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Compliance with oral medication regimen in persons with COPD

Author
Chisholm, Patricia A.

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COMPLIANCE WITH ORAL MEDICATION REGIMEN IN PERSONS WITH COPD: A TEST OF THE HEALTH BELIEF MODEL

by

Patricia A. Chisholm

THESIS

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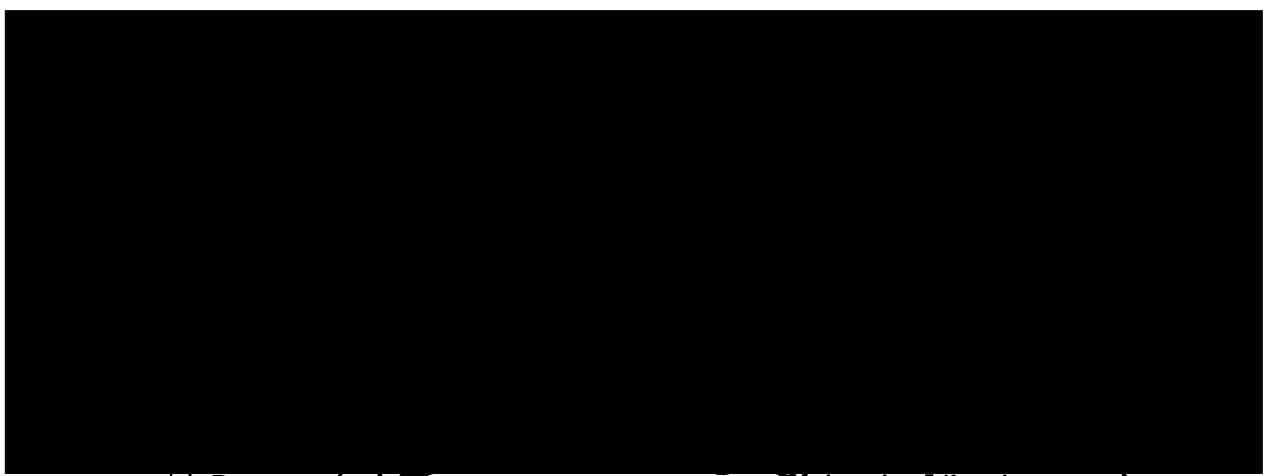

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Abstract

The purpose of this study was to answer the questions:

1. What is the relationship between the perceived costs and benefits of an oral medication regimen and compliance with the oral medication regimen in persons with COPD?
2. What is the estimate of non-compliance with an oral medication regimen in a sample of persons with COPD?

A descriptive survey design was used to collect nominal and ordinal data from a sample of 40 persons with COPD who were patients at the V.A.M.C. Pulmonary Clinic at Palo Alto. Data on the independent variable, perceived costs and benefits of oral medication regimen, were collected using a Likert-type tool constructed for this study. The dependent variable, compliance with an oral medication regimen, was measured with a randomized response technique to obtain an estimate of non-compliance in the sample. The completed Likert scale instruments were scored to achieve a Perceived Benefits Index (PBI) score for each subject. Estimates of non-compliance for the sample and for subject groups with high and low PBI scores were obtained. Subjects with high and low PBI scores were cross-tabulated with compliers and non-compliers. The χ^2-test for independence was applied to test for significance of differences. Implications of the findings in this study were discussed. Suggestions for future studies on compliance in persons with COPD were given.

Summary

COPD is a major disabling chronic illness in the United States, occurring most frequently in men who would otherwise be productive members of society. As in other chronic illnesses, compliance, defined as the extent to which a person adheres to a prescribed regimen, is likely to be a problem in this large population who must follow complex medication regimens.

This study describes the relationship between the perceived costs and benefits of an oral medication regimen and compliance with that regimen in a sample of persons with COPD. The Health Belief Model is used as a framework for choosing the independent variable for study. A non-probability sample of 40 persons with COPD, was chosen from those who attended the Pulmonary Clinic at the V.A.M.C. at Palo Alto. The independent variable, perceived costs and benefits of an oral medication regimen, was measured using a 10-item Likert scale tool which was then scored to obtain a Perceived Benefits Index (PBI) score for each subject. Compliance was measured by a randomized response technique in which the subject answered "true" or "false" to one of two items chosen randomly by the toss of a die.

The estimate of non-compliance obtained for the sample was 5:40 subjects, a 12.5 percent non-compliance rate. While one should allow for some over-statement of compliance, it is unlikely that compliance would fall as low as 50 percent in a group so dependent on their medications. Most subjects received high PBI scores; that is, they tended to perceive more benefits than costs from their oral medications. Paradoxically, all five non-compliers were found in the half-sample with the highest PBI scores.

Some explanations are offered for this finding. It is possible that the Perceived Benefits instrument was not sufficiently discriminating to reflect the beliefs of the (apparently) extremely believing and complying subjects. However,

one can argue, by exact tests, that the chance of all five non-compliers ending up in the group with the highest PBI scores is < .05, if they were placed at random in the top and bottom PBI groups. Possibly the sample size was not large enough to include a meaningful proportion of non-compliers. One should note, however, that increasing the sample size by 10 subjects would only add an expected number of 1.2 non-compliers, which is not enough to change the percentages significantly. Another possibility is that the non-compliers overstated their beliefs, responding to some vision of how they "should" feel. A final explanation might be that the non-compliers did believe in the effectiveness of their medications, but due to the pressures of advancing illness or an increasing number of medications, they chose to exert some control over their regimens by taking regularly only those pills which provided immediate or noticeable relief of symptoms. If they answered the compliance items truthfully, subjects who followed this scenario would show up as non-compliers in the sample.

The findings in this study have implications for future compliance studies. Compliance among persons with COPD is likely to be more complex that a "do" or "don't" behavior, and may be best measured by "sometimes", "often", or "never". Some medications may be complied with better than others. The length of time the subject has been ill, his perception of his illness and the objective signs of the severity of his illness may correlate with his compliance behavior. Compliance may be different in groups who attend out-patient clinics regularly versus those persons who only show up to have prescriptions filled. Further studies on compliance behavior in COPD, using the Health Belief Model as a framework, are needed. Nurses who work with these patients are in a key position to design meaningful studies which will help health personnel to better understand the medication-taking behavior of persons with COPD.

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Some people were responsible for making this experience both enjoyable and informative. William L. Holzemer gave pertinent feedback which always seem to clarify and move the process along. Ellen B. Clarke was a skillful and wise advisor and teacher. Joyce K. Holohan provided the clinical and practical information needed to construct relevant instruments for the study.

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Chapter I: Introduction

A. Problem Area

The extent to which a person's behavior coincides with the regimen prescribed by a clinician has been labelled compliance (Sackett, 1976). Recent health education literature abounds with studies of non-compliant behavior and attempts to increase patient compliance with therapeutic regimens (Haynes, Taylor and Sackett, 1979). Non-compliance has been discussed as a serious problem in many chronic illnesses (Tagliacozzo, 1973; Finnerty, 1973; Strauss and Glaser, 1975) in which people must adjust to a lifetime of complex medication, and other, therapeutic regimens. Chronic obstructive pulmonary disease (COPD), which includes bronchitis, emphysema and asthma, has not, for some reason, been the subject of compliance studies. In a small attempt to begin to fill that information gap, this study was designed to examine non-compliance with medication regimen in persons with COPD.

COPD ranks as the sixth leading cause of death in the United States (COPD, 1979). Of the 22.4 deaths per 1000 population in 1977 resulting from COPD, 16.7: 1000 were caused by emphysema (U.S. Census, 1979). About three-quarters of those dying from COPD were white males (COPD, 1977).

In addition to the havoc wrought by COPD in human lives through invalidism, discouragement and suffering, there is the cost of pensions, medical care, and lost productivity which have significant repercussions in the economy. In 1972, emphysema was the fifth most frequent primary diagnosis in patients awarded disability allowance under the Social Security Administration (COPD, ALA-ATS, 1977, p. 21). The number of disability allowances based primarily on emphysema increased nearly 13.7% between 1961 and 1972, mainly due to its frequency in men. About 84% of all allowances based on the diagnosis of emphysema in 1972 went to men (COPD, 1977).

COPD is, in fact, a major national health problem. A few studies have documented the difficulties encountered by COPD patients as they manage their disease (Strauss and Glaser, 1975; Fagerhaugh, 1973; Barstow, 1973), not the least being complex medication regimens. Barstow (1979) found that although most people in the eleven person sample she studied did not object to taking medication because of the symptom relief it provided, they often omitted doses due to forgetfulness or confusion. Sometimes they varied prescribed dosages without consulting their physicians. Others believed their prescribed drugs were not effective and went shopping in the local drugstore; often the new drug was the same as the one prescribed but was packaged differently or was marketed by another company.

These behaviors suggest a compliance problem and yet a search of the literature revealed no studies on compliance with medical regimen in persons with COPD. If about fifty percent of people being treated for chronic illnesses, such as hypertension and cardiac disease, fail to take all their prescribed medications (Haynes et al, 1980; Robbins, 1980), it seems reasonable to suspect that non-compliance in persons with COPD who must follow complex medication regimens may also be significant. So far, there is a paucity of research data to support this claim.

Summary

COPD, then, is a major disabling chronic illness in the United States, occurring most frequently in men who would otherwise be productive members of the society. As in other chronic illnesses, non-compliance with complex medication regimens is likely to be a problem in this population but, so far, no studies have been found which address the problem. The size of the COPD population, the high costs of medical care and disability insurance and the complexity of their medication regimens point to a need for such studies.

B. Theoretical Framework

In order to study compliance with a medication regimen in COPD, one needs a theoretical perspective from which to view non-compliant behavior and the variables which affect it. The Health Belief Model (HBM) is one such framework and will be described at this point in the paper because it is the basis of the abbreviated beliefs-compliance model used in this study. The Health Belief Model (Rosenstock, 1974) is based on the assumption that behavior in any given situation is determined by the way in which an individual perceives the world around him. A person will be more likely to take actions to avoid an illness, if he believes that:

a. he is susceptible to the disease in question or to a relapse of that disease.

b. the illness is serious (i.e. threatening to life or, at least, life style and independence).

c. the treatment being prescribed is effective. In other words, perceived benefits, such as reduced vulnerability to illness, outweigh perceived barriers or costs, such as the inconvenience of the preventive measure.

Preventive behavior will be further enhanced if there are "cues to action" to trigger the appropriate behavior; the stimulus can be internal (e.g., perception of bodily states), or external (e.g., mass media campaign). Demographic and sociopsychological variables such as age, race and peer group pressure may affect a person's perceptions but are not seen as directly related to compliance behavior.

Becker (1974) argues that the Health Belief Model can also apply to actions taken by persons already diagnosed as ill; that is, to patient compliance with prescribed regimens. In the case of compliance with prescribed regimens, some

diagnosis of illness has already occurred; thus, measures or indices of health beliefs must also be modified, and new dimensions added. The Health Belief Model applied to illness behavior says that a person will be more likely to comply with a prescribed regimen if he believes that:

a. he is susceptible to a recurrence of the illness (e.g., rheumatic fever) or to an exacerbation of symptoms (e.g., dyspnea in asthma).

b. the illness is serious (e.g., will interfere with life style). Perceiving the illness as life-threating, however, may not result in increased compliance.

c. the regimen being prescribed is effective. In other words, the regimen must be perceived as having more benefits (e.g., relieves symptoms, eliminates illness) than costs (e.g., discomfort of side effects, complexity and energy demands of the regimen).

Compliant behavior will be further enhanced if the person is motivated by cues, such as the presence of symptoms (internal) or reminders from friends or health personnel (external). The Health Belief Model for illness behaviors states, finally, that compliance may be modified by such factors as the character of the physician-patient relationship, the influence of family and friends, and the demographic variable of extremes in age. Other demographic variables, such as race, sex, socioeconomic status or education were not shown to relate consistently to compliance behavior and are not included in the model. The relationship between the HBM variables and compliance with a therapeutic regimen during illness has been examined in numerous studies. In a review of these studies, Becker and Maiman (1975) concluded that there is generally strong support for a relationship between compliance and perceptions of susceptibility to illness, severity of the illness and benefits and costs of the therapeutic regimen. Extremes in age, patient-practitioner relationship and the influence of

family and friends are some additional modifying factors which affect the ill person's compliance behavior.

The conceptual model for compliance behavior used in this study (see Figure 1) is adapted from Becker and Maiman's compliance model and based on the original Health Belief Model. Support for the choice of the independent variable, perception of the costs and benefits of the medication regimen, is offered in the literature. Strauss and Glaser (1975) found that the prescribed medical regimen in chronic illness may be time and energy-consuming, complex and confusing, and may produce discomfort. According to the authors, the patient evaluates these and other factors, judging them against the perceived effectiveness, or value, of the regimen and makes a conscious or unconscious decision to adhere to all, or part, of the treatment. Although oral medication is only one part of the complex medical regimen followed by COPD patients, Fagerhaugh (1975) emphasizes its importance in the person's life as he attempts to balance the positive effects of his bronchodilator drugs with their frequent negative side effects. Often the patient's only criteria for therapeutic effectiveness is how well the medications help him be mobile in his daily activities.

Summary

The Health Belief Model states that it is a person's perception of his illness and the variables affecting it which determine actions taken to prevent or cope with the illness. Perceptions of one's illness and the therapeutic regimen as well as other modifying factors have been theorized to affect compliance behavior. An abbreviated beliefs-compliance model, based on Becker and Maiman's adaptation of the Health Belief Model (HBM), was used in this study as a framework for determining the relationship between the perceived costs and benefits of an oral medication regimen and compliance with that regimen in persons with COPD.

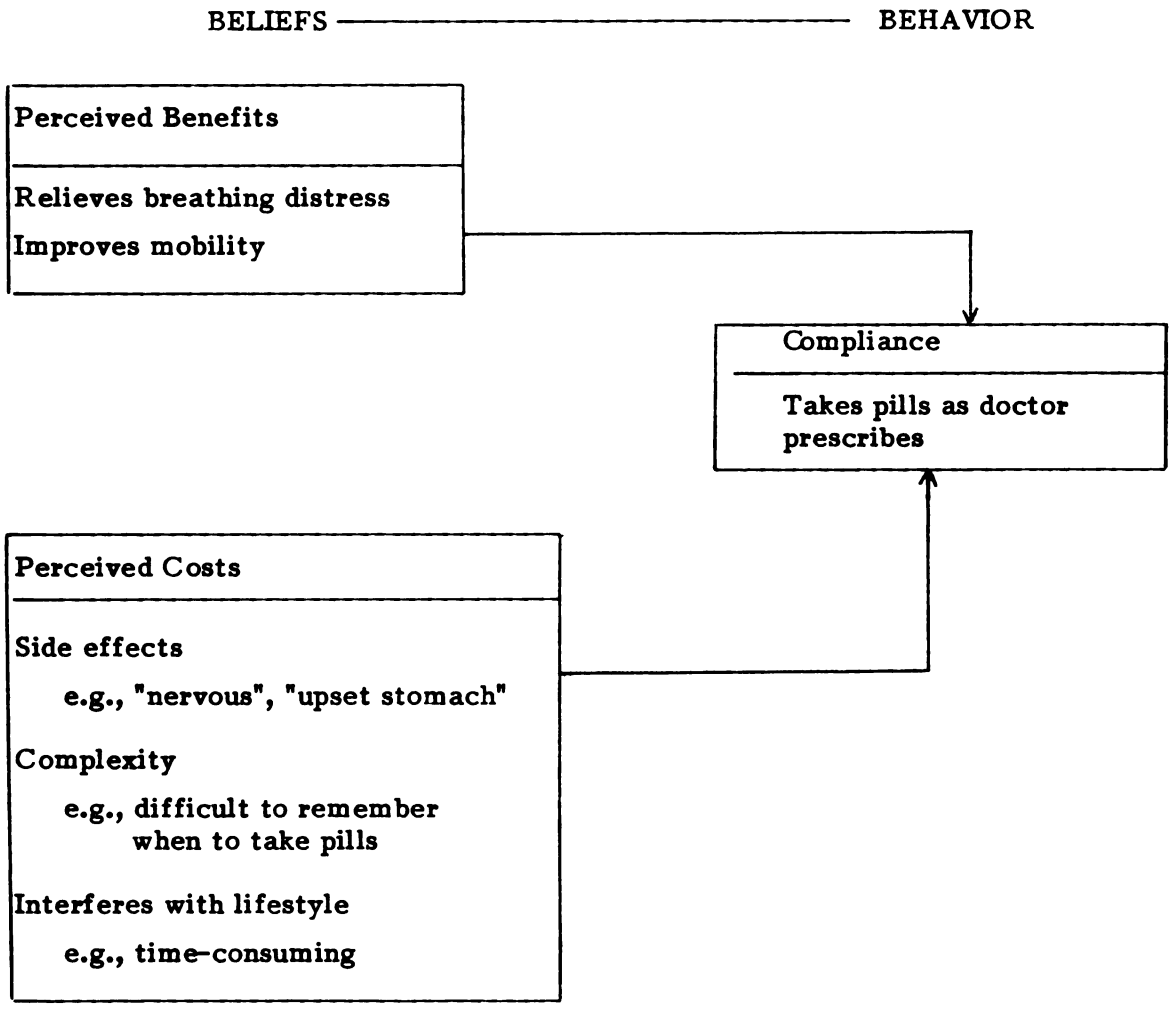


Figure 1. Beliefs-compliance model. Adapted from Becker and Maiman, 1975.

C. Purpose of the Study

The purpose of this study was to answer the questions:

(1) What is the relationship between the perceived costs and benefits of an oral medication regimen and compliance with the oral medication regimen in persons with COPD?

(2) What is the estimate of non-compliance with an oral medication regimen in a sample of persons with COPD?

D. Definition of Terms

Persons with COPD - An out-patient of the V.A.M.C. Pulmonary Clinic who has a primary diagnosis of chronic bronchitis, asthma, emphysema, or COPD.

Oral medication regimen - All oral medications, subsumed under the concept "pills", which are prescribed for the subject through the V.A. Pulmonary Clinic.

Perceived "costs" - Subject's perception of the side effects, complexity and time and energy demands of the oral medication regimen as measured by items on a Likert-type scale.

Perceived "benefits" - Subject's perception of ease in breathing and increase in mobility as measured by items on a Likert-type scale.

Compliance - The extent to which the subject follows his oral medication regimen. Responses including "true" to "I take all the pills the doctor prescribed for me" and "false" to "I do not take all the pills the doctor prescribed for me" will constitute satisfactory compliance, as measured by a randomized response technique (see further explanation under Chapter III, Instruments).

E. Significance of the Study

The estimate of non-compliance with an oral medication regimen obtained on this sample of persons with COPD will be the first such estimate available and can serve as a basis of comparison for subsequent studies. No figures on

compliance with a prescribed medication regimen in COPD are now available.

The randomized response technique (explained in Chapter III), used to estimate non-compliance in the sample, is a non-invasive and easy methodology to use. Its application in this study can serve as an example for future compliance studies.

The independent variable, perceived costs and benefits of an oral medication regimen in persons with COPD, was measured with an instrument constructed specifically for the COPD subject. This instrument can serve to guide the construction of future measuring devices in COPD compliance studies. The implications for future studies which arise from this study are significant and will be discussed in Chapter V).

F. Limitations and Delimitations

The study is limited for the following reasons:

(1) The sample was not random and may be smaller than is optimal. It is, therefore, not possible to claim that the sample represents the target population of all COPD patients in the United States. Any claim that the sample represents the accessible population and that findings can be generalized to this population must be made cautiously, if at all.

(2) Independent variables other than the one being studied will, no doubt, influence the compliance of the sample. While acknowledging that these variables exist, the investigator believes that they should not negate any relationship between perception of costs and benefits of an oral medication regimen and compliance with that regimen, as measured in this study.

(3) The dependent variable, compliance with an oral medication regimen, offers a one-dimensional view of a medical regimen that has many dimensions. Oral medication, for example, does not include the

inhaled medications which many COPD patients use. While realizing these limitations, the investigator chose to narrow the focus of the dependent variable in order to make the study manageable in the time frame available.

(4) The question of obtaining a measure of non-compliance by the direct question method as a basis of comparison with the randomized response estimate of non-compliance was considered for this study. It was decided not to compromise the promise of anonymity made to the subject by confronting him with a direct question, especially since this would have to be done during the same brief session that the Likert scale and randomized response items were administered. If each subject was seen on more than one occasion, the direct question method as a basis for comparison would have been more feasible. The researcher decided instead to use previous estimates of non-compliance with a drug regimen in chronic illness (Haynes, Taylor, & Sackett, 1980) as a basis of comparison with the randomized response estimate obtained in this study.

G. Summary

This study examined compliance behavior among a sample of persons with COPD, using a measuring device labelled the randomized response technique. The independent variable for study was the COPD subject's perception of the costs and benefits of his prescribed oral medication regimen. The implications of the results of this study should serve to direct the path of future studies on compliance in persons with COPD.

Chapter II: Literature Review

A review of the literature relevant to this study focuses on studies which:

(1) use the Health Belief Model (HBM) as a framework for examining compliance behavior in prescribed therapeutic regimens. Particular attention will be directed to whether the independent variables used relate significantly to compliance.

(2) examine the advantages and disadvantages of different methods of measuring compliance with a therapeutic regimen.

(3) use the randomized response technique (RRT) as a method for reducing verbal response distortion to threatening or sensitive questions.

A. Health Belief Model (HBM) and Compliance

In a descriptive study, Becker, Maiman, Kirscht, Haefner, and Drachman, (1978) tested the ability of the HBM variables to predict compliance in mothers who brought their children to a pediatric emergency room for treatment of an acute episode of asthma. A convenience sample of 111 mothers was interviewed on the following HBM dimensions: perceived illness threat (e.g., susceptibility to asthma attacks; severity of asthma; interference with social functioning) and perceived benefits and barriers of medication regimen (e.g., effectiveness of medication in preventing, curing or delaying asthma attacks; structure of regimen). Compliance was measured in all mothers by a direct question about whether the most recently prescribed asthma medication had been administered. Blood theophylline levels, as a measure of compliance, were obtained on 80 of the 111 children. The following probability levels reflect the significance of correlations obtained from the verbal reports (n=111) of compliance.

Perceived seriousness of the child's asthma and the belief that the child may take asthma medication for life correlated significantly with compliance (.550 and .503 respectively, $p < .01$, n=111). Adherent mothers were significantly

more likely to believe that the prescribed medication could help but not cure asthma ($r=.374$, $p < .05$). Disruption of activities, inaccessibility to stores, and administration schedule were perceived barriers which also correlated significantly ($p < .05$) with compliance behavior. In general, the HBM variables operationalized by the authors were found to relate to compliance in the predicted direction.

Of particular interest is the finding that compliant mothers were less likely to believe that giving the asthma medicine regularly and on time would prevent an asthma attack, even though they believed that the medicine would help but not cure asthma. The authors suggest that compliers may be more realistic and knowledgeable about the value of their medications, understanding both their limitations and value. An expansion of that interpretation might be that compliers with chronic illness (or their mothers) have more realistic expectations about the power of their medications. In other words, compliers in chronic illness may follow their prescribed regimens faithfully and still suffer relapses; thus, they come to state goals in terms of "not missing school" or "getting around better" rather than cure or preventing attacks.

A prospective study (Maiman, Becker, Kirscht, Haefner, & Drachman, 1977) evaluated the ability of the Health Belief Model to explain differential adherence by mothers to diet regimens prescribed for their obese children. One hundred and eighty-two (182) mothers were interviewed for about one hour; most of the questions were constructed as indices of the HBM dimensions. Compliance was measured by outcome; this is, the change in weight over a two-month period.

The perceived benefits (likelihood that diet will help overweight; feeling of control over weight) and perceived barriers (unsafeness of diet) of the diet regimen were significantly correlated ($p < .05$) with weight loss. Other perceived barriers (e.g., mother's ability to help child, interference of regimen with child's

normal activities) did not correlate significantly with weight loss in this sample. These findings, however, reflect only the mother's perception of the barriers rather than the perceptions of the child (mean age = 11.5 years) enduring the regimen and so may be less reliable. An adult with a chronic illness may well be more aware of the barriers, or costs, of following a demanding regimen and more susceptible to non-compliance because of them.

In a less rigorous study, Cummings, Jette, and Rosenstock (1978) used a multi-trait-multi-method design to demonstrate the validity of the HBM variables. Data was obtained from a sample of 85 undergraduates who, the authors admit, do not represent any general population. Each of six traits related to perceptions about influenza was measured by three methods: a seven-point Likert scale, a fixed-alternative multiple choice questionnaire and a vignette. Results revealed that the original components of the HBM- perceptions of susceptibility, severity, barriers and benefits - can be measured with substantial convergent validity using Likert scale and multiple choice methods. The Likert scale showed some superiority. An interesting finding was the substantial negative correlation (- .655) between perceived barriers and benefits of the therapeutic regimen. The authors suggest that these constructs may be on opposite ends of a continuum and should not be treated as separate health beliefs.

If this is true, and it seems plausible, then one could conceivably obtain a measure of a benefits to barriers ratio of the perceived effectiveness of a regimen. In other words, when questioned about perception of the benefits and barriers of a regimen, a subject would likely obtain either a high perceived benefits or a high perceived barriers score. This result could, in turn, be correlated with some measure of compliance with a regimen. In research with COPD patients, this would be appropriate because there are specific costs (e.g.,

side effects, complexity) and specific benefits (e.g., ease in breathing, increased mobility) which the patient deals with constantly as he follows a medication regimen.

The final two studies reviewed here used the health belief framework to examine compliance in adults with hypertension. They found interesting and conflicting results.

In a retrospective design, Hershey, Morton, Davis, and Reichgott (1980) measured Health Belief Model components and their relationship to compliance with a medication regimen in a random sample of 132 high blood pressure patients. Health Belief components were operationalized by using questionnaire items administered over 15 to 30 minutes during the subject's regular clinic visit. Compliance was measured by verbal response to a multiple-choice question about missing pills. Log-linear multivariate analysis revealed that three independent (HBM) variables - control over health matters, perceived barriers and duration of treatment - contributed independently to compliance. Goodness of fit of the Health Belief Model was high. In other words, the model would predict that as high as 74 percent of those classified as having high perceived control over health matters, low barriers and short duration of treatment would be more likely to take their medications. The authors found no significant relationship between perceived severity of the illness or perceived benefits, and compliance.

It is worthwhile to note that the items in the perceived benefits index had a relatively low reliability coefficient (r=.473) compared to those in the perceived barriers index (r=.621). In addition, items in the former index were not as specific to hypertension as were those in the latter. It might be true that Hershy's et al. (1980) subjects did not find the perceived benefits items pertinent. For example, they may have been symptom-free and unable to perceive any direct benefit from their medication. More general benefits referring to the

future may have had little meaning for this low income, inner-city population. Finally, although it is a chronic illness, hypertension may not generate the same compliance problems as other more symptomatic long-term illnesses.

Finally, Taylor (1979) measured health beliefs in a random sample of 128 men from a hypertension screening and treatment program, who were subsequently started and continued on anti-hypertensive therapy by a physician over a twelve-month period. Compliance with the regimen was measured at six and twelve months into the therapy by verbal report and an unobtrusive pill count. Patients who felt that illness did not imply a state of dependency on others were more likely to comply with their regimens at six and twelve months than those who believed that illness entailed dependency ($p < .01$). All other independent variables measured before treatment, including perceived belief in the medication regimen, showed no significant relationship with compliance at six and twelve months. To determine whether an assessment of health beliefs would add significantly to the identification of a compliance problem, beyond that which could be learned by asking the patient to estimate his own compliance, partial correlations were computed between each of the six-month beliefs and the six-month pill measure of compliance. Patient reports of compliance explained 52 percent of the variance in the objective measure of compliance. In contrast, all partial correlations between six-month beliefs and the objective measure of compliance were near zero. The researcher concluded that an assessment of health beliefs before treatment is not helpful in the identification of patients who will have future problems with compliance. Health beliefs, he suggests, develop along with compliance behavior as people experience their treatment and its effects.

However, the investigator does admit that the study results may be peculiar to persons with hypertension or other asymptomatic conditions where

the objective is to prevent further serious illness. Patients who have a more extensive history of previous and co-existing illness may have built up a more extensive repertoire of beliefs and perceptions, the author proposes, which may, in turn, influence their response to treatment.

Summary

A review of studies on the Health Belief Model and compliance demonstrates that:

(1) the Health Belief Model is useful for examining compliance with therapeutic regimens. Perception of the benefits and barriers of the regimen, in general, relates significantly to compliance.

(2) Health Belief indices have been operationalized in many ways. Most studies use items related to side effects, interference with daily activities and complexity of the regimen when referring to barriers. Benefits have been less clearly delineated, possibly because no studies were done in which relief of symptoms is the key benefit felt from medical regimens.

B. Methods of Measuring Compliance

There are a multitude of ways to measure compliance behavior, including verbal report of the patient, outcome behaviors, pill counts and serum or urine assay (Gordis, 1979), each with its advantages and limitations.

Verbal report

Asking patients to state whether they take their medications as prescribed is the most practical method of assessing compliance. However, studies report conflicting findings about the accuracy of verbal reports. Patients have been found to overstate compliance or understate non-compliance (Gordis 1979), when their verbal reports are compared to objectives measures of compliance, such as serum levels (Sheiner, Rosenberg, Marathe & Peck, 1974) and urine assay

(Preston & Miller, 1964).

Hershey et al. (1980), on the other hand, showed a significantly positive correlation between the verbal report of missing no pills, missing some pills and missing three or more pills, and blood pressure control. The relationship was most strong when comparing those who missed no pills with those missing three or more pills (difference = 47 percent, p .01). Becker et al. (1978) reported a correlation of 0.913 between the mother's verbal report of giving medication to her asthmatic child and the level of theophylline in the child's blood - arguing for the validity of the mother's statement as a general indicator of her compliance with the prescribed regimen.

No evidence in the studies reviewed suggest that compliers misrepresent themselves as non-compliers or that those who admit to non-compliance are lying. If one is concerned only with measuring the number of non-compliers in a group, then many can be identified by verbal report (Gordis, 1979). A researcher essentially allows for the probability of obtaining a somewhat inflated report of compliance in the group given the practicality and ease of the method.

Outcome behaviors

Objective measures of compliance such as pill counts and serum drug levels have been significantly correlated with such outcome behaviors as drop in blood pressure (Hershey et al., 1980), therapeutic response to diphenylhydantoin (Kutt, Haynes & McDowell, 1966) and reduced antistreptolysin-O titers in rheumatic fever patients (Markowitz, 1970). There are, however, a number of conceptual problems in using outcome behavior as an indicator of compliance. Inherent in the method is the assumption that the effect of the regimen in improving the patient's outcome is mediated through compliance. In fact, other factors may be affecting the outcome. For example, the patient may receive reassurance from his health provider with consequent reduction in stress that may, in turn, reduce

blood pressure (Gordis, 1979). Furthermore, in some long-term illnesses, compliance with a therapeutic regimen does not result in any specific outcome, or, in other cases, it may be slow to develop. With asthma, for example, the course of the disease is extremely variable, and may depend more on stress level and seasonal changes rather than compliance. For some patients, maintaining the status quo is a positive outcome. Such a subjective feeling is difficult to subsume under the objective label of outcome behavior.

Pill counts

Pill counts or, more accurately, the comparison between the amount of medication remaining in the patient's bottle and the amount that should have remained (judged from prescription) have tended to overestimate compliance when compared to more objective measures (Gordis, 1979). In their study of children (n = 59) on ten-day penicillin therapy, Bergman and Werner (1963) found that by the ninth day, on the basis of urine tests, only 8 percent of the sample was taking penicillin whereas on the basis of pill count, 18 percent would have been considered compliant at this time. Such problems may be even greater when the medication prescribed can be used by other members of a household.

Serum and urine assay

The most objective and accurate measures of compliance with a medication regimen are serum and urine assays. However, difficulties arise in obtaining samples (Becker, 1978) and in correlating sample collection with drug excretion times based on the time of administration, peak-effect and half-life of the drug (Gordis, 1979). The method quickly becomes unrealistic for out-patient use except in well-controlled clinic situations.

Ethics and compliance studies

Added to the difficulties in measuring compliance is the ethical issue of using deception to obtain compliance information (Jonsen, 1979). Full disclosure

of the study intent is sometimes not made by researchers so as not to vitiate the study. For example, in one study, "unobtrusive" pill counts were conducted during home visits after the subject had left the room to produce a urine sample (Taylor, 1979). From the report of the study, it is not clear whether the urine sample had any purpose other than providing an opportunity to count the subject's pills. Jonsen (1979, p. 119) states that explanations for procedures which are harmless need not be provided in specific terms but that concealing information should be considered "sinful deception" if it involves withholding information which one could presume might influence the patient's decision to participate in the study or the treatment planned.

Summary

Compliance with a medication regimen can be measured by evaluating therapeutic outcome behavior, counting pills, analyzing urine and blood samples, and by asking the patient how well he manages his regimen. Although patients tend to overstate their compliance, the verbal report is the most available, ethical and least invasive of all the methods reviewed. When used to measure non-compliance in a group, it can provide useful information.

C. Randomized Response Technique

In typical patient-provider interactions, compliance is viewed as the responsibility of the client; acknowledgement of non-compliance constitutes an admission of failure, even moral culpability, on the part of the client. Such acknowledgement, then, is relatively unlikely to occur, even in response to a direct question (Stone, 1979). But the probability that the direct question is posed is low, claims Stone (1979), because a variety of psychological mechanisms operate to oppose it. If non-compliance is the fault of the patient, then confrontation may seem impolite or inconsiderate. If it is something the provider should be addressing but is not, there may be a tendency to deny its

presence. Phsycians, for example, systematically overestimate the extent to which their patients adhere to prescribed regimens (Gordis, 1979).

Researchers, on the other hand, do ask patients if they take their medicines but always run the risk of threatening the patient and compromising the data collection. If there were a way to ask patients for information related to compliance while providing them with a measure of anonymity, then the process might be less intimidating and might result in a more accurate measure of non-compliance.

In an attempt to address such concerns, a data-gathering tool called the randomized response technique will be used in this study as a method of measuring compliance with a medication regimen. What follows is a brief explanation of the method and a review of the randomized response literature applicable to this study. In each of the studies reviewed here, randomized response technique is used to obtain answers to sensitive questions which, if posed directly, may have yielded some degree of response distortion. Some studies reviewed were also designed to validate the randomized response as a data-gathering tool. Emphasis in this review will be placed on those findings which point to the ability of the randomized response technique to reduce the proportion of distorted responses (incorrect answers) in sensitive question situations as well as those which verify the tool's reliability.

In 1965, Warner developed a statistical method, called randomized response techinque (RRT), to deal with the response distortion which results because people are often reticent about giving information in questionnaires or interviews which they feel is socially unacceptable or too revealing. The method is based on the premise that "...cooperation should be naturally better if the questions allow answers which reveal less, even to the interviewer" (Warner, 1965, p. 63). Use of the method should reduce some of the under-reporting of undesirable behavior

which most often comprises response distortion.

In its simplist form, the randomized response technique has the respondent answer one of two questions selected randomly without revealing to the interviewer which question he has answered. Generally, the respondent would answer "true" or "false" to one of the following statements.

I am a member of a Group A (e.g., had illegal abortion).

I am not a member of Group A

By knowing the probability of answering each question, the sample size and the total number of "true" replies, the proportion of the population that answered "true" to the sensitive question (member Group A) can be estimated (Locander, Sudman, & Bradburn, 1976).

A modified verison of randomized response states that one question should be threatening and the other innocuous and unrelated (Horwitz, Shah, & Simmons, 1967). The respondent would then answer "true" or "false" to one of the following randomly selected questions.

I am a member of Group A (e.g., had illegal abortion).

I am a member of Group B (e.g., born in April).

With this method, the unrelated question data are treated as a separate sample for estimating purposes. By knowing the probability of answering each question, the true proportion with attribute B, and the number of "true" replies, the proportion of the population that answered "true" to the sensitive question (member Group A) can be estimated (Locander, Sudman, & Bradburn, 1976).

In a descriptive study, Barth and Sandler (1976) elicited responses on alcohol use from 63 high school students, using the randomized response technique and a self-report questionnaire for comparison. The 20-item questionnaire which contained one question about whether 50 drinks of alcohol were consumed over the past year was administered by an investigator at Session

1. Session 2, 10 days later, was conducted by a different investigator who administered the sensitive question using the randomized response method. Each student received two dimes, was instructed to toss them and to answer the question determined by the toss; that is, if two heads turn up, then answer question 1 (sensitive) but for all other combinations (head, tail; tail, tail), answer question 2.

The proportion of "yes" responses to the 50-drinks question was .63 (40/63) in Session 1. In Session 2, the estimated proportion of subjects answering "yes" to the sensitive question was calculated to be .85, indicating a reduced response distortion when randomized response was the method of questioning. Because of the small size and non-probability selection of the sample, the authors make no attempt to generalize findings. The findings are limited to a comparison of methods.

A personal survey among a national probability sample of 2000 adults, aged eighteen and older, estimated response to a child abuse question as a sensitive issue (Zdep and Rhodes, 1976). After screening the sample for presence of children in the household, the screened respondents were divided into random halves. Each half responded to the randomizing device (coin toss) by answering either the sensitive question related to deliberately using force to hurt one's child, or the non-sensitive question related to attending a PTA meeting in the last year. Eight weeks later, as a validating measure, a new probability sample of adults responded to the sensitive question directly by marking their answer on a form, sealing it and returning it to the interviewer at the time of the interview, or by mail. Chief among the findings was the 98 percent response rate among those administered the randomized response technique (n = 995). In the second sample (n = 1003), 8 percent handed their sealed responses to the interviewer while 75 percent mailed them to the survey office. The unbiased

estimate of the percent of child abusers among those administered the randomized response method (n = 995) was 15 percent; three percent of those who handed back sealed direct responses (n = 538) and four percent of the sample who mailed direct responses (n = 465) admitted to incidences of child abuse. The results indicate that the randomized response technique was more successful in getting people to admit to a socially undesirable behavior than either of the two direct methods.

A few methodological issues emphasized by the researchers are relevant to this study. In explaining the randomizing device to the subject, it is important not to present more information than can be assimilated. Too much information tends to confuse and possibly alienate the subject. For this reason, the authors recommend pre-testing the randomizing device used. Related to this is the complexity of the randomizing device; for example, using red, white and blue balls in a box versus using a die. Although a simpler device may result in greater inefficiency and more error in the estimate sought, it may be worthwhile if the subject can be more assured that the game is not "rigged" in any way.

In a later survey, Zdep, Rhodes, Schwarz and Kilkenny (1979) sought to validate the randomized response technique (RRT) by comparing it to another method of obtaining the same information. It would, they reasoned, be possible to conduct a validation by using a sensitive issue that is rapidly approaching acceptability among vast segments of our society. Marijuana usage was chosen; the sensitive question being "Have you at any time used marijuana?" By comparing the results obtained independently using direct questioning at approximately the same time, the study demonstrated criterion-related validity as defined by the American Psychological Association (1966). In addition, some hypotheses related to differential usage rates in the population, based on the Sixth Annual Report ...HEW ... on Marijuana and Health, were tested. A coin

toss determined whether the sensitive or non-sensitive question would be answered by a probability sample of 2,084 adults. Subjects were also asked the sensitive question directly. For the total sample, RRT estimates of usage were slightly greater than the number of users determined by direct questioning (24 percent versus 21 percent). For all age groups the patterns obtained were as predicted. Direct questioning yielded a slightly higher usage (53 percent versus 48 percent) in the youngest age group, due possibly to the false-positive reporting of a behavior fashionable in this age group. More notable is the finding that among the group aged thirty-five to forty-nine, direct questioning seemed to underestimate usage by a factor greater than three (6 percent versus 19 percent). In other words, the estimate of 19 percent users obtained with randomized response technique seemed to reduce the response distortion to a sensitive question; there were more positive responses to what was likely perceived as a socially undesirable behavior. These results suggest that the RRT tends to become increasingly appropriate as the perceived sensitivity of the question increases.

In a survey which relates to the findings of Zdep et al. (1979), Locander, Sudman and Bradburn (1976) examined the joint effects of question threat and method of administration on response distortion using four data-gathering techniques: telephone, face-to-face, self-report questionnaire and randomized response technique. The level of threat was varied by asking questions about library card ownership, voting, bankruptcy involvement and drunken driving charges. For these questions it was possible to obtain validation information from public records and, thereby, measure the actual response error.

A random sample of 800 people was subdivided into groups of 50 respondents, each group receiving one question method and belonging to one threat level.

The randomizing device was a 3 x 5 inch plastic box containing 50 beads; 70 percent red and 30 percent green. The box was designed so that, when shaken, either a red or a green bead would randomly appear in the window. The subject was then instructed to answer the question on a flip card which had a ball beside it that was the same color as the one appearing in the window. The investigator recorded only the "yes" or "no" response given by the respondent.

Interview bias was controlled for by training the interviewers and randomly assigning them over the different methods of administration but matching them with respondents for race.

Findings from this study were varied and only some will be discussed here. The proportion of distorted responses (incorrect answers) to the drunken driving question could be calculated by the researchers because it was known that all drunken driving respondents had been charged with drunken driving in the six to twelve months before the starting date of the study. For each of the methods administered, the proportion of distorted responses to the drunk driving question and the standard errors are as follows: face-to-face - 47%, n = 30, S.E. = .090; telephone - 46%, n = 66, S.E. = .073; self-administered - 54%, n = 28, S.E. = .094; random response - 35%, n = 23, S.E. = .141. Analysis shows that in the highest threat condition, drunken driving, randomized response yielded the lowest rate of response distortion, even though the method was more personal than telephone or questionnaire. The investigators acknowledge, however, that a 35 percent understatement is still a major response bias. In the somewhat less threatening condition, bankruptcy declaration, the randomized response method yielded no response distortion (0.00) whereas the face-to-face, telephone and self-administered methods yielded response distortion rates of 32%, 29%, and 32%, respectively.

Although randomized response gave the lowest distortion rate on

threatening questions asking about drunken driving and bankruptcy, it is clear from these results that the subject's perception of what is undesirable is important. For example, some subjects in the bankruptcy condition may have viewed their action as a smart financial maneuver rather than undesirable behavior. Although each of the data-gathering methods is best under certain conditions, and no one method is always best, the authors conclude that for sensitive or threatening question situations, randomized response produces the least response distortion.

Summary

The studies reviewed indicate that randomized response technique is a valid method of collecting data from groups when the question to be asked is "sensitive" or threatening and may result in distorted, incorrect, or biased reporting. The usual direction of bias is to under-report undesirable behaviors when data is gathered by a direct method. Randomized response tended to reduce this under-reporting of behaviors perceived by the subject as undesirable.

D. Summary/Conclusions

From the preceding literature review, one can draw some conclusions about the Health Belief Model, compliance and randomized response.

(1) Although studies have used the Health Belief Model as a framework for studying compliance in long-term therapeutic regimens, no studies were found which examined compliance with a therapeutic regimen in persons with COPD.

(2) People with COPD take numerous prescribed medications for their breathing and related problems, on a relatively long-term basis. It is likely that they have acquired, over time, perceptions and beliefs about the relative costs and benefits of their medication regimens, and that these perceptions may relate to their compliance behavior.

(3) Of the many methods used by researchers to measure compliance the verbal report of the patient may be the most realistic available. It is, however, less accurate in that patients tend to under-report non-compliance.

(4) Patients may under-report non-compliance because it is viewed by health providers as undesirable behavior.

(5) Randomized response, as a method of reducing response bias to threatening questions, may be useful in increasing the accuracy of non-compliance estimates in groups. It will allow subjects to give responses which are not known to the interviewer, thereby reducing the tendency to under-report undesirable behavior or, conversely, over-report desirable behavior.

(6) Since no estimates of non-compliance with a medication regimen in persons with COPD were found in the literature, it seems reasonable to use the 25-50 percent rate quoted for persons with other chronic illnesses (Haynes, Sackett, & Taylor, 1980).

(7) An estimate of non-compliance with a medication regimen in persons with COPD can be assessed using the randomized response technique as a non-threatening data-gathering method. An adaptation of the Health Belief Model provides a framework for looking at the perceptions of the costs and benefits of an oral medication regimen in persons with COPD and the relationship of this independent variable to compliance with a medication regimen in the sample group.

Chapter III: Methodology

A. Study Design

This study used a descriptive survey design in which the intent was to describe the relationship between two variables in a sample of persons with COPD. Information was obtained from each subject in a fifteen minute interview situation during which he completed a questionnaire and answered three questions verbally.

The descriptive design was considered appropriate for this study because no other studies on compliance with a drug regimen in persons with COPD were found in the literature. It was intended to be a first level study in an area where more study is needed. Compliance with a drug regimen was posed as a problem in the literature among persons with chronic illness (Strauss & Glaser, 1975; Haynes, Taylor, & Sackett, 1979) but reference to compliance with medication regimen among persons with COPD was scant (Fagerhaugh, 1975; Barstow, 1979). In order to build a data base on non-compliance in persons with COPD, the Health Belief Model was used as a framework from which to choose the independent variable for study. Other studies, it was felt, could use the same framework to study other independent variables and their relationship to compliance in persons with COPD.

Independent variable

Perceived costs and benefits of an oral medication regimen, the independent variable, as operationalized as ten items in a Likert scale instrument which measured the subject's beliefs about the advantages and disadvantages of the medication he was taking for his breathing problems. The literature reviewed provided the basis for choosing the indices which comprise "perceived costs and benefits"; that is, perceptions of breathing difficulty, ability to get around, side effect discomfort, complexity of the regimen and whether taking

pills, in general, is worth it. Perception of costs and benefits is viewed as one construct, or variable. In other words, subjects who perceive many benefits from their medication regimen should perceive few, or no, costs, as measured in this study. In fact, this occurred and will be discussed later as a reliability issue.

Dependent variable

Compliance with an oral medication regimen, the dependent variable, was operationalized as a verbal response to either of two statements, posed randomly:

A. I take all the pills the doctor prescribed for me.

B. I do not take all the pills the doctor prescribed for me.

The literature suggested that there are many questions which can be asked to ascertain medication compliance (Hershey et al., 1980; Becker et al., 1978). Since no strong arguments existed in the literature for any particular question, the choice in this study was based on the need for a comprehensive question which covered the essence of compliance; i.e., taking versus not taking medication. One question was considered optimal because the sample was anticipated to be mostly older men with limited education and fairly advanced pulmonary disease. The question had to be simple and straightforward because many of the subjects were extremely short of breath and unable to concentrate for very long on any thing but the actions needed for their routine clinic visit. As it happened, 34 out of the 40 subjects (85 percent of the sample) were 60 years or older, and at least two subjects who were under 60 years, were the most incapacitated in the group.

B. The Sample

A non-probability sample of convenience was used. The accessible population was identified as persons with COPD who are out-patients in the Veterans' Administration Hospital system. Subjects for the study were chosen

from those who attend the Pulmonary Clinic at the Veterans' Administration Medical Center in Palo Alto, California.

Because the sample was not selected randomly, the inherent danger of sampling bias was controlled for in the following manner.

(1) The medical records of persons attending the Pulmonary Clinic were examined to select subjects according to pre-set criteria.

(2) To meet these criteria, subjects had to: have a primary diagnosis of emphysema, asthma, chronic bronchitis, or COPD; be taking three, or more, prescribed oral medications; be 50-75 years old, and able to speak and read English.

(3) All subjects had the same primary diagnosis and were attending the same pulmonary clinic. It was assumed that their oral medication regimens would be similar, as was the case. All subjects were receiving one, or more, forms of aminophylline. Terbutaline, prednisone, diuretics and digoxin comprised the rest of the regimens.

(4) The homogeneity of the sample was further enhanced in that all subjects were male and were veterans of World War II, or Korea. A sample chosen from a non-V.A. COPD population may well have included a small proportion of women.

In spite of this degree of homogeneity in the sample, it was recognized that other variables, such as availability of friends or relatives, might influence the behavior of subjects. No attempt, however, was made to control for that effect in this study.

Sample size was dictated somewhat by using the randomized response method. A large sample tends to decrease the variance in the estimate obtained and, thereby, increases the accuracy of the results (Warner, 1965). Also, a large sample, as well as its potential homogeneity, increases the likelihood that the

non-randomized sample represents the population intended (Polit & Hungler, 1978). Therefore, an attempt was made to collect data from as large a sample as time would allow.

Based on studies using randomized response (Barth & Sandler, 1976; Locander et al., 1976), the minimum sample number was set at 40 subjects and the projected sample size was 50 subjects. Because of anticipated time constraints, data was collected from an acceptable sample of 40 subjects with COPD.

C. Instruments

Likert scale instrument

The purpose of this instrument was to provide a measure of how the benefits and costs of their oral medication regimen were perceived by a sample of people with COPD. The data from the instrument were then correlated with an estimate of compliance for the sample, in order to determine if any significant relationship existed.

Development

The stages of developing this instrument incorporated validity, and in small part, reliability checks. Information from these checks was used in constructing the final instrument. 1. Strauss and Glaser's (1975) conclusions about how people with chronic illness decide to adhere or not adhere to regimens provided content categories from which an item pool (see Appendix I) was developed. 2. Content validity was further ensured by asking two Respiratory Nurse Clinician "experts" to judge the original item pool, according to criteria (Kerlinger, 1973) concerned with whether the items: a) seemed to reflect the content categories, b) reflected relevant content, and c) would be understood by and relevant to the subjects. Changes recommended by these experts focused on increasing the clarity and relevancy of the items. For example, using terms like "short of

breath", "hard to breathe", feeling "nervous", or having an "upset stomach" were suggested. Every attempt was made to incorporate these recommendations into the items. 3. The next issue was that of construct validity. Were the items which were originally constructed to reflect sub-categories of content and the over-all construct of perceived costs and benefits, able to be placed back into those categories? An attempt at a "by-hand" factor analysis involved giving the thirty-six items and the content categories to a professional nurse familiar with the study, who was then asked to match each item to a category. This proved difficult and illustrated that the categories were too broad and that the items covered too many constructs. A subsequent revision resulted in more focused and homogenous content categories (see Appendix II) as an attempt to ensure that the final tool would measure one construct (Polit & Hungler, 1978), perceived costs and benefits of an oral medication regimen. 4. A final step in the construction of the instrument resulted in numerous insights, changes and, eventually, the completed tool. For purposes of accurate tool development, it seemed necessary to try to assess whether the items in the pool would elicit responses which varied in expected directions and, thereby, discriminated between those subjects who perceived their medication as beneficial and those who perceived it as having many costs. This, in effect, would be a check on the reliability of the accuracy of the data.

It would have been ideal to administer the items to a sample similar to the intended real sample, but access to this group was not possible at the appropriate time. Instead, a simulated sample was used. Sixteen nursing students were programmed in the following manner. All were told:

> You are a 55 year old male veteran who has COPD, which you know to be emphysema, asthma, chronic bronchitis, or all three. You are an out-patient at the V.A. Pulmonary Clinic and are on a number of pills for your breathing and, maybe, other problems.

Some (n = 7) of the group were told (out of hearing range of the others) that they felt "negative, to very negative" about the effectiveness of their pills. The rest (n = 9) were told that they felt "positive, to very positive" about the effectiveness of their pills. All were then asked to complete an instrument comprised of items from the pool which had been set up in a Likert scale format. Of the thirty-six items in the pool, nineteen were positively-worded and seventeen were negatively-worded, in an attempt to balance the two directions (Nunally, 1969). The hypothesis for this exercise was that the "programmed positives" would respond to most items differently from the "programmed negatives".

The results were valuable in pointing out that items which stated the presence of a symptom were, in effect, neutral and provided no discriminating effect. The final items (Appendix III) were then constructed in such a way as to polarize the subject's response. Subject response to the completed tool will be reviewed in the discussion of the field test of the instruments.

Format

A Likert-type scale was used because this method tends to produce more reliable information than a simple true/false method for the same items (Oppenheim, 1966), and is also easy to construct and administer.

Reliability, in the form of the correlation coefficient, will usually increase as the number of items and number of scale steps in each item increase (Nunally, 1969). This assumes that all items are equally important and valid. Because members of this sample group would likely have short attention spans or even be short of breath when completing the tool, it was decided to limit the number of items to ten; i.e., five positively-worded and five negatively-worded items. Five scale steps would provide more sensitive data than two or three, but would still be easy enough to understand. The type of scale steps used was recommended by

the nurse experts as the clearest and easiest to see and understand. In positive items (1, 3, 6, 8 and 10), "strongly agree" was scored as 5, with "strongly disagree" receiving a score of 1. Scoring was reversed for negative items (2, 4, 5, 7 and 9).

It was anticipated that the relative homogeneity of the sample group might result in less score variance and a lower reliability coefficient for the instrument (Polit & Hungler, 1978). However, this possibility was traded off in the attempt to keep the tool appropriate for the sample. The split-half reliability coefficient obtained for the instrument is given in the Field Test section of this chapter.

Randomized response technique

Argument still exists in the literature as to whether Warner's (1965) related question randomized response method is better at evoking truthful responses than the unrelated question technique. Some authors report that the unrelated question technique offers a harmless escape from incrimination (Horwitz, Shah, & Simmons, 1967), whereas with Warner's method, either a "true" or "false" answer could indicate membership in the sensitive group. Others feel that the unrelated question technique is too revealing because only a "yes" response can implicate the respondent (Campbell & Joiner, 1973). Given the realization that a "yes" response alone can incriminate, there may be a tendency for the respondent to say "no" to whatever question turns up and, thereby, distort the response estimates.

Warner's (1965) method, on the other hand, does not seem, at face value, to offer a greater chance of incrimination with either response and, in that way, may increase the respondent's feeling of protection from discovery. Given no evidence of a mathematical reason to choose one method over the other (Fligner, Policello & Singh, 1977), Warner's related question method was used in this study to obtain a measure of non-compliance with an oral medication regimen. Key

reasons were that it was simple to administer and considered easy for even an older and sicker subject to understand. In Warner's method, there are also fewer parameters to measure; that is, no estimate of "yes" response to the innocuous question is needed, thereby, reducing the chance of estimate error.

The randomized response method was operationalized as two statements related to compliance behavior typed on a 5 x 8 index card (see Appendix IV) with brief instructions. The randomizing device was a die, considered large enough for those with vision problems to see clearly. Beside each item on the card were pictures of dice with the appropriate number of dots. The one set of items was administered three times. Increasing the number of trials, in this way, minimizes the variance of the estimate of non-compliance obtained, without increasing sample size (Liu & Chow, 1976). The die was thrown once for each trial to ensure that the three events were independent. After each throw of the die, the investigator recorded the subject's verbal response of "true" or "false" on the front page of his previously completed Likert scale instrument. The investigator did not see the number on the die and did not know which statement was being answered. The protocol for administering the randomized response tool will be included in the discussion on Data Collection.

Field test

A field test of the instruments was conducted with a sample of seven persons with COPD who met the same criteria outlined for the subjects in the study sample. The purposes and results of the field test follow.

(1) Could the data be collected from the subject in the time predicted? In fact, the time spend collecting data from each subject was less than expected; that is, fifteen versus thirty minutes.

(2) Was the randomizing device and the researcher's explanation of how to use it clear? All subjects were able to follow instructions

accurately after practicing a few times with practice cards set up exactly like the study cards, but using innocuous items (see Appendix V).

(3) Were the Likert scale items clear, understandable, and relevant to the subject? Minor changes were made in two items because three subjects did not experience the side-effects stated. Reference to feeling "nervous" was used instead of feeling "jittery" in item # 8. Item # 4 was altered to refer to a generally negative feeling versus a specific side effect. When asked, subjects stated that they could understand the items and that the language used was familiar to them.

(4) Were the items able to discriminate between subjects who perceived high benefits and those who perceived high costs from their regimens? One subject marked all items "strongly" positive, receiving the highest possible score of 50. He stated, when asked, that he felt the items were "right on". Another subject came into the interview room declaring, unasked, that his medications were no help and then proceeded to complete the instrument acccordingly. In other words, his response to each item indicated a consistent belief that the benefits of his medication were low, or non-existent, giving a check on the discriminating ability of the items. The remaining three out of seven subjects who could answer all the items had scores greater than 40. In other words, their responses to each item were consistent with the belief that their medication regimens had more benefits than costs. It was concluded that, following minor changes, the Likert scale instrument was able to discriminate on items and could be used in the study.

(5) Was the Likert scale instrument internally consistent? The actual measure of internal consistency of the tool was done on the final data set. A split half (odd/even) correlation coefficient for the instrument was .65, n = 40. Corrected with the Spearman-Brown prophecy formula, the reliability coefficient for the complete instrument was .78, indicating a fairly high degree of internal consistency among the items in the Likert scale instrument.

As mentioned previously, care was taken when designing the study to enhance the validity of the randomized response method by increasing the sample size as much as was feasible and by increasing the number of trials for each subject. These actions tend to decrease the variance in the estimate obtained, making it a more accurate measure of non-compliance in the group.

The literature has reported that the randomized response technique has consistently reduced response distortion to sensitive questions which had previously been asked in a more direct method. From this evidence, it was assumed that randomized response is a fairly reliable tool for eliciting accurate responses to sensitive questions.

Summary

Two instruments were used to collect data in this study of persons with COPD. A Likert scale instrument was constructed to measure perception of the costs and benefits of an oral medication regimen, the independent variable. Validity and reliability checks during development resulted in an instrument which had a relaibility coefficient of .78, using the Spearman-Brown formula.

Randomized response, as a method of measuring compliance, required that the subject answer "true" or "false" to a statement on compliance, chosen randomly by the toss of a die. The die was tossed three times to insure that each trial was independent. The subject's verbal responses were recorded as

compliance data. Both instruments were field-tested with a sample of seven subjects with COPD from the accessible population. After minor changes, the instruments were used to collect all data for the study.

D. Data Collection

All data were collected by this investigator during the period of November 1980 to April 1981. Subjects were approached on their usual appointment days in the Pulmonary Clinic at Palo Alto V.A.M.C. as they waited to see the physician. The investigator asked each subject if he would give fifteen minutes of his time to participate in a study of how people manage the medications they must take for their breathing problems. Two persons refused to participate. Some persons were not approached even though they were on the sample list because they were assessed as being too short of breath on that appointment day.

All interviews were conducted in a small conference room near the clinic check-in room. Patients were reassured that the door would be left ajar in order to hear their names being called. Every effort was made to reassure patients that participating in the study would not delay their appointments nor affect their treatment at the V.A. Each subject was asked to read and sign a consent form if he agreed to participate in the study (see Appendix VI).

Subjects were asked to complete the Likert scale instrument. All written instructions were repeated out loud with emphasis placed on the fact that there were no right or wrong answers. Subjects were encouraged to question any item they didn't understand. Usually, reading the item out loud was clarification enough and subjects were encouraged to do this. Thirty-two out of 40 subjects (80% response rate) answered all items. On the two items where subjects couldn't answer, the modal response for that item was used in scoring (discussed further in Chapter IV, A).

The explanation of the randomized response technique was standardized for

all subjects. Each subject was handed a 5 x 8 practice card and allowed to read the instructions. Then the instructions were repeated out loud as the researcher went through the actions. "What I want you to do is throw the dice... (throws dice). Look at the number which comes up... (points to number). Now match that number with the dice (sic) pictured on your card... (points to appropriate picture). Read the statement beside that number to yourself and answer, out loud, "true" or "false".

Emphasis was placed on not telling the investigator which number came up nor which item was being answered. The subject was told that it was important to respond only to the item indicated by the number on the die and to respond as accurately as possible. Subjects were encouraged to ask questions. All subjects practiced the method using the three practice item cards.

When it appeared that he understood the method, the subject was handed the actual study cards. He was reassured that the method was the same with these cards. It was explained that there would be three trials of throwing the die and giving a "true" or "false" response. Although all three item sets were identical, he was told, the numbers were likely to come up differently with each throw, so that he would not always answer the same item. The important thing was to "do as the dice tells you to". The subject's three responses were recorded on the front of his completed Likert scale instrument so that all the data from one subject was in the same place.

Most subjects responded positively to the randomized response method and seemed to enjoy throwing the die. Some were curious about how it worked but none indicated that they felt the method was foolish. A few subjects wanted to answer the items outright but agreed good-humoredly, to "play the game" when the investigator explained a need for this type of information.

E. Summary

A descriptive survey design was used to collect nominal and ordinal data from a sample of 40 persons with COPD who were patients at the V.A.M.C. Pulmonary Clinic at Palo Alto. Data on the independent variable, perceived costs and benefits of an oral medication regimen, were collected using a Likert-type instrument constructed for this study. The dependent variable, compliance with an oral medication regimen, was measured using a randomized response method to obtain an estimate of non-compliance in the sample.

The data was analyzed to determine:

(1) an estimate of non-compliance in the sample.

(2) the relationship between the perceived costs and benefits of an oral medication regimen and compliance with an oral medication regimen in persons with COPD.

Chapter IV: Results

The complete summarized data set will be given in this section in order to facilitate any re-analysis and to help exposit the randomized response methodology. Section A will discuss the scoring of the Likert scale data and the distribution of the scores; and will describe the division of subjects into groups with high and low Perceived Benefits Index scores. Section B will report the derivation of an estimate of compliance with oral medication regimen in the sample and in each of the groups described in Section A. The number of compliers and non-compliers in each group will be compared with the Perceived Benefits Index score for that group in 2 x 2 tables. The chi square (χ^2)-test for independence will measure the significance of the cross-tabulated data.

A. Likert Scale Data

Scoring

The raw data from the completed Likert scale instruments, summarized in Appendix VII, gives the number of subjects who marked each response. The modal response to each item is indicated.

Responses were weighted from 1 to 5. In the positively-worded items 1, 3, 6, 8 and 10, the response "strongly agree" was weighted five, and "strongly disagree" was weighted one. Scoring was reversed in the negatively-worded items 2, 4, 5, 7 and 9, such that "strongly agree" and "strongly disagree" were weighted one and five, respectively. Seven subjects (n = 7) were unable to answer item 6 and those seven, and one other (n = 8), were unable to answer item 8 because they did not experience the side-effects of "upset stomach" or nervousness. When calculating the total score for each of these subjects, the modal score for that item was used in an attempt to make that subject's score representative of the way he perceived his medications.

The total score for each subject, obtained by adding the weighted responses

to each item, was then doubled to broaden the range between the top and bottom scores and, thereby, facilitate diagramatic presentation. The final score for each subject comprised what will be referred to, from here on, as the Perceived Benefits Index (PBI) for that subject. A high Perceived Benefits Index score indicates that the subject tended to perceive more benefits than costs from his prescribed medication regimen, as measured by the Likert scale instrument in this study. The subject with a low score, on the other hand, tended to perceive more costs than benefits from his medication regimen. The highest possible score was 100; the lowest possible score was 20.

As seen in Figure 2, thirty-one of 40 subjects (77 percent) scored 80 or greater, indicating that the group, as a whole, tended to perceive their prescribed medication regimens as beneficial.

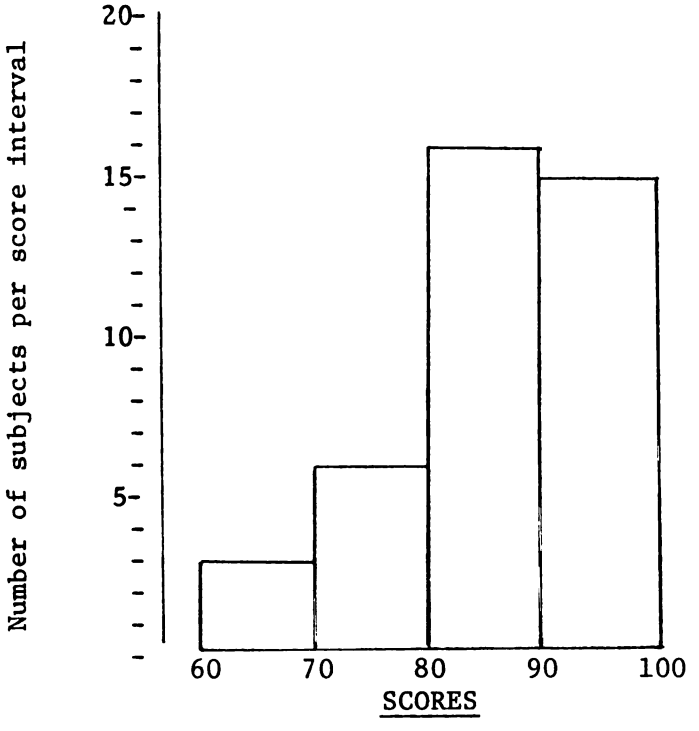


Figure 2: Histogram of the Perceived Benefits Index scores. The highest possible score is 100; the lowest score possible is 20. Score intervals include the left end point, but not the right end point.

The actual subject scores are displayed, in descending order, in a stem-and-leaf plot (Figure 3), which allows one to easily determine the median score and the upper and lower quartiles for the sample by counting to the appropriate places (Mosteller & Tukey, 1977, pp. 43-44). The stem of each score (actually the first 1 or 2 digits) is read in the column and the leaf of each score (2nd or 3rd digit) is located in the row which corresponds with its stem. So, for example, the 2 in row 2 indicates that one subject received a score of 92. The number of leaves in the plot equals the sample size (n = 40).

STEM	LEAF
10	000
9	8 8 8 8 6 6 [6] 4 4 4 2 0
8	8 8 6 4 [4] 4 4 2 2 2 2 2 2 2 [0] 0
7	8 8 8
6	6 2 2

Figure 3: Stem-and-leaf plot for Perceived Benefits' Index (PBI) Scores. The median score (actually the 20th observation in a list of 40) is double-boxed. The upper and lower quartiles are indicated by a single box.

Subject groups according to Perceived Benefits Indices (PBI)

Subjects were then divided into groups according to their PBI scores. Table 1 gives the median scores and the differences between the medians for the upper and lower division of each group.

Table 1

Differences Between The Median Scores for Each Subject Group[a]

GROUPS	MEDIAN SCORE	DIFFERENCE
Balanced		
Top half	96	16
Bottom half	80	
Discriminated		
Top quartile	98	26
Bottom quartile	72	

[a]Subjects grouped according to Perceived Benefits Index (PBI) Score.

The purpose of the groups was to discriminate, by PBI score, between those subjects who perceived many benefits from their oral medication regimens and those who perceived few benefits (high costs). Since the scores for the sample were generally high (range = 62 - 100), two divisions were made in an attempt to get the best separation between high and low scores. A balanced division of the scores resulted in the top half versus the bottom half group. To ensure a more discriminating division of the scores, the top versus the lower quartile was designated a second group, under the hypothesis that the persons with the ten lowest scores would likely perceive fewer benefits from their medications than those with the top ten scores.

Before the group was analyzed, an estimate of the number of non-compliers in the total sample of persons with COPD was calculated. What follows is an exposition of the randomized response methodology used to compute the estimates of compliance with oral medication regimen in this study.

B. Estimates of Compliance

Exposition of randomized response computation

Let N denote the number of subjects who responded to the items which were randomized as indicated on the instruction card given in Appendix V. The subjects responded in three independent randomized responses to the same item set, and for each subject a set of three responses (T's and F's) were recorded.

Let N_{NC} and N_C denote, respectively, the number of non-compliers and the number of compliers in the group of N subjects. Let F* denote the total number of recorded F's and let T* denote the total number of recorded T's. To fix ideas, note that one must have $N = N_{NC} + N_C = 1/3\ (T^* + F^*)$.

Now let E(T*) and E(F*) denote the expected number of T's and F's, under the hypothesis that there are N_{NC} non-compliers and N_C compliers. Since a non-complier answers item A with probability 1/3, a non-complier has probability 1/3 of responding with an F. Similarly, a complier has probability 2/3 of responding to item B with an F (see Figure 4).

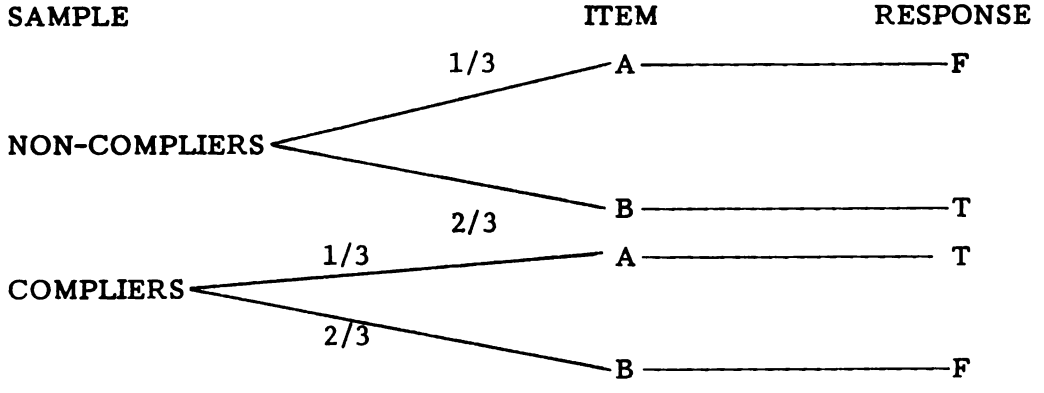


Figure 4: Diagram for the expected value computation used in randomized response methodology.

In terms of expected values, we then have:

(1) $E(F^*) = 1/3(3N_{NC}) + 2/3\ (3N_C)$.

In the same way, we get a relation for E(T*):

(2) $E(T^*) = 2/3(3N_{NC}) + 1/3(3N_C)$.

To obtain the estimates $\hat{N}_{NC}$ and $\hat{N}_C$ for N_{NC} and N_C, we replace E(F*) and E(T*) in (1) and (2) by the truely observed values F* and T*, and then solve for the estimates. That is, solving:

$$F^* = 1/3(3\hat{N}_{NC}) + 2/3(3\hat{N}_C)$$

and

$$T^* = 2/3(3\hat{N}_{NC}) + 1/3(3\hat{N}_C)$$

we derive the basic formulae:

$$\boxed{\hat{N}_{NC} = 1/3(2T^* - F^*)}$$

and

$$\boxed{\hat{N}_C = 1/3(2F^* - T^*).}$$

Compliance in sample and groups

To obtain an estimate of the number of non-compliers in the sample of persons with COPD (n = 40), the observed values of T* and F* (see Appendix VIII) were substituted in the formulae:

$$\hat{N}_{NC} = 1/3\ 2(45) - 75$$

$$= 1/3\ (15)$$

$$\boxed{\hat{N}_{NC} = 5}$$

Similarly, the estimate of the number of compliers in the sample was obtained:

$$\hat{N}_C = 1/3\ 2(75) - 45$$

$$= 1/3\ (105)$$

$$\boxed{\hat{N}_C = 35}$$

The estimates of the number of non-compliers and compliers in the balanced and discriminated subject groups are given in Appendix IX.

The estimate of the number of non-compliers in the total sample was as expected. In other words, in a group who, for the most part, perceived more benefits than costs from their medication regimens, the number of non-compliers was low (five out of 40 subjects). What is noteworthy about this result is that the non-compliers are found in the group(s) with the highest Perceived Benefits Index (PBI) scores. In other words, the results suggest that the non-compliers in this sample of persons with COPD are among those who perceive more benefits than costs from their oral medication regimens. Some explanations for this finding will be discussed in Chapter V.

C. Cross-Tabulation and Significance

Two-by-two contingency tables were constructed to relate high and low PBI scores with the number of non-compliers and compliers in each group of subjects. Table 2 shows the observed frequencies.

Table 2

Compliance by Perceived Benefits Index (PBI) Scores in Two Groups: 2 x 2 Tables

GROUPS	ESTIMATED NUMBERS	
	Non-Compliers	Compliers
Top half	5	15
Bottom half	0	20
Top quartile	4	6
Bottom quartile	0	10

The chi square (χ^2)-test for independence was done for each 2 x 2 table (see Appendices X and XI for computations). The observed differences in each group (top half, bottom half; top quartile, bottom quartile) were found to be significant at the $\alpha = .05$ level. Although significant, the observed differences noted in Table 2 were in the opposite direction to what one would expect intuitively. For this reason, an additional analysis was done of the raw data from item 6 in the Likert scale instrument (see Appendix XII).

In item 6, over 50 percent of the sample responded either "agree" or disagree (15 agree; 8 disagree) to the statement; "I can put up with an upset stomach from my pills because they help me get around so much better." Subjects who answered "agree" to the item had scores greater than 80; subjects who answered "disagree" scored below 80. It was hypothesized that responses to this item would discriminate between subjects who perceived high versus low benefits from their oral medication regimens. The cross-tabulation of observed frequencies is given in Table 3.

Table 3

Compliance by Response to Item Six on Likert Scale Instrument

	NC	C
[a]Agree	2	13
Disagree	0	8

[a] $\chi^2 = 7.29 \{\chi_1^2 (.01) = 6.64\}$

The observed differences were found to be significant at the $\alpha = .01$ level. The observed differences in item 6, then, seem to reflect a real difference in the sample responses, rather than chance variation. More will be said about the interpretation of these findings in Chapter V.

Summary

A complete summarized data set was given to facilitate any re-analysis and to clarify the randomized response computation used in this study. The completed Likert scale instruments were scored to achieve a Perceived Benefits Index (PBI) for each subject. Subjects were then divided into groups according to their PBI scores in a manner which separated those with high PBI scores from those subjects with low PBI scores; that is, the top half of the scores versus the bottom half, and the top quartile versus the bottom quartile. The number of non-compliers and compliers in each of these groups was computed and the relationships shown in 2 x 2 tables. The χ^2-test for independence indicated that the observed differences in each of the two groups were significant at the = .05 level. In other words, the observed number of non-compliers and compliers in each of these groups in the sample reflects a real difference in the sample, rather than chance variation. The difference, however, was in the opposite direction to what one would expect intuitively; that is, the non-compliers were found in the group(s) who perceived more benefits than costs from their medication regimens, judging from their high PBI scores. Some plausible explanations for this finding will be discussed in Chapter V.

Chapter V: Discussion

This chapter discusses the significant statistical and clinical findings from the study as well as the implications for future studies and for nursing research and practice. Reference to related studies and to some areas found wanting in this study will be included.

A. Statistical and Clinical Findings

Estimate of compliance

The number of compliers with an oral medication regimen estimated for the sample of persons with COPD was 35 out of 40 subjects. Generalization from this sample to the target population of persons with COPD in the Veterans' Administration hospital system must be made cautiously because the sample was not random. The sample was, however, selected according to pre-determined criteria in order to reduce selection bias. The ages of the subjects in this study also reflected a claim repeated often in the literature that COPD has "a peak incidence in the sixth and seventh decades" (Block, 1979, p. 70). For example, more than half (n = 23) of the subjects studied here were in their 60's; all, but three, of the remaining subjects (n = 14) were in their 50's. Subject ages ranged from 50-73 years; the modal age was 59 years. Given these similarities, it seems reasonable to generalize results to the immediate target population of V.A. patients with COPD as a primary diagnosis who also meet the other criteria outlined for sample selection. This is a worthwhile generalization because the number of persons with COPD in the U.S. is large and, given their usual age range, it is highly likely that many of these persons are V.A. patients.

The estimate of the percent of compliers ($\hat{P}_C$ = 87.5) in the target population of persons with COPD in the V.A. hospital system is high, but not unreasonable. Most studies on non-compliance in chronic illness have been done on persons with hypertension or tuberculosis (Haynes, Sacket, & Taylor, 1980).

The problem being studied, in these cases, is compliance with a medication regimen in asymptomatic illnesses. Persons with COPD, on the other hand, usually only seek attention and begin medication therapy after symptoms are present. Barstow (1979) found that most of her COPD subjects took their medications because they found that they obtained relief from their symptoms. It is possible that compliance with medication regimen is better in COPD than in other chronic illnesses because these persons rely so heavily on their medications to help them breathe.

In fact, many subjects from this sample volunteered their opinions about the value of their medications. Comments such as "If I didn't have my pills, I'd die" were not uncommon among the group. The high estimate of compliance for this sample also coincided with the investigator's intuition about the group. Most subjects were obviously symptomatic (e.g., short of breath, dusky color, wheezing) and indicated in casual conversation that they relied on their medication to breathe and get around.

It must be pointed out that one should allow for some over-statement of compliance in this group. Although randomized response technique has been shown to reduce this response distortion in other studies, it still allows for some overstatement (Locander et al., 1976). Those subjects who do comply with their regimens would have no need to deny it, but some non-compliers may well have responded as compliers. Nevertheless, the estimate would still likely be greater than 50 percent, which seems plausible for a group of persons so dependent on their medications.

The main point is that an estimate of compliance with an oral medication regimen was obtained for a group of persons on whom no previous compliance studies had been conducted. No comparisons to similar subject groups can be made, at this point, so that the relative accuracy of the estimate remains to be

tested. Randomized response technique was also introduced, in this study, as a non-invasive methodology for measuring compliance and was found to be practical and reasonable. This beginning investigation will be most useful if it serves as a basis of comparison for future studies of compliance with medication regimen in persons with COPD.

Relationship of compliance and perceived benefits

Although significant, the comparison between compliance and high and low PBI scores in two groups of subjects were paradoxical. For purposes of specificity and precision in this dicussion, let us examine the table of observed frequencies in Appendix X. Note that the observed value, 5, for the (NC, top half)-cell is large compared to the observed value, 0, in the (NC, bottom half)-cell. One would intuitively believe that the opposite would be true since it is likely that persons who perceive many benefits (high PBI score) from their medications would comply with their regimens. One would expect non-compliers to be found among subjects with low PBI scores. This, in fact, did not happen and there are several plausible explanations for this anomaly.

It is conceivable that the Perceived Benefits (Likert) instrument was not sufficiently discriminating to provide a PBI score which reflected the perceptions of the (apparently) extremely believing and complying subjects. However, one can argue against this possibility as follows. There were estimated to be five non-compliers in the whole sample (n = 40). It these were just placed at random in the top half or bottom half of the PBI groups, the chance of all five ending up in the top would be $1/2^5 = 1/32 < .05$. Thus, one would reject the hypothesis that the Perceived Benefits Index (PBI) is independent of non-compliance by exact tests as well as by chi square (χ^2). It so happens that the effect goes in the opposite direction to one's intuition, which is not, in this context, a strong argument for intuition. Nor does it seem to argue against the ability of the

Perceived Benefits instrument to give appropriate choices to compliers with strong beliefs in the effectiveness of their oral medication regimens.

Possibly, the sample size was not large enough to include a meaningful proportion of non-compliers. Note, however, that if the sample size was increased to 50, this would only add an expected number of 1.2 non-compliers. Even if one found two non-compliers out of an extra 10 subjects, it would not make that much difference to this argument. It is also possible that the sample was biased in the direction of compliance since the subjects were all persons who kept a clinic appointment. While that might account for the low number of non-compliers in the sample, it sheds no light on the finding that four out of five non-compliers were among those ten subjects with the highest PBI scores.

It may be that the non-compliers over-stated their beliefs, responding to some vision of how they "should" feel. It is possible that the Perceived Benefits instrument, although administered before the randomized response tool, was perceived as threatening enough to merit some overstatement, just as direct questions about compliance have done in the past.

One final explanation might be that the non-compliers in this study did believe in the effectiveness of their medications, but, nevertheless, for various reasons, did not take all of them as prescribed. For example, as persons with COPD become more debilitated, their prescribed medications are often increased because more organ systems are involved. In other words, cardiac medications such as diuretics, digitalis, and potassium supplements may be added to a regimen that already includes bronchodilators, antibiotics, and cortisone. In fact, a physician may prescribe more than one type of bronchodilator for the severely debilitated patient, in a final attempt to give him some measure of breathing comfort. A subject for whom this scenario is true would be faced with an even more complex medication regimen when he is least able to cope with

complexity. In an attempt to simplify and exert control, he might compromise by taking regularly only those pills which provide immediate symptom relief and be less diligent about taking the others. If he answered the randomized compliance items truthfully, then that subject would be a non-complier as measured by the randomized response items in this study. More will be said in Section B on the implications of this plausible explanation for future studies which measure compliance with medication regimen in COPD.

Summary

Whatever the reason, the results of this study show an inverse relationship between perceived benefits and compliance; that is, all non-compliers were found in the half sample with the highest PBI scores. In view of this, the a priori belief measure, perceived costs and benefits of an oral medication regimen, is unlikely to provide a valid prediction of compliance with oral medication regimen in COPD. This is not a claim that the Health Belief Model is not useful in predicting compliance in COPD, but rather a statement about a single variable in the model. Some implications of the paradoxical findings of this study will be discussed in Chapter V, Section B.

B. Implications for Nursing Research and Practice

Nurses who work with respiratory patients in the community are in an excellent position to conduct research on compliance with therapeutic regimens in COPD. They have the unique opportunity of seeing patients in their homes as they cope with their regimens. The particular problems of persons with COPD, documented by the nurses who work with them, will become the information base for designing future studies. At present, there is little information in the literature to contribute to this base.

More studies on compliance in COPD, using the Health Belief Model (HBM) as a framework, are needed. One path for future study is to examine compliance

with an oral medication regimen in COPD in the presence of numerous co-variates of the HBM, and to use factor analysis to provide a predictive instrument for compliance (Maiman et al., 1977). Some questions which arise from this study could be used as guides for constructing instruments measuring the HBM indices. For example, how does the subject perceive the seriousness of his illness? How would he compare the severity of his illness to that of other persons with COPD? Is there a significant correlation between these subjective data and such objective criteria for severity of disease as pulmonary function data, length of illness, number of pills taken per day, and presence of clinical findings? Pursuing the question further, one could ask whether there is a significant relationship between the severity of the illness, measured subjectively and objectively, and the degree of compliance obtained for the group? Maybe persons with COPD do tend to comply less strictly with their prescribed regimens as their illness worsens and their medications increase, as was suggested earlier. Non-compliance may then be a method of coping with complexity rather than a reflection of belief in a medication's effectiveness. It might be a compromise made by a person who only has limited energy and tries to exert some control over his regimen. If this were the case, then the non-compliers in this study could have perceived benefits from their medications, but, nevertheless, did not take all, or some, of them as prescribed. More information is needed on how persons with COPD comply with their medication regimens and, specifically, on whether compliance behavior is the same for all types of medications taken.

Compliance was viewed, in this study, as "I take my pills as the doctor prescribed" or "I do not take...prescribed". But there are other aspects of compliance to consider. Do these patients tend to "forget" their pills rather than deliberately not take them? Do they get "mixed up" about pill times and amounts? Are there varying degrees of non-compliance among the population

that would be best measured by "sometimes", "often", or "never"? For example, do persons with COPD take their prescribed bronchodilators more accurately than cardiac or other drugs? Weintraub, Au, and Lasagna (1973) found that compliance was significantly decreased among subjects taking two or more prescribed drugs in a cardiac regimen. Several patients who decided they did not need digoxin stopped taking the drug completely but were still considered adequately treated by their physicians. The investigators point out that at least some patients could be adequately treated with fewer drugs (in this case, diuretics alone), especially when increasing the number of drugs tends to reduce compliance. COPD subjects may respond in a manner similar to Weintraub's et al. subjects, taking most faithfully those medications which give the most immediate and noticeable relief of symptoms, and choosing when, and if, to take others. In addition, this variability in compliance behavior may relate to subjective and objective measures of the subject's disease status. What is clear is that compliance with an oral medication regimen in persons with COPD, rather than a simple "do" or "don't" behavior, is likely to be more complex. Future investigators would be wise to consider this factor when devising instruments to measure compliance behavior.

Therapeutic regimen need not always be oral medications, as it was in this study. Persons with COPD are usually prescribed medications which they must inhale through the use of nebulizers or intermittent positive-pressure breathing (IPPB) machines. Are there abuses in these areas specific to compliance behavior? For example, do patients tend to overuse their nebulizers? Often, COPD patients are prescribed breathing exercise regimens, as well as medications. Little is known about how well, or whether at all, they do these exercises. Nurses who have intimate contact with these patients and their problems can provide that information base.

Nurses who work in the community hold another valuable research advantage. They have access to persons who miss or have stopped keeping clinic appointments, whom Sackett and Snow (1979, p. 21) call the "inception cohort". Most studies examine compliance in groups after they have been initiated on regimens and are being followed up in clinics. For example, on could say that the sample in this study was biased in the direction of compliance because the subjects were persons who kept clinic appointments. Evaluating those persons on prescribed regimens who no longer attend any treatment facility would provide crucial data.

Taylor (1979) reported findings from a study on compliance in persons with hypertension which have implications for future studies on compliance in COPD. The investigator found that the pre-treatment health beliefs of hypertensive steelworkers bore no significant relationship to their compliance with a medication regimen at six months; health beliefs at six months, however, related significantly to compliance with a drug regimen. This suggests that health beliefs, instead of preceding and determining compliance, develop with compliance behavior as a result of experiences gained in the first few months of the treatment. In addition, health beliefs at six months were less effective at explaining the variance in subjects' compliance than simply asking subjects to estimate their compliance with the prescribed medication regimen. These findings may argue for the limited usefulness of health beliefs as predictors of compliance behavior but this still has to be determined for persons with COPD. The relationship between perceived health beliefs and compliance may, however, be different for subjects beginning treatment and those who have been ill for a long time, arguing for length of illness as one objective index that should be correlated with compliance with medication regimen. The relationship between length and severity of illness may well correlate significantly with compliance

behavior, albeit in a direction different from what one would expect. In other words, the finding in this study that non-compliers were among those with the highest Perceived Benefits Index (PBI) scores may be paradoxical, but true, and remains to be explained further in future studies using the Health Belief framework, and more comprehensive measurements of compliance behavior

Summary

More research is needed on compliance with a therapeutic regimen in persons with COPD. Nurses who have access to these patients in their homes as they carry out their regimens can provide the information base to design further studies, using the Health Belief Model as a framework. Compliance must be operationalized in various ways in order to elicit any patterns followed by particular sub-groups of persons with COPD. The instruments used in this study can serve as a model for operationalizing the Health Belief indices and compliance. Much more information is needed before health personnel can claim to understand the medication-taking behavior of persons with COPD. Nurses are in the thick of patient compliance problems, particularly compliance in persons with COPD, and could do much to fill the information void that presently exists in the literature.

APPENDIX I: SAMPLE ITEMS FROM ORIGINAL ITEM POOL

*3. I don't like to take so many pills.

4. If I want to breathe easier, I have to take all my pills.

*5. It takes too long for my "breathing" pills to start working.

*6. My pills sometimes make me feel sick.

7. Every pill I take helps my breathing in some way.

8. Taking my pills makes it easier for me to walk around.

*9. Some of my pills make me feel "jittery" or "nervous".

*14. There is a chance that my pills are not helping my breathing problem.

*20. Some of my pills give me an upset stomach.

*21. My pills only help me some of the time.

22. Taking my pills every day is a habit.

*23. All the pills in the world won't make me feel better.

*24. It is hard for me to remember when I am supposed to take my pills.

25. Taking pills does not interfere with my daily activities.

26. I believe that all my pills are helping me.

27. I can easily manage my day around the times I must take my pills.

28. If I didn't take my pills, it would be hard for me to breathe.

*29. I do not know if my pills are doing me any good.

*30. Sometimes, I feel better when I <u>don't</u> take my pills.

*32. I take my pills to please the doctors and nurses.

*33. I have to take my pills too many times during the day.

*34. It is too hard for me to take all the pills the doctor ordered.

* Negatively-worded items

APPENDIX II: CATEGORIES (STRAUSS & GLASER, 1975) USED TO FORM: SCALE OF PERCEIVED COSTS AND BENEFITS OF ORAL MEDICATION REGIMEN

I. Existence of positive effects.

i.e. Does the medication work?

Positive effects: helps breathing

increases mobility

II. Balance of positive and negative effects.

i.e. Do the positive effects outweigh the negative, or vice versa?

Negative effects: discomfort of side effects

- upset stomach

- "jittery", "shakey", "nervous"

time and energy demand

complexity of the regimen

APPENDIX III: LIKERT-TYPE INSTRUMENT

This is a questionnaire to find out how you feel about the pills you are taking for your breathing, and maybe, other problems. THERE ARE NO RIGHT OR WRONG ANSWERS to these statements.

Please read each statement and mark an "X" beside the words which are CLOSEST TO THE WAY YOU FEEL about that statement. Some of the statements may look, or sound, like others but each is different. Please consider your answer to each statement as separate.

EXAMPLE # 1

Baseball is the favorite sport of many Americans.

1. strongly disagree _____
2. disagree _____
3. undecided _____
4. agree _____
5. strongly agree X

In this example, you are in strong agreement with the statement.

1. I can really feel that my pills help me to breathe easier.

   strongly disagree _____
   disagree _____
   undecided _____
   agree _____
   strongly agree _____

2. I mainly take my pills to please other people.

   strongly disagree _____
   disagree _____
   undecided _____
   agree _____
   strongly agree _____

3. I think my pills do enough good to be worth the time it takes to take them.

   strongly disagree _____
   disagree _____
   undecided _____
   agree _____
   strongly agree _____

4. Sometimes, I would rather have a little more trouble breathing than put up with the "shakey" feeling I get from my pills.

   strongly disagree _____
   disagree _____
   undecided _____
   agree _____
   strongly agree _____

5. It's pretty hard to say if my pills help me very much.

   strongly disagree _____
   disagree _____
   undecided _____
   agree _____
   strongly agree _____

6. I can put up with an upset stomach from my pills because they help me get around so much better.

strongly disagree _____
disagree _____
undecided _____
agree _____
strongly agree _____

7. Sometimes, I believe I would feel better if I didn't take my pills.

strongly disagree _____
disagree _____
undecided _____
agree _____
strongly agree _____

8. The "jitters" I sometimes get from my pills are not as bad as the trouble I would have breathing if I didn't take them.

strongly disagree _____
disagree _____
undecided _____
agree _____
strongly agree _____

9. My pills don't really seem to be worth all the trouble it takes to remember when to take them.

strongly disagree _____
disagree _____
undecided _____
agree _____
strongly agree _____

10. I can get around better because of my pills.

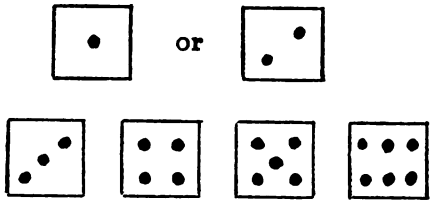
strongly disagree _____
disagree _____
undecided _____
agree _____
strongly agree _____

APPENDIX IV: RANDOMIZED RESPONSE ITEM SET

Instructions:

Please roll the dice to select the question. Do not let me see which side is facing up. If you get a 1 or 2, answer question A. If you get a 3, 4, 5, or 6, answer question B. Answer only "true" or "false". Do not tell me which question you are answering.

Set I:



or

A. I take all the pills the doctor prescribed for me.

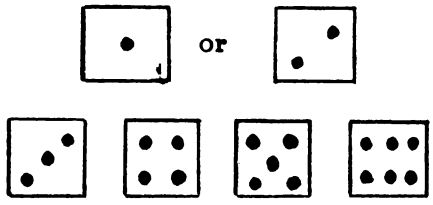
B. I do not take all the pills the doctor prescribed for me.

APPENDIX V: PRACTICE RANDOMIZED RESPONSE ITEM SET

Instructions:

Please roll the dice to select the question. Do not let me see which side is facing up. If you get a 1 or 2, answer question A. If you get a 3, 4, 5, or 6, answer question B. Answer only "true" or "false". Do not tell me which question you are answering.

Set I:



A. I read my local newspaper every day.

B. I do not read my local newspaper every day.

APPENDIX VI: CONSENT FORM

V.A.M.C. AT PALO ALTO
CONSENT TO BE A RESEARCH SUBJECT

Ms. Pat Chisholm is a nurse-researcher and a student in the masters program in nursing at the University of California, San Francisco. She is doing a study to find out how people with emphysema, asthma, or chronic bronchitis feel about their medications.

If I agree to be in this study, I will:

(1) fill out a questionnaire dealing with my feelings about the medicine I take.

(2) answer "true" or "false" to three additional questions about taking my medicine. (To find out which question I will answer, I will first have to throw dice).

This process will take no more than fifteen minutes and will happen in the V.A.M.C. Pulmonary Clinic at Palo Alto during one of my regular visits.

The information I give will be confidential and will be used only by Ms. Chisholm in her study. My name will not be recorded on the questionnaire form so that I will remain anonymous.

There will be no direct benefit to me from this study. Other people with breathing problems may benefit in the future.

I have talked with Ms. Chisholm about this study and she has answered my questions. If I have other questions I may call her at (415) 941-5250.

I have been offered a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

Participation in research is voluntary. I may refuse to participate or may withdraw at any time without any effect on my further care at the V.A.

Date:_____ Signature:_____

APPENDIX VII: RAW DATA SET

1. I can really feel that my pills help me to breathe easier.

strongly disagree	0
disagree	1
undecided	3
agree	16
* strongly agree	19

▽ 2. I mainly take my pills to please other people.

* strongly disagree	32
disagree	7
undecided	0
agree	1
strongly agree	0

3. I think my pills do enough good to be worth the time it takes to take them.

strongly disagree	0
disagree	0
undecided	2
agree	17
* strongly agree	21

▽ 4. Sometimes, I would rather have a little more trouble breathing than put up with the things I don't like about my pills.

* strongly disagree	27
disagree	6
undecided	1
agree	0
strongly agree	1

▽ 5. It's pretty hard to say if my pills help me very much.

strongly disagree	9
* disagree	13
undecided	3
agree	7
strongly agree	1

6. I can put up with an upset stomach from my pills because they help me get around so much better.

strongly disagree	0
disagree	8
undecided	4
* agree	15
strongly agree	6

No answer: 7

▽ 7. Sometimes, I believe I would feel better if I didn't take my pills.

* strongly disagree	19
disagree	11
undecided	1
agree	3
strongly agree	1

8. The "nervous" feeling I sometimes get from my pills is not as bad as the trouble I would have breathing if I didn't take them.

strongly disagree	1
disagree	3
undecided	1
* agree	13
strongly agree	12

No answer: 8

▽ 9. My pills don't really seem to be worth all the trouble it takes to remember when to take them.

* strongly disagree	24
disagree	14
undecided	1
agree	1
strongly agree	0

10. I can get around better because of my pills.

strongly disagree	1
disagree	0
undecided	2
agree	18
* strongly agree	19

▽ = negatively-worded item

* = modal response for item

APPENDIX VIII: SUMMARY OF T* AND F* DATA

Group(s)	T*	F*[a]
Sample[b]	45	75
Balanced		
Top half	25	35
Bottom half	20	40
Discriminated		
Top quartile	14	16
Bottom quartile	10	20

[a](T* + F*) = 120 observed responses

[b]n = 40 subjects

APPENDIX IX: ESTIMATES $\hat{N}_{NC}$ AND $\hat{N}_{C}$ FOR THE BALANCED AND DISCRIMINATED SUBJECT GROUPS

Formulae: $\hat{N}_{NC} = 1/3\ (2T^*-F^*)$

$\hat{N}_{C} = 1/3\ (2F^*-T^*)$

Groups	Estimates
Top half	$\hat{N}_{NC} = 1/3\ (2x25-35) = 5$
	$\hat{N}_{C} = 1/3\ (2x35-25) = 15$
Bottom half	$\hat{N}_{NC} = 1/3\ (2x20-40) = 0$
	$\hat{N}_{C} = 1/3\ (2x40-20) = 20$
Top quartile	$\hat{N}_{NC} = 1/3\ (2x14-16) = 4$
	$\hat{N}_{C} = 1/3\ (2x16-14) = 6$
Bottom quartile	$\hat{N}_{NC} = 1/3\ (2x10-20) = 0$
	$\hat{N}_{C} = 1/3\ (2x20-10) = 10$

APPENDIX X: χ^2-TEST FOR COMPLIANCE BY PBI SCORES (TOP HALF, BOTTOM HALF)

Observed Table

	NC	C
Top half	5	15
Bottom half	0	20

Population Estimates = Total = 40

$\hat{P}_{NC} = 5/40$

$\hat{P}_{C} = 35/40$

$\hat{P}_{t\ 1/2} = 20/40$

$\hat{P}_{b\ 1/2} = 20/40$

Expected Values

$E_{NC,t\ 1/2} = T \cdot \hat{P}_{NC} \cdot \hat{P}_{t\ 1/2} = 40 \cdot 5/40 \cdot 20/40 = 2.5$

$E_{NC,b\ 1/2} = T \cdot \hat{P}_{NC} \cdot \hat{P}_{b\ 1/2} = 40 \cdot 5/40 \cdot 20/40 = 2.5$

$E_{C,t\ 1/2} = T \cdot \hat{P}_{C} \cdot \hat{P}_{t1/2} = 40 \cdot 35/40 \cdot 20/40 = 17.5$

$E_{C,b\ 1/2} = T \cdot \hat{P}_{C} \cdot \hat{P}_{b\ 1/2} = 40 \cdot 35/40 \cdot 20/40 = 17.5$

Expected Table Under H_o (independence)

	NC	C
Top half	2.5	17.5
Bottom half	2.5	17.5

Difference Table

	NC	C
Top half	2.5	-2.5
Bottom half	-2.5	2.5

$$\chi^2 = \frac{(2.5)^2}{2.5} + \frac{(-2.5)^2}{17.5} + \frac{(-2.5)^2}{2.5} + \frac{(2.5)^2}{17.5}$$

$$= 2.5 + 3.57 + 2.5 + 3.57 = \underline{5.71}$$

Significant at the $\alpha = .05$ level { χ^2_1 (.01) = 6.64, χ^2_1 (.05) = 3.84}

APPENDIX XI: χ^2-TEST FOR COMPLIANCE BY PBI SCORES (TOP QUARTILE, BOTTOM QUARTILE)

Observed Table

	NC	C
Top q.	4	6
Bottom q.	0	10

Population Estimates T = Total = 20

$\hat{P}_{NC} = 4/20$

$\hat{P}_{C} = 16/10$

$\hat{P}_{tq} = 10/20$

$\hat{P}_{bq} = 10/20$

Expected Values

$E_{NC,tq} = T \cdot \hat{P}_{NC} \cdot \hat{P}_{tq} = 20 \cdot 4/20 \cdot 10/20 = 2.0$

$E_{NC,bq} = T \cdot \hat{P}_{NC} \cdot \hat{P}_{bq} = 20 \cdot 4/20 \cdot 10/20 - 2.0$

$E_{C,tq} = T \cdot \hat{P}_{C} \cdot \hat{P}_{bq} = 20 \cdot 16/20 \cdot 10/20 = 8.0$

$E_{C,q} = T \cdot \hat{P}_{C} \cdot \hat{P}_{bq} = 20 \cdot 16/20 \cdot 10/20 = 8.0$

Expected Table Under H_o (independence

	NC	C
Top q.	2.0	8.0
Bottom q.	2.0	8.0

Difference Table

	NC	C
Top q.	2.0	-2.0
Bottom q.	-2.0	2.0

$$\chi^2 = \frac{(2.0)^2}{2.0} + \frac{(-2.0)^2}{8.0} + \frac{(-2.0)^2}{2.0} + \frac{(2.0)^2}{8.0}$$

$$= 2.0 + 0.5 + 2.0 + 0.5 = \underline{5.0}$$

Significant at the $\alpha = .05$ level $\{\chi^2_1 (.05) = 3.84, \chi^2_1 (.01) = 6.64\}$

APPENDIX XII: SUMMARIZED RAW DATA AND χ^2-TEST FOR RESPONSES TO ITEM SIX ON LIKERT SCALE INSTRUMENT

Summarized T* and F* Data

	T*	F*
Agree	17	28
Disagree	8	16

Randomized Response Computation

Agree $\hat{N}_{NC} = 1/3\ (2X17-28) = 2$

$\hat{N}_{C} = 1/3\ (2X28-17) = 13$

Disagree $\hat{N}_{NC} = 1/3\ (2X8-16) = 0$

$\hat{N}_{C} = 1/3\ (2X16-8) = 8$

APPENDIX XII: (con't)

χ^2-Test

Observed Table

	NC	N
Agree	2	13
Disagree	0	8

Population Estimates T = Total 23

$\hat{P}_{NC} = 2/23$ $\hat{P}_{a6} = 15/23$

$\hat{P}_{C} = 21/23$ $\hat{P}_{d6} = 8/23$

Expected Values

$E_{NC,a6} = T \cdot \hat{P}_{NC} \cdot \hat{P}_{a6} = 23 \cdot 2/23 \cdot 15/23 = 1.3$

$E_{NC,d6} = T \cdot \hat{P}_{NC} \cdot \hat{P}_{d6} = 23 \cdot 2/23 \cdot 8/23 = 6.9$

$E_{C,a6} = T \cdot \hat{P}_{C} \cdot \hat{P}_{a6} = 23 \cdot 21/23 \cdot 15/23 = 13.7$

$E_{C,d6} = T \cdot \hat{P}_{C} \cdot \hat{P}_{d6} = 23 \cdot 21/23 \cdot 8/23 = 7.3$

Expected Table under H_o (independence)

	NC	C
Agree	1.3	13.7
Disagree	6.9	7.3

Difference Table

	NC	C
Agree	.7	-.7
Disagree	-6.9	.7

$$\chi^2 = \frac{(.7)^2}{1.3} \quad \frac{(-.7)^2}{13.7} \quad \frac{(-6.9)^2}{6.9} \quad \frac{(.7)^2}{7.3}$$

$$= .3 + .03 + 6.9 + .06 = \underline{7.29}$$

Significant at the $\alpha = .01$ level $\{\chi^2_1 (.01) = 6.64\}$

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