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Graduate School

Facilitation of C.O.P.D. Patient Compliance in Self-Administration of Medical Modalities Through In-Hospital Specialized Education Program

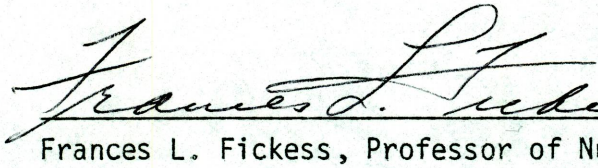
by

Elizabeth Maddox

A Project Submitted in Partial Fulfillment
of the Requirements for the Degree
Master of Science in the Field of Nursing

May, 1984

The person whose signature appears below certifies that she has read this research project and that in her opinion it is adequate in scope and quality as a nonthesis research project for the degree Master of Science.

 , Research Advisor

Frances L. Fickess, Professor of Nursing

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CHAPTER ONE

The Problem

Introduction

One task of the health professional is to assure prescribed treatments are carried out accurately and consistently by the patient at home. Literature is rich in data describing the problem of patient non-compliance with self-administration of medical modalities (Christensen, 1978, pp. 171-187).

In "Health Care in the Elderly: Report of the Technical Group on Use of Medicaments by the Elderly", The World Health Organization supports the fact that poor followthrough in self-administration of home treatment is even more of a problem among the world's aged (1981).

Much speculation and research has been done to explain the phenomenon of noncompliance and variables that relate to it. The main causal themes in literature include lack of motivation, lack of adequate medication education and multiple other differentiating characteristics (Anderson, 1980, pp. 299-304; Fry, 1981, p. 152; Talkington, 1978, pp. 591-595). Still others add that inability to follow prescribed regimens at home is not just one of the causes listed above but generally, a combination of these factors (Ellor, 1982, p. 330).

Problem Statement

This study explores the problem of patient non-compliance in self-administration of medical treatment in a home setting. For numerous

reasons many patients are unable or unwilling to carry out medical treatment as prescribed by their physicians. One instructional approach used by health professionals has been proven entirely effective in preparing and motivating patients to do so.

Study Need

If noncompliance is a multicausal problem, then the solution(s) should incorporate multiple intervention modalities. However, few research studies reflect an effort to test any one teaching or motivational modality, much less the use of several such modalities in one program. The variety of modalities suggested by other researchers that could be used include: patient-responsibility mechanisms, such as contracts; combinations of individualized and group teaching; repetitive practice; written, individualized schedules; or role-modeling and use of team collaboration.

There is need for a study that would test a program that incorporates interventions researchers have shown to alleviate but not completely alter the patterns of noncompliance. A specialized teaching program called Self-Administration of Medical Modalities (SAMM) has been developed to meet such a need and will be tested in this study.

Study Objectives

The objective of this study is to test the ability of a specialized teaching program to increase patient medication knowledge and in turn increase patient compliance in the home over an extended period of time.

Research Question

The study will explore the problem of patient compliance in spite of traditional instructions given in a hospital setting. The research question asks: does the use of a program employing multiple individualized teaching methods of hospitalized patients make a difference in patient knowledge and compliance at home on both a short-term and long-term basis?

Theoretical Framework

Systems Theory

The study is couched in Systems Theory which suggests that all parts of a whole are interdependant. Each part is complete in its-self yet necessary to the functioning of a larger unit (Bertalanffy, 1963). When a patient presents with a compliance problem regarding his treatment program, the medical professional is usually faced with not only one causative factor, such as inadequate family support, but many inter-relating factors such as combination of low motivation, sensory loss and inadequate knowledge level impacting on the patient's decision-making process.

The use of a team approach and multiple teaching modalities takes into consideration that not just one event or experience of the client and his support system impacts on his behavior or choices. Instead, it considers a variety of interlocking events, decisions, ideas, feelings and perceptions which culminate in a patient's overt behavior and in what observers interpret as compliance.

Learning Theory

Central to the SAMM program is learning theory which suggests conditions that must be present for the learner to change behavior. One is

learning readiness: the learner must be ready to accept information mentally and motivationally (Hallberg, 1976; Pohl, 1978).

Knowledge, frequently the only aspect addressed in patient teaching programs, is a good starting point, and has repeatedly been demonstrated to be a necessary but not sufficient condition for adherence. The presence of knowledge has failed to be a consistent predictor of compliance (Becker, 1979).

After gaining knowledge, the learner still may not alter his methods of dealing with change if he does not perceive a problem or perceive methods suggested as helpful to him (Arakelian, 1980, pp. 25-38; Becker, 1978, pp. 268-277).

Compliance Behavior

Research has identified more than 200 factors associated with compliance behaviors (Sackett, 1976) which revolve around four topics: the patient, his illness, the regimen and patient-clinician relationship.

The decision to change personal beliefs and initiate actual practice is the patient's (Becker, 1978, pp. 268-277). The information, attitudes and expectations communicated by health professionals should be supportive of patient motivations and contribute to the treatment process and the ability to carry it out (Schulman, 1979, pp. 267-284).

Theoretical Assumptions

The following assumptions are made in this study:

1. Patients want and seek help in management of their health problems.

2. Prescribed therapy is appropriate and essential to recovery or maintenance of health.

3. Patients need information communicated in understandable terms.

4. Patient compliance cannot be expected without sufficient information.

5. With proper preparation, all members of the health care team are appropriate educators for patients.

Null Hypothesis

For the purpose of this study the following null hypothesis was constructed:

Subjects who receive a planned program of instruction on an inpatient basis will demonstrate no difference in knowledge level and compliance at home from those who receive traditional instructions or no formal education. (=0.05)

Variables

The independent variable is a teaching manipulation by the use of the SAMM Program. The dependent variables are the subject's knowledge and compliance level at home up to and at six months.

Definition of Terms

Noncompliance

Theoretical: The subject is considered noncompliant when he does not carry out his physician's prescribed treatment regimen.

Operational: As a method of assessing compliance, this study will measure errors in three ways: patient report, pill counts and blood theophylline levels. A quantification of the subject's medication errors will be described under section on Interpretation of Compliance Measurements and Appendix A.

Traditional Patient Instruction

Theoretical: An informal instruction session to briefly explain prescribed treatment for the patient's use at home. The instruction is given on an inpatient or outpatient basis. These oral and/or written instructions usually do not include indepth explanation of reasons for treatment or possible side-effects. They are usually given shortly before the patient leaves the hospital or clinic. Traditional patient instruction usually does not include self-practice by the client, especially on a repetitive basis.

Operational: A patient instruction program as usually performed; does not include the SAMM program format.

Treatment Approach

Self-Administration of Medical Modalities

The Self-Administration of Medical Modalities (SAMM) Program is a teaching approach that recognizes the individuality of each person, differences in cognitive styles, and perceptual and expressive differences. It is defined as a formalized patient education program employed by the Pulmonary Rehabilitation Team at Loma Linda University Medical Center (1982). Its design to involve patients in their own care includes a variety of modalities to facilitate patient responsibility, raise patient knowledge level, and to provide collaboration between team members. Those modalities are described in the section on methodology.

Learning Levels. Three graduated learning levels are used and criteria for moving from one to the next depends on patient competency. The levels are as follows:

Level I - The subject receives instruction regarding actions and potential side-effects of medications. Medications are administered by staff. When designated staff determines the subject has safely demonstrated use and knowledge of medication at this level, the subject will be progressed to Level II. This is determined by the completion of specific tasks for each level as shown on the SAMM Program Level Progression Checklist (Appendix B). Any level can take from 24 hours to several days to complete.

Level II - The subject assumes responsibility for self-administration of medications. The subject comes to the nursing station not later or earlier than 15 minutes of the prescribed time with only minimal assist and monitoring by staff and takes the medication, answering staff regarding the action and possible side effects of the medication. The subject maintains a record of medication administration. The staff will monitor this record and correct or reinforce any needed data correction.

When designated staff determines demonstrated use and knowledge of medication at this level, the subject will be progressed to Level III.

Level III - The subject will self-administer prescribed medications at the bedside in accordance with the home medication schedule and record it. The staff will be available for assistance upon the subject's request but will not initiate and/or participate in administration of medications. The designated staff member will check the subject's record every shift, noting appropriateness and accuracy of use. This will be ascertained by counting the remaining medications and comparing that number against what the subject records as taken and was originally dispensed. Theophylline levels will be determined and observed for discrepancies in the record (see Interpretation of Compliance Measurements and Appendix A).

When successfully progressed through all three levels, the subject will be recommended to the attending physician as sufficiently prepared for discharge.

Proficiency Levels. Proficiency areas specified on the Levels Checklist (Appendix B) include:

1. knowledge of action and use of medication
2. knowledge of major possible side-effects
3. actual performance of use and storage of medications
4. and any problem-solving situation.

The use of reinforcement and repeated practice is generously used. The program is individualized so that sensory deficits are compensated for. For example: provision of braille-marked medication boxes for the blind, easy to open pill bottles for arthritic or weak hands and large lettered print on medication schedules for impaired vision.

Methods/Content for Patient Education

Content of the educational program includes reasons for and use of prescribed treatments, medication side effects and problem-solving techniques. Both individualized and group dynamics are used as well as formal and informal teaching methods in the classroom and at the bedside. Three graduated learning levels are used and criteria for moving from one to the next depends on patient competency.

Methods to Facilitate Patient Responsibility

Formal, written patient contracts are used in the program outlining

program goals (Appendix C). Individualized educational objectives are informally worked out with patient and discussed in a formal team conference.

Summary

Literature indicates there are multicausal problems with follow through by patients in management of their medications at home. If patients want help in management of their health problems but need knowledge communicated in an understandable way to follow through, then a patient education program tailored to the patient's individual needs can make a difference in his compliance.

CHAPTER TWO

Review of Literature

Introduction

A review of the literature about patient compliance with prescribed medical regimens reveals that compliance is related to knowledge level. Increasing knowledge levels is discussed with learning theory.

Self-care concepts central to the SAMM program are discussed in the literature and stress patient responsibility and contracting for self-care.

Related Articles on Compliance

A variety of researchers have studied the frequency of non-compliance in many populations and its possible causes. Aging and inadequate knowledge levels are frequently recurring companions of non-compliance.

Frequency of Noncompliance

Literature reveals that 20 - 50% of patients do not comply with prescribed therapeutic regimens (Christensen, 1978, pp. 171-187; Connelly, 1978, pp. 15-18; Marston, 1970, pp. 312-323; Mitchell, 1974, pp. 75-87). Christensen points out that this noncompliance occurs in all ages, disease states, and socioeconomic backgrounds (1978, p. 171).

Major findings regarding treatment noncompliance point towards lack of patient motivaton, his health beliefs, and inadequate knowledge base (Bille, 1977, pp. 55-57; Dall, 1982, pp. 283-290; Fry, 1981, p. 152;

Kasl, 1966, p. 266; Kennedy, 1981, p. 37; Kinsman, 1980, p. 107; Schwartz, 1975, p. 1810; Talkington, 1978, pp. 591-595; Webb, 1980, pp. 1047-1055; World Health Organization report on drugs, 1981, p. 279).

Other factors cited as significant indicate that the greater the number and frequency of medications prescribed, the greater the noncompliance; the greater the degree of communication and interaction with the appropriate health professional, particularily the physician; the greater the cost, educational level, family support and sensory deficits hearing and sight, the higher the chances for compliance variations (Beck, 1980, p. 1097; Brand, 1977, p. 78; Dall, 1982, p. 290; Ellor, 1982, p. 330; Fletcher, 1979, p. 189; Kinsman, 1980, p. 107; Norell, 1981, p. 731; Shulman, 1982, pp. 24-27; Talkington, 1978, p. 595).

Many authors concede that the reasons for noncompliance are most likely a combination of the above factors, that is, the problem of noncompliance is multicausal (Ellor, 1982, p. 330; World Health Organization report on drugs, 1981, p. 280).

Knowledge and Compliance

Knowledge level is associated with noncompliance. Although research does not support the idea that raising an individual's knowledge-level will ensure proper follow through in taking the medication (Beck, 1980, pp. 1094-1097; Bille, 1977, pp. 55-62), it does attest to the fact that compliance cannot occur if the client/patient does not understand what he is to do (Milazzo, 1980, p. 1081). Therefore they stress programs that are educative in nature to allow the patient the choice of compliance (Christensen, 1978, pp. 171-187).

Raising Patient Knowledge

A variety of studies have demonstrated that patient knowledge can be raised by educational programs (Linde, 1979, pp. 282-286; Milazzo, 1980, pp. 1079-1082; Sechrist, 1979, pp. 51-58). However little research has explored specific methods for raising that knowledge level. Studies that have been done included education techniques such as formal versus informal teaching (Bille, 1977, pp. 60-62; Milazzo, 1980, pp. 1079-1082) repetitive/individualized learning (D'Altroy, 1978, pp. 131-136; Hecht, 1974, pp. 113-129; Sechrist, 1979, pp. 51-58), Master's prepared versus "floor nurse" instructors (Linde, 1979, pp. 282-286), more than one teaching modality (Levine, 1979, pp. 1700-1703), behavioral patterning, role modeling, and counseling (Anderson, 1982, pp. 1673-1675; Cockerman, 1980, pp. 164-172; Talkington, 1978, pp. 591-595).

Theories on Learning

Learning theories indicate that specific conditions must be present for the learner: (1) motivation and physical/mental readiness, (2) ability to perceive his environment and meaningfulness in the material/activities, (3) some type of conditioning stimulus with repetition, trial and error experiences, all based on previous knowledge and experience and (4) imitation and satisfactory reinforcers (Hallburg, 1976, pp. 13-14; Pohl, 1978, pp. 6-27).

Assessing learner readiness is stressed by Shaw as the first step towards successful teaching (1981, p. 238). Knowledge of a patient's educational status and perception of his needs would begin to fulfill the first learning conditions and serve as an on-going assessment of the person's continuing readiness for further learning.

Gagne lists a variety of learning activities: (1) association, (2) trial and error, (3) conditioned-response, (4) verbal association and (5) insight. However, he states one must look for the capabilities of the learner and the situation outside the learner and tailor the learning experience to where the learner is at that point. He stresses that there is no "one way" (1965, pp. 8-20).

Patient Self-Help Considerations

Just as important as the patient's motivational preparation is his subsequent assumption of active responsibility for his own health care. Preparing the patient through knowledge and motivation must be followed by promotion of self-reliance. Self-responsibility, or self-help can be encouraged through collaborative team interactions with the patient and behavioral agreements.

Theories on Self-Help

Beckner advocates the use of self-reliance and individual responsibility for health maintenance and health care learning (1978, pp. 268-277). Studies on hypertension stress the need for collaborative-type interactions between patient ahd health professionals to encourage self-responsibility (Shulman, 1979, pp. 67-384). Shulman feels, however, that certain pre-existing conditions must occur prior to what he calls "active patient orientation". These include: (1) attitudes and expectations communicated by health professionals that are supportive to patient's motivations and abilities, (2) a collaborative treatment process between the patient and health professional, involving two-way communication and joint decision-making, and (3) medical resources provided in a way to insure usefulness to the patient (1979, p. 267).

Contracts as Behavioral Agreements

Verbal and written contractual agreements are suggested as a method of clarifying patient/health professional needs and goals and assuring committment on both sides and movement toward specific behavioral objectives (Becker, 1978, pp. 57-59; Levy, 1979, pp. 281-284; Rosen, 1978, pp. 410-415). Rosen outlines the components necessary for this agreement of effort: (1) selection of treatment goals, (2) setting of time limits, (3) selection of treatment methods and personnel, and (4) definition of the patient's role. In the case of a written agreement, this process is concluded with signatures (1978, pp. 410-411).

Discussion of Similar Studies

Many studies have described the problems and causes with patient self-administration of medical modalities. Few research studies reflect efforts to test tools for facilitating patient knowledge and compliance.

Formal and Informal Teaching

Formal versus informal teaching format was compared in a pre- and post-test intervention study in two metropolitan Milwaukee hospitals. The purpose was to investigate the possible relationship between knowledge of disease and compliance with post-hospital prescriptions. A sample of 24 subjects were divided into two equal groups treated to either a teaching program of structured information or a program of the hospital's existing informal teaching methods. Findings suggested a nearly equal amount of learning by both methods of teaching and that compliance was not significantly related to the patient's knowledge of his disease entity (Bille, 1977, pp. 55-62).

Another study to determine the effects of formal teaching on patient's knowledge level of his medication management was designed as an experimental, three group, before-and-after design. The setting was a large urban teaching hospital; the sample, 25 patients. The teaching was on a one-to-one basis. The test was administered prior to discharge (Milazzo, 1980, pp. 1079-1082). The study used a control group to assess for test-wiseness and depended more on an objective knowledge test. They reported the subjects receiving formal teaching exhibited greater knowledge than those receiving informal teaching.

Repetition/Graduated Learning

Repetition was the theme of a study done in an inpatient and outpatient department in a large university teaching hospital and a smaller state hospital in a large city outside the USA. A post-test only control group design was used where the control group of 41 was treated only once (Sechrist, 1979, pp. 51-58). The hypothesis was supported and stated that repetitive teaching regarding use of drugs to be taken at home will increase adult patient's knowledge when compared to single event teaching. No attempt was made to determine the relationship to long-term memory or compliance.

Hecht studied 47 adult tuberculosis subjects attending an outpatient chest clinic and demonstrated that reinforcing one-on-one conversations with clinic nurses regarding directions for administration of medications resulted in a large increase in the accuracy of medication administration at home. The study used a comprehensive method of measuring compliance through two home visits in order to interview the subjects, check urine medication levels, and do a pill count (Hecht, 1974, pp. 113-129).

One study involving reinforcement took its subjects through a three-step educational program and graduated subjects according to their level of accomplishment and self-responsibility. The sample of 76 inpatients received formal lessons, written drug infomation, and one-on-one teaching. It included assuring patient readiness for learning and opportunity for problem-solving. Results showed an increase in patient knowledge and compliance, especially for internally oriented, self-reliant patients. However, after one month, patients forgot most of what they had learned (D'Altroy, 1978, pp. 131-136).

Using More Than One Teaching Modality

The idea that a multicausal problem such as noncompliance requires multimodality solutions has been strongly emphasized. A study of 400 hypertensive subjects attempted to evaluate the effects of one or more therapeutic interventions on patient compliance with prescribed medical treatment (Levine, 1979, pp. 1700-1703). After a formal education program, additional treatment interventions included one or a combination of the following: an exit interview, family support and/or all three modalities but significantly more with a combination of two or more treatment modalities. Long-term compliance lasting up to 18 months after starting the study was reported. Other studies have not shown this compliance.

Collaborative Effects

One last study illustrates the impact of collaborative efforts between subject and a health professional and compliance. Study treatment

included interactions that educated the subject regarding specific medical problems, medication regimen and outcomes expected. It was based on good rapport and free communication between patient and physician. Patient participation was an intergral part of the experimental group. The study consisted of 182 experimental and 156 control subjects from a family practice clinic and a nearby comprehensive health care clinic. Four compliance catagories were formed: medication, appointments, treatment and behavioral changes. The weakness of the study was that compliance was determined by subjects' reporting by telephone two weeks following the clinic visit. Compliance rates were higher in each category for the experimental group (Talkington, 1978).

Summary

Chapter two has presented the area of noncompliance as discussed in the literature. The literature review revealed that much effort has gone into describing the problem with less effort in testing structured learning formats to increase compliance. Theories in learning and self-help were discussed.

Many programs and studies were planned with the goals of knowledge and compliance which have utilized a variety of methods. They include: value of one-on-one teaching in addition to group; formal and informal teaching; repetitive teaching; team collaboration; use of more than one modality; increasing patient knowledge; tailoring teaching approach to the individual's health locus of control; and patient responsiblity including behavioral agreements.

CHAPTER THREE

Study Methodology

Introduction

This chapter describes the methodology of this study. It details the projected design which incorporates a selected population and designated setting. It will specify what instruments will be used, how data will be collected, and under what protection to the participant. Data analysis used for its methodology are concluded with the limitations of the design.

The main question relates to the effectiveness of the Self-Administration of Medical Modalities model (SAMM) in raising knowledge levels and resulting in improving medication compliance.

Design

This study is a quasi-experimental longitudinal design with convenience sampling. Pre- and post-testing is to determine increase in knowledge impacting on compliance over a period of 6 months.

Sampling

A convenience sampling of 120 subjects admitted to the study over a six month period will be selected. Patients will be selected as they are admitted to one of two inpatient units. Criteria for admission to the study are described in Appendix D, and include a diagnosis of Chronic Obstructive Pulmonary Disease (COPD), documentation of medication administration needs willingness to sign a SAMM Program contract, absence of

rehabilitation in the past two years, and 46-75 years of age. Patients meeting these criteria will be invited to participate in the study. Assignments to the experimental group (Group A) are made as a matter of convenience. Group A includes those admitted to the pulmonary medical unit where the staff is familiar with the SAMM program. The control group (Group B) are those subjects accepted into the study who are admitted to the general medical unit and who will receive traditional teaching.

Setting

The setting of the study is two medical units in a tertiary, acute care, selected, 500 bed, private, suburban hospital in Southern California and in the subjects' homes.

Protection of Rights

Admission to the study will be voluntary. Patients will be approached for participation by this investigator upon recommendation of team members.

The purpose of the research, subject protection and potential benefits of participation will be explained to the prospective subject. Each subject will sign a consent to participate in the study (Appendix E for Group A, and Appendix F for Group B). Permission to conduct the study will be obtained from nursing administration from those private physicians whose patients will be included and from appropriate hospital staff. The research proposal will be submitted for approval to the Research in Nursing Committee a subcommittee of the Institutional Review Baord. Only after permission is obtained will data collection occur. Subjects will be referenced by consecutive numbering rather than by name.

Financial support for the study to purchase theophylline prescriptions will be supplied by the pharmaceutical company sponsoring this study.

Procedure for Data Collection

Data will be collected upon hospital admission, at hospital discharge and every month for 6 months during home visits to ascertain subject knowledge level and compliance (Appendix E).

Hospital Admission

Upon admission to the hospital, demographic and medical baseline data will be collected from the patient's medical record and during patient interview using the Initial Assessment Form (Appendix H). Upon fulfilling the criteria for admission to the program (Appendix D), the subject will be assigned to Group A or B as specified in the samping procedure.

Subjects will then be administered the knowledge test (Appendix K) to assess understanding of medication administration. In order to assure appropriate dosage and adequate bronchodilation, the subject will be regulated on theophylline pills (Theodur) to maintain blood theophylline levels between 10-20 ug/ml. The SAMM Program treatment will be given to Group A and traditional or no teaching to Group B.

Hospital Discharge

The day of hospital discharge the subject will be assessed again for further demographic and medical data (Appendix I). The knowledge test will again be administered to assess change in knowledge level since admission. The subject will be given a prescribed number of pills (100)

of the same theophylline preparation used throughout his hospitalization. He will be instructed to return any pills he does not use with the excuse of conserving money. He will not be informed that his pills are being counted.

Monthly Home Visits

Each subject will be interviewed in his home on a monthly basis by a research assistant who is a Home Care Respiratory Therapist (Appendix J). The investigator who interviewed the patient in the hospital or who teaches medication principles will not be the same investigator who visits in the home. This is to prevent subjects associating the teaching program with the home visitor, and is an attempt to avoid the Hawthorne effect.

During the monthly visit by the Home Care Respiratory Therapist, any remaining pills will be collected and the patient will be given a fresh supply of 100 tablets. A blood theophylline level will be drawn by the therapist at 3 and 6 months.

The therapist will then ask the following questions:

1. How frequently have you been taking your Theodur?
2. At what dosage have you been taking it?
3. Have you missed any doses?
4. If so, approximately how many have you missed over an average week?
5. Do you feel you have been able to take your medication as prescribed?
6. If not, why not?

The old pills will be returned to the researcher who will document the number of pills remaining, subtract the total number prescribed to

ascertain the number of pills expected to be remaining out of 100 tablets. The therapist then notes any discrepancy between the pill count and the subject's report of medication usage. The subject will not be informed the pills are being counted nor when the therapist will visit. Blood theophylline levels will be compared with the subject's reporting of pill consumption and compared for consistancy with the level expected at a given dosage of oral theophylline (Appendix A).

Interpretation of Compliance Measurements

The Performance Index is designed as a means of quantifying subject compliance or medication performance, based on pill count data. The Reliability Factor is to measure how accurately patients report errors compared to the actual pill count. Some studies suggest the interview method of testing compliance with medication taking is not necessarily as valid as others, as many times subjects do not report accurately (Kinsman, 1980, pp. 97-107; Roth, 1978, pp. 361-370). For this reason, a blood theophylline level is also compared with the pill count, with the subject's reporting at discharge, and at 3 and 6 month intervals post discharge.

Any errors in the pill count are compared against the subject's report of error and given a score according to the scale in Appendix A. If the subject's Reliability Factor (subject's report of error) agrees with the subject's Performance Index (the actual pill count) and is below 4 on each scale, and the theophylline level falls between 10-20 ug/ml, the subject will be considered compliant and not making any serious medication errors.

If the subject's Performance Index is greater than 3, the Reliability Factor is less than 4 and the theophylline level between 10-20 ug/ml, compliance will be questioned and the subject reinstructed in proper dosage administration. If this inconsistancy continues, it will be considered noncompliance.

If the Performance Index is greater than 3 and the Reliability Factor less than 4 and the theophylline level is less than 10 or greater than 20 ug/ml, a need for dosage adjustment will be considered. Blood theophylline levels that are too high or too low and not obviously due to improper administration, may indicate improper oral theophylline dosage and contribute to noncompliance.

As data is analysed, subjects making serious errors (error more than 15% on the pill count) will also be examined separately as a matter of interest and not considered to support the null hypothesis.

Instrumentation

The Pulmonary Medication Knowledge Test will be administered upon admission to the study to measure the subject's level of medication understanding prior to the teaching program. The same test will be given upon discharge from the SAMM Program and the hospital to determine his increased level of knowledge on the day of discharge. The test is administered again at three and six months after discharge in the subject's home, to assess retention of knowledge (Appendix F).

Because no standardized knowledge test is available for COPD patients in the SAMM Program, a test has been designed and consists of ten multiple choice questions and ten true-false qustions covering relevant points from major content areas of the teaching program. These areas include:

action of an oral bronchodilator; adverse effects; time and dosage management; scheduling; and problem-solving skills.

Instrument Validity

Content and face validity have been accomplished through a team of pulmonary staff members who have judged that the items do reflect congruity between what is actually included and what would be included (Dempsey, p. and Dempsey, A., 1981, pp. 69-70; Green, 1975, pp. 138-143).

Instrument Reliability

COPD patients outside the study but fitting its criteria will be administered the knowledge test to ascertain reliability. The split-half method will be then used with the Spearman-Brown formula ($rxx=\frac{2roe}{1+roe}$) to correlate subjects' scores on even number test items against scores on odd-numbered items (Green, 1975, pp. 146-147).

Item analysis will be conducted on these trial test scores and the difficulty value obtained. The Kuder-Richardson formula ($rxx=\left[\frac{N}{N-1}\right]\left[1 - \frac{pg_2}{S_t}\right]$) will be used for calculating internal consistency (Green, 1975, p. 147).

Post-test Wiseness

One of the major problems with test-retest method of evaluation is realistically deciding how long a time interval between the two tests should be. If the interval is too short individuals tend to remember their responses to the items on the first administration. To reduce the possiblity of subjects becoming test-wise, even numbered items from the knowledge test will be administered on the day of admission to the study and at 3 months post discharge. Odd numbered items will be administered on the day of hospital discharge and at 6 months post discharge. (Dempsey and Dempsey, 1981, p. 72; Green, 1981, p. 146).

Data Analysis

The acceptance or rejection of the null hypothesis will depend upon the significant differences occuring in each subject's knowledge level between admission and discharge, and at three month and six month intervals after discharge; and the compliance level as determined by significant variations between Performance Indexes computed at monthly intervals post discharge.

These statistics will then be compared between Groups A and B at each interval in knowledge level and compliance.

Descriptive Data

Descriptive statistics will be presented in table form with the percent of subject error as shown by a pill count error greater than one or by inappropriate theophylline level. This table will also show the percent of subjects making serious errors (more than 15%) or theophylline levels not within appropriate range. A second table will show the mean scores and standard deviations of each group computed from the scores on the knowledge test and the monthly Performance Index, Reliability Factor, and theophylline levels.

Inferential Statistics

Inferential statistics will be used to determine if the differences noted between groups A and B are statistically significant and whether they are dependent on the SAMM treatment. They will be used to determine whether the hypothesis will or will not be accepted. Using parametric tests, a level of statistical significance will be set at $\alpha = 0.05$ for all analysis.

Tables to delineate data generated by t-tests ($t=\frac{y-u}{s/\sqrt{n}}$) and ANOVA ($F=\frac{ns_{\bar{y}}^2}{S^2_{pd}}$) will include a comparison of individual group mean scores longitudinally within each group and horizonally between Group A and Group B mean scores. Categories will include: knowledge test means between and among Groups A and B; Performance Index between and among Groups A and B; Reliability Factor between and among Groups A and B; comparisons between Performance Index and Knowledge Test mean scores of both the experimental groups and comparison between the performance and reliability of the experimental and control groups.

Methodological Assumptions

It is assumed that: (1) subjects will accurately report medication useage, (2) the pill count will accurately reflect patient compliance, (3) the knowledge test measures accurately subjects' understanding about medication and (4) that subjects are interested and perform at their maximum capacity.

Limitations of Study

Due to the small sample size, limited age range and the exclusiveness of a rehabilitation population, the results from this study will not be generalizable to any other population. However, it will demonstrate the effectiveness of the SAMM program in this population.

Data collection is dependant on the subject's accurate reporting of pills used and on his saving unused medication. However, Hecht has reported that although a patient reporting alone may have questionable reliability, pill counts in addition to verbal report can raise one's confidence in the accuracy of predicting compliance (1974, pp. 113-129).

Summary

This study is to test the ability of SAMM, a specialized inpatient teaching program to increase a subject's medication knowledge and compliance in a home setting.

This study uses an experimental pre- and post-test control group. Data will be analysed to assess significant change in each subject's knowledge level from admission pre-testing to post-testing on discharge and at three and six month intervals. It will also be analysed to assess change in each subject's compliance in pill taking as compared on discharge to monthly home visits. Data will also be analysed to determine significant differences between knowledge and compliance levels between Group A and Group B.

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Appendix A

Performance Index and Reliability Factor

Performance Index and Reliability Factor

Adapted from

Hecht (1974, p. 119)

PERFORMANCE INDEX

Pill Count Performance	Performance Index
No error, or one pill in error	0
One pill to 4% error	2
5-9% error	3
10-19% error	4
20% error or more	5

RELIABILITY FACTOR

Patient Performance	Reliability Factor
No error, single pill error, or any reported error	0
Pill count error less than 5%, denied	2
5-10% error, denied	3
11-15% error, denied	4
16-20% error, denied	5
21-25% error, denied	6
26-30% error, denied	7
31-35% error, denied	8
36-40% error, denied	9
Greater than 40% error, denied	10
Plus 5 for each theophyllin level below 10 or above 20 ug/ml for maximum of	10

Appendix B

SAMM Program

Level Progression Checklist

Date Entered Program _____ DATE _____ SIGNATURE

Date Completed Level I _____ DATE _____ SIGNATURE

Date Completed Level II _____ DATE _____ SIGNATURE

Date Completed Level III _____ DATE _____ SIGNATURE

PATIENT OBJECTIVES (Patient will be able to:)	LEVEL I	LEVEL II	LEVEL III
1. State names of medications correctly & know where to find the correct bottle. Can identify medication by color, shape, size, etc.			
2. State the correct dosages and times to take the medications/treatments.			
3. State the possible side effects or know where to find this information.			
4. Know what actions to take when side effects occur.			
5. State special instructions relevant to treatment program (e.g., take with antacids, avoid milk, rinse mouth after treatment, avoid after major meals, etc.)			
6. State reason/purpose for taking medications/ treatments & importance of following regimen.			
7. Understand how to adjust medications/ treatments (e.g., starting, discontinuing, following a tapering schedule, etc.)			
8. Understand consequences of no use or improper use of medications/treatments.			
9. Understand principles of & need for decontaminating equipment.			
10. Take medication/treatment as provided by nurse/therapist.			
11. Seek nurse/therapist when medication/treatment is due.			
12. Choose correct medication to be taken at appropriate time and explain why this is necessary.			
13. Choose correct positions for specific lobe of lung to be drained.			
14. Demonstrate ability to disassemble and reassemble breathing manifold, and attach to breathing machine.			
15. Demonstrate correctly the ability to manually percuss and vibrate.			
16. Demonstrate ability to clean equipment.			
17. Seek help when equipment is malfunctioning.			
18. Develop medication schedule to be implemented at home.			
19. Use schedule to take medications/ treatments correctly and at the right time.			
20. Verbalize understanding of need to refill appropriate prescriptions before the medications run out.			

Loma Linda University Medical Center

Self-Administration of Medical Modalities
Progression Checklist

23-1129 (8-82)

PATIENT IDENTIFICATION

Appendix C

SAMM Program Agreement

SAMM PROGRAM AGREEMENT

Loma Linda University Medical Center

Upon entering in the Self-administration of Medical Modalities (SAMM) Program, I will be evaluated by the comprehensive pulmonary care team. An individualized program will be recommended for me. I will then be educated and supervised in regards to my treatments and medication. The objective of the SAMM Program is to provide me with an opportunity to learn about my health care. I, along with the various team members, will be setting goals for my competent self-administration of treatments and medications. We will set up a schedule together and will institute this schedule here at LLUMC as I will be using it at home. This may help me to develop my skills for becoming as independent as possible.

After discussing this matter with a pulmonary rehabilitation team member and reading this summary, I understand the nature of this program and agree to participate.

SAMM PROGRAM CANDIDATE

PULMONARY REHABILITATION TEAM MEMBER

DATE

23-1134 (8-82)

Appendix D

Criteria for Admission to a SAMM Program

Criteria for Admission to a SAMM Program

The prospective subject demonstrates:

1. Symptomatic pulmonary disease but has a room air PO2 greater than 60 mm/Hg
2. Ability to read, speak, write and comprehend English
3. Willingness to participate
4. No underlying disease that would interfere with teaching (e.g., organic brain syndrome, psychosis, unrehabilitated substance abuse).
5. Alertness, orientation and potential for mentally and physically assuming responsibility for his activities of daily living
6. No SAMM Program in the past three years
7. Age between 46-75 years of age
8. Medical stability (e.g., controlled arrhythmias/ failure, no evidence of acute MI within preceeding six months)
9. Adequate financial resources and is within traveling distance for Home Care Therapists
10. Followup by LLUMC physician
11. No use of medication listed as a controlled substance in the Federal Act and Regulations, excluding medications designated under Article I, Section 6.4, but including all other narcotics, hypnotics and tranquilizers

Appendix E

Scheme for Pre- and Post-testing of Groups A and B

Scheme for Pre- and Post-testing of Groups A and B

Group	Intervals								
	Pre	SAMM	Post	1mo	2mo	3mo	4mo	5mo	6mo
Experimental A	KDSb	X	KSa	CSa	CSa	KDSCa	CSa	CSa	KDSCa
Control B	KDSb		KSa	CSa	CSa	KDSCa	CSa	CSa	KDSCa

Key: KDSb - Knowledge test, demographic data collection before manipulation of independent variables

X - Experimental manipulation of independent variable (SAMM)

KSa - Knowledge test after manipulation of independent variable

CSa - Compliance testing after manipulation of independent variable

KDSCa - Knowledge test, demographic data and compliance (pill counts, theophylline level and self report) testing after manipulation of independent variable

Schedule of Data Collection:

Demographic and Medical Data	Admission to Study	Day of Hosp Discharge	Monthly	3 & 6 mo Intervals
Age	X			
Diagnosis	X			
Name of Physician	X			
Language	X			
Previous SAMM Program	X			
Source of Income	X			
Related Medical Problems	X			
Further Medical Problems		X	X	X
Medications	X	X	X	X
Orientation Level	X	X	X	X
Compliance Checks Data				
Pill counts		X	X	X
Theophylline levels		X		X
Patient Self-report of pill Consumption		X	X	X
Knowledge Test	X	X		X

Appendix F

SAMM Program Study Consent Form

(Experimental Group)

LOMA LINDA UNIVERSITY MEDICAL CENTER

S.A.M.M. Program Study

Consent Form

I am willing to participate in a study to be conducted at the Loma Linda University Medical Center.

I have been told that:

1. the study is designed to help health care personnel understand the effect of a medication teaching program called SAMM and that it will involve my learning how to take my own medications and practice using them while supervised in the hospital.

2. during the course of the study, I will be expected to undergo periodic testing to check my knowledge, attitudes and health behavior related to my illness.

3. a respiratory home care therapist will visit my home monthly for 6 months to administer these tests.

4. I will be informed of change in the nature of the study or in the procedures described above.

5. the study involves no financial cost to me. There may be a potential risk of fatigue as a result of taking written tests that measure my knowledge and health behaviors. I have been told that these tests will have general and personal questions.

6. among the potential benefits that have been described to me are the possibility of gaining greater knowledge about my disease and medications and learning more individualized ways of coping with them. I will also receive a free supply of any oral Theodur prescribed for me during the length of the study.

7. because of the experimental nature of this study, it is possible that these benefits may not occur.

8. trained personnel will be available at all times during classes and testing so that any questions I may have shall receive attention. I further understand that if at any time in this study it is determined that my assigned medication program is found to be less beneficial than another, I will be promptly notified.

9. refusal to participate in this study will involve no penalties or loss of benefits to which I am entitled. I have been told that the information obtained in this study is confidential

and that my name and identity will not be disclosed without my consent in any published document.

10. that my participation in this study is voluntary and I may leave the study at any time unconditionally and without prejudice to my continued care.

11. in the event of difficulties as a result of participation in the research program, I may contact Glenn Sharman, Patient Representative at (714) 824-0800, extension 4634, for information.

I have read the contents of this consent form and have listened to the verbal explanation of the investigator. My questions concerning this study have been answered to my satisfaction. I may call Elizabeth Maddox, RN, researcher, at the Pulmonary Rehabilitation Department (714) 824-4495 if I have additional questions or concern about my participation in this study. I have been given a copy of this consent form.

_____ _____

Signature of Subject Date

_____

Witness

I have reviewed the contents of this form with the person signing above. I have explained potential risks and benefits of the study, as described above.

_____ _____

Investigator Date

For all inpatient studies, to insure that patients receive coordinated care from the investigator and the primary physician or rehabilitation team, the primary physician or rehabilitation team coordinator must sign this form as indicating he/she has knowledge of this research study.

_____ _____

Signature of Primary Physician or Rehabilitation Team Coodinator Date

Appendix G

SAMM Program Study Consent Form

(Control Group)

LOMA LINDA UNIVERSITY MEDICAL CENTER

S.A.M.M. Program Study

Consent Form

I am willing to participate in a study to be conducted at the Loma Linda University Medical Center.

I have been told that:

1. the study is designed to help health care personnel understand the effect of medication teaching on patients.

2. during the course of the study, I will be expected to undergo periodic testing to check my knowledge, attitudes and health behavior related to my illness.

3. a respiratory home care therapist will visit my home monthly for 6 monts to administer these tests.

4. I will be informed of change in the nature of the study or in the procedures described above.

5. the study involves no financial cost to me. There may be a potential risk of fatigue as a result of taking written tests that measure my knolwedge and health behaviors. I have been told that these tests will have general and personal questions.

6. the benefits of being involved in this study is that I will receive a free supply of any oral Theodur prescribed for me during the length of the study.

7. if at any time in this study it is determined that my assigned medication program is found to be less beneficial than another, I will be promptly notified.

8. refusal to participate in this study will involve no penalties or loss of benefits to which I am entitled. I have been told that the information obtained in this study is confidential and that my name and identity will not be disclosed without my consent in any published document.

9. my participation in this study is voluntary and I may leave the study at any time unconditionally and without prejudice to my continued care.

10. in the event of difficulties as a result of participation in the research program, I may contact Glenn Sharman, Patient Representative at (714) 824-0800, extension 4634, for information.

I have read the contents of this consent form and have listened to the verbal explanation of the investigator. My questions concerning this study have been answered to my satisfaction. I may call Elizabeth Maddox, RN, researcher, at the Pulmonary Rehabilitation Department (714)824-4495 if I have additional questions or concern about my participation in this study. I have been given a copy of this consent form.

_____ _____

Signature of Subject Date

_____

Witness

I have reviewed the contents of this form with the person signing above. I have explained potential risks and benefits of the study, as described above.

_____ _____

Investigator Date

For all inpatient studies, to insure that patients receive coordinated care from the investigator and the primary physician or rehabilitation team, the primary physician or rehabilitation team coordinator must sign this form as indicating he/she has knowledge of this research study.

_____ _____

Signature of Primary Physician or Rehabilitation Team Coodinator Date

Appendix H

Data Collection Form

Initial Assessment

Data Collection Form

Initial Assessment

Date:

Name:

Address:

Physician:

Patient number:

Age:

Pulmonary diagnosis:

Speaks English?:

Alert and Oriented?:

Ever in the SAMM Program?: Date

Other related disease processes:

Is patient medically stable?:
(per primary physician)

Source of Income:

Present Medications:

Appendix I

Data Collection Form

Hospital Discharge Assessment

Data Collection Form

Hospital Discharge Assessment

Date:

Patient number:

Physician:

Further medical problems?:

Alert and oriented?:

Present medications:

Blood theophylline level:

Pill count (# bronchodilator pills sent home):

Knowledge test given?:

Appendix J

Data Collection Form

Monthly Home Assessment

Data Collection Form

Monthly Home Assessment

Date:

Patient number:

Physician:

Alert and oriented?:

Further medical problems?: List

Change in source of income?: How?

Ask subject:

1. How frequently have you been taking your Theodur?
   Response_____
   _____
2. At what dosage have you been taking the Theodur?
   Response_____
   _____
3. Have you missed any doses? Response_____
4. If so, approximately how many pills have you missed over an average week? Response_____
5. Do you feel you have been able to take your medication as prescribed? Response_____
6. If not, why not? Response_____
   _____

Theophylline level (3 & 6 month only): Month:

Pill count:

supplied last visit _____
remaining in container this visit _____
supplied at this visit _____

Knowledge test given? (3 & 6 month only): Month:

Appendix K

Pulmonary Medication Knowledge Test

Pulmonary Medication Knowledge Test

Please circle the letter beside the correct answer of each question:

Multiple Choice

1. A bronchodilator medication is to

   a. heal my lungs
   b. open airways
   c. I don't know

2. The name of my bronchodilator is

   a. Theodur
   b. Choledyl
   c. Brethine
   d. I don't know

3. Bronchodilator medications can cause

   a. shakiness, nervousness
   b. backache
   c. sores in the mouth
   d. I don't know

4. Other side effects of bronchodilator medications might include (pick any/all answers that apply)

   a. rapid heart beat
   b. headache
   c. sleeplessness
   d. wheezing

5. If I become dizzy from my bronchodilator medication I should

   a. change my dose
   b. stop taking my medicine until I see my doctor again
   c. call my doctor's office for instruction
   d. I don't know

6. If a pharmacist fills your prescription, and the name is different from what you remember, you should first:

   a. remember the pharmacist knows what he is doing and forget it
   b. ask the pharmacist for clarification
   c. realize he may have given you a generic name on the label, and go ahead and take it
   d. I don't know

7. The main job of the lungs is

   a. to exchange oxygen for carbon dioxide
   b. to clean the air coming in
   c. I don't know

8. The following things help protect the lungs from irritants

   a. air sacs, trachea, capillaries
   b. coughing, cilia and macrophages
   c. I don't know

9. Mucus

   a. should always be totally eliminated as it can cause infections
   b. is a part of the lung's defense system
   c. I don't know

10. When wheezing starts

    a. I should call my doctor immediately and then go to an emergency room
    b. first find a quiet place and use pursed lip breathing
    c. I don't know

True and False: circle T if the statement is true and F if it is false

11. If a bronchodilator medicine does not work in 30 minutes I should take another smaller dose. T or F?

12. Over-the-counter medicines can be used without consulting my physician. T or F?

13. If I forget my bronchodilator medicine, and a friend has another one that is similar, I can take it instead just this once. T or F?

14. If a dose of bronchodilator medicine is missed and the next dose is in 4 hours, I whould go ahead and take the missed dose. T or F?

15. When traveling, a good idea is to put one day's supply of all my different pills together in a smaller container. T or F?

16. Each medicine has two names -- a brand name and generic name. Generic medicines are usually less expensive than brand name types. T or F?

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17. If I am taking several types of medicine, it is a good idea for me to go to the same pharmacist, who can check on possible problems with drug interactions. T or F?

18. I should always take my medicines with me when I go to a hospital emergency room. T or F?

19. It is my doctor's job to worry about my medicines, I just take them. T or F?

20. If I get very short of breath in the night I should immediately call the paramedics. T or F?