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The Effect of Individual Instruction versus Group Instruction on Compliance in C.O.P.D. Patients

Renee L. Hills

Abstract

THE EFFECT OF INDIVIDUAL INSTRUCTION VERSUS GROUP INSTRUCTION ON COMPLIANCE IN C.O.P.D. PATIENTS

by Renee L. Hills

Because of the evolution of hospitals from general care to acute care centers, the need for more outpatient therapy programs had increased in an effort to aid patients in managing their health care at home. As a result, health care professionals were concerned with the extent to which patients would follow their medication and treatment programs. Marston estimated that approximately 30 to 35 percent of patients fail to follow their physicians' medical recommendations (Marston, 1970).

Discovering a means of insuring patient compliance was a prevalent concern in the nursing and medical professions. Previously we had attempted to blame noncompliance on physiological and/or psychological factors with an excuse that nothing can be done to promote patient compliance. Researchers investigated many factors affecting patient compliance such as sex, race, education, psychological variables, physician-patient interaction, attitudes, and nursing interventions.

The nurse came into closer and more frequent contact with patients than did the physician, and thus ought to be in a position to influence their health behaviors toward compliance. Nursing staff might work with the patient in the scheduling of treatments and medications coordinated with daily activities in an attempt to positively affect patient compliance. Another potentially important contribution of nurses to patient compliance was that of assisting them to understand

both the nature of their illnesses and the reasons for their treatment. Nursing staff who were in repeated contact with the patient could institute such education and make themselves available and approachable for the expression of questions, doubts, and fears. The overall objective of the current compliance study was to compare the efficacy of individual instruction on compliance with that of group instruction in patients with chronic obstructive pulmonary disease (C.O.P.D.). The study was also aimed at looking at the effect of symptomatology, physical findings, pulmonary function, and locus of control on compliance.

The research method implemented in the compliance study in the C.O.P.D. patient was quasi-experimental and correlational. The 36 randomly assigned participants were alternately assigned to an experimental or control group. The experimental group contained 18 patients receiving individual instruction and the control group contained 18 patients receiving group instruction. The research design was the randomized control-group pretest-posttest design. The participants were then randomly assigned to test times and rooms as they were individually evaluated over a three-month period.

Analysis of the data concluded that there was no significant difference (α=.05) in the degree of compliance with the medical treatment regimen in the C.O.P.D. patient resulting from instruction given on an individual basis and that given in a group as measured by the following factors: pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked.

There was no significant relationship between a C.O.P.D. patient's degree of symptomatology or change in physical findings and his compliance

with the medical treatment regimen. Neither was there a significant relationship between the pulmonary function (FEV_1 and FVC) in the C.O.P.D. patient and his compliance. The Rotter I:E Score had no significant effect on the C.O.P.D. patient's compliance to his medical treatment regimen.

Findings that were significant included the Rotter I:E Score, the FVC, and the degree of symptomatology that significantly affected pill taking only and the individual instruction that significantly affected the use of the liquid medication only. The lack of significant findings could be related to the wide variability of compliance among patients in both groups. The study of a larger number of patients for a longer period of time could compensate for this variability.

A conclusion derived from the current compliance study was that group instruction for the C.O.P.D. patient might be more economical and just as effective as individual instruction which required more time and staff. We could not rely upon a patient's increase in symptoms or changes in his physical findings as a means of insuring compliance. In this study, pulmonary function had no significant effect on whether a patient would comply or not.

The locus of control significantly affected the pill taking of the C.O.P.D. patients. Research into the use of the locus of control could aid in the development of solutions for noncompliance problems. Teaching methods could be directed at an individual's locus of control as a means of promoting compliance.

The implications for nursing were that nurses must be open to clues from the patient as to why he is noncompliant. Speaking to him about possible problems that may interfere with him following his program and working on solutions with the patient should prove helpful. Nurses should become more involved in problem-solving programs, because the nurse has many opportunities to speak with the patient about this particular subject.

LOMA LINDA UNIVERSITY

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by

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Chapter 1

DELINEATION OF THE PROBLEM

A major difficulty in caring for chronically ill patients was that of their compliance with a treatment program. They were sent home with pills and usually minimal directions as to their use. They were given little instruction as to dietary recommendations, activity instructions, etc., with the assumption that they would comply with the regimen. As it turned out, compliance was not the rule, and medical and nursing staff were frustrated in dealing with the problem of poor compliance. Reviewed here were several studies conducted with patients suffering from various chronic diseases in order to identify factors which influenced their compliance or noncompliance with a treatment program. Unfortunately, no concise solution was formulated for insuring compliance by each and every patient.

The problem area to which this thesis was directed concerned compliance on the part of patients with chronic obstructive pulmonary disease (C.O.P.D.) who participated in a pulmonary rehabilitation program. These patients had either a simple treatment program or a complex, comprehensive program. In either case, it was found that compliance was often as important a problem to deal with as the disease itself. One of the potential solutions evaluated was the effect of patient education on patient compliance. For the purpose of this thesis, comparisons were made between patients who were instructed on an individual basis and patients who received group instruction.

Background of the Problem

Due to the development of outpatient therapy programs for various illnesses and the evolution of hospitals from general care to acute care centers, patients were being given the responsibility for managing much of their own care at home. As a result, health care professionals were concerned with the extent to which patients would follow their medication and treatment programs. Marston estimated that approximately 30 to 35 percent of patients failed to follow their physicians' medical recommendations (Marston, 1970, p. 312).

Researchers investigated many factors affecting patient compliance such as sex, race, education, psychological variables, physician-patient interaction, attitudes, etc., but few studies were found in which the role that the nurse plays in promoting compliance was carefully evaluated. Studies have found "noncompliance to be related to deviant and difficult physician-patient communication . . . and to attempts by physician or patient or both to control one another." (Gillum; Barsky, 1974, p. 1565) The nurse came into closer and more frequent contact with patients than did the physician, and thus should have been in a position to influence their health behaviors toward compliance. Treatment planning coordinated with activities of daily living could affect a patient's adherence to his medical regimen. This planning could be implemented by members of the nursing staff who would take the time to work with the patient in the scheduling of treatments and medications. Another potentially important contribution of nurses to patient compliance was that of assisting them to understand

both the nature of their illnesses and the reasons for their treatment. Nursing staff who were in repeated contact with the patient could institute such education and make themselves available and approachable for expression of questions, doubts, and fears.

Statement of the Problem

Discovering a means of insuring patient compliance was a prevalent concern in the nursing and medical professions. Was compliance something we could control or influence or was it something which we could not affect? Previously we had attempted to blame "noncompliance" on physiological and/or psychological factors with an excuse that nothing could be done to increase patient compliance. There was a definite need for investigation into how health professionals could aid in achieving patient compliance.

Delimitation of the Problem

For the current study on the compliance in C.O.P.D. patients, the nurse researcher gathered the patients together for a group class on the anatomy, physiology, pathophysiology and treatment of C.O.P.D. One group of C.O.P.D. patients participated in group instruction while another group of C.O.P.D. patients was given instruction on an individual basis with the nurse researcher. This was done to compare the efficacy of individual education with that of group education in improving patient compliance. Relationships were also measured between a patient's degree of symptomatology, changes in physical findings, and changes in pulmonary function and his compliance.

Importance of the Study

Due to increased medical knowledge and treatment programs, the life expectancy of humans had been extended, leading to an increased number of people with chronic illness. Of necessity, these people would continue their medical care at home either with the support of a family member or by themselves. Noncompliance with their treatment programs would lead to an increase in hospitalization related to an increase in exacerbations. Although it may not be possible to cure the chronic disease, the progression of the disease may be slowed down through a comprehensive pulmonary rehabilitation program that entails not only a medication program but also an exercise, nutritional, and respiratory care program.

After receiving instruction in a comprehensive program, the patient was responsible for maintaining that program in order to receive its highest benefit. Since it was impossible for personnel to continually observe a patient's compliance, the medical staff needed to find ways and means of insuring compliance with the program. This study was aimed at finding a way of promoting compliance in the C.O.P.D. patient.

Objectives of the Study

The overall objective of this study was to evaluate how well a patient complies with information regarding his disease and the treatment program given him by a nurse. In particular, comparison was made between the efficacy of individual instruction and group instruction on

compliance. One potential outcome of the study was to give nurses incentive and reason for participating in patient education as well as to provide administration with justification for sufficient staffing in order to provide an education program for patients. A related factor to be evaluated in the study was the part that symptoms and signs of disease played in determining whether a patient would faithfully follow his medical regimen.

Research Questions

What was the effect of individual instruction as compared to group instruction by nursing personnel on the patient's compliance with the medical regimen in C.O.P.D. patients? Did the presence or absence of symptoms in the C.O.P.D. patient affect his compliance with his treatment program? What was the relationship between a C.O.P.D. patient's changes in physical findings and his compliance with this treatment program? Was a patient's compliance affected by changes in his pulmonary function? Did his locus of control play a part in compliance?

Conceptual Assumptions and Rationale for the Study

The types of interaction which occurred between patients and their physicians were found to be predictive of compliant behavior (Marston, 1970, p. 321). This could have affected a patient's compliance as he administered self-care in the home. The ambulatory patient tended to become an active participant in the treatment process

rather than the passive recipient of care that was more characteristic of the hospitalized patient. "Every compliance problem with medication orders encountered in a hospital is carried forward, magnified, and becomes almost completely dependent upon the patient when he is treated outside of a hospital." (Wilson, 1973, p. 334) Compliance could better be assured if the staff did the following: recognized the "at risk" patient, planned treatment carefully, and properly explained the treatment to the patient (Blackwell, 1972, p. 251).

An important contribution to compliance could have been the understanding a patient had of his illness, the need for treatment, and the likely consequences of both. Too frequently patients would be handed a treatment program and told they must follow it with no further explanation. In discussing the "whys" with the patient, the health professional placed upon the patient a responsibility that could increase his feeling of self-worth and importance, leading to increased compliance (Blackwell, 1972, p. 252). Nursing staff could affect compliance by interaction with a patient, using a consistent approach so that the patient knew what was expected of him. He could not be expected to follow a program blindly as this would have been an insult to his intelligence (Vincent, 1971, p. 514).

The attitude of the physician toward the medication and the treatments he prescribed was important in determining the outcomes of that treatment. This attitude could be conveyed not only verbally but also nonverbally. However, if the physician did not positively prescribe, the patient was not inclined to follow a program of self-care (Marston, 1970, p. 321). Compliance was usually promoted when patients

understood the purpose or knew the names of their medications whether the instruction came via physician, nurse, pharmacist, or other health professional (Stewart; Cluff, 1972, p. 424). Compliance with medication regimens or other health advice was potentially influenced by a patient's perception of his health (i.e., severity of disease, his susceptibility to its complications, the efficacy of the proposed treatment, etc.) (Sackett, 1978, p. 278).

If these concepts and assumptions were valid, instruction presented to the patient regarding his disease process and the need for following a medical treatment program as well as the patient's positive perception of his health status should have affected compliance with the medication orders and treatment plan on an outpatient basis. Nursing personnel, who spent more time with the patient in the hospital than the physician and who provided patients with medical treatment instruction, should have had a positive effect upon the compliance of the patient with his medical regimen in the home. In contrast, the severity of the patients' symptoms could have had a negative effect upon compliance as well as the disease's impact upon his quality of life. Disruption in the interaction between physician and patient could have fostered noncompliance.

Patients with chronic obstructive pulmonary disease in a rehabilitation program were responsible for carrying out their medical treatment program at home. Medical and nursing staff were dependent upon the patients to faithfully follow the program that had been outlined for them. A comprehensive pulmonary rehabilitation program was aimed at decreasing the rate of deterioration of the pulmonary system,

decreasing symptomatology of the disease, and restoring patients to their highest possible functional level. If a patient refused to comply with the comprehensive care program, exacerbations leading to hospitalization could have occurred.

A high degree of compliance in the pulmonary rehabilitation patient with C.O.P.D. could have been achieved by having staff members examine the patient for those factors thought to affect compliance. Careful development of a treatment program that was tailored to the patient's activities of daily living was necessary. Providing adequate explanation and education for the patient and family about the disease, medications, and other treatments were important in promoting compliance in the C.O.P.D. patient.

Statement of the Hypotheses

The hypotheses of the study were stated as follows:

1. There was no significant difference (α=.05) in the degree of compliance with the medical treatment regimen in the C.O.P.D. patient resulting from instruction given on an individual basis and that given in a group as measured by the following factors: pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked.

2. There was no significant relationship (α=.05) between a C.O.P.D. patient's degree of symptomatology (i.e., coughing, sputum production, shortness of breath, wheezing, and fluid retention) and his compliance with his medical treatment regimen as measured by the

following factors: pill counts, liquid medication measurement, breathing machine meter readings, and number of cigarettes smoked.

3. There was no significant relationship (α=.05) between a C.O.P.D. patient's change in physical findings (i.e., blood pressure, heart rate and rhythm, respiratory rate, breath sounds, heart sounds, jugular venous pressure, pedal edema, hepatomegaly) and his compliance with his medical treatment regimen as measured by the following factors: pill counts, liquid medication measurement, breathing machine meter readings, and number of cigarettes smoked.

4. There was no significant relationship (α=.05) between a C.O.P.D. patient's change in pulmonary function (FEV_1 and FVC) and his compliance with the medical treatment regimen as measured by the following factors: pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked.

5. There was no significant relationship (α=.05) between a C.O.P.D. patient's Rotter I:E score and his compliance with the medical treatment regimen as measured by the following factors: pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked.

Definition of Terms

For the purpose of this study, the following terms were theoretically and operationally defined.

Individual Instruction

Consultation of a patient with the nurse researcher who was a pulmonary nurse specialist for the purpose of acquainting the patient

with the anatomy and physiology of the pulmonary system, pathophysiology as related to his specific disease and treatment including medications (i.e., bronchodilators, antibiotics, corticosteroids, etc.), pulmonary hygiene, breathing exercises, physical conditioning, activities of daily living, nutrition, infection control, and factors to avoid.

Group Instruction

Consultation of two or more patients with the nurse researcher for the purpose of acquainting the patients with the anatomy and physiology of the pulmonary system, pathophysiology as related to his specific disease and treatment including medications (i.e., bronchodilators, antibiotics, corticosteroids, etc.), pulmonary hygiene, breathing exercises, physical conditioning, activities of daily living, nutrition, infection control, and factors to avoid.

Medical Treatment Program

A comprehensive pulmonary rehabilitation regimen including the use of oral bronchodilators, inhaled bronchodilators via cartridge inhaler and the Bennett IPPB machine or the Bennett compressor nebulizer machine, and exercise program.

Oral Bronchodilator

A long-acting theophylline preparation.

Inhaled Bronchodilator

A metaproterenol or Bronkometer cartridge inhaler and a metaproterenol or Bronkosol premix solution in a Bennett IPPB machine or

Bennett compressor nebulizer machine, each piece of equipment equipped with an elapsed-time indicator.

Breaching Machine

A Bennett IPPB machine or a Bennett compressor nebulizer, each equipped with an elapsed-time indicator for meter readings.

Medication Error

Medicine taken by the patient but not ordered by the physician; medicine ordered by the physician but not taken by the patient; and/or medicine ordered by the physician but taken in incorrect doses or at the wrong time.

Exercise Program

A regimen outlined by the respiratory physical therapist which may include walking, bicycling, or engaging in other physical conditioning exercises, depending on the abilities of the participant.

Patient Compliance

Participation in all aspects of a medical treatment program for 100 percent of the time indicated.

Chronic Obstructive Pulmonary Disease Patient

A participant with at least one form of chronic obstructive pulmonary disease (i.e., asthma, chronic bronchitis, emphysema).

Forced Expiratory Volume in One Second (FEV_1)

The volume of air expired in one second as determined by spirometry.

Forced Vital Capacity (FVC)

The amount of air that can be exhaled quickly and forcibly after maximal inspiration as determined by spirometry.

Rotter Internal:External Test

An assessment of each participant in an attempt to discover whether or not a patient perceives a contingency relationship between his behavior (his actions) and his reinforcements (his outcomes).

Organization of Remainder of Study

Many factors may have influenced compliance, but this study was aimed at determining if instruction given to the patient on an individual basis significantly affected compliance by the patient. An individual's concept of how his life was controlled and its effect on compliance was also evaluated.

Chapter 2 includes a review of literature written on factors that affected compliance in patients with various disease entities as well as factors that had been found to influence compliance. These factors may have involved the patient alone or may have included outside influences such as health staff, family members, etc.

A description of the study emphasizing methodology and design is presented in Chapter 3. The procedure used in conducting the study (i.e., selection of subjects, instrumentation, data collection and recording, statistical analysis) is also presented in this chapter. The methodological assumptions and limitations in the study are emphasized.

The findings for each hypothesis are presented in Chapter 4. These findings will be related to conclusions of previous studies.

The significance of the study and its conclusions are discussed in Chapter 5. The implications of the research findings on nursing are described. Suggestions and recommendations for further studies in this area are presented in the form of researchable questions. These recommendations are in line with the need for continued research in the field of nursing.

Chapter 2

CRITICAL REVIEW OF RELATED LITERATURE

The historical background of the problem of compliance in various types of patients is presented in Chapter 2. The review of the literature describes reports dealing with patient compliance. These studies are compared to the present study as to differences and similarities. The need for and significance of research into patient compliance problems is reviewed.

Historical Background

For many years, physicians and nurses had been faced with the overwhelming problem of patient noncompliance. Hypertensive patients whose blood pressure was predominantly regulated by medication had been a serious problem as they might not have been able to detect a difference in physical feelings when they took a pill compared to when they did not take a pill. Diabetics were often discouraged by not being able to eat what they wanted and participate in activities as others did and they were "forced" to cheat "just a little." Children posed another problem in that health staff relied upon the parents to comply with a program outlined for their child. Because they apparently "knew what was best" for their child and did not feel what the child felt, parents could regulate or discontinue medication as they thought best. A compliance problem also arose with the elderly who either could not remember to take their medication, could not afford

to buy the medication, or just plain refused to take it because they "have lived this long without it so why take it now?" What did health care personnel do to remedy the situation of patient noncompliance?

Critical Review of Research on Compliance

A study by Berkowitz, Malone, Klein, and Eaton (1963) examined patient follow-through in the outpatient department. In this study, a questionnaire was given to physicians in 55 clinics of seven urban hospital outpatient departments. The follow-up time period covered five clinic sessions and each clinic was staffed with a nurse. The questionnaire dealt with patient follow-through and was compared to each patient's medical record. Approximately 3800 patients were analyzed for the study. The results showed that physicians had a tendency to overrate compliance when compared to the medical record. The level of patient compliance seemed to be affected by the nature of the follow-through requirement. There was lowest compliance when the patient was exclusively responsible for his own care at home. The problem of low compliance in home self-care as described directly related to the compliance study in C.O.P.D. patients as the majority of them were completely responsible for their care in the home. Allusion was made in this study as to the potential positive effect of patient teaching and motivation in treatment compliance.

The authors presented data substantiating the reliability and validity of the study findings. The questionnaire was included in the paper and the reliability and validity of that questionnare were presented. Adjustments were made to recheck the responses and another

study was done to evaluate the adjustments. Interval data were presented with no comment as to their significance or use in the clinical setting (Berkowitz, and Others, 1963).

Another study by Neely and Patrick (1968) examined the problems with aged persons taking medications in the home. Study participants consisted of 59 randomly selected patients between the ages of 60 and 84 who were attending a private clinic in an urban-rural area on the West Coast. An interview schedule was used to gather data and the results showed that age, sex, marital status, education, birthplace, employment, and duration of illness had no effect on the number and types of medication errors committed. The patients that committed potentially serious medication errors were those who had larger numbers of prescribed medications, had no regular method of remembering to take medications and felt the impact of illness as a big problem. The study (Neely and Patrick) suggested eliminating the variables of age, sex, marital status, education, etc., which was done in the current C.O.P.D. study as it appeared that older patients who make medication errors could not be identified by these variables. The data on these variables were collected as demographic data. Special emphasis in the individual instruction program in the current compliance study was aimed at providing scheduling and education in medication programs in order to eliminate medication errors and promote patient compliance.

The questionnaire was not included in Neely and Patrick's report and no reference was made as to its reliability and/or validity. The only significant statistical analysis reported was the relationship

of the number of prescribed medication to the number of medication errors made by patients. The statistical analysis performed was significant at a .05 level. The study could be replicated in other population groups provided the questionnaire would be obtained and tested for reliability and validity. Comments directed to future studies included measuring a patient's perception of his illness in an effort to measure more subtle variables. Methods that could be used by nursing staff to decrease home medication errors were implemented in the current compliance study in C.O.P.D. patients as a part of the individual instruction program (Neely; Patrick, 1968).

Francis, Korsch, and Morris (1969) evaluated the effect of physician-patient communication on compliance as well as patient satisfaction on 800 patient visits in the outpatient clinic of the Children's Hospital of Los Angeles. The results showed that those mothers that expressed high satisfaction also demonstrated 53.4 percent compliance while those mothers who were grossly dissatisfied demonstrated only 16.7 percent compliance. Factors that encouraged noncompliance were "the extent to which patients' expectations from the medical visit were left unmet, lack of warmth in the explanation of diagnosis and cause of the child's illness" as well as the complexity of the medical regimen and patient dissatisfaction. Compliance was found when mothers regarded the illness as serious. Again the individual instruction in the current C.O.P.D. compliance study was aimed at decreasing unmet expectations and lack of knowledge of the disease process. Time was taken with each patient to allow him to ask his questions during the instruction period.

The scientific accuracy of the Francis study was difficult to assess. The interview was pretested in a pilot study for acceptability and ease of comprehension but no distinction was made as to its reliability or validity. The questions on compliance were not included in the report. From the information that was gathered from the report, one could have assumed that ordinal or nominal data were analyzed but no mention was made as to the statistical analysis or its significance. The study would be difficult to impossible to replicate given the information presented (Francis, and Others, 1969).

A study by Gordis, Markowitz, and Lilienfeld (1969) evaluated 103 children and adolescents taking daily oral penicillin prophylactically with histories of rheumatic fever. Each patient was examined in clinic every two months for six months at which time both parent and child were questioned as to whether or not the child was taking the penicillin. Urine checks were done to test for penicillin excretion. Results of the study showed a discrepancy between actual measured compliance and responses from the patient and the parent. Seventy-three percent would be considered compliant as described by responses of parent or child, but in actuality only 42 percent were found to be compliant as demonstrated by urine test results. Thus, for the purposes of the current compliance study in C.O.P.D. patients, subjective data compiled in patient interviews were compared with objective data obtained through pill counts, liquid medication measurements, and breathing machine meter readings.

The Gordis report contained few details and was therefore difficult to evaluate as to its merits or to delineate scientific procedures.

Trained individuals were used to administer an extensive interview. Only two questions were reported as valid when compared to the objective evidence (i.e., urine test). No other reliability or validity data were presented. An attempt to control bias was directed at the interviewer refraining from encouraging participants to improve adherence to the medication program. When compared to similar studies conducted in patients with other illnesses, the authors stated that their results correlated with the previous studies (Gordis, and Others, 1969).

Canadian steelworkers with hypertension were studied by Sackett, Gibson, Taylor, Haynes, Hackett, Roberts, and Johnson (1975) to evaluate the effect of follow-up care and mastery learning on compliance. Results showed that neither necessarily increased the compliance of the experimental group as compared with the control group. Because follow-up care was made so readily accessible to patients, actual compliance could have been altered. This study could be replicated from the information presented in the paper to further assess the effect of mastery learning upon compliance. Failure to demonstrate a positive correlation between knowledge and compliance did not negate the worth of health education nor did it release clinicians from existing ethical obligation to inform the patient (Sackett, and Others, 1975).

Haynes, Gibson, Hackett, Sackett, Taylor, and Roberts (1976) continued the previously-mentioned hypertensive compliance study on 38 Canadian steelworkers who were not compliant with medications or at their recommended diastolic blood pressures six months after starting treatment. These men were placed either in a control group without education or an experimental group with education to chart their home

blood pressures and pill taking. The experimental group was taught how to tailor their pill taking to their activities of daily living. They were also given reinforcement training by a non-health professional. It was found in six months that compliance had risen 21 percent in the experimental group while it had fallen one and one-half percent in the control group. The authors presented several biases that could have entered their study with explanations as to why they did not affect the participants. They admitted the bias of extra attention from the experimenters could possibly increase compliance in the experimental group. The increase in compliance over the year was statistically significant. The importance of health education, training, and reinforcement was an integral part of the current compliance study of C.O.P.D. patients (Haynes, and Others, 1976).

Linde and Janz (1979) conducted their research on cardiac patients evaluating the effect of a teaching program on knowledge and compliance. The 48 patients included in the study had had valve replacement surgery or coronary artery bypass. A comprehensive patient education program was developed by the researchers and included information on the disease process and surgical intervention, activity progression, medication and dietary regimens. Also included was instruction on warning signs and special concerns such as prevention of subacute bacterial endocarditis and risk-factor modification. All teaching was done by individual rather than group instruction. Another factor included in the study was that of master's-prepared nurses vs. staff nurses instructing the patients.

The results of the Linde and Janz study showed a significant increase in the discharge test scores from the preoperative test scores. They also found that there were no significant declines in scores following discharge. This factor could have been explained by the fact that each post-discharge clinic visit included continued teaching and reinforcement. The researchers also demonstrated high compliance rates which they related to the teaching program as well as continuity of personnel involved in follow-up.

The study showed that the master's-prepared nurses had a greater impact on patient learning although staff nurses did influence patient knowledge. This could have been related to the knowledge and skills gained from advanced preparation as well as experience in patient teaching. The overall impression was that "nurses are appropriate health care providers to design, implement, and evaluate a patient education program." (Linde; Janz, 1979, p. 286) This study showed significant increases in compliance and knowledge scores as compared to other studies measuring these components and should be replicated with various populations to determine if it would still hold true that education does significantly improve compliance. No comment was made as to the reliability and validity of the testing tools used by the researchers. If the study were replicated on other groups of cardiac patients, a tool to evaluate the patients would be necessary. This study demonstrated the influence nursing and patient education could have upon knowledge and compliance (Linde; Janz, 1979).

A major problem in compliance was that of administering medications at the required hours. This has been a problem in pulmonary

patients who require therapeutic theophylline levels to remain symptom-free during the day and night. Tinkelman, Vanderpool, Carroll, Page, and Spangler (1980) evaluated the compliance differences between administration of theophylline at six- and 12-hour intervals in a pediatric outpatient population. The study consisted of placing 20 children on theophylline preparations. Half of the children received a short-acting preparation requiring administration every six hours and half of them received a sustained-release tablet requiring administration every 12 hours. Each subject's theophylline dose was titrated until he was in a therapeutic range and clinically stable without toxicity. The subjects were evaluated every two weeks for six weeks and then switched to the second study drug. At the end of the study, 75 percent of the children were reported to have significantly better compliance when required to take the medication only twice daily as opposed to every six hours. Even though the subjects were aware that they were participating in a study, significant difference in compliance rates was noted between the two drugs. Also noted was that the amount of theophylline required to maintain a therapeutic theophylline level was significantly lower in the sustained-release tablet than the short-acting tablet. Thus, the current compliance study used a long-acting theophylline preparation in an attempt to aid compliance (Tinkleman, and Others, 1980).

Kleiger and Dirks (1979) studied 100 adult and adolescent chronic asthmatics to determine aspects of patient noncompliance with prescribed medication regimens. In assessing the frequency with which

such patients report medication noncompliance, it was found that 54 percent admitted noncompliance in the form of over abuse, under abuse, or cyclical abuse (both over and under abuse). Each subject was given the MMPI Panic-Fear Scale to determine whether basic personality characteristics would affect the patient's characteristic style of noncompliance. Those subjects with a high Panic-Fear score were more likely to be cyclical abusers while lows were more likely to be under abusers. When evaluating the frequency with which physicians would question their patients about medication noncompliance, the researchers found that only 27.3 percent of the physicians routinely asked their patients about medication abuse. This may have reflected an attempt on the physician's part to avoid this problem by ignoring possible noncompliance to the medication regimen. It may be necessary to increase the working alliance between patient and physician in order to increase compliance. No mention was made in the study as to the statistical significance of these data nor were recommendations for further studies made by the researchers (Kleiger; Dirks, 1979).

Becker, Radius, Rosenstock, Drachman, Schuberth and Teets (1978) used the Health Belief Model as a means of evaluating compliance in mothers with asthmatic children. One hundred eleven mothers were interviewed in emergency rooms where they had brought their children suffering from "asthma attacks." At the same time, theophylline levels were drawn from the child to obtain an objective measurement of compliance. The study was conducted using the Health Belief Model to determine whether personal health behaviors and psychosocial factors influence the acceptance and following of therapeutic advice. The interview consisted of

of questions about the mother's general health motivations and attitudes as well as about her view regarding the child's asthma condition and its ramifications. Mothers were found to adhere to the medication program if they believed their child to be vulnerable to illness. Also, if mothers believed that their child had a serious illness, they were more likely to comply. The most statistically significant positive association was between the mother's belief that she could do something to assist her child and compliance. What was surprising to the researchers was the fact that mothers who expressed negative evaluations of physicians were found to be more compliant as the mothers themselves felt better when heeding medical advice despite these negative attitudes. The researchers discussed future projects to be investigated in an attempt to prescribe therapies promoting adherence to a medical treatment program (Becker, and Others, 1978).

Spector, McGrath, Uretsky, Newman, and Cohen (1978) investigated the possibility of nursing intervention affecting medication compliance. The 105 patients who agreed to participate in the study were taking digoxin or methyldopa. These patients were divided into two groups with one group receiving educational intervention by a nurse and the second group receiving no educational intervention. The intervention consisted of interviewing and discussing with each patient possible factors that could influence medication compliance and then identifying problem areas with the patient. The interventionist then attempted to correct these inadequacies. Blood assays were then drawn monthly to determine compliance. A third group was selected from the clinic as a whole from which blood assays were drawn on a one-time basis.

The results documented that the patients who were exposed to the educational intervention methods were not more compliant than the non-intervention group. But it was noted that the first two study groups were more compliant than the general clinic population. Reasons for the lack of significant difference between the compliant behavior of the two groups could have been related to the fact that both groups were cognizant of the fact that they were study subjects and may have wanted to be cooperative to assure success of the study. The authors described the results as to their statistical significance and to the statistical test used. Replication of the study could be performed with the information provided. The current compliance study was also conducted in an attempt to demonstrate the use of nursing personnel to promote compliance (Spector, and Others, 1978).

A study was conducted by Jamison, Gerner, and Goodwin in 1979 to evaluate the relationship of patient and physician attitudes toward lithium and compliance. The two subject samples included a clinician sample consisting of 50 physicians and a patient sample consisting of 47 patients. Each subject filled out lengthy questionnaires exploring the issues of patterns of lithium usage, perceived importance of different factors in noncompliance, and the perceived effectiveness of lithium and of psychotherapy. Although the clinicians and the patients showed discrepancy in their reasons for noncompliance, there was no statistically significant data to promote the reasoning that noncompliance could be related to differences in attitudes by physicians and patients toward lithium therapy. The study emphasized that patients who were on long-term therapy were more likely to be noncompliant than

those patients taking a short course of medication therapy. In order to reproduce this study, the questionnaire would have to be obtained as well as knowledge about the statistical testing used. The current compliance study dealt with patients who were receiving long-term treatment which according to the study conducted by Jamison and associates could be another factor leading to noncompliance (Jamison, and Others, 1979).

A study conducted by Levy, Yamashita, and Pow (1979) compared overt commitment to compliance. Not only did compliance affect a patient's health, but also affected experimental regimens leading to a loss of valuable information. The subjects were given flu vaccinations and then given a symptom report postcard to be returned after 48 hours. In the two control clinics, nothing further was said to the patients; while in the two experimental clinics, the patients were asked if they would send back the postcards. All patients indicated that they would do so. The results showed that the patients who were asked if they would comply mailed back significantly more cards and significantly faster than those who were not asked to give such a commitment. This type of commitment raised compliance rates by 19.5 percent. The investigators suggested that a simple procedure such as asking patients to make commitments to compliance was extremely low cost in time and effort and demonstrated effectiveness in raising compliance. It should not be regarded as a panacea to noncompliance but appeared to have advantages when used with techniques to ensure compliance. This simple testing procedure could be easily imitated in other settings along with the statistical analysis described in the article (Levy, and Others, 1979).

Faigel (1972) investigated the effect of communication upon compliance. He felt that much of the mutual discontent between patients and physicians could be related to a lack of communication. A detailed five-year study involving 800 pediatric clinics and 800 different patients was conducted by taping patient-doctor interviews. The results showed that 11 percent of the 800 patients did not follow the physician's advice at all while 38 percent followed them only in part. Faigel related compliance to satisfaction with the physician as 53 percent of the highly satisfied mothers as compared to only 17 percent of the highly dissatisfied mothers had followed the doctor's advnce completely. Suggestions were presented by the researcher as a means of alleviating noncompliance due to dissatisfaction with the medical care. These suggestions included such "rules" as introducing yourself to the patient, discussing the findings in clear, basic English, being friendly and interested, putting recommendations in writing, and spending as much time listening as you do talking (Faigel, 1972).

Compliance rates were very inadequate and especially so in low-income populations. In an attempt to determine factors influencing compliance in this population group, Becker, Drachman, and Kirscht (1974) employed health motivations, perceptions, and attitudes of mothers as predictors of compliance. They studied the mothers of a random sample of 125 children being treated for otitis media with an antibiotic in a clinic setting. These mothers were interviewed using the "Health Belief Model" as a predictor of preventive health behavior. It was found that compliant mothers were relatively more interested in

their child's health in general. They also perceived the child's illness as a threat and in order to reduce this threat, the mothers were willing to engage in behavior to prevent future illnesses. They also had satisfactory experiences with the clinic and seemed better able to handle life's problems. By becoming aware of these predictors, the health worker could tailor his interventions to apply to that individual. The study being quite extensive would require more details concerning the interviewing tool before it could be replicated. The statistical test implemented for determining significance was absent from the report (Becker, and Others, 1974).

D'Altroy, Blissenbach, and Lutz (1978) described noncompliance to a medication regimen as a major factor leading to higher hospitalization rates, longer lengths of stay, and increased visits to physicians. Their response to this factor was emphasis on education. The investigators planned a self-administered medication program in which information was presented to patients in three levels. Level 1 included the pharmacist taking a drug history of each patient and then conferring with the nurse about further educational plans. The pharmacist was also responsible for initiating the first contact and instruction with the patient. He would visit the patient several times to teach and reinforce the learning. In Level 2, the nurse assisted the patient in setting up his own medication schedule. The medications were brought to the patient at the appropriate times. He would then make his selection with explanations of why he chose that particular drug. When the patient had mastered his medication schedule, the medications were kept in fully-labeled bottles at his bedside (Level 3). He was

then responsible for administering and recording his own medications. The nurse continued to check the patient on a daily basis. One month after discharge, the patient was reevaluated concerning his knowledge about his drugs and how to take them and on his compliance to the medication regimen. Those patients in the experimental program had a significantly higher rate of compliance than did the control group of patients. The researchers felt that the significant improvement could not be related only to the knowledge of drugs but was also attributed to the patients' participation in the program. On the follow-up visit, the patients were given a "locus of control" test and it was determined that those in the experimental group who were more compliant were more internally oriented. A suggestion was made by the investigators that this test be given before the program in an attempt to predict noncompliance and then formulate interventions to deal with this. The authors also briefly described some general aspects of the program that should be considered before institution of drug self-administration on the hospital units (D'Altroy, and Others, 1978).

A study concerning the effect of pharmacist counseling on medication compliance was conducted by Dickey, Mattor, and Chudzik (1975). The study involved 100 pediatric patients suffering with ear infections for which they were receiving antibiotics and decongestants. Those placed in the experimental group received: (1) a patient instruction list containing such information as the proper method of administration, possible adverse reactions and what to do about them, and a special medication calendar to aid parents in keeping up to date with the administration of the drugs; (2) a uniform measuring and administration

device; (3) verbal instructions from the pharmacist; and (4) standard labeling of the drug container. The results showed that 50 percent of the patients in the experimental group achieved complete compliance while the control group had a rate of 8.5 percent full compliance. Although no statistical analysis was presented, this study demonstrated the valuable contribution of providing patients with a step-by-step guide in taking medications and aiding them in developing a proper attitude toward the use of medications (Dickey, and Others, 1975).

Did patients gain more knowledge from structured instruction than unstructured instruction was a question investigated by Bille (1977). Twenty-four patients with myocardial infarctions were divided into a control group receiving unstructured teaching and an experimental group receiving structured teaching. The results showed no statistically significant difference in knowledge scores between the two groups. The research study also showed that compliance was not significantly related to the patient's knowledge of his disease entity. Nurses commented that the unstructured instruction was provided usually when the patient asked questions which in effect was then meeting their needs for education. Instead, the researcher found that compliance improved with age which could be related to the fact that these people were probably retired allowing them more time to follow their treatment program. He also suggested that a warm interpersonal relationship may be a predictor variable in compliance (Bille, 1977).

When a group of physicians was surveyed as to what they felt were the reasons patients were noncompliant, the majority responded that he (the patient) either could not understand or had an

uncooperative personality. In response to this, Geersten, Gray, and Ward (1973) studied 123 arthritic patients who were all being followed by the same physician. The factors studied were temporal (i.e., waiting to see the doctor, etc.), relational (i.e., personal vs. business-like relations with physician), and treatment (i.e., faith in treatment, physical effects of treatment, and patient evaluation of treatment). The study revealed that patients who had to wait long periods of time to see the physician, especially those who became irritated over this situation, were poor compliers with regard to taking medications and keeping clinic appointments. Also those who did not feel that the physician spent enough time with them and who perceived that physician as being more businesslike than personal were again found to be poor compliers as well as those who had no faith in the treatment regimen. These findings suggested there was importance in decreasing waiting room time, personalizing the treatment relationship, and assisting patients in overcoming discouragement and pessimism. Before replicating this study, the questionnaire would need to be acquired along with the reliability and validity data. The findings were described as well as the statistical procedure (Geersten, and Others, 1973).

Tagliacozzo, Luskin, Lashof, and Ima (1974) also studied the effect of nursing intervention upon patient behavior. Involved in the study were 192 patients who were all black with a relatively low educational status. The experimental group received a maximum of four teaching sessions by a nurse while the control group received only limited contact with a nurse. The results were not statistically

significant and in some cases, the effects were only slight. Nurse intervention had little effect on compliance to medication programs and clinic appointments. Possibly the most important result discovered was the various effects of nurse intervention with patient and treatment characteristics. The intervention reacted positively in patients with a desire for knowledge of their illness, multiple illnesses, high anxiety, favorable attitudes toward the clinic, and in those who felt their illness was serious. There was little to no difference in the control group. There was no description of the structural teaching sessions nor of the tests that were given the participants and their reliability and validity data. The authors discussed questions that should be considered when dealing with noncompliance (Tagliacozzo, and Others, 1974).

A study was conducted with Navajos at a Family Health Center by Mealey and Kane (1977) in which the researchers studied a means of insuring compliance with appointments. Decisions were made to work intensively on patient education with those under 40 and those who demonstrated a wish to change some health care practices and to introduce an appointment system in place of the routine open clinic. Instead of receiving medications for infections, the Navajos were instructed on simple therapeutic measures along with the appropriate antibiotic. Previously the clinic was open for a patient to walk in for whatever reason. A new system was initiated where each patient or family was given a definite time for their clinic visit. The results showed those who kept their appointments had a smaller average family size, lived closer to the clinic, were on an average from a higher

income group, and had fewer numbers of appointments. The average age of those who kept their appointments was 16.2 years while the average age of those who did not keep their appointments was 19 years. The average number of years of education for those who did keep their appointments was 9.32 years and for those who did not keep their appointments was 7.22 years. The later data were statistically significant. No mention was made as to the statistical tools used. Recommendations were made for future research with the Navajos. The investigators summarized their findings that those younger, more educated Navajos were more likely to keep their appointments but further study was needed in order to make a statement as to the Navajo's ability and/or desire to keep clinic appointments (Mealey; Kane, 1977).

No studies were found on the effect of a C.O.P.D. patient's quality of life upon compliance. Research into the specific problem of compliance in C.O.P.D. patients was not located.

Summary of Literature Reviewed

In summary, it was shown that health care personnel were faced with the problem of noncompliance with medical regimens. This was a common difficulty in all types of patients with a variety of illnesses. Various reasons for noncompliance were cited: poor knowledge of illness, lack of communication between patient and physician, discrepancies between expectations by patients and unmet needs, complete responsibility for one's own care at home, complex medication progarms, etc. Many suggested methods of attempting to solve the dilemma of how to get patients

to follow medical orders were recommended but no effective solution had been developed. The purpose of the current compliance study was to gather evidence about the efficacy of one treatment regimen (individual instruction) on the compliance of C.O.P.D. patients compared to another treatment regimen (group instruction).

Chapter 3

METHODOLOGY OR PROCEDURES

In Chapter 3, the research methodology is described along with the research design that was used in formulating the C.O.P.D. compliance study. The type of study patients and the criteria for their selection into this study is also described. Instrumentation used in the study as well as methods of collecting data, recording the information collected, and data processing and analysis are discussed in this chapter. The limitations of the C.O.P.D. study and the methodological assumptions are described. These areas are summarized at the conclusion of the chapter.

Research Method

The research method implemented in the current compliance study in the C.O.P.D. patient was quasi-experimental and correlational. The randomly-assigned participants of an on-going National Heart, Lung and Blood Institute (NHLBI) IPPB versus Compressor Nebulizer Study being conducted at a 500-bed University Medical Center were alternately assigned to an experimental or control group for the present study. The sample distribution should be normal.

Research Design

The research design was the randomized control-group pretest-posttest design. Differences may have arisen between the experimental

group which received individual instruction and the control group which received group instruction as they were tested and treated separately which may have adversely affected the internal validity. These differences could have been related to the physical environment or to personality clashes. In an attempt to solve these problems the patients were randomly assigned to test times and rooms as they were individually evaluated.

Variables that influenced the outcome of this study were grouped into four separate categoreis: (1) controlled variables; (2) recorded variables; (3) measured variables; and (4) uncontrolled variables.

Controlled Variables

The variables which were controlled for in this study were:

1. Individual instruction was provided by the nurse researcher for all patients in the experimental group.

2. Group instruction was provided by the nurse researcher for all patients in the control group.

3. Patients used for this study lived in close proximity to the medical center.

4. Pill counts and liquid medication measurements were performed by the same person for all patients.

5. Breathing machines were checked monthly to insure their proper functioning.

6. Biweekly contact was made with the patients to remind them of appointments and test schedules.

Recorded Variables

The variables which were recorded as reported by patients but not controlled for in this study were:

1. age;
2. sex;
3. present employment status;
4. marital status;
5. duration of C.O.P.D.;
6. any chronic illness other than C.O.P.D.;
7. treatment programs other than that for C.O.P.D.;
8. frequency of non-hospitalized pulmonary exacerbations in the three months of the study; and
9. frequency of hospitalized pulmonary exacerbations in the three months of the study.

Measured Variables

The variables counted as subjectively reported or measured objectively for this study were:

1. number of cigarettes smoked per day;
2. number of theophylline pills per day ordered;
3. number of theophylline pills distributed to the patient;
4. number of days since pills distributed;
5. number of pills left when pill supply collected;
6. number of pills used per day;
7. number of breathing treatments per day ordered;
8. amount of liquid medication distributed to patient;

9. amount of liquid medication left when supply collected;

10. amount of liquid medication used per day;

11. meter reading on breathing machine last visit;

12. meter reading on breathing machine this visit;

13. number of minutes per day machine was used;

14. results of Rotter I:E Test;

15. ranking of symptomatology upon patient interview (cough, sputum, shortness of breath, wheezing, and fluid retention) as to none (0), mild (1), moderate (2), or severe (3);

16. findings upon physical examination (blood pressure; respiratory rate/minute; heart rhythm and regularity; apical heart rate/minute; breath sounds--wheezing, rales, and/or decreased; use of accessory neck muscles at rest; increased jugular venous pressure; hepatomegaly; and peripheral edema); and

17. FEV_1 and FVC.

Uncontrolled Variables

The variables which were uncontrolled in this study were:

1. patients discarding pills rather than taking them;

2. patients allowing their breathing machines to run without taking a treatment;

3. patients' inability to accurately remember the number of cigarettes smoked per day or a patient's dishonest answer to the question;

4. unsupportive family members which could possibly promote noncompliance;

5. patients going to Mexico for "cure-all" respiratory medications;

6. patients answering the Rotter I:E Test in a way they think should give them an "A" grade;

7. patients with psychosocial problems; and

8, patients with decreased coping abilities and/or an increase in recent life changes.

A major threat to external validity lies in the fact that the experimental group received intensified instruction but also received increased attention from the nurse researcher which might have also influenced compliance. The patients selected for this study were those with a chronic disease which made it difficult to generalize for patients experiencing acute illness or a short-term disease.

Selection of Subjects

The sample for this study included 36 patients between the ages of 46 and 74 with chronic obstructive pulmonary disease who had met the criteria for the NHLBI IPPB versus Compressor Nebulizer Study and were being treated on an outpatient basis. The patients entered the study on a voluntary basis and informed consent was obtained previous to the onset of the study (see Appendix C). The criteria used for selection of participants in this study and the rationale for the use of those criteria are discussed in the following paragraphs.

The patients were diagnosed as having symptomatic chronic obstructive pulmonary disease. Studies have been done on compliance with medical treatment programs in diabetics, arthritics, cardiac patients,

hypertensive patients, and children, but no studies were located in which pulmonary patients were evaluated. The age group was 46 to 74 years of age. Spirometry done on the patients demonstrated FEV_1 < 60% and FEV_1/OBS VC < 60% thus demonstrating moderate to severe obstructive pulmonary disease. It had been noted in previous studies that severity of disease and extent of disability often showed an unexpected inverse correlation with compliance (Wilson, 1973, p. 337).

A willingness to participate in a pulmonary rehabilitation program was a criterion for selection. The patients were able to speak, read and comprehend English and lived in close proximity to the medical center for the sake of convenience in attending the education classes and for home visitation purposes. The patients were retired or disabled or working in a job that would allow them to follow the medical treatment program thus avoiding a conflict with the study. In order to participate in an exercise program (i.e., walking, bicycling, or other physical conditioning exercises), it was necessary for the patients to be ambulatory. The patients were symptomatic as demonstrated by dyspnea, cough, and/or sputum production. Thus, Wilson's suggestions that relief from the manifestations of a disease may provide incentive for compliance could be assessed (Wilson, 1973, p. 337).

Another criterion for selection was that the patients had families who were able to participate in learning the various aspects of the pulmonary rehabilitation education program with the patients because compliance can be dependent on the patient's assets, one of which is a supportive family (Gillum; Barsky, 1974, p. 1564). The patients were

able to participate on an outpatient basis. The outpatient department was unique in that the ambulatory patient was an active participant in the treatment process (Berkowitz, and Others, 1963, p. 16).

The sample was a purposive random sample consisting of 16 patients (eight with IPPB and eight with compressor nebulizer) in the experimental group and 16 patients (eight with IPPB and eight with compressor nebulizer) in the control group. All had been contacted to be considered for participation in the IPPB versus Compressor Nebulizer Study at the medical center. The patients were contacted within 24 hours after they had been entered into the NHLBI IPPB versus Compressor Nebulizer Study. Each prospective subject was observed and interviewed for at least one hour weekly for one month and then monthly for an overall total of three months.

Instrumentation

A Likert-type scale was used in this study--the Rotter Internal: External Locus of Control Scale. This scale produces ordinal levels of measurement.

The Rotter I:E Scale was a forced-choice 19-item scale including six filler items. It represented a continuum, marked at one extreme by people who tended to believe that they generally controlled their own destinies and that they were predominantly responsible for the accomplishments and problems of their lives. These individual demonstrated lower scores on the I:E Test and were considered to be internal. At the other extreme were people who tended to view life as being controlled by luck, fate, broad political and economic conditions, or

other factors outside their personal control. These individuals were considered to be external and demonstrated higher scores on the I:E Test. Knowledge of the patient's I:E score aided the treatment team in their approach. While "internals" tended to make use of relevant information to improve their situations, "externals" needed to be motivated to take advantage of knowledge by giving it in the form of directives from a prestigious source (Ritchie; Phares, 1969). "Internal" patients could be expected to take more responsibility for their treatment and to make more creative use of rehabilitation opportunities than "externals." On the other hand, "externals" needed a more authoritarian approach. It needed to be emphasized to the "external" patient that his compliance would be checked.

Reliability

Upon examination of the Rotter I:E Scale, item analysis and factor analysis showed reasonably high internal consistency for an additive scale. Test-retest reliability was satisfactory and the scale correlated well with other methods of assessing the same variable such as questionnaire, Likert scale, interview assessments, and ratings from a story-completion technique. Discriminant validity was indicated by the low relationships with such variables as intelligence, social desirability, and political liberalness. Differences in means of selected populations was generally a weak criterion of validity. Nevertheless, differences obtained for different types of populations were generally consistent with expectancies (Rotter, 1966, p. 25).

Validity

The most important evidence of the construct validity of the I:E Scale came from predicted differences on behavior for individuals above and below the median of the scale or from correlations with the behavioral criteria. A series of studies provided strong support for the hypothesis that the individual who had a strong belief that he controlled his destiny was likely to (1) be more alert to those aspects of the environment which provided useful information for his future behavior; (2) take steps to improve his environmental condition; (3) place greater value on skill or achievement reinforcements and be generally more concerned with his ability, particularly his failures, and (4) be resistive to subtle attempts to influence him.

Clinical Procedures

The patients and their spouses were contacted and the study was fully explained. The risks and benefits, and the procedures and tests to be performed were discussed. After the patients agreed to participate in the study, they signed the consent form and were given the Rotter I:E Test to complete.

The control group attended a group education class conducted by the nurse researcher while the experimental group received instruction individually from the nurse researcher. The instruction included anatomy and physiology of the pulmonary system, pathophysiology of pulmonary disease, and an explanation of their treatment program. The oral and inhaled bronchodilators were explained as to their actions and side effects as were other medications such as diuretics,

analgesics, corticosteroids, and cardiac medications. In addition, nutritional therapy, good health practices, stop smoking hints, and descriptions of the effect of lung disease on family and work relationships were included in the instruction.

Each patient was placed on an oral bronchodilator, Theodur or Sustaire, which was taken every eight to 12 hours according to the patient's tolerance and/or theophylline level. Levels were drawn approximately one to two hours before the next theophylline dose and dosages were regulated to reach a therapeutic range of 10-20 ug/ml. The patients were also taught the use of a metaproterenol or Bronkometer cartridge inhaler which was to be used four times a day.

Following the patients' randomization into the NHLBI IPPB versus Compressor Nebulizer Study, they were taught the use of either a Bennett IPPB machine or a Bennett compressor nebulizer. The machines were distributed to the patients free of charge and were to be used by each patient four times a day. They were given a bottle of metaproterenol or Bronkosol premix solution of which they were to use three millimeters for each breathing treatment. The patients were also provided with a dropper bottle in which the dropper was calibrated to measure one millimeter.

The patients were then visited weekly for one month and then monthly for a total of three months. During the visits, symptomatology was determined from the patients and physical examinations were conducted. The number of cigarettes smoked was also recorded.

Data Collection and Recording

After the patients agreed to engage in this study, they were assigned to a treatment group. They completed the Rotter I:E Test and received either group or individual instruction. A specific number of theophylline pills were given to each patient. The number of cigarettes smoked, symptomatology of cough, sputum, shortness of breath, wheezing, and fluid retention, and physical examination findings of blood pressure, respiratory rate, apical heart rate, breath sounds, heart sounds (i.e., presence or absence of S_3 or S_4), jugular venous distension, pedal edema, and hepatomegaly were recorded.

At the end of one month, the patients were randomized into the NHLBI Study at which time they were taught the use of either a Bennett IPPB machine or a Bennett compressor nebulizer. Each received a new bottle of theophylline pills and liquid medication to be used in their breathing machine. Once again the number of cigarettes smoked and the existing symptomatology were recorded. The physical examinations were performed.

The patients were then visited weekly in their homes through the first month. During the weekly visits, they were interviewed as to the number of cigarettes smoked and their existing symptoms. They were observed using their breathing machines to check for any problems with their methods or with the machines themselves.

At the end of the month, pill bottles and bottles of liquid medication were exchanged, meter readings on the breathing machines were recorded, and physical examinations were performed on the home visit.

The patients were interviewed as to the number of cigarettes smoked and the presence or absence of symptoms. The second month home visit involved the same process. Pill counts and liquid medication measurements were performed at the medical center.

The patients came into the medical center for a clinic visit in the third month of the compliance study and brought in their bottles of medication (liquid and pills) for exchange. They were interviewed as to the number of cigarettes smoked and their existing symptoms. They received physical examinations as well. Again the pill counts and liquid medication measurements were done. Pulmonary function testing was performed at both the beginning and the conclusion of the study.

Statistical Analysis

The purposive random sample analyzed consisted of 16 patients in the experimental group and 16 patients in the control group. The level of measurement was interval and ratio for pill counts, liquid medication measurements, breathing machine meter readings, number of cigarettes smoked, FEV_1, FVC, blood pressure, heart rate, and respiratory rate. The ordinal data included the symptomatology ratings. The statistical test chosen was the two-way analysis of variance that assumed at least ordinal data on an independent sample (Siegal, 1956). The frequency, mean, and standard deviation were done on all variables. The general linear hypothesis was performed with each of the compliance variables (i.e., pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked) as dependent

variables and group, machine, Rotter I:E Score, FEV_1, FVC, symptom score, changes in blood pressure, heart rate, and respiratory rate, and changes in symptoms as independent variables.

Methodological Assumptions

The following were methodological factors that were assumed in this study:

1. that C.O.P.D. patients selected for this sample were representative of the general C.O.P.D. population;

2. that the patients were reliable in their responses during the interview (i.e., number of cigarettes smoked, etc.) and on the Rotter I:E Test;

3. that the patients honestly followed their medical regimen (i.e., not discarding theophylline pills and/or liquid bronchodilator);

4. that the pill counts and liquid medication measurements were done accurately;

5. that the assumptions of the Rotter I:E Test were applicable to the sample; and

6. that the validity and reliability of the Rotter I:E Test were applicable to the study.

Limitations

The methodological limitations in this study are commented upon in the following sentences.

Although the subjects were asked to stop smoking, they were not required to stop smoking nor was the study restricted to nonsmokers.

The subjects could have developed positive or negative feelings about being required to attend an instruction class whether it be the group instruction or the individual instruction. The subjects at various times during the study experienced exacerbations of their pulmonary disease which could have affected their compliance to the medical regimen. There may have been unidentified confounding variables which would have influenced the findings of the study. Subjects who continued to work may have had less tendency to comply to the treatment program. The subjects could have thrown out medications or run their breathing machines without taking a treatment to give the nurse researcher the conception that the subjects were being compliant.

Summary

The C.O.P.D. compliance study was a quasi-experimental study using a randomized control-group pretest-posttest design. No pilot study was performed as the NHLBI Study was already in progress. The patients were chosen to be participants if they were between the ages of 30 and 74 with symptomatic C.O.P.D. Spirometry on the patients demonstrated values with an $FEV_1 < 60\%$ and an $FEV_1/OBS\ VC < 60\%$. Requirements were a willingness to participate in a pulmonary rehabilitation program as well as the ability to speak, read, and comprehend English and live in close proximity to the medical center. If the patient was disabled or working at a job not in conflict with the study, the patient was allowed in the study. Patients randomly and alternately assigned were 16 for the control group and 16 for the experimental

group with eight in each group using an IPPB machine and eight using a compressor nebulizer.

The data collection instrument used was the Rotter I:E Test. Also described in this chapter were the means of collecting data (i.e., pill counts, liquid medication measurements, etc.) and the procedures used (i.e., education program, home visits, clinic visits). In analyzing the collected data, the statistical test used was the two-way analysis of variance that assumed at least ordinal data on an independent sample.

Limitations to the study were listed such as the patients' inability to stop smoking and patients experiencing exacerbations. Also discussed were the methodological assumptions such as the C.O.P.D. patients selected for this study were representative of the general C.O.P.D. population, the patients were honest in their interview answers, and pill counts and liquid medication measurements were performed accurately.

Chapter 4

PRESENTATION AND DISCUSSION OF DATA ANALYSIS

The purpose of the study reported in this section was to compare the effects of individual instruction versus group instruction on the compliance of C.O.P.D. patients. The compliance of patients was to be measured by pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked. Other variables considered were the degree of symptomatology, change in physical findings, change in pulmonary function, and Rotter I:E Scale.

Demographic Data

This study of compliance in C.O.P.D. patients was conducted on 36 patients, 18 in the experimental group and 18 in the control group. Variables that were recorded on each patient were summarized in Table 1. The mean age for the control group was 60.3 years while for the experimental group it was 61 years. The majority of patients were male (100 percent for the control group and 78 percent for the experimental group) and the majority were also retired or on disability. In the control group, 72 percent were married, 22 percent were separated or divorced, and 6 percent were widowed. In the experimental group, 88 percent were married, 6 percent were separated or divorced, and 6 percent were single. The data revealed that 33 percent of the control group had had C.O.P.D. between 0 and 10 years, 39 percent had had it for 11-20 years, and 28 percent had had it for over 20 years. In the

Table 1

Demographic Data of C.O.P.D. Patients

Variables	Control Group	Experimental Group
Mean Age	60.3 years	61 years
Sex		
Male	100%	78%
Female	--	22%
Present Employment Status		
Disabled/retired	67%	89%
Employed	33%	11%
Marital Status		
Married	72%	88%
Separated/divorced	22%	6%
Single/widowed	6%	6%
Duration of C.O.P.D.		
0-10 years	33%	78%
11-20 years	39%	22%
Over 20 years	28%	--
Any other Chronic Illness	0%	11%
Frequency of Nonhospitalized Pulmonary Exacerbations		
(0)	39%	50%
(1)	50%	28%
(2)	11%	22%
Frequency of Hospitalized Pulmonary Exacerbations		
(0)	83%	89%
(1)	17%	11%
Treatments Other than for C.O.P.D.	0%	5.5% diuretics 5.5% eye drops

experimental group, 78 percent had had C.O.P.D. for 0-10 years and 22 percent had had it for 11-20 years. There was no other chronic illness in the control group while 11 percent in the experimental group had some other chronic illness.

In looking at the frequency of nonhospitalized exacerbations in the control group, 39 percent of the patients had no exacerbations in the three months of the study, 50 percent had one exacerbation, and 11 percent had two exacerbations. In the experimental group, 50 percent had no exacerbations in the three months of the study, 28 percent had one exacerbation, and 22 percent had two exacerbations. Eighty-three percent of the control group were not hospitalized, while 17 percent were hospitalized for one respiratory exacerbation. In the experimental group, 89 percent were not hospitalized, while 11 percent were hospitalized for one exacerbation. In the control group, no patients were on any treatment other than for C.O.P.D., while in the experimental group, 5 percent were on diuretics and 5 percent on eye drops for glaucoma.

Hypothesis 1--Individual Instruction vs. Group Instruction

Using a general linear hypothesis with use of liquid medication as a dependent variable and group (experimental and control), machine, Rotter I:E score, FEV_1, FVC, and degree of symptomatology as independent variables, the individual instruction was found to be statistically significant ($p=.027$). The patients who received the individual instruction were significantly more compliant in using their liquid medication.

There was no statistically significant difference between individual instruction and group instruction on compliance as measured by pill counts, breathing machine meter readings, or number of cigarettes smoked. As a whole, the null hypothesis which stated there was no significant difference between individual instruction and group instruction was supported by the data collected.

Hypothesis 2--Symptomatology and Compliance

Using a general linear hypothesis with pill counts as the dependent variable and degree of symptomatology (i.e., ranked score of difficulty with coughing, sputum production, shortness of breath, wheezing, and fluid retention), group machine, Rotter I:E score, FEV_1, and FVC as the independent variables, the degree of symptomatology had a borderline statistically significant effect on compliance with pill taking ($p=.057$). The patients who experienced more difficulty with their symptoms in both groups were more compliant with their pill taking. There was no statistically significant relationship between the ranked score on symptomatology and compliance as measured by liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked. The null hypothesis which stated there was no significant relationship between the degree of symptomatology and compliance was supported (see Table 2).

Table 2

Percentage of Physical Findings Present
in C.O.P.D. Patients Monthly

Variables	Control Group						Experimental Group					
	IPPB			CN			IPPB			CN		
	Month			Month			Month			Month		
	1	2	3	1	2	3	1	2	3	1	2	3
Regular Heart Rhythm	100%	89%	100%	89%	89%	89%	89%	78%	89%	89%	100%	89%
Gallop Rhythm	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Rales	33%	44%	33%	22%	33%	33%	22%	67%	22%	0%	67%	22%
Wheezes	56%	33%	44%	0%	22%	22%	44%	33%	44%	44%	22%	33%
Decreased Breath Sounds	100%	33%	78%	89%	78%	89%	89%	78%	67%	89%	89%	78%
Jugular Venous Distention	0%	0%	22%	11%	0%	0%	11%	33%	22%	0%	11%	0%
Pedal Edema	0%	11%	0%	22%	11%	22%	0%	11%	22%	22%	33%	22%
Hepatomegaly	0%	11%	0%	0%	0%	0%	0%	0%	0%	0%	11%	0%

Hypothesis 3--Physical Findings and Compliance

Using a general linear hypothesis with pill counts, liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked as dependent variables and changes in physical findings (i.e., blood pressure, heart rate and rhythm, respiratory rate, breath sounds, heart sounds, jugular venous distention, pedal edema, and hepatomegaly) as independent variables, the presence of physical findings had no statistically significant effect on compliance. The null hypothesis which stated there was no significant relationship between changes in physical findings and compliance was retained (see Table 3).

Hypothesis 4--Pulmonary Function and Compliance

Using a general linear hypothesis with pill counts as the dependent variable and group, machine, Rotter I:E Score, degree of symptomatology, FEV_1, and FVC as the independent variables, the FVC was found to be statistically significant ($p=.030$) as it relates to compliance as demonstrated by pill counts. The higher the FVC value, the more compliant the patient was with his pill taking. The FEV_1 had no statistically significant effect on pill counts and both the FEV_1 and the FVC had no statistically significant effect on liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked. The null hypothesis that stated there was no

Table 3

Means and Standard Deviations of the Biophysical Data Used to Measure Compliance in C.O.P.D. Patients

Variables	Control Group		Experimental Group	
	IPPB	CN	IPPB	CN
Systolic Pressure mm/Hg				
Month 1	131 ± 11.4	147 ± 18.5	131 ± 14.5	127 ± 16.8
Month 2	125 ± 16.6	127 ± 17.9	125 ± 14.5	136 ± 20.0
Month 3	126 ± 15.4	131 ± 17.8	121 ± 19.3	133 ± 15.6
Diastolic Pressure mm/Hg				
Month 1	84 ± 5.8	89 ± 14.7	80 ± 8.3	74 ± 8.5
Month 2	77 ± 8.0	77 ± 6.4	75 ± 6.4	81 ± 8.8
Month 3	76 ± 6.6	76 ± 10.6	75 ± 9.9	80 ± 6.2
Heart Rate				
Month 1	82 ± 15.2	83 ± 11.1	84 ± 14.2	97 ± 15.5
Month 2	90 ± 14.4	79 ± 10.6	88 ± 19.4	92 ± 8.7
Month 3	91 ± 16.0	81 ± 6.7	90 ± 14.3	90 ± 15.1
Respiratory Rate				
Month 1	16 ± 4.2	18 ± 2.9	19 ± 4.7	19 ± 3.3
Month 2	21 ± 5.9	18 ± 4.4	20 ± 4.5	19 ± 4.4
Month 3	18 ± 3.9	19 ± 4.2	18 ± 4.0	20 ± 2.8

significant relationship between changes in pulmonary function (FVC and FEV_1) and compliance was retained.

Hypothesis 5--Rotter I:E Score and Compliance

Using a general linear hypothesis with pill counts as the dependent variable and group, machine, Rotter I:E Score, degree of symptomatology, FEV_1, and FVC as the independent variables, the Rotter I:E Score was found to have a statistically significant ($p=.027$) effect on pill counts. The lower the score and, therefore, the more internal the patient, the more compliant the patient was with his pill taking. There was no statistically significant relationship between the Rotter I:E Score and liquid medication measurements, breathing machine meter readings, and number of cigarettes smoked. The null hypothesis which stated there was no significant effect of the Rotter I:E Score (internal or external orientation) on compliance was retained.

Discussion

The current compliance study revealed a large amount of variability among individuals in both the experimental and control groups (see Table 4). As an example, one individual was overcompliant one month at 120 percent and then noncompliant at 77 percent the next month. There were other individuals who refused to take any oral bronchodilator while another individual in the group overcomplied at a rate of 153 percent. This variability could account for the small number of statistically significant relationships between independent variables and dependent variables. A larger number of

participants than were used in this study would be necessary to compensate for this wide variability.

There was a statistically significant relationship (p=.027) between the individual instruction and the liquid medication measurements. This did not correlate with the breathing machine meter readings. The breathing treatments with the machines were to be taken using a specified amount of liquid medication. But there was no statistically significant relationship between the meter readings and the individual instruction. The lack of correlation could have been related to the possibility that individuals discarded medication in an attempt to appear compliant to the nurse researcher.

The higher ranked symptomatology score as reported by the patient had a borderline significance (p=.057) on the number of pills taken. When looking at the individual data collected, it was noted some individuals took more pills when they symptomatically felt worse and some individuals took less pills when they symptomatically felt worse. Physical findings such as blood pressure, heart rate, and respiratory rate were found to be within the normal range in all patients with no significant changes during the course of the study. The physical findings had no significant effect on compliance.

The current compliance study showed that the individual time and instruction given to a patient by the nurse researcher did not result in higher level of compliance when compared to a patient who received group instruction. No comparison was made to patients who received no instruction so a general statement could not be formulated concerning the value of any instruction. A study conducted by Spector

Table 4

Ranges and Medians of Compliance Variables
in C.O.P.D. Patients

Range	Control Group	Experimental Group	Median	Control Group	Experimental Group
		MONTH 1			
Pills %	0 - 153	0 - 115	Pills %	79	91
Liq. %	14 - 106	31 - 113	Liq. %	58	82
M. Rdg. %	7 - 87	38 - 104	M. Rdg. %	55	68
Cigarettes	0 - 40	0 - 20	Cigarettes	9	.3
		MONTH 2			
Pills %	0 - 110	0 - 110	Pills %	81	95
Liq. %	0 - 99	15 - 136	Liq. %	53	79
M. Rdg. %	0 - 98	8 - 113	M. Rdg. %	56	74
Cigarettes	0 - 40	0 - 30	Cigarettes	5	.1
		MONTH 3			
Pills %	0 - 104	0 - 110	Pills %	80	8
Liq. %	10 - 100	17 - 120	Liq. %	54	81
M. Rdg. %	0 - 89	36 - 102	M. Rdg. %	60	75
Cigarettes	0 - 40	0 - 30	Cigarettes	2	.3

and others (1978) investigated two groups of patients taking either digoxin or methyldopa, one group receiving educational intervention by a nurse and one group receiving no educational intervention. They found no significant difference on compliance between the two groups. In this study when analyzing a general clinic group who were not informed of the research being conducted as were the previous two groups being studied, it was discovered that the group not informed of the research were more noncompliant than the other two groups. The fact that both groups in the current compliance study were aware that they were participating in the study could have accounted for the lack of significant difference between the two groups.

It has been the belief of health professionals and researchers that nursing intervention could significantly influence a patient to be compliant with his medical treatment program. It was the nurse who had frequent close contact with the patient. The study by Linde and Janz (1979) evaluated the effect of a comprehensive patient education program on the knowledge and compliance of cardiac patients. The experimental group received the comprehensive education program while the control group received education as they asked for it or as it became available to them. The knowledge discharge test scores showed a significant increase over the knowledge preoperative test scores in the experimental group. They also demonstrated high compliance rates as measured by blood levels (i.e., low cholesterol levels, therapeutic digoxin levels) and higher activity levels. The researchers related these results to the combination of the factors: (1) the teaching

program, (2) post-discharge follow-up visits, and (3) the continuity of personnel at follow-up. In contrast, although the patients in the experimental group in the current compliance study were exposed to all three factors, significant high compliance rates were not achieved which could be related to the high variability in a small number of patients.

The study by Becker and others (1978) emphasized that a person's beliefs could affect his rate of compliance. Specifically, a person who had positive beliefs about his health and how he himself could manage his health would tend to accept and follow therapeutic advice. An individual who was "internal" believed that he could control his own life including wellness or illness, while an "external" left his life to chance, luck, or fate. The current compliance study showed that "internals" were not significantly more compliant when compared to "externals" except in the case of pill counts. It could have been possible that the reason for this was that pill taking was a simple part of the program requiring minimal work.

A major problem with compliance was that of administering medications at the prescribed hours as studied by Tinkleman and others (1980). In order to minimize this problem, the patients in the current compliance study were placed on long-acting theophylline preparations requiring administration only once every eight to 12 hours rather than four times a day when taking the short-acting preparations. The researchers found that patients were more compliant when they could cut down on the number of pills that needed to be taken per day. This

factor could also have affected the patients in the current compliance study.

D'Altroy and others (1978) studied a thorough inpatient instruction program on medications that was organized into three levels. Level 1 included instruction by the pharmacist on the use of the drugs and their side effects. In Level 2, the nurse worked with the patient in organizing his own medication schedule and in reinforcing what he had learned in Level 1. In Level 3, the patient was then allowed to take his own medications and keep a record of them. The control group received routine medication instruction that did not consist of these three levels. Pill counts were done on all patients one month following discharge and the patients who were placed on the self-administered program demonstrated a higher rate of compliance than those patients who received the routine instruction. These individuals receiving the self-administered medication program were found to be "internally oriented" which the researchers also believed contributed to compliant behavior. They felt that determining an individual's locus of control would assist health professionals in predicting compliance. The individual instruction in the current C.O.P.D. compliance study entailed a thorough explanation of the medications taken and the development of a medication schedule tailored to the patient's daily activities. The study revealed that there was no significant difference between individual instruction and group instruction on the pill counts. Statistical analysis showed that the "internally oriented" patient in both groups was significantly more compliant with his pill taking than the "externally oriented" patient.

This information suggested the need for more research in the area of locus of control and its effect on compliance when using locus of control as a predicting factor in compliance. Research may assist in the discovery of a means of using the locus of control to determine the type of teaching approach that should be implemented with "internals" and "externals."

Tagliacozzo and others (1974) also found that nursing educational interventions had little effect on patient behavior such as compliance with medication programs and compliance with clinic appointments. The experimental group in Tagliacozzo's study received a maximum of four teaching sessions with a nurse while the control group received limited contact with a nurse. The experimental group was not significantly more compliant with medications or clinic appointments. The study showed that patients who were more interested in learning about their disease or who were suffering with multiple illnesses were more responsive to the nursing intervention and therefore, were more compliant. The individually instructed patients in the current compliance study were not significantly more faithful in keeping clinic appointments than the patients instructed in the group session. There was no significant effect of either instruction upon the pill taking. It was not determined as to whether other factors affected patient compliance. There was a significant relationship between the FVC and compliance with pill taking in the C.O.P.D. compliance study which might infer that compliance increased as the patient's condition improved and not as it worsened. Possibly those individuals got more effective responses to medication and tended to be more compliant.

The data from some of the studies reviewed suggested that compliant behavior had been achieved by thorough instruction of the patient. It should be noted that instruction was only one variable that could affect compliance and there may be many factors in an individual's life that must be considered when trying to promote compliance. This current compliance study demonstrated no significant difference between group instruction and individual instruction. It showed a significant relationship between pill taking and the lower Rotter I:E Score, the higher FVC level, and the higher degree of symptomatology. Individual instruction significantly affected the use of the liquid medication but since this did not correlate with the time shown on the breathing machine meter readings, there may have been extraneous variables affecting this finding.

Summary

The findings of the study comparing individual instruction with group instruction and their individual effects on compliance were presented in Chapter 4. Each hypothesis was evaluated by analysis of the data collected and each null hypothesis was retained. The findings were compared with findings of other researchers as presented in Chapter 2. A summary was made as to the significant results shown by the current compliance study.

Chapter 5

SUMMARY, CONCLUSIONS AND IMPLICATIONS FOR NURSING, AND RECOMMENDATIONS

Because of the evolution of hospitals from general care to acute care centers, the need for more outpatient therapy programs had increased in an effort to aid patients in managing their health care at home. This in turn posed the question to health professionals as to how they could better assure that these patients would follow the treatment program outlined for them in this setting. The problem of noncompliance had been studied by many investigators who had formulated suggestions on how to treat the problem. One method of dealing with noncompliance promoted by some researchers was education of patients regarding their disease and its proposed treatment. The current compliance study was concerned with the comparison of using individual instruction versus group instruction provided by the nurse researcher, in an attempt to determine each method's effect on compliance.

Summary

The overall objective of the study was to compare the efficacy of individual instruction on compliance with that of group instruction. The study was also aimed at looking at the effect of the degree of symptomatology, changes in physical findings, changes in pulmonary function, and locus of control on compliance. A review of the literature delineated the problems of noncompliance that were evident in patients with various types of diseases, in all nationalities, age

groups, and employment statuses. Research revealed that problems with compliance stemmed from poor communication between patient and physician or other staff members (Faigel, 1972), the absence of another support system to assist the patient in complying with the program (Neely; Patrick, 1968), lack of knowledge about the disease and its treatment (Francis, and Others, 1969), dissatisfaction with the clinic or individual staff members (Francis, and Others, 1969), lack of consistent follow-up (Linde; Janz, 1979), lack of commitment from the patient to comply (Levy, and Others, 1979), lack of adjusting the treatment to the patient's individual needs (D'Altroy, and Others, 1978), or lack of belief in the value of health (Becker, and Others, 1974). No studies were found evaluating the effect of education on compliance in the C.O.P.D. patient population specifically which became an incentive for conducting this research study.

The research method implemented was quasi-experimental and correlational using the randomized control group pretest-posttest design. There were 36 subjects participating in the study with half in the experimental group receiving individual instruction and half in the control group receiving group instruction. Variables that influenced the outcome of the study were categorized as (1) controlled variables (individual instruction provided by the nurse researcher, patients living in close proximity to the medical center, etc.); (2) recorded variables (age, sex, marital status, etc.); (3) variables to be measured (number of cigarettes smoked, etc.); and (4) uncontrolled variables (patients discarding pills rather than taking them, patients with psychosocial problems, etc.).

The patients selected for the study ranged in age from 46 to 74 years, were willing to participate in a pulmonary rehabilitation program, demonstrated moderate to severe C.O.P.D. on spirometry, and were symptomatic. These patients could speak, read, and comprehend English. They were able to participate in an exercise program.

The Rotter I:E Test, a Likert-type scale, was used in the study. This test was given to the patients at the beginning of the study as a means of measuring internal and external orientation.

Each patient was studied for a total of three months. In order to determine compliance, pill counts and liquid medication measurements were performed and breathing machine meter readings were recorded. The patient was also interviewed concerning the number of cigarettes smoked per day and his degree of symptomatology. Physical examinations were performed on a monthly basis. Pulmonary function testing was performed at the beginning of the study and at its conclusion.

The statistical test chosen was the two-way analysis of variance which assumed at least ordinal data on an independent sample. The null hypothesis regarding the difference between individual instruction and group instruction on compliance was supported as was the null hypothesis comparing the effect of the degree of symptomatology on compliance. There were no significant findings that resulted from a patient's change in physical findings (i.e., blood pressure, heart rate and rhythm, respiratory rate, breath sounds, heart sounds, jugular venous distension, pedal edema, hepatomegaly) and its effect on compliance. The severity of pulmonary function (FEV_1 and FVC) had no significant effect

on compliance. The data also supported the null hypothesis that there was no significant relationship between the Rotter I:E Score and compliance except in the area of pill taking where having an internal orientation significantly increased compliance.

Conclusions and Implications for Nursing

Does it pay for us to continue educating our patients? Would they do just as well if left on their own? Are we merely confusing them with our teaching? From this current compliance study it might be concluded that instead of taking the time and staff to provide individual instruction for C.O.P.D. patients, that group instruction for C.O.P.D. patients would be more economical and as effective.

The current compliance study revealed no statistically significant effect on compliance when the patient became more symptomatic. This enforced the impression that we could not rely upon a patient being compliant because he demonstrated an increase in the amount and severity of symptoms. This was also true for worsening of physical findings. The analysis revealed that the C.O.P.D. patients participating in this study were within normal range in blood pressure readings, heart rate, and respiratory rate. These did not change significantly during the study and changes involving heart sounds, breath sounds, pedal edema, jugular venous distension, and hepatomegaly were not significant.

A worsening in pulmonary function may cause a patient to feel more symptomatic and as stated above, this symptomatic change may not affect a person's compliance. In the current compliance study, it was

found that as the FVC improved, compliance in pill taking improved. This could have occurred because the patients felt results from taking their medication or the medication could have caused an improvement in the FVC. The internal orientation of patients as determined by the Rotter I:E Test revealed a significant effect on pill taking but not in the other areas of compliance. Research into the use of the locus of control could aid in the development of solutions for compliance problems.

An additional implication for nursing was that we should be open to clues from the patient as to why he was so noncompliant. Speaking to him about possible problems that may have interfered with his following the program and working on solutions with the patient should prove helpful. Nurses should become more involved in problem-solving with patients because the nurse has many opportunities to speak with the patient about this particular subject.

Recommendations

During the process of conducting this study, ideas for further research in this area became apparent. The following recommendations for continued study in the field of compliance are described in the following paragraph.

What effect would the progression of the severity of C.O.P.D. have upon compliance? This would entail looking at groups of patients for longer periods of time. Comparison between a worsening pulmonary function and its effect on compliance could be evaluated. Another variable that might be significant is the effect of continual follow-up

and reinforcement during this time period. What part does a therapeutic relationship with a physician, nurse, or therapist play in compliance?

An area that could be evaluated during long-term investigation would be to look at recent life changes such as death of a spouse, loss of a job, etc., to determine the effects of these life changes on patient compliance and/or the progression of the disease process itself. Does a positive or negative stress in life affect how an individual will comply? Does a change in the life system affect the disease or does the disease affect life changes?

Although some comparison was made in the current compliance study between exacerbations and compliance, an in-depth study over a longer time period with more patients could be valuable in assessing the effects of exacerbations on compliance. Do patients follow their treatment programs when they "feel" sick? Do they follow their treatment programs when their physical condition worsens? Does what the patient views as a significant illness or what the clinician views as a significant illness affect the rate of compliance?

The Locus of Control Assessment was used in this currrent compliance study as a means of determining if "internal" individuals tend to be more compliant than "external" individuals with this type of educational approach. One recommendation would be to use the locus of control before education is initiated and then at subsequent intervals to determine the effect of education and reinforcement upon an individual's locus of control. Can education itself change beliefs about the control of the individual's life and the individual's health? Individuals could be studied to see what type of teaching methods are most effective for

"internals" versus "externals." A teaching method designed to meet specific needs of "internals" and "externals" could possibly have a dramatic effect on compliance.

Health professionals often will determine what they themselves feel is the best approach for the patient without consulting with the patient. What a patient feels is important for his quality of life may be in conflict with what health professionals feel is important. Study into a patient's own definition of his quality of life and its effect on compliance should be completed. Families can play a significant part in a patient's health and quality of life. What effect does an extensive educational program for the family have on quality of life and/or compliance?

Using a large population group, a review of the demographic data could be useful to determine if there are significant variables that if present, help predict compliant behavior. Previous studies have emphasized that these variables have no significant effect on compliance but a larger study looking at many variables may prove otherwise.

Some researchers have used the Health Belief Model as a means of determining what affects an individual's compliance. In using this model within the context of an educational program, researchers could determine the effect on compliance of the following beliefs: (1) belief that one is vulnerable or susceptible to disease; (2) belief in the severity of disease; (3) belief that treatment would make a difference; (4) knowledge of "cues" for action by the patient such as a smog alert should cue a severe asthmatic to stay inside and reduce activity; and

(5) belief that health is a valuable commodity (U. S. Department of Health, Education, and Welfare, 1977, pp. 133, 134).

In evaluating the C.O.P.D. patient and his compliance, an area that needs research is the neurophysiologic effects of C.O.P.D. and its subsequent effect on behavior. Findings from this research could answer questions regarding the physiological effects of this disease on compliance/noncompliance. Investigation could also be made into the neuropsychological aspects of care as related to education. How is neuropsychological impairment related to learning? Do patients with C.O.P.D. demonstrate neuropsychological impairment?

A major questions that should be answered is: What areas of compliance are most important? Is it necessary that a patient be compliant in every aspect of his program or are there certain areas that are most significant for that patient's health and/or survival? Is it mandatory for the patient's health and/or survival that he demonstrate 100 percent compliance? The purpose of increased compliance is that of increasing the patient's quality of life and health professionals working with the patient himself may determine the amount and type of compliance necessary to improve both his health and his quality of life.

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APPENDIX A

STATEMENT OF APPROVAL OF PROPOSAL SUBMITTED TO THE ETHICS IN STUDENT RESEARCH COMMITTEE

Loma Linda University
A Seventh-day Adventist Institution

Graduate Division in Nursing
Loma Linda Campus
714/796-7311 Extension 2139, 2601

Approval Date May 19, 1979

Renee L. Weisz
439 La Verne St.
Redlands, CA 92373

Dear Renee:

The Ethics in Student Research Committee has reviewed the proposal you submitted for a research study to partially fulfill the School of Nursing requirements for a Master of Science degree from Loma Linda University.

The Committee has voted that your study is:

___x_ Approved as submitted in the specified setting for one year.

_____ Approved in the specified setting for one year after the recommended changes have been made and a memo from your research chairman to this effect has been received by the committee chairman.

_____ Not approved as submitted to the committee. See the attached comments for recommended changes. Must be resubmitted prior to any data collection.

_____ Deferred to: ___UCOHS ___Research Chairman ___Other

_____ Please see attached recommendations and/or comments regarding this action.

Please remember to give all signed consent forms to the Research Coordinator. Please contact the Chairman of the Ethics in Student Research Committee if you have questions related to the decision of the Committee. If any changes are made in the hypothesis, tool, consent form, or the procedure for data collection, this proposal must be resubmitted to this Committee. If data collection extends beyone one year the proposal must be resubmitted to the Committee.

We pray that the Lord will continue to bless your endeavors.

Sincerely,

Evelyn L Elwell

Evelyn L. Elwell, Chairman
Ethics in Student Research Committee

xc: Research Committee Chairman
Advisor - L. Lewis

APPENDIX B

PERMISSION TO UTILIZE THE ROTTER I:E TEST

The University of Connecticut

STORRS, CONNECTICUT 06268

THE COLLEGE OF
LIBERAL ARTS AND SCIENCES
Department of Psychology

August 21, 1979

Renee Weisz, R.N.
Pulmonary Rehabilitation Center
Loma Linda University Medical Center
Loma Linda, California 92354

Dear Ms. Weisz:

You have my permission to use the I-E Scale for your master's research and to include a copy in the appendix of your thesis.

Very truly yours,

Julian B. Rotter

Julian B. Rotter
Professor of Psychology

JBR/isw
Encl.

APPENDIX C

PATIENT CONSENT FORM

I desire to engage voluntarily in a study to be conducted at the Loma Linda University Medical Center, under the auspices of the National Heart, Lung and Blood Institute. I understand that the study is designed to assess the comparative value of the Intermittent Positive Pressure Breathing (IPPB) machine and the Compressor-driven Nebulizer (CN), both of which may be beneficial in the treatment of my diagnosed condition of Chronic Obstructive Pulmonary Disease.

I have been informed that my assignment to either the IPPB or the CN shall be made on a random basis, and that once assigned I shall undergo treatment three to four times per day for three years. Prior to my assignment, I have been informed that I will be carefully observed for four weeks on a standard treatment program without the use of IPPB, CN, or oxygen, unless my physician concludes that going without these treatment modalities would be harmful. I understand that during the course of the study, I will also be expected to undergo periodic testing to monitor treatment results.

I acknowledge that before signing this consent form, I have been provided with a full explanation of the procedures to be followed in the study, of the potential risks and benefits, and of the alternative modes of treatment. Among the potential benefits that have been described to me are slowing of deterioration in pulmonary function, greater exercise tolerance, lessening of pulmonary symptoms, improved mental ability, and more intensive diagnosis and treatment. Among the potential risks of which I have been informed are the following:

1. Catheterization, the insertion of a small tube into the artery, will be required for an exercise test. If such catheterization should result in formation of a blood clot, surgery may be necessary to remove the clot from the artery.
2. A bicycle exercise test will cause shortness of breath and fatigue and may cause an irregular heart rate. An exceedingly rare complication is the development of an abnormal heart rhythm with ineffective heart beat (cardiac arrest or ventricular fibrillation). This may require drugs intravenously, electrical countershock to the chest wall, or chest compression with assisted breathing to convert the heart back to normal beat. Death during stress-testing has occurred in approximately 1 in 10,000 tests performed (and this is primarily heart disease patients).
3. Psychological tests will have general and personal questions that will require several hours to answer. These tests may cause fatigue.
4. One of the breathing tests requires you to swallow a small inflatable balloon (that is attached to a very narrow tubing) into your esophagus (which is just above your stomach). This may cause some discomfort in your nose, and there may be some gagging as you swallow the balloon.
5. Some of the drugs which have been studied as drugs under investigation for use in the treatment of patients with your disease have been found to be associated with the development of benign tumors in the reproductive system of rats when the drugs were administered to rats at relatively high dosages. It should be noted that the drugs which gave the tumor-producing results are not presently available for this study.
6. The effect of the drug that will be used in this study on the mother and child during pregnancy is unknown. Because of this fact, all female patients who become pregnant will be excluded from the study.

I understand that trained personnel will be available at all times during treatment and testing so that any adverse reaction shall receive immediate attention. I further understand that if my assigned treatment routine, either IPPB or CN, is determined to be less beneficial than another mode of treatment, I will be promptly notified. 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.

If during the course of the study I develop medical problems as a direct result of being a participant in the study, I will be able to get medical attention at Loma Linda University Medical Center.

I have been informed that I may withdraw from this study at any time, that I may receive IPPB or CN treatment without participating in the study, and that necessary medical treatments will not be denied to me solely because of a decision not to participate or to withdraw from the study.

I agree that physicians, qualified research personnel who participate in this study, and any additional persons whom I may authorize shall have access to my medical records. My name will not be released in connection with any reports or publications resulting from the study. In the event of my death during the course of this study, the director of the study shall request a post mortem examination, including the removal and retention of specimens and tissues.

I have read and understood all of the foregoing, and I have received all the information that I desire concerning the study. I accept the risks and agree to have the treatments and procedures performed upon me as mentioned. I hereby consent to participate in the study.

Patient Signature	Witness Signature	Date and Time

LOMA LINDA UNIVERSITY MEDICAL CENTER

RESPIRATORY REHABILITATION NIH STUDY

02-0947 (7-79)

PATIENT IDENTIFICATION

APPENDIX D

ROTTER I:E TEST

Rotter's I-E Scale

Directions: Following are pairs of statements about personal belief. Tell me (or mark) the one of each pair that you believe, or comes closest to what you believe.

1. a. Children get into trouble because their parents punish them too much.
   b. The trouble with most children nowadays is that their parents are too easy with them.

2. a. Many of the unhappy things in people's lives are partly due to bad luck.
   b. People's misfortunes result from the mistakes they make.

3. a. One of the major reasons why we have wars is because people don't take enough interest in politics.
   b. There will always be wars, no matter how hard people try to prevent them.

4. a. In the long run people get the respect they deserve in this world.
   b. Unfortunately, an individual's worth often passes unrecognized no matter how hard he tries.

5. a. The idea that teachers are unfair to students is nonsense.
   b. Most students don't realize the extent to which their grades are influenced by accidental happenings.

6. a. Without the right breaks one cannot be an effective leader.
   b. Capable people who fail to become leaders have not taken advantage of their opportunities.

7. a. No matter how hard you try some people just don't like you.
   b. People who can't get others to like them don't understand how to get along with others.

8. a. Heredity plays the major role in determining one's personality.
   b. It is one's experiences in life which determine what they're like.

9. a. I have often found that what is going to happen will happen.
   b. Trusting to fate has never turned out as well for me as making a decision to take a definite course of action.

10. a. In the case of the well prepared student, there is rarely if ever such a thing as an unfair test.
    b. Many times exam questions tend to be so unrelated to course work that studying is really useless.

11. a. Becoming a success is a matter of hard work; luck has little or nothing to do with it.
    b. Getting a good job depends mainly on being in the right place at the right time.

12. a. The average citizen can have an influence in government decisions.
    b. This world is run by the few people in power, and there is not much the little guy can do about it.

13. a. When I make plans, I am almost certain that I can make them work.
    b. It is not always wise to plan too far ahead because many things turn out to be a matter of good or bad fortune anyhow.

14. a. There are certain people who are just no good.
    b. There is some good in everybody.

15. a. In my case, getting what I want has little or nothing to do with luck.
    b. Many times we might just as well decide what to do by flipping a coin.

16. a. Who gets to be the boss often depends on who was lucky enough to be in the right place first.
    b. Getting people to do the right thing depends upon ability; luck has little to do with it.

17. a. As far as world affairs are concerned, most of us are the victims of forces we can neither understand, or control.
    b. By taking an active part in political and social affairs the people can control world events.

18. a. Most people don't realize the extent to which their lives are controlled by accidental happenings.
    b. There really is no such thing as "luck."

19. a. One should always be willing to admit mistakes.
    b. It is usually best to cover up one's mistakes.

20. a. It is hard to know whether or not a person really likes you.
    b. How many friends you have depends upon how nice a person you are.

21. a. In the long run the bad things that happen to us are balanced by the good ones.
    b. Most misfortunes are the result of lack of ability, ignorance, laziness, or all three.

22. a. With enough effort we can wipe out political corruption.
    b. It is difficult for people to have much control over the things politicians do in office.

23. a. Sometimes I can't understand how teachers arrive at the grades they give.
    b. There is a direct connection between how hard I study and the grades I get.

24. a. A good leader expects people to decide for themselves what they should do.
    b. A good leader makes it clear to everybody what their jobs are.

25. a. Many times I feel that I have little influence over the things that happen to me.
    b. It is impossible for me to believe that chance or luck play an important role in my life.

26. a. People are lonely because they don't try to be friendly.
    b. There's not much use in trying too hard to please people; if they like you, they like you.

27. a. There is too much emphasis on athletics in high school.
    b. Team sports are an excellent way to build character.

28. a. What happens to me is my own doing.
    b. Sometimes I feel that I don't have enough control over the direction my life is taking.

29. a. Most of the time I can't understand why politicians behave the way they do.
    b. In the long run the people are responsible for bad government on a national as well as on a local level.