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ANTECEDENTS OF ADHERENCE TO ANTITUBERCULOSIS THERAPY

by

MARCIA MCDONNELL

A DISSERTATION

Submitted in partial fulfillment of the requirements for
the degree of Doctor of Science in Nursing
in the School of Nursing in the Graduate School,
The University of Alabama at Birmingham

BIRMINGHAM, ALABAMA

1996

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ABSTRACT OF DISSERTATION
GRADUATE SCHOOL, UNIVERSITY OF ALABAMA AT BIRMINGHAM

Degree DSN Major Subject Health Policy

Name of Candidate Marcia McDonnell

Title Antecedents of Adherence to Antituberculosis Therapy

The purpose of this study was to identify antecedents of adherence to antituberculosis therapy. Several research questions related to the effect of patient perceptions, patient characteristics, and system services on self-reported adherence were addressed. Data were collected from 11 public health districts and 1 clinical research trial in the state of Georgia. The sample of 62 English-speaking adults, although non-randomly selected, was similar to the larger population of TB patients in the state of Georgia with the exception of a lower percentage of HIV positive patients and more reported alcohol use. Student's t tests, Pearson product moment correlations, analysis of variance, and multiple regression analyses were conducted to identify predictors of self-reported adherence. Higher levels of self-reported adherence were associated with an annual income of $11,000 or more, an education beyond high school, no current alcohol use, the perceived presence of supports and absence of barriers to medication taking, a strong intent to adhere, and a high capacity for self-care. These 6 variables account for 28% of the adherence variance. Additionally, belief in the usefulness and benefit of the medications was strongly correlated with intentions to adhere, and interpersonal aspects of care were significantly correlated with perceptions of medication utility, supports/barriers, intentions, and self-care. A finding that

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HIV coinfected subjects had significantly lower adherence was also identified. Characteristics such as the number of times an individual reported having TB, duration of therapy, age, gender, race, birthplace, employment status, living arrangement, or drug use were not significantly associated with adherence. Small subsample size for those who reported having TB more than once, or those who were homeless, foreign born, current drug users, or HIV positive precludes generalization of the findings related to these groups.

Abstract Approved by: Committee Chairman John A. Turner/pm

Program Director Carol Dashiff

Date 10/3/96 Dean of Graduate School Joan S. Gordon

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DEDICATION

This dissertation is lovingly dedicated to my husband, Bob, my children, Heather, Bobby, and Amy and to the memory of my mother.

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ACKNOWLEDGEMENTS

I gratefully acknowledge the work of the following individuals: Dr. Joan Turner, committee chair, Naomi Bock, MD, Dorothy Gauthier, PhD, RN, Kathryn Redwood, DSN, RN, Michael Weaver, PhD, RN, Esther Sumartojo, PhD, committee members, and Ms. Karen Buckner for her assistance with grant management.

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CHAPTER I

Background and Significance

The White Plague is back. Tuberculosis (TB), a preventable and curable disease once thought to be well controlled by public health professionals, has resurfaced. In the United States, the incidence of TB cases has increased from a low of 22,201 (9.3 cases per 100,000 persons) in 1985 to a high of 26,673 (10.5 cases per 100,000 persons) in 1992. Public health efforts have contributed to the decrease in 1993 to 25,287 cases for a rate of 9.8 per 100,000 (Centers for Disease Control and Prevention [CDC], 1994b). Public health officials must persevere in their diligence to continue this downward trend.

Several reasons have been offered for the resurgence of tuberculosis: the association of TB with HIV Disease; an increase in spread in congregate facilities such as prisons, homeless shelters, and hospitals; an influx of persons from countries where there is a high incidence of TB; and the deterioration of the health care infrastructure, resulting in fewer public health dollars, and, consequently, less effort in TB treatment and control efforts (CDC, 1994a). Another major contributor to the re-emergence of TB is a lack of adherence to antituberculosis medication regimens. Nonadherence has been a persistent problem throughout the history of tuberculosis treatment (Addington, 1979). Authorities at the CDC estimate that in 1992, 77% of patients completed treatment within 12 months, and only 79% took their medications continuously (personal communication, Dr. Bess Miller, Division of TB Elimination, CDC, January 27, 1995). This rate drops to 11% in

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groups with a high incidence of injectable drug use, crack cocaine use, and homelessness (Brudney & Dobkin, 1991). These rates are well below the national adherence objective of 90% (CDC, 1989).

It has been estimated that, on average, one person with active TB infects about 21-23% of his contacts (CDC, 1994a). Each immunocompetent contact has a one in ten chance of developing active TB sometime in his or her lifetime. Tuberculosis is curable, and over 95% of immunocompetent persons with new-onset TB will be cured if they take all of their medications as prescribed (American Thoracic Society [ATS], 1992). Therefore, adherence becomes the primary determinant of cure, and conversely, nonadherence leads to increased spread, treatment failure, relapse of disease, emergence of difficult to treat drug-resistant forms, disability, or death (ATS, 1994; 1992). Nonadherence is costly to the individual and to society in terms of morbidity, disability, and mortality. Estimates of the cost of hospitalization to treat drug-resistant TB are approximately $26,747 per case (Etkind, Boutette, Ford, Singleton, & Nardell, 1991).

In 1989, the Advisory Committee for the Elimination of Tuberculosis recommended reducing the incidence of TB to 3.5 per 100,000 persons by the year 2000 and eliminating TB by the year 2010 (CDC, 1989). Tuberculosis is curable; however, the typical medication regimen involves taking four medications for 6 months. More medications or longer duration may be indicated in those with a drug-resistant form or those infected with the Human Immunodeficiency Virus (HIV) or diagnosed with AIDS, Acquired Immunodeficiency Syndrome (CDC, 1993b). There exists documentation that people tend to decrease adherence to a therapeutic regimen the longer and more complicated it is (Blackwell, 1979; Meichenbaum & Turk, 1987). It is, therefore,

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important to identify characteristics of both the patient and the health care system that promote adherence to antituberculosis medications. The purpose of this research is to identify these characteristics. Once identified, appropriate interventions can be developed to promote medication adherence.

Conceptual -Theoretical Framework

The investigator has merged Orem's Self-care Deficit Theory of Nursing (Orem, 1991) with the model of adherence proposed by DiMatteo and DiNicola (1982) and Gritz, DiMatteo, and Hays (1989) to form the conceptual framework for this project. In this framework, medication adherence is viewed as a self-care behavior that is associated with and affected by certain characteristics of the health problem, the patient, and the health care system.

The Self-care Deficit Theory

Orem's self-care theory is based on the premise that individuals or their agents will perform the activities necessary to care for themselves. The capacity and ability to care for oneself is called self-care agency. Self-care agency, according to Orem, is learned and requires decision making and deliberate action. The development of self-care agency is dependent on many factors. Ten power components provide the foundation necessary for developing self-care agency. An individual moves through three self-care operations as she or he moves toward self-care behaviors. These operations are (a) estimative, determining if one has the need and the necessary conditions for self-care behaviors; (b) transitional, deciding what action will be taken; (c) productive, performing, monitoring, and deciding whether to continue behaviors. The first two operations are included in Phase I, and the third operation is in Phase II of self-care agency.

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Self-care refers to those behaviors required daily in order to attend to one's personal needs. It may be altered by one's state of health, environmental conditions, effects of medical care or other factors. Each person has self-care requisites. These requisites, such as the need for rest and sleep, are the needs which must be met if human functioning and development are to remain within acceptable norms. If a person or his agent is unable to perform these activities, a self-care deficit exists.

Self-care deficits may be actual or potential. When a self-care deficit exists, the nurse may act as "another self" for the patient. This process, whereby the nurse enables the patient to meet self-care demands, may be accomplished in three different ways: (a) wholly compensatory, provision of total care; (b) partly compensatory, partial assistance with care; and (c) supportive-educative, provision of knowledge, skill, or psychological support necessary for self-care.

Adherence Model

The conceptual model of adherence as described by DiMatteo and DiNicola (1982) and Gritz et al. (1989) is based on a social psychological perspective which views influence as the essential condition for behavior change. The authors define adherence as following a clinical or therapeutic recommendation. They interchange the term compliance with adherence and feel that adherence should be studied within the context of the patient system, the provider system, and the interaction between these two (Gritz et al., 1989). Elements from other theoretical and conceptual models are reflected in this model. At the core of the model is Fishbein's model of reasoned action which states that intentions are predictors of behavior and that intentions are influenced by one's attitudes toward the behavior and the feelings of significant others about the behavior (subjective norms).

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Components from the health belief model include personal attitudes and beliefs which directly affect one's intention to adhere.

The six factors described in the model of DiMatteo and colleagues are as follows: Factor I, effective communication of information is essential for the patient's understanding of his condition and treatment regimen. Factor II, or rapport with the health professional, refers to a partnership in which there is mutual respect and trust, which is the primary context for behavior change to occur. These two factors are prerequisite to Factors III and IV. Factor III comprises components from the health belief model of beliefs and attitudes, perceived susceptibility to illness, perceived severity of illness, judgements about the benefits compared with the cost of the treatment, and motivation to adhere. Factor IV of the adherence model is social climate and norms, or those cultural beliefs and norms prevalent in a client's family, friends, and ethnic group which influence how the regimen will be followed. In Factor V of the model, behavioral intentions directly influence behaviors and are molded by the first four factors. In Factor VI of the model, supports for and barriers to adherence include factors that may either enhance or obstruct adherence, such as transportation to appointments and financial cost of continued treatment. Other cognitive and behavioral elements that may modify how one's intention is operationalized include locus of control and coping ability.

Inter-relationships between self-care and adherence

The concept of adherence fits quite well within Orem's framework. Self-care requires the consistent and regular exercise of activities on one's own behalf to "maintain life, health, and well-being" (Orem, 1991, p. 117). Adherence is a process whereby an individual incorporates recommended preventive or therapeutic activities into his lifestyle

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for the purpose of attaining, regaining, maintaining, or promoting his health. The decision to adhere is made in collaboration with a health care professional (e.g., a nurse) within the context of self-care. The conceptual-theoretical-empirical structure which depicts this merger and forms the framework for the proposed research is depicted in Figure 1. The structure was developed in the format recommended by Fawcett and Downs (1992) for theory testing. Instruments to be used and parameters which will be studied are indicated in the figure.

In Figure 1, the first row contains the concepts from Orem's theory that pertain directly to the research. The appropriate factors from DiMatteo and DiNocola's model are contained in the second row. The third row contains the empirical indicators for the concepts and factors which will be measured in this study. Bi-directional arrows indicate a bi-directional relationship between concepts and factors. Unidirectional arrows indicate a one-way relationship; in this model that relationship is from the general to the specific or from the more abstract to the more concrete. A description of the structure by columns follows.

Conceptual Model

Self-care deficit. Tuberculosis is a communicable disease for which the treatment requires multiple medications taken for a long time. The treatment of TB can create an actual or potential self-care deficit. The diagnosis of TB includes a health history for symptoms such as a cough, weight loss, fever, night sweats, past exposure to TB, past TB infection, past history of active TB, TB risk factors and a positive skin test, chest x-ray, and/or sputum smear or culture positive for *Mycobacterium tuberculosis* (MTB). Individuals with symptoms of TB and a positive chest x-ray or a positive sputum smear

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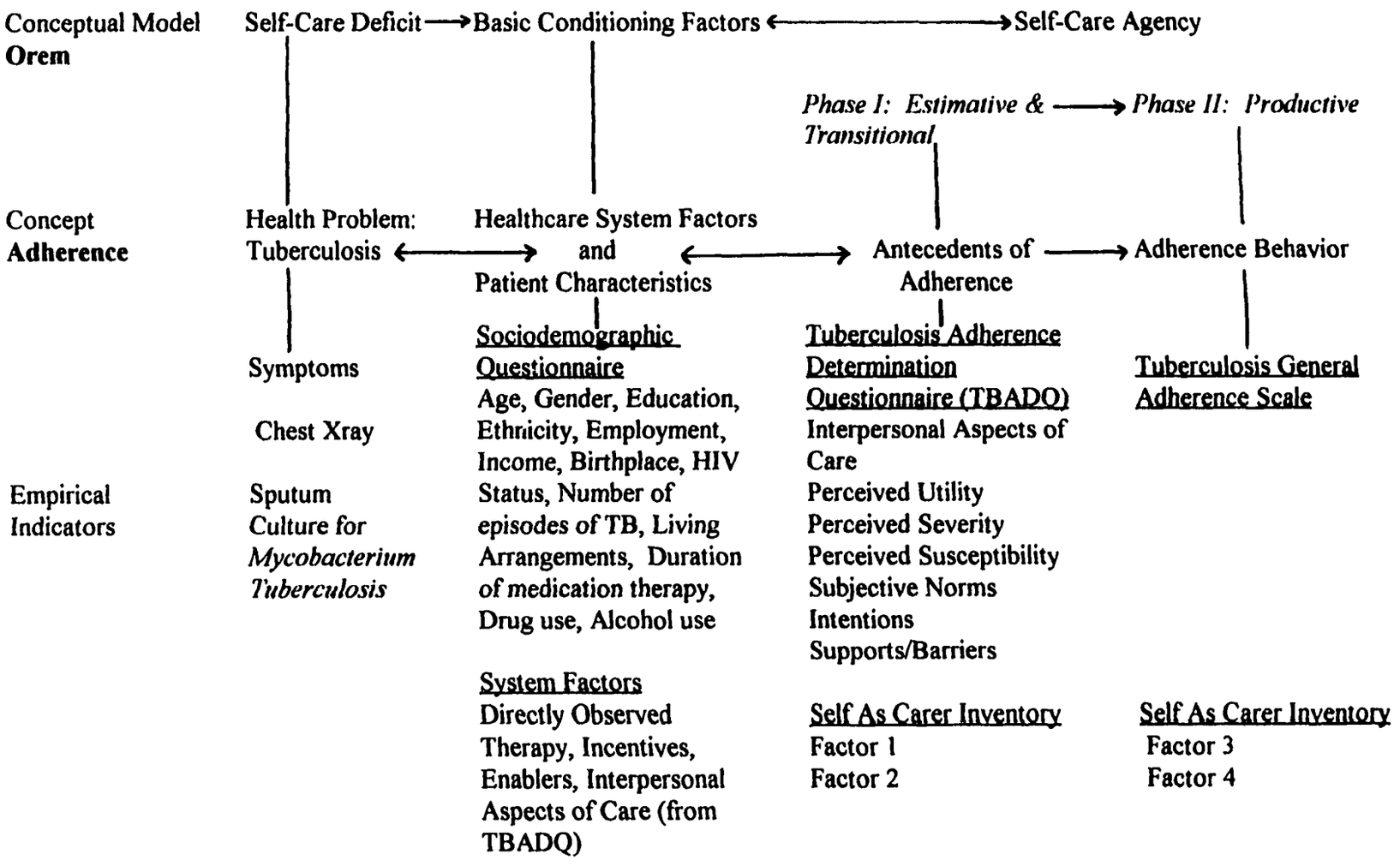

Figure 1. A conceptual-theoretical-empirical structure for adherence to antituberculosis therapy as a self-care behavior.

for acid fast bacilli (AFB) may be presumed to have TB and are started on medications until results of the sputum cultures are obtained. Although a positive sputum culture is the "gold standard" for diagnosing pulmonary TB, it may be diagnosed clinically in the absence of a positive culture. TB can also occur in other organs of the body; isolation of MTB organisms from those organs is essential to establish the diagnosis (CDC, 1994a; ATS, 1990).

Basic conditioning factors. Certain factors that are internal or external may predispose an individual to TB, as well as to self-care deficits related to medication adherence. Orem calls these characteristics basic conditioning factors and lists 10 that nurses need to consider when assessing the self-care of a patient. Nine of these factors are pertinent to this study. These are age, gender, environmental factors, state of health, sociocultural orientation, family system factors, health care system factors, pattern of living, and resource availability. These are monitored by the items on the Sociodemographic Questionnaire and the System Factors listed in Figure 1.

Self-care agency. In order to evaluate adherence as a self-care behavior, it is important to assess the client's capacity for self-care. The first phase of self-care agency involves the estimative and transitional operations. When an individual is deciding whether to adhere to a medication regimen, certain attitudes, beliefs, and perceptions about the disease and the medications may affect the intention to adhere. These intentions may be influenced by family and friends, and the value placed on health. These antecedents to adherence will be measured by the Tuberculosis Adherence Determination Questionnaire (TBADQ). In addition, two factors of the Self As Carer Inventory (SCI) which correspond to Phase I will be measured. These are Factor 1,

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knowledge of self, and Factor 2, judgement and decisions affecting production of self-care (Geden & Taylor, 1991).

The productive operations, or Phase II, of self-care agency includes performance of the behaviors associated with taking antituberculosis medications. Factors 3 and 4 of the Self As Carer Inventory, attention to and awareness of self and self-monitoring and physical skills, and satisfaction with self-care routines, correspond with Phase II (Geden & Taylor, 1991). The Tuberculosis General Adherence Scale (TBGAS) will be used to measure self-reported medication adherence.

Research Questions

The preceding conceptual formulations led the investigator to the following research questions:

1. Are predictors of adherence as measured by the Tuberculosis Adherence Questionnaire (TBADQ) related to adherence to antituberculosis medications?

2. Is self-care agency as measured by the Self As Carer Inventory related to adherence to antituberculosis medications?

3. What patient sociodemographic characteristics are related to adherence to antituberculosis medications?

4. What characteristics of the tuberculosis care system are related to adherence to antituberculosis medications?

5. Is there a difference in adherence to antituberculosis medications between patients who receive direct observed therapy and those who do not?

6. What variables should be included in a model to predict adherence to antituberculosis therapy?

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Definition of Terms

The following terms will be used in this study. They are defined conceptually and empirically.

1. Adherence: Following a prescribed clinical or therapeutic regimen (DiMatteo & DiNicola, 1982; Haynes, Taylor, & Sackett, 1979). It will be measured by the TBGAS.

2. Self-care agency: The capacity and ability to care for oneself (Orem, 1991) as measured by the Self As Carer Inventory.

3. Antecedents: Events or characteristics which precede and are associated with a behavior. In this study, antecedents of adherence to antituberculosis therapy will be evaluated by the TBADQ, SCI, and an interview with the tuberculosis program coordinator or a review of documents describing the tuberculosis program within the health care setting.

4. Antituberculosis Medications: Medications used to treat the disease of tuberculosis.

5. Incentives: Rewards given for completion of a particular behavior (e.g., taking medications).

6. Enablers: Items given to persons to facilitate a particular behavior (e.g., bus tokens provided to enable a patient to get to his clinic appointment to pick up his medications).

7. Directly Observed Therapy (DOT): A method of administering antituberculosis medications whereby the patient is observed ingesting the pills. The pills may be delivered to the patient at a predetermined location and ingestion

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witnessed, or the patient may come to the clinic where the pills are obtained and ingestion is witnessed.

8. Tuberculosis (TB): A reportable and communicable disease caused by the *Mycobacterium tuberculosis* bacillus (MTB). The disease most commonly affects the lungs and is characterized by abnormal lesions in the lungs. Less commonly, TB can affect other organs of the body, and it is then referred to as extrapulmonary TB. The body's response takes two forms: infection, where the bacillus enters the body and is contained and inactivated via an immune response; and disease, where lesions are formed in the lung or other organs, and physical signs and symptoms develop. About 10% of those infected will develop disease during their lifetime. This risk increases to 7% to 10% per year for persons with HIV Disease (CDC, 1994a).

Assumptions and Limitations

This study is based on the assumption that adherence is a multifactorial concept. The need to adhere arises from a situation, symptom, problem, or state of health that requires treatment. Three preconditions deemed necessary for adherence are (a) the correct diagnosis should be made; (b) the treatment should do more good than harm; and (c) the patient should be an informed, willing participant (Sackett, 1979). Adherence to antituberculosis therapy is part of the self-care regimen of persons with TB. Adherence can be influenced by factors within the TB health care system and by perceptions and beliefs of the patient.

Limitations of the proposed study are as follows. First, self-reported adherence may not accurately reflect actual medication taking behavior because of factors such as recall and honesty. Second, it is known that cross-sectional research designs may

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overestimate adherence since those potential subjects who were "lost" to follow-up due to nonadherence will not be included and that those who change their adherence behavior during the course of treatment may not be accurately classified as adherent or nonadherent. Third, a sample of convenience may not be representative of persons with TB. Sample selection may be biased towards compliant individuals because most of the subjects will be approached while presenting themselves for health department services. Those who do not come for services or refuse services will be excluded. Also, those who refuse to participate may do so because of fear of admitting nonadherence.

Summary

Since 1985 the incidence of tuberculosis has increased. TB is readily curable if medications are taken consistently and for the prescribed duration of treatment. Because adherence to antituberculosis medications is problematic and because TB is curable when medications are taken consistently and for the duration of treatment, research to investigate antecedents of adherence to antituberculosis medications was undertaken. A conceptual model which merges Orem's Self-Care theory and the adherence model proposed by DiMatteo and DiNicola (1982) and Gritz et al. (1989) guided the research project.

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CHAPTER II

Review of the Literature

In the early days of medicine, Hippocrates postulated that patients may not always be truthful when they say they have taken their medications (Haynes et al., 1979). In those days, however, nonadherence probably saved many from the effects of unproven and bizarre treatments. As medicine developed and successful treatments became available, interest in adherence increased. In the early 1950s, when medications to cure tuberculosis were discovered, adherence became more important for disease control and containment and, thus, protection of the health of the public. These concerns prompted some of the first scientific research on adherence.

This chapter will review pertinent empirical research on predictors or antecedents of medication adherence. Antituberculosis medications will be the focus, but other relevant studies will also be included. Patient factors, health care system factors, and theoretical models, as well as measurement and methods, will be examined.

Variables Associated with Adherence

For over 30 years, researchers have studied factors associated with adherence and nonadherence. Much of the research on medication adherence has been conducted on specific subgroups. Hypertensives, diabetics, epileptics, psychiatric patients, substance abusers, patients with tuberculosis, and the elderly comprise a large segment of these studies. Adherence to health-related behaviors have also been studied. Two

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comprehensive reviews of the adherence literature have been published in which numerous factors related to adherence have been identified (Haynes, Taylor, & Sackett, 1979; Meichenbaum & Turk, 1987). These factors have been classified by Meichenbaum and Turk (1987) into five general categories: (a) characteristics of the client; (b) nature of the disease; (c) characteristics of the therapeutic plan; (d) the clinical setting; and (e) the patient-provider relationship (p. 41). Table 1 contains a reprint of the factors related to nonadherence which they identified after conducting an extensive literature review.

Table 1

Factors Related to Treatment Nonadherence

Patient Variables
Characteristics of individual
Type and severity of psychiatric diagnosis (in particular, diagnosis of schizophrenia, bipolar affective disorder, paranoia, personality disorder)
Sensory disabilities
Forgetfulness
Lack of understanding
Inappropriate or conflicting health benefits
Competing sociocultural and ethnic folk concepts of disease and treatment
Implicit model of illness
Apathy and pessimism
Failure to recognize that one is ill or in need of medication
Previous or present history of nonadherence with other regimens
Health beliefs (e.g., misconceptions about disorder, no understanding of prophylaxis, belief that medicine is necessary only in acute illness)
Dissatisfaction with practitioner or treatment
Characteristics of individual's social situation
Lack of social supports
Family instability or disharmony
Parent's expectations and attitudes toward treatment
Residential instability
Environment that supports nonadherent behavior
Competing or conflicting demands or other pressing demands (poverty, unemployment)
Lack of resources (transportation, money, time)
Disease or disorder variables
Chronic condition with lack of overt symptomatiolgy
Stability of symptoms
Disorder-related characteristics (e.g., confusion, visual distortion, psychological reactions)

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Table 1 (Continued)

Treatment variables
- Characteristics of treatment setting
- Absence of continuity of care
- Long waiting time
- Long elapsed time between referral and actual appointment (more than 8 days)
- Timing of referral
- Absence of individual appointment times
- Lack of cohesiveness of treatment delivery system
- Inconvenience associated with operation of clinics (e.g., inefficiency, unfriendly personnel)
- Poor reputation of treatment facility
- Inadequate supervision by professionals
- Characteristics of treatment recommendations
- Complexity of treatment regimen (e.g., multiple medication)
- Long duration of treatment regimen
- Degree of behavioral change (e. g., interferes with personal behavior and depends upon alteration of one's lifestyle)
- Inconvenience (e.g., location of clinic, poor transportation)
- Expense
- Characteristics of treatment
- Characteristics of medicine (e.g., color of pill, drug size, preparation form)
- Inadequate labels
- Awkward container design
- Failure of parents to supervise drug administration
- Medication side effects or side effects associated with altered behavior (e.g., sedation, extrapyramidal involvement)

Relationship variables: patient-health care provider interaction
- Inadequate communication
- Poor rapport
- Attitudinal and behavioral (verbal and nonverbal) faults on the part of either provider or patient
- Failure of the provider to elicit negative feedback about problems stemming from treatment regimen
- Patient's dissatisfaction
- Inadequate supervision

Note. From Facilitating Treatment Adherence (pp. 43-44), by D. Meichenbaum and D. C. Turk. 1987. New York: Plenum Press. Copyright 1992 Plenum Press. Reprinted with permission.

Early adherence studies tended to focus on the effects of one or two variables on adherence. Later studies include multiple variables and multivariate analyses and are more consistent with the multifactorial nature of this concept. Some of the current and relevant studies of variables associated with adherence will be described.

In 1987, a model was developed by Stanton to explain adherence to antihypertensive medications in 50 subjects attending a health maintenance organization

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for care. Independent variables included knowledge of the medical regimen, information communication between the patient and provider, satisfaction with the provider, health locus of control, social support, and treatment disruption to the patient's lifestyle. These variables were assessed by multiple questionnaires and a home interview. Subjects were followed for 10 weeks. Adherence was measured by pill counts, self report of medication adherence and general regimen adherence, and percentage of total appointments which were kept. Blood pressure change was assessed as an outcome of adherence. Adherent subjects ($n = 27$) had significantly lower diastolic blood pressure, higher reported medication and general treatment adherence, and a larger percentage of kept appointments. These subjects reported significantly higher levels of satisfaction with the provider, locus of control, social support, knowledge of the treatment regimen, and lower perceived disruption to their lifestyle. When LISRAL structural modeling was applied, the researchers found that significant determinants of adherence were subject characteristics, such as internal locus of control, perceived social support, knowledge of the medication regimen. Medication adherence was a significant predictor of diastolic blood pressure change. In addition an internal locus of control promoted satisfaction with the health care provider. Results of the LISRAL analysis are essentially unuseable since it was conducted on an inadequate number of subjects.

Qualitative evaluations of adherence have been reported in the last five years. Hunt, Jordan, Irwin, and Browner (1989) conducted a qualitative study of 19 women who sought medical care for a variety of symptoms. Beginning before the first appointment, five interviews were conducted over a 15-week period to explore how the subjects utilized their treatments on a day-to-day basis. Physicians were also

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interviewed, and medical charts were reviewed to compare respondents' understanding of their conditions and treatments with medical explanations. Based on comparisons of the subjects' self-reported behavior with the recommendations of the physician, subjects were categorized as non-compliant, somewhat compliant, and compliant. Medical diagnoses included hypoglycemia, allergies, stress, thyroid problems, infections, coronary heart disease; most of the women had more than one diagnosis. Treatment recommendations included oral medications (e.g., vitamins, antibiotics, tranquilizers) and behavioral recommendations (e.g., diet, smoking cessation, stress reduction). The researchers cited a 66% noncompliance rate at two weeks and 74% noncompliance at the end of the study. The authors conclude that noncompliance was not related to a misunderstanding of the diagnosis or treatments, but rather to an inconsistent fit between the subjects' perceptions of their problems and their daily life activities. On average, the degree of change required by the treatment negatively affected compliance. Respondents often modified regimens to fit their daily routines or were noncompliant until their symptoms resurfaced and then resumed treatment. The compliant subjects followed recommendations that were compatible with their daily patterns of living.

As a preliminary step to developing a long-term medication behavior self-efficacy scale, Geest, Abraham, Gemoets, and Evers (1994) interviewed 14 patients on a life long medication regimen. Subjects were questioned regarding knowledge and skills necessary to take their medication correctly and situations in which it is difficult to take medications correctly. Data were analyzed using a phenomenological method. Thirteen themes were categorized into three aspects of Bandura's model of self-efficacy, personal attributes, environmental factors, and task and behavior factors. Four

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themes for personal attributes which influenced compliance were emotional distress, perceived health status, normalcy, and confidence in the physician. Four themes for environmental factors influencing compliance were personal routine, distraction (e.g., traveling, visitors, watching an exciting TV show), cost of medication, and social support. Five themes for task related and behavioral factors that influence compliance were medication aids, medication schedule, drug delivery system (e.g., size of pills), knowledge, and side-effects. From these themes, a 33 item scale will be developed and tested.

Three studies on adherence have resulted from the Medical Outcomes Study (MOS), a very large multicenter descriptive study of variations in physician practice style and patient outcomes (Sherbourne, Hays, Ordway, DiMatteo, & Kravitz, 1992). In 1992, Sherbourne et al. reported on longitudinal data of 1198 subjects with three chronic diseases to ascertain antecedents of adherence. DiMatteo and DiNicola's six factor model of adherence formed the framework for this study. Multiple self-report instruments were used to measure five factors that have been consistently associated with adherence. These factors were past adherence behavior, health perceptions, individual characteristics, such as coping style, barriers and supports, and satisfaction with the interpersonal aspects of care. Adherence was measured via three researcher developed reliable and valid self-report scales: general adherence scale, specific adherence scale and separate adherence scales for diabetes, hypertension, and heart disease. The initial level of adherence and the use of avoidance coping mechanisms were the strongest predictors of general and specific adherence two years later. Lower levels of adherence were associated with high levels of distress with one's health, poor

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physical/role functioning, diabetes, and dissatisfaction with interpersonal aspects and financial aspect of care. These seven variables accounted for 26% of the variance in the general adherence model. Adherence models differed for the primary medical problems; however, past adherence behavior was the strongest predictor for each. Variables which had no significant effect on adherence were life stress, health outlook, value of health, will to function, general health knowledge, active coping, number of supports, anxiety and depression, and satisfaction with access to care. The strengths of this study are its longitudinal design, large mixed sample size, reliable and valid measures, examination of multiple antecedents based on theoretical models, and appropriate use of multivariate statistical methods.

Kravitz et al. (1993) examined 1751 subjects from the MOS to discern the relationship of recall of medical advice and adherence 3 to 4 months after advice was given. At their doctors' appointments, subjects and their physicians were given a screening questionnaire. After their appointments, subjects received a telephone interview to evoke recall of recommendations. A physical exam, laboratory studies, and a medical history survey were also conducted by the research staff. Three or four months later, a self-administered questionnaire which assessed health status and adherence was given to subjects. Physiologic measures were also used to assess adherence. The researchers found that of all the recommendations made, medications were the most consistently recalled and most consistently adhered to. Over 90% of diabetics, hypertensives, and persons with heart disease reported recalling and following a prescribed medication regimen. Patient recall was directly and significantly related to the amount of time physicians spent in adherence-related discussions.

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Adherence to recalled information varied by physician subspecialty with cardiologists' advice receiving more adherence than that of family practitioners ($p < 0.05$). On average, self-reported adherence was significantly correlated with improvement in certain physiologic measures, such as glucose levels in diabetics, systolic and diastolic blood pressure in hypertensives, and episodes of shortness of breath in patients with heart disease. Strengths of the study include a large, multi-site sample, prospective design, and use of physiologic measures to validate self-report, with the realization that improvement in health indices may be multifactorial. A weakness of the study is the moderate reliabilities of the disease specific adherence scales, and that medical recommendations were provided by patients without validation from physicians or medical records. The adherence rates cited in this study are higher than noted in other studies on adherence. The researchers cite bias from self-report or a highly motivated sample as possible reasons, but they take some comfort in the fact that adherence was assessed prospectively and was correlated with objective measures.

In 1993, DiMatteo, Sherbourne, et al. reported on another adherence investigation from the Medical Outcomes Study data. They analyzed data from a subsample of 1,828 patients with diabetes, heart disease, hypertension, depressive symptoms, or a combination of these problems to determine the effect of physician characteristics on adherence. The two scales described above were used to assess the general tendency to adhere and specific adherence behaviors. Three additional subscales also were used to evaluate the frequency of medication, exercise, and dietary adherence. Numerous physician characteristics were evaluated by either the patients' or the 186 physicians' self-reports. Over two years, the general tendency to adhere

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improved significantly, but medication adherence significantly dropped. Consistent with the findings of Sherbourne et al. (1992), baseline adherence rates were predictive of adherence to all types of regimens two years later. When patient variables (identified in the study by Sherbourne et al. 1992) were controlled, medication adherence after two years was significantly increased when the physician scheduled a follow-up appointment, saw more patients per week, or was a cardiologist. Patient perceptions of emotional distress about health negatively influenced medication adherence. Personal characteristics of the physician, such as age, gender, and ethnicity had no effect on adherence.

Stewart (1987) compared responses to interview questions with pill counts. Ninety-eight patients of 24 physicians in two Canadian provinces were interviewed at home 10 days after the visit with the doctor. Each was asked background questions about the medication's name and purpose. The compliance questions asked were, "Have you done this [taken the medication] every day or might you have missed some doses? How many doses might you have missed in the 10 days?" (p. 96). Responses were correlated with pill counts. Compliance was defined as taking 100% of the pills, which included antibiotics, analgesics, diuretics, antihypertensives, antihistamines, and hormones. The interview correctly identified compliers and noncompliers 74.5% of the time, the overall accuracy rate. The questions had an 80% sensitivity, that is, 80% of subjects correctly identified that they had missed some pills, as verified by pill counts. Sensitivity significantly increased for subjects who had new prescriptions, took only one drug, and knew their doctors either less than a year or between two and four years. The researcher concluded that when compliance questions are used for research purposes,

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high levels of accuracy are important, and when compared to others' works in this area, the accuracy rates of the questions used in this study rival the 59.8% to 78.1% accuracy rates of those reported in earlier studies.

In a similar vein, Steele, Jackson, and Gutman (1990) conducted a sociolinguistic analysis of three types of interview questions to monitor adherence. The indirect questions (asking the patient if he has noted changes since starting on the medication) were ineffective; the simple direct questions (asking if the patient has been taking his pills, run out of medication, or missed any doses) identified about 68% of nonadherent patients; and the information intensive discourse (asking specific questions about the medication dose and schedule and giving information that is needed) was 100% effective in identifying noncompliers. A weakness of this study was that no objective measures validated the self-reports; rather subjects were pre-interviewed about their compliance by the researcher prior to their interview with the physician, and results were withheld from the physician who used subject responses to the questions to categorize each as adherent or nonadherent.

Two studies described the relationship of beliefs and attitudes to adherence. Perceived barriers and perceived benefits of treatment were found to be significant predictors of medication adherence in a study of health beliefs and behaviors in elderly chronically ill males (Lacey, 1988). Miller, Wikoff, and Hiatt (1992) tested the predictive ability of Fishbein's theory of reasoned action on compliance behaviors of 56 predominantly male hypertensives. Their causal model for medication adherence showed significant direct effects of attitude and motivation to comply. Motivation was

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significantly affected by the perceived beliefs of others. In this study, intention was not a significant predictor of medication adherence.

Much of the research testing Orem's theory in relation to medication adherence has been conducted in the elderly, and none of the studies have identified a significant generalizeable link between self-care agency and adherence. In 1991, Conn, Taylor, and Kelley found a nonsignificant negative relationship between medication regimen complexity and adherence in a group of 276 elders. Pavlides (1993) reported no significant association between self-care capacity and adherence in her study of 94 homebound, older adults. She examined the relationship of several predictor variables including medication complexity, capacity for self-care activities, and mental health to medication adherence. She found that mental health and capacity for self-care were directly related to adherence. The best predictors were better mental health and economic resources. An incidental finding was that there was a significant relationship between self-reported medication behavior and pill counts. Wesemen (1992) examined the relationship between medication adherence, self-care agency as measured by the Self As Carer Inventory, medication regimen complexity, and functional status in 179 elders. Again, no significant relationships between adherence and the independent variables were identified. Haynes (1988), however, found a significant relationship between perceived exercise of self-care agency, as measured by the Exercise of Self-Care Agency Scale, and self-reported compliance with a diabetic regimen in adult diabetics. This is the only study which shows a statistically significant link between self-care agency and adherence. Her sample size ($n = 11$) prevents generalization of these results.

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Scope of Adherence to Tuberculosis Treatment

Despite the shorter treatment duration and advent of combination pills, rates of adherence to antituberculosis medications have changed little in the past 20 years. In 1979, Addington reviewed copies of reports from the CDC on persons completing the then recommended 18 month treatment regimen within 24 months. He found that from 1970 to 1975, between 23-31% of patients did not complete medication therapy. Case reports for 1990 were reviewed by Sumartojo (1993) and approximately 25% of persons with active TB did not complete the newer six month medication regimen within 12 months. When these data are compared with 1992 CDC case reports, there is little change; 23% of persons with active disease did not complete treatment within 12 months (CDC, 1994c). The latest available data for 1993, however, show an improvement to an 82.5% medication completion rate (CDC, 1995b).

Cross-sectional and longitudinal methods of measuring adherence were compared on a sample of 179 TB patients attending a community clinic in Cape Town, South Africa (Youngleson & Joubert, 1991). Compliance was defined as attending the clinic for a least 75% of the required 120 daily doses of medication. It was measured on one day for the cross-sectional study and at the end of treatment for the longitudinal design. The cross-sectional compliance rate was reported at 80.5%, and the longitudinal rate was 59.7%. Subjects 15 years or over had higher compliance at both points of analysis than those under age 15. There was no association between gender, medication regimen, employment status, or geographic region in either analysis. The authors failed to substantiate denominators used to calculate compliance percentages. If these were adjusted to include subjects who defaulted prior to the day on which the

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cross-sectional data were collected, the cross-sectional adherence rate would be 69%. Despite these problems, the study did point out that compliance can decrease over time and that bias is incurred when data are collected at only one point. This bias could be minimized by statistically controlling for the length of treatment in the analysis of cross-sectional data.

Characteristics of Nonadherent TB patients

One of the first studies of nonadherence was conducted by Curry (1964) on patients who signed themselves out of the hospital against medical advice (AMA) or left surreptitiously (AWOL) over a 10-year period from 1952 to 1961 at San Francisco General Hospital. AMA patients were married or single and defected largely to take care of personal, financial, or family matters which arose due to sudden hospitalization. They always returned to resume therapy. AWOL patients were single, mostly males who had long histories of social, emotional, and behavioral problems such as alcoholism, frequent incarceration, and irregular employment. Programs for each group were instituted in 1955 to address patients' needs. These programs reduced irregular discharges from 26.4% of all admissions between 1952 and 1954 to 3.5% in 1961. The author concluded that TB care should consider physical, emotional, social, and cultural characteristics and tailor programs to meet the needs of the total patient. This report is an excellent example of how changes in the system can affect adherence.

As part of a clinical trial to evaluate six month medication therapy for TB, Combs, O'Brien, Geiter, and Snider (1987) examined characteristics of 853 noncompliant subjects. Noncompliance was defined as missing more than 14 consecutive days of medications, refusing treatment, withdrawing from the study, or

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missing one or more clinic appointments. Variables examined were age, gender, race, ethnicity, place of birth, cavitary disease, education level, smoking status, alcohol use, use of combination tablet, marital status, drug addiction, and treatment group. Age less than 60 years, being unmarried, drug addiction, lack of transportation, and membership in the treatment group without a combination pill were characteristics associated with a high relative risk for noncompliance.

Wardman, Knox, Muers, and Page (1988) examined urine specimens for rifampicin in 113 consecutive TB patients attending a chest clinic in Leeds, England. Two, three, or four specimens were collected per subject at different visits. Seventeen percent (n = 19) of the patients had one or more negative specimens and were labeled noncompliant. These subjects were from a lower socioeconomic class ($p < 0.01$), tended to miss clinic visits without reason, and be of Asian ethnicity. Physicians correctly identified 32% (n = 6) of the noncompliers, but incorrectly labeled 8% of the compliers as noncompliant. A subsample of 70 patients completed a compliance questionnaire. Seventy-four percent (n = 52) of this group reported never missing their medication, 20% (n = 14) admitted missing pills no more than once a month, and 6% (n = 4) admitted missing pills one day a week. Forgetfulness was the most commonly cited reason for noncompliance. Half of the 10 known noncompliant subjects who completed the questionnaire reported never missing a pill. In addition, 22% of the compliers reported missing medications. This study points out the limitations of three measures of compliance, urine testing, self report, and physicians' evaluations. It is interesting to note that self reported compliance rates were actually lower than those

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determined by objective measurement (74% versus 83%), and that both are comparable to the rates cited above for the United States.

Interrelationships between treatment regimen, personal characteristics, compliance, and relapse of TB were examined by Ormerod and Prescott (1991) in Blackburn, United Kingdom. Charts of 1009 patients of predominately Indian Subcontinent (ISC) ethnic origin were examined retrospectively from 1978 to 1980 and prospectively from 1981 to 1987. Compliance was based on a judgement by the physicians and monthly health visitor reports which included pill counts and clinic attendance, and was rated good (all appointments kept and satisfactory assessments), fair (1 to 2 appointments missed or 1 to 2 unsatisfactory assessments), or poor (3 or more appointments missed or negative assessments). Variables examined were ethnicity, site of TB, histology, type of medication, and duration of treatment. Compliance was significantly associated with ISC ethnicity, age 60 years or over, shorter duration of treatment, and using the medication pyrazinamide.

Adherence rates were compared with personal characteristics, management characteristics, and interventions associated with adherence via a retrospective chart review of 352 patients at the Montreal Chest Hospital TB clinic from 1987 to 1988 (Menzies, Rocher, & Vissandjee, 1993). Fifty-two of the patients were treated for active tuberculosis, and 300 were prescribed preventive therapy. Data were collected on demographics, medication type and duration, interval until first follow-up appointment, INH metabolites in the urine, punctual clinic attendance, language spoken, nursing assessment of how well the patient understood the treatment, and nursing assessment of compliance during the follow-up visit. Compliance was a

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dichotomous variable. A subject was noncompliant if he or she defaulted from clinic appointments after at least three reminders, and the total duration of uninterrupted therapy was at least one month less than prescribed; or if the physician discontinued treatment because the patient failed to take the medication. Eighty-three percent of those with active disease and 54% of those on preventive therapy were compliant; the overall compliance rate was 59%. Chi square and t tests were used to test bivariate associations. A nursing assessment of fair/poor compliance at the first follow-up visit was significantly associated with non-compliance ($p < 0.001$). Compliant individuals were prescribed a shorter duration of treatment ($p < 0.01$), hospitalized for initiation of treatment ($p < 0.05$), assessed by the nurses to have a good understanding of their treatment ($p < 0.05$), and kept follow-up appointments within four weeks of starting treatment ($p < 0.01$). When entered into a multivariable analysis, diagnosis, length of treatment, and nurses' evaluation of understanding and compliance were significantly associated with compliance. The interval of time until the first appointment was borderline significant, and age, gender, immigration status, and year of immigration were not significantly associated with compliance. The language spoken by the patient affected the nurses' ratings of understanding; 58% of patients who needed a translator, compared to 74% of those who spoke the nurses' native language, were judged to have a good understanding of their disease and treatment. Limitations of this study include the lack of standardized nursing assessment forms, the small sample of patients with active TB, and the assumption that appointment keeping can be a surrogate variable for medication compliance.

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Characteristics of the Tuberculosis System and Adherence

Since the early studies of patients who defect from tuberculosis treatment, it has become apparent that certain characteristics of the tuberculosis care system may diminish or enhance adherence to antituberculosis medications. Numerous studies have cited problems with TB clinic management and provided examples of effective interventions.

Directly observed therapy has repeatedly been shown to significantly improve medication regimen adherence and completion (Allwood, Keruly, Moore-Rice, Stanton, Chaulk, & Chaisson, 1994; Weis, Slocum, Blais, King, Nunn, Matney, Gomez, & Foresman, 1994; Wilkinson, 1994; Westaway, Conradie, & Remmers, 1991), improve sputum conversion (Williamson, Hammack, & Burks, 1986), decrease relapse and drug resistance (Weis et al., 1994), and contribute to reduction in rates of tuberculosis (Hotchkiss, 1993; CDC, 1993a). It is labor intensive and expensive to implement, but when consequences of nonadherence are considered; i.e., hospitalization for untreated, inadequately treated, relapsed, or drug resistant TB, it is cost-effective (Weis et al., 1994; CDC, 1993a; Cohn, 1990). Authorities at the Centers for Disease Control and the American Thoracic Society recommend that DOT be considered for all patients with TB (CDC, 1993a, 1993b). It may also be administered under court order to patients who are nonadherent and considered a threat to the health of the public. Frequently DOT is combined with other services, such as enablers, incentives, or substance abuse treatment.

McDonald, Memon, and Reichman (1982) evaluated the effects of DOT combined with food incentives and transportation services or carfare as enablers.

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Twenty-one recalcitrant patients, with mostly drug resistant TB were placed on daily DOT administered at the clinic for six months followed by 18 months of self-administered medications. Adherence was measured as a percentage of the total DOT attendance and a percentage of total clinic appointments kept during the self-administration phase. Courteous and respectful care was provided by the same physician; waiting time for care and medications was reduced, and intense follow-up was implemented when two or more appointments were missed. During the DOT phase, compliance ranged from 42% to 100%, with an average of 80%. One patient who was lost to follow-up after 7 weeks and later died achieved only 18% compliance. Compliance, however, waned once supervision ceased. All except the deceased subject converted sputum to negative within 6 months. Correlations between adherence rates and time to sputum conversion were not reported. One subject with a 72% compliance rate sustained reactivation of TB after 8 months of follow-up.

Comprehensive services in the form of education, counseling, incentives, rewards, and intense follow-up affected self reported medication adherence in both subjects with active TB (NS) and those on preventive therapy ($p < 0.001$) (Morisky et al. 1990). Although mean medication adherence rates in those with active TB were high for both experimental and control groups, 93% and 90% respectively, more subjects who received the intervention reported taking 95% or more of their medication than did the control group ($p < 0.01$). The authors attributed the high adherence rates to the routinely more conscientious follow-up of those with active TB by the agency. The researchers were unable to separate out the effects of each strategy though they report, based on exit interviews, that education and intensive follow-up may have had a

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stronger effect on adherence. Medication adherence in this study was measured by pill counts (percentage of the total pills that were consumed), urine metabolites for isoniazid, and self-reports. Self-reported time of last medication dose correlated strongly with urine metabolites; in fact, over 90% of the subjects who reported taking their last dose within 24 hours tested positive for INH metabolites.

Establishing a specialized TB clinic run by clinical nurse specialists at a Veterans Hospital in Chicago helped to significantly improve documented treatment completion from 12% to 86% ($p < 0.0001$) (Werhane, Snukst-Torbeck, & Schraufnagel, 1989). Documented follow-up also improved from 31% to 100%. The reasons for nonadherence were cited as increased waiting time, low regard for health, and poor knowledge regarding the need for continued treatment after hospitalization. Success was attributed to implementing strategies to establish a strong relationship between the treatment team and the patient, obtaining a verbal contract to complete therapy, decreasing the waiting time, providing transportation funds, evaluating socioeconomic problems, providing telephone reminders of clinic appointments, and follow-up of missed appointments. The cost of treatment for one patient (6-8 clinic visits and 3 medications) was $1000 compared to $7,636 for a 15-day hospital stay for relapsed TB in a nonadherent patient.

Comprehensive services including travel expenses, food, daily outreach worker visits during the first month, 3 months of cash payments, and follow-up of clinic non-attenders were instituted in a rural Haitian TB control program (Farmer, Robin, Ramilius, & Kim, 1991). Though no statistical analyses were conducted in this quasi-experimental evaluation study, remarkable differences were noted when

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compared to the usual care group in cure rate (100% vs. 56%), average weight gain per year (10.4 vs. 1.7 pounds); return to employment (93.3% vs. 46.7%), and mean number of clinic visits per year (11.4 vs. 5.8). This study also examined whether differences in beliefs about the role of sorcery in the etiology of TB affected compliance; about the same number of patients in each program group denied the role of sorcery (5 out of 30 versus 4 out of 30, $n = 60$). These results supported the hypothesis that improving economic factors combined with close supervision enhance adherence and cure.

In India, a program which utilized repayment of a deposit from each subject after completion of therapy showed lower levels of treatment completion (62%) when compared to the above cited studies, but higher levels (23%) when compared to the two years prior to implementation (Hill, 1992). Subjects placed money on deposit according to their income. The deposit entitled them to a reduction in the cost of rifampicin and ethambutol and was lost if patients missed and failed to reschedule a clinic appointment within a week. The default rate was significantly related to deposit amount and thus income. The lowest income group was placed on the cheapest and longest duration of treatment; this group had a slightly shorter average time to default than the higher income groups (2.1 months versus 2.6 months).

Jin, Kim, Mori, and Shimao (1993) conducted a randomized controlled clinical trial to ascertain if intensive efforts to motivate TB staff affected medication pick-up rates, treatment results, and staff performance. Staff who served 1,300 newly diagnosed TB patients in three urban and four rural health centers in Korea during the year beginning April 1980 were randomized according to the health center at which they worked, to either the intensive or control group. Motivational efforts included

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increased supervision, staff administration of a survey to patients, as well as encouragement and support. The intensive group displayed an almost perfect follow-up of x-rays and sputum smear and culture results. More patients who received care from the staff in this group picked up their medications on time (89% vs. 77.1%, $p < 0.01$), completed treatment (78.8% vs. 65.2%, $p < 0.05$), and displayed sputum conversion (75.2% vs. 45.8%, $p < 0.01$). These findings suggest the important effect staff motivation and encouragement have on patient adherence and cure rates. The staff administered survey may also have promoted opportunities for patient education and development of an interpersonal relationship. A weakness of this study is methodological in that picking up medications was considered evidence for actual ingestion.

Summary

Studies on adherence within the last ten years reflect a theoretical and multivariable approach to adherence. Measurement and design are problematic in any study examining adherence and further solidify the amorphous nature of this concept. Prospective studies tend to capture those who fall off the adherence wagon as treatment progresses; however, controlling for duration in cross-sectional studies may reduce some of the bias which results from loss of subjects. Medication adherence may be treated as a dichotomous variable which requires a sometimes arbitrary cut-off point for defining when adherence has or has not occurred. Defining adherence as a continuous variable allows for more flexibility in analysis and probably is more consistent with the way patients take medications over a period of time. Definitions of medication adherence in the above-cited studies vary from taking 80% to 100% of the

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prescribed medication. Several of the tuberculosis studies employed appointment keeping or other variables as proxies for medication adherence. The multiple operational definitions make comparison between studies difficult.

Many methods have been used to measure medication adherence. Pill counts are subject to the respondent's honesty and may not directly relate to ingestion. Urine assays are costly, consider adherence only within a circumscribed point of time, and are subject to other factors such as metabolism. Outcome measures, such as improvement in the state of health result from many factors including medications. Self-reports provide depth and are easy to obtain; however, they are subject to recall and truthfulness. Many of the studies described in this chapter have reported a positive correlation between self-reported medication adherence and objective measures. In addition, the use of a reliable and valid instrument containing questions phrased in a sympathetic, non-threatening manner and administered in an environment which promotes confidentiality will enhance accuracy (Gordis, 1979; Hays & DiMatteo, 1987; Rudd, 1979; Strecher, Becker, Clark, & Prasada-Rao, 1989).

While acknowledging the above limitations, one can summarize the factors which appear to contribute to medication adherence in general and antituberculosis medications in particular as follows. Patient variables which significantly predict adherence include internal locus of control, social support, knowledge of the regimen, past adherence behavior, avoidance coping style, perceived barriers, perceived benefits, attitude, and motivation. Other variables associated with adherence are perceived health status, mental health status, low disruption to one's lifestyle or routine, high capacity for self-care, medication schedule, and side effects. Poor adherence has been

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significantly associated with dissatisfaction with interpersonal aspects and financial aspects of care, and emotional distress about one's health. Physician practice characteristics associated with adherence are the specific scheduling of follow-up appointments, a busy medical practice (which may reflect more follow-up appointments), time spent discussing adherence topics, and a subspecialty of cardiology.

Studies within the last 10 years which examine adherence to antituberculosis medications have predominantly focused on system factors. These provide good evidence for the use of the short course of therapy, DOT, enablers, incentives, intense follow-up, nursing assessments of the patient's understanding and medication adherence, staff motivation, and comprehensive services that recognize the many needs of the patient with TB. Nonadherent TB patients have lower incomes, lack transportation, abuse substances, and keep fewer appointments. Though studies describe the socioeconomic and demographic characteristics of TB patients who are not adhering to therapy, many have been conducted outside the United States; few have examined the beliefs and perceptions, and none have examined the self-care characteristics of this group. In addition, none have examined the combination of patient beliefs and system factors in a multivariate manner.

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CHAPTER III

Methodology

This chapter contains a description of how this correlational study was implemented. The setting and sample are described. Methods to protect the rights of human subjects are identified, and procedures and instruments for data collection are outlined. Finally, the methods used to analyze the data are presented.

Setting

In 1994, the state of Georgia had the tenth highest rate of tuberculosis in the nation, 10.5 compared to 9.4 per 100,000 persons nationally (CDC, 1995). Thirteen health districts in Georgia were selected to participate in this project, based on the number of TB cases in 1994 and geographic accessibility to the researcher. In 1994, 82% of the TB patients within the state resided in those13 districts (Georgia Department of Human Resources, 1995). Administrators from 11 of the health districts agreed to participate in this study.

In Georgia, a health district may contain one or more counties. Each county has a separate health department, which is the responsibility of the district administrator. The health districts, in turn, are part of the state department of health and human services. Tuberculosis care is administrated at the state and district level and implemented through the health departments. Depending on need and resources, health departments may have a separate TB division or may designate TB care to a nurse or

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epidemiologist, who also may have responsibilities for implementing additional programs. All medications administered through the health departments are provided free of charge from the state.

An additional source of subjects was a clinical drug trial which was conducted by researchers at the Emory University School of Medicine. This trial was designed to compare two types of drug therapy for tuberculosis and was being conducted within the metropolitan Atlanta area. The clinical trial began about the same time as the present research project. Subjects were enrolled in the trial after 2 months of treatment for tuberculosis and received a total of at least 6 months of therapy.

Sample

Health care system information was obtained from an interview with either the district TB program coordinators, the nurse or epidemiologist in charge at the health department level, or both. The health system information collected included the use of DOT, incentives, and enablers.

A convenience sample was drawn from adults with clinically active TB, either pulmonary or extrapulmonary, who had been placed on a treatment regimen. English-speaking patients over age 18 receiving care for TB were asked to participate. Patients who were unable to give informed consent (e.g., were mentally retarded or had an altered mental status) were excluded.

A power analysis was conducted using the program developed by Bavry (1991). With R-square set at 0.26 and an alpha of 0.05, 80 subjects were required to achieve a power of 0.83. The R-square used was reported by Sherbourne et al. in their large multi-center study on antecedents of adherence. Based on the findings from a pilot

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study conducted at a metropolitan Atlanta health department in Fall, 1993 (McDonnell, 1994), it was anticipated that the sample will be reflective of those known to have a high incidence of TB: ethnic and racial minorities, substance abusers, persons with HIV Infection, and the poor (CDC, 1994a; Etkind, Boutotte, Ford, Singleton, & Nardell, 1991; Brudney & Dobkin, 1991; ATS, 1992).

The sample was limited in size to 65 participants due to a lower than anticipated number of eligible subjects available during the project funding period. Two primary reasons for this shortfall were the denial of access to TB patients and the exclusion of non-English-speaking patients. The two districts which did not agree to participate contained 32% of the TB cases reported in Georgia in 1994.

Non-English speaking patients were common in 50% ($n = 6$) of the agencies within and surrounding metropolitan Atlanta. In these six agencies, anywhere from 20% to 50% of the patients spoke English very poorly or not at all and were ineligible for this study.

Safety and geographic accessibility also contributed to the difficulties associated with enrolling subjects. In the rural areas, it was not unusual for the data collectors to drive between 80 to 100 miles to interview one or two patients. Patients who were violent, difficult to find (even for the health department staff), or in a contagious state could not be interviewed.

Protection of Human Subjects

The proposal for this study was approved by the Institutional Review Board of the University of Alabama at Birmingham on February 22, 1995, and Emory University School of Medicine in October 1995. Agency consent was obtained from the

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appropriate agency representatives using the Agency Memorandum of Agreement Concerning a Nursing Study found in Appendix A. The purpose of the study and a description of activities requested from the agency (i. e., allowing access to patients, provision of a private area for interview, provision of information about the tuberculosis program) were outlined. Measures to protect the identity of the agency and the confidentiality of the subjects were described. A copy of the individual agency general adherence rate as well as a copy of the results of the study was offered to each participating agency.

Potential subjects were approached by the data collectors in the clinic or in their homes. If a home visit was deemed necessary, agency staff briefly discussed the project with the patient and obtained permission for the researcher or her assistant to visit the patient in his or her home. The study was described, and a written explanation of the study and measures to protect confidentiality were handed to and read to each person (Appendix B). If the patient agreed to participate, the questionnaires were administered via interview by the investigator or her assistant in a quiet and private area.

No risks of physical harm existed for the subjects. However, potential psychosocial risks may be associated with anxiety about reporting HIV status and recording any negative responses to questions about medication adherence or care by health professionals at the clinic. Potential liability could exist for those patients who admit to not taking their TB medications. The health department has the power to seek court ordered compliance or commitment to a TB inpatient facility as a last resort. Precautions to avoid these risks include informing the subject that his or her name would not be written on the questionnaires, obtaining verbal consent so that the subject

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did not have to write his or her name, assuring strict confidentiality, handling of the forms only by the investigator and her assistant, providing privacy during the interview, and assuring that information will be reported as aggregate data only. Subject names were kept on a separate list so that a subject would be approached only once. Each subject was told that this list would be destroyed after the data were analyzed (see Appendix B).

Since TB clinics, as a matter of routine, monitor patient improvement and patient adherence to antituberculosis medications, individual information obtained by the researcher was kept confidential. Subjects who chose the responses on the TBGAS that they take their medications some of the time, a little of the time, or not at all were counseled after the interview on the importance of taking medications regularly and encouraged to discuss this with the staff.

Instruments

Self As Carer Inventory

The SCI (see Appendices C, D) is a 40 item self-report questionnaire which is used to measure one's perceived capacity to care for oneself (Geden & Taylor, 1991). The theoretical foundation for this instrument is Orem's self-care deficit theory. This inventory is action oriented. It includes questions which tap the 10 power components and the two phases of self-care operations that are important to the development of self-care agency.

Responses are on a 6-point Likert scale where 1 = very accurate and 6 = very inaccurate. The items are summed, and the total possible score ranges from 40 to 240. Higher scores indicate low perceived self-care ability, and low scores indicate a high

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perceived capacity to care for oneself. The questionnaire also contains three final 6-point questions where the subject is asked to rate his or her health at the moment, and in general, and the amount of care he or she provides for his or her self. The current version of this instrument has been tested on an ethnically diverse group of English speaking men and women in various states of health. The authors report a content validity index of 94% and test-retest reliability correlation coefficient of 0.85. Internal consistency for the total instrument, as measured by coefficient alpha, was 0.96 (Geden & Taylor, 1991).

The current instrument is the third version and was tested for construct validity by factor analysis (Geden & Taylor, 1991). Using a promax rotation set for four factors, the following factors were described.

1. Knowledge of self--measured by items 14, 15, 16, 17, 18, 21, 22, 23, 28, 29, 31, 32, 33, 34, and 35, which include values, conditions, and goals for self-care. The alpha coefficient for this factor was 0.92.

2. Judgement and decisions affecting production of self-care--measured by items 2, 4, 20, 24, 26, 30, 37, 38, 39, and 40. The alpha coefficient for this factor was 0.89. These two factors correspond to Phase I of Orem's self-care operations.

3. Attention to and awareness of self and self-monitoring--measured by items 6, 7, 8, 10, 11, 12, and 19. The alpha coefficient for this factor was 0.83.

4. Physical skills and satisfaction with self-care routines--measured by items 1, 3, 5, 9,13,25, 27, and 36. The alpha coefficient for this factor was 0.87. The last two factors correspond to Phase II of self-care operations.

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Tuberculosis Adherence Determination Questionnaire (TBADQ)

The Adherence Determination Questionnaire (ADQ) was developed to study the factors related to adherence to cancer control regimens (DiMatteo, Hays, Gritz, Vastani, Crane, Elashoff, Ganz, Heber, McCarthy & Marcus, 1993), but has been adapted by the researcher, with permission (Appendix D), for tuberculosis. The 38-item norm referenced questionnaire is composed of seven scales which relate to seven theoretical determinants of adherence. These scales are Interpersonal Aspects of Care (IPAC), Perceived Severity of illness (PSV), Perceived Susceptibility to illness (PS), Perceived Utility (PU) of the treatment plan such as costs, benefits, efficacy, Subjective Norms (SN) which influence the decision to adhere, Intentions (INT) to adhere to the treatment plan, and Supports and Barriers (SB) to adherence. Responses are reported on a 5 point Likert scale (1 = Strongly Disagree, 2 = Disagree, 3 = Neither Agree nor Disagree, 4 = Agree, 5 = Strongly Agree).

As had been done by DiMatteo et al. (1993), the 38 adapted items were randomized, and the resultant instrument is contained in Appendix E. Questions 10, 11, 12, 13, 15, 16, 18, and 31 comprise the IPAC scale; 1, 21, 22, 25, 27, 28, 33, and 34 are contained in the PU scale; 2, 9, 19, and 36 complete the PSV scale; 3, 14, 17, and 38 are in the PS scale; 20, 24, 29, and 30 constitute the INT scale; and 5, 6, 7, and 23 comprise the SB scale. The SN scale contains 3 sets of 2 multiplicative questions related to the beliefs family, friends, and relatives hold about taking TB medicines (items 4, 35, and 37); and the motivation to do what these sources want (8, 26, and 32). These items are scored following the interpretation of Ajzen and Fishbein by DiMatteo et al. for such questions. Belief items (4, 35, and 37) are scored +2 for

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strongly agree, +1 for agree, 0 for neither, -1 for disagree, and -2 for strongly disagree. Motivation items (8, 26, and 32) are scored 3 for strongly agree, 2 for agree, 1 for neither, and 0 for disagree and strongly disagree. The scores for the corresponding belief and motivation items for each source (family, friends, and relatives) were multiplied together, and then the results from each source were summed to form the SN score. The remainder of the scales are scored summatively after reverse ordering items 2, 3, 5, 7, 9, 11, 12, 16, 20, 21, 25, 28, 30, 31, 34, and 38. To facilitate comparison across scales, each scale score was linearized from 0% to 100% by dividing the achieved score by the maximum possible score. Raw scores were used in the statistical analyses. The scale scores were used to measure correlates of adherence.

The theoretical foundation of this questionnaire primarily rests on the Theory of Reasoned Action espoused by Ajzen and Fishbein and the Health Belief Model described by Becker and his colleagues (DiMatteo et al., 1993). It was developed by DiMatteo et al. (1993) in a two-stage process using subjects participating in four cancer treatment and cancer prevention intervention studies. In the first stage, 54 items were tested on a sample of 101 primarily-middle aged women, and this resulted in the present 38 item, 7 scale instrument. Validity of the seven scales was assessed by multitrait scaling analysis; the results of which are analogous to confirmatory factor analysis. The ADQ was then tested on a sample of 355 predominantly middle aged females of mixed ethnic background from the aforementioned cancer control studies. Construct validity was examined by testing hypothesized relationships between the scales and general adherence (measured by GAS), specific adherence (self-report of following a recommended treatment), and objective measures of adherence. PU was a consistent

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predictor of intentions to adhere; SB was a consistent predictor of self-reported general and specific adherence across all groups in the studies. IPAC and INT were significant predictors of adherence in a group of low income women with abnormal pap smears and individuals with head and neck cancer respectively. INT was associated with objective levels of smoking cessation in subjects with head and neck cancer, and SB was associated with the number of referral appointments kept in the abnormal pap smear group.

Alpha reliability coefficients for each scale ranged from 0.65 to 0.85 with a median of 0.76, with PS, PSV, and SB having the lowest coefficients. The scales with mean acceptable alpha reliabilities (> 0.7) across all four groups were IPAC, PU, SN, and INT.

Tuberculosis General Adherence Scale (TBGAS)

This adherence instrument is composed of five items, each on a six-point Likert scale, which assesses the patient's general tendency to adhere to medical advice. It has been used on patients with a variety of chronic medical problems in the Medical Outcome Study adherence research (Sherbourne, Hays, Ordway, DiMatteo, Kravitz, 1992) and has been adapted, with permission (Appendix D), to focus on tuberculosis medication adherence (Appendix F). Questions focus on the ease and ability to take TB medications as the doctor recommended; a final question concerns how often the subject took the medications in the past 4 weeks. Questions are similar to those described by Stewart (1987) and are phrased in a nonthreatening, nonjudgmental manner. Responses range from 1 = none of the time to 6 = all of the time. The scale is scored by averaging the responses to all five items after reverse ordering Items 1 and 3.

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For easy comparability, scores may be linearized to a 0% to 100% distribution as described previously. Scores on the TBGAS reflect self-reported medication adherence. The authors of the GAS report that factor analysis and multitrait scaling analysis have provided strong support for the unidimensionality of the scale. Alpha reliabilities range from 0.78 to 0.81, and, the 2 year stability was between 0.39 and 0.41 (DiMatteo, Hays, & Sherbourne, 1992; DiMatteo, Sherbourne, Hays, et al., 1993; Sherbourne et al.,1992).

Sociodemographic Form (SF)

This form was used to record information about the duration of the current treatment regimen for TB, how many times the subject has had TB, the subject's age, gender, race or ethnicity, birthplace (within or outside the United States), educational level, current living arrangements, income, employment status, alcohol and drug use, and HIV status. An agency code, the date of the interview, and information about the use of DOT, incentives, and enablers by the agency for the subject were placed on this form. The form is found in Appendix G.

Procedure for Data Collection

Data were collected between August 30, 1995, and March 26, 1996. Data collection was terminated after 7 months due to funding constraints and reaching near saturation of the pool of potential subjects. After agency consent was obtained, information about the use of directly observed therapy, incentives, and enablers, was obtained from the district TB program coordinator and the health department TB staff. This information was recorded for each agency and separately for each participant.

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Data were collected in a staggered manner from many of the agencies. Because of the bureaucracy involved in obtaining official consent and scheduling data collection, the time from initiation of a request until actual data collection occurred was extremely variable. In four agencies (33.3%), it required from 1 to 4 months for agency approval and coordination with individual health department staff before subjects were interviewed. It took 4 months to obtain approval from the investigators of the clinical trial, and subject interviews began about 1 month later. This was due to the time required for obtaining IRB approval, the nature of the clinical trial (Subjects had to be on medication for two months before entry.), and scheduling conflicts. One agency was added in the final 2 months as the need for additional subjects became apparent.

Clients receiving TB services were screened by agency staff for eligibility. Typically patients were interviewed where they received services, which was either at the agency or in their home. At the agency, potential subjects were approached by the investigator or her representative who described the study. If interested in participating, the subject was taken to a private area where verbal informed consent was obtained, and the questionnaires were administered. As mentioned previously, permission to visit a subject in his or her home was obtained by the agency staff. The investigator or her representative then visited the home, explained the study, and obtained verbal informed consent.

Questionnaires were administered at the interview in the following order: SCI, TBADQ, TBGAS, and, finally, the Sociodemographic form. Subjects were given a large handout of the Likert scaled responses for the SCI, TBADQ and TBGAS to look

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at while the data collector read the questions. On average, it took 20-30 minutes to complete the interviews; however, a few subjects required as long as 45 minutes.

Data Analysis

Data were analyzed using SAS 6.10 for Windows statistical package (SAS Institute Inc, 1994). Descriptive statistics, such as frequencies, means, and standard deviations, were used to provide a summary of sample characteristics and scores on the instruments. Alpha coefficients were calculated for the TBGAS, SCI, and scales of the TBADQ. These were compared with those reported by the authors of the instruments. TB general adherence rates were computed. Correlational statistics and regression analyses were used to examine relationships between antecedents and scores on the TBGAS. Student *t* tests and analysis of variance were conducted to identify significant sociodemographic variables and system factors. A multiple regression analysis which included the six most important variables was conducted to develop a prediction model. This analysis complied with the recommendation of Kleinbaum, Kupper, and Muller (1988) that approximately 5 to 10 subjects per variable are needed to ensure validity of the regression model.

Prior to running the regression analyses, statistical diagnostic studies were conducted to ensure that data complied with the assumptions underlying regression analysis. These assumptions and diagnostics will be reviewed briefly.

Linearity. A plot of the residuals for each independent variable versus TBGAS score portrayed a general linear relationship between each independent variable and the dependent variable.

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Homoscedasticity. An analysis of the plot of the residuals of each independent variable versus the predicted value of TBGAS score and a plot of the TBGAS score residuals against the predicted values of TBGAS score yielded a general concentration about zero, ranging between + 4 and -4. Thus, there was a constant variance.

Normality. Histogram and probability plots indicate a normal distribution of the residuals of the dependent variable. Low kurtosis (-0.03, normal = 0) and skew (-0.3, normal = 0) values, and a nonsignificant Wilks-Shapiro statistic corroborate this observation. Three potential outliers in TBGAS scores were identified by Jacknife residual analysis. Cook's D statistic was well below 1 for each of these observations, and the scores were within acceptable practical limits. One outlier was identified for the independent variable of SCI score, using the leverage value analysis. This score was the highest score for the sample (213), but within acceptable practical limits for the instrument and was retained in the analysis.

Independence. Variance inflation factors were less than 5, indicating no evidence of collinearity of the continuous independent variables.

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CHAPTER IV

Presentation and Analysis of Data

In this chapter the sample is described, and reliability data are presented for the questionnaires used to collect the data. The analysis of data for each research question is presented. The research questions, restated from chapter I, are as follows.

1. Are predictors of adherence as measured by the Tuberculosis Adherence Questionnaire (TBADQ) related to adherence to antituberculosis medications?

2. Is self-care agency as measured by the Self As Carer Inventory related to adherence to antituberculosis medications?

3. What patient sociodemographic characteristics are related to adherence to antituberculosis medications?

4. What characteristics of the tuberculosis care system are related to adherence to antituberculosis medications?

5. Is there a difference in adherence to antituberculosis medications between patients who receive direct observed therapy and those who do not?

6. What variables should be included in a model to predict adherence to antituberculosis therapy?

The Sample

The sample was obtained from 11 of the 19 health districts in Georgia. Five of the subjects were part of the clinical trial evaluating the effectiveness of tuberculosis

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medications. These subjects were among the 39 (60%) who were from the four participating health districts within the metropolitan Atlanta area. The remainder of the subjects were from rural and urban areas in the northern, middle, and southwestern part of the state.

Sixty-five subjects agreed to participate in this project; however, only 62 questionnaires were useable. Subjects ranged in age from 21-79 years with an average age of 46.5 years (SD = 11.6). In Table 2, characteristics of the sample are summarized and compared with data from the state of Georgia and the United States (US).

As can be seen in the table, the subjects were predominately male and African American. The majority were poor and poorly educated. Approximately a third reported being employed, and of those, 17 worked full time. Most of the subjects lived with their families, and a very small number were homeless or resided in a shelter. Some subjects who lived in a shelter may have chosen to report that they lived with others (nonfamily) rather than subject themselves to the stigma of homelessness.

Slightly more than one-third of the sample reported past alcohol use. The researcher did not attempt to elicit how far in the past this use occurred, and it is possible some subjects stopped drinking when they began TB therapy. About one-fourth of the participants reported current alcohol use; 6 admitted to daily use and 10 reported occasional use. Only 4 subjects were current drug users, and one of these reported daily use. Seven of the current non-users stated they had used drugs in the past, how recently was not elicited. Eighty-two percent of the participants reported being tested for the human immunodeficiency virus. Seven (11.3%) of the subjects were HIV positive.

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Table 2

Summary of Sample Characteristics and Comparison with the State of Georgia and the United States (US)

Characteristic	Sample		Georgia[a]	US[b]
	n	Percent	Percent	Percent
Gender				
Male	44	67.7	68.4	65.0
Female	21	32.3	31.5	35.0
Race/ethnicity				
African American	44	71.0	68.9	34.3
Hispanic	0	0.0	1.8	20.8
White	17	27.4	21.4	26.7
Asian/Pacific Islander	1	1.6	7.8	15.7
Foreign Born	5	7.9	9.1	31.3
Education				
<12th grade	34	54.8	--	--
High school	13	21.0	--	--
College	15	24.2	--	--
Income				
$0-10,999	37	68.5	--	--
$11,000-20,999	10	18.5	--	--
>$21,000	7	13.0	--	--
Employment				
Unemployed	22	35.5	--	68.2[d]
Disabled	20	32.3	--	--
Employed	20	32.3	--	--

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Table 2 (Continued)

Characteristic	Sample		Georgia[a]	US[b]
	n	Percent	Percent	Percent
Alcohol Use				
None	21	34.4	17.4	--
Past use	24	39.3	--	--
Current use	16	26.2	10.9[c]	13.0[d]
Drug Use				
None	51	82.3	--	--
Past use	7	11.3	--	--
Current use	4	6.4	9.9[c]	7.1[d]
Living Arrangement				
Alone	8	12.9	--	--
Family	41	66.1	--	--
Non-family	10	16.1	--	--
Shelter/Homeless	3	4.8	4.1	5.7
HIV Status				
Not tested/Don't know	11	17.8	--	--
Result unknown	9	14.5	57.1 [e]	--
Negative	35	56.5	23.0 [e]	--
Positive	7	11.3	19.7 [e]	--

Note. Statistics for Georgia and the US include all ages and are for 1994. Dashes indicate data not reported.

[a]From Tuberculosis in Georgia 1982-1994, by Georgia Department of Human Resources (DHR). Copyright 1995 by Georgia DHR.

[b]From Reported Tuberculosis in the United States, 1994, by CDC. Copyright July 1995 by CDC.

[c]Alcohol use unknown for 71.6% of TB cases; drug use was unknown for 90.1% of TB cases in Georgia.

[d]1993 statistics from Expanded Tuberculosis Surveillance and Tuberculosis Morbidity-- United States, 1993, by CDC, 1994, Morbidity and Mortality Weekly Report, 43, pp. 361-366.

[e]1993 statistics from Tuberculosis in Georgia 1982-1994, by Georgia Department of Human Resources (DHR). Copyright 1995 by Georgia DHR.

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On a scale of 1 (healthy) to 6 (unhealthy), mean scores for the subjects' perceived state of health in general and at the moment were 2.8 (SD = 1.4) and 3.1 (SD = 1.4), respectively. The majority of the patients had TB for the first time; however, 6 (9.7%) reported that this episode was their second. The duration of TB therapy ranged from 1 week to 13 months, with an average of 4.7 months (SD = 3.4). Forty-five subjects (72.6%) received direct observed therapy, and 17 (27.4%) received enablers. The 5 participants (8.1%) from the clinical trial were the only subjects who received incentives. Seventy-nine percent (n = 49) of the participants received some type of agency service to facilitate adherence. Use of these services is summarized in Table 3.

Table 3

Services Received to Promote Adherence

Type of Service	n	Percent
Direct observed therapy alone	27	43.5
Direct observed therapy and incentives/enablers	18	29.0
Enablers alone	4	6.5
None	13	21.0

As noted in the table, direct observed therapy was the most frequently provided service. Examples of enablers provided were transportation to clinic appointments, shelter referrals for homeless patients, provision of monthly exams in the home rather than the clinic, and delivering the monthly supply of medications to the home. As mentioned earlier, in Georgia, all patients who receive TB medications through the health department receive them at no cost.

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Measurement of Variables

Adherence was measured by the scores on the TBGAS questionnaire. Possible scores ranged from 0 to 30, which corresponds to 0% to 100% for comparability. Scores for the sample ranged from 18 (60%) to 30 (100%), with a mean score of 27.8 (92.6%) and a standard deviation of 3.3. Cronbach's coefficient alpha for this instrument was 0.68, compared to the previously reported alphas which range from 0.78 to 0.81 (DiMatteo, Hays, & Sherbourne, 1992; DiMatteo, Sherbourne, Hays, et al., 1993; Sherbourne et al., 1992).

Scores on the Self As Carer Inventory ranged from 40, the highest possible level of self care agency, to 213, a low capacity to care for oneself. The lowest possible score was 240. The mean was 62.8 (SD = 28.6). The alpha coefficient of 0.97 for the SCI was almost the same as the 0.96 coefficient reported by Geden and Taylor (1991). The alpha coefficients for Factors 1, 2, 3, and 4 of this instrument were 0.95, 0.92, 0.86, and 0.89, respectively. These closely compare with previously reported alphas of 0.92, 0.89, 0.83, and 0.87 (Geden & Taylor, 1991).

Summary statistics for the seven characteristics measured with the TBADQ are presented in Table 4.

Based on the mean scale scores, the subjects expressed a very good perception of the effectiveness of the medications and had strong intentions of adhering to the medication regimen. They were very satisfied with the interpersonal aspects of their care and felt they had the support they needed to take their TB medications. Based on the medium range PSV and PS scores, TB was perceived to be a moderately serious

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Table 4

Summary Statistics of the TBADQ (n = 62)

Scale	Items & range	Sample range	Mean	SD	Linearized mean
Interpersonal Aspects of Care (IPAC)	8 8 - 40	21 - 40	34.5	4.7	86.1
Perceived Utility (PU)	8 8 - 40	24 - 40	35.1	3.8	87.7
Perceived Severity (PSV)	4 4 - 20	4 - 17	10.6	3.3	52.9
Perceived Susceptibility (PS)	4 4 - 20	4 - 19	9.5	2.6	47.5
Subjective Norms (SN)	6 -18 - 18	0 - 18	8.5	4.8	47.5
Intentions to Adhere (INT)	4 4 - 20	14 - 20	18.1	1.7	90.6
Supports/Barriers (SB)	4 4 - 20	10 - 20	16.7	2.4	83.3

disease to which they may be susceptible again in the future. The moderate scores on the SN scale convey an average influence of friends, relatives, and family on the subjects' ability to follow the medication regimen. Cronbach's alpha coefficients for the scales on the TBADQ are displayed and compared with those reported by DiMatteo, Hays, et al. (1993) in Table 5.

With the exception of lower reliabilities on the PS, SN, and SB indices, the reliability coefficients were consistent with those reported by DiMatteo, Hays, et al. (1993). The three scales with the lowest alphas, SB, PSV, PS, were the same for this study as that reported by the original authors.

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Table 5

Cronbach's Alpha Reliability Coefficients for the Scales of the TBADQ (n = 62)

Scale	Alpha	Reported alpha[a]
Interpersonal Aspects of Care (IPAC)	0.85	0.84
Perceived Utility (PU)	0.77	0.76
Perceived Severity (PSV)	0.60	0.65
Perceived Susceptibility (PS)	0.54	0.69
Subjective Norms (SN)	0.66	0.85
Intentions to Adhere (INT)	0.78	0.84
Supports/Barriers (SB)	0.51	0.65

[a]From "Patient Adherence to Cancer Control Regimens: Scale Development and Initial Validation," by M. DiMatteo, R. Hays, E. Gritz, R. Bastani, L. Crane, R. Elashoff, P. Ganz, D. Heber, W. McCarthy, and A. Marcus, 1993, Psychological Assessments, 5, p. 111.

Research Questions

Question 1

Pearson product moment correlations were calculated for TBGAS scores with the seven scales of the TBADQ. Results of the correlation analysis are displayed in Table 6. Perceived Severity (PSV) of TB was not significantly correlated with adherence scores nor with the other variables and is omitted from the table.

As can be seen in the table, TBGAS scores were significantly positively correlated with Support/Barriers and Intentions to adhere. To ascertain if the scales contained in the TBADQ were predictive of adherence to antituberculosis therapy, TBGAS scores were regressed on all seven scales. The seven scales of the TBADQ were significantly associated with adherence (F [7, 51] = 2.6, p =0.024, adjusted R^2 = 0.16). The results of this analysis are contained in Table 7. In this model, SB had the largest beta weight.

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Table 6

Zero-order Correlations Between TB General Adherence (TBGAS) Scores, Selected TBADQ Scales, Self-care Scores, Ratings of Health, and Amount of Self-care Provided

	IPAC	SN	SB	PS	PU	INT	Self-care score	General health	Health now	Amount self-care
TBGAS Score	.19 (60)	-.05 (61)	** .41 (61)	-.06 (61)	.21 (61)	* .29 (61)	* -.27 (59)	-.03 (61)	-.07 (61)	-.12 (61)
Interpersonal Aspects of Care (IPAC)		*** .53 (61)	*** .44 (61)	** -.33 (61)	*** .65 (61)	*** .69 (61)	** -.42 (59)	-.17 (61)	-.13 (61)	-.12 (61)
Subjective Norms (SN)			.19 (62)	** -.39 (62)	** .34 (62)	** .36 (62)	-.04 (60)	.07 (62)	.11 (62)	.10 (62)
Support Barriers (SB)				*** -.41 (62)	*** .42 (62)	*** .51 (62)	-.20 (60)	* -.26 (62)	* -.26 (62)	-.10 (62)
Perceived Susceptibility (PS)					-.15 (62)	* -.28 (62)	.16 (60)	* .26 (62)	* .26 (62)	-.18 (62)
Perceived Utility (PU)						*** .83 (62)	** -.36 (60)	-.16 (62)	-.07 (62)	-.16 (62)
Intentions (INT)							-.23 (60)	-.11 (62)	-.05 (62)	-.02 (62)
Self-care score								** .33 (60)	* .31 (60)	*** .53 (60)
General health									*** .73 (62)	** .37 (62)
Health now										** .33 (62)

Note. n is in parentheses.
*p < .05. **p < .01. ***p < .001.

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Table 7

Regression Analysis of TBGAS Scores on the Scores for the Seven Scales of the TBADQ (n = 59)

Scale	Beta	SE	T	p
Interpersonal Aspects of Care (IPAC)	0.09	0.14	0.64	0.53
Subjective Norms (SN)	-0.15	0.11	-1.39	0.17
Supports/Barriers (SB)	0.64	0.22	2.94	0.005
Perceived Susceptibility (PS)	0.15	0.19	0.81	0.42
Perceived Utility (PU)	-0.11	0.20	-0.52	0.60
Perceived Severity (PSV)	0.12	0.13	0.93	0.36
Intentions (INT)	0.39	0.47	0.83	0.41

Question 2

Zero order correlations between TBGAS scores and Self-care scores, perceived health at the moment, perceived health in general, and the amount of self-care provided by oneself are depicted in Table 6. Self-reported adherence was significantly inversely related to Self-care score. Because a low Self-care score indicates a high capacity for self-care, this correlation means that high levels of self-care agency are associated with high levels of self-reported adherence. There was no significant relationship between adherence and the amount of self-care provided by oneself.

Question 3

Pearson product moment correlations were calculated for TBGAS scores with the variables of age, duration of therapy, and the number of times a subject reported having TB. No significant correlations were found.

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Student's t tests were conducted to determine if differences in levels of adherence existed within the variables of birthplace, race, drug and alcohol use, income, and education. For this analysis, race was collapsed into two categories of whites and other; drug and alcohol use were each condensed to current use and no current use; income was collapsed to $0-10,999 per year and $11,000 or more per year; and education was consolidated to high school degree or less and education beyond high school. There was no significant difference in adherence scores based on gender, race, birthplace, or drug use.

Subjects with an annual income of $11,000 or more ($t = 2.10$, $p = 0.04$), no current use of alcohol ($t = 3.06$, $p = 0.007$), education beyond high school ($t = 2.95$, $p = 0.005$), and HIV negative status ($t = 2.51$, $p = 0.02$) had higher mean adherence scores, as compared to their respective alternatives.

A one-way analysis of variance (ANOVA) was conducted to examine whether differences in adherence existed between types of living arrangements or employment status. Both the models and comparisons showed no significant difference in mean TBGAS scores by employment status or types of living arrangements.

Questions 4 and 5

Both of these questions concern the effects of system services on adherence and will be addressed together for that reason. Because many of the subjects received more than one service from the agencies, a four-factor system variable was created to reflect the categories described in Table 3. A one-way ANOVA revealed no significant differences in adherence scores between categories, including when all categories of

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services together were compared with no services. To determine if the system variable was collinear, with or a significant proxy for, the SB variable of the TBADQ, SB was regressed on all system factors. No significant relationship was identified.

The IPAC scale of the TBADQ measures satisfaction with interpersonal aspects of care and can be considered a measure of patient satisfaction with TB care staff. As noted in Table 6, there was no significant correlation between IPAC and TBGAS scores. It was, however, significantly correlated with Supports/Barriers, Intentions, Subjective Norms, and Perceived Utility, and inversely correlated with Self-care score and Perceived Severity.

Question 6

The following variables were selected to be entered into the regression analysis with TBGAS scores because they were significantly associated with adherence in the above analyses: SB, INT, Self-care score, alcohol use, income, and education. Though associated with significant differences in TBGAS scores, HIV status was not included because the very small number of HIV positive subjects may affect generalizeability of the findings. The model significantly predicted self-reported adherence with an F (6, 44) of 4.3, $p = 0.0017$, $R^2 = 0.37$, and adjusted $R^2 = 0.28$. The results are shown in Table 8.

Alcohol use had a negative predictive effect; current alcohol use lowered mean adherence scores.

Additional Findings

Significant intercorrelations existed between the independent variables of Self-care score, perceived health at the moment, perceived health in general, amount of self-care provided for oneself, and the six scales of the TBADQ displayed in Table 6. Self-

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Table 8

Regression Analysis of Self-Reported Adherence on Antecedents (n = 51)

Variable	Beta	Standard Error	T	p
Alcohol	-3.7	1.26	-2.92	0.01
Income	0.53	0.93	0.57	0.57
Education	0.49	1.07	0.46	0.65
Intentions	0.19	0.30	0.63	0.54
Supports/Barriers	0.18	0.21	0.89	0.38
Self-care Score	-0.005	0.02	-0.29	0.78

care score was significantly positively associated with perceptions of state of health and the amount of care performed by oneself. Ratings of health in general and health at the moment were strongly intercorrelated. Supports/barriers (SB) was significantly positively correlated with Interpersonal Aspects of Care (IPAC), Perceived Utility (PU), and Intentions (INT). SB was significantly negatively correlated with Perceived Susceptibility (PS), and ratings of health at the moment, and in general. Recall that low scores on the ratings of health indicate a healthy state and high scores indicate an unhealthy state. Significant positive correlations existed between Intentions (INT) to adhere and Interpersonal Aspects of Care (IPAC), Subjective Norms (SN), Supports/Barriers (SB), and Perceived Utility (PU). The correlation coefficient of 0.83 for Perceived Utility (PU) with Intentions (INT) was high. Intentions were negatively correlated with Perceived Susceptibility (PS). Perceived Susceptibility (PS) was also significantly negatively correlated with Interpersonal Aspects of Care (IPAC), Subjective Norms (SN).

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Supports/Barriers (SB), and ratings of health at the moment and in general. Perceived Utility (PU) of taking the medications was significantly positively correlated with Interpersonal Aspects of Care (IPAC), Subjective Norms (SN), Supports/Barriers (SB), Intentions (INT), and negatively correlated with Self Care scores. Subjective Norms (SN), the desire to behave like significant others would like, was positively correlated with Interpersonal Aspects of Care (IPAC), Perceived Utility (PU), Intentions (INT), and negatively correlated with Perceived Susceptibility (PS).

Summary

In summary, the findings yielded the following answers to the research questions.

1. The combined seven scales of the Tuberculosis Adherence Questionnaire significantly predict adherence to antituberculosis therapy. When zero order correlations were calculated, only the variables of Intentions and Supports/Barriers were significantly correlated with adherence scores.

2. Self-care agency, as measured by the Self As Carer Inventory, was significantly correlated with adherence to antituberculosis therapy.

3. Significantly higher levels of adherence were noted in subjects with the following sociodemographic characteristics: income of $11,000 or more per year, educational level beyond high school, no current alcohol use, and HIV negative status. No significant differences in adherence were noted for the number of times the subject reported having TB, duration of therapy, age, gender, race, birthplace, employment status, living arrangements, or drug use.

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4. No significant differences in adherence scores were seen when mean scores of those who received system services, such as DOT or enablers, were compared to those who did not.

5. There was no difference in levels of adherence between those who received DOT alone or in combination with other services and those who did not.

6. The following model was found to significantly predict self-reported adherence to antituberculosis therapy and accounted for 28% of the variance of adherence: Adherence = 22.2 - 3.67 (Alcohol) + 0.53 (Income) + 0.49 (Education) + 0.19 (Intentions) + 0.18 (Supports/Barriers) - 0.005 (Self-care Agency).

Analysis of the data yielded the following additional findings.

1. With the exception of more alcohol use and fewer HIV positive subjects, the convenience sample for this study closely approximated characteristics of TB patients in Georgia.

2. The Cronbach alpha reliability coefficients for the SCI, INT, PU, PSV, and IPAC were consistent with those reported by the original authors. The reliability coefficients of the PS, SN, SB, and TBGAS were lower than previously reported.

3. The perceived utility of therapy was highly correlated with intentions to adhere.

4. Satisfaction with the interpersonal aspects of care was significantly correlated with subjective norms (the perceived influence of others), the presence of supports, and the absence of barriers to adhere, perceived susceptibility to TB, perceived utility of therapy, intentions to adhere, and self-care agency.

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5. Perceived state of health at the moment was significantly positively correlated with perceived state of health in general.

6. Neither the self-ratings of one's state of health, nor the amount of self-care provided by oneself were significantly associated with adherence. These variables were significantly correlated with the capacity for self-care.

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CHAPTER V

Discussion, Conclusions, and Recommendations

In this chapter the research findings presented in Chapter IV will be discussed. Conclusions will be drawn, implications for nursing practice, education, and theory will be reviewed. Recommendations for research will be offered.

Discussion

The Sample

The difficulties encountered in attaining the anticipated sample size have been described in Chapter III. The sample was not randomly selected, and, consequently, generalizations made about the population of patients with TB may be limited to the population from which the study sample was drawn.

When compared to persons with TB in Georgia, about twice as many subjects in this sample admitted to alcohol use. Since there is no social gain typically associated with such an admission, the investigator will assume that subjects responded honestly to this question and perhaps felt more comfortable answering questions about alcohol use in confidence with an individual not associated with the agency.

There were also about 8% fewer HIV positive subjects in the sample than in the state of Georgia. No subjects refused to answer this question; however, they may have preferred to respond that they did not know their HIV status or that they were HIV negative. In addition, two of the health districts where administrators declined to

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participate in the study were in urban areas where HIV care centers are located, thus reducing access to potential HIV positive subjects.

The broad use of system services, especially DOT, was not unexpected and was consistent with the recommendations of the Centers for Disease Control and Prevention and the American Thoracic Society (CDC, 1993a, 1993b). During the study period, the researcher was told numerous times by TB coordinators that the standard of TB care in the state of Georgia was moving toward universal use of DOT. Of interest, is that, except for the subjects from the clinical trial, no one received monetary incentives.

In the United States, TB cases are increasing in foreign born persons. Between 1992 and 1994, there was a 4.9% increase in TB cases in this group compared with a 15.3% reduction in cases in US born persons (CDC, 1995). Likewise, in Georgia, the proportion of foreign born cases increased from 5% of all cases in 1993 to 9% of the total in 1994 (Georgia DHR, 1995). The researcher feels that the obtained sample is what would be expected, given problems with language barriers and reduction in access to patients. With the exception of higher reported alcohol use and a slightly lower percent of HIV positive persons, the sample is similar to TB patients in the state of Georgia, the population from which it was drawn.

The Instruments

As noted previously, the alpha coefficients of the SCI closely approximated those reported by the original authors. The almost perfect score may indicate some redundancy of the items within this instrument.

The Cronbach's alpha reliabilities of the IPAC, PU, and INT scales, and the TBGAS are within an acceptable range. Alpha scores of the SN (0.66), PSV (0.60), PS

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(0.54), and SB (0.51) scales are modestly low. With the exception of lower alpha coefficients on the SN, PS, and SB indices, and the TBGAS, the reliability coefficients were consistent with those reported by DiMatteo, Hays, et al. (1993). The three scales with the lowest alphas, SB, PSV, and PS, were the same for this study as that reported by the original authors. Recently, experts hesitate to identify strict standards of reliability and defer to the researcher to interpret the scores with respect to the purpose and use of the instruments. These instruments have been adapted for use with TB patients, and as such are in the early stages of development and still under evaluation. One must be aware, however, that instrument unreliability may lower the obtained correlation between variables (Nunnally & Bernstein, 1994; Pedhazur & Schmelkin, 1991). That Supports/Barriers emerged as a significant correlate to adherence, despite this possibility, suggests the strength of this predictor. The low reliability coefficients of the PS, SN, and PSV scales may contribute to the nonsignificant correlations with TBGAS score.

The moderately low alphas may be attributed to several factors. The sample size and bias from nonrandom selection for this study may have affected the reliability results. Calculation of the alpha coefficient is based on the number of items and variability of responses. Relative homogeneity (i.e., low standard deviations), or the small number of items on the TBGAS, PSV, PS, and SB, or both, probably affected the reliabilities of these scales. Misunderstanding of some items also contributes to measurement error which affects the alpha score. For example, several participants voiced confusion about the possibility of getting TB again and, based on the moderate PS scores, did not perceive themselves particularly susceptible to the recurrence of TB. Negatively worded statements comprised about half of the items on the scales and 2 of the 5 items on the

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TBGAS. These statements presented comprehension problems for some subjects. Over half of the sample had less than a high school education, which also may have affected comprehension (Nunnally & Bernstein, 1994; Pedhazur & Schmelkin, 1991).

The large discrepancy between the alpha score on the Subjective Norms scale for this study and that previously reported is of interest. This scale concerns the subject's response to the perceived desires of family, reletives, and friends. Comments such as "I have no close friends"; "It's none of their business"; "What if they don't think I should take the medicine"; "You have to do what the doctors and nurses tell you"; and "I have to depend on myself" reflect a relatively self-reliant group only moderately influenced by significant others. The presence of a high percentage of past substance abusers may indicate that many of the subjects have made a conscious decision not to follow the wishes of others. Thus, an assumption, that friends, family, and reletives want what is best and that their influence is important is probably not accurate for all participants.

The Findings

The sample had a very high mean TBGAS score, 92.6%, indicating a high level of adherence to the medication regimen and few difficulties in taking the medications. This rate exceeds the national objective of 90% set forth by the CDC in 1989 and is similar to the self reported adherence rates cited by Morisky et al. (1990). It is higher than previously described self-reported rates of 74% (Wardman et al., 1988) and the rates measured by attendance for DOT services of 80% as noted by McDonald et al. (1982). Several possible reasons exist for this high rate. Certainly one would like to think that, as the data indicate, the participants had strong intentions and commitment to taking their medications. But the possibility that the sample may be biased toward compliant

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individuals must be considered. Subjects were approached at a health department clinic or through the TB program nursing staff in the rural areas. Those who are highly visible, easy to locate, regular clinic attendees, and willing to participate may be more likely to be the patients who adhere to their treatment regimen. Patients who do not attend their clinic appointments regularly, or who are difficult to locate may be less likely to take their medications. Patients who refused to participate may not wish to disclose their medication taking habits.

A tendency toward social desirability could lead some subjects to overestimate the frequency of medication taking. Judging by the high reported alcohol use, social desirability may not have been a major reason for overestimation. Recent work by Morisky et al. (1990) corroborated that the subjects' self-report of the last medication dose correlated with the urine drug metabolite tests.

There were significant zero order correlations between adherence scores and Intentions to Adhere ($\underline{r} = 0.29$), Supports/Barriers ($\underline{r} = 0.41$) and Self-care scores ($\underline{r} = -0.27$). The finding that both Intentions and Supports/Barriers are positively associated with adherence is consistent with the findings of DiMatteo, Hays, et al (1993). These authors identified Supports/Barriers as the strongest correlate to self-reported general adherence in patients receiving care for various types of cancer. In this same group, they identified the Perceived Utility of adhering as highly correlated with Intentions to Adhere, which also corresponds to the findings in this study. They also noted that Intentions to adhere emerged as a significant correlate to smoking-cessation behavior in a subsample of patients with head and neck cancer. Conversely, in

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hypertensive patients, Intentions was not a predictor of medication adherence (Miller et al., 1992).

Perceived Utility of taking the medication emerged as a strong correlate to Intentions to Adhere ($r = 0.83$) in this research. Subjects weighed information about the effectiveness and importance of taking the medication with the possible problems or side effects and made a decision to take the medications.

Perceived social support and perceived barriers to treatment have also been cited as significant predictors of adherence in subjects with several different medical diagnoses (Geest et al, 1994; Lacey, 1988; Stanton, 1987). These findings suggest that the presence of supports and the absence of barriers to adherence may be generic to adherence to many different therapeutic regimens.

Participants reported a high mean level of self-care agency, which was a significant predictor of medication adherence. Previously cited research studies, which were primarily in the elderly, had conflicting results with respect to the relationship of self-care agency to medication adherence. This study suggests the importance of this variable for TB medication adherence.

Satisfaction with interpersonal aspects of care has been frequently cited and hypothesized to correlate with adherence (Meichenbaum & Turk, 1987; DiMatteo, Hays, et al., 1993; Sherbourne et al., 1992). Interestingly, in this study it had no direct relationship to adherence scores. However, it was correlated with self-ratings of health and each of the antecedents except Perceived Severity.

Perceived Susceptibility (PS) was negatively correlated with each antecedent except Perceived Severity of Disease. Whether a lowered sense of susceptibility to TB is

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a cause or an effect of higher satisfaction with interpersonal aspects of care, more positive influence of significant others, more supports and fewer barriers to care, or a strong intention to adhere is unclear. PS was positively correlated with the reported state of health; such that those who rated themselves as healthy thought they were less susceptible to TB. As mentioned previously, lowered scores may simply reflect confusion about whether TB can be contracted again. This misunderstanding rang clear in comments to Item 38 on the TBADQ, which states, " My body will fight off TB in the future." Frequently subjects would look at the researcher and say "I don't know" or "They didn't tell me."

On average, subjects did not consider TB a very serious disease. This perception may be related to the location of the disease or duration of therapy. Though the site of infection was not elicited, 2 subjects who reported having TB of the brain emphasized to the researcher how sick they were. Also, those who were on medications for a longer duration probably had fewer symptoms and felt better. Perceived Severity was the only variable that was not related to adherence or the other antecedents, including self-ratings of state of health.

In contrast to the reports by other researchers, subjects' perceptions of their state of health were not related to adherence scores. Subjects, in general, rated themselves as moderately healthy.

Based on previous adherence research, it is not surprising to the researcher that no significant association between adherence scores and age, gender, race, birthplace, living arrangements, or employment status were identified. Few of these variables have been consistently studied in TB patients. The age of TB patients has been associated with

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adherence in three studies (Combs et al., 1987; Youngleson & Joubert, 1991; Ormerod & Prescott, 1991), but the results conflict as to the age range associated with compliance. Lower socioeconomic status was noted by one author as a significant predictor of noncompliance (Wardman et al., 1988), corroborating the findings of this study.

It is worthwhile to note that adherence was not related to duration of time taking TB medications. Long duration of medication use has been frequently reported as a correlate to medication nonadherence (Meichenbaum & Turk, 1987, Ormerod & Prescott, 1991; Menzies, Rocher, & Vissandjee, 1993). Perhaps the widespread use of DOT and the standard 6-month TB treatment regimen contributed to this finding. Also of note is that the number of times a participant reported having TB did not affect medication adherence. It is plausible that having TB more than once was actually a result of not adhering to the therapeutic regimen and that the few subjects who reported having it twice ($n = 6$) resulted in inadequate power to produce significance.

Social problems have been associated with nonadherence. In the present study, current alcohol use was associated with statistically significant lower mean adherence scores (83.7% vs. 95.6% for nonusers). Though not statistically significant, mean adherence scores were lower in the four current drug users (88.3% vs. 92.6% for nonusers) and the three homeless subjects (78.9% vs. 92.6% for subjects with homes). Further study of adherence in these groups is warranted.

The discovery that HIV positive subjects had significantly lower medication adherence scores (84.3% vs. 94.6% for HIV negative subjects) is also of concern. TB confers the diagnosis of AIDS in an HIV positive person, which emphasizes the fatality of his or her illness. Avoidance of four more medications is understandable in a person with

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a terminal disease who may already be taking numerous antiretroviral, antifungal, and antibiotic pills. However, these patients are at significant risk for rapid progression of disease in themselves, development of resistant strains, and transmission to others, including other HIV infected persons. Though the subsample size of 7 HIV positive subjects is too small to permit drawing conclusions, this possible trend of lowered adherence deserves further study.

The findings regarding the use of system services are the most surprising to the researcher and are contrary to numerous reports on the effectiveness of DOT. Several factors may have been operating. A posthoc power analysis was conducted using the method recommended by Cohen and Cohen (1988) to determine if sufficient power existed, given the achieved sample size, to find a significant difference. The power for this analysis was 0.10, which is extremely low and insufficient to detect an important difference.

As mentioned earlier, bias in the sample selection toward compliant patients may have occurred. Also, TB care staff may have correctly identified patients who would do well without additional system services or would carefully attend to the follow-up of patients who did not receive directly observed therapy or other system assistance. Menzies et al. (1993) demonstrated that the nursing evaluation of a patient's understanding of treatment and compliance with treatment was significantly associated with objective evidence of treatment adherence. Morisky et al. (1990) attributed finding similar adherence rates in both a control and educational intervention group of patients with active TB to conscientious follow-up by the staff. Thus, seasoned TB nurses can

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probably identify who most needs services and provide effective follow-up to those who do not.

This research project is the first to examine the relationship of demographic characteristics, system factors, and patient perceptions to adherence to antituberculosis therapy. The resultant six-factor model accounted for 28% of adherence variance. With the exception of the absence of system factors, the model is consistent with the literature and with the conceptual framework for this research project. Important basic conditioning factors which emerged were alcohol use, educational level, and income. Influential patient characteristics were the perceived presence of supports and absence of barriers to adherence, intentions to adhere, and the capacity for self-care. A post hoc power analysis was conducted using the formulae recommended by Cohen and Cohen (1983). For this research question the sample size was sufficient to achieve 0.95 power.

Conclusions

The purpose of this study was to identify antecedents of adherence to antituberculosis therapy. Several research questions related to the effect of patient perceptions, patient characteristics, and system characteristics on adherence were addressed.

The findings from this study led the researcher to the following conclusions:

1. The conceptual model upon which this study was based has been generally supported. When TB is diagnosed, a potential self-care deficit regarding adherence to the prescribed medication regimen exists. Several factors contribute to overcoming this potential deficit. The basic conditioning factors of annual income, educational level, and

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alcohol use combine with the individual's capacity for self-care, intentions to take the medications, and the presence of supports and the absence of barriers to taking the medication. The intention to take the medications is influenced by the belief in their benefits and usefulness. One's intentions, belief in the utility of the medications, perceptions of supports and absence of barriers, and capacity for self-care are all correlated with one's satisfaction with the interpersonal aspects of TB care. The combination of these variables in Phase I of self-care agency, where decisions whether to adhere are being made, will contribute to medication adherence behavior portrayed in Phase II.

2. Use of healthcare system services had no effect on the levels of adherence, however, statistical power was too low to detect a significant effect.

3. A finding that HIV co-infection may be associated with lower adherence was identified. The small HIV positive subsample size precludes generalization of this finding.

4. Characteristics such as the number of times an individual reports having TB, duration of therapy, age, gender, race, birthplace, employment status, living arrangement, or drug use were not associated with adherence to antituberculosis therapy. Small subsample size for those who reported having TB more than once, were foreign born, homeless, and current drug users limits the power and ability to generalize findings related to these groups.

5. Finding a diverse and substantial sample size in which to conduct TB research is a challenge. The above listed groups (foreign born, HIV positive persons, homeless, and drug users) are often disenfranchised from mainstream society. Overcoming barriers

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of location, culture, language, and attitudes is essential if information about TB medication adherence behaviors is to be known.

6. The alpha reliabilities for the newly adapted scales on the TBADQ ranged from adequate (0.85) to modestly low (0.51), and that of the TBGAS were modest (0.68). Small, non-random sample size, the presence of low variability within scale scores, few items, and misunderstanding of negatively worded items may have contributed to the low coefficients. Results of the study must be tempered with the fact that low reliabilities of some of the scales (SB, PS, PSV) may lower the observed correlations. That Supports/Barriers emerged as a significant correlate to adherence scores, despite this possibility, suggests the strength of this predictor.

Implications

The results of this study have several implications for nursing practice, theory and education, and research and lead to recommendations for further research. Implications for nursing practice are the following:

1. Important factors to include in the nursing history of patients with tuberculosis are: assessment of the educational level, income level, capacity for self-care, presence of supports for medication taking, presence of potential barriers to adherence, intentions to take the medication, current alcohol use, and HIV status.

2. Nursing interventions for the TB patient should include methods to secure a strong intent to take the medications, such as education and possibly contracting; the provision of support and elimination of barriers to taking the medication; activities to promote and enhance self-care; and referral to substance abuse programs if current alcohol use has been identified.

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3. Patient education should include information that would emphasize the effectiveness, importance and benefits (i.e., utility) of taking the medications.

4. Patients coinfected with HIV may be at risk for lower medication adherence.

Implications for nursing theory and education and research are

1. The conceptual-theoretical framework, which combines Orem's Self-care Deficit Theory (Orem, 1991) with the model of adherence proposed by DiMatteo and DiNicola (1982) and Gritz, DiMatteo, and Hays (1989), has generally been supported as a framework for adherence to antituberculosis therapy. This was an initial exploratory study which identified a model of important predictors. Further research on a large and diverse sample will be needed to validate the findings.

2. When adherence to antituberculosis medication is discussed in the nursing curriculum, the multifaceted nature of this concept should be considered. Future studies should continue to delineate the best combination of variables associated with adherence.

3. Because the numbers of foreign born persons with TB have increased, culturally and linguistically appropriate instruments are needed to measure the perceptions and adherence behaviors of non-English speaking TB patients.

4. It is possible that certain variables, such as supports and barriers, which are generic to medication adherence, may exist. Further study to examine this possibility is needed.

Recommendations for further research include

1. Replicate this study on a larger sample size with wider variation in race and ethnicity, HIV coinfection, homelessness, and drug use.

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2. Revise the Tuberculosis Adherence Determination Questionnaire to decrease the negatively worded questions and increase the number of items on the four item scales in order to increase reliability. Retest the reliability of these revised scales.

3. Conduct a similar study in non-English speaking persons, with attention to culturally and linguistically appropriate questionnaires for the predominant foreign born groups.

4. Further examine the adherence levels of HIV positive persons with TB.

5. Further study the effects of system services on adherence scores on a sample large enough and with sufficient power to identify a significant difference.

6. Examine the effects of nursing interventions designed to promote medication adherence.

7. Examine, perhaps using qualitative methods, what TB patients consider supports and barriers to taking their medications.

8. Replicate this study on subjects with a broad range of health problems who take long term medications to ascertain whether a general model or generic predictors for medication adherence can be developed.

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APPENDIX A

Institution, Agency, or Individual Memorandum of Agreement Concerning a Nursing Study

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INSTITUTION, AGENCY, OR INDIVIDUAL MEMORANDUM OF AGREEMENT CONCERNING A NURSING STUDY

Title of Study: "Antecedents of Adherence to Antituberculosis Therapy"

Name of Institution, Agency:_____

Study discussed with and explained to: _____

Title of agency representative:_____

Received a copy of the proposal and an explanation of the study.

a. Description of Study: The purpose of this research is to identify antecedents of adherence to antituberculosis medications. This correlational study is proposed to ascertain which characteristics of the patient and the health care system are predictive of self-reported adherence.
b. Description of activities the Representative agrees to do: 1. Allow the researcher or her assistant access to patients with active tuberculosis for the purpose of administering questionnaires by interview. 2. Provide a private area for the interview. 3. Provide information about the Tuberculosis program concerning budget, percentage of the budget of the agency allocated to the TB program, use of directly observed therapy, incentives, or enablers in the TB program.
c. Description of safeguards to protect the identity of the agency: The name of the agency will not be used in any written reports or oral presentations. The agency will be referred to as a TB clinic located in a county health department in the metropolitan Atlanta area.
d. Description of concurrent or later review procedure within the agency: The study has been approved by the Internal Review Board of the University of Alabama--Birmingham on February 22, 1995. A copy of the proposal has been given to the agency representative for review.
e. Description of how the agency will be informed of ongoing research process and results of the study: The agency representative will be kept informed of the ongoing progress of the study. Individual subject responses to the questionnaires will be kept confidential. If requested, the agency will receive a copy of the its general medication adherence rate. A copy of the results of the project will be submitted to the agency upon completion of the study.

_____ _____
Date Signature of Representative

_____ _____
Date Signature of Investigator

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APPENDIX B

Explanation of the Research Study

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Marcia McDonnell is a registered nurse and a doctoral nursing student at the University of Alabama at Birmingham who is conducting a research project about why people do or do not take their TB medicine. Please consider participating in this project by taking about 30 minutes to be interviewed about how you take care of yourself, how you feel about TB and taking your TB medicines.

All of your answers will be strictly confidential. Your name will **not** be written on any of the questionnaires. Your name will be kept on a separate list so you won't be approached again, and this list will be destroyed when the questionnaires are analyzed. Your answers will be combined with others so that they will not be directly linked to you as an individual.

Your participation is voluntary and will not affect the care you receive at this agency. If you choose to participate, there is no risk of physical harm to you. You may provide valuable information about how people with tuberculosis take care of themselves and feel about the disease, their care, and taking their medications.

Completion of the interview means that you have agreed to participate in this project. If you decide you don't want to continue, you may stop the interview at any time. If you have any questions, please don't hesitate to ask.

Thank you for your time.

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APPENDIX C

Self As Carer Inventory

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Self As Carer Inventory

Instructions: I am going to read a number of statements about caring for yourself. (The word "self-care" is used a lot in these statements. It means those things you do for yourself to maintain life, health, and well-being.) Please state on a scale of 1 to 6 how you take care of yourself. The number 1 means the statement is a very accurate statement about how you care for yourself and the number 6 means that the statement is not at all accurate.

Remember: 1 = very accurate; 6 = very inaccurate

	Very Accurate					Very Inaccurate
1. My joints are flexible enough for me to take care of myself	①	②	③	④	⑤	⑥
2. I consider health information in choosing solutions to problems in caring for myself	①	②	③	④	⑤	⑥
3. How I take care of myself fits in satisfactorily with my family life	①	②	③	④	⑤	⑥
4. I try out new ways to take care of myself based on information from experts	①	②	③	④	⑤	⑥
5. My self-care routine fits in with other parts of my life	①	②	③	④	⑤	⑥
6. I watch for signs that tell me if I am taking good care of myself	①	②	③	④	⑤	⑥
7. I think about my self-care problems differently depending on the type of problem I have	①	②	③	④	⑤	⑥
8. I watch for things around me that will influence me in taking care of myself	①	②	③	④	⑤	⑥
9. My strength is adequate for the physical work in caring for myself	①	②	③	④	⑤	⑥
10. I pay attention to signals telling me to change the way I care for myself	①	②	③	④	⑤	⑥
11. I plan my self-care according to the energy I have	①	②	③	④	⑤	⑥
12. I am aware of things around me that affect my ability to take care of myself	①	②	③	④	⑤	⑥
13. I have the necessary skills to care for myself	①	②	③	④	⑤	⑥

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		Very Accurate					Very Inaccurate
14.	I stick to my decisions about caring for myself even when I run into setbacks	①	②	③	④	⑤	⑥
15.	I know the resources I need to take care of myself	①	②	③	④	⑤	⑥
16.	I follow through on health care prescribed for me	①	②	③	④	⑤	⑥
17.	I take care of myself because my health is important to me	①	②	③	④	⑤	⑥
18.	I remember health care information about what I should do for myself	①	②	③	④	⑤	⑥
19.	I judge how much energy I need to take care of myself	①	②	③	④	⑤	⑥
20.	To make a decision about my care, I look at the pros and cons of the option	①	②	③	④	⑤	⑥
21.	It matters to me that I care for myself	①	②	③	④	⑤	⑥
22.	I know when I have enough energy to take care of myself	①	②	③	④	⑤	⑥
23.	I know where to find good information I need to help me take care of myself	①	②	③	④	⑤	⑥
24.	I relate my self-care actions to one another to reach my health goals	①	②	③	④	⑤	⑥
25.	I have the physical balance I need in order to take care of myself	①	②	③	④	⑤	⑥
26.	I fit new self-care actions into my existing routine	①	②	③	④	⑤	⑥
27.	My hearing and vision are adequate to allow me to care for myself	①	②	③	④	⑤	⑥
28.	The way I take care of myself is consistent with what I consider important in my life	①	②	③	④	⑤	⑥
29.	I do what I know is best in taking care of myself even though I may not like it	①	②	③	④	⑤	⑥
30.	I do my self-care in a variety of ways	①	②	③	④	⑤	⑥
31.	I follow through with decisions I make about caring for myself	①	②	③	④	⑤	⑥

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	Very Accurate					Very Inaccurate
32. I have an established routine for caring for myself	①	②	③	④	⑤	⑥
33. I consider the effects of decisions on my health and self-care	①	②	③	④	⑤	⑥
34. I knowingly spend my energies on the most important self-care tasks	①	②	③	④	⑤	⑥
35. I use information from authorities to help me take better care of myself	①	②	③	④	⑤	⑥
36. I have enough muscle strength to perform my self-care	①	②	③	④	⑤	⑥
37. I explore several alternatives before I make a decision about my self-care	①	②	③	④	⑤	⑥
38. I know why I make the choices I do in order to care for myself	①	②	③	④	⑤	⑥
39. I know which actions to do first to best to accomplish my self-care	①	②	③	④	⑤	⑥
40. Once I begin to care for myself in a certain way, I check to see if it is working	①	②	③	④	⑤	⑥

41. Using a scale of 1 to 6, how would you rate your health at this moment?

Healthy — Unhealthy

1 2 3 4 5 6

O O O O O O

42. Using a scale of 1 to 6, how would you rate your health in general?

Healthy — Unhealthy

1 2 3 4 5 6

O O O O O O

43. Using a scale of 1 to 6, how much of your own care are you providing?

All — None

1 2 3 4 5 6

O O O O O O

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APPENDIX D

Permission to Use Instruments

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UNIVERSITY OF MISSOURI-COLUMBIA

SCHOOL OF NURSING

Elizabeth A. Geden, RN, PhD, FAAN
S317 School of Nursing
University of Missouri-Columbia
Columbia, MO 65211
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Fax [314] 884-4544

June 30, 1994

Marcia McDonnell
4440 E. Durham Circle
Stone Mountain, GA 30083

Dear Ms. McDonnell:

Thank you for your letter of June 25, 1994. As per your request, you have my permission to use the Self-As-Carer Inventory in your dissertation research. I do in turn request that our work be acknowledged in any subsequent publications or presentations.

Your project sounds interesting and I wish you the best of luck with this research.

Sincerely,

Elizabeth A. Geden, RN, PhD, FAAN
Associate Dean for Research

EG/vh

an equal opportunity institution

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Marcia McDonnell
4440 E. Durham Cir.
Stone Mtn., GA 30083

Dear Marcia;

You are hereby granted permission to use the Adherence Determinants Questionnaire and the General Adherence Scale in your dissertation study of adherence to antituberculosis medications. You can modify them as you see fit to make them appropriate to tuberculosis.

Sincerely,

Ron D. Hays
RAND
310-393-0411 (extension 7581)

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APPENDIX E

Tuberculosis Adherence Determination Questionnaire

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TUBERCULOSIS ADHERENCE DETERMINATION QUESTIONNAIRE

Directions: The following statements describe various feelings and opinions that people with Tuberculosis (TB) may have about TB, TB medicines, and the doctors, nurses, community outreach workers that care for persons with TB. Please state the number that most closely represents your agreement or disagreement with these statements.
1=STRONGLY DISAGREE, 2=DISAGREE, 3=NEITHER AGREE NOR DISAGREE, 4=AGREE, 5=STRONGLY AGREE

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
1. The benefits of taking my TB medicines outweigh any problems I might have in taking them..	1	2	3	4	5
2. TB is not as bad as people say it is.....	1	2	3	4	5
3. I expect to be free of TB in the future.....	1	2	3	4	5
4. Members of my immediate family think I should take my TB medicines.....	1	2	3	4	5
5. Lots of things get in the way of taking my TB medicines.....	1	2	3	4	5
6. I get the help I need to take my TB medicines.....	1	2	3	4	5
7. I need more help in order to take my TB medicines.....	1	2	3	4	5
8. I want to do what members of my immediate family think I should do about taking my TB medicines.....	1	2	3	4	5
9. There are many diseases that are more severe than TB.....	1	2	3	4	5
10. The doctors, nurses and outreach workers treat me in a very friendly and courteous manner.....	1	2	3	4	5
11. Sometimes the doctors, nurses and outreach workers use medical terms without explaining what they mean.....	1	2	3	4	5

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	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
12. The doctors, nurses and outreach workers show little concern for me.....	1	2	3	4	5
13. The doctors, nurses and outreach workers listen carefully to what I have to say.....	1	2	3	4	5
14. No matter what I do, there's a good chance of getting TB again.....	1	2	3	4	5
15. The doctors. nurses and outreach workers answer all my questions.....	1	2	3	4	5
16. The doctors nurses and outreach workers sometimes ignore what I tell them.....	1	2	3	4	5
17. The chances I might get TB again are pretty high.....	1	2	3	4	5
18. I trust that the doctors, nurses and outreach workers have my best interest at heart.....	1	2	3	4	5
19. There is little hope for people with TB.....	1	2	3	4	5
20. Taking my TB medicines is not in my plans.....	1	2	3	4	5
21 Taking my TB medicines is too much trouble for what I get out of it.....	1	2	3	4	5
22. I believe that taking my TB medicines will help to prevent my getting TB again.....	1	2	3	4	5
23. I am able to deal with any problems with taking my TB medicines.....	1	2	3	4	5
24. I intend to take my TB medicines.....	1	2	3	4	5
25. I'll be just as healthy if I avoid taking my TB medicines.....	1	2	3	4	5
26. I want to do what my relatives think I should do about taking my TB medicines.....	1	2	3	4	5

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	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
27. Taking my TB medicines is better for me than not taking them.....	1	2	3	4	5
28. Because it is too hard to take my TB medicines it is not worth taking them.....	1	2	3	4	5
29. I have made a decision to take my TB medicines.....	1	2	3	4	5
30. I have no intention of taking my TB medicines.....	1	2	3	4	5
31. The doctors, nurses and outreach workers act like I'm wasting their time.....	1	2	3	4	5
32. I want to do what my close friends think I should do about taking my TB medicines.....	1	2	3	4	5
33. Taking my TB medicines will help me to be healthy.....	1	2	3	4	5
34. It's hard to believe that my TB medicines will help me.....	1	2	3	4	5
35. My close friends think I should take my TB medicines	1	2	3	4	5
36. TB is a terrible disease.....	1	2	3	4	5
37. My relatives think I should take my TB medicines.....	1	2	3	4	5
38. My body will fight off TB in the future.....	1	2	3	4	5

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APPENDIX F

Tuberculosis General Adherence Scale

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TUBERCULOSIS GENERAL ADHERENCE SCALE

Directions: The following statements describe how people feel and what they do, in general, about taking their Tuberculosis (TB) medicines. Please answer the statements by saying the number that best describes your feelings and actions in the past 4 weeks.
1=NONE OF THE TIME, 2=A LITTLE OF THE TIME 3=SOME OF THE TIME.
4=A GOOD BIT OF THE TIME, 5=MOST OF THE TIME, 6=ALL OF THE TIME

	None of the time	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
1. I had a hard time taking my TB medicines as the doctor advised.	1	2	3	4	5	6
2. I found it easy to take my TB mediciness as the doctor advised.	1	2	3	4	5	6
3. I was unable to do what was needed to take my TB medicines as the doctor advised.	1	2	3	4	5	6
4. I took my TB medicines exactly as the doctor advised.	1	2	3	4	5	6
5. Generally speaking, how often during the past 4 weeks were you able to take your TB medicines as the doctor advised?	1	2	3	4	5	6

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APPENDIX G

Sociodemographic Form

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Today's Date:_____ Agency_____

For Office Use
DOT_____ Incentives_____ Enablers_____

Directions: Please answer the following questions about yourself.

1. How many times have you had TB?____

2. For this episode of TB, how long have you been on TB medications?_____

3. What is your age? _____years

4. What is your sex? ___Male ___Female

5. What is your ethnic group?
___African American/Black
___American Indian/Alaskan Native
___Asian/Pacific Islander
___Hispanic
___Caucasian/White
___Other

6. Were you born inside or outside the United States?
___Inside
___Outside

7. What is your education level?
___Less than 8th grade
___9th to 12th grade
___High school degree or G.E.D.
___Some college
___College degree

8. What is your current living arrangement?
___Alone
___With family in the same house
___With others (non-family) in the same house
___In a shelter
___No permanent residence (homeless)

7. What is your average annual income?
___0-10,999
___11,000-20,999
___21,000-30,999
___31,000-40,999
___41,000-50,999
___over 51,000

8. Are you employed?
___Yes: ___Full time ___Part time
My job is: _____
___No
___Disabled

9. Do you drink alcoholic beverages (beer, wine, liquor)?
___Yes: (choose one)___ Every day
___ Weekly ___ Occasionally
___In the past but not now.
___No

10. Do you use drugs (cocaine, crack, marijuana, speed, etc.)
___Yes: (choose one) ___Every day
___Weekly ____Occasionally
___In the past but not now.
___No

11. Have you been tested for the HIV/AIDS virus?
___Yes
___No
___Don't know

12. If yes, was the test result:
___positive ____negative
___don't know
NA--not tested

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GRADUATE SCHOOL
UNIVERSITY OF ALABAMA AT BIRMINGHAM
DISSERTATION APPROVAL FORM

Name of Candidate Marcia K. McDonnell

Major Subject Nursing Health Policy

Title of Dissertation Antecedents of Adherence to Antituberculosis Therapy

Dissertation Committee:

_____, Chairman

Director of Graduate Program _____

Dean, UAB Graduate School _____

Date 10/3/96

PS-1428

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