding of this phenomenon seems in order.

CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

This retrospective, nonexperimental study was conducted to examine the relationship of patient-perceived disease severity and compliance. The sample was part of a larger study conducted by the Division of Lung Diseases (DLD) in five different areas of the United States.

Setting

The setting for this study was in the southwestern United States. The main headquarters for the overall DLD study were located in a metropolitan area which was easily accessible to a large medical center. Study participants were first seen in the DLD physician's office and pulmonary lab for the initial physiological tests. Monthly home visits by nurses and respiratory therapists followed the initial physician's assessment. At six months, each study participant returned to the office for re-evaluation.

Population and Sample

A convenience sample of the first 50 study participants who endured five months of home treatment in the DLD study was used for this research endeavor. This accessible

population was confined solely to the southwestern site of the overall DLD study. All study participants were adults.

Protection of Human Rights

Each participant, upon entering the DLD study, was required to sign an informed consent as stipulated by the then Department of Health, Education, and Welfare (Appendix D). The investigator obtained agency permission to examine the records of the DLD study from the chief researcher; no further approval was deemed necessary from Texas Woman's University Human Research Review Committee (Appendix D).

In order to protect the privacy of study participants, the investigator used assigned patient numbers to gather the data by computer. There was no direct stress imposed upon the study participants. Due to this fact, and since the anonymity of participants was preserved, the preexisting informed consent which allowed for investigator access to all records was believed to be adequate for purposes of this study.

Instruments

Two measurement instruments were used to obtain the data for this study. The Sickness Impact Profile (SIP) and the Engler Electric Time Meter provided ordinal and ratio data with which to perform the appropriate statistical

analysis. Each instrument and its utilization in this study is discussed in detail as follows.

The Sickness Impact Profile (SIP)

The SIP measures the magnitude of sickness in terms of dysfunction of behavior and/or performance of activities of daily living as perceived by the respondent. This test is a verbal interviewer-administered, scaled measure of 139 items. The items are grouped into 12 categories as follows: (1) Sleep and Rest, (2) Emotional Behavior, (3) Body Care and Movement, (4) Home Management, (5) Mobility, (6) Social Interaction, (7) Ambulation, (8) Alertness Behavior, (9) Communication, (10) Work, (11) Recreation and Pastime, and (12) Eating.

The participant is instructed by the interviewer to answer only those items that describe him/her presently and are related to his/her state of health. Scores are computed for each of the SIP categories and for the overall SIP. The following formula was used to obtain the total score for the SIP, or to calculate a subcategory score:

$$\frac{\text{Sum of scale values of items checked in a category or entire instrument}}{\text{Sum of scale values of all items in a category or entire instrument}} \times 100$$

Development and research of the SIP. Rationale for the initial development of the SIP was to obtain an

instrument that would indicate a measure of health status which could be used as an outcome measure in the evaluation of health care (Pollard, Bobbitt, Bergner, Martin, & Gilson, 1976). The source of SIP items, therefore, sought to incorporate both professional and lay perspectives into the content of the instrument. Over 1,000 statements which describe behavioral dysfunction were obtained from patients, health care professionals, individuals caring for patients, and the apparently healthy. From these sources, 1,250 specific statements of behavioral change were formulated. These statements were combined and condensed to yield 312 unique items, which were classified into categories representing one area of living or a type of activity (Bergner, 1976). These 12 categories are listed in the preceding section.

Three field trials have been conducted to study the feasibility, reliability, and validity of the SIP. Approximately 1,100 subjects in various states of health have completed the test. Following each field trial an item analysis and instrument revision were performed (USDHEW, 1978). The second revision of the SIP was used for this study.

SIP reliability and validity. A collection of test-retest reliability data were analyzed in conjunction

with the collection of data for SIP validation, item analysis, and feasibility assessment purposes. As part of a second field trial the SIP was administered to 119 subjects within 24 hours of the initial administration. The SIP test-retest reliability in terms of overall scores obtained on the two administrations for the total sample was r = .88. Test-retest reliability coefficient scores of the subcategories ranged from r = .90 to r = .62. Reliability tests conducted during a third field test produced comparable results (Gilson, Gilson, Bergner, Bobbitt, Kressel, Pollard, & Vesselago, 1975).

The validity of the SIP was explored by the utilization of three groups of criteria: those based on the subject's self-assessment of health status; those based on the health care professional's assessment of the subject's health status; and those based on the subject's score on another function assessment instrument, the Katz Activities of Daily Living Index. In general, self-assessment of sickness and dysfunction were related moderately to the overall SIP scores (r = .54). For outpatients with chronic illness, the correlation between self-assessment of dysfunction and clinician assessment of dysfunction was r = .52. The correlation between rank classification on the Katz Activities of Daily Living Index and the overall SIP scores was r = .46 (USDHEW, 1978).

These results reflect the fact that validation research is a study of the relationship among measures which is due primarily to the absence of a consensually accepted standard or criterion against which alternative measures can be validated. Also instrument reliability and validity are population specific and must be tested with each respective group. It is believed, however, that although an increase in the previously mentioned correlations is desirable, the results of the measurement relationships lend substantial internal criterion-related validity to the instrument.

Engler Electric Time Meters

The Engler electric time meters were located on the back exterior of either the IPPB or CN machines. The meters measure time in minute increments, and were activated when the machine was in operation. Accurate reliability data for the time meters were not available, however this was not viewed as a great concern with respect to the overall outcome of the study. The meters were checked for time accuracy by DLD researchers when they were initially placed in the participant's home. Monthly machine function testing was conducted during each home visit. Study participants were instructed to note the timing on the meter with each breathing treatment.

Data Collection

The data for this study were collected by computer from the existing files of the DLD study. Participants had at least five months of in-home IPPB or CN therapy evaluations available at the time of the data collection. The initial SIP scores, as well as subcategory scores, were recorded. The metered time readings from the IPPB and CN machines were taken from the home visit evaluation data after completion of the five-month home therapy program. Each participant's identification number, age, and sex also were noted.

Treatment of Data

The convenience sample of this study was addressed through the use of frequency counts, percentages, and mean calculations. The data were treated statistically using the following procedures:

1. The Spearman rank order correlation was applied in relation to the total SIP score vs. machine time-use and to the scores for each subcategory of the SIP vs. machine time-use.
2. The Pearson product-moment correlation was applied to the relationship of age vs. machine time-use.
3. Point biserial correlation was applied to the relationship of sex vs. machine time-use.

4. Multiple regression and discriminant function analyses were performed upon the scores of the subcategories of the SIP to explore the relationship of subcategory topics to machine time-use.

Visual representation of the data was fully determined after statistical procedures and analyses were completed. A table displaying a correlation matrix has been included in the final presentation of the data (Appendix E).

Summary

Patient noncompliance is manifested in a variety of behavioral patterns. The importance of accurate measurement and statistical analyses of data related to compliance can not be understated. This chapter examined the characteristics of the setting, sample, and measurement instruments used to conduct this study. Methods of collection and treatment of the data have also been presented.

CHAPTER 4

ANALYSIS OF DATA

This nonexperimental, retrospective study was conducted to explore the relationship between COPD outpatients' scores on a psychological test, the Sickness Impact Profile (SIP), and their subsequent compliance to an in-home therapy regimen. Data were collected from the charts of 50 patients over a six-month period. This chapter concerns the presentation and analysis of the data obtained from the sample.

Description of the Sample

The sample for this study was selected from the accessible population of a concurrently-conducted National Institute of Health, Division of Lung Diseases (DLD) study of COPD outpatients. Each participant met the preexisting inclusion criteria as stipulated by the DLD (Appendix C).

The participants initially were evaluated at a southwestern medical center by a team of pulmonary physicians, and at that time the SIP was administered. After one month of "stabilization" (Appendix C), each participant was given either an IPPB or CN respiratory machine for a prescribed home treatment regimen. Monthly home visits by DLD personnel were conducted to monitor patient progress and

to check machine accuracy. After a five month period, metered treatment time measurements were recorded. The first 50 participants completing this five months of home therapy comprised the sample for this study.

Male participants totaled 36 (72%); females 14 (28%). The mean age was 62 years with a range of 49 to 76 years. No other demographic variables were examined in this study.

Findings

This research endeavor was employed to test the following hypotheses:

H_1: There is a significant positive relationship between individual study participants' compliance (average daily machine-measured treatment readings) and the study participants' perception of disease severity (total SIP scores).

H_2: There is a significant relationship between age and compliance.

H_3: There is a significant relationship between sex and compliance.

H_4: There is a significant relationship between each SIP subcategory score and compliance.

The findings related to these hypotheses are presented herewith. With respect to the first hypothesis (H_1), the Spearman rank order correlation was computed from the total

SIP scores and the average daily treatment times (converted to ranks). A correction for ties was implemented by the computer. The correlation coefficient obtained was r_s = .0014. This result is nonsignificant (t = .01; df = 48; p = .496).

For the second hypothesis (H_2) the Pearson product moment correlation calculation yielded a significant value of r = .3074 (t = 2.24; df = 48; p = .03). Despite this notable level of correlation, the relationship accounts for only 10% of the total variance possible for this relationship. Hence, the usefulness of the results is doubtful.

A point-biserial correlation was used to test the third hypothesis (H_3) concerning the relationship of sex and machine time-use. A nonsignificant correlation coefficient of r = -.12 was obtained (t = .81; df = 48; p = .25). It should be noted that mean daily time use for women was 20.39 minutes while the mean for men was 23.68 minutes. Interestingly, both means met the prescribed treatment time of 20 minutes per day; however, of the 50 participants only 26 (52%) were compliant to this regimen.

A multiple regression analysis was performed using SIP subcategory scores as independent variables and average daily time use readings as the dependent variable. Examination of the data indicated that only the first four subcategories entering the regression analysis (social

interest, emotional behavior, alertness, and home management) were significant in the formulation of an equation to predict machine time-use ($F = 5.05$; $df = 45$; $p = .01$). While introduction of additional subcategory scores maintained a significant F ratio, the variance accounted for was not significant. The resultant regression equation was found to be:

$$Y_1 = -.7028(X_1) + .6115(X_2) + .3548(X_3) - .2572(X_4) + .2638$$

Where Y_1 = predicted average daily machine time-use

X_1 = social interest subcategory score

X_2 = emotional behavior subcategory score

X_3 = alertness subcategory score

X_4 = home management subcategory score

The correlation matrix used in the regression analysis is presented in Appendix E.

To further examine the predictability of SIP data with respect to machine time-use, a discriminant analysis was obtained. The participants were divided into two groups according to their average daily machine time-use. Those participants averaging at least 20 minutes of machine use per day were considered the compliant group. Those with an average daily machine time of less than 20 minutes were grouped as noncompliant. Initial institution of the discriminant analysis involved all 12 subcategories, resulting

in a 78% correct classification of participants (79.2% noncompliant; 76.9% compliant). It was found that four subcategories in this initial discriminant analysis were most influential in terms of classifying the participants into the two groups. Consequently, a second discriminant analysis was implemented using these subcategories (social interest, emotional behavior, alertness, and body care). It was determined that using these subcategories alone yielded a correct classification rate of 76%--a minimal loss of predictive power (70.8% noncompliant; 80.8% compliant).

A final discriminant analysis was implemented using the two variables with the highest F-ratio (emotional behavior and social interest). A slight drop in correct classification resulted with 74% of all participants properly grouped (70.8% noncompliant; 76.9% compliant). The final two discriminant function coefficients were used to define a discriminant score equation for predicting noncompliance:

$$Z = .0806(X_1) - .0735(X_2) - .1057$$

Where Z = discriminant score

X_1 = social interest subcategory score

X_2 = emotional behavior subcategory score

when Z = subject identified as compliant.

These discriminant score values are compared to a criterion point which defines the boundary between compliance and

noncompliance. It should be noted that neither the discriminant scores nor the criterion point score is measured in terms of machine time-use. Rather, they are artificial constructions of the computer used to identify the predicted group membership.

The subsequent correct group classifications yielded from the discriminant analyses are a measure of the internal consistency of the statistical procedure--that is, the ability of the equation to correctly classify the identical data points used to define the equation. No further statistical analysis of the data was instituted.

Summary of Findings

The study explored the relationship of COPD outpatients' scores on the Sickness Impact Profile and their subsequent compliance or noncompliance to prescribed home therapy regimen. The study was employed in view of the prevalence of COPD and the integral part patient compliance plays in the long term progress of the disease. The sample of 50 participants was chosen from the on-going DLD study described earlier.

Compliance was determined by meeting the prescribed treatment regimen of 20 minutes per day of use on either the IPPB of CN respiratory machines. The average daily time-use

was compared to the SIP which was taken upon initial inclusion into the larger DLD study.

Demographic data are as follows. The sample (n = 50) consisted of 36 (72%) males and 14 (28%) females. The mean age was 62 years. No other demographic data were obtained.

The score on the SIP was interpreted as an indication of the impact of sickness as perceived by the respondent. A higher SIP score reflected a greater perception of illness impact. The lowest total SIP score was .54, while the highest score was 42.65.

The average daily machine time-use was calculated over a period of five months. The mean for the entire sample was 23.53 minutes per day (mean for men 23.68 minutes per day; mean for women 20.39 minutes per day).

Statistically, hypothesis one (H_1) was tested by using the Spearman rank correlation. No significant result was obtained for the total SIP score (independent variable) and machine time-use (dependent variable).

Hypothesis two (H_2), regarding the relationship between age and machine time-use, was examined by employing the Pearson product moment correlation. The resultant correlation coefficient was r = .3074, which was significant at p = .03.

The third hypothesis (H_3), examining the relationship of sex to average daily machine time-use, was scrutinized using the point biserial analysis. No significance was found in relating these two variables.

Finally, the fourth hypothesis (H_4), regarding the relationship of SIP subcategory scores and machine time-use, was examined using a multiple regression analysis. A multiple regression equation was developed to predict time-use. The most significant subcategories were used in the multiple regression equation (social interest, emotional behavior, home management, and alertness).

Subsequently, a discriminant function analysis was performed to further explore the predictability of the SIP subcategory scores with respect to machine time-use. Initially, all 12 subcategories were employed in the discriminant analysis yielding a 78% correct classification rate for the total sample (79.2% noncompliant; 76.9% compliant). A second discriminant analysis was performed using the four most significant subcategories (emotional behavior, social interest, body care, and alertness behavior) with a 76% correct grouping of sample participants. Finally, the two most significant subcategories (social interest and emotional behavior) identified in the previous discriminant analyses were used in the final discriminant function. A

correct sample classification rate of 74% was obtained. No further statistical analyses were performed for this study.

CHAPTER 5

SUMMARY OF THE STUDY

Compliance with prescribed therapeutic regimens is one of the most complex problems affecting the optimal institution of health care delivery. The problem encompasses all age groups, social classes, races, and types of diseases. Compliance can be even more multi-faceted when examining the plight of the chronically ill. Tedious therapeutic regimens, patient-physician interaction, and patient expectations and perceptions all may influence the extent of compliant health behavior.

The purpose of this study was to explore the relationship between a psychological test, the Sickness Impact Profile (SIP), administered to chronically ill outpatients and their subsequent compliance to an in-home therapy regimen. It was asserted that a predictive tool of compliance could be determined from this data.

Summary

A convenience sample of the first 50 outpatients completing five months of an in-home therapeutic regimen using either IPPB and CN respiratory machines was selected from the accessible population of a larger, ongoing NIH study.

Initially, demographic data, total SIP scores and SIP subcategory scores were collected. After five months of home therapy machine-measured treatment time-use calculations were recorded. Measurement of the total SIP and SIP subcategories was given in score values (ordinal data) while time and age values were considered interval data. Research results are as follows:

1. The Spearman rank order correlation was used to relate total SIP scores to the average daily machine time-use of the participants (H_1). The relationship was not found to be significant, therefore H_1 was rejected.
2. A Pearson product-moment correlation was applied to the relationship of age vs. machine time use (H_2). A significantly positive correlation coefficient of $\underline{r} = .3074$ was obtained, therefore H_2 cannot be rejected.
3. The third hypothesis examined the relationship of sex vs. machine time-use, as tested by using a point biserial analysis. No significant relationship was found, therefore H_3 was rejected.
4. A multiple regression analysis was employed to examine the predictive capabilities of the SIP subcategory scores. Four variables (emotional behavior, social interest, alertness behavior, and home management) were found to be most significant in the definition of a regression equation, therefore supporting H_4. Of these,

social interest and home management were inversely related to machine time-use.

5. A discriminant analysis of the data was performed to classify the participants into compliant (time use > 20 minutes/day) or noncompliant (time use < 20 minutes/day) groups. All 12 subcategories were used initially followed by discriminant analyses of the four most significant and the two most significant subcategories. The two subcategory (social interest and emotional behavior) analysis showed a positive relationship between emotional behavior and machine time use and an inverse relationship between social interest and machine time use.

From the data obtained in the final discriminant analysis using the two subcategories it was possible to predict group membership (compliant or noncompliant) correctly for 74% of the sample.

Discussion of Findings

The discussion of various interpretations and the logical rationale regarding research results is an integral part of the research process. Careful examination of the data with critical exploration of relationships (or lack of relationships) as well as tentative explanations for those findings, adds research credibility to the overall study

conclusions (Polit & Hungler, 1978). This section offers a discussion of findings organized according to the initial research hypotheses.

With respect to the first hypothesis, examining the relationship of the total SIP scores and average daily machine time-use, a nonsignificant result was obtained. It is speculated that this lack of correlative power between these two variables is due to the fact that the total SIP score was considered as one variable. As was discussed in Chapter 3, the SIP was developed from a multifactorial analysis of several types of psychological, emotional, and physiological statements. It is, therefore, believed that the "clumping" of all subcategory scores, i.e., the total SIP score, does not yield a correct indication of the meaning of the data. It is possible to score highly on the physiological aspects of the SIP, while the emotional or psychological aspects may show little if any illness impact. The composite of all subcategory scores could yield a high or low total SIP, depending on the average of those scores. Hence, it is believed that it is more appropriate to relate time-use to each subcategory score, as was done in the subsequent multiple regression and discriminant function analyses.

The second hypothesis, exploring the relationship of age and daily machine time-use, yielded a significantly

positive correlation coefficient of r = .3074. It should be noted that this result is not in concurrence with research cited earlier. In Cohen's (1979) review of compliance, it was found that several studies related noncompliance with extremes of age. Reasons for these findings, particularly with respect to the elderly, include incapability to perform tasks of self-care and forgetfulness. These problems are recognized as limitations regarding the abilities of the sample, however their significance is diminished due to the fact that the inclusion criteria for the study require alert, independent individuals capable of instituting self-treatment regimens. It is therefore asserted that:

1. Perhaps older people fear death and are, therefore, more compliant.
2. Older people may be more familiar or comfortable with physicians; and, a more secure patient-physician relationship encourages compliant behavior (Becker, Drachman, & Kirscht, 1972).
3. Older people may be more aware of illness factors through greater experience, general knowledge, and social conversation, leading to more compliant health behavior.

Whatever the cause, the age range of this study (49 years to 76 years) does not explore the plight of those who are

young and chronically ill. It would be an error to generalize these results to those young persons with Cystic Fibrosis, for example. Also, in this study, age accounts for only 10% of the total variance of the sample, further limiting the ability of this variable in predicting compliant machine time-use.

The third hypothesis examined the relationship of sex vs. machine time-use. The point biserial analysis yielded nonsignificant results. This finding is supported in the literature by Cohen (1979). It should be noted that this test was primarily instituted to fortify the results related to the SIP, in that no significant relationship between sex and time use was expected. However, it was found that men had a higher mean machine time-use than women, and the means of both sexes met the prescribed 20 minutes per day of therapeutic regimen.

The fourth hypothesis examined the predictive capabilities (regarding machine time-use) of the SIP sub-category scores. Four subcategories were most significantly related to machine time-use. Social interest and home management were inversely related to machine time-use, and since previous research has not directly explored these specific relationships, the speculation of this investigation is presented herewith.

Logically, it seems that the more social interest and activity that a person is able to maintain, the less he may use his treatment machine. He may have less time for treatments or his perception of the severity of the illness may be very low. Likewise, the activities associated with home management would require time and a less severe perception of illness in order to carry them out; therefore, less time and less perceived need for the prescribed treatment may contribute to this inverse relationship. These interpretations are consistent with the concepts set forth in the health belief model (Rosenstock, 1975).

Emotional behavior and alertness were positively related to machine time-use. This result is reasonable in that those independently participating in treatment must be alert and be emotionally intact during their daily therapy. Also, they must feel emotionally affected by the illness to believe they are gaining support from the use of the respiratory treatment machine. This rationale is supported also in the Health Belief Model by relating patient perceptions regarding the "benefits" of treatment as well as disease "severity" (Rosenstock, 1975).

The regression equation defined including the four subcategories above accounted for only 30% of the total

variance. The remaining 70% appears to be error variance and therefore predicting time use is not practical.

Finally, a discriminant analysis of the data was performed to classify the participants into compliant (time use > 20 minutes/day) or noncompliant (time use < 20 minutes/day) groups. All 12 subcategories were used initially followed by discriminant analyses of the four most significant and the two most significant subcategories. The two-subcategory (social interest and emotional behavior) analysis showed a positive relationship between emotional behavior and machine time use and an inverse relationship between social interest and machine time use. The rationale presumed for these relationships remains as previously stated: (1) those who are socially active may have less time and less perceived need for adherence to the treatment prescription, and (2) those who are greatly affected emotionally by their illness (more perceived severity) will use their machines more compliantly.

From the data obtained in the final discriminant analysis using the two subcategories it was possible to predict group membership correctly for 74% of the sample. It is believed that by using the subsequent discriminant equation a reliable tool for predicting compliance has been developed for this particular sample. Generalizability of all results obtained from the data is limited to the

boundaries associated with this convenience sample, i.e., the constraints noted in the inclusion criteria for the participants as well as the small number (50) that were examined.

Conclusions and Implications

Based on the findings and the limitations of this study, the following conclusions and implications are presented:

1. There is no significant relationship between total SIP scores and machine time-use, therefore the total SIP score is not useful as a predictive tool of compliance.
2. Slightly over one-half (52%) of all the study participants are compliant to the prescribed regimen.
3. Sex is not related to machine time-use, and is therefore irrelevant in the examination of compliant behavior.
4. Age is related to machine time-use, however it accounts for only 10% of the total variance. While age is an important variable to examine when determining compliance, it cannot stand alone as a predictor of compliance.
5. Compliant behavior is predicted with a 74-78% accuracy using selected subcategory scores of the SIP:
    a. There is a positive relationship between emotional behavior and compliance.

b. There is a negative relationship between social interest and compliance.

The effective use of these subcategory scores can provide a predictive tool for identifying compliant patients.

Recommendations for Further Study

The following recommendations for further research endeavors are suggested:

1. Studies should be conducted that detail and compare the expectations of patients and caregivers with respect to progress or benefits resulting from adherence to prescribed therapy.
2. Studies should be carried out to perfect the use of various psychological tests such as the Sickness Illness Profile (SIP) as indicators, partially or in total, of patient compliant behavior.
3. There should be further investigation of the characteristics associated with compliant and noncompliant behaviors to aid in further definition of this problem.
4. Replication of this study should be accomplished with the same accessible population but with a different sample in order to examine the external consistency of the statistical analysis developed, such as the discriminant functions equation for predicting compliance.

5. A comparative study should be conducted using acutely ill patients in order to determine differences in compliance between short term and chronic illnesses.
6. A similar study should be conducted initiating psychological testing and therapeutic regimen on an inpatient basis and progressing to outpatient followup to give more generalizability to the data.
7. Long-range studies using repeated administrations of the SIP at varying intervals and subsequent analyses of compliance to the prescribed regimen to examine compliance trends or changes should be conducted.

APPENDIX A

SICKNESS IMPACT PROFILE

SICKNESS IMPACT PROFILE*

Clinical Study of IPPB

Form 7 3 0 0 1-4

Date administered Mo Day Yr 5-10

A. PATIENT IDENTIFICATION

1. Treatment center number 11
2. Patient number 12-15
3. Date of birth Mo Day Yr 16-21
4. Month number (0-36) 22-23

B. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I spend much of the day lying down in order to rest.	1	2	3	30
2. I sit during much of the day.	1	2	3	31
3. I am sleeping or dozing most of the time - day and night.	1	2	3	32
4. I lie down more often during the day in order to rest.	1	2	3	33
5. I sit around half-asleep.	1	2	3	34
6. I sleep less at night, for example, wake up too early, don't fall asleep for a long time, awaken frequently.	1	2	3	35
7. I sleep or nap more during the day.	1	2	3	36

C. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I say how bad or useless I am, for example, that I am a burden on others.	1	2	3	37
2. I laugh or cry suddenly.	1	2	3	38
3. I often moan and groan in pain or discomfort.	1	2	3	39
4. I have attempted suicide.	1	2	3	40
5. I act nervous or restless.	1	2	3	41
6. I keep rubbing or holding areas of my body that hurt or are uncomfortable.	1	2	3	42
7. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen.	1	2	3	43
8. I talk about the future in a hopeless way.	1	2	3	44
9. I get sudden frights.	1	2	3	45

Read the 'Instructions to the Respondent' to the subject before starting the questionnaire. Check YES if the subject is sure that the item describes him, NO if he is not, and UNK if the subject cannot understand an item or refuses to consider it.

Patient #_____

D. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I make difficult moves with help, for example, getting into or out of cars, bathtubs.	1	2	3	46
2. I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid.	1	2	3	47
3. I stand only for short periods of time.	1	2	3	48
4. I do not maintain balance.	1	2	3	49
5. I move my hands or fingers with some limitation or difficulty.	1	2	3	50
6. I stand up only with someone's help.	1	2	3	51
7. I kneel, stoop, or bend down only by holding on to something.	1	2	3	52
8. I am in a restricted position all the time.	1	2	3	53
9. I am very clumsy in body movements.	1	2	3	54
10. I get in and out of bed or chairs by grasping something for support or using a cane or walker.	1	2	3	55
11. I stay lying down most of the time.	1	2	3	56
12. I change position frequently.	1	2	3	57
13. I hold on to something to move myself around in bed.	1	2	3	58
14. I do not bathe myself completely, for example, require assistance with bathing.	1	2	3	59
15. I do not bathe myself at all, but am bathed by someone else.	1	2	3	60
16. I use bedpan with assistance.	1	2	3	61
17. I have trouble getting shoes, socks, or stockings on.	1	2	3	62
18. I do not have control of my bladder.	1	2	3	63
19. I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces	1	2	3	64
20. I spend most of the time partly undressed or in pajamas.	1	2	3	65
21. I do not have control of my bowels.	1	2	2	66
22. I dress myself, but do so very slowly.	1	2	2	67
23. I get dressed only with someone's help.	1	2	2	68

E. THIS GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO IN CARING FOR YOUR HOME OR YARD. CONSIDERING JUST THOSE THINGS THAT YOU DO, PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I do work around the house only for short periods of time or rest often.	1	2	3	69
2. I am doing less of the regular daily work around the house than I would usually do.	1	2	3	70
3. I am not doing any of the regular daily work around the house that I would usually do.	1	2	3	71
4. I am not doing any of the maintenance or repair work that I would usually do in my home or yard.	1	2	3	72

Patient #_____

	NO	YES	UNK	
5. I am not doing <u>any</u> of the shopping that I would usually do.	1	2	3	73
6. I am not doing <u>any</u> of the house cleaning that I would usually do.	1	2	3	74
7. I have difficulty doing handwork, for example, turning faucets, using kitchen gadgets, sewing, carpentry.	1	2	3	75
8. I am not doing <u>any</u> of the clothes washing that I would usually do.	1	2	3	76
9. I am not doing heavy work around the house.	1	2	3	77
10. I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget.	1	2	3	78

F. PLEASE RESPOND TO <u>ONLY</u> THOSE STATEMENTS THAT YOU ARE <u>SURE</u> DESCRIBE YOU TODAY <u>AND</u> ARE RELATED TO YOUR STATE OF <u>HEALTH</u>.

	NO	YES	UNK	
1. I am getting around only within one building.	1	2	2	79
2. I stay within one room.	1	2	2	80
3. I am staying in bed more.	1	2	2	81
4. I am staying in bed most of the time.	1	2	1	82
5. I am not now using public transportation.	1	1	1	83
6. I stay home most of the time.	1	2	2	84
7. I am only going to places with restrooms nearby.	1	1	1	85
8. I am not going into town.	1	2	1	86
9. I stay away from home only for brief periods of time.	1	1	1	87
10. I do not get around in the dark or in unlit places without someone's help.	1	2	1	88

G. PLEASE RESPOND TO <u>ONLY</u> THOSE STATEMENTS THAT YOU ARE <u>SURE</u> DESCRIBE YOU TODAY <u>AND</u> ARE RELATED TO YOUR STATE OF <u>HEALTH</u>.

	NO	YES	UNK	
1. I am going out less to visit people.	1	1	1	89
2. I am not going out to visit people at all.	1	1	1	90
3. I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help.	1	1	1	91
4. I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily.	1	2	1	92
5. I show less affection.	1	1	1	93
6. I am doing fewer social activities with groups of people.	1	2	1	94
7. I am cutting down the length of visits with friends.	1	2	1	95
8. I am avoiding social visits from others.	1	1	1	96
9. My sexual activity is decreased.	1	1	1	97
10. I often express concern over what might be happening to my health.	1	2	1	98
11. I talk less with those around me.	1	2	1	99

Patient #_____

	NO	YES	UNK	
12. I make many demands, for example, insist that people do things for me, tell them how to do things.	1	2	3	100
13. I stay alone much of the time.	1	2	3	101
14. I act disagreeable to family members, for example, I act spiteful, I am stubborn.	1	2	3	102
15. I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them.	1	2	3	103
16. I isolate myself as much as I can from the rest of the family.	1	2	3	104
17. I am paying less attention to the children.	1	2	3	105
18. I refuse contact with family members, for example, turn away from them.	1	3	3	106
19. I am not doing the things I usually do to take care of my children or family.	1	2	3	107
20. I am not joking with family members as I usually do.	1	3	3	108

H. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I walk shorter distances or stop to rest often.	1	2	3	109
2. I do not walk up or down hills.	1	1	3	110
3. I use stairs only with mechanical support, for example, handrail, cane, crutches.	1	1	3	111
4. I walk up or down stairs only with assistance from someone else.	1	2	3	112
5. I get around in a wheelchair.	1	2	3	113
6. I do not walk at all.	1	2	3	114
7. I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg.	1	2	3	115
8. I walk only with help from someone.	1	2	1	116
9. I go up or down stairs more slowly, for example, one step at a time, stop often.	1	2	3	117
10. I do not use stairs at all.	1	2	3	118
11. I get around only by using a walker, crutches, cane, walls, or furniture.	1	2	3	119
12. I walk more slowly.	1	2	3	120

I. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I am confused and start several actions at a time.	1	2	3	121
2. I have more minor accidents, for example, drop things, trip and fall, bump into things.	1	2	1	122
3. I react slowly to things that are said or done.	1	2	3	123
4. I do not finish things I start.	1	2	3	124
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	1	2	3	125

Patient #_____

	NO	YES	UNK	
6. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is.	1	2	3	126
7. I forget a lot, for example, things that happened recently, where I put things, appointments.	1	2	3	127
8. I do not keep my attention on any activity for long.	1	2	3	128
9. I make more mistakes than usual.	1	2	3	129
10. I have difficulty doing activities involving concentration and thinking.	1	2	3	130

J. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I am having trouble writing or typing.	1	2	3	131
2. I communicate mostly by gestures, for example, moving head, pointing, sign language.	1	2	3	132
3. My speech is understood only by a few people who know me well.	1	2	3	133
4. I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly.	1	2	3	134
5. I don't write except to sign my name.	1	2	3	135
6. I carry on a conversation only when very close to the other person or looking at him.	1	2	3	136
7. I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words.	1	2	3	137
8. I am understood with difficulty.	1	2	3	138
9. I do not speak clearly when I am under stress.	1	2	3	139

K. THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN MANAGING YOUR HOME. BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS.

	NO	YES	
1. Do you usually do work other than managing your home?	1	2	140
If YES, SKIP to Section L.			
If NO:			
2. Are you retired?	1	1	141
3. If you are retired, was your retirement related to your health?	1	2	142
4. If you are not retired, but are not working is this related to your health?	1	2	143
SKIP to Section M.			

L. NOW CONSIDER THE WORK YOU DO AND RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH. (IF TODAY IS A SATURDAY OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)

	NO	YES	UNK	
1. I am not working at all (If you checked YES to this statement, SKIP to the next Section.)	1	2	3	144
2. I am doing part of my job at home.	1	2	3	145
3. I am not accomplishing as much as usual at work.	1	2	3	146

Patient #_____

	NO	YES	UNK	
4. I often act irritable toward my work associates, for example, snap at them, give sharp answers, criticize easily.	1	2	3	147
5. I am working shorter hours.	1	2	3	148
6. I am doing only light work.	1	2	3	149
7. I work only for short periods of time or take frequent rests.	1	2	3	150
8. I am working at my usual job but with some changes, for example, using different tools or special aids, trading some tasks with other workers.	1	2	3	151
9. I do not do my job as carefully and accurately as usual.	1	2	3	152

M. THIS GROUP OF STATEMENTS HAS TO DO WITH ACTIVITIES YOU USUALLY DO IN YOUR FREE TIME. THESE ACTIVITIES ARE THINGS THAT YOU MIGHT DO FOR RELAXATION, TO PASS THE TIME, OR FOR ENTERTAINMENT. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

	NO	YES	UNK	
1. I do my hobbies and recreation for shorter periods of time.	1	2	3	153
2. I am going out for entertainment less often.	1	2	3	154
3. I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading.	1	2	3	155
4. I am not doing any of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading.	1	2	3	156
5. I am doing more inactive pastimes in place of my other usual activities.	1	2	3	157
6. I am doing fewer community activities.	1	2	3	158
7. I am cutting down on some of my usual physical recreation or activities.	1	2	3	159
8. I am not doing any of my usual physical recreation or activities.	1	2	3	160

N. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

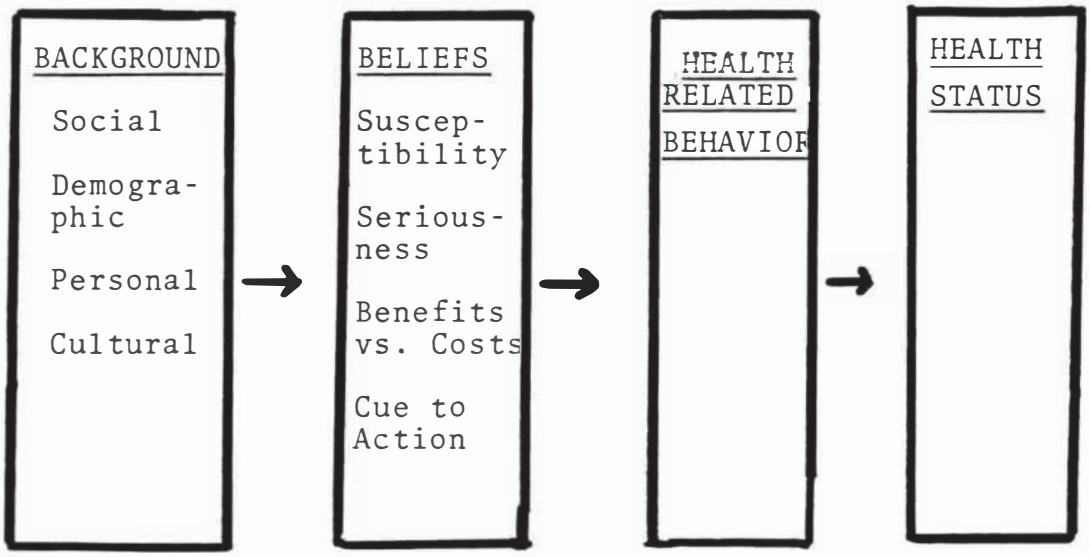
	NO	YES	UNK	
1. I am eating much less than usual.	1	2	3	161
2. I feed myself but only by using specially prepared food or utensils.	1	2	3	162
3. I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar.	1	2	3	163
4. I eat no food at all but am taking fluids.	1	2	3	164
5. I just pick or nibble at my food.	1	2	3	165
6. I am drinking less fluids.	1	2	3	166
7. I feed myself with help from someone else.	1	2	3	167
8. I do not feed myself at all, but must be fed.	1	2	3	168
9. I am eating no food at all, nutrition is taken through tubes or intravenous fluids.	1	2	3	169

O. Person responsible for the information recorded on this form:

_____ Date _____

APPENDIX B

HEALTH BELIEF MODEL/THEORY



Health Belief Model. Adapted from Rosenstock (1966) by Bauman. Research Methods for Community Health and Welfare 1980 (p. 12).

APPENDIX C

DIVISION OF LUNG DISEASES INCLUSION CRITERIA

DIVISION OF LUNG DISEASES INCLUSION CRITERIA

A. Patient Selection

All patients who have symptomatic COPD (including at least one of the following: chronic cough, sputum production, or dyspnea) and who are referred to one of the clinical centers will be reviewed for admission to the study. Patients who meet entry criteria (a - d below) will be considered eligible for the stabilization phase of the study (Section B). After the completion of the stabilization phase, allpatients who satisfy all entry criteria and have none of the exclusion criteria (Section A-2) will be entered into the study.

1. Entry Criteria

a. All patients must have a clinical diagnosis of COPD upon entrance into the DLD study.

b. All patients must be 30 - 74 years of age upon entrance into the DLD study.

c. All patients must have an initial prebronchodilator $FEV_{1.0}$ of less than 60% predicted and a prebronchodilator $FEV_{1.0}$/FVC ratio less than 60%.

d. All patients must be capable and willing to participate in the clinical study, and:

1) be ambulatory and capable of sitting and pedaling a bicycle ergometer;

2) live close enough to the medical center to be accessible for home and clinic visits;

3) provide informed consent.

e. All patients must have completed a 30-day stabilization phase on the standard regimen.

f. All patients must satisfy the following pulmonary function measurements twice, not less than one week or more than 90 days apart, while on the standard regimen:

1) The prebronchodilator $FEV_{1.0}$ is less than 60% predicted and the prebronchodilator $FEV_{1.0}$/FVC is less than 60%.

2) the $FEV_{1.0}$ must be reproducible; that is agree within .2 liter or 15%, whichever is greater.

g. All patients must demonstrate reliability during the stabilization period. Reliability will be established by adherence to the treatment program regimen (as documented by pill counts and maintenance of appointments for baseline evaluation purposes.

2. Exclusion Criteria

The presence of any one of the following characteristics before or during the stabilization period will exclude a patient who otherwise meets the DLD study requirements:

a. In response to 150 micrograms of inhaled isoproterenol, the FEV_1 increases to 80% or more of the predicted value or the FEV_1/FVC increases to 75% or more.

b. There is radiologic evidence of significant complicating lung disease.

c. The total lung capacity is less than 80% of the predicted value.

d. There are other illnesses that could be expected to alter the quality or duration of life. A list of examples follows which was in no way intended to be exhaustive.

1) malignant neoplasms (excluding basal cell carcinoma);

2) cardiac disease defined by cardiomegaly (cardiothoracic ratio greater than 0.5), angina pectoris, clinical or electrodardiographic evidence of myocardial infarction;

3) serum creatinine of more than 1.8 mg/dl;

4) significant neuromuscular dysfunction including evidence of cerebrovascular accident;

5) evidence of active liver disease;

6) insulin dependent diabetes.

e. The patient must not have been taking either propranolol or cromolyn sodium during the 30 days of stabilization.

f. The patient cannot have used home IPPB or compressor nebulizer during the 30 days of stabilization. In addition, such devices cannot have been used for more than 30 continuous days in the 6 months prior to identification.

g. The patients can neither have used home oxygen supplementation during the 30 days of stabilization or used such treatment for more than 12 hours a day for 30 continuous days in the 6 months prior to identification.

h. The patient cannot be pregnant.

3. Quotas

a. At least 25 percent of subjects will have moderate airflow obstruction (FEV_1 between 40% and 60% of predicted).

b. At least 25 percent of subjects will be severely obstructed (FEV_1 less than 40% predicted).

c. At least 20 percent of subjects will show evidence, at least once, of reversibility ($FEV_{1.0}$ will increase at least 15% with acute bronchodilator administration).

B. Stabilization Phase

All patients considered as potential candidates for the study require a 30-day stabilization phase prior to baseline studies. The definition of clinical stability remains the judgment of the attending physician. In the event of an acute illness during this time, the patient will be treated with appropriate therapy. Following the acute illness, either baseline or repeat $FEV_{1.0}$ measurements must agree within 0.2 liter or 15% of previous value, whichever is greater. During the stabilization phase:

1. Standard treatment regimen is to be applied with the following specific restrictions:

a. no propranolol or cromolyn sodium;

b. no home use of IPPB or compressor nebulizer;

c. no home use of oxygen supplementation.

2. Pre- and post-bronchodilator measurement of $FEV_{1.0}$ and FVC must be

obtained after patient has been on standard treatment for at least one week. A second set of measurements must be obtained not less than a week or more than 90 days from the first.

APPENDIX D

APPROVALS AND INFORMED CONSENT

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
DENTON, TEXAS 76204

DALLAS CENTER
1810 INWOOD ROAD
DALLAS, TEXAS 75235

HOUSTON CENTER
1130 M. D. ANDERSON BLVD.
HOUSTON, TEXAS 77025

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE National Institute of Health--Division of Lung Diseases. Center #1

GRANTS TO Jana Quatkemeyer, R.N.
a student enrolled in a program of nursing leading to a Master's Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem:

The relationship of Sickness Impact Profile scores and outpatient compliance to home IPPB and CN therapy regimes.

The conditions mutually agreed upon are as follows:

1. The agency (may) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) (may not) be identified in the final report.
3. The agency (wants) (does not want) a conference with the student when the report is completed.
4. The agency is (willing) (unwilling) to allow the completed report to be circulated through interlibrary loan.
5. Other Cannot be published w/o previous approval from VIH.

Date: March 6, 1981.

Signature of Agency Personnel

Signature of Student

Signature of Faculty Advisor

* Fill out and sign three copies to be distributed as follows: Original-Student; First copy - agency; Second copy - TWU College of Nursing.

GP:GEN 13
07026074 cd

REVISED CONSENT FORM

I, _____, understand that this study is designed to compare the value of the two devices, the Intermittent Positive Pressure Breathing (IPPB) machine and Compressor Nebulizer (CN), in the treatment of my diagnosed condition of Chronic Obstructive Pulmonary Disease.

If I agree to participate in the study, I understand that I will receive the benefit of careful followup care, with frequent visits to my home by trained nurses. The nurses will check on my machine to be sure it works well and will also check my medications and my overall status. Additionally, the complete lung function tests which are done will allow my doctor to understand my disease as well as is currently possible; this may be of help in designing my specific therapy. All these benefits will be given me without cost.

I understand that I have a 50% chance of receiving IPPB and a 50% chance of receiving CN. The best form of treatment is unknown. The device I receive will be determined by an independent research center and not my doctor.

I understand that before my assignment to a device is made, I will be carefully observed for 30 days on a standard treatment program without the use of IPPB or CN unless my physician concludes that going without these treatment modalities will be harmful.

I acknowledge that I have been provided with a full explanation of the procedures to be followed in the study, of the potential risks and benefits of the alternative modes of treatment. Among the potential benefits that have been described to me are slowing of deterioration of pulmonary function, greater exercise tolerance, lessening of pulmonary symptoms, and more intensive diagnosis and treatment.

I understand that several kinds of test will be done at intervals during the study. Although the likelihood of life-threatening complications are remote, some possible side effects of these tests may be uncomfortable and are mentioned below:

a. Arterial catheterization, or the insertion of a small tube into the artery to obtain blood, is a very commonly done test and may be performed on me during the exercise evaluation. On rare occasions a clot may form, requiring surgical removal.

b. In order to evaluate my ability to exercise, I will be asked to pedal a bicycle until I am short of breath or tired. On very rare occasions, especially in patients with heart disease, exercising like this may cause cardiac problems. For this reason all tests are done with a physician and resuscitative equipment present, so that if any problem occurs it may be promptly handled.

c. Tests will be given and personal questions asked that will require several hours to answer. These tests may cause fatigue.

d. One of the breathing tests requires that I swallow a small balloon (that is attached to a very narrow tubing) into my esophagus (just above the stomach). This may cause some discomfort in my nose, and there may be some gagging as I swallow the balloon.

I understand that trained personnel will be available at all times during testing so that any adverse reaction may receive immediate attention. I also know that either IPPB or CN may be used if I am hospitalized regardless of the device which I am assigned for home use.

It has been explained to me that all drugs have side effects. Some investigational drugs which are chemically and pharmacologically related to the drugs I may be taking for my disease, have been shown to cause benign tumors in rats. These tumors occurred in significantly high numbers in the animals' reproductive systems when they received relatively large dosages of the drugs. Those drugs directly shown to cause tumors will not be used in this study.

Because the risk of these drugs in women who are pregnant is not known, I understand that I should not be in the study if I am pregnant or plan to become pregnant. Further, if I should become pregnant, I should immediately inform my doctor and withdraw from the study.

I understand that if my assigned treatment routine, with IPPB or CN, is determined to be less beneficial than another mode of treatment, I will be promptly notified.

I agree to allow my name and medical records to be made available only to physicians and research workers participating in the project.

I have been informed that I may withdraw from this study at any time, that I may receive IPPB or CN treatment without participation in this study, and that necessary medical treatment will not be denied to me solely because of a decision not to participate or withdraw from the study. If I do not wish to perform any of the scheduled lung function tests, I have the right to refuse.

I have discussed the above information with my physician and he has answered my questions about my treatment program.

I, _____, understand the study as outlined above and agree to participate in it.

_____ _____

(Date) (Patient)

_____ _____

(Witness) (Witness)

APPENDIX E

CORRELATION MATRIX

Table A

Correlation Matrix of Sickness Impact Profile Scores for 50 Chronic Obstructive Pulmonary Disease Outpatients

	Time	Emotional Behavior	Body Care	Home Management	Mobility	Social Interest	Ambulation	Communication	Work	Recreation	Alertness	Eating	Sleep/ Rest
Time	1.000	.140	.075	.104	.060	.260	.100	.040	.005	.050	.040	.045	.010
Emotional Behavior		1.000	.540	.600	.520	.530	.440	.600	.270	.470	.330	.140	.250
Body Care			1.000	.330	.280	.400	.600	.380	.140	.285	.010	.130	.215
Home Management				1.000	.525	.500	.370	.450	.390	.530	.490	.260	.300
Mobility					1.000	.660	.375	.450	.320	.480	.660	.200	.445
Social Interest						1.000	.480	.660	.360	.540	.410	.270	.220
Ambulation							1.000	.380	.340	.370	.240	.100	.200
Communication								1.000	.310	.350	.400	.300	.070
Work									1.000	.530	.330	.460	.350
Recreation										1.000	.430	.280	.380
Alertness											1.000	.200	.230
Eating												1.000	.180
Sleep/Rest													1.000

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