ABSTRACT

RELATIONSHIP BETWEEN THE PROCESS AND OUTCOME COMPONENTS OF PATIENT CARE: AN EVALUATION MODEL

By

Barbara Given

The purpose of this study was to construct a model for assessing the relationships between the process and outcome components of patient care. Relationships were determined between the independent process variables of diagnostic approach, therapeutic approach, and patient compliance with the dependent outcome variables of functional status, medical health status, perception of health and care, and knowledge and understanding of disease and therapy. Criteria used for both the process and outcome dimensions were developed based on a literature review. Data were collected by the use of a medical record audit and two patient interviews. This model was applied to 103 patients with hypertension who were followed for a five-month period.

To determine the relationships between the independent variables and the dependent variables cross tabulations and multiple regression analysis was used. Analysis of variance was used to determine the difference in group means.

The study found relationships between the independent variables diagnostic approach, therapeutic approach, patient compliance, and the dependent variables medical health status, perception of health care and

knowledge and understanding of disease and therapy. The only dependent variable which did not relate significantly with the independent variable was functional status. Patient compliance was found to be the most important process variable. Patient knowledge and perception levels were also found to be important.

The conclusion from this study was that the model, while time consuming and requiring much effort on the part of reviewers could be used to implement studies of the evaluation of patient care. Alternative methods for implementing this model are examined and discussed.

RELATIONSHIP BETWEEN THE PROCESS AND OUTCOME COMPONENTS OF PATIENT CARE: AN EVALUATION MODEL

By

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I dedicate this dissertation

to my beloveds:

Bill and Jason

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CHAPTER I

EVALUATION OF PATIENT CARE

Introduction

Awareness of the need for quality health care has emerged as a major professional and public concern in recent years. Changes in organizational structure, multiprofessional health teams, continued rise in cost of medical care, federal legislation, emergence and proliferation of new forms of health care delivery systems, such as health maintenance organizations, and ambulatory care centers have been accompanied by a growing concern for the quality of health services. Implicit in the call for quality of health care is a need for systematic evaluation of care delivered so that deficiencies can be identified and corrected.

The purpose of health care delivery systems is to assist patients to achieve a state of well-being. The health care goal is to improve the patient's health status. When the disease cannot be controlled, the goal is to maintain comfort and/or to achieve a functional level. The goal of improving the health status of the patient depends on two major factors. These two factors are those physiological states (disease process) and behavioral components within the patient himself and those dimensions that relate to the performance

activities of the health care professional as he delivers care to the patient.

Definition of Health Care Delivery

The term health care delivery system refers to those arrangements for potential rendering of care to consumers. The delivery system has two main elements: resources and organization. Resources are the labor and capital devoted to health care. This includes health personnel, structures in which health care and education are provided and the equipment and materials used in providing health services. Resources also include the volume and the distribution of medical resources in an area.

Organization describes what the system does with the resources. It refers to the manner in which medical personnel and facilities are coordinated and controlled in the processes of providing medical services (Aday and Anderson, 1975). The components of organization are entry and structure. Entry refers to the process of gaining entrance to systems. This term is usually called access and is the means through which a patient enters the medical care system and subsequently receives the treatment process.

The second component of organization is structure and is concerned with the characteristics of the system that determine what happens to the patient when he has entered the system--by whom and how he is treated. The scope of health service functions provided by health care systems include: health education, health maintenance, diagnosis and management of illness or symptomatic abnormalities, care and

rehabilitation of chronic illness and disability, and custodial and comfort care for unremedial conditions. Other forces affecting the effectiveness of the system on the patient are: the nature of the disease, its severity, and the natural course of the disease process. Depending on the acuteness or chronicity of the disease there are also effects on the patient's functioning, behavior, and comfort. The physiological responses of the disease to diagnosis and therapy are crucial elements to the success of any health care delivery system.

The component of the health care system least often recognized is the patient. The patient participates in and contributes to the delivery system. Patient contributions to the health care delivery system (relates primarily to patient) include such behaviors as co-operation, return for medical follow-up, participation and compliance with the recommended regimen. If patients choose not to follow a medical regimen or do not seek further care during an episode of illness, there is little control the health care profession may have over the outcome of that illness.

As can be seen from the brief examination of the health care delivery system the problems of evaluating the effectiveness of health care are numerous and complex. Evaluation must include the examination of both the activities of the health care professional and the patient as well as the interrelationship and interaction of both. In addition, the natural course of illnesses and their severity may complicate the direct effect of the process activities on the patient outcome. Despite the complexity of the health care delivery system, there is

a need to begin to describe the relationships between the process activities and the patient outcome dimensions.

Need for the Study

During the past one and one-half decades numerous attempts have been made to conceptualize "evaluation" of patient care; yet, today, there exists much documented confusion as to what is important to evaluate. Further, there has been little examination of the inter-relationships of components of care. Despite the lip service to quality of care of patients, scant systematic attention has been given to the subject. Developing a means of evaluating care appears to be the key to achieving high quality care. Without systematic evaluation it is impossible to ascertain quality components or to know what improvements or changes are needed in the delivery system.

The lack of a comprehensive systematic approach, of accepted methodology to measure health care, and of indicators of health status have been deterrents to effective evaluation. Seldom do evaluation studies examine the status of the patient to determine how care given by health professionals alters the patient outcome. To date there is little evidence to suggest *what* effect health care professionals have on effecting change in patient status. Contributing to the problem of evaluation of health care professional intervention is the complexity of factors affecting health and the disease process.

If, in fact, the process of delivery of care does affect outcome, then a change in process should bring about a resultant

change in patient outcomes; yet many of the limited follow-up studies indicate that without continuity, compliance, or follow-up, the patient often survives without severe progression of the disease process. Patients who ignore significant symptoms or therapeutic regimens often get well. If, indeed, certain process of care factors in ambulatory situations do have an effect on patient outcome, then these factors should receive more emphasis in the actual delivery of care so that improvement in patient outcome would be likely. Evaluative research of health care to date has been unable to establish causal relationships between care and the effect of that care on the patient. Research has not provided controlled data which indicate to what extent changing care activities results in alteration in patient status.

Comprehensive evaluation of the quality of care received is only possible if follow-up and outcome data are combined with process data. A proper balance between process and outcome data is essential to an evaluative approach since health care professionals are responsible for follow-up, maintenance, and long-term care. Since there are few follow-up studies from which one can postulate a relationship between process and outcome data, studies are needed to begin to describe existing relationships.

Previous evaluative studies tend to define patient care in terms of technical management of illness. Patient care must not be defined so narrowly. Patient care is more than technical management of illness; it includes maintenance of health, rehabilitation, prevention of illness, reducing functional impairment, decreasing a discomfort,

preventing regression or recurrence, as well as provision of and continuity of care.

An evaluation system of patient care that incorporates outcome measures implies a responsibility of the patient to participate in care, return to receive care, and comply with medical advice. Attention to diagnosis, treatment and prescription is not enough. Patient compliance behavior is vital to preventive care and effectiveness of a medical regimen, although this is seldom examined as a component of health care evaluation.

New patient outcome is generally indicated by improvement in symptoms, functional level, and morbidity and mortality based on health care professional performance in the process of care. Patient care is difficult to evaluate since there are multiple and multifaceted intervening variables having an impact on structure, process, and outcome of care. Health status is the result of interactions between the natural course of a patient's disease, his environment, health care process, and the patient's behavior.

A comprehensive evaluation system of patient care, then, must include both patient and physician contributions to the process and overall outcome of care. It is necessary in an evaluation schema to examine how the patient participates to facilitate the process and outcome of his care. There is a need to determine the information the patient has about his illness, medical therapeutic regimens, and the extent of compliance with the therapeutic regimen and its relationship to outcome of care. In addition, there is a need to study

the physician's contribution to the process and outcome of care by an examination of the completeness and accuracy of diagnosis and therapy when compared to predetermined standards. There is a need to determine what the combined effects of patient and physician process factors have on the outcome status of the patient.

Purpose of the Study

The purpose of this study was to identify process factors, medical and others, that may affect the outcome status of hypertensive patients in an ambulatory medical care system. This study will attempt to specify the kind of information needed to assess process and outcome status. It represents an attempt to determine the dimensions of care that can be quantified and measured and that ultimately relate to process and outcome evaluation. These dimensions could then be used as criteria to evaluate factors that have an effect on patient outcome status. These would serve as the framework to explore relationships between the professional and patient factors of care and patient outcomes.

The objective of the study was to determine the relationships between process of patient care and patient outcome.

Statement of the Problem

The central question of this study was: *What is the relationship between elements of process of patient care and outcomes of care provided in an ambulatory care setting?*

Current authors stress the significance of looking at process and outcome together but emphasize that outcome is the ultimate factor (Brook, 1971; Williamson, 1971). It would be beneficial to know what factors within the control of health care professionals do affect the outcome and overall effectiveness of care. If these areas can be identified, perhaps a more rigorous focus by health care professionals could lead to documented improvement in patient health care status. This study will examine aspects of care to delineate any significant relationships between process and outcome components of health care.

Research Questions

The following section will include the questions to be studied. Specifically, these questions will focus on how diagnosis and therapy, as determined by the physician, and patient compliance behavior, effect functional status level, medical health status, perception of health and care, and knowledge dimensions. See Figure 1 for schematic presentation of research questions. The research questions to be used in this study include the following:

Research Question I.--What is the relationship between comprehensive diagnostic approach and the patient outcome?

A. *What is the relationship between a comprehensive diagnostic approach and functional status outcome?*

B. *What is the relationship between a comprehensive diagnostic approach and medical health status outcome?*

C. *What is the relationship between a comprehensive diagnostic approach and patient's perception of his health and care?*

D. *What is the relationship between a comprehensive diagnostic approach and patient knowledge and understanding of his disease and therapy?*

Research Question II.--What is the relationship between a comprehensive therapeutic approach and patient outcome?

A. *What is the relationship between a comprehensive therapeutic approach and functional status outcome?*

B. *What is the relationship between a comprehensive therapeutic approach and medical health status outcome?*

C. *What is the relationship between a comprehensive therapeutic approach and patient's perception of his health and care?*

D. *What is the relationship between a comprehensive therapeutic approach and patient knowledge and understanding of his disease and therapy?*

Research Question III.--What is the relationship between patient compliance and patient outcome?

A. *What is the relationship between patient compliance and functional status outcome?*

B. *What is the relationship between patient compliance and medical health status outcome?*

C. *What is the relationship between patient compliance and perception of his health and care?*

D. *What is the relationship between patient compliance and patient knowledge and understanding of his disease and therapy?*

Summary of Research Questions

1. *What is the relationship between a comprehensive diagnostic approach, comprehensive therapeutic approach, patient compliance, and functional status outcome?*

2. *What is the relationship between a comprehensive diagnostic approach, comprehensive therapeutic approach, patient compliance and medical health status outcome?*

3. *What is the relationship between a comprehensive diagnostic approach, comprehensive therapeutic approach, patient compliance, and patient's perception of health and care?*

4. *What is the relationship between a comprehensive diagnostic approach, comprehensive therapeutic approach, patient compliance and patient's knowledge and understanding of his disease and therapy?*

Rationale for Research Questions

Rationale for Question I

An important element of medical care is the diagnostic process. Diagnostic evidence confirms the presence of a given disease entity. These data are used to determine needed therapy as well as the effectiveness of therapy. Thoroughness and completeness of diagnostic information would seem to be necessary for instituting therapy which, in turn, leads to the patient outcome. If the diagnostic process is thorough, then, the physician should have more information on which to plan and evaluate therapy. Research Question I will examine the relationship between a comprehensive diagnostic approach and patient outcome. If there is no relationship between diagnostic measures and patient outcome one may have to examine more carefully how diagnosis relates to the therapeutic activities and how the combined diagnosis and therapy affect patient outcome. The combined effect may be more relevant to patient outcome than diagnosis alone.

Rationale for Question II

Utilizing the diagnostic data the physician recommends needed therapeutic activities. The diagnostic information guides the administration of therapy and charts the patient's course of illness toward the desired outcome. Research Question II will examine the existing

relationship between the comprehensive therapeutic approach and its effect on patient outcome. A significant relationship between the medical therapeutic approach and patient outcome would be expected. If there is no relationship between therapy and outcome, it will be necessary to look for other factors that do bring about a change in patient outcomes.

Rationale for Question III

The patient by his behavior, cooperation, and participation with therapeutic recommendations made by the physician plays an important part in ambulatory care. He may be advised to take certain medications at prescribed intervals, or adjust his diet, activity, or habits. Whether or not the patient complies with the regimen prescribed has a direct effect on the result (outcome) of the therapy. Patient compliance level should have an effect on the improvement in the course of the patient's illness. Research Question III will examine the relationship between the compliance level of the patient and the patient outcomes. A significant relationship would be expected. If no relationship exists between compliance and outcome one would need to examine carefully the appropriateness of the therapeutic regimen to the needs of the patient. If there is no relationship between compliance and patient outcome one must consider the accuracy of the reported compliance level.

It is necessary to examine separately the specific effect of each process of care component on medical health status, functional status, perception of health and care, and knowledge and understanding

of disease and therapy. If there are existing relationships that appear this should provide insight into which process activities should receive more emphasis in the delivery of health care to effect greater improvement in patient outcomes. These data should be provided from answers to Research Questions I, II, and III.

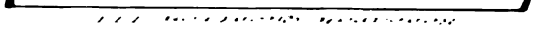
Rationale for Summary Research Questions

The summary research questions will examine the combined effect of the diagnostic approach, therapeutic approach, and patient compliance, all components of process, on each dimension of patient outcomes. By examining the combined effect of the processes of care on the patient outcome, one should be able to identify the relative contributions of each process component on the outcome status of the patient (see Figure 1).

Assumptions

Assumptions for this study are as follows:

1. *A relationship does exist between process of care activities and patient outcomes.* The focus of health care delivery is based on the assumption that activities of the health care personnel will help the patient recover, gain relief of symptoms, or achieve improvement in his health status. It is also assumed that early diagnosis and specific therapy activities do, in fact, alter the natural course of the disease process. Although there are few existing data to justify a cause and effect relationship between process activities and patient outcome for most disease processes, literature does document that changes in



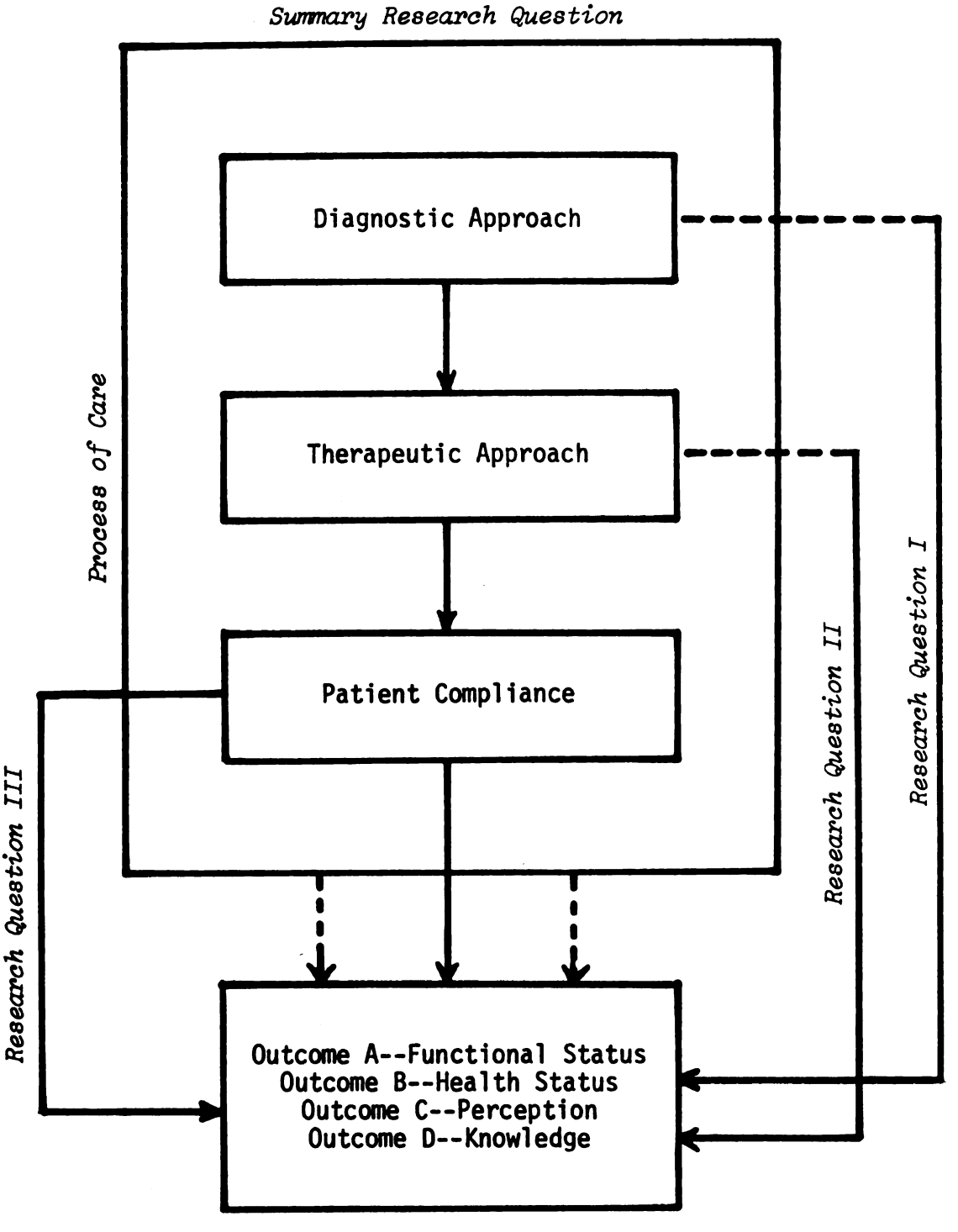


Figure 1. Schematic Presentation of Research Questions.

morbidity and mortality rates in hypertension can be related to therapeutic activities. Thus, hypertension was selected as the condition to which this evaluation model will be applied.

2. *Instruments will be sensitive enough to actually measure process and outcome variables.* Because of the state of the art of methodology for evaluation there are few reliable instruments. In addition, there is confusion over the indicators of patient outcomes that actually reflect the true status of these outcomes. Patients may have many symptoms with early disease or no symptoms with advanced disease. Instruments must reflect symptoms as well as end organ involvement to reflect true severity status. Another complicating factor is that process will be measured not by actual observation but indirectly through patient recall and through documented data from the patient record. Data in patients' records may be inaccurate or incomplete. It is important that health care professionals be able to depend on data reported by patients since these are the data from which vital decisions are made by health care professionals. Further, patients' records are sources used by professionals to plan therapy, change regimens, determine effectiveness of a previous therapy and observe progress of disease. Records are vital to this end and should be indicators of processes used for these decisions even though some data may not be documented within them. The assumption is made that enough accurate data can be collected by these means to measure process and outcome parameters.

3. Components used for evaluating hypertension would be similar to other chronic diseases in an ambulatory care setting. At this point in evaluative studies, there are few existing data to suggest the applicability of process and outcome parameters to a wide variety of diseases. It is assumed that the process and outcome components used in this study could be elicited with any disorder treated in an ambulatory care setting. Process includes examination of diagnosis, therapeutic activities, level of compliance, and continuity factors which are essential to all medical therapy for a chronic disorder. Outcome is determined by examination of functional status and medical health status, patient knowledge and understanding of disease and therapy, and perceptions of health and care. These factors are indicators of outcome for all patients receiving care within an ambulatory health care delivery system. Thus, this approach should be applicable to the evaluation of care of chronic diseases other than hypertension.

4. Findings will be similar to other settings serving a similar patient population. The setting used for the study was a family practice center with an approved residency training program in Family Practice. The facilities, educational program and services rendered appear to be typical of other family practice settings. The level of care and types of patients served within this setting should be comparable to those of other settings with similar educational programs, population, and geographic location.

Definitions of Terms

Process of Care

Process of care is defined as a series of activities carried out by the health care professionals while establishing a diagnosis based on signs and symptoms and the prescription of a therapeutic regimen to manage the episode of illness. This includes continuity and follow-up care. Patient compliance with the recommendations of the therapeutic regimen is a part of the process component. Both professional personnel activities and patient compliance behavior is a part of the process of care as defined for this study. Specifically,

Diagnostic process--those activities used by the physician to establish a diagnosis. This includes history, physical examination, signs and symptoms as well as diagnostic tests.

Therapeutic activities--those activities followed by health care professionals to manage an episode of hypertension. This includes medications, diet, habit restrictions, activity, and follow-up.

Compliance--is the extent to which the patient follows the prescribed therapeutic regimen.

(See Chapter IV for operational definitions of these terms.)

Outcome of Care

Outcome of care will be defined as the *result* of care, a measurable aspect of health status. For this study, outcome status will be limited to (1) functional health status, (2) medical health status (symptomatology and discomfort and end organ involvement), (3) the patient's self-perception of his health status and the

management of his care, and (4) the patient's knowledge and understanding of his disease and therapeutic regimen. Specifically,

Functional health status--the extent to which symptomatology affects the patient's ability to perform daily activities. A measure of functional disability.

Medical health status--includes the signs and symptoms, end organ involvement (cerebrovascular, optic, heart, lungs, and renal) and blood pressures.

Perception of health and care--includes the impression and satisfaction the patient has about his care (explanations, interest, thoroughness) as well as how the therapeutic regimen affects his health status.

Knowledge and understanding of his disease and therapy--includes the information the patient is able to express about the disease, control, signs and symptoms, as well as specific information about his medications, diet, activity, and needed medical follow-up.

(See Chapter IV for operational definitions of these terms.)

Input

Input is defined as factors that may have an influence on process and outcome. These include age, sex, socioeconomic status, occupation, severity of illness, length of illness, and associated diseases or medical problems. Certain data about the professional care component such as physician background, educational experience, qualifications and judgments, facilities, accessibility, availability and services are also input components. For this study these factors are identified primarily as descriptive components.

Family Practice Centers

Family practice centers provide prolonged primary responsibility for health care of a consumer group. These centers are responsible for continuing and comprehensive patient care over time. There usually is a centralized record system with past and current episodic details that should allow management and direction of patient care. The setting generally provides family care and provides therapy to those patient care management problems that can be done on an ambulatory basis. Health services provided to family groups include a full spectrum of services including prevention, rehabilitation, continuity of care. Emphasis on social and personal aspects of disease management and referral to specialty services or other health care professionals may be indicated; however, the primary responsibility for care resides within the family practice center.

Limitations of the Study

The study is limited to one disease process in one ambulatory practice care center. Results may not be generalized beyond this setting, or for other types of disease processes.

The patients are to be followed for a five-month period of time. This time was selected as the time in which an episode of hypertension should be brought under control. This period is a small segment of a chronic illness and may not be indicative of a true representation of the process of care either from health professional or patient perspectives. Thus, findings may be applicable to short-range management of care for hypertensive patients.

An attempt was made to limit the study to primary and uncomplicated hypertensive disease, thus preventing findings from being projected to complicated disease states or patients with multiple diseases. Hypertension was the disease selected for study; other chronic conditions as well as acute conditions, may require some revision of the methodology used in this study. The data were collected primarily from medical records and direct patient interviews. The data from records may be incomplete if the record keeping of the physician group was incomplete, and may not reflect all of the process activities of findings expressed by the patient. However, in an ambulatory primary care setting with multiple physicians seeing and managing patients, it is crucial that findings and recommendations are recorded in order that changes in symptoms or ineffective medical therapy treatments may be duly noted and altered if need be. In this way continuity of care can be provided. A further limitation to the study is that obtaining the patient's data regarding his functional capacity and symptoms, compliance, and knowledge depends on the patient's perception of his state of health and his presenting himself at the ambulatory center for medical treatment. With the multiple variables examined, the sample size may prevent the power of analysis to detect accurately the relationship.

A final limitation is that patients included were to agree to be followed during the entire study period, thus requiring the utmost in patient cooperation. It is possible that patients who did not wish to cooperate have unique outcomes from those who did choose to participate.

This is primarily a descriptive study of an evaluation methodology to examine the interrelationship between process and outcome dimensions. Results may be used to formulate parameters for further evaluation studies but contribute little beyond a methodological approach.

Overview of the Study

This study is organized into six chapters. Chapter I presents an introduction to the nature of the study, the need for the study, statement of the problem, definition of terms, limitations, and assumptions underlying the study. It describes the problem of evaluation of patient care and offers an explanation of the significance of the problem.

Chapter II provides an overview of the conceptual framework for evaluation of care and dimensions to be examined in this study.

Chapter III provides a review of the literature pertaining to this study illustrating the complexity, previous approaches for process and outcome studies and confusion, and supports the need for study.

Chapter IV explains the methodology, design, and procedures used in the study. Discussion of setting sample, patient interview guide, and medical record audit guide are presented. The procedures followed in collecting the research data are delineated and the method of data analysis is explained.

Chapter V contains an analysis of the data collected to answer the research questions.

Chapter VI consists of a summary of findings and conclusions drawn from the study as well as recommendations for further research.

CHAPTER II

CONCEPTUAL FRAMEWORK FOR EVALUATION OF PATIENT CARE

Introduction

Concern with evaluation of health care has emerged within recent years. Changes in structure and multiprofessional health teams, as well as the more institutional and bureaucratic character of medical practice have each served to emphasize health care evaluation.

The need for quality assurance through evaluation has moved from the voluntary professional perspective to that of legislative mandate and from private and professional accountability to that of public accountability. The trend in this direction started with Medicare and Medicaid programs that required evidence of quality of care as a condition for reimbursement.

Government and other third party payers are beginning to ask that quality review mechanisms be introduced to substantiate the services rendered and the costs incurred in treating diseases. For example, the social security amendment of 1972 (U.S. Congress Public Law 92-603) contains provisions for instituting government sponsored reviews of quality by 1976 if such mechanisms are not initiated by professional groups themselves. This movement toward public

accountability is forcing health professionals to develop methodologies and criteria for evaluating the processes and outcomes of medical care.

To facilitate the development of evaluative models the objectives of health care must first be established. Medical care, however, has multiple objectives as the following definition indicates: medical care applies knowledge to prevent illness, disability and premature death, or, when this is not possible to ameliorate the effect of illness and disability and contribute to a comfortable death. Such a holistic definition of health is not concerned with a single episode of illness, which is presently the focus of most evaluative efforts, but with the natural history of disease. Such broad definitions have made it difficult to develop evaluative models for assessing good health care (Donabedian, 1972).

Sherman, in a paper presented at the 1968 Health Forum, cited a 1967 report of the Committee on the Role of Medicine in Society of the California Medical Association. This report had this to say about quality of care and evaluation:

> Part of the difficulty is that there is no easy definition of high quality, or "health care." Nor can one easily describe what is meant by, and what are the advantages and disadvantages of, "custom care," (who would be entitled to this?) "high quality care," (higher quality than what?) and "cut rate" or "supermarket" care (whatever these may be). Yet there is a clear need to know with some precision what "high quality health care" is and the circumstances which make it effective and efficient [Sherman, 1968].

Quality medical care is a multidimensional concept. To the consumer of care, quality is assessed in terms of ready accessibility and the relief of symptoms and discomfort associated with disease.

To third party payers quality is based on the rendering of the most appropriate mix of services at the most reasonable cost. To physicians quality means the opportunity to provide optimal medical care within the scope and talents of those professionals and institutions comprising the delivery system. To the government, as a representative of public services, it means effecting an amalgam of these objectives which serve the interests of all parties engaged in producing and delivering health services.

Evaluation of quality of care refers to a degree of excellence or poorness but also to the appropriateness of care to the individual, the timeliness of the services provided, and the efficiency with which health care resources are utilized. Traditionally, health professions have used negative indices to evaluate health and sickness care. Death, disease, autopsy rates, complications, referral rates, disability, discomfort, and dissatisfaction are commonly found indices of quality of care. Statistics describing the lives saved or survival rates do not reflect the quality of those lives, nor do they reflect patient or third party satisfaction with the care rendered. Evaluation of the quality of health care can employ a multiplicity of approaches to determine the end result of continuing and improving health care to the public served. Evaluation may focus on an examination of such system properties as the accessibility, availability, competency, cost, continuity, comprehensiveness, and effectiveness of care provided to the patient. Evaluation also involves such characteristics as needs, expectations, and satisfactions of the individual patient. Assessing

the quality of these health services presupposes a standard to which the activities or its outcome can be compared. Evaluation introduces the concepts of value, relative worth, merit, and importance. Values are revealed in the things we measure, how they are measured, the form in which the data are recorded, analyzed, and how results are reported.

Many influences in addition to medical care play a part in determining patient health status--the problem of attributing specific professional competencies and related activities to changes in health status is formidable, but interrelationships should be examined.

It is crucial in the evaluation of care that we measure the relationship that exists between change in patient health status and intervention by the health service organization. However, it is difficult to know and define what strategy health care personnel should use to bring about change in the health status of the patient. For some conditions such as urinary tract infections, hypertension or diabetes we have reliable and valid normative standards derived from expert physicians; for other conditions we have little scientific knowledge, and there are no normative standards of practice. Another problem is that an effective system of health care seems to generate more illness. Better health care reveals previously undiagnosed illness. More effective health status permits people to live longer and to suffer more chronic illness and disability. Another problem in health care evaluation is that some effects of health care are in part short-term and direct while other aspects are long-term and indirect. The inability to clearly conceptualize quality of health care may be a major

constraint to the development of evaluation systems, yet studies need to be conducted to help develop a concept of quality of care. This study will attempt to develop an evaluation model for analysis of the relationship that exists between process and outcome parameters. The following section includes a discussion of the conceptual framework used for this study.

Components of the Patient-Physician Encounter

Overview

This overview of the patient-physician encounter describes the flow of information and the decision-making processes involved in making a diagnosis and preparing a therapeutic plan for the care of a patient. The interaction between the patient and his physician and the relationship between process and outcome components of care will be briefly described.

The purpose of health care is to assist a patient to achieve a state of well being, to improve the patient's health or functional status or to achieve a state of disease control and/or relief of symptoms. When the disease processes cannot be cured or controlled, the goal of therapy may be to maintain patient comfort. Health care, with the goal of improving the health status of the patient, implies that there are two forces affecting the outcome and process of care--these forces are those that reside within the patient himself and those that relate to the performance of the health care professionals. When a patient perceives that he is ill, he seeks advice from a physician.

To care for a patient the physician must first identify the cause of the patient's problem; that is, he must make a medical diagnosis.

Diagnostic Activities

Evaluation of the diagnostic processes of care centers around adequacy, accuracy, and completeness of the data obtained. Methods of evaluating these dimensions of the diagnostic process involve judgments by peers regarding how well the diagnostic evidence confirms the presence of a given disease entity. Necessary information for making a diagnosis comes from four sources: a medical history, a physical examination, diagnostic and laboratory procedures, and careful ongoing assessment of the course of the disease through symptoms and symptom complexes. When a conclusive diagnosis cannot be made, careful observation, search for new signs or symptoms, and additional laboratory procedures must be carefully planned and evaluated at subsequent encounters.

The data obtained through the diagnostic process are used to determine needed therapy. How the diagnostic information is organized by the physician to determine therapeutic choices represents the essence of clinical judgment. A diagnosis is not an end in itself and becomes useful to the extent that it sets out certain courses of therapeutic action.

Therapeutic Activities

Once a diagnosis is made the physician then prescribes a variety of medical recommendations for the patient to follow. He may be advised

to take certain medications on schedule, adjust his dietary habits to conform with a therapeutic diet, adjust his activity level, discontinue use of alcohol and tobacco, or present himself for certain diagnostic tests. Such recommendations are called the therapeutic medical regimen.

The therapeutic aspect of the process of care are the specific therapeutic recommendations the physician uses to manage or control the disease process in an attempt to reach a desired level of patient functioning and comfort within the natural limitations of the disease process itself. In evaluation of this aspect, completeness, accuracy, and follow-up would be essential.

The patient by his behavior, cooperation, and participation within the regimen suggested by the physician has a part in his own improvement. His ability to report new symptoms early and/or to follow a modified diet or activity schedule may be vital to the continuation or alteration of his therapeutic regimen. If the patient chooses to miss an appointment or does not seek further care during an episode of illness, there is little control the physician has over the outcome of that illness.

Evaluation of the therapeutic process of care involves both the physician and the patient. The physician is evaluated according to the appropriateness, accuracy, comprehensiveness, continuity, and efficiency of the therapy prescribed in view of the known standards of treatment for the disease based on the results of the diagnostic process. If the diagnostic process is inadequate or inaccurate it is therefore likely that deficiencies will also be found in the therapeutic regimen.

Evaluation of a therapeutic regimen is not complete without knowing the patient's compliance with and knowledge of his prescribed role in the treatment of his disease. To a certain extent the physician is responsible for informing the patient about his regimen of care. The patient, however, must comply with the treatment and to the extent that he does not, therapy may fail. Patient-related measures of therapeutic process focus on compliance and knowledge of the disease and treatment prescribed.

Patient Outcome

Finally, outcomes are the result of the diagnostic and therapeutic processes. The outcome of care describes the impact of the medical services on the health status of the patient at a selected point in time. The outcome thus represents a summary measure of the effect of the health care delivery system on the patient. Outcomes of care may be measured in clinical terms such as normal blood pressure, remission of leukemia, or in functional terms such as time by which the patient is no longer confined to bed, when a patient no longer needs assistance with personal care such as dressing, or the time at which he returns to work. Outcomes are the parameters a health care professional uses to modify the therapeutic activities and determine the state of the natural course of the disease. Process activities may be revised based on the outcomes of care.

Evaluation Conceptual Framework

In the past 15 years many approaches have been developed to measure the quality of patient care. Careful examination of the approaches indicates a common evaluation of patient care schema that includes three categories. These categories are structure, process, and outcome. Donabedian (1966) was the first to present this organizing perspective for evaluation of components of health care. This is the perspective that will be used in this study and will be discussed in the remaining section of this chapter. This framework is visually depicted in Figure 2 and is used to analyze the patient-physician encounter for an episode of illness.

Structure

The structural component of this framework includes the human and material resources that are needed to carry out the desired health care delivery activities and their supporting organization.

The structural elements of patient care include purpose of the organization program and its legal authority to carry out its mission, organizational setting, administrative support (supplies, facilities, and equipment), fiscal resources and management, and number, type status and qualifications of health professionals and the other personnel. Information and record systems as well as range and scope of services are also a part of structure. Existing external federal and state regulation is heavily related to measures of structure. This includes professional certification, ownership and approval by governmental and

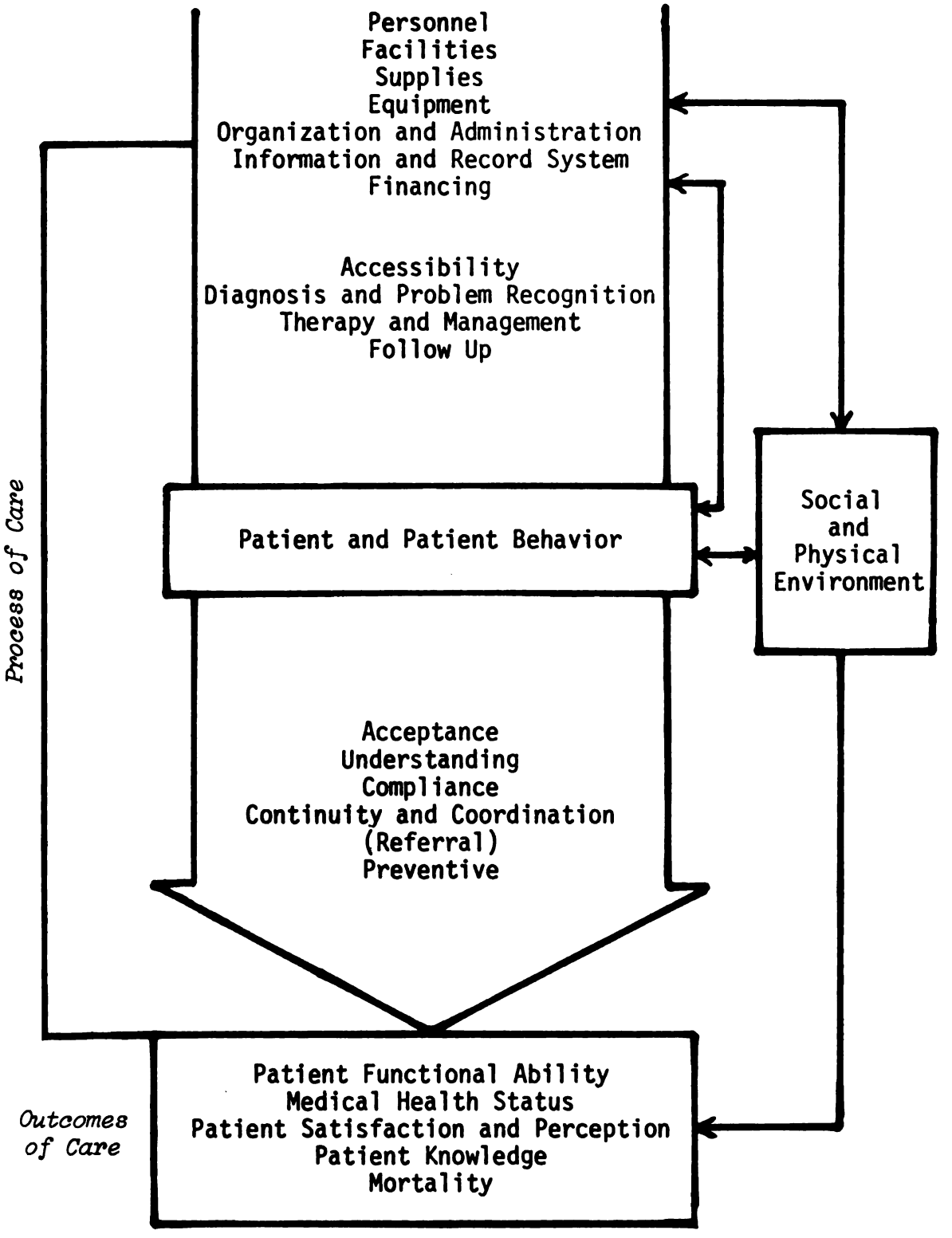


Figure 2. Health Care Delivery Systems (adapted from Starfield, July 1973).

governing bodies, professional licensure and institutional accreditation (Donabedian, 1966). This input data includes number of health facilities and ratio of physicians to population served. Distribution of educational background and interdependent functioning of health professionals have been found important to qualify the care measurement. Geographic factors such as distance, isolation, availability, and accessibility are important structural factors. These are fixed characteristics that do not change in the natural course of the disease process or with the physician-patient interaction (Morehead, 1967).

Structural information is relatively easy to collect and categorize. Items such as physical facilities, place of medical training, number of meetings attended, and other data can be obtained by simple routine questionnaires. A structural approach to quality of care makes the assumption that excellence in resources results in excellence of outcomes. The problem with structural data is deciding how to use it most effectively. Relationship of structural data to health outcomes is not known and studies attempting to show a relationship have found unpredictable or weak correlations so that quality in structural components have not been shown to correlate with outcome (Peterson et al., 1956; Clute, 1963). In this study, structure will be used only in a descriptive way.

Process--Provider Components

Process of care emphasizes the behavior of the professional and includes those activities encompassed in making a diagnosis and providing therapy to a patient. Evaluation focuses on the extent to which diagnostic and therapeutic efforts have been achieved. It does not determine the effect on the patient. "Process takes into consideration the sequence of events in the delivery of care and interactions between the patient and different kinds of health workers. Coordination of the work and cooperation among health care members are important components" (Degeyndt, 1970). The process component includes the steps a health care professional follows in responding to a patient diagnosis or complex of symptoms as a means of managing his care. Judgments on quality of process of care are based on appropriateness and completeness of information and therapeutic activities. Evidence of preventive management in health and illness, coordination, follow-up and continuity of care are important components of process. Process encompasses the assignments, judgments, problem recognition and decisions followed by health care practitioners in response to a complex of symptoms or patient diagnosis as well as the choice of therapeutic regime for the management of care.

Patient behavior and patient-doctor relationship, as well as medical practice, are part of the process that influence care. Patients may or may not seek care, accept or understand the help proffered or comply with recommendations. This patient involvement in his own case is a crucial component in the process of care of the ambulatory care patient.

The process approach has received the most attention in evaluation studies to date since it examines activities related to the production of services. In addition, it is useful in the management of day-to-day patient care. Process reflects adherence to operational objectives and reflects decision-making.

Process data may be subject to interpretation and difficult to categorize. Process review examines whether the actual performance meets a professional standard. Process studies that examine the activities of the professional make the assumption that processes are highly correlated with desirable outcomes without careful examination if, in fact, the activities do in any way directly affect outcome. The process approach to evaluation ignores the outcome aspect of health care and patient status. Studies carried out by Kroeger et al. (1965), Brook (1970, 1971), and Fitzpatrick, Riedel, and Payne (1962) reveal that records on which process activity analyses are based are often incomplete or even unavailable. They suggest that process studies may reflect a deficiency in recording rather than in actual therapeutic activities.

There is no body of literature that designates process as adequate or inadequate as it correlates with symptoms, activity level, or physiological measurement. Attempts by Fessel and Van Brundt (1972) and Brook and Stevenson (1970) found no significant correlation between process judgment and outcome as reflected by impairment at follow-up. Data are lacking as to what effect diagnosis has on outcome (Brook, 1973).

Standards for assessing quality processes are currently defined for individual patients, through statistical patterns of care by surgical team committees and/or utilization review committees. Standards are also established by professional organizations such as the American College of Surgeons, Commission on Hypertension, and the Joint Commission on Accreditation of Hospitals. Criteria and standards differ based on the expertise, time, setting, and preferences of the groups preparing them. This has prevented the utilization of criteria and standards in a uniform and systematic manner to evaluate medical care. The process approach to evaluation requires the specification of dimension, values and standards and an examination of how medicine is practiced (Donabedian, 1968). To assess process quality actual behaviors are compared with a set of model or criterion behaviors. Complexity of the structural components such as therapeutic setting, interrelationship of professionals, paucity of standards, policies, patient's health status, and assumptions of care are all related to the problem of process evaluation.

Process evaluation studies generally should contain socio-economic, psychological, or continuity and coordination management of health and illness or client-provider relationships. Unless these dimensions are included, the evaluated material presents an incomplete view of the total scope of process measures (Brook, 1973). The effect of physician-patient relationships on quality of process of care is unknown at this time but should be included in the study. Process studies are means oriented since it is through process evaluation

results that fees, utilization standards, expansions of services and promotions of personnel are based. Process evaluation focuses on the quality of things done and provides an inventory rather than an answer to the question, "What difference did the care make?" (Lewis, 1974). An assumption of the process approach to evaluation of care is that elements in the care process will result in better health status of the recipients of care. Yet, from the process studies reported to date, this assumption has not been validated.

Outcome--Provider Contribution

Outcome or end result evaluation is concerned with the impact of the diagnostic and therapeutic processes on patient welfare and patient status. Shapiro (1960) delineates outcome as "a measurable aspect of health status influenced by an element . . . of medical care." This includes what happens to the patient in terms of symptoms and disease, major activity, disability level, and satisfaction with care. Mortality, morbidity, length of hospital stay, number of visits to physicians, disability days are part of outcome yet this quantitative outcome data is insensitive to the quality of that care given (Kessner, Kaik, and Singer, 1973). The assumption is made that given similar cases better care should result in a shorter illness period, reduced incidence of death, and reduced pain and discomfort in the personal health aspects of the patient (Le Bow, 1974).

Outcome evaluation necessitates the definition of an objective or goal. Outcome goals are difficult to establish. In order to set such goals it is necessary to understand the natural course of each

illness including the duration of symptoms, the possibility of residual impairment and the effect of the therapeutic intervention on the disease. Further complicating the evaluation of outcome are the characteristics which accompany the patient and may impinge upon his outcome status. Socioeconomic and cultural factors may also be related to the outcome status. Such characteristics unrelated to the specific disease include age, sex, race, presence of other chronic conditions, and nutritional status. Thus, outcome studies may require long-term follow-up of patients to monitor the natural course of the disease process, but outcome studies also demand information about the intervening factors affecting the patient in order to construct measures which separate the impact of related factors from professional intervention factors. This adds to the complexity of outcome evaluation. Appraisal of outcomes of care or alterations in patient's health status is a powerful means for quality assurance. It represents appraisal of the results of the collective efforts of those involved in the delivery of care.

Despite the complexity and limitations, outcome by and large remains the ultimate validator of the effectiveness and quality of medical care (Donabedian, 1968). Outcome can aid in establishing operational and process objectives but does little in helping with day-to-day decision making and management of care. The long-held outcome goals of reducing morbidity and disability and preventing death are of little help in defining and specifying operational objectives. Outcome measures used today, such as cancer survival rates, are often limited to actual five years' survival rate but not

the quality of those five years or recurrence rate of the disease processes. Theoretically, it is assumed that effective outcome of care would result if medical practice and patient behavior converge for an episode of care, for long-term care, or for the prevention of disease. There are few data to support this. We do not know if a cause-and-effect relationship exists between the quality of process of care and outcome. There is a need to establish a relationship between the process care activities and outcome effect on the patient. The framework of this study will consider the outcome parameters of medical health status, functional status, patient's knowledge level, perception of health and care, and mortality. Each of these dimensions will be examined for an episode of lack of control for one chronic disease.

The preceding has been a discussion of the provider components of process and outcome. The following section will present the patient components of process and outcome. An important part of the process perspective of evaluation of ambulatory care is the patient's behavior that he brings to an episode of illness (see Figure 2). The next section will present a perspective on two important patient behaviors: the process component of compliance and the outcome component of knowledge and understanding. These are important dimensions to consider in an evaluation schema since the success of any medical therapy is dependent on the patient's participation in the recommended regimen.

Process--Patient Contribution

Compliance.--Patient's compliance with the medical regimen may reflect the extent to which he follows the provider's recommendations. As such, it is an important component of process evaluation. When an individual is ill and seeks attention, he will be given a variety of medical recommendations to follow. He may be advised to take certain medications on schedule, adjust his eating habits and conform to a therapeutic diet, discontinue use of alcohol and tobacco, or present himself for certain diagnosis. Such recommendations are called medical regimen. Some of these recommendations are more important to the well being of patients, while some disrupt the patient's life activities more than others. Added to this are the patient's own ideas concerning the relevance and importance of the regimen, the aspects of the regimen easily managed and parts they can safely ignore. Some recommendations may be followed carefully, and others rarely if at all. Studies suggest that at least one-third of the patients in most studies fail to comply with physician's orders (Davis, 1968). Peer compliance includes taking medications for the wrong reason, errors in dosage, and mistakes in timing or sequence.

Most literature does not relate physical conditions of patients as a criterion of patient compliance, since correspondence between medical regimen and state of health is not substantiated by research although patients with long-term illnesses are more compliant if given careful instructions. Some investigators (Preston, 1964) speculate that recurrent episodes of illness with chronic condition may be

explained by defection from therapy. Patients with prolonged conditions and prolonged therapy are clearly prone to lapses in compliance, especially when treatment is prophylactic or suppressive, when the condition is mild or asymptomatic or when the consequences of stopping therapy are delayed (Blackwell, 1973; Brook et al., 1971; Bonnar, Goldberg, and Smith, 1969).

The physician's relationship with and attitude toward the patient can have a powerful consequence on compliance as evidenced from compliance rates in private practice and clinics (Jackson and Cooper, 1966) and family physician versus an unknown physician (Charney and Bynum, 1967). Several studies have shown that compliance with therapeutic regimen was two times higher when the mother or patient was satisfied with the initial contact, when the continued care was perceived as having their expectations of care being met, and when it was thought that the physician understood the complaint for which the care was being sought (Korsch, Francis, and Morris, 1968; Charney, 1967).

Mild threat and continuity over time with the patient-doctor relationship seem to exert an effect on compliance (Marston, 1970). When physicians fail to clearly convey the significance of a regimen to the patient, there is a reciprocal failure on the part of the patient to comply. A large number of therapeutic recommendations to follow has been associated with an increased noncompliance rate (Francis, Korsch, and Morris, 1969). Patients chose to follow that regimen which was least difficult and necessitated the least personal habit change.

There are conflicting data on the relationship between the patient's level of knowledge and understanding of his medical regimen and his compliance level of the regimen (Williams, 1967; Starfield, 1972; Mohler, 1955). Blackwell (1973) suggests that an important contribution to compliance is the understanding a patient has of illness, the need for treatment and the likely consequences of both. It is important that the patient understand his illness and the consequences so his therapeutic regimen appears logical and necessary to him. For example, it is important to explain the expected action and possible side effects of medications and to distinguish between those of infrequent and unimportant concern and those that demand frequent and immediate attention.

Incentives for compliance may be related to value-expectancy concepts. Studies indicate that patient behavior to follow a recommended regime is related to the value and expectations the patient has for the outcome. If the patient perceives that following instructions will affect the disease, he may choose to follow them. Conversely, if he perceives that his disease cannot be affected by anything, he may not comply. Further, the extent to which a disease interferes with his own goals affects the patient compliance level.

For the patient compliance to occur there must be complementary expectations of patients and physicians. Patients must believe they ought to carry out orders. Patients also should have an orientation to the "goal" that will result if they follow the regimen such as "improving or maintaining the patient's state of health."

Compliance behavior is particularly relevant to ambulatory patients because they are often treated for their chronic disorder at home with medications. The patient compliance with the physician's recommendations may be vital to disease control and, as such, facilitates the effectiveness of the prescribed regimen on the patient outcome. For example, if the patient takes the medication, his blood pressure may be brought under control. If, however, he chooses not to take it, physician activities alone will not have an effect on outcome. Compliance will be an important dimension of process for the evaluation framework of this study.

Outcome--Patient Status

Perception and satisfaction with health status and care.--Another important patient aspect of patient outcome evaluation is the patient's perception of health and care. Although this dimension is often grouped with process or outcome of care, this labeling is an oversimplification, especially in ambulatory care. The patient's perception is more complex than either process or outcome evaluation, but fits best with outcome. The perceptions are an outcome of the provider relationships and have an effect on the compliance of the patient.

The patient's own ideas concerning the relevance of a regimen to patient care improvement may affect his perception and satisfaction with care, as well as how the patient perceives the illness may affect normal daily activities. A positive attitude toward the therapeutic regimen has been associated with patient outcome (Sheard, 1963).

Korsch, while studying the relationship of patient satisfaction with expectations, found that patients are more likely to follow through with medical recommendations when their expectations of the visit are met. Patients were concerned that physicians understand their anxiety, are interested in them as individuals, are thorough, spend time with them, and ultimately, care whether or not their conditions improve. Failure to confirm an expectation, to learn the cause of a disorder, to receive an x-ray, injection, cure, or medication has been related to increased patient satisfaction levels. When parents were dissatisfied with the visit, they perceived expectations as unmet and were less likely to follow medical recommendations (Korsch, Francis, and Morris, 1967).

Overall patient satisfaction is thought to be related to the explanations and information received by patients. Explanations about the disease process as well as practical instructions for reducing or eliminating symptoms have been found to be effective in motivating patients to seek medical care as well as to follow instructions. This should lead to improved results and positive patient perception (Davis, 1968; Marston, 1970). Understanding the purpose of treatment was found by Mohler (1955) to be related to compliance with the medication regimen. Blackwell (1973) suggests that it is important for patients to understand illness, the need for treatment, and the consequences of both illness and treatment for compliance and satisfaction with care.

Although health care literature acknowledges the psychological aspects of health, classical evaluation literature fails to include these aspects in their evaluation instruments and data collection.

Hulka, Zyzanski, and Cassel (1970) have presented one of the few studies which develop the attitudinal and perceptual level of patients as an important dimension to evaluation of care.

They also suggest "patients' attitudes and physicians' awareness of these attitudes as a criterion measure in a model for the evaluation of primary medical care." They assume that communication from patient to physician is a desirable element in the "care" function of medicine.

Hulka, Kupper, and Cassel (1975) have developed a scale to measure attitudes toward physicians and primary medical care. This approach was used to determine attitudes toward professional competence of physicians, personal qualities of physicians and the cost/convenience of care. An attempt was made to assess patient's perceptions in relation to physician's current knowledge, training, and judgment regarding diagnosis and treatment. The concern for perceptions and attitude dimension looks at how the physician manifests an interest in the patient as a person opposed to merely looking at a disease process. It is suggested that these factors provide evidence of the effectiveness of patient attitudes and expectations in fostering better doctor-patient communication and contribute to compliance with medical advice (Francis, Korsh, and Morris, 1969; Reader, Pratt, and Mudd, 1957).

Another major methodological concern about perception of care is the extent to which patient perceptions accurately reflect care given. The only way to determine the validity of these data would be to compare perception with other measures and sources of measures of care such as structure, process, or outcome.

Patient perception and satisfaction are seldom included as components of outcome evaluation. Since the patient's perception will have an impact on return for follow-up medical care and extent of compliance with the medical regimen prescribed, perception is a necessary component of the evaluation system. Knowledge and understanding are also vital outcome components and will now be discussed.

Knowledge and understanding of disease and therapeutic approach.--Effective medical care for ambulatory patients with chronic diseases requires that the patient has a knowledge and understanding of the disease process, risks of untreated hypertensions, benefits of treatment and information about drugs (Gifford, 1974; Finnerty, 1974). Such knowledge enables patients to plan and alter their lifestyles. In chronic and long-term illnesses patients must be a participant in their care. They need to know about health management, prevention, and symptoms. Compliance with physician recommendations appears to be related to patient knowledge. It is assumed that the more a patient knows about his disease and regimen, the better he will follow physician recommendations and hence result in an improvement in health status. Williams (1967), Elling (1960), and Heinzelman (1962) report a positive correlation between knowledge and the degree to which patients followed a therapeutic medical regimen. Starfield (1972), however, found that it was not necessary to induce a change in understanding of a disease process to gain acceptance of a new therapeutic regimen.

Hernandez and Hackett (1962) report that patients being treated for recurrent ulcers who said they did not understand the reason for

treatment and were critical toward physicians were less likely to comply with regime. Roth (1960) suggests that patients affected with ulcers hold beliefs about the course of their illness which may limit the kinds of treatment these patients are willing to undertake. It appears, then, that only knowledge of illness and therapy is not enough motivation for patients to follow a regimen. More explanation and presentation of advice in a noncomplex manner may affect this motivation.

Specific explanations and instructions given to a patient seem to be of consequence to the following of a regimen. Nineteen percent of the patients in one study reported they did not take medications because they did not understand the purpose of treatment (Mohler, 1955). The most important contribution to compliance is the understanding a patient has of illness, the need for treatment, and the likely consequences of both (Blackwell, 1973). Prescriptions, for example, should be explained and the patient should be encouraged to ask questions. It is important that the patient understand his illness and the consequences so his therapeutic regimen appears logical and necessary to him. With medications, for example, it is important to explain the expected action and possible side effects of medications and to distinguish between those of frequent and unimportant concern and those that demand immediate and serious attention. This was considered an important outcome dimension to include in an evaluation model.

Summary

This evaluative model for describing the quality of patient care relates three dimensions of process (activities) to patient outcomes (results). The first process dimension focuses on the activities of the physician in arriving at a definition of patients' problems, i.e., the diagnoses. The second dimension describes the therapeutic actions taken by the physician to manage the problem or disease process. The third dimension assesses the compliance level with the physicians' prescriptions for management. The effect of these three process activities on patients' medical status are then examined.

In this model, quality of care is viewed as a process which effects a state of health (outcome). The three activities described above will be measured and compared against accepted performance norms to determine if activities which compare most closely with the norms result in more desirable outcomes. Second, the model suggests an examination of which set of activities has the greatest effect on the observed outcomes.

The outcomes examined in this study are functional status, medical health status, patients' perceptions of health and care, and patients' knowledge of disease and therapeutic regime. See Figure 3 for schematic presentation of the conceptual framework.

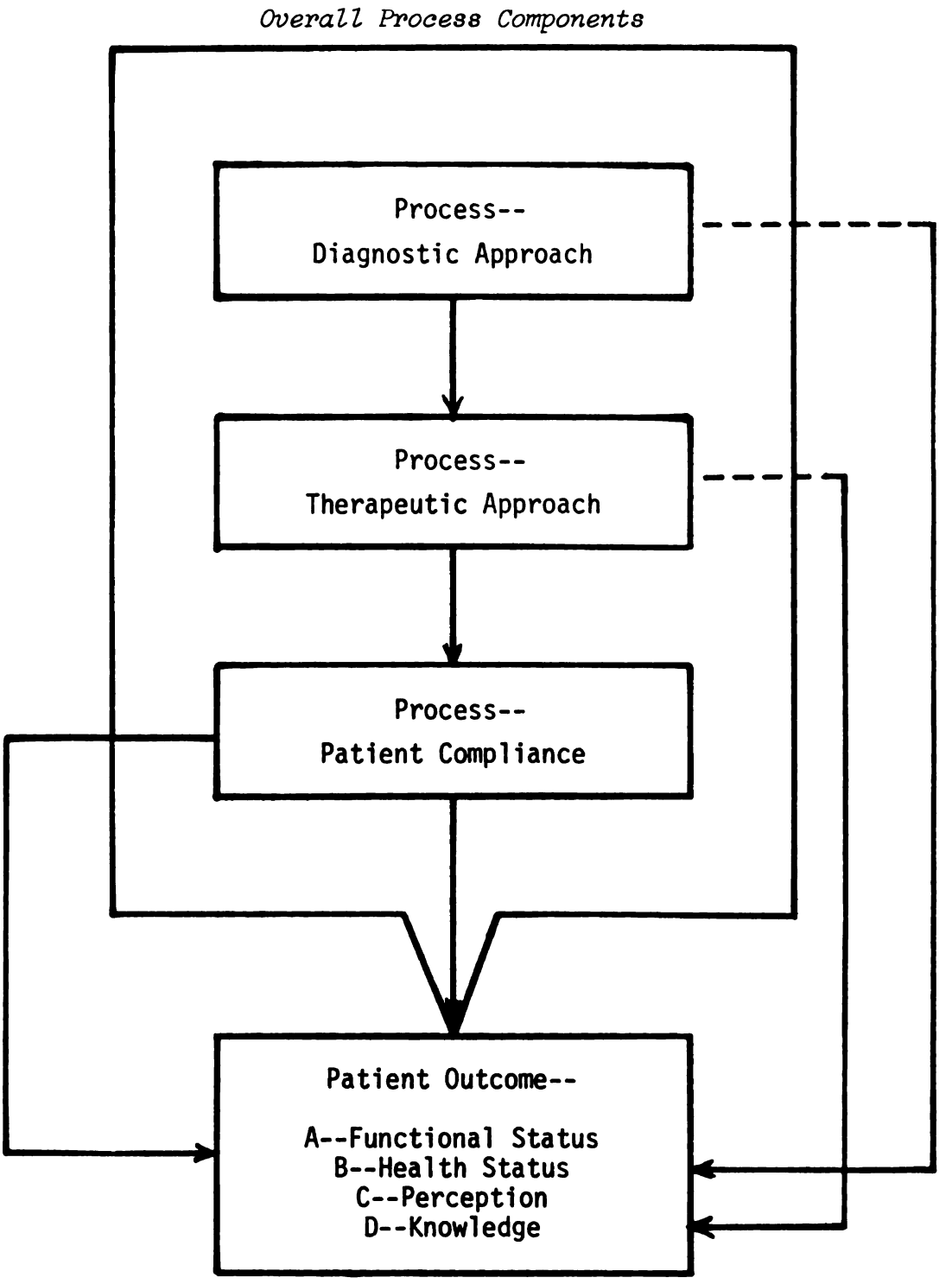


Figure 3. Schematic Presentation of Conceptual Framework.

CHAPTER III

REVIEW OF LITERATURE

Introduction

A review of literature on evaluation of patient care reveals a wide variety of approaches. Even more varied and confusing are the results obtained. Lack of comprehensive and systematic approach as well as a lack of building upon the work of others may be the prime factor for this confusion and variation. A review of existing studies is vital to the understanding of the process and outcome components of patient care evaluation.

This review of literature will focus on representative approaches, methods used, and results obtained in assessing the quality of care where process or outcome dimensions were used. The literature review will have the following objectives:

- To review major or classic studies and papers in evaluation of process and outcome dimensions of medical care.
- To review those process and outcome dimensions which have been included in evaluation of care studies.

In reviewing the literature, it was found that most studies measured the *process* of medical care. Many of the outcome studies have employed gross assessment of dimension such as mortality or

unnecessary operations. Activity or functional assessments of outcomes are almost nonexistent, as are studies that examine the number and duration of symptoms and changes in medical health status. Even fewer studies relate both process and outcome as an assessment of medical care. Most studies reviewed collected only process data from the medical record and few examined outcomes through direct patient interviews or direct patient follow-up.

McKillop (1974) indicates that there is agreement that we should evaluate the quality of health care. He suggests that agreement evaporates when we discuss *concepts* of assessing care and *means* of assessing care. He suggests that there is general agreement on approaches to assessing quality of care. Everyone concedes that the four main approaches are: (1) formulation of selected standards for adequate care, (2) determination of components of the medical care process, (3) evaluation of clinical performance by experts, and (4) indexing the effects of care on patients. McKillop indicates, however, that there is no general agreement about the content of these four approaches.

The evaluation of care is limited when the outcome is measured not by prevention, reduction, or postponement of mortality but by indices concerned with morbidity or disability, functional capacity, or--vaguer still--with the state of well-being (Falk et al., 1967). It is likely that for a long time to come there will be an almost infinite number of situations in which the method of outcome evaluation may be inapplicable because of the variety, complexity, and subtlety of

the variables. This points up the difficulty of measuring quality of care under certain conditions and the impossibility of developing a single measuring device that will be applicable in all situations, settings, or disease processes.

Traditionally, an indicator used to measure health care has been an activity count of selected parameters such as the quantity of health services, number of physicians and nurses, number of hospital beds, utilization rates, hospital care, dental services, physical examinations, total physician visits, usual source of care, and immunizations. Hospital care may be measured by cases, admissions, days of care, and/or diagnostic categories (Densen, 1969). The National Health Survey makes extensive use of morbidity indicators. These reports present data on the populations' acute and chronic conditions, days lost from work and school, and activity limitations. These counts are based on the assumptions that the number of services provided and personnel and facilities available are somehow related to health status. Activity counts are quantitative indicators--and do not account for "quality" medical care, but can be useful to program planning (Morehead, 1970; Tenny et al., 1974).

Early definitions of outcomes of care as defined by Codman (1916) were related to survival, extent to which the disease was cured or arrested, the complications that resulted from care as well as the effect of treatment on the relief of patients' symptoms. Elinson (1972) suggests outcomes be measured in terms of death, disease, social and physical dependability, discomfort, and dissatisfaction. Mortality

and morbidity have been the traditional measures of health. Death is the well-defined and recorded event that has had great value as an indicator.

Goldsmith (1972) suggests:

> Morbidity is conceptually and pragmatically more difficult to use as a health status indicator than mortality. Conceptually, one encounters the problems of definition and classification. When is a person sick? How sick is sick? . . . How can the different morbid states be measured? How can assurances be built into the system so that a measurement taken by one person on one day is comparable to another's measurement on a different day? [pp. 210-212].

With the recent focus on more specific evaluation, "quality" factors have been stressed. There has been a proliferation of studies focusing on process or outcome dimensions of health care services. Few studies deal with both dimensions. The following sections will present a review of the most significant works on process and outcomes of care.

In the final section there will be a brief review of studies that examine both process and outcome dimensions of patient care.

Process Studies

Process dimensions focus on the activities of the practitioner and practices utilized. Process factors, however, assume a predictable relationship between an activity and a desirable patient outcome. The consequences of practice activities as they relate to overall effectiveness of care received, however, are not known or well documented in the literature.

Quality of service (process) examines activities actually rendered rather than the effect of that service on the outcome of a patient or total population. Quality measurement based on the process approach rests on the assumption that at any point there is a consensus among acknowledged experts on what constitutes "good" or "high-quality" health care and studies examine the extent to which this is practiced. However, until recently this criterion has been implicit. The task of the process approach is to call upon an expert observer to examine, either directly through observation or more often indirectly through medical record audit, the services actually provided in a program and to make judgments on the degree to which the services coincide with these accepted implicit standards of merit. Rosenfeld (1957) and Lembcke (1967) have used the medical audit technique widely. The widely publicized studies of quality of care of the Teamster's Union under a health insurance plan used an audit approach (Daily and Morehead, 1956; Shapiro et al., 1960, 1967; Morehead, 1967). Other investigations have been made concerning rates of surgical procedures (appendectomy and hysterectomy) associated with nonpathological findings or proportions of post-mortems that did not confirm the original diagnosis (Lembcke, 1952; Lewis et al., 1969).

Process studies have been done primarily through medical record review by Makover (1951), Eisele and Hoffman (1956), Peterson et al. (1956), Blankenhorn (1957), Rosenfeld (1957), Huntley et al. (1961), Trussel et al. (1962), Clute (1963), Kroeger et al. (1965), Medalie and Mann (1965), Muller (1965), Stapleton (1965), Beaumont et al. (1967),

Gonnella et al. (1970), Morehead (1970), Morehead, Donaldson, and Seravalli (1970), Schonfeld (1970), and Dreyfus et al (1971).

Most of these studies have no predetermined explicit criteria upon which to base their evaluation of the care process. Most often, no level of acceptable or nonacceptable care has been specified, thus leaving the decision up to the reader or individual preferences of the researcher to decide on "goodness" or "quality" of care. From the review of process studies that follow, it can be ascertained that there are few data and few similarities of studies on which evaluation methodology models could be built.

Two process studies examined the ability of judges to determine quality of care. Kroeger et al. (1965) studied internists' office practice in New York by reviewing medical records. This study compared the ability of physicians and nonphysicians to abstract data from medical records and assess the quality of care from records. Of the internists assessed, 67 percent had kept records usable to be reviewed. Worksheets were used to abstract data and quality of care was judged from excellent to poor. This study found that board certification of the physician did not distinguish good medical record keepers from poor ones.

Denton et al. (1967) compared two methods for judging the quality of physician care administered in hospitals. He used physician opinion and hospital statistical data. Physicians were asked to indicate on a scale of "1" to "5" the quality of care given within the hospital. A positive correlation was found between physician judgment

regarding quality and approved residency programs, number of beds, and average length of hospital stay. Hospital statistics partially predicted the quality of care as judged by the physicians.

Muller (1965) was one of the few researchers to look at appropriateness of process of care components. He audited inpatient and outpatient records in two hospitals to determine appropriateness of drug prescribing pattern. This study revealed that criticisms of prescriptions were not valid when the record was reviewed in *toto*, as compared to only looking at Professional Activities Survey. This study indicated an inadequateness of gross quantitative measures of process such as the activity surveys.

Several process studies compared how physicians stated patient care situations should be managed and how these physicians practiced in actual situations.

Goran, Williamson, and Gonnella (1973) in a study to evaluate practice problems with how clinic physicians did in actual practice, found a discrepancy in how they functioned in problem situations compared to what they recorded in actual practice situations, indicating a need for more than simulation as a measure of process activities.

Hare and Barnoon (1973) asked practicing internists in different regions of the United States to generate criteria for diagnosis and management of certain conditions. Correlations of criteria selected were high. However, when the internists were asked to report their own process activities for these groups of patients, there was little or no correlation between the physician's actual practice and his stated theoretical approach to the problem.

Many of the process research studies examined diagnostic activities of the physician as an indicator of quality of care. These activities were used to determine effectiveness of care.

Huntley et al. (1961), Clark et al. (1961), and Starfield and Scheff (1972) used the process approach to determine effectiveness of physician activities. Huntley et al. reviewed medical records to evaluate medical process by sampling completeness of patient work-up. He sampled 20 percent of 600 new patient work-ups in a medical clinic. He identified the proportion of abnormalities that were not followed up with medical therapy. Results of his study indicated that 15 percent of the routine laboratory tests were not done and during the first year of clinic operation 34 percent of the abnormal laboratory results were not followed up by medical practitioners.

Clark et al. (1961) and Lashoff and Turner (1964) were unable to find recorded diagnosis in more than three-fourths of abnormal hemoglobin values, two-hour post-prandial blood glucose test results or urine sediment. Starfield and Scheff (1972) followed records of abnormal hemoglobins in children and youth projects. Patients were interviewed at the end of the follow-up period to determine if diagnosis and therapy had been instituted. They found that in 45 percent of the cases low hemoglobin levels were not recognized, and 42 percent had therapy started, but eight had not completed it. At the end of the follow-up, 50 percent still had low hemoglobin levels. These studies point out the use of laboratory tests as indicators of the process component to evaluate care.

Helfer (1967) examined the quality of patient care of two interns in a pediatric emergency room. Staff pediatrician criteria were used to determine proficiency and efficiency of the interns' histories and physical examinations documented in patient records. Helfer found that diagnosis was appropriate in 95 percent of the patients, treatment appropriate in 79 percent of the patients, and follow-up was appropriate in 38 percent of the patients. No level of acceptable criteria were set. Scores were determined by noting the number of items recorded, divided by the total number of items required.

Rosenfeld (1957) examined quality of patient care via medical record audit with use of general criteria guidelines. Records were evaluated in medicine, surgery, and gynecology by two consultants in each specialty. About 50 percent of the care was judged fair to poor in two teaching hospitals and 75 percent was judged as fair to poor by implicit criteria in the two nonteaching hospitals, thus suggesting better health care delivery in teaching centers.

Schonfeld (1970) interviewed physicians to determine estimates of what constitutes quality of medical care for selected disease entities. These estimates formed the indices to be used to determine the quality of care. Examination of medical records to determine the completeness of medical history and physical examination as well as length of stay and number of laboratory tests ordered was conducted. Results showed that teaching hospitals had more complete history and physical, more laboratory tests, and shorter hospital stays. The

study also found agreement in quality of medical process among diverse physicians, study team, an advisory committee, and internists.

Eisele and Hoffman (1956) evaluated the hospital practice of internal medicine in 15 hospitals using implicit process criteria on individual process parameters. This study examined the justification of treatment of appendicitis, diabetes, and pneumonia. Results of the study revealed that treated diabetcis were treated without fasting blood sugar levels and pneumonia was diagnosed without chest x-rays. Positive pathological findings of appendicitis varied widely among the hospitals, ranging from 18 to 68 percent.

Frohlich et al. (1971) retrospectively evaluated records for quality of the diagnostic process of 200 hypertensive patients. He found a lack of a recorded therapeutic plan for 108 patients who had blood pressure readings of 160 mm. Hg. systolic or 100 mm. Hg. diastolic. Fewer than 50 percent of the patients had diagnostic tests to investigate this elevation of blood pressure even though hypertension was the primary diagnosis.

Despite recognition of the value of elevated blood pressure in the morbidity and mortality of hypertensive patients, physicians ignored it in the process of their care. Further, the patient admitted for hypertension did not have adequate recorded evaluation of standard hypertension diagnostic tests. Thirty-five percent of the patients had no recorded evaluation of optic fundi, 8 percent had no evaluation of abdominal bruits, 86 percent had no record of femoral pulse, and 90 percent had no mention of extra heart sounds. Physicians did not

rule out renal disorders as a cause of hypertension in 70 percent of the patients and serum potassium levels were not carried out on 50 percent of the patients to rule out aldosteronism as a cause of hypertension. Thus, in this study, the specific and differential cause of severity of hypertension was absent in patient records (Frohlich et al., 1971).

Lembcke (1956) examined gynecological surgical rates and found an excess of between 25 to 100 percent of unneeded surgery in some areas. Lembcke developed criteria for gynecological surgery and applied it to one setting. He allowed for a standard degree of variance in compliance. He suggests that this allowed for clinical judgment and variation in severity of illness. The use of the criteria resulted in a decrease of 600 major surgeries in one year with an increase in justifiable operations from 30 to 80 percent.

Gonnella et al. (1970) and Morehead (1970) conducted more extensive process evaluation studies. Gonella et al. (1970) used a process approach to examine the management of urinary tract infections in one clinic. They compared the status of the patient with that described in the record. New patients were screened to ascertain symptoms of urinary infections. A urine culture was taken. Three months later a follow-up was conducted by the study team to determine if the physician providing care had carefully investigated urinary tract infections and obtained necessary data from the patient. He found 108 of the 131 patients presented some indication of urinary tract disturbance. The actual treating physician recorded significant data

on 31 of the 108 patients with a positive history and only 6 of the 18 patients with positive urine cultures were detected. Gonnella et al. indicate that there is a deficiency in gathering historical data, appropriate cues, and following up the patient cues to order diagnostic tests. This study also points out that judging morbidity or analysis of diagnostic and therapeutic methods is accurate only if the proper diagnosis is made. Establishing the correct diagnosis is essential before crediting the doctor for correctly treating the disease. Gonnella et al. also pointed out that physician knowledge, as evidenced from written examination varies widely with actual practice.

Morehead (1970) evaluated, via record review, the quality of medical care in 24 Office of Economic Opportunity Neighborhood Health Centers to determine the extent to which selected criteria were met in fields of adult medicine, infant care, and obstetrical care. Specific findings included that baseline audits revealed lack of routine hemoglobin and urinalysis in children while obstetrical services lack recording information about delivery period or method of contraception of the patients. General findings based on audit criteria which included history, physical exam, diagnostic management, treatment, and follow-up, revealed that program design, patient volume, medical school evaluation, and administrative expertise were major factors in centers with high performance ratings on quality dimensions. Again, in this study, the process criteria were implicit without an acceptable level of performance.

As has been indicated previously, process studies have been conducted by data collection from the medical record. Few studies have actually examined services by direct observation. Two early well-known studies did use the direct approach. Clute (1963) and Peterson et al. (1965) examined general practitioners through direct observation by specialists. Results were variable due to methodological problems and reluctance on the part of physicians to participate.

From the review of literature of the process evaluation studies, one can note that most of the data used in the studies have been collected retrospectively from medical records (Rosenfeld, 1957; Trussel et al., 1962; Kroeger et al., 1965; Muller, 1965; Lembcke, 1967; Dreyfus et al., 1971; Gonnella et al., 1970; Morehead, 1970; Frohlich et al., 1971). Only the studies of Clute (1963) and Peterson et al. (1965) used direct observations as a method of data collection. Schonfeld et al. (1968) and Shonfeld (1970) used a detailed, structured questionnaire to ask physicians to arrive at estimates of what constitutes good medical care.

These studies of the process of care have not had specific predetermined and agreed-upon explicit criteria to use when evaluating the quality of medical care. Only the studies of Helfer (1967), Gonnella et al. (1970), Morehead (1970), and Dreyfus et al. (1971), used explicit criteria to evaluate care as either acceptable or unacceptable. The other studies have allowed the judges to use their own nonsystematic implicit criteria and impressions to determine the adequacy and acceptability of care (Eisele and Hoffman, 1956;

Rosenfeld, 1957; Kroeger et al., 1965, Muller, 1965; Beaumont et al., 1967). The lack of explicit criteria permits different rules and guidelines that interfere with comparison across settings.

Few studies have actually compared data based on actual observations or direct patient contact to determine medical and functional status. This prevents the comparison of data from medical records with actual patient status to determine if the patient received the appropriate care. In addition, few studies follow the patients to determine the effect of the process on patient outcome (Eisele and Hoffman, 1956; Huntley et al., 1961; Helfer, 1967; Lashoff and Turner, 1964; Schonfeld, 1970; Frohlich et al., 1971). These deficiencies in the evaluation of care have pointed out the need of patient status prior to initiating therapeutic process and then precise evaluation of patient status at the end of an episode of illness. Because process studies did not seem to meet the total needs for evaluation schema, outcome studies have developed.

Outcome Studies

A health delivery program may have as its immediate goal the provision of certain services (for example, prenatal examinations or intensive care of patients with coronary attacks), but the long-term goal is to improve the health status outcome of the patient. This outcome may be in medical health status, functional status, comfort, satisfaction, or knowledge.

Evaluative studies of patient outcomes are illustrated by comparisons of the membership of the Health Insurance Plan of Greater New York with the rest of the New York population, matched for socio-demographic characteristics. In the early 1950's, Shapiro et al. (1960) in an important study showed lower perinatal mortality in a population eligible for this prepaid group practice program, and in the 1960's (Shapiro et al., 1967), a study showed a lower death rate among indigent aged (old-age assistance recipients) enrolled in the group plan, compared in both instances with matched populations entitled to traditional medical care. Even this gross comparison measure provides a clue for more searching types of measurement of the effects of the systems of health service at the deepest level of evaluation, namely, the outcome of health status.

Health status outcomes have also been applied in comparative studies of populations actually served in varying medical settings; most frequently, in hospitals of different types. Thompson et al. (1968) and colleagues compared perinatal mortality as an indicator of obstetrical care in two U.S. Air Force hospitals. Roemer (1971) found lower post-operative deaths for certain surgical procedures in large, compared with small, hospitals in Saskatchewan.

Although mortality data still have a role in the broad measure of quality, there are many other measures of the ultimate outcome of a health service program. Prepaid group practice plans desiring to prove the benefit of their health care system have probably stimulated the focus on broader outcome dimensions. These outcome measures may be

applied either to total populations eligible for care or to persons definitely served by the program. A more sensitive outcome measure involves the various measures of recovery from illness or days of disability, such as absenteeism from work or school, functional disabi disability, social, restricted activity days, or days in bed (Ellwood, 1966; Shapiro et al., 1967; Williams et al., 1967; Morehead, 1970; Sullivan, 1971).

Health status outcomes may be reflected in measurements of the capacities of persons to function, as applied by Katz (1962) and his colleagues in studies of rehabilitation of the aged sick. Katz was one of the early users of outcome data by determining the application of function and Activity of Daily Living Scale, an explicit outcome criteria, to patients with a fractured hip. One group received rehabilitation and the other did not. Using the Activity of Daily Living Scale, Katz found the rehabilitation group to rate significantly higher on the functional scale than those without rehabilitation.

Several outcome studies focus on mortality or removal of a diseased organ in surgery (Lee, Morrison, and Morris, 1957; Shapiro et al., 1960; Williams et al., 1967). Data obtained from 3,000 autopsies at Massachusetts General were compared with physician impressions of cause of death. Results found an accuracy rate of 95 percent for diabetics and only 16 percent for acute nephritis.

Restricted activity days, bed disability days, and school loss days are other important dimensions in outcome studies. Mortality still plays a role in the broad measure of quality. Recent impetus to

evaluation of outcomes has been the federal government in evaluating the effectiveness of programs such as Medicare, Medicaid, and Emergency Care Systems (Makover, 1970; Morehead, 1970).

After auditing records, Lembcke (1952) found that in a three-year period acute appendices by tissue exam positive pathology rose from 55 to 81 percent with fewer ruptures and complications; resulting hysterectomy complications fell from 25 to 13 percent; and appropriate antibiotic use improved from 30 to 60 percent. Thus, it would appear that audit may serve as a useful evaluative tool to improve patient care if results are fed back to the practitioner.

In two follow-up studies, the results obtained were deviant from physician projected outcome. Williamson (1970) found mortality of hypertension patients one year from diagnosis to be two times the projected rate of the physician studying the record.

Lee, Morrison, and Morris (1957) examined mortality rates for appendicitis, peptic ulcer, and hyperplasia of prostate. They compared teaching with nonteaching hospitals without an acceptable criterion level and showed the mortality rate to be higher in nonteaching medical centers. Brook and Stevenson (1970) found that of 75 acute coronary patients, 37 percent of the 46 living patients were not working at the end of a year, despite the physician's projection that only 20 percent should be unable to be productive. These results would suggest a need for follow-up to determine the cause for this wide discrepancy.

In another study, Brook and Stevenson (1970) followed 141 patients in an emergency department through a nonemergency radiological

examination. They looked at quality of follow-up care of patients by chart review and patient interview to review the medical service and emergency setting. Forty-five percent of the patients had insufficient work-up to determine if they were well or ill. Fifteen percent with confirmed abnormal findings had no medical treatment. It was found that while 70 percent of the patients on a medical service received effective care, only 27 percent of the patients in the emergency group received effective care.

Sanazaro and Williamson (1968) using the critical incident technique asked physicians to recall episodes of effective and ineffective patient care. One-fourth of the identified ineffective activities were those where death occurred and another 25 percent were episodes in which there was an exacerbation of physical abnormalities. Effective patient care episodes selected were those in which there was increased patient functioning and relief of physical symptoms. They also suggest that the manner in which physicians deal with patient attitudes and patient education may have a valuable contribution to effective and ineffective physician performance. The courses of 403 consecutively discharged patients from a teaching hospital were studied to determine their medical care after hospitalization and to evaluate the effectiveness. Outcome measures used were symptomotology, functional disability, and death. Data were obtained on 341 of the 363 patients that were alive six months after discharge. Thirty percent of the patients had received care rated adequate. Outcome data indicated that 46 percent of the patients experienced decreased functional capacity. Forty patients had died; of those alive and

interviewed, 27 percent experienced no change or an increase in symptoms. Thirty-seven percent of the patients experienced a decrease in ability to perform the major activity and 30 percent had impaired ambulatory function. For 39 of these patients quality of outcome was judged to be due to inadequate medical care.

Fessel and Van Brunt (1972) through a review of records, studied outcome of patients with appendicitis and myocardial infarction. Records were reviewed in three hospitals of patients with the diagnosis of acute appendicitis. Findings revealed considerable disparity in the frequency of documentation of commonly sought symptoms or signs of this condition; yet at each hospital the disease was diagnosed with the same accuracy. Similarly, recorded data of patients with acute myocardial infarction showed no significant relationship to various post-hospitalization outcomes, including length of time lost from work, occurrences of angina, congestive heart failure, myocardial reinfarct and death. The findings show that neither quantity nor quality of recorded data was related to the outcomes of either acute appendicitis or myocardial infarction. They suggest that a valid medical audit should also include measures of *actual* outcomes of the patient's illness by direct patient contact.

Fessel and Van Brunt (1972) suggest outcomes that may be evaluated in many common conditions included the following: the number of days spent in the hospital; histological confirmation of the asserted diagnosis; numbers and types of post-operative complications in the hospital; complications after leaving the hospital;

later recurrences of conditions thought to have been treated definitively; long-term and short-term survival rates; elapsed time before returning to work; and improvement in functional status in the case of chronic disease. Finally, they suggest that some measure of the patient satisfaction with management and a comparison of the associated costs are necessary as a measure of quality.

Outcome studies have focused on gross measures such as mortality, morbidity, and nonpathological findings in surgical specimens. From these studies results could be compared across institutional settings and communities (Lembcke, 1952; Shapiro, 1958; Shapiro, 1967; Thompson et al., 1968). More recently, outcome studies have focused on functional disability and health status by examining days lost from work, bed disability, and interference with activities of daily living. In addition, some studies have followed patient outcomes over long periods of time to determine the complication rate, disability and institutional confinement and mortality rates (Katz, Jacobson, and Jalfee, 1962; Ellwood, 1966; Shapiro, 1967; Williamson, Alexander, and Miller, 1968; Morehead, Donaldson, and Seravalli, 1970; Brook and Stevenson, 1970; Sullivan, 1966; Fessel and Van Brunt, 1972). Many of these outcome studies, however, still do not use explicit criteria of acceptable and unacceptable outcome levels.

Outcome studies focus on the achievement of patient oriented objectives. The results of this can be dangerously sterile, when process is not also examined, one cannot know what caused the favorable or unfavorable outcomes (Fessel and Van Brunt, 1972). Outcome may be

unrelated to the recorded process of care because the wrong things were done, even though the right result has ensued. But outcome may be worse than expected, even though the right things were done at the right time and recorded in the patient's chart.

Cayten (1973) writes that the use of end result (outcome) studies as indicators of the quality of medical care is based on the assumption that good results are brought about by good care. Many other variables including the patient's prior health status and his degree of cooperation may affect the end result. Only an evaluation that encompasses both process and outcome has the potential for impact on the quality of care in order to know the extent that achievement can be attributed to the activities of the medical care program.

Some combined process-outcome studies have evolved in the past few years. A brief review of these efforts will follow.

Combined Process and Outcome Studies

Recent studies focus has been placed on the process-related to outcome-type of evaluation. With this approach, it is necessary to develop criteria and methods for measuring process and outcome dimensions. Generally this approach has been applied to a group of patients for a specific type of disease process such as hypertension or urinary tract infections. Most of these studies are recent, and some are still at the theoretical stage of development. Few study results are available at this time.

Williamson (1971) presents an interesting model for evaluating quality of care. This model includes diagnostic outcomes and processes, and therapeutic outcomes and processes. The diagnostic outcome includes data needed to determine specific therapy while processes are those procedures needed to furnish the facts. Therapeutic outcome is the health status of a patient at a given period following treatment while the process is planning, implementing, and evaluating the therapy. Williamson points out that to implement this model, outcome criteria would be developed and then measured. Williamson's model examines diagnostic and therapeutic outcomes routinely and addresses therapeutic and diagnostic process only if outcomes do not meet or match accepted standards and predicted outcomes. He indicates that outcome is difficult to predict since it is dependent upon severity of illness, age, social and environmental, and economic conditions.

Brook (1973) modified Williamson's model and defines problems as symptoms or symptom complexes. He then seeks from a group of patients the percentage having a diagnosis as supported by minimum standards. He uses the medical record along with the patient status to determine outcome. Thus, he is able to combine both the process and outcome measures of care.

Sanazaro and Williamson (1968) used a modification of the critical-incident technique applied to a selected group of internists engaged in the full-time private practice of medicine to determine categories of patient outcomes. They say,

> The comprehensive description of categories of outcomes is proposed as a point of departure for developing specific criteria and techniques for validating current professional judgments of what constitutes effective performance by an internist. Further prospective empirical studies are required to determine whether the classification and its future modifications can provide an index for assessing patient care objectively and reliably [p. 129].

From the study they defined critical incidents in two categories--patient end results and process outcomes including longevity, physical abnormalities, physical symptoms, and individual function. Process outcomes were delineated to include attitude toward physician, understanding the condition, care, compliance, risks, hospitalization, cost, and general improvement.

In summary, studies by Sanazaro and Williamson (1968), Williamson (1971) and Brook (1973) reflect a more comprehensive approach to patient care evaluation through the use of conceptual and methodological perspectives rather than mere collection of data to answer a question about the quality of care.

Kessner, Kaik, and Singer (1973) developed a method for evaluation of quality of care based on the tracer concept. Brook discusses the tracer methodology indicating that tracers are discrete identifiable health problems each of which helps explain how the health system works. Brook says that a set of tracers are selected so that the ability to understand the health delivery system is enhanced.

The tracer approach to quality of care is the selection of a condition or disease that has significant functional impact, is relatively well-defined, can be easily diagnosed, occurs frequently, requires much care, has effective therapy and whose epidemiology can

be comprehended. Additional requirements are that there is effective therapy and that natural history varies with the medical care. The medical management should be defined and nonmedical factors understood. A tracer is common in a specific age-sex-race group and uses major types of health services. The assumption of this method is that medical care for selected problems will be an accurate predictor of the general level of care delivered as well as a measure of the efficacy of the health care delivery system (Brook, 1973). The tracer methodology also allows one to look at the impact of medical care on defined populations within communities. As such, the method permits both process and outcome evaluation. Kessner, Kaik, and Singer (1973) using the tracer methodology examined the impact of a Neighborhood Health Center on care in a whole community. Selected disorders were used and a random sample of households were used to determine the high-risk cases and their sources of health care. Tracers selected for this study were visual disorders, anemia, urinary tract infection, iron deficiency anemia, essential hypertension, and cancer of the cervix. Data were collected on environment, effects of medications, incidence of complications, and other outcome measures. Data were evaluated according to diagnostic, therapeutic, and follow-up processes for the set of tracers according to outcome effectiveness of treatment.

Hulka (1973) also used the tracer methodology to study the quality of patient care. Hulka measured the effectiveness of medical care on communities through a method of case indicators. She also combined process and outcome factors of health care. Hulka followed

cases of diabetes, congestive heart failure, infancy and pregnancy. She used a comprehensive approach by examining such items as number of visits, referrals, costs, time spent getting to and from office, and waiting time. Physician performance was obtained primarily from the records but compliance, patient satisfaction, communication, and outcome were obtained through personal interview with patients.

Hulka defines elements for assessment and criteria used. Massive amounts of data are collected regarding prescribing patterns, patient compliance, patient satisfaction, by direct communication with the patients, as well as from physician interview.

Hulka found that "perceived morbidity," which represented a combination of restricted activity days, discomfort, and an increasing number of symptoms was important to seeking medical attention. She suggests that:

> No meaningful scheme for categorizing complaints could be devised, primarily because complaints did not occur as unitary events, but existed in groups. Few groups or symptom-complexes were composed of identical symptoms, and any one symptom was associated with a great variety of symptom-complexes. Categorization would require some arbitrary rule to designate the order of importance of symptoms, which would allow a symptom-complex to be placed in the grouping of its most important symptom. Not only was there no logical basis for establishing such an ordering rule, but it seemed likely that the imposition of such a rule would destroy a significant feature of the data, that is, the pattern of symptoms within the cluster. The pattern of symptoms may reveal a great deal more about an illness or condition than does any one individual symptom isolated from the complex [Hulka, 1972, p. 309].

Thus, for her study she used more than symptom-complexes as a measure of patient outcome.

Brook (1973) looks at comparable measures of appraising quality of care, taking into account outcomes. His main focus was to test major methodological procedures for assessing the quality of care for three chronic conditions. The study included 296 patients of whom 114 had hypertension, 107 urinary tract infections, and 75 had peptic ulcers. He compared five methods: implicit process judgment, implicit outcome judgment, combination of implicit process and outcome judgment, explicit process judgment and explicit outcome judgment. His results showed that each method gave different results. The explicit method based on previously determined criteria is least workable. Brook concluded that outcome expectations are best stated for populations. In that way it is possible to determine if goals are met and, if not, focus can then be placed on care processes.

Brook suggests knowledge is evident that it would be better to state outcome expectations for treatment and then determine whether we are meeting the goals rather than focusing our attention solely on evaluating the care process. He indicates that there is virtually no information correlating outcome in terms of function, morbidity, or mortality to the natural history of disease or medical therapy. Lewis (1974) also supports Brook by reporting that in pilot studies at UCLA utilizing ambulatory health care problems no significant association was found between quality of processes and outcomes of care.

The combined process and outcome studies have been conducted primarily by Sanzaro and Williamson (1968), Williamson (1971), Brook (1973), Hulka (1973), and Kessner, Kaik, and Singer (1973). These

researchers used outcome measures to evaluate patient status. Most of these studies begin by establishing minimum acceptable outcome criteria; when these levels are not achieved, then studies of the process are undertaken to explain the observed deficiencies. Process-outcome studies employ representative diseases and conditions for which explicit process and outcome criteria can be specified. In addition to conducting a medical record audit for the medical care process, most of the researchers follow the patient with a direct interview to ascertain appropriateness of care as well as for follow-up outcomes. Some of the results of these studies indicate that results of the combined process-outcome studies are applicable to populations as well as individuals as they reflect a pattern of health care practice on patient outcomes.

Summary of Review of Literature

McKillop (1974) offered suggestions as to the state of the art of health care evaluation. An overview of his critique provides an important summary to the literature review of process and outcome evaluation studies. The following section will discuss his perspectives.

He suggested that evaluation is primitive and *nonsystematic.* Medical care is evaluated when it is on an individual, randomized, episodic basis. The results contribute little to continuing medical education, quality of patient care, and quality control of health care practices. Health care evaluation has been primarily *disease-oriented.* It is necessarily concerned with those persons whose health status

deviates from a generally accepted, but poorly defined, set of norms regarding the natural history of diseases and the management of that disease.

Evaluation of health care is also *crisis-oriented*. The evaluator of health care practice is concerned with those who have deviated from the norm. Consequently, the review process usually does not elicit patterns and levels of care within a health care setting, but rather identifies apparently questionable problem individual cases and isolated professional activities. Unless such questionable acts are identified during the audit process, the reviewer and/or the reviewing agency need take no action to upgrade or change health care practice. Even if they are identified, little is done to correct the deficiencies, nor is there follow-up review to determine if a change in practice actually did occur.

A *retrospective approach* to the review of medical care examines the process of care through patient records after discharge. Records are essential to the evaluation of health care regardless of the method used; however, this does not have to be the only means of collecting data. The problem with strictly retrospective review is that it pays little or no attention to patient "outcome," but merely examines the process of care the patient received as it is documented. Further, it provides no opportunity to improve care during the patient's hospitalization, when care might have favorably affected the outcome of hospitalization. Evaluation data results should be fed into the system to provide data to those managing the overall care of that patient

so that care could be altered. The ideal method of medical care evaluation would include short-term, intermediate, and long-term mechanisms providing continuous feedback to the evaluators and health care delivery professionals.

Evaluation of care is addressed to the *least common denominator*. A group of competent professionals review the clinical work of the staff, but they really direct their attention to the lowest level of professional performance in specific instances rather than the ideal or desired level of performance and overall pattern of care. Standards are generally minimal if they are available at all. In most studies the criteria are implicit without acceptable levels of performance designated.

Evaluation of care is also *exploratory*. No one method of measuring the quality of medical care has been demonstrated to be clearly superior to others. All participants in the game are playing by different rules, guidelines, and methods. Compare, for instance, the different methods and interests represented by a community hospital medical audit committee, a university hospitalization utilization committee, a Blue Cross plan, a medical care foundation, the Joint Commission of Hospital Accreditation and the Professional Activity Studies. Yet, all of these approaches imply a goal of the improvement of patient care. This is not to negate the importance that each approach contributes to the better understanding of the medical care delivery system, but to point out the necessity of establishing some uniform guidelines if the goals are similar.

Medical care evaluation is *evolutionary*. This may be its most valuable characteristic, for it permits experimentation. A clearer identification of the components of the process of evaluating care and a more systematic organization of these components will lead to more fruitful ways of assessing quality of care and to more effective means of providing and maintaining quality control. McKillop (1974) says,

> No single approach can be used with complete validity across the entire continuum of health care and throughout the total health system. Outcomes also must be developed to maximize the understanding and cooperation of the patients. Every clinician knows that lack of patient cooperation can jeopardize the success of a well-planned therapeutic regimen. Clearly, some composite approach will be needed or some combination of methods, applied singly or in combination depending on the setting of care and the needs of the assessor, if we are to have a meaningful measurement of patient care [pp. 42-43].

The poor state of the art of quality of care evaluation studies is not an indictment of the health care system professionals but is rather a reflection of the multidimensional problems in assessing quality of care by any method. The intent of this study is to overcome some of the difficulties in previous endeavors and to profit from their findings and experiences. The following chapter will present the methodology used in this study. The approach will be a systematic method with predetermined criteria. Process and outcome parameters will be used and data will be collected both retrospectively and concurrently.

CHAPTER IV

METHODOLOGY AND PROCEDURE

Overview

This descriptive study examines how the quality and appropriateness of patient care is related to patient outcomes. Criteria for quality care and patient outcomes were ascertained through a review of the medical literature. The goal of the study was to construct a methodology for quality of care appraisal that could be used to test the relationship between process and outcome dimensions.

The primary data collection instruments for this study were a structured medical record audit and a patient interview guide. Questions were formulated based on the assumption that medical care process affects the outcome of the patient during an episode of illness. Data were collected from the patient at the onset of an episode of illness, at the end of five months, and from the medical record at the end of five months. The results were analyzed to determine existing relationships between outcome and process dimensions.

A pilot study using ten hypertensive patients was conducted to test the procedure and to determine if data could be obtained. At the same time a pre-test was conducted to test the patient interview guide as well as the medical record audit form utilized to collect

process data from the medical record. Revisions in both of these forms resulted from the pilot test. After the revisions were made, the study was conducted utilizing the format to be described in this chapter.

The purpose of this chapter is to present the research design employed for this study. Included are: procedures, techniques, and instruments used in data collection; criteria used to formulate data collection instruments; and the methodology used to analyze the data.

Population--Source of Data

Hypertension was selected as the health care problem for the study. Hypertension is a commonly occurring problem in an ambulatory patient population. Further research evidence suggests that control of the disease process will reduce morbidity and mortality (Cheitlin, 1974; Ayers et al., 1973).

The initial step in selecting the population sample was to establish the criteria for identifying hypertensive patients to be included in the study. Since the Family Practice Center at St. Joseph's Hospital was utilizing an encounter form (see Appendix A), the hypertension population was readily identifiable. From the diagnosis written on the encounter form it was possible to identify the hypertensive patients. From the encounter form the patient's name, address, telephone number, and record number were also obtained. This enabled easy access to the medical record to determine if, in fact, the patient met the criteria for inclusion in the study.

During the six months prior to the beginning of the study approximately 12 to 15 percent of all patient visits were for hypertension. This disease was considered to be prevalent enough to identify a population for study. It was determined that 100 patients would be needed to conduct this study. Hypertensive patients selected for this study were previously diagnosed hypertensives who were out of control at the time of their visit to the Center. Out of control was defined as having a blood pressure that exceeds the diastolic pressure of 95 mm. Hg. on two of three successive determinations (see Figure 4). A time period of 10 months was required to identify 100 patients who met this criterion for inclusion in the study.

Patients were selected from only one setting since the purpose of the study was to develop the system and framework for determining the relationship between process and outcome components rather than focusing on the quality of care in family practice settings. If, however, positive and discriminatory results occurred, the same approach could be used to compare the quality of care in multiple family practice settings for a variety of diseases. Although the specific intent of the study was not to determine the quality of care in the setting, the data could be used in that way.

Overview of Hypertension

Hypertension is a major health problem occurring in at least 10 percent of the population. Hypertension can be detected readily through the elevation of the blood pressure. Antihypertensive drug

therapy may be expected to prolong life and to reduce the incidence of certain cardiovascular morbid events in a large proportion of the hypertensive population, namely, those patients with primary hypertension. Hypertensive patients often do not have symptoms until complications occur; therefore, they cannot rely on symptoms to alert them to higher blood pressure. There is considerable evidence that elevated systolic or diastolic pressure is associated with increased morbidity and mortality from stroke, congestive heart failure, ischemic heart disease, and from renal failure.

Hypertension can either be primary, in which no etiology can be discovered; or, secondary, that in which underlying etiology can be identified such as an adrenal tumor or renal pathology. The only known means of controlling primary hypertension is through medical antihypertensive therapy. A small proportion of the patients with secondary hypertension can be cured by surgery such as removal of a body part or reconstruction of a renal artery.

Description of Setting

The Family Practice Center is located on the campus of St. Joseph's Hospital in Flint, Michigan (see Appendix B). It is a general ambulatory care facility in which there is a broad variety of patients with a range of socioeconomic statuses represented. The Family Practice Center is a unit for a family practice residency program which has been in operation since 1972. Medical students from Michigan State University also obtain ambulatory patient care experience within this setting.

There were six residents in training during the period of the study. The patient load is in excess of 1,200 families with visits about 800 per month at the beginning of the study, increasing to about 1,000 visits per month by the end of the study period. Permission was obtained from the medical director of the Family Practice Center to have access to the patient population as well as to the patient records.

Patient Encounter and Data Collection Procedure

For each patient visit to the Family Practice Center, an encounter form (see Appendix A) was completed on that patient. Encounter forms were sent to Michigan State University and reviewed by the researcher to identify hypertensives. Of those patients diagnosed as hypertensive, actual patient records were reviewed to select patients who met the criteria for inclusion in the study (see Figure 4).

Criteria were applied by the investigator to each individual patient by examination of the patient record (see criteria, Figure 4). If the hypertensive patient met the criteria and had a blood pressure out of control, he was identified to become a subject for this study. At that time basic data needed to send the request letter and conduct telephone interviews were collected. These data included address, telephone number, age, sex, and functional status.

Those patients meeting the criteria had a letter mailed to them within 7 to 14 days after the visit to the Center, explaining the purpose of the study, the upcoming telephone interview, and asking for his

A. Patients meeting the following criteria were included:

1. Diastolic blood pressure greater than or equal to 95 mm. Hg.

2. Elevated blood pressure readings on two of three successive determinations on different days.

B. Patients meeting the following criteria were excluded:

1. Pre-existing known chronic renal disease (creatinine greater than 7)

2. Cardiac cripple--patients with pacemakers or who had cardiac surgery.

3. Acute myocardial infarction or acute stroke.

C. Patients were categorized into three classifications, according to the following criteria:

1. Age 20-39	>	140/90	<	150/95
2. Age 40-59	>	150/95	<	160/100
3. Age 60+	>	160/100	<	170/105

Figure 4. Criteria for Selection of Hypertensive Patients for the Study.

cooperation (see Appendix C). Within 3 to 5 days after the letter was mailed, patients were contacted by a trained interviewer and interviewed according to the Entry Interview Form (see Appendix D).

Numerous attempts to contact patients via telephone were used when necessary. If the patient did not have a telephone or was too ill to respond to the telephone interview, a letter was mailed to him explaining the study, and the questionnaire was mailed 3 to 5 days after the letter. This was done since it was decided that it was vital that data be gathered from all segments of the population who met the criteria.

The telephone questionnaire was selected as a means of data collection over direct personal interview because of interviewer safety and the long distance some of the patients lived from the Family Practice Center. In addition, the questionnaire allowed the patient anonymity throughout the study period. The patients were not contacted when they visited the Family Practice Center for care since the medical director did not want the physicians and residents to be aware of the study. He wanted to determine the existing pattern of care within the Center rather than risk having the care altered because providers knew they were being monitored.

The interviewer was trained by a specialist in teaching interview skills. The concept, meaning, and purpose of each question contained in the guide was described and discussed with the interviewer. In addition, a role playing session followed, utilizing the entire interview format. After this, an actual patient interview was conducted

by the interviewer with the specialist available to provide feedback and constructive suggestions. In addition, an interview guidebook was prepared to be utilized by the interviewer. At the end of each month the interviewer was asked to identify special problems and questions. Problem areas and potential solutions were addressed with the interviewer at the end of each month (see Appendix E).

During the five-month period after the initial patient interview, no contact was made with the patient for purposes related to the study. The patient continued to receive needed care at the medical center without further contact from the interviewer. At the end of five months, another letter (see Appendix C) was sent to the patients asking them to participate again in the telephone interview. Three to five days after the follow-up letter was mailed, patients again were contacted via telephone for a follow-up interview (see Appendix D). The same standardized interview guide was used to obtain follow-up data from the patients. Patients who had mailed questionnaires at the beginning of the study also received a letter informing them that follow-up questionnaires would be forthcoming, and questionnaires were mailed in 3 to 5 days. After both data sets were collected from the patient, the researcher obtained physician process data as well as patient outcome data through audit of the individual patient medical record at the Family Practice Center. A standardized process data collection form was used (see Appendix G), thus completing the collection of both process and outcome data.

At this time the data were complete for each patient for a five-month period. Data were then processed, coded, tabulated, and analyzed. Figure 5 presents the flow chart indicating the procedure used in collecting patient data.

The following section will discuss the formulation of the data collection instruments.

Variables--Operational Definitions

The independent variable utilized in this study was process of care. Measures of process of care included diagnostic and therapeutic approaches utilized by the health care professionals and the compliance by the patient with the prescribed therapeutic regimens.

The dependent variable was defined to be patient outcome. Measures of patient outcome included functional status, medical health status, perception of health and care, and knowledge and understanding of the disease and the therapeutic regimen.

A structured audit form was developed to collect the process and outcome data from the patient's medical record, while an interview guide in the form of a questionnaire was formulated to collect process and outcome data directly from the patient. The following section will present these variables in operational form.

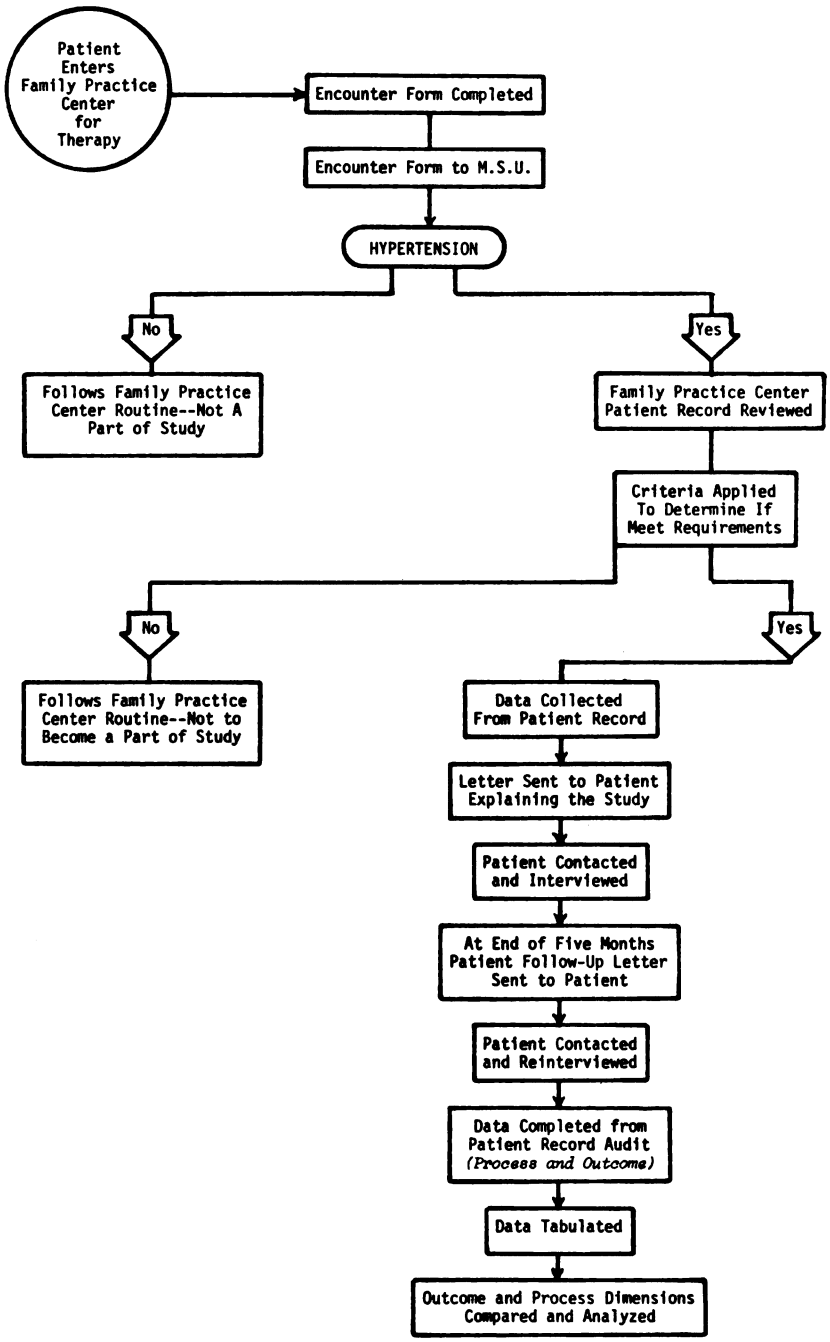


Figure 5. Flow Chart for Patient Encounter for Study and Data Collection Procedure.

Process Variables

Criteria

A set of criteria to describe standardized acceptable levels of care for the ambulatory hypertensive patient was established from a review of the literature (see Appendix F). Actual process of care activities provided for the study population were assessed according to the predetermined criteria. Since there is a current concern for hypertensive disease as a major public health problem, it was possible to find multiple lists of criteria to be followed for the medical management (diagnosis, therapy, and follow-up) of an ambulatory hypertensive patient. See Figure 6 for summary of the components to be included in the diagnosis and therapeutic management of hypertensive patients.

The purpose of this section is to discuss and present the criteria for diagnostic and therapeutic approach for patients with hypertension. This review of the literature and selection of criteria from experts provides face validity to the process criteria measure to evaluate process activities.

These criteria are not intended to be all-inclusive but rather to reflect the present state of medical practice in basic diagnosis and therapy of the ambulatory hypertensive patients. Sources used to establish the criteria were those in which there was frequent reference made in the literature reviewed. If the component was utilized three times by these experts it was used as a criterion measure. Continuity of care criteria was an exception. Few studies or experts provide guidelines for follow-up and continuity, yet much of medical literature

SCREENING

1. Indications for Ambulatory Hypertensive Treatment.

DIAGNOSIS

1. History--specific reference to previous and family history as well as signs and symptoms documented in record.
2. Physical Examination--specific reference to examination components as documented in record.
3. Laboratory and Radiographic Examination--(x-rays, other) performed and documented.

THERAPY AND MANAGEMENT AS DOCUMENTED

General

1. Explanation of Disease--patient's knowledge and understanding.
2. Diet Restrictions.
3. Physical Restrictions (activity and work).
4. Resources Used.
5. Medications Ordered and Evaluation.
6. Psychosocial Management and Support--response documented as to patient's fears, anxieties, stresses.
7. Habit Restrictions and Alterations.

Continuity

1. Follow-Up and Frequency of Visits.
2. Number of Physicians Providing Primary Care.
3. Evaluating Compliance of Therapeutic Recommendations.
4. Recording of Recommendations.
5. Evaluating Effectiveness of Drug Therapy.
6. Evaluation of Change in Signs and Symptoms.

PATIENT COMPLIANCE

1. Drugs.
2. Clinic Appointments and Returns.
3. Diet.
4. Activity.
5. Habit Restrictions.

Figure 6. Categories for Process Criteria.

indicates a need for this. In view of these indications, the researcher chose to include continuity dimensions.

The process data determines the completeness of the medical work-up, follow-up, and therapeutic management. Most of the data obtained for this study were determined from documentation in medical records and not from actual direct observation of care; thus there may be a discrepancy between the actual medical practice and documentation. Categories for Process Criteria used in the structured medical record guide are listed in Figure 6.

Diagnostic process.--Diagnostic evaluation is a prelude to rationale therapy. Information gleaned from diagnosis should determine the need for treatment, the type of treatment, urgency of treatment, and influence the selection of medications for the individual patient. Treatment should be initiated, maintained, altered, and discontinued pending the results of continued diagnostic processes. The purpose of diagnostic evaluation is to determine the presence or absence of disease to brain, heart, eye, or kidney (target organ involvement) that may affect the prognosis as well as determine the severity of the elevated blood pressure. Literature suggests that 5 to 20 percent of hypertensive patients may have a surgically correctable lesion. Diagnostic evaluation of these patients is vital to the determination of those patients that can be cured by surgery versus those that can be managed only by a continued medical regimen.

The history and physical are important parts of process evaluation and are used to determine and describe the severity of

hypertension, presence of or extent of target organ involvement, and presence of surgically curable causes.

History. The first step in the diagnostic work-up is a careful and complete medical history. This should be taken for every hypertensive patient. The history should be directed toward evaluating the target organ damage of the hypertensive process in the cardiovascular, brain, and renal systems. Symptoms and signs of congestive heart failure should be ascertained because hypertension is the cause of heart failure in 75 percent of such patients. The diagnostic data should search for the curable causes of hypertension through the signs and symptoms of pheochromocytoma, urinary tract infections, primary aldosteronism, hyperdynamic circulation, and nephritis. The extent of involvement or presence of complications affect prognosis and often influence the therapeutic management through the choice of drugs.

Further diagnostic evaluation of the patient's history can identify coexisting disease that might affect prognosis, alter the therapeutic approach to the patient, or identify risk factors for stroke or coronary disease. A family history of hypertension is more common in patients with essential hypertension than in those with most other forms of hypertension (Ayers et al., 1973; Cohn, 1974; Gifford, 1974). See Figure 7 for history measures used in this study. Each record was reviewed to determine if this data had been obtained.

Physical examination. The next step in diagnostic process of hypertension is a complete physical examination, looking for possible causes but also for evidence relevant to hypertensive cardiovascular

(Total Possible Score for Overall Diagnostic, 27 points)

HISTORY *(total points = 8)*

1. Past history of hypertension.
2. Family history of hypertension.
3. Cardiovascular history--peripheral vascular.
4. Cardiovascular history--cardio ischemic.
5. History of medications.
6. Renal history.
7. Cerebrovascular history.
8. Length of signs and symptoms.

PHYSICAL *(total points = 10)*

1. Blood pressure
2. Carotid pulses
3. Renal artery bruits
4. Ocular fundus
5. Heart
6. Lungs
7. Peripheral pulses
8. Peripheral edema
9. Abdomen
10. Weight

LABORATORY, RADIOLOGICAL, AND OTHER DIAGNOSTIC TESTS *(total points = 9)*

1. Blood urea nitrogen
2. Urinalysis
3. Uric acid
4. Serum potassium
5. VMA or other catecholamine test
6. Blood sugar
7. EKG
8. Intravenous pylogram
9. Chest x-ray

Figure 7. Diagnostic Process Criteria.

disease. The physical examination should also be performed with the purpose of assessing target organ damage. Important components of the physical examination include the ocular fundi, heart, lungs, peripheral vascular system, neurological, and abdominal examination.

Examination of the ocular fundi gives the only direct information about arteriolar disease. There is a positive relationship between the degree of retinal arteriolar disease and the overall severity of hypertension and prognosis of hypertension. This parameter is a more reliable index than are casual blood pressure readings. Fundoscopic examination is invaluable in determining the severity of hypertension and its prognosis. Fundi should be examined for arteriovenous compression, hemorrhages, exudates, and papilledema.

The *heart* and *lungs* are often target organs for hypertension. Left ventricular hypertrophy, congestive failure, angina pectoris, coronary insufficiency, and myocardial infarction are frequently complications of untreated hypertension.

Examination of the *peripheral vascular system* is aimed at the detection of occlusive disease bruits and aneurysms. Vessels to be examined include carotid, abdominal aortic, renal artery, and femoral arteries. Delayed and diminished lower extremity pulses may reflect coarctation of the aorta. Edema of the extremities are reflective of the presence of congestive heart failure and evidence of fluid retention. Abdominal bruits may indicate renal arterial disease, while enlarged kidneys indicate polycystic disease and flank tenderness is indicative of pyelonephritis. The *carotid and subclavian pulses* should be palpated

and neck bruits osculated. The patient should be examined for signs of circulatory congestion. The *abdominal examination* may also reveal aortic aneurysm, enlarged kidneys due to polycystic disease or a displaced kidney due to an adrenal tumor. *Neurological examination* for deficits from cerebral infarcts should be a part of the physical exam (Ayers et al., 1973; Barnoon and Hare, 1973; Brook, 1973; Dustan, 1973; Gifford, 1974).

Laboratory and radiographic diagnostic tests. Laboratory and diagnostic tests should be carried out with the purpose of evaluating the patient's general health status, finding the cause of hypertension and assessing the extent of vascular disease and target organ effects. Recommended laboratory and radiographic tests include blood urea nitrogen, urinalysis, uric acid, serum cholesterol, chest x-ray, electrocardiogram, blood sugar, serum potassium, intravenous pyelogram, and urine catecholamines. *Measurement of blood urea nitrogen or serum creatinine* are used as an initial screen for renal function. Urinalysis should be performed with emphasis on the screen for proteinuria, casts, and red and white cells. Proteinuria is more common in renal disease.

Serum potassium is a screening test used in the diagnosis of primary aldosteronism and also serves as a baseline for subsequent diuretic therapy. A serum glucose should be determined because of the relative frequency of diabetes among hypertensives and because diabetes is an additional risk factor for stroke and coronary disease. Glucose tolerance is abnormal in Cushing's syndrom and pheochromocytoma or may be caused by diuretic agents.

Serum uric acid should be determined because of the increased incidence of hyperuricemia in hypertension. It is also useful as a base when treatment includes diuretic therapy, especially chlorothiazides. *Urinary catecholamines* or VMD should be determined to exclude the presence of pheochromocytoma (a curable cause) in all hypertensive patients.

An *electrocardiogram* is indicated in all hypertensive patients; it is a valuable prognosticator of the extent of vascular disease and may change with treatment. Left ventricular hypertrophy correlates positively with heart size and systolic blood pressures. The *chest roentgenogram* is valuable for evaluating heart size and pulmonary vascular engorgement and should be obtained in all patients to determine the extent of cardiopulmonary vascular disease. The *hypertensive or rapid sequence intravenous pyelogram* is the most common screening procedure used to evaluate renal impairment (Ayers et al., 1973; Barnoon and Hare, 1973; Brook, 1973; Dustan, 1973; Gifford, 1974).

See Appendix F for more detailed summary of diagnostic measures used.

Blood pressure. The level of the blood pressure is the single most important criterion for correctly diagnosing, evaluating, and classifying the degree of hypertension. A major difficulty in evaluating and classifying hypertensive patients is the variability in the level of blood pressure. Blood pressure varies moment to moment and has a diurnal pattern, being lowest in the morning upon waking and increasing until evening hours. Anxiety, apprehension, and other

emotional stimuli such as sudden change in surroundings, loud noises, fear, discomfort, pain, body position, cigarette smoking, and exercise may alter the blood pressure. The blood pressure should be taken with the patient in the supine and upright position. An orthostatic drop in blood pressure may be marked in the presence of pheochromocytoma as well as cerebrovascular disease, diabetic neuropathy, or in patients receiving sympatholytic drugs.

Blood pressures should be measured in both arms after the patient has been supine for five minutes. A disparity of 10 mm. Hg. in systolic or diastolic between the two arms should be confirmed by repeated measurements in both arms. For follow-up purposes and evaluation of treatment the blood pressure should always be taken in the arm that gives the highest reading. If there is no disparity in blood pressure between the two arms in the supine position, it is unnecessary to measure it in both arms while standing. Standing blood pressures should be measured after the patient has been standing for at least 60 seconds (Fries, 1974; Ayers et al., 1973; Gifford, 1974; Brook, 1973; Dustan, 1973).

In this study, three blood pressures were evaluated to document sustained hypertension. Two of the three successive blood pressure determinations had to be evaluated in order for the patient to be included in the study. Once the patient was included, all blood pressures recorded during the five-month study period were noted on the medical audit form (see Appendix G). Specific designations such as lying, standing, sitting, right, or left arms were also recorded on the data collection instrument.

Scoring of diagnostic process variables.--At the end of the five-month study period diagnostic process data were collected from the patient record utilizing the medical record audit form (see Appendix G). In scoring diagnostic measures, a positive score was given for each history and physical component included in the record whether obtained for this episode or at a recent previous time. These were included in the diagnostic process since the parameters were deemed by the experts as essential to plan and manage care. Any diagnostic information such as history and physical examinations that were from hospitalizations during the study were included since the data were available to be used when assessing and treating the patient. Absence of each diagnostic item from the record was noted on the process data collection form at the end of the five-month period.

The laboratory and radiological measures deemed vital to the diagnostic process of hypertensive patients were also included in the process data collection form. Components included were those necessary to evaluate severity of hypertension and target organ involvement. Since it was necessary that they be evaluated once during this episode of lack of control this was noted for laboratory or radiographic measure. When the process data were collected from the patient record at the end of the five-month follow-up period, a score was given to laboratory and radiological examinations which included urinalysis, blood urea nitrogen, potassium, uric acid, cholesterol, blood sugar, intravenous pyelogram, chest x-ray, and electrocardiogram.

Certain observations and data need to be collected more than once during the five-month period of time. The frequency depended upon the severity of disease, therapeutic regimen, and number of office visits. For this reason, each patient's score was individualized on those parameters that would be unique to his severity of health status or therapeutic regimen. Experts suggest the importance of assessing multiple blood pressures, weight, cardiopulmonary status, renal status, and peripheral edema at each visit. Since each patient varied on number of measures obtained, data were collected and tabulated separately for each visit for peripheral edema, weight, blood pressure, lung and heart examination, and protein in the urine. For scoring on these items, if the patient had these items noted more than half of the visits to the Center, he received a positive score and if less than one-half of the visits, a negative score. The total number of diagnostic process points were 27. Each patient received a score that was a proportion of his possible individualized score. This was then tabulated as the overall diagnostic score for each patient.

Procedure for scoring diagnostic process measures.

1. Each diagnostic item noted in the record was scored +1.

2. Each item of the diagnostic processes for which there was no evidence in the record had a 0 scored for that item.

3. There were a total of: (a) 8 points possible for history, (b) 10 points possible for physical examination, and (c) 9 points possible for diagnostic tests.

4. A score was obtained for *history* based on the number of items scored (+1) one point divided by the total possible of 8 (i.e., if a patient had four of the eight items included, he had a history score of .50). Each item for history need only be documented in the medical record once.

5. A score for *physical examination* was obtained based on the number of items scored one point (+1) over a possible 10. For diagnostic process, however, literature resources suggested that some items be tabulated on each visit. This necessitated that each patient would have a different score. To ensure uniformity, a proportion score was determined.

Blood pressure Weight Heart Lungs Peripheral edema	were areas that needed evaluation at frequent intervals for effective therapeutic management.

Because of this, these items were only recorded as +1 if they had been documented on one-half or more of the visits. If the areas were evaluated less than one-half of the time, a 0 was scored by the parameter. Carotid pulses, peripheral pulses, and ocular fundi categories were given one point (+1) if noted at any time during the five-month study period and 0 if there was no documentation. Again, a proportion score was obtained based on a total possible 10 points. The proportion score was recorded as a physical score.

6. A score for procedures--*laboratory and radiological procedures*--was based on number of diagnostic tests. If the diagnostic tests were conducted during the study period, one point (+1) was

recorded for that parameter. If it had not been carried out, a 0 was noted. Urinalysis had to be documented at least one-half of the visits to receive one point (+1). If documented less than one-half of the visits, a 0 was assigned. All of the other tests were given one point (+1) if conducted any one time during the five-month study period. A proportion score was obtained for diagnostic procedure based on a total of 9 points.

7. After the separate diagnostic scores (history, physical, and diagnostic procedures) were obtained, *an overall diagnostic score* was obtained by counting the number of diagnostic items included (+1) and dividing that score by 27 (the total points possible) to obtain a proportion score. This overall diagnostic score was computed and tallied for each patient.

Therapeutic process variables.--*General therapy*. The treatment of hypertension is palliative because the cause and cure are unknown. Nevertheless, it has been demonstrated that effective therapy will prevent or forestall complications and prolong life. To accomplish this, the blood pressure must be reduced to normal or near normal levels. This, then, is the goal of therapeutic process. Many physicians recommend treatment at a blood pressure of diastolic pressure between 90 and 100 mm. Hg. Since antihypertensive drugs are the most important aspect of therapy, detailed information was obtained for this study on medications from the process recording in the patient records.

Therapeutic process are those activities prescribed by the physician to be followed by the patient at home as well as measures taken to provide continuity of care to the patient. Therapeutic process activities included explanations of medications, diet, activity restrictions, psychosocial support and weight control.

Continuity of therapeutic activities. Continuity dimensions include physician recording of recommendations, restrictions, or instructions and guidelines given to the patient (see Figure 8).

The impact and effectiveness of therapy is evaluated through ascertaining the signs and symptoms that determined the change in the patient's status or side effects of the therapy. It is recommended that the following six items be checked in the three-month follow-up visit: (1) a record of blood pressure in both the supine and upright positions, (2) a review of the cardiovascular and renal status, (3) a record of side effects appropriate to the particular antihypertensive therapy, (4) a brief check of the patient's overall health, (5) tests for blood urea nitrogen, potassium, and glucose, and uric acid (these tests should be made within six weeks of initiating therapy), and (6) a decision concerning medication adjustment. After two years of follow-up study, an SMA-6 and uric acid determination may be obtained every six months for patients on continuing diuretic therapy or when new symptoms appear (Ayers et al., 1973; Cohn, 1974). These parameters were evaluated for each patient on an individual basis depending on their severity of illness and return visits to the Center. Documentation of each of these parameters on successive visits was noted from the medical record.

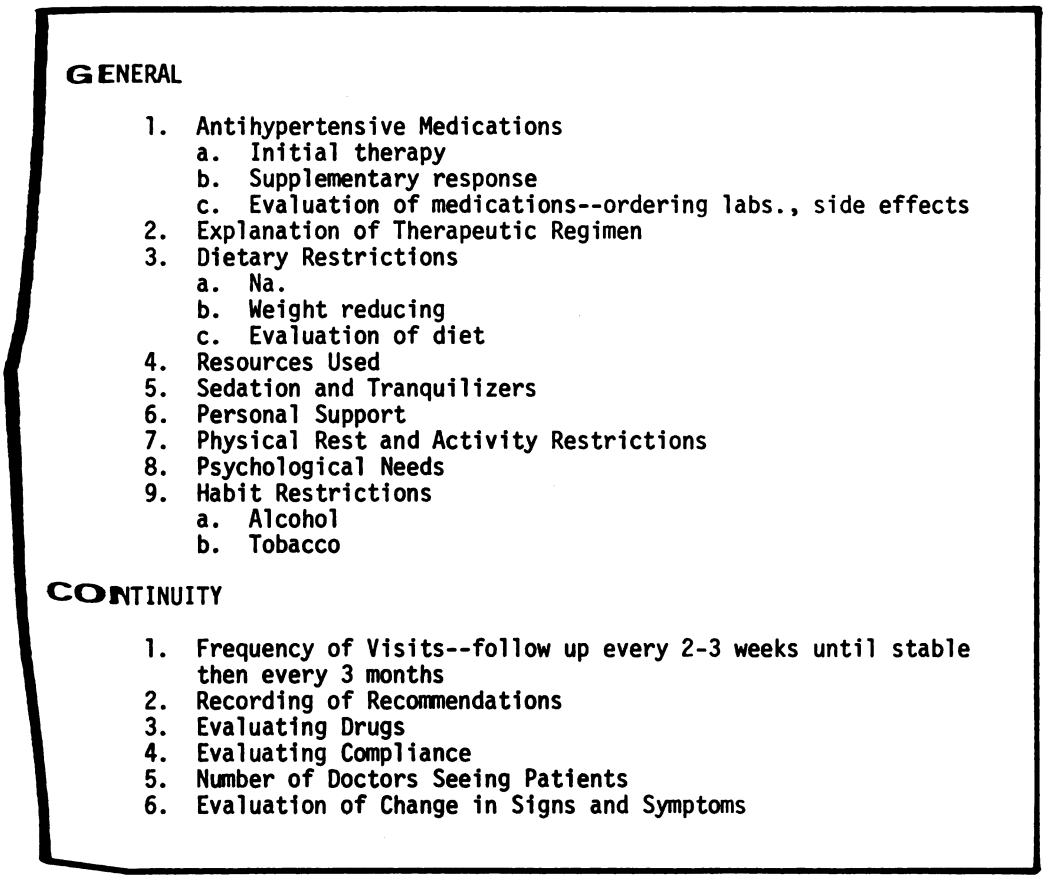


Figure 8. Therapeutic Process Categories.

Scoring for therapeutic process.--The following sections describe how each dimension of the therapeutic prescriptions was scored for analysis.

There are three classes of antihypertensive drugs. These are diuretics, vasodilators, and sympathetic inhibitors. An oral diuretic alone controls blood pressure for one-third of patients with mild or moderate hypertension. It is recommended that therapy be initiated with an oral diuretic agent, usually a thiazide or chlorothalidone. These drugs act to lower total peripheral arterial resistance which is increased in essential hypertension. The choice of diuretic is of little importance if renal function is normal. When complications occur, spironolactone may be added or substituted. The approved drugs are reserpine, methyldopa, hydralazine, and guanethidine. If success is not obtained with one drug, then other available drugs and dosages should be tried, separately and together, in an attempt to achieve a normal blood pressure (Cohn, 1974; Gifford, 1974; Ayers et al., 1973). Figure 9 presents the ordering of antihypertensive medications recommended by the National High Blood Pressure Education Program (Gifford, 1974). This figure suggests that when the diastolic blood pressure is less than 120 mm. Hg., the preferred treatment begins with an oral diuretic. If the blood pressure does not respond after three to six weeks, a second drug usually methyldopa, should be added. A third drug may be added to the diuretic and second drug if the blood pressure is not adequately controlled after another three weeks. At higher beginning levels other medications may be used. This is the regimen followed

Pretreatment Diastolic Blood Pressure (mm. Hg.)			
	< 120 mm. Hg.	120-140 mm. Hg.	> 140 mm. Hg.
Initial	Oral Diuretic	Oral Diuretic and Methyldopa	Oral Diuretic, Methyldopa, and Guanethidine
Supplementary #1	Methyldopa or Reserpine	Guanethidine	Hydralazine
Supplementary #3	Hydralazine	Hydralazine	Propranolol
Supplementary #2	Guanethidine or Propranolol	Propranolol	

Figure 9. Suggested Medication Regimens for Uncomplicated Hypertension.

(Source: Ray Gifford, *The Hypertension Handbook* (West Point, Pa.: Merck, Sharpe and Dohme, 1974).

to evaluate the effectiveness of the regimen. It was expected that treatment began with an oral diuretic and that medications were changed at three to six week intervals if the patient's blood pressure did not respond to the drug therapy (see Figure 9 for recommended pattern).

The utilization of a weight-reducing diet for the obese is recommended, not to bring about a significant reduction in blood pressure, but for overall medical reasons. A low sodium diet is not indicated unless the patient has cardiac problems or is on diuretics. Sedation and tranquilizers were also noted as were activity restrictions; however, positive scores were not tallied since they are not considered an integral part of therapy for the uncomplicated hypertensive patient. Unless the patient has severe cardiac or renal disease extra daily rest or restrictions in daily activity is not necessary with antihypertensive drug therapy (Gifford, 1974; Ayers et al., 1973; Brook, 1973). Smoking habit restrictions were also tabulated since smoking is a risk factor for death from coronary disease.

A summary score was computed for the therapeutic recommendations for drugs, diet, and evaluation of medications and habit restrictions, explanation, resources, psychosocial management. Other factors such as sedation and activity restrictions were only tabulated as frequencies to determine the pattern within the Center but not as a needed part of therapy for the individual patient. A summary score was computed taking the number of positive activities as a proportion of all therapeutic activities based on the therapeutic orders that allowed for variation according to severity, status, and number of visits, and thus was individualized for each patient.

Follow-up and continuity. It is recommended in the literature that patients undergoing antihypertensive therapy should be followed-up frequently (every two to three weeks) until their blood pressure is stabilized, then at three month intervals. Based on this criteria, patients should have three or more visits within the five-month study period. If the patient had one or two visits, a satisfactory follow-up was not maintained. For purposes of this study more than two visits were considered adequate (Gifford, 1974; Ayers et al., 1973; Brook, 1973).

Other continuity dimensions for this study included documentary therapeutic recommendations in the patient record, evaluation of effectiveness of medications, evaluation of compliance, and evaluation of signs and symptoms of medical health status. It is vital for long-term care that activities be recorded to enable a physician to recall the recommendations he made at a particular visit. This should enable him to better evaluate effectiveness of therapy or allow another physician to follow the patient. The record would enable physicians to use documentation of past recommendations as a guide for further management. Drugs, compliance, and signs and symptoms should be evaluated *each visit* to ensure effectiveness of therapy and to ascertain any needed changes in the therapeutic processes. It would be expected that more continuity could be maintained if a smaller number of physicians were seeing the patient, as they would be more familiar with the patient's status and progress. For purposes of this study it was considered adequate if one or two physicians saw the patient within the five-month period, while

more than two were considered inadequate for continuity of therapeutic management.

Continuity parameters of care included six items. Each patient received a proportion continuity score based on these six items. Continuity items were obtained through a medical record audit of each patient's record at the end of the five-month period. Finally, the general therapeutic score was combined with the continuity therapeutic score to obtain an overall therapeutic score.

Procedure for scoring therapeutic measures. The following steps were taken to construct the therapeutic process index:

1. Each patient record was reviewed to make determinations about the individualized parameters necessary to determine the score. It was noted if the patient was obese and was on diuretics. In addition, specific blood pressure recordings were noted to determine if the drug therapy ordered was appropriate for his level and if there was a need for supplemental therapy (see Figure 9).

2. The score for the general therapeutic process varied with the actual regimen of the patient and was dependent upon the orders of the physician as well as the patient status. Thus each patient was assessed on an individual basis. The total possible items varied for each patient (see #5 below for detail). All patients were evaluated on the same continuity measures. Six items were possible for therapeutic measures of continuity; thus each patient had the same possible score for this parameter.

3. Each item noted in the patient record received a score of one point (+1) on the scoring sheet.

4. Each measure of therapeutic process for which there was no evidence in the patient record received a 0 score.

5. A score was obtained for *therapeutic process* based on the number of items scores one point (+1) divided by the total number of therapeutic process measures for each patient on a specific individualized regimen.

In computing the therapeutic regimen the patient received one point (+1) if there was evidence in the record that items had been included during the five-month study period. These items were:

- explanation of disease or therapeutic regime
- diet restriction
- physical restrictions
- resources use
- evidence of personal support or encouragement
- attention to psychosocial aspects of care
- evaluation of overall health status
- appropriateness of therapy
- need for supplemental therapy

A few of the therapeutic measures were included in the score based on the status of the patient and critiqued on an individual basis. These items were:

- obesity control for obese patients
- diet restrictions, serum potassium level, blood sugar, and uric acid if patient was on diuretics
- obesity control was evaluated at the end of the five-month study period while the other parameters were evaluated if completed once within the study period after therapy started.

The first set of nine items was included and assessed on each patient while the latter set was dependent upon the therapy (diuretics) and patient status (obesity). Each patient had a unique score based on his needs. If items were not included, he received a 0 for that item. Only items needed to be considered on all patients were used as a base score.

6. A score for *continuity* was obtained, based on the number of items in which patients received one point (+1). There was a possible continuity score of six. Patients received one point (+1) if they had more than two visits during the study period and a 0 if only one or two visits. They received one point (+1) if recommendations were recorded, if drugs were evaluated, if compliance was evaluated, or if signs and symptoms were evaluated. If these items were not documented a 0 was recorded for those items. If there were one or two physicians who cared for the patient during the five months, one point (+1) was recorded for that item. A 0 was recorded for patients who had more than two physicians caring for him. Each of these items was recorded one time based on a medical record audit at the end of the study period.

After auditing the patient record, a proportion score was computed based on the number of items documented in the record over

the total possible six items. This proportion was then used as the continuity score.

7. After the separate therapeutic and continuity scores were obtained, an *overall therapeutic score* was formulated combining the two scores. Since the therapeutic process score varied on the number of possible dimensions, each possible score varied with the individual patient. The index was obtained by taking the scores for the appropriate therapeutic items and combining it with the scores for continuity items and subsequently dividing by the total possible points for appropriate therapeutic and continuity items. Each item presented, received one point (+1) while each item not included received a 0. The resulting proportion was the overall therapeutic score.

Patient compliance with therapeutic recommendations--process.--Patient compliance was considered to be an integral part of the therapeutic process. Compliance with therapeutic recommendations was determined through patient interview (see Appendix D). Compliance was considered crucial to ambulatory care since the physician has a small part in the therapeutic activities. The physician recommends to the patient certain activities for the patient to follow in an attempt to achieve control. It is then up to the patient to choose whether or not and to what extent he will follow the recommendations.

For this study, the patient's expressed and verbal report was ascertained and used as the compliance measure. It is recognized that what the patient reports may be different than what he in fact does;

however, the physician must make his judgments regarding new medications and/or restrictions based on objective criteria, namely, blood pressure readings, signs or symptoms, and patient's report of compliance with previous recommendations. Alterations in therapeutic approach are based on what the patient reports to the physician. For this reason reported compliance was used as the determinant of compliance behavior.

Scoring of patient compliance.--The compliance components were operationalized by the reported follow-through with recommendations ordered by the physicians. Recommendations involved patient initiative at home. This category included prescription medications, recommended diets, changes in rest and activity habits, limitation of smoking and alcohol consumption, and changes in work activities. Recommendations also included those related to participating in the delivery of care. Here, examination of extent of compliance included diagnostic procedures, referral to other health care resources, and revisits to the Family Practice Center. Medical records were used to ascertain a list of specific recommendations made for each patient.

After patients were asked which recommendations they recalled, the patient was asked how closely he followed these recommendations. Medical records were also reviewed to determine how closely the patients followed physician advice. The responses were coded for each drug regimen as follows:

0 none of the time
1 seldom, less than 1/2 the time
2 1/2 the time
3 more than 1/2 the time
4 all the time

Activity, diet, habit, work, and return to the Family Practice Center were evaluated for each patient. Compliance with these components were scored as:

0 none of the time
1 some of the time
2 all of the time

A patient was categorized as not at all compliant when there was a recommended regimen that the patient did not recall as well as if the patient reported a noncompliance. It was assumed that a patient who did not recall a recommendation was not following the advice.

Each patient received a drug compliance score and a compliance score for other therapeutic recommendation individualized to his needs. Finally, a composite compliance score was obtained by combining the drug and other compliance dimensions.

Procedure for scoring of compliance.

1. Each patient record was evaluated to determine the list of drugs, dietary restrictions and other components of the therapeutic regimen. These were noted and used as a base for each patient's individualized score.

2. Compliance index scores were formulated for drugs, other recommendations and overall compliance. Compliance with drug regimen was weighted to reflect the extent of compliance with a regimen. By assigning numerical values it was possible to determine variation in the compliance levels. If the patient followed a regimen part of the time, he received some credit for that effort. Weightings given were consistent with those documented in other research studies (Davis, 1966; Davis, 1968; Williams, 1967).

The composite drug compliance score is a proportion score of the weighted scores divided by the sum of the possible weights. It is, then, a weighted average of patient's follow-through with physician recommendations. Each drug ordered for the patient had a possible weight of four. Consequently, if the patient was to be on four medications, he had a possible sum of 16. If he complied with that regimen only, more than one-half the time (3) for each medication, he would have a drug compliance score of 12 of the 16 possible. His proportion score was tallied as .75.

3. Compliance with recommendations for activity, diet, habits, work, and return visits to the Family Practice Center, comprised the components used to determine the other compliance score. These components were scored as:

0 none of the time
1 some of the time
2 all of the time

Of these dimensions there was a total possible of two for each physician recommendation. If the patient had four physician recommendations, his possible score would be eight. The actual score tallied was a proportion of that possible. A patient who reported some compliance with four items would have a score of 4/8 or .5.

4. Finally, a composite compliance score was obtained. Since the questionnaire used only had like categories for the compliance components of none of the time, some of the time, and all of the time, these are the categories used to determine the overall compliance score. For each patient, then, the drugs and other compliance factors were weighted as:

0 none of the time
1 some of the time
2 all of the time

Each patient had a unique set of therapeutic recommendations. These therapeutic recommendations were used to determine the overall compliance score. The patient who had three drugs, diet restrictions, and return visits, specified as his recommended regimen, would have a possible value of 10. If he complied with each drug all of the time and with the diet and return visit some of the time, he would have a score of 3 x 2 for drugs and 2 x 1 for other, for a total of 8 of the 10 possible. Thus, the compliance score would be tallied as .80.

Outcome Variables

Outcome was measured by patient functional status, medical health status, knowledge, and understanding level of therapeutic regimen and perception of health care at the end of the study period of five months (see Figure 10).

Data used to classify patient outcomes were collected at two points in time. The status at onset of this episode of illness was obtained from the medical record and patient interview. A final status was also determined at the end of the five-month treatment period. This was necessary to determine the changes achieved by the patient during the study period.

Functional health status.--Functional status as a measure of health is common in chronic illness research and has been widely used in National Health Surveys. Measures of functional disability were used as a means of describing the impact of illness on the patient's

FUNCTIONAL HEALTH STATUS

1. Performs Major Activity Without Symptoms
2. Performs Major Activity With Symptoms
3. Restricted
4. Limited Mobility
5. Bed Disabled
6. Died

MEDICAL HEALTH STATUS

1. Frequency of Signs and Symptoms
2. Severity Index (target organ involvement)--Cerebrovascular Cardiac, Renal, Blood Pressure, Optic Fundus
3. Blood Pressure
    a. Systolic
    b. Diastolic

PATIENT KNOWLEDGE AND UNDERSTANDING

1. Of Disease
    a. Cause
    b. Control
    c. Personal Control
    d. Signs and Symptoms
    e. Cured vs. Controlled
2. Of Blood Pressure
    a. Own
    b. Abnormal
3. Of Regimen
    a. Diet
    b. Medication
    c. Activity
    d. Habits
    e. Follow-Up
4. Of Medications
    a. Name
    b. Length
    c. Purpose
    d. Precautions

PATIENT PERCEPTION

1. Of Care
    a. Frequency of Office Visits
    b. Number of Physicians
    c. Freedom to Discuss
    d. Explanation
    e. Interest
    f. Time
    g. Thoroughness
    h. Improvement of Condition
2. Of Health Status
    a. How Medication Affected
    b. How Dietary Restrictions Affected
    c. How Habit Restrictions Affected
    d. How Activity Restrictions Affected
    e. Control

Figure 10. Outcome Categories.

ability to perform normatively defined social roles. Disability measures have had extensive use and are the only measures presently used in ongoing studies of the National Center for Health Statistics to evaluate the health of the United States population. Second, these measures classify persons according to degrees of limitation rather than by the presence or absence of a sign, symptom, condition, or disease. Third, these measures distinguish between physical impairment and social dependency. Disability measures are consistent with the ideas of perceived need since it is the disability experience (deviation from normal social roles) which prompts most people to seek medical services. Fourth, measures of disability are discrete behavioral events understandable to the patient, his family, and members of the health system. Finally, disability classification also is sensitive to changes in the course of illness and can be used to measure patient's decline or progress toward a state free of disability (Akpom, Katz, and Densen, 1973; Given, 1973; Goldsmith, 1972; Sullivan, 1966).

The Functional Health Status Index on the encounter form asks providers of care to evaluate level of patient functioning (see Appendix A). This level was ascertained at the beginning and end of an episode of illness to determine the level of functioning as a result of illness or therapy for an episode of illness. Functional status was determined prior to treatment at the first visit for this episode of illness and at the end of five months. The change in the functional status from the first visit to the end of the episode was determined and recorded. Categories for functional status will be discussed below.

Functional disability was defined as the individual level of functioning at a point in time, the capacity to perform activities usual for the patient's age and social role. This included physical activity and mobility as well as a change in degree of major activity. Specifically, the categories used for this study were:

1. Performs usual major activity (work, school, play, retired, housekeeping). Not symptomatic.
2. Performs usual major activity and symptomatic--experiences discomfort.
3. Cut down major activity but able to care for self. Mobile--not bed disabled--symptomatic.
4. Restricted from major activity. Limited mobility--dependent--needs help in self-care--confined to house. Symptomatic.
5. Bed disabled.
6. Died.

These data were tallied utilizing the values listed above. Data were obtained from each encounter form for visits to the Center. It was possible to determine the change in functional capacity from onset to the end of the five-month follow-up period. At onset and end scores, a one through six was scored for each patient based on his capacity to function.

Specific definitions for functional categories. *Major activities*--this category refers to all things that a person originally does during a day. For a pre-schooler, it is play; for a school-age child, the major activity is going to school; for the worker, it is

ability to work. For the retiree and housewife, major activity refers to their ability to function in their usual daily activities.

Bed disabled--this category is used to identify a person who stays in bed all or more than one-half of usual awake hours.

Cut down major activity--this definition refers to a person who is not able to engage in his major activity because of symptoms. He is confined to his house though not in bed. He is usually inactive but able to care for self and is limited in the amount of daily and social activities in which he engages.

Restricted usual major activity--limited mobility, not bed disabled, reduced effort for the day and engages in only minimum activity, may be dependent and need help in self care. The patient is generally confined to the house, unable to work and engage in social activities (Given, 1973).

In addition to recording of actual status at onset and end, a score was obtained by comparing the onset functional status with the functional status at the end of five months. If the functional status had improved, one point (+1) was recorded; if the functional status had deteriorated, a minus one point (-1) was recorded; a 0 was recorded if there was no change in status. It was possible to determine how many patients had changed in functional health status throughout the study period.

Medical health status.--The condition of the patient according to signs, symptoms, and target organ involvement was used as criteria to define the medical health status for this episode of illness. Signs

and symptoms were obtained from the medical record as well as from each interview with patients. Data were collected at the onset of this episode and at the end of the five-month study period. Signs and symptoms expressed by the patient were only one measure of medical health status since many hypertensive patients are asymptomatic.

The total number of symptoms was tabulated for each patient at the beginning and end of the study. The number of expressed symptoms at onset were compared with symptoms at end of study period to determine improvement, no change, or worsened status. These categories were used to tabulate a changed score in the five-month study period. A new sign or symptom indicated a worsened condition (see Appendix D). A complication such as a stroke or hypertensive crisis was considered a worsened condition with new signs and symptoms. Symptoms evaluated in this study were headaches, dizzy spells, blurred vision, shortness of breath, edema of extremities, pain or discomfort in extremities, or limitation of physical activity.

Since some patients may be asymptomatic until late in the course of hypertensive disease, it was not applicable to give a weighted value to the number of symptoms. Each symptom was recorded only as it occurred. With the use of this method it was possible to determine changes in number of symptoms for the group of patients during the five-month period of time. The medical outcome variable for symptoms was divided into several levels:

Patients reporting reduction in number of symptoms	(+1)
Patients reporting no change in number of symptoms	(0)
Patients reporting increase in number of symptoms	(-1)
Dead (if attributed to hypertensive causes, this was coded differently so that medical status could be included).	

A -1 was tabulated for an increase in symptoms (deteriorated status), while a +1 was tabulated for fewer numbers of symptoms (improved status) and a 0 was tallied for no change in status. In this way it was possible to determine gross changes in patient's health status by an alteration in the number of symptoms the patient manifested.

Medical health status (severity index). Once a diagnosis is established it is necessary to identify the severity of the hypertension. A measure of severity can determine the prognosis and the need for, and type of, medical therapy required. Several experts recommend that such a classification system is an important and objective way to evaluate the medical health status of the hypertensive patient. Such a classification provides a broad clinical status perspective (Figure 11). It classifies severity according to blood pressures as well as target organ involvement (Dustan, 1960).

The data for the severity index were obtained from the medical record. The medical record was used as a more objective measure of medical status than patient reports of symptoms. The severity index was computed at the beginning and end of the study. Each patient received a score based on the dimensions of this index. The index included systolic and diastolic blood pressure, cardiac, renal, optic, and cerebrovascular status (target organ involvement). Each dimension was assigned a weight based on the classification of the severity of that parameter. Each patient received a score for each parameter as well as an overall severity index at onset and at the end of the five-month study period. It was then possible to determine a change during the study period in overall health status based on this severity index.

Systolic / Diastolic	0	1	2	3	4
Supine systolic blood pressure mm. Hg.	< 140 ( )	140-174 ( )	175-199 ( )	200-224 ( )	> 224 ( )
Supine diastolic blood pressure mm. Hg.	< 90 ( )	90-104 ( )	105-114 ( )	115-134 ( )	> 134 ( )
Cardiac	Normal EKG; no x-ray evidence of cardiomegaly; and no history of angina or congestive heart failure ( )	X-ray evidence of cardiomegaly and/or EKG evidence of LVH but no overt symptoms ( )	X-ray evidence of cardiomegaly and/or EKG evidence of LVH but w/symptoms (history of angina; EKG evidence of MI) ( )	Physical findings of congestive heart failure ( )	Severe comgestive heart failure ( )
Optic fundi KWB scale	Normal or KWB 1 mild narrowing of retinal sclerosis of retinal vessels difficult to distinguish normal fundi ( )	A-V knicking arteriolar narrowing; marked retinal change; sclerosis arteriovenous crossing KWB 2--retinopathy absent ( )	S A M E --KWB 2 ( )	Retinopathy; sclerotic changes; retinal edema; hemorrhage; spots; KWB 3 ( )	KWB 4 (papilledema) All signs in KWB 1, 2, and 3; diffuse retinopathy ( )
Cerebral vascular	No history of CVA ( )	History of CVA w/o residual physical findings ( )	History of CVA w/residual findings ( )	Recent CVA (w/in 2 mos.) ( )	Hypertensive encephalopathy ( )
Renal	Proteinuria absent; normal BUN (8-20 mg%); and normal serum creatinine (below 1.6 mg %) ( )	Proteinuria (1+, 2+, etc.) ( )	Serum creatinine from 1.6 to 3 mg % (or BUN from 20 to 40 mg %) ( )	Serum creatinine above 3 mg % (or BUN above 40 mg %) ( )	Proteinuria > 5 mg % BUN > 40 or nephrotic syndrome ( )

Figure 11. Hypertensive Severity Index

Based on a review of literature and classification system, a severity index was formulated for use in this study. The categories used in this index are based on end organ damage and the severity stages. In each category for each organ the graduations are such that 0 is the normal or near normal status of that parameter while 4 is the most severe. In general, patients who had an overall severity index of four would not be managed in an ambulatory setting.

Scoring of severity index.--Each patient had a beginning and end score tallied for each dimension, that is, systolic blood pressure, diastolic blood pressure, cardiac, renal, ocular fundi, and neurological status. This data was obtained from the medical record audit of each patient. For example, a patient may have a diastolic blood pressure of between 105-114 mm. Hg. and receive a three for that parameter, while he may have a systolic pressure of 180 mm. Hg. for which he would receive a score of two. Each of the six parameters were scored separately and in the same manner.

If the patient did not have the parameter evaluated in the medical record, no score was tabulated for that parameter.

For a composite severity index each of the six individual were totaled and divided by the number of dimensions included to obtain an overall severity index score. One patient may have a score of three for systolic blood pressure, a two for diastolic blood pressure, a two for cardiac status, a one for retinal status, a one for cerebrovascular status, and a two for renal status. These numbers totaled 11. This score was divided by six (total number of dimensions in severity index)

to get a severity score of 1.8. Each patient had each dimension of the severity index tabulated at onset and at the end of the five-month period, and each patient had an overall severity score tallied at onset and end of the study period. It was then possible to determine a change in the overall severity index from the beginning to the end. For example, a patient may have a severity index score of 2.5 at the beginning and a 2.0 at the end.

The change in severity index was obtained and tabulated in such a way that an improvement in status received a +1, a deterioration in status a -1, and no change in status was scored as 0. This is a gross measure, as it did not tell which of the six dimensions changed; only that the change was in overall severity status. The severity index was considered a good measure of health status since it reflects a multiple body system measure of the effect of hypertension.

Knowledge and understanding of diseases and therapy.--It was assumed that there would be a positive relationship between knowledge and compliance; the more the patient knows about his disease and regimen, the better he will carry out physician recommendations and return for needed follow-up care; and, hence, an improvement in health status would occur. Thus, knowledge and understanding were considered to be an important patient outcome dimension to be included in an evaluation study. Knowledge levels were ascertained at onset of study and at the end of the five-month period.

Effective comprehensive medical care requires that the patient have a better understanding of risks of untreated hypertension, benefits

of treatment, information about his drugs, and when to return for further medical therapy (Gifford, 1974; Finnerty, 1974). In addition, patients are concerned that they have information which would enable them to plan realistically for their lives, immediate and long-term. The patient must be a participant in this care, especially when his condition is chronic such as hypertension. The patient needs to have information about health management, prevention, symptoms to observe, complications, and the needed modifications in his lifestyle.

This study ascertained the level and understanding the patient had about his own blood pressure, basic understanding of hypertension complications and control, and his medical regimen. Each patient had a knowledge score determined for his medications, one for knowledge about hypertension and a final summary knowledge score.

To ascertain knowledge scores for medications, patients were asked to list their medication, the purpose, length of time medication has been taken, frequency, precautions, and side effects of each medication. Questions were also asked relating knowledge of restrictions such as diet, activity, habits, and needed medical follow-up (see Appendix D). Other parameters included were knowledge of disease control, signs and symptoms, complications, and their own blood pressure. Individual scores were formulated for drug and other knowledge. Then all knowledge items were combined to form an overall knowledge score.

Scoring for Knowledge.

1. Each patient record was reviewed to ascertain the drugs prescribed for patients, as well as to determine restrictions in diet,

regimen activity or habit. In addition, actual tests, blood pressure recording, and extent of control were noted to determine what knowledge patient had of his own regimen and disease control.

2. Each knowledge item the patient answered correctly in the interview was scored as +1.

3. Each knowledge item the patient did not answer correctly received a 0 for that item.

4. The patient knowledge items included: a variable number for drug knowledge based on the number of drugs in this therapeutic regimen, and 15 items possible for other knowledge items.

5. A score was obtained for *drug knowledge* based on the number of drugs the patient was on. Knowledge items were name of drug, length of time he was on it, purpose of drug, and precautions with drug. Thus there were four knowledge items for each drug. If the patient was on five drugs, there would be a possible total of five drugs times four items or a possible total of 20 knowledge items. If he knew four drugs, he would have a knowledge score of 16/20 or .8. The score tallied for drug knowledge was that proportion the patient knew of the total possible knowledge items.

6. A score for *other knowledge* was based on the number of items the patient knew of items other than drugs. Specifically, these categories included: cause, control, diet, activity, work habit, complications, degree of control, and what is hypertension. There were a total of 14 points in this category (see Questionnaire, Appendix D). A proportion score was obtained of patient's knowledge level as compared

to possible total of 14 points. Each correct response received a +1, while an incorrect response received a 0.

7. After the two separate knowledge scores were obtained, an *overall knowledge score* was obtained by combining the scores for appropriate drug and other knowledge and dividing it by the total possible items for appropriate drugs and other knowledge. This proportion was tallied for each patient.

Scores on all knowledge indexes were obtained at onset and end of study period.

Patient perception with health status and management of care.--Patient perception was defined as that satisfaction the patient expressed about his health status and the health care he received. Disruption of normal life activities may be perceived negatively by the patient despite the effect of the recommendations on his well-being. If components of the regimen are perceived by the patient as relevant or important to the well-being, it may affect his compliance rate with the recommendations made by the physician. Positive attitudes toward the suggested therapeutic regimen has been associated with patient's expectations, perception, and outcome of therapy. Patients are concerned that physicians understand their concerns, are interested in them, are thorough, spend time with them, and that their medical condition improves. Explanation of their condition was also deemed as important to patients. Because of the correspondence between what the patient expects of care and outcome, it was determined that these factors have an influence in overall medical care. Thus, patient

perception was considered a significant component of an outcome evaluation system (Hulka et al, 1971; Hulka, Kupper, and Cassel, 1973; Hulka, Kupper, and Cassel, 1975).

Patient perception was operationalized by asking the patient via interview to relate his perception of his health status and the effect of the therapeutic regimen (medications, habit, diet, and activity restrictions) to his health status. Patients were asked to relate perceptions of health care. Specifically, questions related to satisfaction with number of physicians seen, freedom to ask questions, the degree to which physician explanations satisfied them, personal interest shown, and amount of time the physician spent with them, as well as their perception of the thoroughness of the care they received.

Positive perceptions of the patient were scored as +1, and negative perceptions were scored as 0. Each patient has a perception score tallied for his health status, perception, and overall perception. The overall score was a positive score out of all the perception items included, both perception of health status and perception of health care.

Scoring of perception of health and care.

1. Each patient's perception of care was determined on his individual therapeutic regime. The initial step was to find out each drug and restriction. For each of these the patient was asked to indicate the effect this had on his hypertension. Each patient would have a unique set of items.

2. Each perception item that was a positive response was scored as +1.

3. Each perception item that was a negative response was scored as 0.

4. The patient perception of care items included eight dimensions for all patients and a variable number for perception of care based on the individual patient's therapeutic regimen. This varied with the number of medications and restrictions. Perception of health had only two items which were the degree to which the patient thought his blood pressure was in control and the rating of his health status.

5. A perception of health care score was obtained by determining the number of positive items of eight in a general category. Parameters included in this dimension were frequency of office visits, number of physicians, freedom to discuss, explanations, interest, time, thoroughness, and improvement in condition.

6. In addition, a part of the health care perception score was formulated by determining which items were consistent with the patient's individualized therapeutic regimen of medications, diet, habits, and activity. For each item the patient was asked to indicate the effect on the health status. A perception of health care proportion score was obtained based on the total possible for the individual patient's therapeutic recommendations. This proportion was tabulated as the perception of health care score.

7. A perception of health score was determined by obtaining a proportion on the two items, perception of health status and perception of degree of control. This proportion was tallied as the perception of health score.

8. After the individual perception scores were tallied, an *overall perception index* was determined. For this the patient's scores on the perception of health care and health status were combined and a proportion determined from the possible number of perception items. This proportion was tallied as the overall perception index.

9. Perception indexes were formulated and tallied at onset and at the end of the study period.

Summary of Scoring of Process and Outcome Parameters

In all of the outcome indices formulated for this study except for compliance, the score was obtained by tallying +1 for presence of an item and 0 when the item was not present. This was done in an attempt to obtain proportion scores that could be used when working with an unequal number of parameters that varied with the individual patient on the independent and dependent variable items. It was felt that proportions would better facilitate comparisons across parameters. Further, the intent of the study was not to equate certain items of value or to give some items a higher weighting; instead the intent was to determine how the extent of completeness in one variable related with the extent of completeness in another variable.

Patient Interview Guide

The Patient Interview Guide (see Appendix D) was formulated based on the determination of process and outcome criteria dimensions from the review of the literature (see Appendix F). Telephone interviews were used as a means of data collection. The telephone interview conducted by a trained interviewer took 10 to 15 minutes to administer. Patients were interviewed 7 to 14 days after onset of a new episode of being out of control and again at the end of a five-month period.

In telephone interviews misunderstanding about questions can be minimized by clarifying words and questions as the respondent answers questions. With a telephone interview items were not omitted. The interviewer probed when the respondent was unable or unwilling to initially respond to the questions; thus, a high response to all questions was obtained. The interviewer followed leads and amplified a question or probed for clarification when needed for an ambiguous patient response. In addition, in this study, the subject did not need to be literate, well, or have perfect vision and motor coordination to respond to the telephone interview. Hearing difficulties were not a problem. This means of data collection was important as the age of the patient, illness, and previous strokes and disabilities were important factors in the study patient population. Often patients are more willing to communicate feelings and concerns verbally than in writing, especially in a situation where further medical care is desired.

A major disadvantage of the telephone interview was that it required much time to contact, locate, and interview each person individually. It took numerous telephone calls to contact many patients. Other problems were that several patients important to the study did not have a telephone and numerous patients moved during the study period. The cost in time and effort was great with the telephone interview but less than there would be by personal interview in which travel time would be added. Using a structured interview format minimized problems in administration, recording, and interpretation of the collected data. In addition, responses were put in standardized categories to facilitate recording by the interviewer and interpretation by the patient. This also facilitated data analysis.

Process Data Collection Guide

The structured medical record audit was formulated based on process criteria determined from the review of the literature (see Appendix F). Patient records were reviewed at onset to ensure that patients met the criteria for inclusion in the study. At the end of the study period the records were audited using structured collection guides (see Appendix G). All needed process data, results of diagnostic tests, referrals, and physician progress notes were recorded at that time.

The advantage of using the patient record was that the data could not be affected by the researcher; it facilitated following an episode of illness and details of the management of the care of that

patient during the five-month study period. Utilizing patient records was an inexpensive and convenient source of data since all of the data were available at once. The disadvantage of utilizing a record as a data source was that there was no assurance of the accuracy and completeness of the record. More activities, procedures, or assessments may have been carried out for the patient than are actually documented in the record. In a center where several physicians may provide care to the patient it is essential that documentation be completely reliable. Even if the record is not complete, those providing care will plan, prescribe, and evaluate the effectiveness of the control program based on records and current patient status. Process data were recorded based on contents of the record. There is no attempt in this study to determine the accuracy or thoroughness of the documented care as compared to the actual care received.

Pilot Study

A small-scale pilot study of five patients was conducted during the early stage of the study to pretest the effectiveness of the data collecting instrument and to run a preliminary trial of the research methodology. This was done to determine problems in the instruments, to refine the interview process, and to determine the feasibility and effectiveness of the telephone interviews. In addition, the pilot study was used to determine if it were possible to collect the data from the patient by telephone interview and from the medical record in a systematic fashion. Data analysis procedures were also briefly

examined. Ten telephone patient interviews and 10 patient records were used for the pilot study. None of these patients were used in the final study. Results of the pilot study indicated that telephone interview guide and process audit revisions were needed. It was necessary to provide probes for the open-ended questions to provide the interviewer with key words to elicit data from the patient. Key areas for revision related to control and understanding of hypertension. In addition, it was necessary to provide the patient with options on how therapeutic regimen components had altered their health (Appendix D). A change in format of the questionnaire was also necessary to facilitate interviewer recording of data while interviewing via telephone.

The *Medical Record Audit Collection* form was also revised to facilitate a more organized recording of medications, laboratory data, blood pressure from the chart, and to place the data in chronological order for each visit during the five-month period of time.

After revisions were finalized, new data collection instruments were made and data collection began. The final form of the Medical Record Audit can be seen in Appendix G.

Data from pilot interviews and charts were tabulated and analyzed. Revisions were made in both instruments based on the pilot study analysis. The original direction and focus were kept; however, several questions were reworded and the organization of the format for collecting data from patient records was changed to facilitate ease of data collection. The interviewer who was a nonmedical person provided suggestions during her training period on the refinement of wording of

questions to facilitate patient understanding of terms. The pilot study also provided experience in classification and categorization for data to ensure that data would be collected in a form that could be scored to facilitate analysis. It was at this time that the medical health care severity index and functional status indices were formulated.

Comparison of Process and Outcome Dimensions

The previous sections of this chapter discuss the method by which the individual process and outcome indices were obtained and scored. After all data were collected and indices formulated, it was necessary to combine these indices in such a way as to determine what relationships existed between the process and outcome variables. Establishing the relationship between process and outcome variables was necessary to answer the research questions posed for the study (see Chapter I). Specifically, relationships were analyzed between each of the independent process variables of diagnostic and therapeutic process and patient compliance, and the dependent outcome variables of functional health status, medical health status, knowledge level and perception of health and care level. In order to determine relationships between independent and dependent variables, cross tabulations, correlation, and multiple regression were the main data analysis techniques used. Analysis of variance was used to determine the effect of the independent variables on the dependent variables.

Following will be a brief discussion of the statistical techniques.

Data Analysis

Cross Tabulations

Cross tabulations are joint frequency distributions of cases according to two classificatory variables. The relationship is examined by means of a measure of association and a test of statistical significance. A measure of association indicates how strongly two variables are related to each other and to what extent two variables occur together--to what extent prior knowledge of a value on one variable enables one to predict the value on the other variable.

Chi Square

Chi square is a test of statistical significance. It helps to determine whether a systematic relationship exists between two variables or if the relationship is absent (statistically independent). It helps one to determine whether the variables are independent or related but does not indicate how strongly they are related.

The larger the chi square, the greater the obtained frequencies deviate from the expected chance frequencies.

The .05 level was utilized as the level to test statistical significance. This means that an obtained result that is significant at the .05 level could occur by chance only five times in 100 trials.

Correlations

Correlations were carried out for each independent variable with each dependent variable. A correlation summarizes the relationship

between two variables and indicates the degree to which variation in one variable is related to variation in another. The correlation coefficient *summarizes* the direction and strength of the relationship between variables.

The Pearson correlation is a measure of relationship indicating the direction and strength of the linear relationship between two variables and varies from -1 to +1. The objective in using correlational analysis is to determine the extent to which variation in one variable is linked to variation in the other (concomitant variation).

Multiple Regression

Multiple regression requires that variables be measured on an interval or ratio scale. This technique can be used to analyze the relationship between a dependent variable and a set of independent variables. It is a descriptive tool which summarizes the linear dependence of one variable upon other variables. This type of data analysis was employed in this study to evaluate the contributions of the independent variable on the dependent variable. It provided a measure of the overall dependence of the outcome variable on the independent variables of diagnostic and therapeutic process and patient compliance. The intent was to examine relationships and not to focus on predictions.

Analysis of Variance

Analysis of variance is used to determine whether there are differences between group means. Analysis of variance is a technique

for measuring the statistical (not necessarily causal) effect of a given factor on the dependent variable. The question asked is: Do the means differ between groups beyond chance fluctuations?

Level of Significance

The level of significance selected for this study was .05. This means that results considered significant at the .05 level could occur by chance only five times in 100.

In the next chapter there will be a presentation of the findings obtained in the study. Data will be presented according to the outcome and process variables identified earlier.

CHAPTER V

ANALYSIS AND FINDINGS

Overview

This chapter presents findings based on the data collected from 103 hypertensive patients in one family practice center. The focus of the data collected includes process and outcome components of care (see Appendices D, F, and G). The data describe the diagnostic, therapeutic, and patient compliance components of process of care and the outcome components of functional status, medical health status, perception of health and care, and knowledge. The findings presentation will be divided into:

1. Descriptive findings of the study population.
2. Relationships of independent variables with dependent variables.
    a. Relationships of independent variables, diagnosis, therapy, and compliance with dependent variable functional status outcome (Research Question I).
    b. Relationships of independent variables, diagnosis, therapy, and compliance with dependent variable medical health status (Research Question II).
    c. Relationships of independent variables diagnosis, therapy, and compliance with dependent variable perception of health and care (Research Question III).

d. Relationships of independent variables diagnosis, therapy, and compliance with dependent variable knowledge and understanding of his disease and therapy (Research Question IV).

e. Summary relationships of the combined independent variables with each dependent variable (Summary Research Question).

To answer the research questions, the relationships between the independent and dependent variables were determined by analysis of the data. Statistical techniques used for analysis were cross tabulations, correlations, multiple regression analysis, one way analysis of variance, and chi square.

Descriptive Information

The study population consisted of patients attending the clinic with diagnosed hypertension for an episode of illness in which they were out of control.

All hypertensive patients coming to the Center meeting the criteria were included in the study until 100 patients were obtained. Two patients of the group contacted initially refused to be interviewed for the study and another 10 patients were unable to be contacted via telephone or located to respond to a mailed questionnaire. Many other hypertensive patients were seen in the Center but did not meet the criteria for inclusion in the study (see Figure 4). Only 30 percent of the total group was employed.

There were 71 (68.9%) women and 32 (31.1%) men. Two women died during the five months; one from a stroke and one from advanced breast cancer.

Of the two patients who died, the patient with breast cancer died with her blood pressure under control during the last phases of her life. The patient with the stroke was a patient who was not highly out of control at onset of the study but was not brought under control by medical therapy and became increasingly worse until she was admitted to a hospital as an emergency admission and died soon thereafter.

One patient had a slight stroke; however, she recovered with slight residual damage and no disability. During the period of the study, four patients were lost to medical follow-up. Of those, three patients decided not to return to the setting, one could not be reached. At the end of the study period, 97 patients were still returning on a regular basis and receiving needed care for hypertension. During the five-month period of time, 20 patients were hospitalized with an additional six patients having been to the Emergency Room for one or more visits.

The age range of the group of patients can be seen by examination of Table 1. It can be seen that the majority of the patients were 50 years of age or older. Examination of the table reveals that 12 of the patients were 20-39, while 44 patients were between 40-59, and 46 patients were between 60-79, with only one patient above 80.

Table 1

Age and Sex of the Study Population (N = 103)

		Number of Patients	Percentage (%)
Sex:	Male	32	31
	Female	71	69
Age:	20-39	12	12
	40-49	15	15
	50-59	29	29
	60-69	23	23
	70-79	23	23
	80-89	1	1

Severity Status of the Population

Table 2 presents the data of the entry profile and Table 3 presents the exit profile of the patients according to severity index (see Figure 11).

It can be seen by looking at Table 2 that the patients were distributed in all five severity categories; however, as expected in an ambulatory care setting, most patients followed were found to be in the lower severity index levels, that is, near control.

An examination of Table 2 and 3 reveals that blood pressures were a routine part of the assessment obtained at the time of the patient visits to the Family Practice Center while most of the patients did not have assessment of the parameters of the cardiac, optic, cerebrovascular and renal systems to evaluate end-organ involvement.

Table 2

Descriptive Profile of Patients' Severity Index at Onset of Study (N = 103)

Severity Index Parameter	Severity Index Category										Missing Data	
	0		1		2		3		4		5	
	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%
Supine systolic blood pressure	2	2	49	48	35	34	13	12	4	4	0	0
Supine diastolic blood pressure	8	8	53	51	36	35	4	4	2	2	0	0
Cardiac	41	40	30	29	15	14	4	4	1	1	12	12
Optic fundi KWB scale	18	18	16	15	12	12	--	--	--	--	57	55
Cerebrovascular	24	23	23	22	7	7	-	--	--	--	49	48
Renal	64	62	17	16	10	10	--	--	--	--	12	12

Table 3

Descriptive Profile of Patients' Severity Index at End of Five-Month Study (N= 103)

Severity Index Parameter	Severity Index Category										Missing Data	
	0		1		2		3		4		5	
	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%
Supine systolic blood pressure	18	17	59	57	15	15	5	5	--	--	2 died 4 n.d.[a]	6
Supine diastolic blood pressure	29	28	44	43	21	20	2	2	--	--	2 died 5 n.d.	7
Cardiac	32	32	24	23	13	13	4	4	--	--	2 died 25 n.d.	2 25
Optic fundi KWB scale	19	19	10	10	7	7	--	--	--	--	2 died 62 n.d.	2 62
Cerebrovascular	22	22	15	15	5	5	3	3	--	--	2 died 53 n.d.	2 53
Renal	51	51	12	12	7	7	2	2	--	--	2 died 26 n.d.	2 26

[a] n.d. = no data.

This is especially evident when noting that 62 percent of the patients did not have optic fundi assessment, 53 percent of the patients did not have documented cerebrovascular status, 26 percent did not have renal status and 25 percent did not have documented cardiac status evaluation.

Tables 4 and 5 present the data of actual changes in severity category for individual patient's systolic and diastolic blood pressure during the study period. At onset, severity index category 0 had two patients (1.9%) with systolic blood pressure (< 140 mm. Hg.) with 18 patients (17.4%) in this category at the end for a change of 16 patients. Diastolic blood pressure (< 90 mm. Hg.) in the severity index category 0 at onset revealed eight patients (7.8%) with 29 patients (28.2%) by the end of the study. There were 21 more patients in this 0 diastolic category by the end of the study.

Severity index category 1 had 49 patients (48.5%) in the systolic blood pressure category (140-174 mm. Hg.) at onset with 59 patients (57.3%) in this category at the end. This constituted a change of 10 more at the end of the study in systolic severity index category 1. Diastolic blood pressure (90-104 mm. Hg.) severity index category 1 at onset had 53 patients (52%) and 44 at the end of the study. This reflected a change in status of nine or more patients in this category.

In severity index category 2 there were 35 patients (34%) at onset with systolic blood pressure (175-199 mm. Hg.) in this range while 36 patients (35%) had a diastolic blood pressure (105-114 mm. Hg.)

Table 4

Severity Index Category for Systolic Blood Pressure at Onset and End of Study (N = 103)

Systolic Blood Pressure Severity Index Category	Onset		End		Change in Category
	No. of Patients	%	No. of Patients	%	No. of Patients
0 (< 140 mm. Hg.)	2	2	18	18	+16
1 (140-174 mm. Hg.)	49	49	59	58	+10
2 (175-199 mm. Hg.)	35	34	15	14	-20
3 (200-224 mm. Hg.)	13	12	5	5	-8
4 (> 224 mm. Hg.)	4	3	0	0	-4
Deaths	0	0	2	2	+2
No data	0	0	4	3	+4

Table 5

Severity Index Category for Diastolic Blood Pressure at Onset and End of Study (N = 103)

Diastolic Blood Pressure Severity Index Category	Onset		End		Change in Category
	No. of Patients	%	No. of Patients	%	No. of Patients
0 (< 90 mm. Hg.)	8	8	29	28	+21
1 (90-104 mm. Hg.)	53	53	44	43	-9
2 (105-114 mm. Hg.)	36	35	20	19	-16
3 (115-134 mm. Hg.)	4	4	2	2	-2
4 (> 134 mm. Hg.)	2	1	0	0	-2
Deaths	0	0	2	2	+2
No data	0	0	6	6	+6

in severity index 2. At the end of the study period, 15 patients (14.6%) were in systolic severity index category 2. This was a change of 20 more patients in this systolic blood pressure category. The diastolic blood pressure end score revealed 21 patients in the severity index category 2. This was a change in 15 additional patients.

At onset of the study there were 13 patients (12.6%) in severity index category 3 systolic blood pressure category (200-224 mm. Hg.) while there were seven patients (3.9%) in the severity index 3 diastolic blood pressure category (115-134 mm. Hg.). The end study profile revealed five patients (4.9%) with systolic blood pressure in severity index category 3 for a change of eight more patients in this category. The end diastolic blood pressure range revealed two patients (1.9%) for only a change of two more patients in this severity index category at the end of the study.

Severity index 4 revealed four patients (3.9%) in this systolic blood pressure category (> 224 mm. Hg.) on onset while no patients were in this category at the end of the study; however, one patient had died of high blood pressure and one patient had had a stroke and had now been brought into hypertensive control with minimal residual damage. Diastolic blood pressure severity index 4 (> 134 mm. Hg.) at onset revealed two patient (2%) and no patients in this category at the end. Again, the death and stroke patient are a part of study and changes during the study are not clearly reflected in this fourth category.

Table 6 presents the summary of changes in status on blood pressure recordings and overall severity index during the study period.

Table 6

Change in Systolic Blood Pressure, Diastolic Blood Pressure, and Overall Severity Index During Study (N = 99)[a]

Parameter	Change in Status		
	No. of Patients Improved	No. of Patients With No Change	No. of Patients Worsened
Systolic blood pressure	43 (42%)	46 (45%)	10 (10%)
Diastolic blood pressure	45 (44%)	39 (38%)	15 (14%)
Overall severity index	41 (40%)	37 (36%)	21 (21%)

[a]Four patients with no end data.

This reveals actual changes in the individual patients. It will be noted that there is a close comparison of numbers of patients who changed during study period between severity index and blood pressure readings although severity index has a larger number of patients who deteriorated. This may reflect the fact that in addition to the blood pressures reading the overall severity index examines end organ involvement. It would be more indicative of extent of damage of hypertension rather than the mere blood pressure recording at a point in time. Looking at the individual patient's recording of systolic blood pressure total changes for the study population, we find that 43 patients improved while 46 had no change in severity index category and 10 patients deteriorated.

Examination of Table 6 reveals that for diastolic blood pressure 45 patients improved, 39 patients had no change, and 15 patients had a more elevated diastolic blood pressure by the end of the study.

This suggests that for those patients that did not change, examination of the therapeutic regimen may be necessary to determine why there was no change. For patients who deteriorated, there is a need for very careful analysis of the regimen as well as the compliance level. It would appear for the severity index that about 40 percent did benefit from the therapeutic regimen followed to bring the hypertensive episode into control while 21 percent of the patients deteriorated.

Patient Visits

Patients had a wide variation in frequency of visits to the Center during the five-month study period. From Table 7, one can see that the most patients visited the Center was between 5-7 times. Forty-three patients (42%) visited the Center 5-7 times while 31 patients (30%) were seen between 2-4 times during the five-month study period. According to the criteria designated in Chapter IV, one would expect that patients who were out of control needed to be seen every three weeks; one would then expect about 7 visits per patient during the study period. If the patient was brought under control, visits might be every six weeks; that would mean 3-4 visits in the five-month study period.

The visit pattern of patients in this study was typical of that expected. Breaking appointments varied with the study population (Table 8). Sixty-three patients (61.2%) did not miss any appointments.

Table 7

Number of Patient Visits to the Center During the Study
(N = 103)

Number of Visits	Number of Patients	Percentage of Patients
1	1	1
2-4	31	30
5-7	43	42
8-10	16	15
11-13	9	9
14-16	3	3
Total	103	100

Table 8

Rate of Broken Appointments During the Study
(N = 103)

Broken Appointments	Number of Patients	Percentage of Patients
0	63	61
1	22	21
2	10	10
3	2	2
4	2	2
5	1	1
6	0	0
7 or more	3	3
Total	103	100

Twenty-two patients (21.4%) missed one appointment. Eighteen patients missed two or more scheduled appointments. Three patients missed seven or more scheduled appointments. These three patients were severe hypertensives who were also in poor control. One would question how the breaking of appointments contributed to the change in status of these 18 patients.

Physicians Seeing Patients

Table 9 presents data on number of physicians who saw patients during the five-month study period. Thirty-four of the patients (33%) were seen by three or more physicians during the five months. It would appear to be quite difficult to maintain continuity and to evaluate change in status with the number of physicians caring for the patients. Of the 11 patients who had four or five doctors, four of the patients had missed four office visits for medical care during this period of time.

Table 9

Number of Physicians Seeing Patients During Study
(N = 103)

Number of Doctors	Number of Patients	Percentage of Patients
1	27	26
2	42	41
3	23	22
4	8	8
5	3	3

Functional Status

In order to gain a perspective on the function capacity of patients at onset of the study, the function status was tabulated (see Table 10). The Functional Status Index was determined by asking the patient to indicate his functional capacity. Functional status was also determined from the encounter form at the onset. The categories used to classify functional capacity were:

1. Performs usual major activity--not symptomatic.
2. Performs usual major activity and symptomatic with discomfort.
3. Cut down major activity.
4. Restrict major activity.
5. Bed disabled.
6. Died.

Patients at onset of their episode of illness described the functional status such that all but eight of the patients had symptoms to the extent that it interfered with their functional capacity. Most of the patients were able to carry out their usual activities but with some symptoms.

At the end of the study, results indicated the functional status changed so that six more patients were in functional status category 1; there were four fewer patients in functional status category 2; however, there were 28 fewer patients in category 3. It can be seen that 10 additional patients ended up in functional status category 4. No patients were in this category at onset. This does not reflect the two patients who died and the one who had a stroke, who at the end of the study was in category 3.

Table 10

Functional Status Level at Onset and End of Study (N = 103)

Functional Status Level	Study Period				Change in Category
	Onset		End		
	No. of Patients	%	No. of Patients	%	No. of Patients
1. Performs usual activity without symptoms	8	8	24	23	+16
2. Performs usual activity with symptoms	49	48	45	44	- 4
3. Cut down major activity	46	44	18	17	-28
4. Restricts major activity	0	0	10	10	+10
5. Bed disabled	0	0	0	0	0
6. Died	0	0	2	2	+ 2
7. No data	0	0	4	4	+ 4
Total	103	100	103	100	

Only 30 percent of the patients in this study are employed; thus the restriction and decrease in activity reflects for the most part the household activities of the females of this study population. Ten percent of those persons who did work or have major activities outside the home indicated that during this episode of illness they had to miss work, although the actual number of days missed were limited to one or two days.

Data on functional status changes during the study period were obtained (see Table 11) and noted for each patient. Results revealed that 40 patients improved while no changes occurred in 40 patients, and 19 patients (18%) deteriorated during the study period. Of the two patients who deteriorated, two patients died and one had a stroke. Data were unavailable on four patients.

Table 11

Change in Functional Status During Study (N = 99)[a]

Parameter	Change in Status		
	No. of Patients Improved	No. of Patients With No Change	No. of Patients Worsened
Functional status	40 (39%)	40 (39%)	19 (18%)

[a]Four patients with no end data.

Signs and Symptoms

Signs and symptoms were also ascertained as a dimension of the patient status (see Table 12). At onset and end of the study, patients were asked to list those symptoms they had at this episode of illness (see Appendix D). At onset, 44 patients had five or more symptoms while at the end only 20 patients had five or more symptoms. At onset 20 patients had 0-2 symptoms compared to 49 in this category at the end of the study. At onset 39 patients had 3-4 symptoms while only 30 had 3-4 symptoms at the end of five months. The symptoms most commonly

Table 12

Patients' Description of Signs and Symptoms at Onset and End of Study (N= 103)

Number of Symptoms	Number of Patients				Number of Patients Who Changed
	Onset		End		
	No. of Patients	%	No. of Patients	%	
0	5	5	16	16	+11
1-2	15	14	33	32	+18
3-4	39	38	30	29	-9
5-6	26	25	14	14	-12
7-8	18	18	6	5	-12
No data	--	--	4	4	+4

occurring were headache, dizziness, blurred vision, shortness of breath, and pain or discomfort in the legs. Again, at the end, the most frequent symptoms were headaches, dizziness, and blurred vision with leg discomfort and shortness of breath being less frequent. By the end of the study period, the average number of signs and symptoms per patient was three, while at onset the average number was four. It appears there was a reduction in the number of symptoms the patients experienced from onset to end of the study five months later.

Being more specific for the individual analysis, it was found that 64 patients improved, 13 patients did not have a change in signs and symptoms and 22 patients had more signs and symptoms by the end of the five-month study period (Table 13).

Table 13

Change in Number of Signs and Symptoms in Patients During Study (N = 99)[a]

	No. of Patients	Percentage of Patients Who Changed
Fewer signs and symptoms	64	62
No change	13	12
Increased signs and symptoms	22	22
Total	99	97

[a]Four patients with no end data.

Patient Ranking of Health Status

Patients were asked to rank their general health at the onset and end of the study. Patients ranked their general health status as excellent, good, fair, or poor. Results are revealed in Table 14. An observation that can be noted from the table is that although patients improved in health status, they did not change their health status ranking. The changes that did occur probably reflect the no data at the end.

Cross tabulations were carried out to examine the comprehensiveness of the independent variables diagnostic approach, therapeutic approach, and patient compliance when patients were divided into onset severity categories.

Table 14

Patients' Ranking of General Health Status at Onset and End of the Study (N = 103)

Ranking of Health Status	Study Period				Number of Patients Who Changed
	Onset		End		
	No. of Patients	%	No. of Patients	%	
Excellent	8	8	6	6	-2
Good	47	46	44	42	-3
Fair	35	34	36	35	+1
Poor	11	10	10	10	-1
No data	2	2	7	7	+5
Total	103	100	103	100	

Comprehensiveness of Process Components According to Severity Category

Diagnostic approach.--The comprehensive diagnostic index is outlined in Chapter IV, Figure 7. The diagnostic process is obtained from patient's records (see Medical Record Audit Process Guide in Appendix G) at the end of the five-month study period. It had been intended that the scores would be classified based on the thoroughness of the diagnostic approach so that scores over 75 percent would be considered good, and between 50-74 percent fair, and poor below that level. Actual scores did not permit this classification breakdown since very few scores fell in the high level. Levels were then set to classify the patients according to the actual ranges of the distribution of the scores to allow patients to fall within several

classification categories. Level I included scores in which 0-32 percent of the items were completed, Level II included those scores in which 33-49 percent of the diagnostic items were completed, and Level III included those scores that fell above 49 percent.

Complete history and physicals had been completed on 62 patients (59%). Of those completed, 18 were history and physical examinations that had been completed during hospitalization. This means that 41 patients (39%) did not have a complete history and physical on their record. Table 15 presents the data examining how comprehensivenss of diagnosis varied by severity category at onset. From this table one can see that 57 patients were in category 1 of severity, 36 patients were in category 2, while only 10 patients were in the more severe category. Thirty patients (29%) had the least level of diagnostic measures completed, 42 patients (41%) had between 33-48 percent of the diagnostic measures completed, while 31 patients had 49 percent or more of the diagnostic items completed.

The highest percentage on the diagnostic scale was 71 percent with the mean at 40 percent. About 60 percent of the patients had less than one-half of the criteria diagnostic items completed and documented in the record. Even in the most severe medical status category, patients had below 48 percent of the items conducted. Only one patient of the 10 most severe class had 48 percent of the diagnostic items completed. It would appear that comprehensiveness varied between 0-71 percent with the greatest frequency between 33-48 percent. As can be seen from Table 15, there was no difference in the comprehensiveness of the diagnostic approach when patients were classified into severity

Table 15

Cross Tabulations of Onset Severity Category with Independent Variable Diagnostic Approach (N = 103)

	Independent Variable Diagnostic Approach[a]			
	Level I (0-32% of Total Items Possible)	Level II (33-43% of Total Items Possible)	Level III (49-80% of Total Items Possible)	Row Total
Onset severity index	1	2	3	
Category 1 (0-1.0)	15	22	20	57 (55%)
Category 2 (1.1-2.0)	13	13	10	36 (35%)
Category 3 (2.1-2.5)	2	7	1	10 (10%)
Total for column	30 (29%)	42 (41%)	31 (30%)	103 (100%)

[a]Chi square = 5.27452 with 4 df; significance = .26.

categories. It would appear that onset severity health status did not alter the diagnostic approach of the physician. The chi square was 5.27452 with 4 df. This was not significant, but may be distorted by the small number of patients in category 3. There was no significant difference between groups beyond what may have occurred by chance. Table 16 presents one way analysis of variance to determine if there was a significant difference between severity groups. Again, one can see that there was no significant difference in the level of diagnostic activities based on the severity groups.

Therapeutic approach.--Table 17 presents the data on comprehensiveness of the therapeutic approach as categorized by severity status at onset. Levels used for analysis were: 0-39 percent of the therapeutic items were labeled Level I, 40-52 percent of the therapeutic items were labeled Level II, and patients who had 53 percent or more of the therapeutic items included during the study period were labeled Level III. It was the intent of the researcher to set acceptable levels of therapeutic comprehensivenss above 50 percent of the criteria items. Actual data, however, did not find enough therapeutic scores at this level for such a breakdown. Data presented in Table 17 reflects actual distribution of patients in categories rather than according to predetermined categories of thoroughness of therapy.

Examination of Table 17 indicates that 29 percent of the patients received Level I of the therapy, indicating that the physician completed between 0-39 percent of the items designated in the process criteria (see Figure 8) of the components of therapy. Forty patients

Table 16

One Way Analysis of Variance of Diagnostic Approach by Onset Severity Category

Source	df	Sum of Squares	Mean Squares	F Ratio	Significance
Between groups	2	511.6530	255.8265	1.870	.160
Within groups	100	13681.8421	136.8184		
Total	102	14193.4951			

Cell Analysis of Diagnostic Approach by Onset Severity Category

Group	Count	Mean	Standard Deviation	Standard Error
Category 1 (0-1.0)	57	41.9474	12.2042	1.6165
Category 2 (1.1-2.0)	36	37.1667	11.6116	1.9353
Category 3 (2.1-2.5)	10	41.0000	8.3133	2.6289
Total	103	40.1845		

Table 17

Cross Tabulations of Onset Severity Category with Independent Variable Therapeutic Approach (N = 103)

Onset Severity Index	Independent Variable Therapeutic Approach[a]			Row Total
	Level I (0-39% of Total Items Possible)	Level II (40-52% of Total Items Possible)	Level III (53-80% of Total Items Possible)	
Category 1 (0-1.0)	14	28	15	57 (55%)
Category 2 (1.1-2.0)	15	10	11	36 (35%)
Category 3 (2.1-2.5)	1	2	7	10 (10%)
Total of column	30 (29%)	40 (39%)	33 (32%)	103 (100%)

[a]Chi square = 12.313 with 4 df; significance = .0152.

(39%) had Level II (40-52%) of the therapeutic items included during the five-month study period while 32 patients (33%) had Level III (53-80%) of the therapeutic items completed. Of the 10 most severe patients, three received Level I or Level II comprehensiveness in the therapeutic approach, while seven had Level III (53-80%) therapeutic items completed. In severity category 2, 15 patients received the lowest range of therapeutic activities (Level I). Evidence from Table 17 indicates that an additional 10 patients (28%) of that group had only Level I; thus only 11 of the 36 patients in severity category 2 (31%) received a level of therapeutic activities in which 53 percent or more of the criteria items were included in the management of patient care.

In severity category 1, more of the patients (28) were in Level III of comprehensiveness of therapeutic activities. An almost equal number of patients were found in therapeutic Level I (14) and Level III (15).

The chi square for this analysis is 12.31 with 4 df. This is significant and would suggest a difference in treatment based on the onset severity status; however, the small number of patients in severity category 3 may distort this. Analysis of variance was used as another method to determine whether there was a significant difference between severity groups. Table 18 presents this analysis and one can see that there was no significant difference in the level of therapeutic approach based on the severity at onset.

Table 18

One Way Analysis of Variance Therapeutic Approach by Onset Severity Category

Source	df	Sum of Squares	Mean Squares	F Ratio	Significance
Between groups	2	825.2444	412.6222	2.204	.116
Within groups	100	18718.6003	187.1860		
Total	102	19543.8447			

Cell Analysis of Therapeutic Approach by Severity Category

Group	Count	Mean	Standard Deviation	Standard Error
Category 1 (0-1.0)	57	46.421	13.9948	1.8537
Category 2 (1.1-2.0)	36	45.6389	13.9328	2.3221
Category 3 (2.1-2.5)	10	55.6000	10.3086	3.2599
Total	103	47.0388		

Patient compliance.--Patients' compliance levels were tabulated according to onset severity status. Table 19 presents these tabulations.

Table 19

Cross Tabulations of Onset Severity Category with Independent Variable Patient Compliance (N = 103)

	Independent Variable Patient Compliance[a]			
Onset Severity Index	Level I (0-34% Compliance)	Level II (35-66% Compliance)	Level III (67-99% Compliance)	Row Total
Category 1 (0-1.0)	10	13	32	55 (55%)
Category 2 (1.1-2.0)	9	11	14	34 (33%)
Category 3 (2.1-2.5)	3	3	4	10 (10%)
Total of column	22 (22%)	27 (27%)	50 (50%)	99 (99%)

[a]Chi square = 3.8256 with 4 df; significance = .4302.

From the table one can see that 22 patients reported 0-34 percent compliance while 27 patients reported 35-66 percent compliance with therapeutic regimen. Fifty patients reported compliance rate with the regimen between 67-99 percent. It can be noted that in all severity categories patients' reported compliance is distributed across all three levels. The chi square for compliance levels based on severity index was 3.8256 with 4 df. This was not significant, suggesting that compliance levels did not differ according to the onset severity status of the patient.

One way analysis of variance was also conducted to determine if there was a significant difference between severity groups. Again, from Table 20, one will note that there was no significant difference in level of compliance based on the severity status of the patient.

In summary, the cross tabulations indicate that there was no alteration in process, either diagnostic and therapeutic approach by the physician or patient compliance, with the onset severity status of the patient.

Summary

The preceding section presented an overview of the population characteristics under study. The specific characteristics of the population presented were: age, sex, severity status, diastolic and systolic blood pressure, visits to center, broken appointments, and number of physicians seeing patients. In addition, functional status, signs and symptoms, ranking of health status, and cross tabulation of process components with severity status were presented.

Now that the reader has a perspective of the study population at onset, changes throughout the study and at the end of the study period, the research questions will be presented.

The research questions for this study focused on how diagnosis and therapy, coupled with the patient compliance behavior, affected the outcome status of the patient. Specifically, the outcome measures were functional status, knowledge, medical health status, and perception of health and care. The next section of this chapter will present the findings from the data analysis in an attempt to answer the research

Table 20

One Way Analysis of Variance of Patient Compliance by Onset Severity Category

Source	df	Sum of Squares	Mean Squares	F Ratio	Significance
Between groups	2	1897.0109	984.5054	1.168	.315
Within groups	100	81203.8047	812.0380		
Total	102	83100.8156			

Cell Analysis of Patient Compliance Level by Severity Category

Group	Count	Mean	Standard Deviation	Standard Error
Category 1 (0-1.0)	57	62.9825	28.7424	3.8070
Category 2 (1.1-2.0)	36	54.7222	27.2644	4.5441
Category 3 (2.1-2.5)	10	53.2000	31.4883	9.9575
Total	103	59.1456		

questions posed for the study. The level of significance used to answer each question was .05. The first question to be presented is concerned with the diagnostic approach and the affect on outcomes.

Research Questions

Diagnostic Approach

Research Question I: What is the relationship between comprehensive diagnostic approach and the patient outcome?

This question was subdivided into four parts, each of which will be examined prior to answering the overall question.

I-A. What is the relationship between a comprehensive diagnostic approach and functional status outcome? By examining Table 21, it can be noted that there is only negligible correlation with history as a measure of diagnostic approach and the functional status outcome for the hypertensive patient. None of the diagnostic measures except for history were related to the functional measures; thus, there is no relationship between a comprehensive diagnostic approach and functional status outcome.

I-B. What is the relationship between a comprehensive diagnostic approach and medical health status? Medical health status (severity index) was used as a parameter of outcome as it reflected a more comprehensive approach to the status of the hypertensive patient since it reflects multiple organ effect of the disease process. Blood pressure alone would not reflect a broad picture of the medical status of the patient.

Table 21

Pearson Correlations of Independent Variable Diagnostic Approach and Dependent Variable Functional Status Outcome (N = 99)

Independent Variable Diagnostic Approach	Dependent Variable Functional Status Outcome
History	.18*
Physical	-.09
Laboratory and radiological exam	.04
Overall diagnostic approach	.07

*Significant at the .05 level.

Although the overall medical health status (severity index) is the parameter to be used to answer the research question, Table 22 reflects examination of several medical health status outcome measures and their correlation with the components of diagnostic approach. From this table one can see that history, laboratory tests, and the overall diagnostic process are inversely correlated at a significant level with systolic blood pressure, that is, as the diagnostic approach becomes more complete, the systolic blood pressure outcome is lower. Systolic blood pressure correlated at -.23 with history, -.17 with laboratory and radiological examinations, and -.20 with overall diagnostic approach. All three of these correlations are significant at the .05 level. Diastolic blood pressure was not significantly related to the diagnostic parameters except with the history. (This correlation is -.23.)

Table 22

Pearson Correlation of Independent Variable Diagnostic Approach and Dependent Variable Medical Health Status Outcome (N = 99)

Independent Variable Diagnostic Approach	Dependent Variable Medical Health Status Outcome					
	End Systolic Blood Pressure	End Diastolic Blood Pressure	End Medical Health Status (Severity Index)	End Signs and Symptoms	Change in Signs and Symptoms	Change in Medical Health Status (Severity Index)
History	-.23*	-.23*	-.20*	.17	.06	.22*
Physical	-.06	.09	.04	-.22*	.14	-.08
Labs	-.17*	-.13	-.12	.08	.04	.11
Overall diagnostic	-.20*	-.15	-.15	.04	.11	.13

*Significant at the .05 level.

The key medical health status indicator (severity index) showed a significant inverse relationship with history. The physical examination overall diagnostic score did not correlate with medical health status, meaning that health status did not improve with a more comprehensive physical examination or overall diagnostic. The history dimension correlated with the health status at -.20, while the comprehensiveness of the overall diagnostic approach did not correlate significantly with health status.

The end of study signs and symptoms showed no significant relationship with diagnostic approach except for a relationship with physical examinations. The other parameters of history, laboratory, and radiological examination and overall diagnostic process did not correlate with signs and symptoms. As the diagnostic approach becomes more complete, the patients' signs and symptoms did not become fewer. Change in signs and symptoms throughout the five-month study period also did not show any significant relationship with any of the diagnostic parameters.

The medical health status changes did not show significant relationship with diagnostic approach except for the history which is significant at the .05 level, with the correlation being .20. Thus, in summary, the only significant relationship between comprehensive diagnostic approach found was with systolic blood pressure and the magnitude of correlation was low.

I-C. What is the relationship between a comprehensive diagnostic approach and patient's perception of health and perception of care? Examination of Table 23 shows that *overall* diagnostic approach was significantly related to perception of health (.20) and overall perception (.18). Perception of health and overall perception were significant although the correlation was negligible. It appears from the table that there was a negligible relationship between a comprehensive diagnostic approach and patient's perception of his health as well as perception of his medical care. It would appear that the diagnostic approach would have only a slight effect on patient's perception of care and his health status.

Table 23

Pearson Correlations of Independent Variable Diagnostic Approach and Dependent Variable Perception of Health and Care and Overall Perception Outcome (N = 99)

	Dependent Variable Perception Outcome		
Independent Variable Diagnostic Approach	Perception of Health	Perception of Care	Overall Perception
History	.10	.05	.06
Physical	.14	.01	.03
Laboratory and radiological exams	.14	.19*	.20*
Overall diagnostic approach	.20*	.16	.18*

*Significant at the .05 level.

I-D. What is the relationship between a comprehensive diagnostic approach and a knowledge and understanding of disease and therapy? Examination of Table 24 indicates that history and physical examination had no significant relationship to knowledge of drugs, general knowledge of other components of the regimen, or with overall knowledge.

Table 24

Pearson Correlations of Independent Variable Diagnostic Approach and Dependent Variable Knowledge and Understanding of Disease and Therapy Outcome (N = 99)

Independent Variable Diagnostic Approach	Dependent Variable Knowledge and Understanding Outcome		
	Knowledge of Drugs	General Knowledge	Overall Knowledge
History	.05	.13	.08
Physical	.04	.03	.04
Laboratory and radiological examinations	.19*	.30*	.28*
Overall diagnostic approach	.17*	.29*	.25*

*Significant at the .05 level.

Laboratory and radiological examination, however, was positively related at a significant level for knowledge of drugs, general knowledge, and the overall knowledge level. Laboratory and other diagnostic tests correlated significantly with knowledge of drugs at .19, with general knowledge at .30, and with overall knowledge at .28. The laboratory correlation was negligible while general and overall correlations were low.

The overall diagnostic approach was significantly related to the outcome patient knowledge level of the patients. The overall diagnostic score had a negligible but significant correlation with knowledge of drugs at .17. General knowledge parameters had a low but significant correlation with overall diagnostic approach at .29.

The overall knowledge and overall diagnostic approach correlation coefficient was low at .25. This correlation was significant. The research question can now be answered. The relationship between the independent variable comprehensive diagnostic approach and the dependent variable knowledge outcome level of the patient *did* exist at a significant level, however, the magnitude of this correlation is low.

Research Question I can now be answered. There was a significant relationship between a comprehensive diagnostic approach and some of the outcome parameters. Examination of Table 25 shows that there was a significant correlation with patient perception of health and outcome and with patient knowledge. There was not a significant correlation found with medical health status or with functional status

Table 25

Pearson Correlations of the Independent Variable Diagnostic Approach and the Dependent Outcome Variables (N = 99)

Independent Variable Diagnostic Approach	Dependent Variable Outcome			
	Function	Medical Health Status	Knowledge	Perception
History	.18	.20*	.08	.06
Physical	-.09	.04	.04	.03
Labs	.04	-.12	.28*	.20*
Overall diagnostic approach	.07	-.15	.25*	.18*

*Significant at the .05 level.

outcome. The perception correlation was negligible at .18 and knowledge outcome correlation was low at .25. These two parameter correlations were significant.

The significant relationships between diagnostic approach and perception of health and care may suggest that the more diagnostic measures the patient received the more positively he perceived his health status and care. A significant relationship between diagnostic approach and knowledge may indicate that through the necessity of contact to elicit patient participation for the diagnostic tests as well as the necessity of the physician to justify the need for the test to explain results or purposes of diagnostic measures, more information is disseminated to the patient. On the other hand, maybe the

relationship merely suggests more frequent physician-patient encounters in which information can be exchanged.

Therapeutic Approach

Therapeutic approach was determined by the therapy activities the physician utilized to bring the patient's hypertension under control. General therapy was used to define the general aspects such as medications ordered, diet, or activity restrictions or weight reduction. The continuity aspect of therapy was used to designate those therapeutic activities that indirectly affected hypertension control such as number of doctors seeing patients, documentation of recommendations in record, and evaluation of compliance. The overall therapeutic approach was obtained then by combining the scores of the general therapy parameters with the continuity measures.

The components of the comprehensive therapeutic index are outlined in Chapter IV, Figure 9. The therapeutic process data was obtained from the medical record audit based on documentation and included such items as return visits and therapeutic regimen such as drugs, activity, or diet restrictions. The process data was collected at the end of the five-month period (see Appendix G).

Research Question II: What is the relationship between a comprehensive therapeutic approach and patient outcome?

This question was subdivided into four parts. These sub-questions will be presented first, followed by discussion of the findings to answer each question, then the overall question will be answered.

II-A. What is the relationship between a comprehensive therapeutic approach and functional status outcome? Examination of Table 26 indicates that there was no significant correlation between the therapeutic approach and functional status outcome. Correlations were .14 with therapy, .11 with continuity and .15 with overall therapy which combined the general therapy components score with the continuity aspects of therapy score. No relationship existed between a more comprehensive therapeutic approach and improvement in functional status outcome, possibly reflecting the fact that since many patients were asymptomatic their functional status was not altered.

Table 26

Pearson Correlations of Independent Variable Therapeutic Approach and Dependent Variable Functional Status Outcome (N = 99)

Independent Variable Therapeutic Approach	Dependent Variable End Functional Status Outcome
General therapy	.14
Continuity aspects of therapy	.11
Overall therapy	.15

II-B. What is the relationship between a comprehensive therapeutic approach and medical health status outcome? Several parameters were used as indicators of medical health status outcome. These included diastolic blood pressure, systolic blood pressure, medical health status (severity index), signs and symptoms, change in signs and symptoms, and change in medical health status. These data are presented in Table 27. By examining the table one will note that general therapy and overall therapy had significant relationships with medical health status parameters, but that continuity was not significantly correlated with any of the medical health status outcome parameters.

Both systolic and diastolic blood pressure were significantly correlated at a low level with comprehensiveness of general therapy. Systolic blood pressure correlated at -.31 and diastolic blood pressure correlated at -.25. For overall therapy the correlation for diastolic blood pressure was -.21 and systolic blood pressure, -.29. The negative correlation reflects that as comprehensiveness of therapy increased the systolic and diastolic blood pressure levels decreased. The systolic and diastolic blood pressure were significantly related with overall therapy at the .05 level.

Medical health status was determined through the use of the severity index (see Figure 11). There was a significant correlation between therapeutic activities and medical health status. General therapy was significantly correlated with the medical health status at -.24 while overall therapy correlated at -.23. Continuity was not

Table 27

Pearson Correlations of the Independent Variable Therapeutic Approach with Dependent Variables Medical Health Status Outcome (N = 99)

Independent Variable Therapeutic Approach	Dependent Variable Medical Health Status					
	End Systolic Blood Pressure	End Diastolic Blood Pressure	End Medical Health Status[a]	Change in Medical Health Status[a]	End Signs and Symptoms	Change in Signs and Symptoms
General therapy	-.31*	-.25*	-.24*	.28*	-.23*	-.09
Continuity aspects of therapy	-.13	-.21	-.09	.14	.10	-.02
Overall therapy	-.29*	-.21*	-.23*	.28*	.22*	-.08

[a]Medical Health Status (severity index).

*Significant at the .05 level.

significantly correlated (-.09). One will note from the negative correlations that medical health status improved as therapeutic activities were more comprehensive.

End of study signs and symptoms were correlated at .23 for general therapy, .10 for continuity, and .22 for overall therapy. Although significant, these correlations were not in the expected direction in that as comprehensive therapy increased so did the symptoms. The asymptomatic nature of hypertension may distort data on symptomatology. The increase in symptoms with therapy may suggest side effects from the medication ordered. Because of the asymptomatic nature and side effects that can occur, medical health status (severity index) was selected as a better measure of patient status since it reflects both blood pressure levels and end organ involvement.

Changes in signs and symptoms during the study period were examined. Change in signs and symptoms correlated with therapy at -.09, continuity at -.02, and overall therapy at -.08. These changes were not significant.

Therapeutic approach was also correlated with medical health status (severity index) changes. As can be seen from Table 27, general therapy correlated with changes in the severity index at .28 while continuity correlated at .14 and overall therapy correlated at .28. General therapy and overall therapy correlations were significant, indicating that a positive change in medical health status (severity) was noted with a higher comprehensive therapy score. Continuity aspects of therapy did not correlate significantly with changes in medical health status.

In summary, it can be noted that there *was* a *significant* relationship between overall therapy and end of study diastolic blood pressure, end of study systolic blood pressure, overall medical health status (severity index), as well as change in the medical health status. The parameter used as the dependent outcome variable to answer the research question was medical health status as measured by the severity index. Overall therapy *did* correlate at a low level with medical health status index at -.23. This indicated, then, that there was a significant relationship that existed between therapeutic activities and medical health status outcome.

II-C. What is the relationship between a comprehensive therapeutic approach and a patient's perception of health and care? Table 28 presents the correlations of therapeutic approach with perception of illness and therapy. Examination of this table shows that general therapy correlated with perception of health at .07; perception of care, .21; and, overall perception at .20. Patient perceptions of care and the overall perception were significantly related to general therapy. Continuity aspects of therapy correlated with perception of health at .04, perception of care at .10, and overall perception at .10. None of the continuity measures of therapeutic activity correlations were significant. When the general therapy and continuity components were combined into overall therapy, one can see that there was a correlation with perception of health at .07, with perception of care at .20, and overall perception at .19. Perception of care and overall perception correlation coefficients were significant but negligible.

Table 28

Pearson Correlations of the Independent Variable Therapeutic Approach and Dependent Variable Perception of Health and Care Outcome (N = 99)

Independent Variable Therapeutic Approach	Dependent Variable Perception of Health and Care		
	End Perception of Health	End Perception of Care	Overall Perception
General therapy	.07	.21*	.20*
Continuity aspects of therapy	.04	.10	.10
Overall therapy	.07	.20*	.19*

*Significant at the .05 level.

The research question can now be answered. The relationship between a comprehensive therapeutic approach was significantly correlated with patient's perception of his care and overall perception but there was *not* a significant relationship with patient perception of health. The correlation between the independent variable therapeutic process of care and the dependent variable overall perception was negligible at .19 but significant at the .05 level.

II-D. What is the relationship between a comprehensive therapeutic approach and the knowledge and understanding of disease and therapy. Comprehensiveness of therapeutic approach was correlated with knowledge levels of the patient. Knowledge was separated into drug knowledge and general knowledge which reflected other components

of therapy such as diet, activity, habits, and understanding of the disease process. Finally, an overall knowledge level was determined by combining drug knowledge and general knowledge into one score.

Examination of Table 29 shows that general therapy was positively correlated with knowledge. The correlations were negligible at .17 for drug knowledge, low at .35 for general knowledge, and the overall knowledge level correlation was low at .26. All were significant at the .05 level; thus, general therapy was significantly related to overall knowledge level. Continuity aspects of the therapeutic approach was significantly related with general knowledge (.17) and not with drug knowledge (.13) or with overall knowledge (.15). When the overall therapeutic approach was correlated with knowledge levels, significant correlations were found. Overall therapy was significantly correlated with drug knowledge at .18. General knowledge was significantly correlated with overall therapy, the correlation coefficient was low at .35. Overall knowledge was significantly correlated at a low level of .27.

To answer the research question, one can say that a comprehensive therapeutic relationship is significantly related to knowledge, that is, drug knowledge and general knowledge of the disease and therapeutic process. Finally, one can say that the patient's overall knowledge correlated at a low level with overall therapeutic approach with the correlation coefficient at .27.

Table 29

Pearson Correlations of the Independent Variable Therapeutic Approach and the Dependent Variable Knowledge and Understanding of Disease and Therapy (N = 99)

Independent Variable Therapeutic Approach	Dependent Variable Knowledge Outcome		
	Drug Knowledge	General Knowledge	Overall Knowledge
General therapy	.17*	.35*	.26*
Continuity aspects of therapy	.13	.17*	.15
Overall therapy	.18*	.35*	.27*

*Significant at the .05 level.

Research Question II can now be answered. Table 30 presents the correlation of the dependent outcome variables with the independent variable comprehensive therapeutic approach. It can be noted that the comprehensive therapeutic approach was significantly related to health status outcome (severity index), knowledge outcome, and perception of health and care. All of these outcome parameters are significant at the .05 level. The correlation coefficient for medical health status (-.23) and for knowledge (.27) were low and negligible for perception (.19). Functional outcome correlation was .15 but was not significantly related to therapeutic approach.

To answer the research question, one can say that there is a relationship between a comprehensive therapeutic approach and outcome

measures, specifically medical health status, knowledge, and perception of health and care.

Table 30

Pearson Correlation of the Independent Variable Therapeutic Approach and the Dependent Outcome Variables (N = 99)

Independent Variable Therapeutic Approach	Dependent Variables			
	Functional Status	Medical Health Status[a]	Knowledge	Perception
General therapy	.14	-.14*	.26*	.20*
Continuity aspects of therapy	.11	-.10	.15	.10
Overall therapy	.15	-.23*	.27*	.19*

[a]Medical health status (severity index).

*Significant at the .05 level.

Patient Compliance

Patient's participation in the therapeutic process was determined by utilizing compliance as the indicator of his adherence to the therapeutic regimen.

Compliance scores were "reported" compliance of the patient with his medication regimen, diet, habit or activity restrictions, and return to the family practice center for follow-up or diagnostic tests. Drug compliance was separated from the other dimensions of compliance

since drugs are the primary method of controlling hypertension. Thus, this study examined drug compliance and general compliance with other parameters of the therapeutic regimen other than drugs. An overall compliance score was then derived by combining drugs and general compliance scores into one. The research questions relating to compliance will now be discussed.

Research Question III: What is the relationship between patient compliance and patient outcome?

III-A. What is the relationship between patient compliance and functional status outcome? Examination of the compliance level of the patients when correlated with the functional status outcome revealed that there was no significant relationship between functional status and patient compliance. Change in functional status during the study period was also correlated with functional status outcome. Examination of Table 31 revealed that change in functional status was not significantly correlated with compliance. Specifically, the drug compliance correlation coefficient was .06, while general compliance correlated at .03, and overall compliance correlated at .11.

Table 31

Pearson Correlations of the Independent Variable Patient Compliance and the Dependent Variable Functional Status Outcome (N = 99)

Independent Variable Patient Compliance	Dependent Variable Functional Status	
	End Functional Status	Change in Functional Status
Compliance with drugs	-.05	.06
General compliance	.003	.03
Overall compliance	-.05	.11

III-B. What is the relationship between patient compliance and medical health status outcome? Compliance was correlated with several medical health status outcome parameters. From Table 32 one can see that diastolic and systolic blood pressure are significantly related to compliance. Specifically, drug compliance was moderately related to diastolic blood pressure at -.43, and systolic blood pressure at -.32. Blood pressures correlations are in a negative direction; that is, as drug compliance got higher, the blood pressure reading dropped and became closer to the normal range. Although general compliance measures were related, they were at a lower level than were the correlations for drugs; that is, -.18 for diastolic blood pressure and -.17 for systolic blood pressure. Both of these correlations were significant at the .05 level.

Table 32

Pearson Correlations of the Independent Variable Patient Compliance and the Dependent Variable Medical Health Status Outcome (N = 99)

Independent Variable Patience Compliance	Dependent Variable Medical Health Status				
	End Diastolic Blood Pressure	End Systolic Blood Pressure	End Medical Health Status (Severity Index)	Change in Medical Health Status (Severity Index)	End Signs and Symptoms
Drug compliance	-.43*	-.32*	-.26*	.27*	-.01
General compliance	-.18*	-.17*	-.25*	.25*	-.05
Overall compliance	-.33*	-.22*	-.29*	.29*	-.05

*Significant at the .05 leve.

When the overall medical health status (severity index) was examined, there was also significant inverse relationships. The drug compliance correlated at -.26 with medical health status, while general compliance components correlated at -.25. Both of these relationships were significant. The overall compliance correlation with medical health status was -.29, significant at the .05 level. These correlations suggest that compliance does have an effect on medical health status.

The change in medical health status was significantly related with drug and other compliance factors. A higher drug compliance score was related with a positive change in the severity index as indicated by a correlation of .27, significant at the .05 level. Other compliance was related with change in severity index as indicated by a correlation of .25, significant at the .05 level, while overall compliance was significantly correlated with the change in severity index at .29. These results suggest that patient compliance level did have a significant effect on the change in medical health status of the patient.

Signs and symptoms were not significantly related with drug or general compliance levels. The correlation for drug compliance was -.01 and general compliance was -.05, neither of which were significant.

When overall compliance was related with medical status outcome, significant relationships were found with diastolic blood pressure, systolic blood pressure, medical health status (severity index), and

change in medical health status. There was no significant relationship found with signs and symptoms. A low relationship was found with compliance and the outcome variable diastolic blood pressure; the correlation was -.33. Medical health status correlated at -.29 and change in medical health status correlated at .29. A low correlation of -.22 was found with systolic blood pressure. These variables show statistically significant relationships at the .05 level. The parameter used to answer the research question was the medical health status (severity index), which correlated with compliance at -.29, that is health status improved with high compliance scores.

Thus, to answer the research question, there is a relationship between compliance and medical health status outcome; this low correlation of -.29 was significant at the .05 level. This correlation was squared to obtain a score that explains the amount of variance that occurred in medical health status that can be attributed to the variable compliance. The R square was .05 and indicates that 5 percent of the variation in systolic blood pressure can be attributed to compliance. The R square of .108 for diastolic blood pressure would suggest the 11 percent of the variation in diastolic blood pressure could be attributed to patient compliance. Medical health status (severity index) had an R square of .08 which suggests that 8 percent of the variation in health status outcome may be dependent upon patient compliance. In summary, the relationship between compliance and medical health status was low.

III-C. What is the relationship between patient compliance and perception of health and perception of care? Table 33 presents the correlations showing the relationship between the independent variable compliance and the dependent variable perception. Of the components of perception studied, the strongest relationship was between perception of care and compliance with drugs. Specifically, the level of relationship is moderate at .67 and is significant. Compliance with drugs correlated with health perception at .24 which was significant. Drug knowledge correlated significantly at a moderate level with overall perception at .65. General compliance was not significantly correlated with any of the perception components.

Table 33

Pearson Correlations of the Independent Variable Patient Compliance and the Dependent Variable Perception of Health and Care (N = 99)

	Dependent Variable Perception Outcome		
Independent Variable Patient Compliance	Perception of Care	Perception of Health	Overall Perception
Drug compliance	.67*	.24*	.65*
General compliance	.11	.00	.09
Overall compliance	.45*	-.05	.41*

*Significant at the .05 level.

When the overall compliance levels are correlated with overall perception, significant relationships are evident with perception of care at .45 and overall perception at .41. There was no relationship between overall compliance and perception of health. The R square was .17. It can be assumed then that 17 percent of the variation in perception may be explained by the compliance level of the patient.

To answer the research question, compliance is statistically significant in relation to overall perception. The strength of the relationship reflected in the correlation of .41 which is a moderate relationship.

III-D. What is the relationship between patient compliance and the knowledge and understanding of disease and therapy? Table 34 presents the correlation coefficient expressing the relationship between the independent variable compliance with the dependent variable knowledge. The overall compliance variable was divided into drug compliance, compliance with therapeutic activities, and overall compliance. Knowledge of drugs and patient compliance was correlated at a marked level of .72, while patient compliance and overall knowledge correlated at a marked level of .68, and general knowledge had a moderate correlation coefficient of .50 with patient compliance. All three of these knowledge correlations were significant. There was no significant relationship noted with the general compliance level and general knowledge level.

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Table 34

Pearson Correlations of the Independent Variable Patient Compliance with the Dependent Variable Knowledge and Understanding of Disease and Therapy (N = 99)

Independent Variable Patient Compliance	Dependent Variable Knowledge Outcome		
	Drug Knowledge	General Knowledge	Overall Knowledge
Drug compliance	.72*	.50*	.68*
General compliance	.01	-.04	-.03
Overall compliance	.43*	.16*	.34*

*Significant at the .05 level.

When the overall compliance levels were correlated with overall knowledge levels, significant relationships were again evident. Overall compliance was significantly correlated with drug knowledge at .43 with general knowledge at .16 and overall knowledge at .34. The R square for overall knowledge was .12; this would suggest that 12 percent of the variation in overall knowledge could be explained by patient compliance. This relationship between these two variables were significant, supporting the fact that there was a relationship between patient compliance and patient knowledge. Thus, to answer the research question, compliance was significantly and statistically correlated at a low level with the overall knowledge level of the patient, especially the patient's drug knowledge, which correlated at a moderate level.

Table 35 presents a summary of the correlations of the dependent outcome variables with the independent variable patient compliances. Overall compliance levels were correlated with outcome dimensions to answer the third research question. Drug compliance was correlated significantly at a low level of -.26 with medical health status outcome (severity index) and with perception at marked level of .65. Overall knowledge correlated markedly and significantly with drug compliance at .68.

Table 35

Pearson Correlations of the Independent Variable Patient Compliance and the Dependent Outcome Variables (N = 99)

Independent Variable Patient Compliance	Dependent Variable Outcome			
	End Functional Status	End Medical Health Status Outcome[a]	End Overall Perception of Health and Care	End Overall Knowledge
Drug compliance	-.05	-.26*	.65*	.68*
General compliance	.003	-.25*	.09	-.03
Overall compliance	-.05	-.29*	.41*	.34*

[a]Medical health status (severity index).

*Significant at the .05 level.

General compliance components did not relate with the outcome measures except for medical health status. Functional status outcome was not significantly correlated with general compliance. The correlation coefficient was .003. The medical health status outcome (severity index) correlated significantly at -.25, suggesting that health status improved as patient compliance level increased. Perception of health and care did not correlate significantly with general compliance nor did knowledge level. The perception correlation was .09 for general compliance and knowledge was -.03.

Overall compliance was not significantly correlated with the functional status measure. Medical health status outcome (severity index) correlated at -.29 and was significant at .05. Perception correlated with overall compliance at .41 and was significant. This was the strongest relationship of the compliance variable with the outcome variables, although it was only a moderate correlation. Overall knowledge had a low correlation coefficient of .34 which was significant.

To answer the overall research question regarding the relationship between the independent variable patient compliance and the dependent variable outcome dimensions, one can say that there was a significant relationship between compliance and medical health status outcome (.29), overall perception of health and care (.41), and overall knowledge (.34), but that there was no significant relationship found between compliance and functional status outcome (-.05). It would appear from the magnitude of the correlational levels that patient compliance had an impact on the patient outcome dimensions except for functional status.

The summary research questions will now be presented. Multiple regression analysis was used to answer these questions.

Each of the research questions are answered by the examination of how the combined independent variables contribute to the dependent variables. Specifically, diagnostic approach, therapeutic approach, and patient compliance are combined to note the relationship these independent variables have on the dependent variables of functional outcome, medical health status outcome, patient perception of health and care outcome, and patient knowledge outcome.

Summary Research Questions

Summary Research Question I

What is the relationship between a comprehensive diagnostic approach, a comprehensive therapeutic approach, patient compliance level, and functional status outcome?

Stepwise multiple regression was used for analysis of the effect of the combined independent variables had on the dependent outcome variables. This means that the independent variable that explains the greatest amount of variance in the dependent variable was entered first, the variable that explains the greatest amount of variance in conjunction with the first was entered second, and the final variable that explains the least was entered last. In other words, the variable that explains the greatest amount of variance that is unexplained by the variables already in the equation are entered at each step. The independent variable that is entered first is the one

with the largest squared partial correlation with the dependent variable. A variable may not be entered into the regression equation if the statistical criteria are not met. A variable may be entered if the proportion of its variance not explained by other independent variables exceeds 0.1 percent.

Table 36 presents the stepwise multiple regression analysis of the effect of the independent variables of diagnostic approach, therapeutic approach, and patient compliance on the dependent variables functional outcome. It can be noted that the multiple correlation is not significant at the .05 level. The actual multiple correlation coefficient is .16.

Examination of Table 36 shows that neither compliance nor therapy was significantly related with functional outcome. The F level was so low for diagnostic approach that it was not even added to the stepwise regression analysis because the statistical criteria of the program were not met. It can be seen from the table that therapy R square was .03 and when compliance was added in conjunction with therapy, the R square change was .003. It appears from noting the R square change that the independent variables do not contribute to explaining the functional status outcome measure. Examination of the simple R column shows the correlation of each independent variable alone. The reader will recall that this was the value presented when the individual independent variables were correlated with the dependent outcome variable functional status. The R square values indicate the proportion of the variation in the dependent variable accounted for by

Table 36

Stepwise Multiple Regression Analysis of Independent Variables Diagnostic Approach, Patient Compliance, and Therapeutic Approach with Dependent Variable Functional Status Outcome

Variable Entered	Significance	Multiple R	R Square	R Square Change	Simple R	Overall F	Significance
Therapy	.128	.15110	.02283	.02283	.15110	2.35980	.128
Compliance	.611	.15930	.02538	.00254	-.05001	1.30180	.277

F level insufficient for further computation.

Multiple R = .15930		Analysis of Variance	Df	Sum of Square	Mean Square	F
R Square	.02538	Regression	2	4.7880	2.394	1.30180
St. Dev.	.135621	Residual	100	183.92965	1.840	

the independent variable. The higher R square, the stronger is the variation that can be explained by the independent variables. The answer to the summary research question is that there is no significant relationship between a comprehensive diagnostic approach, a comprehensive therapeutic approach, the patient compliance level, and functional status. Since the individual correlations were not significant, one would not expect the multiple regression analysis to be significant. Since the functional status categories were not broadly distributed in this study population due to the ambulatory nature of hypertensive patients, there was little variance in the patients' functional scores at the end of the study. This may account for the lack of significant correlations. In addition, examination of onset and end of study functional status scores indicates a reduction of variance after the treatment period.

Summary Research Question II

What is the relationship between a comprehensive diagnostic approach, a comprehensive therapeutic approach, the patient compliance level, and medical health status outcome?

Table 37 presents the data of the stepwise multiple regression analysis of the independent variables on the dependent variable medical status outcome. The multiple R is .38 with the R square being .15. This would indicate that 14 percent of the variation in medical outcome could be attributed to the combined independent variables. This relationship was significant. It can be noted that compliance contributed the most variance to the dependent variable. By examination of the

Table 37

Stepwise Multiple Regression Analysis of Independent Variables Diagnostic Approach, Therapeutic Approach, and Compliance with Dependent Variable Medical Health Status

Variable Entered	Significance	Multiple R	R Square	R Square Change	Simple R	Overall F	Significance
Compliance	.003	.28936	.0837	.0837	-.28936	9.2294	.003
Therapy	.016	.36769	.1352	.0515	-.22769	7.8170	.001
Diagnosis	.347	.378	.1430	.0077	-.15420	5.50262	.002

Multiple R = .3780	Analysis of Variance	Df	Sum of Squares	Mean Square	F
R Square .14292	Regression	3	5109.92	1703.307	5.5026
St. Dev. 17.59388	Residual	99	30644.91	309.5446	

R square change (.08) one can see that compliance contributes the most to the variation in functional status with therapy being next with .05, while the contribution of diagnosis was miniscule at .008. The Simple R column shows what the individual independent variable contributes to the outcome variable while the multiple R square shows how each variable in combination with the others effect the outcome variable. From this table we can see that compliance has an R square of .08; this is significant and explains the greatest amount of variance in medical status outcome. Therapy in conjunction with compliance explains an additional 5 percent of the variance which is significant. Diagnosis in conjunction with compliance and therapy only accounts for an additional .07 percent of the variance which is not significant.

To answer the research questions then, there is a statistically significant relationship between a comprehensive therapeutic approach, the patient's compliance level, and the dependent variable medical health status outcome. The stepwise analysis suggests that compliance with medical regimen and medical therapeutic process in conjunction with one another accounts for 14 percent of the variation in medical health status outcome. Diagnostic process was not significant in accounting for the variance in medical health status outcome. Actual compliance with drug and other therapy should result in a change in status if the therapy is appropriate.

Summary Research Question III

What is the relationship between a comprehensive diagnostic approach, a comprehensive therapeutic approach, patient compliance, and the patient's perception of health and care outcome?

Perception related with each of the independent variables as can be seen from Table 38. From examination of Table 38, it can be noted that when the independent variables diagnostic approach, therapeutic approach, and compliance are combined, the multiple R was .47 and the R square was .23. The measures of association were significant at the .05 level. The R square would suggest that 23 percent of the variation in the dependent variable perception could be explained by the combined independent variables.

Table 38 presents the data of the stepwise multiple regression analysis of the independent variables on the dependent variable perception of health and care.

By examination of the R square change, one can see that compliance accounts for the largest variation (.17) in perception of health and care and was entered first. Diagnostic approach explained the next greatest amount of variance (.04) in conjunction with compliance and was entered second. Both of these independent variables were significant and account for 21 percent of the variation in perception of health and care. Therapy was not significant in conjunction with the other variables. The multiple R shows what the combined independent variables in combination with the others do to affect the dependent outcome variable. From Table 38 we can see that compliance has an

Table 38

Multiple Regression Analysis of the Independent Variables Diagnostic Approach, Patient Compliance, and Therapeutic Approach with the Dependent Variable Perception of Health and Care

Variable Entered	Significance	Multiple R	R Square	R Square Change	Simple R	Overall F	Significance
Compliance	.000	.41098	.16891	.16891	.41098	20.52679	.000
Diagnosis	.024	.45892	.21061	.04170	.18068	13.3401	.000
Therapy	.179	.47427	.22493	.01432	.19217	9.57686	.000

Multiple R = .47427	Analysis of Variance	DF	Sum of Squares	Mean Square	F
R Square .22493	Regression	3	15545.57103	5181.85701	9.57686
St. Dev. 23.26115	Residual	99	53567.03092	541.08112	

R square of .17 which is significant and explains the greatest amount of variance in perception of health and care. Diagnosis in conjunction with compliance explains an additional significant 4 percent of the variance. Therapy in conjunction with compliance and therapy only accounts for an additional 1 percent of the variance. This is not significant.

To answer the research question, one can see that there was a statistically significant relationship between the independent variables of comprehensive diagnostic approach, patient compliance, and the dependent variable patient perception of health and care. Compliance and perception may be related in that as the patient complies his health status improves so that actual perception of both health and care are more positive. The diagnostic-perception relationship might be explained by the frequency of contact and feedback with the patient who then perceives his care and health in a more positive perspective since something is being done to him for his condition.

Summary Research Question IV

What is the relationship between a comprehensive diagnostic approach, a comprehensive therapeutic approach, patient compliance, and patient's knowledge and understanding of disease and therapy outcome?

Table 39 presents the stepwise multiple regression analysis of the independent variables diagnostic approach, therapeutic approach, patient compliance, with the dependent outcome variable patient knowledge. It can be noted that the multiple R is significant at .47 with

Table 39

Multiple Regression Analysis of the Independent Variable Diagnostic Approach, Patient Compliance, and Therapeutic Approach with the Dependent Variable Patient Knowledge

Variable Entered	Significance	Multiple R	R Square	R Square Change	Simple R	Overall F	Significance
Compliance	.000	.3385	.11457	.11457	.33848	13.06911	.000
Diagnosis	.004	.43248	.18704	.07247	.24966	11.50387	.000
Therapy	.058	.46498	.21621	.02916	.26470	9.10293	.000

Multiple R = .46498	Analysis of Variance	DF	Sum of Squares	Mean Square	F
R Square .21621	Regression	3	8034.8009	2678.2669	9.10293
St. Dev. 17.15285	Residual	99	29127.8010	294.2202	

the R square being .22. The R square would indicate that 22 percent of the variation in the dependent outcome variable knowledge can be explained by the three combined independent variables.

It can be noted that compliance contributed the most variance to the dependent variable. By examination of the R square change of compliance (.12) one can see that this independent variable contributes the most to the variation in patient knowledge and understanding. Diagnosis is next with an R square change of .07 while the contribution of diagnosis is small at .03. Compliance with an R square of .12 is significant and explains the greatest variance in patient knowledge, while diagnosis in conjunction with compliance explains an additional 7 percent of the variance. This is also significant. Therapy in conjunction with compliance and diagnosis only accounts for an additional 3 percent of the variance and is not significant.

To answer the research question, there is a statistically significant relationship between the combined independent variables of diagnosis and compliance with the dependent variable patient knowledge. Compliance level is related to the patient's knowledge in that the more the patient complies the more he has the opportunity to better understand his health, his medical regimen, as well as results in a change in health status. Diagnosis may be related to knowledge in that the more diagnostic measures that were carried out, the more there was the opportunity for the physician and patient to have contact in which questions could be asked and information transmitted to the patient. The therapeutic contribution does not explain additional variation that is not explained by compliance and diagnosis.

Summary

Table 40 is a summary table of the R square values derived from the stepwise multiple regression analysis when the independent variables are combined in a stepwise method to note their effect on the dependent outcome variables. This table presents the answer to the summary research questions. One can note that for functional outcome when variables were added in conjunction with one another there was not a significant variation. For medical health status compliance and therapy in conjunction with one another accounted for a significant R square at .15. The significant variation in perception of health and care of 21 percent was accounted for by compliance in conjunction with diagnostic process. Compliance in conjunction with diagnostic processes accounted for a significant variance of .19 in knowledge and understanding of disease and care. Thus, all of the dependent variables except functional status had significant variance that could be attributed to the independent variable. It is important to note from the stepwise multiple regression analysis that compliance was the first independent variable added to the stepwise analysis for the three significant variances in outcomes (medical health status, perception of health and care, and knowledge and understanding of disease and therapy). It should be noted that not only did compliance have significant variance with the patient associated measures of perception and knowledge but also the more objective outcome measure, medical health status. Perception and knowledge data were collected from the patient while the source of data for medical health status

Table 40

Summary Table of the Stepwise Multiple Regression Analysis of the Independent Variables with the Dependent Variables

Independent Variable as Entered	Dependent Variable	Multiple R	R^2
Therapy, compliance, diagnosis	Functional status outcome	.16	.03
Compliance, therapy	Medical health status	.37	.14*
Compliance, diagnosis	Perception of health and care	.46	.21*
Compliance, diagnosis	Knowledge and understanding of disease and therapy	.43	.19*

*Significant at the .05 level.

was from the patient record. The importance of the compliance measure is a major finding of this study and will be discussed in Chapter VI.

This chapter has presented data to answer the research questions regarding the relationships between process and outcome components of patient care. The general characteristics of the study populations were presented. The relationship between the independent variables diagnostic approach, therapeutic approach, and patient compliance and the dependent outcome variables functional status, medical health status, perception of health and care, and knowledge have been determined. Discussion of significant relationships between the process and outcome variables and the importance of these findings will be presented in Chapter VI.

CHAPTER VI

SUMMARY AND IMPLICATIONS FOR FUTURE STUDIES

The purpose of this study was to develop and test a model for evaluation of patient care. Specifically, the model established a set of process criteria and measured their effect on patient outcomes.

The model for evaluation of care that was developed can be seen in Figure 1, page 13. The process components were defined to include diagnostic approach, therapeutic approach, and patient compliance. These dimensions were considered as important activities of a health care delivery system which affect patient outcomes. Patient outcomes were operationally defined as functional status, medical health status, patient knowledge and understanding of disease and therapy, and patient perception of health and care. This model was developed to serve as an overall framework for evaluation of patient care. Specifically, the questions addressed in this study were:

1. *What is the relationship between comprehensive diagnostic approach and patient outcome?*
2. *What is the relationship between a comprehensive therapeutic approach and patient outcome?*
3. *What is the relationship between patient compliance and patient outcome?*

The summary question was: *What is the relationship between comprehensive diagnostic approach, comprehensive therapeutic approach,*

patient compliance, and patient outcome (functional status, medical health status, knowledge, and perception of health and care)? The intent was to determine if there were relationships between these process and outcome components of patient care and then to examine the feasibility of this model for the evaluation of ambulatory health care. The data to test this model were collected from a patient record review and two telephone interviews with each patient. These instruments were refined by conducting a pilot study of 10 patients in the setting in which the study was conducted. Modifications and revisions were made in the data collection tools. The study was then carried out with 103 patients, each being followed for a five-month period.

To implement the model, criteria were developed for the process components of care. A literature review was conducted to establish criteria for the diagnostic and therapeutic components to be included. These criteria serve as a basis for the evaluation of the pattern of care administered by the health care professionals. The evaluation identifies the level of discrepancy between established criteria and actual level of practice. The discrepancy between the established criteria and the actual pattern of care provides a data base for decision-making by the providers regarding the need for improvement in the pattern of care.

The second process dimension, patient compliance, was evaluated based on each patient's "reported" level of compliance. In the patient population compliance with the prescribed regimen is crucial to control since health care professionals alter their diagnostic and therapeutic

activities based on doctor's observations of the patient's clinical condition and patient's reported compliance. Thus, following the prescribed regimen to its fullest was the basis used to evaluate the pattern of compliance. Again, the model of evaluation identifies the reported level of discrepancy between the desired and actual pattern of compliance and provides data for decision-making by the provider regarding the need to enhance patient compliance.

The evaluation model also sets up a need to determine desired levels of patient outcomes. For the population used for this study, the overall desired state was control of the blood pressure without end organ involvement as can be seen in Figures 4 and 11. This provides a perspective of desirable outcome criteria for the specific patient population. Levels for blood pressures were determined by experts. Blood pressures, end organ involvement, functional status, perception, and knowledge were all included to provide a broad perspective of the patient status. These characteristics can be determined and the assessment of the degree of discrepancy between the desired outcome and actual outcome level is possible. With the exception of the blood pressure, this model did not explicitly determine specific outcome criteria. This could be set by the health care providers based on the purpose of the evaluation and the duration of an illness for which the model was used. The review of medical records using the outcome categories was considered to be an objective judgment about functional status and medical health status since actual data were recorded.

The model used here provides a circular and dynamic framework in that at each level of the process data can be fed back to the health care system to allow new decision-making. As such, this model demonstrates the dynamic nature of evaluation of care to maintain a quality level. At each level of the model there is constant change and interaction between levels.

Each component of the model articulates with each of the other components and as such the interaction of the components is in a constant state of change. For example, diagnostic measures affect the therapeutic recommendations which affect the patient compliance which in turn affects the patient outcome. If diagnostic process is not appropriate the therapeutic prescriptions may not be appropriate. If the patient does not comply with the prescription because of no or negative effects the patient outcome is altered.

The dynamic nature of the health care system points out the extreme importance that an evaluation model include both process and outcome components, both patient and provider assessments *and* follow-up on a longitudinal basis. The model used in this study includes these components.

This model can be used to evaluate the quality of patient care by individual health care providers, health care researchers, or groups who are interested in measuring the effect of a pattern of care received by patients. Groups for which this model appears appropriate are:

1. *Ambulatory Care Administrators* who are held accountable for the quality of patient care in their setting.

2. *Medical Care Directors of Family Practice Settings* who are accountable for the practice of medicine administered to patients for whose care they are responsible.

3. *Directors of Medical Education* who are interested in the outcomes of educational programs as measured by the pattern of care delivered by the students or faculty to the patients.

4. *Nursing Service Administrators* who are held accountable for the quality of patient care and are now concerned with the expanded role of the nurse practitioners and the functions of that role needed to provide the quality patient care.

5. *Graduate Nursing Education Faculty* who are interested in developing and expanding the care that can be delivered by patients in ambulatory care settings.

6. *Academy of Family Practice* who is concerned with information systems to monitor the quality of care within ambulatory care settings.

7. *Health Care Planners*, state and local, who provide the environment, resources, and processes to support health care delivery system.

8. *Medical and Nursing Researchers* who are interested in the development and testing of theories of health care, health care education, health care systems, and the effective administration of those systems and evaluation in terms of care actually received by patients as well as the effect of the care to the outcome in patient status.

Prior to the implementation of this model each setting would have to determine the purpose of the evaluation as well as a plan for how the results would be used for decision-making within the setting. Is the concern for provider or patient processes, or both? Is the purpose to examine the pattern of care actually delivered or the impact of the pattern of care on the patient, or both? Is the purpose to change a pattern of practice and note its effect? Is the purpose to

evaluate a past state, a current state, or to follow on a long-term basis? This model would allow any or all of these questions to be answered. The group implementing the model should decide the purpose and then select both the criteria as well as components of process and outcome measures on which data will be collected.

Summary of Findings

This section will describe the application of the evaluative model and discuss the findings. Each question addressed in the study will be presented and briefly discussed.

Summary Research Question I: What is the relationship between a comprehensive diagnostic approach and patient outcome?

Diagnostic approach was examined with the patient outcomes of functional status, medical health status, perception of health and care, and knowledge and understanding of disease and therapy. *Functional outcome* was not related with any of the dependent variables. The reason for the lack of significant correlation of the functional measure may be due to the fact that signs and symptoms were closely related to the patient's functional score. The functional score is based on the degree to which symptoms affect the functional ability of the patient. At both onset and end of study there was a high level of association between functional status and signs and symptoms. The functional status did change for these patients, although one would not expect a marked change since the population was ambulatory and would not begin with impaired functional disability. The hypertensive patient with multiple

symptoms and severe functional disability would be treated in the hospital; thus, the findings of no relationship between functional status and the independent variables can be explained by the nature of the population under study and the small variation in functional categories.

From these results one might question the use of functional status as an outcome measure on all ambulatory patients, especially the ones with long-term chronic disease with no disturbed functional capacity. The change in functional status was consistent with the change in both systolic and diastolic blood pressure and severity index.

Medical health status outcome related with diagnostic approach ($r = -.15$). History, laboratory, and other diagnostic tests significantly related, but physical examination was not related.

Diagnosis probably only indirectly has an effect on the outcome of the patients once the diagnosis has been established, and thus one would not expect a high correlation. If, however, the diagnostic process was more complete, one could anticipate that the physician would have more data on which to base his therapeutic plan and detect patient changes, responses to therapy or progression of the disease. If data are available for action, then the outcome should improve based on completeness of the diagnostic process leading to and effecting comprehensiveness of therapy. The effect, then, of diagnostic measures might only be indirect on outcome--the direct effect of diagnostic measure would be on therapy. It would be important to follow

chronically ill patients over a longer period of time in which there might be more end organ involvement or for more episodes of illness and then examine how the relationship between diagnostic measures and medical outcome are related.

More emphasis on accuracy and appropriateness of diagnostic measures may be a more valuable evaluation of diagnostic process measures than to determine the percent of diagnostic tests completed with the effect on patient outcome.

Perception of health and care was significantly correlated with diagnostic approach. This correlation was .18. This finding suggests that patients' perception of their health may be related to the services they receive. Thus, as more diagnostic tests are completed the patients may translate these activities into a positive perception of their health care and status. As there are more tests completed there may be more interaction and exchange between the patient and the health care provider.

Knowledge and understanding of disease and therapy was significantly correlated at a low level with diagnosis ($r = .25$). This correlation might be explained by the fact that the patient who had multiple diagnostic tests may have more explanations given to him. Further, because more diagnostic measures were completed, especially laboratory tests and x-rays, the results of those tests would be interpreted to the patient and as such provide more data to him about his disease and therapy since more explanations are given to him. This suggests that patients are likely to know more about their disease when

they are placed in a situation where they can interact and have contact with health care professionals about certain process measures of care. Knowledge and understanding may be related to amount of services they receive. This is an important parameter to note and to be studied in patients who do not have multiple diagnostic tests. What happens to the knowledge level of the disease and how does this relate to the patient compliance level? Although the effect might be indirect, diagnostic measures, especially "tests," may have an impact on patient's knowledge level and hence on his compliance.

Summary Research Question II: What is the relationship between a comprehensive therapeutic approach and patient outcome?

Patient outcomes included functional status, medical health status, knowledge and understanding of disease and therapy and per ception of health and care. Functional outcome and therapeutic approach were not significantly related. The explanation for this is probably the fact that there was little variance in the *functional status*. If functional status was followed from the time of the diagnosis on a longitudinal basis, one might expect to see a relationship between the functional outcome and therapeutic approach as variation in status occurred. This would be especially apparent if one followed the patients long enough for end organ involvement to occur and affect patient's functional level. If, however, the disease process is not resulting in a change in functional disability, then function and medical care process may not be related.

Therapy is inversely and significantly related to *medical health status* ($r = -.23$). (The inverse and negative correlation implies that as therapy scores become more comprehensive, the medical status score improves, that is, becomes lower.)

Medical health status did correlate significantly with overall therapeutic approach. One would expect that if the therapy were more complete and comprehensive this would be reflected in changes in the blood pressure, both systolic and diastolic as well as changes in the end organs such as heart, lungs, and kidneys. One would expect the relationship between therapuetic approach and health status to be higher than the -.23; however, with an ambulatory patient, multiple intervening factors such as psychosocial factors may affect the outcome, specifically, the compliance. Obtaining any significance at all was considered to be an important finding.

Since therapy is the process parameter for which one seeks medical attention, it is imperative that this area be related to outcome. In this study, compliance is the highest correlate with patient outcome and would indicate a closer examination of the therapy components of a disease that are having the most effect on outcome. As in the case of hypertension, maybe the most significant aspect is that the physician orders the *correct* medication and the patient complies with it--the other therapy parameters may not be important for this target population.

Relating comprehensive therapeutic activities with various medical health status outcome parameters might make a valuable contribution to the understanding of the natural course of a disease, the effectiveness of therapeutic regimes, for either episodes of illness or for long-term care.

There was a low correlation between the continuity measure of therapy and medical status outcome. A question remains as to why there is no significant relationship between continuity and outcome. It may be that continuity factors are a better measure of the process of care given by health providers than they are outcome dimensions in the patient himself. Further study may be needed to see how continuity affects both comprehensiveness of therapy and patient outcomes.

Overall therapy was significantly related to *perception* of health and care ($r = .19$). Overall therapy may be directly related to perception in that as the therapy became more comprehensive, the patient perceived that his care was complete and that as more activities were suggested for the control of his disease the more positive he perceived the care. Further, the more feedback he received the more control he may feel was being exerted over the natural course of the disease.

A more comprehensive therapeutic approach may also contribute to patient's perception of his care and his illness. As such, the perception may affect the patient's involvement in the therapeutic process. Further study would be indicated to examine how perception, therapy, and compliance are interrelated.

In summary, therapy is related to outcome measures of medical health status, knowledge, and perception of health and care. There should be more study to determine which of the comprehensive therapeutic components have the most effect on the patient outcome.

Knowledge was correlated at a low level with overall therapeutic approach ($r = .27$). Knowledge may be related to therapy in that the more comprehensive the therapy the more the patient is required to know about his disease and his regime to actively participate in it. The physician may see the patient more often or have more direct contact and communication with the ambulatory patient to ensure that therapeutic aspects are carried out, that is, the doctor must involve the patient as an active participant in the care. In addition, as a means of monitoring the patient's progress, the physician may inquire about his disease status which may disseminate to the patient information about his disease.

On the other hand, because the patient has the knowledge, this may in fact make him more amenable to therapeutic processes since he may report more of the negative effect of drugs, new signs and symptoms, and know more to discuss with the physician about the disease. This may, in fact, alert the physician to the need for a more comprehensive therapeutic approach.

It would be interesting to know if more health care provider emphasis on knowledge and patient education would improve patient outcome even more. Since patient knowledge level and therapy are significantly related to outcome, the findings stress the importance

of more than physician's orders and restrictions being a part of the therapeutic approach to care. Patient education should be a routine part of the therapeutic approach. Further, this study indicated that knowledge data can be easily obtained from the patient.

Summary Research Question III: What is the relationship between patient compliance and patient outcome?

Compliance was significantly correlated at a low level with the outcome measures of medical health status, with overall perception of health and care at a moderate level, and overall knowledge at a low level, but not with functional status.

As with the other process variables *functional outcome* is not significantly related to compliance. Since there was little variation in functional status one would expect that a relationship would not exist.

All aspects of compliance were significantly related with the *medical health status* outcome. The r was -.29 for patient compliance and medical health status. This result would be expected since medications, diet restrictions needed, and follow-up are aspects that appear to affect the extent and severity of end organ involvement as a result of hypertension. It would be expected that the more comprehensive the appropriate therapy and the better the compliance with the therapy, the better the result, and medical control of the disease so that patient improvement would be expected.

It would be important in other studies to examine carefully the components of compliance that affect outcome and which are most significant in both acute and chronic illnesses. The health care delivery system should then emphasize these aspects in the therapeutic approach to ensure a high rate of compliance.

Overall compliance was significantly correlated with *perception* at a moderate level ($r = .41$). While drug compliance correlated at a marked level of $r = .65$, it appears patients who complied had a positive perception of health and care. If they complied, they had a positive outlook toward their care. Maybe because they complied, the outcome of their disease improved; thus, one would expect the perception to be more positive. When one looks at the perception of care, one would also expect that patients who complied must have believed in the care they were receiving and thus followed the regimen and returned to the Center. Other studies have supported this relationship. The importance of the physician-patient relationship would be related to compliance in that if the patient agrees with the suggested therapeutic activities he has a positive perception and will comply with that regimen. If they take the medications as ordered, they must believe there is something they can do to control or have an impact on the disease.

Overall *knowledge* correlated at a marked level ($r = .68$) with drug compliance and overall compliance at a low level ($r = .34$). One would expect that knowledge and compliance would be correlated in that a minimum amount of knowledge is necessary for compliance to take place, especially to take the drugs. Diet and habit restriction instructions

given to patients are not as clearly spelled out as are the orders for medications which specified number and time. This might explain the reason for a higher correlation. This study would suggest the importance of the knowledge factor to ensure patient compliance. If more emphasis and focus is put on the knowledge factors as an outcome of patient care, then compliance might be higher. Concern for patient knowledge should be a part of the therapeutic approach.

Previous compliance studies and critiques of those studies suggest that compliance was not an objective measure and that patients tend to report inflated rates. In this study, reported rates varied from 10 percent to 99 percent compliance. There was, however, more reported noncompliance by the patient to the investigator than the physicians had detected and documented in the medical records.

By having a systematic way of evaluating patient compliance the health care providers could detect potential noncompliers by interview as well as noting the health status outcome. More therapeutic activity focus can be put on the noncompliers in an attempt to gain cooperation in order to achieve more disease control. Since the patient's reported compliance is an important parameter on which the health care providers prescribe medications, change regime, and base evaluation of effectiveness of the regimen, then reported compliance will remain an important process measure in ambulatory care and should be included as a process parameter.

Table 41 summarizes the results obtained for each of the research questions. This table presents correlation coefficients expressing the relationships between the study's independent and dependent variables based on the process of care over a five-month study period as documented in the record and from patient interviews. This table shows that there are statistically significant relationships between process and outcome parameters even though these correlations are low.

Table 41

Correlation of Independent and Dependent Variables Relationship Between Process and Outcome Components of Care

Independent Variables Process Variables	Dependent Variables Outcome Variables			
	Functional	Medical	Knowledge	Perception
Diagnosis	.069	-.15*	.25*	.18*
Therapy	.15	-.23*	.27*	.19*
Patient compliance	-.05	-.29*	.34*	.41*

*Significant at the .05 level.

Of the three independent variables in Table 41 there was a moderate relationship between compliance and perception of care (r = .41) and a low relationship between compliance and knowledge (r = .34) and between compliance and medical outcome status (r = -.29). Therapeutic approach reflected a significant relationship at a low level with medical status outcome (r = -.23), with knowledge (r = .27), and a negligible relationship with perception of care (r = .19). Diagnosis has a negligible correlation level with medical health status (r = -.15), a low correlation with knowledge (r = .25), and negligible correlation with perception (r = .18) outcomes. All of the process variables did not show a significant relationship with functional outcome.

Table 41 presents 12 measures of association. Nine of these achieve statistical significance at the .05 level. Thus, Table 41 largely supports the study's research questions showing that there are relationships between measures of process of care on the one hand and the four parameters of outcomes on the other although the magnitude of the relationships are small.

Combined Research Questions

What is the relationship of the combined independent variables--diagnostic approach, therapeutic approach, and patient compliance on functional status?

The stepwise multiple regression revealed that therapy entered the regression analysis first with compliance second. Diagnosis was not entered due to the fact that the F value was not sufficient to

permit computation. There was no significant variation in functional status that could be accounted for by the combined independent variables.

Since the observations in the end of the study functional status were confined to the first two functional categories, there was not a wide enough distribution to implement a linear model. When changes in functional status were examined in view of changes in blood pressures, it was found that for functional status 40 patients improved and 19 patients deteriorated while for diastolic blood pressure 45 patients improved and 14 patients deteriorated, and for systolic blood pressure 43 patients improved and 10 patients deteriorated. This would suggest a similarity in changes in functional status and blood pressures, the criterion measure for hypertension. The functional status must have some validity as an outcome measure for hypertensive patients. The lack of relationships of the combined independent variables on the dependent variables is probably due to the limited distribution across functional categories.

What is the relationship between the combined independent variables diagnostic approach, therapeutic approach, and patient compliance on medical health status?

When stepwise multiple regression was conducted compliance was entered in the first step, therapy entered second, and diagnosis was entered last. Only compliance and therapy were significant. Compliance in conjunction with therapy accounted for 14 percent

of the variation in medical health status. Compliance with the recommended medical regimen did result in change in the medical health status of the patient. This variation, although small, reflects the importance of compliance in predicting medical outcome. It suggests that for hypertensive patients therapeutic recommendations by the health care providers is only one dimension of the concern for process. An important concern to the providers should be to elicit the cooperation of the patients with the recommended therapeutic regimen. Diagnosis may be directly related to therapeutic activities rather than outcome. This may account for the lack of variation in medical health status due to diagnostic approach.

What is the relationship between the combined independent variables diagnostic approach, therapeutic approach, patient compliance, and patient perception of health and care?

Stepwise multiple regression of these combined variables revealed that compliance entered the analysis first. Diagnosis entered second, and therapy was entered last. Only compliance and diagnosis were significant. Compliance, in conjunction with diagnosis accounted for 21 percent of the variation in perception. As was indicated in the correlational analysis the diagnostic activities are probably related to physician-patient interaction. High compliance levels reflect patients' acceptance of the therapeutic regimen and this combined with the diagnostic activities account for most of the variation.

A closer examination needs to be conducted to see if it is the patient-physician interaction that causes a positive reaction or if the fact that multiple diagnostic tests were conducted that resulted in a positive patient perception. Compliance and diagnosis may account for the variation together if the fact that a comprehensive diagnostic process results in more visits to the center and/or more contact with the health care providers. This may elicit the patients' cooperation to comply with the therapeutic regimen. Therapy is not significant since variation may already be accounted for by compliance with the therapeutic regimen.

What is the relationship between the combined independent variables diagnostic approach, therapeutic approach, patient compliance, and knowledge and understanding of disease and therapy?

Stepwise multiple regression analysis of the combined variables found that for knowledge, compliance entered the model first, followed by diagnosis, and finally therapy. Only compliance and diagnosis were significant. Compliance and diagnosis accounted for 19 percent of the variation in the knowledge variable.

Compliance and diagnosis account for variation in knowledge in much the same way as with perception. Compliance levels explain the most variation in the dependent variables which is about 12 percent. The fact that the patient complies over time suggests that he knows something about his therapeutic regimen and repeated compliance

reinforces knowledge. Diagnostic activities are related in that as the patient had more diagnostic test he has more contact with the health care providers to have the opportunity to reinforce the values of compliance. Another explanation may be that since compliance effects the results of the tests, data are supplied to the patient about disease and control so from the discussion of the test results, the overall knowledge level of the patient is affected. Further study should more clearly determine at what point patient knowledge becomes an input to compliance as an outcome.

Although broad generalizations from such a study are unwarranted, the author feels confident that these patients are representative of those commonly seen in ambulatory care centers. The study demonstrates the importance of knowledge, perception of health and care, and compliance as crucial elements to ambulatory care for hypertensive patients. Further and more extensive study of these components may provide new insights into the scope of ambulatory medical practice.

When we consider the rather large individual variability among patients' patterns of medical care, it is surprising that even these modest levels of association were achieved using process variables which are measures that have multiple intervening effects.

Generalizing the Results

All cases selected were drawn from a single family practice center; thus, the results must be extended or generalized with that in mind. The physicians providing the care did not formulate the criteria used. The criteria were derived from a review of literature for lists of recommended and basic components to be included in the management of ambulatory hypertensives. Since that is so, the criteria may be more stringent than they themselves would select.

Data were collected and analyzed for only one condition, and this condition is of a chronic nature with no clear etiology, and one in which there are silent and end organ manifestations. Process and outcome factors of disease conditions that are not of these same characteristics may not show a relationship between process and outcome.

Even though relationships between process judgments and outcome were statistically significant and correlated at a low level, it is noteworthy that there were significant relationships. Of particular importance is the notation of which variables had the highest level of relationship. Very few patients were reluctant to share data and many gave additional data beyond the questions asked. It was possible to collect detailed and extensive process and outcome data. At least for this one institution, these data should provide some meaningful insight on the scope of care made available to one set of patients. These data have implications for health-care education as well as health care practice within the setting.

The findings of this study must be interpreted with caution since the number of patients is not large; they represent medical practice in one family practice setting with a residency training program. In addition, the patient group is limited to diagnosed ambulatory care hypertensives without a wide range of severity. It would be worthwhile now to take this approach and use it on another disease process to determine if the methodology is appropriate to all disease conditions and more acute conditions. In addition, it would be valuable to note if there is a relationship between process and outcome in other disease process. The results of this study can be interpreted to provide feedback to this family practice center regarding the pattern of care for the model disease covered. This evaluation framework could be used in other family practice centers to evaluate the pattern of care for hypertension. Comparisons across centers could reflect a general pattern of care for a select disease condition.

Implications

This section of the study will discuss the implications of findings of this study for the health care practitioners and for the health care researchers and evaluators.

Implications for Practitioners

Based on the findings of this study, it is important to note the value that patient compliance contributed to the dependent variables outcome. Very few of the evaluation studies place any importance

on this process component and fewer yet provide any in-depth analysis of compliance on patient outcome.

Reasons for patient compliance with regimens are complex and not easily explained. The importance of this process component should be emphasized. It would appear from findings in this study that compliance is related to patients' expectations and perceptions. As was reported in the literature, this study found that patients reported poorer compliance rates with their therapeutic regimens than physicians had noted. Noncompliance was not consistently related to severity of hypertension.

Results of this study are consistent with findings in previous studies in that relationships between patient's perception of health and care and knowledge and compliance would suggest that the patient's beliefs about his health and illness can exert a powerful influence on his behavior as it relates to the therapeutic regimen. Patients who perceived that their medications were important to their control and management were better compliers than those with the opposite perception. It was not the severity of the illness but rather the meaning that the regimen and illness had to the patient that affected compliance rate.

Compliance was higher in patients who had a positive perception about their health and care. Thus, it would appear that improving perception of health and care may be vital to compliance and should be an important part of the therapeutic plan of the health care providers.

Patients who had a more thorough knowledge of their illness, diagnosis, and treatment regimen and consequences of both were more likely to follow and comply with the therapeutic regimen. It would appear that this knowledge assisted the patient to see the treatment process as logical and necessary. Reinforcement of the knowledge should also be a routine part of the therapeutic plan of the health care provider. It is important to remember that the patient is an active participant in dealing with his illness and will take what he regards as appropriate steps to follow a medical regimen within his own life framework.

There was a decrement in compliance behavior over time. This therefore suggests that health care providers should re-enforce the importance of patient compliance with the therapeutic regimen at frequent intervals to ensure the continuation of the compliance behavior.

Compliance should be examined as a routine part of therapeutic regimens. If compliance is a problem, it is necessary that an attempt be made to foster compliance with the therapeutic regimen. This may necessitate that the family be involved to enforce and support compliance behavior. Health care providers may have to strive to simplify the therapeutic regiman to ensure that it is easier to follow and that the regimen does not impose a drastic departure from the patient's normal lifestyle and does not require major behavior reorganization for the patient. It is also important that health care providers understand patients' beliefs about their illnesses and correct any misconceptions or misinformation.

Patient perception of illness and sick role as well as expectations of care and the regimen must be attended to by the health care providers since compliance behavior appears to be closely tied to effective provider-patient communication. Physicians and health care providers need to build patients' faith in the program which they are prescribing for the illness. Patients must believe that the regimen will in fact reduce the severity of the illness or prevent future problems. The patient must also believe that the costs associated with compliance do not outweigh the perceived benefits of the regimen. Monitoring compliance behavior because of the effect of this behavior on patient outcomes should become a routine part of providers' process of care.

This study looks beyond the narrow confinement of the technical management of patient care and points out the importance of enlisting the patient as an active partner in medical treatment. The tendency of health care providers is to consider the patient as a *passive* recipient of health care. This study strongly indicates the efficacy of encouraging patients to take a more active role in their health care and the benefits this can have on patient outcomes. There is a need to focus on the patient as an active participant in the health care process since he has responsibility for outcome of care by following the therapeutic regimen as well as by appropriate use of follow-up care.

For example, patient compliance with medical prescription affects the outcome of medical intervention and, subsequently, the outcome of the disease process. While the data in this model strongly

support this conclusion, it is not usually addressed in most approaches to the evaluation studies. It appears from this study that at least *some* differences in outcome measurement of quality of medical care can be attributed to patient compliance with prescribed medical regimens. Thus, it would be vital to the evaluation of the ambulatory chronically ill patient.

Knowledge of disease and therapy and perception of health and care also had significant relationships with patient outcomes. Compliance levels were significantly correlated with perception and knowledge. Previous evaluation studies have not included knowledge, perception, or compliance. Results from this study would suggest that more emphasis needs to be placed on knowledge and perception level of the patient. It would appear that knowledge and perception are related with each other and each is related to compliance.

It would appear from the diagnostic impact on outcomes that the frequency of contact and services play an important role in patient knowledge and perception. This may indicate a need for the health care provider to provide time in other therapeutic activities to relate, contact, and interact with the patient so that knowledge and perception levels could be improved.

Results in this study would suggest that despite a low level of physician performance of therapeutic activities patients who complied with the prescribed drug regiman had an improved health status. If high compliance and high knowledge correlate significantly with patient outcome, then examination of key therapeutic activities may be more

important than focusing on a comprehensive list of provider activities. A high score on technical competencies by the provider may not be as important as key patient behaviors in response to key provider activities.

It is important that further studies carefully examine the relationships between knowledge, perception, therapeutic regimen, and compliance.

Patient education should be viewed as a vital part of therapeutic activities. This study found a low positive relationship ($r = .34$) between knowledge and compliance. Since compliance has an impact on medical status, it would appear that there is a need for more emphasis on education. Further, this study found that knowledge and compliance levels deteriorated during the study period. Knowledge deteriorated on 33 patients during the study and compliance level deteriorated for 28 patients. Patient knowledge should be assessed periodically as a part of continuing medical care. It is essential that the chronically ill patient receive explanations so that he continues to comply with prescribed regimens.

This model allows the health care provider to follow patients during an episode of illness and to examine changes in their health status. The indices used in this study allow evaluations to monitor functional status, medical health status, knowledge, and perception at two points in time so that a transition in patient's status can be determined. There were similarities noted between the changes that occurred in medical status and functional status (see Tables 6 and 11,

Chapter V). This would suggest the value of this model to collect data to determine patient changes.

As a model to determine patient changes this could also be used beyond an episode of illness. Data can be collected on longitudinal basis. This would facilitate evaluation of both process and outcome data or either parameter alone at selected and specified, intermediate and long-term periods of time. As such, this may be a model for longitudinal follow-up of chronic diseases in ambulatory care patients since the true effect of therapy may not become apparent until after a considerable period of time. By allowing for long-term follow-up the model serves to evaluate an episode of illness, determine remedial action needed to correct existing deficiencies, change a pattern of delivery of care and then to note the effect of the change on patient outcome. This would facilitate in-depth evaluation for selected conditions.

The continuity dimension of the therapeutic activities did not correlate with the outcome dimensions. It is surprising in view of all that is publicly said of the importance of continuity of care, that outcome was not related to this dimension. It would appear that continuity may be a dimension that has an impact on the health care provider by altering the comprehensiveness of his therapeutic activities but does not directly affect patient outcome. Based on this finding, more detailed analysis is needed to facilitate better understanding of how continuity relates both to process and outcome components of patient care.

Implications for Health Care Evaluators

The value of this model for comprehensive care analysis, longitudinal follow-up, and as a means of detecting changes in patient status, has been presented in the section discussing the implication for health care practitioners. These strengths of the model also apply to health care evaluators. It is useful and feasible with this model to collect comprehensive data on a long-term basis. It is not a static model but can provide retrospective, concurrent as well as prospective process and outcome data.

To the evaluator this model is also useful in that it can serve as a screening device to determine problems or crisis situations. It is possible to use the model to determine outcome data initially and if a desirable outcome is not achieved, then to examine the process parameters which had contributed to the unacceptable outcome.

This model would facilitate describing a level or pattern of care within one institution or to compare the pattern of care of several institutions. It would also be possible to compare process of care activities among physicians to identify similarities and dissimilarities for a particular disease entity. If the outcome for a pattern of care were determined, it would be possible to describe the effect of the pattern of care as well as the effect of changes in care on the patient. Further, patterns as observed on different providers can be compared according to the differences in outcome. Patterns of care across settings could be determined in the same way, by examination of both the process activities as well as the results

of those activities. In such a way this model would serve to establish data needed to set standards and criteria for practice for a specific disease.

Comprehensive data can be collected from patients. This study pointed out that patients are willing to provide data on their status and that as a source of data regarding their status, provide useful information. Most patients appreciated the interest expressed in their health as well as the opportunity to relay comments about their health. Further, as a method of data collection, the telephone interview was an effective means. The benefit that can accrue to patients by telephone interviews is that patients can be followed on a longitudinal basis, intermediate outcomes can be determined, and data can be gathered on a few important parameters at each interview. In addition, telephone follow-ups can replace additional office visits; thus, saving both health care provider and patient time.

It would appear that health care evaluators should place more importance on contacting the patient directly instead of using the medical record as the only source of data. Patient contact provides current and valuable data not documented in the health care delivery system.

The instruments developed for data collection were structured in such a way that they enabled nonprofessional, nonmedical personnel to collect data. The structure used for the instruments would serve well to be put into a computerized information system. All provider components of process as well as provider components of outcome

parameters could easily be transferred to a data system either as a comprehensive set of information or as a profile of selected key measures. It would be possible to include a series of key medical activities and outcome parameters on a patient encounter form and then to review these periodically using a computerized medical information system. In addition, it would be possible to put key process and outcome dimensions into an encounter system. Selected criterion levels of performance or outcome statuses could be determined. If these were not met, then a more detailed medical record audit or patient interview could take place.

The scoring used within this model gave equal weight to process items. Persons using the method could themselves determine acceptable versus unacceptable levels of therapeutic activities, or use the scoring system to detect improvements over time. If it were desirable to weight some factors more than others this could also occur with no alteration in the data collection instruments.

It is important that an evaluation model allow one to quantify the data in such a way as to be able to interpret the results with meaning. The format and scoring of this model allowed the researcher to quantify the data for both the individual patient as well as to determine aggregate data for the target population. In addition, it was possible to individualize the scores based on severity of illness and frequency of visits to the Center. This model is amenable to alternative statistical analyses.

Problems with the Evaluation Model

Two major problems remain with this evaluation model. The first is the development of the instruments for data collection. It is essential that the measures have demonstrated reliability and validity. It is also necessary that the instruments be precise enough to measure and differentiate the physiological and psychosocial effects of process on the patient outcomes. Further work is necessary for the refinement and testing of the instruments to establish reliability and validity.

The second major drawback to this model is the comprehensiveness and the amount of data to be collected over a prolonged period of time. It is essential that the instruments be at a level of detail attractive to the health care practitioner, manpower, or finances to collect the extensive range of data needed to evaluate the pattern of care within a health care setting. As such, this model would probably be more applicable to the researcher than the practitioner.

Recommendations for Future Study

1. Future studies would need to refine the process criteria parameters and carefully examine the parameters included. It is vital that evaluators of health care do not overestimate the effect that certain process components have on outcomes. There is a need to quantify the impact of process on outcome so key process components can be selected. Results of this study indicated that many of the

process components cited in the criteria list from the experts did not appear to have an impact on patient outcome.

2. There is a need for more combined process and outcome studies to better understand the effect of a pattern of care on the patient. These studies should be conducted utilizing explicit process and outcome criteria. It is important that criteria and instruments used be evaluated to establish both reliability and validity.

3. There is a need for replication studies to evaluate comparability of findings for other institutions and target populations. Most evaluation studies today report findings without explicit criteria and methodology. It is not possible to replicate this study because of the lack of the explicit criteria. This prevents comparison of the quality from one institution to another or from one type of patient population to another.

4. Since the findings indicate the importance of the patient component of process (compliance) and outcome (knowledge and perception), it is important that evaluation studies include the patient components such as compliance, knowledge, and perception. More emphasis should be placed on the patient as an active participant in his care.

5. This study did not attempt to control the pattern of care delivered within the setting. There appears to be a need to evaluate outcomes when there is a more rigid adherence to a predetermined pattern of care. The same regimen and therapeutic activities should be followed by all providers. This should enable the investigator to begin to examine all relationships and look more closely at causal

relationships and not mere low level correlations between process and outcome components.

6. Based on the review of other research efforts as well as this one there must be untiring effort expended toward the development of measurement instruments that are both valid and reliable measures of both process and outcome. Too often this issue is not addressed in a study or the rationale for not determining this information is that there are too many interacting variables affecting the components of patient care. It is for that very reason that valid and reliable measures must be developed. This author was unable to find any studies that reported measures of reliability and validity for the instruments used to evaluate care.

7. Based on the impact of compliance on outcome in this study it is recommended that compliance be a concern for all health providers and evaluators. Providers must take an active role to ensure compliant behavior while researchers need to focus more on means of evaluating this dimension. There is a need for more standard definitions of what constitutes compliant behavior. A major task will be to establish valid and reliable measures of compliant behavior. It is also vital to determine more specifically the impact of that behavior on patients who are ambulatory and chronically ill.

8. Based on the results of this study it is possible to evaluate care on an ongoing intermediate and long-term basis. This model should be applied to chronic illnesses to determine the most appropriate time perspective for follow-up in order to: (1) evaluate

outcome, (2) establish intermediate effects of therapy, and (3) establish long-term effects of therapy and the disease process.

9. Based on the findings of this comprehensive model as well as the tracer methodology, there is a need to put more emphasis on the models that provide a more comprehensive approach to specific health problems. This comprehensive approach provides a framework for evaluating the interaction of providers and patients and their environments for a health episode rather than for a single visit. The tracer methodology should be extended and adapted to incorporate patient process parameters such as patient compliance as an integral part of the system. In addition, patient outcome behaviors such as knowledge and perception parameters need to be a more important part of the tracer methodology.

This systematic evaluation model does look at the impact of the health care provider on the patient outcome. Neither process nor outcome are examined irrespective of the other; they are examined together. This study does show a relationship between the process of medical care and the effect on outcome, but the importance of the patient's parameters of process were the most significant finding of this study. If the findings of this study are valid, then further study is needed to see if a pattern in practice will bring about a change in outcome.

This study provided an opportunity to examine the interactions among disease, medical processes of care, and patient outcomes. This should facilitate a better understanding of the natural course of a

disease as well as the elements that have an effect on it. It was possible to identify types of information needed to evaluate both process and outcome parameters in a systematic and comprehensive way. It was possible to quantify functional status, medical health status, perception, knowledge, and compliance. This model does provide a comprehensive framework for health care evaluation.

It seems likely that for some time to come there will not be one single comprehensive model to measure the quality of patient care. There is still a need for multiple approaches; the important factor is that each effort means a contribution to the knowledge base of evaluation and quality of patient care.

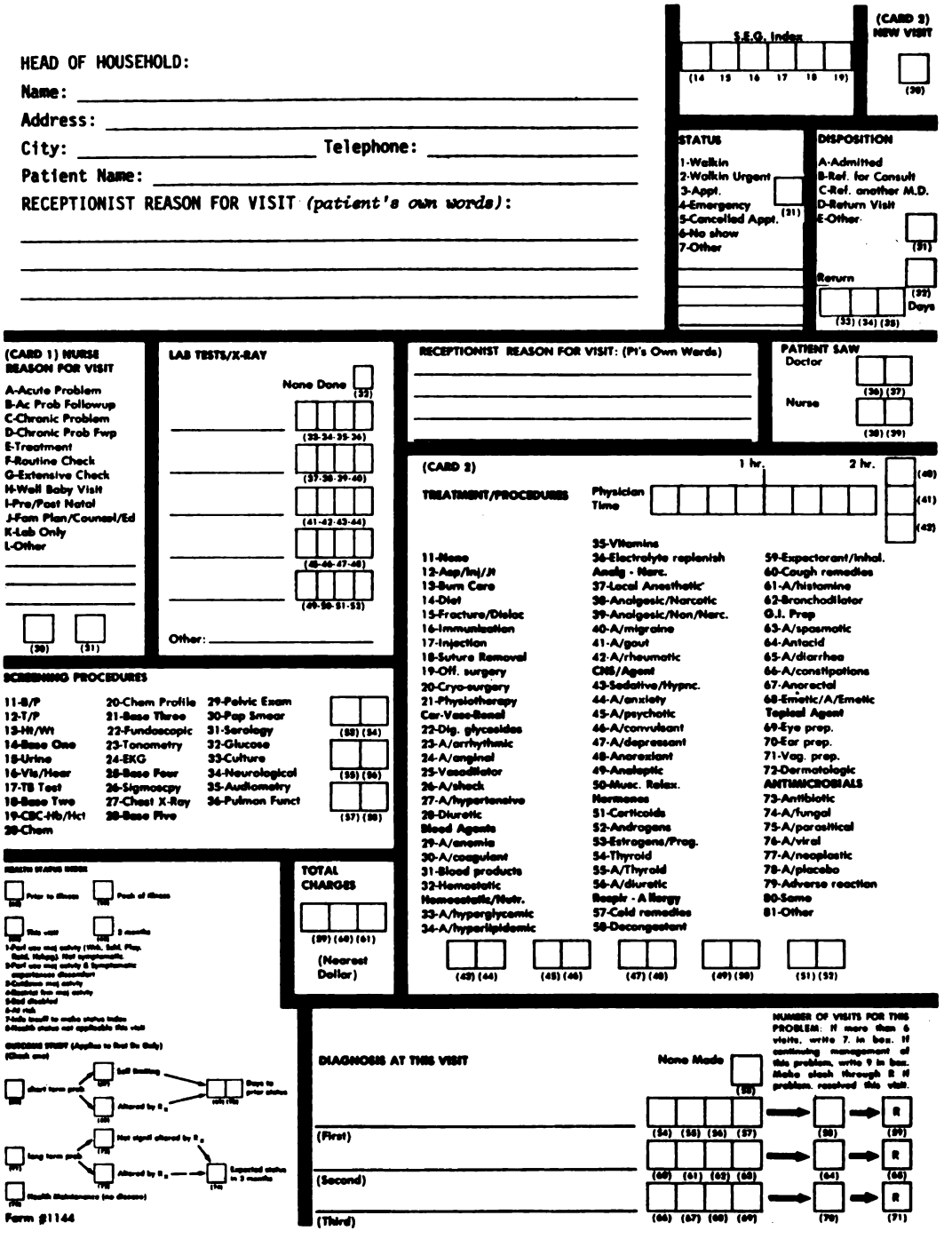
If health care professionals are committed to excellence, then steps must be taken to ensure that the public receives high quality care. To such an end, health care professionals need to be accountable for the quality of care provided. Health care practitioners should demonstrate to society that they can set standards for practice and assume responsibility for the evaluation of their practice. To this end this evaluation model could serve to assure quality of care to patients.

APPENDIX A

ENCOUNTER FORM USED TO IDENTIFY PATIENTS

APPENDIX A

ENCOUNTER FORM USED TO IDENTIFY PATIENTS



APPENDIX B

LETTER DESCRIBING THE FAMILY HEALTH CENTER

St. Joseph | HOSPITAL
302 KENSINGTON AVENUE
FLINT, MICHIGAN 48502
(313) 238-2601

November 26, 1973

Charles W. Given, Ph.D.
106A East Fee Hall
Michigan State University
East Lansing, Michigan - 48823

Dear Dr. Given:

The Family Health Center (F. H. C.) is the "Model Unit" for the Family Practice Residency Program based at St. Joseph Hospital, Flint, Michigan.

The Center has 13,500 square feet of space divided into 46 rooms. At present 11,600 square feet are utilized for patient care which are broken down as follows:

1 - 46 Passenger waiting rooms. (internal waiting for 12 more)
2 - Nursing stations
9 - Consultation rooms/offices
18 - Examining rooms (4 large treatment)
1 - Library
3 - Lounge

The Nursing and support staff on-board are:

1 - RN (Another projected for February 1974)
1 - LPN
1 - Medical Assistant
1 - Cashier
1 - Receptionist
1 - Business Clerk

The F. H. C., has been in full operation since August 1972. Our residents in-training number six.

3 - Third year - work 5 half days F. H. C.
1 - Second year - work 3 half days F. H. C.
2 - First year - work 2 half days F. H. C.

The patient load is in excess of 1,200 families with visits around 800 per month now. There is expected a steady increase in patient load.

The anticipated resident-in-training load will change with the following probable additions:

1 - First year resident February 1, 1974
10 - First year residents July 1, 1974
2 - Second year residents July 1, 1972
1 - Third year resident July 1, 1973
The goal for resident-in-training is 10 in each year.

The charts are being presently modified again and will maintain the problem-oriented-record format. Charts will be coded numerically and by color also. Numerical blocks will be alphabetized. "Parking Cards" will be utilized.

The resident's work and patient billing will continue to be monitored by the hospital's computer services.

Michigan State University Medical Students will continue to experience a half day of ambulatory patient care for 12 months each. Encounter forms are to be used here also.

Peace!

LEWIS E. SIMONI, M. D.
DIRECTOR, FAMILY PRACTICE
RESIDENCY PROGRAM

LES/og

APPENDIX C

LETTERS TO PATIENTS DURING STUDY PERIOD

St. Joseph | HOSPITAL
302 KENSINGTON AVENUE
FLINT, MICHIGAN 48502
(313) 232-6101

FAMILY HEALTH CENTER

(LETTER ASKING PATIENTS TO PARTICIPATE IN PHONE INTERVIEW)

The St. Joseph's Family Practice Center is evaluating the care given to patients with high blood pressure. Some of the information regarding your care is contained in our records. However, it is necessary that we obtain additional information from you personally about this care and how effective we have been in helping you.

In a few days, you will receive a letter asking you a series of questions about high blood pressure. We hope that you will answer these questions to the best of your ability. At no time will the answers be identified with you personally. All information will be confidential and will be used for evaluation purposes only.

Thank you for your cooperation.

Lewis Simoni, M.D.

LS/dj

St. Joseph HOSPITAL
302 KENSINGTON AVENUE
FLINT, MICHIGAN 48502
(313) 232-6101

FAMILY HEALTH CENTER

(LETTER ASKING PATIENTS TO PARTICIPATE WITH MAILED QUESTIONNAIRE)

(for patients without phone)

The St. Joseph's Family Practice Center is evaluating the care given to patients with high blood pressure. Some of the information regarding your care is contained in our records. However, it is necessary that we obtain additional information from you personally about this care and how effective we have been in helping you.

In a few days, you will receive a phone call asking you a series of questions about high blood pressure. We hope that you will answer these questions to the best of your ability. At no time will the answers be identified with you personally. All information will be confidential and will be used for evaluation purposes only.

Thank you for your cooperation.

Sincerely,

Lewis Simoni, M.D.

LS/dj

St. Joseph HOSPITAL
302 KENSINGTON AVENUE
FLINT, MICHIGAN 48502
(313) 232-6101

FAMILY HEALTH CENTER

(LETTER ASKING PATIENTS TO PARTICIPATE WITH FOLLOW-UP PHONE INTERVIEW)

The St. Joseph's Family Practice Center is now concluding the evaluation of the care given to patients with high blood pressure. Some of the information regarding your care is contained in our records. However, it is necessary that we obtain additional information from you personally about this care and how effective we have been in helping you.

In a few days, you will receive a second phone call asking you another series of questions about high blood pressure. It is important to our study that you help us this second time. We hope that you will answer these questions to the best of your ability. At no time will the answers be identified with you personally. All information will be confidential and will be used for evaluation purposes only. This will then conclude our study.

Thank you for your cooperation.

Sincerely,

Lewis Simoni, M.D.

LS/jn

St. Joseph HOSPITAL
302 KENSINGTON AVENUE
FLINT, MICHIGAN 48502
(313) 232-6101

FAMILY HEALTH CENTER

(FOLLOW-UP LETTER ASKING PATIENTS TO COMPLETE MAILED QUESTIONNAIRE)

Dear

I'm working with Dr. Simoni of St. Joseph's Family Planning Center. We are interested in evaluating the care received by patients who have high blood pressure and we need answers to some questions so that we can try to improve the care for patients with this condition.

Several months ago you responded to our initial inquiry. We appreciated your cooperation at that time. It is necessary to collect information from you one more time. We hope you will cooperate this time again and assure you that no further inquiries for this study will be made. Your participation is valuable to the improvement of patient care. All of your answers will be kept completely confidential and never identified with you personally.

I'm going to ask that you complete the enclosed questionnaire about your health and your most recent visit to the center. Let's start with your health during the two-week period before your last visit to the center.

Thank you for your assistance.

Sincerely,

(Mrs.) Barbara Given

APPENDIX D

INTERVIEW GUIDES AND PATIENT QUESTIONNAIRES

ENTRY INTERVIEW FORM

SURVEY OF PATIENTS WITH HYPERTENSION

RESPONDENT I.D. #_____

TELEPHONE #_____

INTERVIEWER:_____

RECORD OF CALLS:	1	2	3	4	5
DATE:					
TIME OF CALL:	AM PM	AM PM	AM PM	AM PM	AM PM

RECORD OF CALLS:	6	7	8	9	10
DATE:					
TIME OF CALL:	AM PM	AM PM	AM PM	AM PM	AM PM

INTERVIEW STATUS:

____ Completed Interview

____ Partial Interview (specify)_____

_____

____ Refusal (specify)_____

_____

____ Unable to contact after _____ attempts.

____ Other (specify)_____

_____

(MARK TIME INTERVIEW STARTED: _____ A.M. OR P.M.)

Hello, this is _____, and I'm working with Dr. Simoni of St. Joseph's Family Practice Center. We are interested in evaluating the care received by patients who have high blood pressure and we need answers to some questions so that we can try to improve the care for patients with this condition.

Is this _____ (name of respondent)? *(Remove identifying name when editing questionnaire.)*

(If the person answering the phone is the respondent, proceed. If the person answering the phone is not, repeat the introduction when the respondent comes to the phone.)

Recently, we mailed a letter you you explaining this study. If you've had a chance to read it, you probably noticed that we said all your answers will be kept completely confidential and never identified with you personally.

I'm going to be asking you questions about your health and your recent visit to the center. Let's start with your health during the two week period before you came to the center.

1. During that two week period, did you have: *(Read alternatives and check one for each.)*

a.	Headaches?	___ Yes	___ No	___ Sometimes	___ NA
b.	Dizzy spells?	___ Yes	___ No	___ Sometimes	___ NA
c.	Blurred vision?	___ Yes	___ No	___ Sometimes	___ NA
d.	Difficulty in breathing or shortness of breath?	___ Yes	___ No	___ Sometimes	___ NA
e.	Swelling in your legs?	___ Yes	___ No	___ Sometimes	___ NA
f.	Pain or discomfort in your chest?	___ Yes	___ No	___ Sometimes	___ NA
g.	Or, did you have to limit your exercise activity?	___ Yes	___ No	___ Sometimes	___ NA
h.	Did you have any problems I haven't mentioned?	___ Yes ↓	___ No → *(If "No," go to Question 2.)*		
i.	Could you tell me what they were? *(Write in description of each problem. PROBE: What kind of trouble was it?)*				

Other: Specify _____

_____

j. Other: Specify _____

_____

k. Other: Specify _____

_____

2. When you were at the center two weeks ago, did someone take your blood pressure? *(Check one.)*

___ Yes ___ No → *(If "No," go to Question 3.)*

a. Did that person tell you what it was at that time? *(Check one.)*

___ Yes ___ No ___ Don't remember

b. What was it? *(Write in)*

_____

_____

_____

_____

_____

c. Were you ever told anything about your blood pressure? *(Check one.)*

___ Yes ___ No → *(If "No," go to Question 3.)*

d. What were you told? *(Write in.)*

_____

_____

3. What is normal blood pressure for a person your age? *(Write in.)* _____

_____

4. Now, when people come to the center, often lab tests are done. When you were at the center two weeks ago, did you have any tests? *(Check one. PROBE: For example, blood tests or x-rays?)*

___ Yes ___ No → *(If "No," go to Question 5.)*

a. What tests were done? *(Write in. If respondent does not know which tests, write in "DK".)*

_____

_____

b. Do you know what the test(s) was (were) for? *(Check one.)*

___ Yes ___ Some ___ No → *(If "No," go to Question 4-d.)*

c. What was (were) it (they) for? *(Write in.)*

_____

_____

d. Did you know what would happen to you during the test(s)? *(Check one.)*

___ Yes ___ Some ___ No

e. Do you know the results of the test(s)? *(Check one.)*

___ Yes ___ Some ___ No

f. What were the results of the test(s)? *(Write in.)*

_____

_____

g. Were you not told or don't you remember? *(Check one.)*

___ Wasn't told

___ Doesn't remember

Question 5	Medicine #1	Medicine #2	Medicine #3	Medicine #4	Medicine #5
And now can you tell me what medicines you have taken in the last two weeks? *(Write in name of medicines or description in columns 1-5. If more than five medicines, prepare a second sheet and re-number columns. PROBE: Any others?)*					
(For each medicine listed, ask:) a. How long have you taken ______? (name of med.) *(Write in appropriate column. PROBE: two weeks, a month, or how long?)*					
b. What is the purpose of ______? (name of med.) *(PROBE: What does it do for you? Write in purpose for each medicine in appropriate column.)*					
c. Are there any precautions with ______ (name of med.)? What are the side effects? *(Write in precautions for each medicine in appropriate column.)*					
d. How often do you take ______? (name of med.) *(Read alternatives and check one for each medicine.)*	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often? (Specify): ______	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often? (Specify): ______	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often? (Specify): ______	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often? (Specify): ______	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often? (Specify): ______
e. How many ______ (name of medicine) do you take each time? *(Read alternatives and check one for each medicine.)*	___ One ___ Two ___ Three ___ Four ___ or how many? (Specify): ______	___ One ___ Two ___ Three ___ Four ___ or how many? (Specify): ______	___ One ___ Two ___ Three ___ Four ___ or how many? (Specify): ______	___ One ___ Two ___ Three ___ Four ___ or how many? (Specify): ______	___ One ___ Two ___ Three ___ Four ___ or how many? (Specify): ______
f. Do you take ______ (medicine) all the time, some of the time, or none of the time? *(Check one for each medicine.)* *(go to h)*	___ All the time ___ None of the time ___ Some of the time ↓	___ All the time ___ None of the time ___ Some of the time ↓	___ All the time ___ None of the time ___ Some of the time ↓	___ All the time ___ None of the time ___ Some of the time ↓	___ All the time ___ None of the time ___ Some of the time ↓
g. Would you say you take ______ (name of med.) more than 1/2 the time, 1/2 the time, or seldom? *(Check one for each medicine.)*	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom
h. Do you feel ______ (medicine) has improved your health, worsened your health, or had no effect on your health? *(Check one for each medicine.)*	___ Improved ___ Worsened ___ No effect ___ No time to see if has effect	___ Improved ___ Worsened ___ No effect ___ No time to see if has effect	___ Improved ___ Worsened ___ No effect ___ No time to see if has effect	___ Improved ___ Worsened ___ No effect ___ No time to see if has effect	___ Improved ___ Worsened ___ No effect ___ No time to see if has effect
i. Do you have any negative effects from ______? (name of medicine) *(Check one.)*	___ Yes (Specify): ______ ___ No	___ Yes (Specify): ______ ___ No	___ Yes (Specify): ______ ___ No	___ Yes (Specify): ______ ___ No	___ Yes (Specify): ______ ___ No

Question 6.

Have you stopped taking any of the medicine your doctor told you to take? *(Check one.)*

___ Yes *(For each medicine stopped, ask:)* ___ No → *(Go to Question 7.)*

↓

	Medicine #1	Medicine #2	Medicine #3	Medicine #4	Medicine #5
a. What are the names of the medicines? *(Write in name or description in columns 1-5. If more than five medicines, prepare a second sheet and re-number columns. PROBE: Any others?)*					
b. When did you stop taking (name of medicine(s))? *(Write in appropriate columns. PROBE: A week ago, a month ago, or how long ago?)*					
c. Why did you stop taking (name of medicine(s))? *(Write in reason in appropriate columns.)*					

Now, I'd like to ask you a few general questions about high blood pressure.

7. What is high blood pressure? That is, what does the term high blood pressure mean to you?

(Write in) _____

_____

8. What do you think is the single most important cause of high blood pressure? *(Write in)*

_____

_____

9. And what helps control high blood pressure? *(Write in. PROBE: What do you think has to be done to control it? If respondent does not answer, suggest: medicines, diet, activity restrictions, or what?)*

_____

_____

10. What can you personally do to help keep your blood pressure under control? *(Write in)*

_____

_____

_____

Question 11	Special Diet Restrictions	Activity Restrictions	Changes in Work Habits	Changes in Habits
When you were at the center two weeks ago, did the doctor suggest you follow a special diet? --restrict your activity in any way, or change your work habits? Do you work? Did he ask you to change <u>any</u> habits? *(PROBE: For example, smoking? Check one in each column.)* *(For all doctor recommendations answered "No," ask,* "Has the doctor ever suggested you _____ (recommendation)? *Check one.)*	___Yes (Ask a, e, f, g) ___No ___DK	___Yes (Ask b, e, f, g) ___No ___DK	___Yes (Ask c, e, f, g) ___No ___DK ___Doesn't work ___Works part time	___Yes (Ask d, e, f, g) ___No ___DK ___Doesn't smoke
a. What type of diet did the doctor suggest? *(Read alternatives. Check one.)*	___Reducing diet ___Low salt diet ___Other (Specify): _____	N.A.	N.A.	N.A.
b. In what way did the doctor suggest you restrict your activity? *(Write in.)*	N.A.		N.A.	N.A.
c. In what way did the doctor suggest you change your work habits? *(Write in.)*	N.A.	N.A.		N.A.
d. In what way did the doctor suggest you change your habits? *(Write in.)*	N.A.	N.A.	N.A.	
For <u>ALL</u> recommendations answered "Yes," ask e, f, g:				
e. Has it been difficult for you to follow _____ (recommendation)? *(Check one in appropriate columns.)*	___Yes ___No ___DK ___Somewhat	___Yes ___No ___DK ___Somewhat	___Yes ___No ___DK ___Somewhat	___Yes ___No ___DK ___Somewhat
f. Would you say that you follow _____ (recommendation) all of the time, some of the time, or none of the time? *(Check one in appropriate columns.)*	___All the time ___Some of the time ___None of the time ___DK	___All the time ___Some of the time ___None of the time ___DK	___All the time ___Some of the time ___None of the time ___DK	___All the time ___Some of the time ___None of the time ___DK
g. Do you feel _____ (recommendation) has improved, worsened, or had no effect on your health? *(Check one in appropriate columns)*	___Improved ___Worsened ___Had no effect	___Improved ___Worsened ___Had no effect	___Improved ___Worsened ___Had no effect	___Improved ___Worsened ___Had no effect

12. Have you lost any weight during the past month? *(Check one.)*

___ Yes

a. How many pounds have you lost? *(Write in.)*

_____ pounds

___ No

b. Have you gained any weight during the last two weeks? *(Check one.)*

___ No → *(Go to instructions.)*

___ Yes

c. How many pounds have you gained? *(Write in.)*

_____ pounds.

FOR ALL THOSE WHO WORK, ASK: QUESTIONS 13, 14, and 15.

FOR ALL THOSE WHO DO NOT WORK, GO TO QUESTION 16.

13. Do you feel your blood pressure has affected your job satisfaction? *(Check one.)*

___ Yes ___ No

14. Have you had to be away from work because of your blood pressure? *(Check one.)*

___ Yes ___ No → *(Go to Question 11.)*

15. How much time have you lost from work in the past month because of your blood pressure? *(Write in.)* _____

_____

16. How often does the doctor expect you to come back to see him? *(Write in. PROBE: For specific intervals?)* _____

_____

17. Could you tell me what some typical symptoms of high blood pressure are? *(Write in.)*

_____

_____

18. Is your high blood pressure presently under control? *(Check one.)*

___ Yes

a. What do you feel is the main reason it is under control? *(Read alternatives. Check one.)*

___ Followed doctor's recommendations.
___ Understood the doctor's recommendations.
___ Condition wasn't that severe.
___ The doctor's ability.
___ Or, is there some other reason?
(Specify):_____

_____

___ No

b. What do you feel is the main reason it is not under control? *(Read alternatives. Check one.)*

___ Failure to follow doctor's recommendations.
___ Didn't understand doctor's recommendations.
___ Severity of your condition.
___ The doctor's ability.
___ Or, is there some other reason?
(Specify):_____

_____

19. Do you believe some can be cured of high blood pressure or must treatment always be continued? *(Check one.)*

___ Usually cured. ___ Continue treatment. ___ Not sure.

20. Now I'm going to read some things people sometimes say about doctors. I'd like to know whether you personally think they are true of your doctor(s), or not. For example, *Read "a"*--Do you think that's true of your doctor(s), or not? *(Continue reading through list. Check one for each statement.)*

	True	Not True	Don't Know
a. They give you a chance to tell them exactly what your trouble is.	___	___	___
b. They take enough personal interest in you.	___	___	___
c. They tell you enough about your condition; they explain just what the trouble is.	___	___	___
d. They tell you enough about your medicine; they explain their importance to you.	___	___	___
e. Their treatments or medicines often make you feel worse than before you started taking it.	___	___	___
f. They rush too much when they examine you.	___	___	___

21. How satisfied are you with your doctor? *(Write in.)* _____

_____

22. What problems would cause you to seek immediate medical attention? *(Write in.)* _____

_____

Finally, just a few general questions.

23. Of the following diseases, which to you consider very serious for someone your age? *(Read "a" below)*--Do you consider that very serious, fairly serious, or not serious for someone your age? *(Continue reading through list. Check one for each disease.)*

	Yes, Very Serious	Yes, Fairly Serious	No, Not Serious
a. Cancer	___	___	___
b. A stroke	___	___	___
c. A heart condition	___	___	___
d. Diabetes	___	___	___
e. High blood pressure	___	___	___
f. Ulcers	___	___	___

24. And, in terms of your general health, would you say it was *(read alternatives. Check one.)*

___ Excellent
___ Good
___ Fair
___ Poor

Thank you very much for your cooperation.

(MARK TIME INTERVIEW ENDED: _____ A.M. OR P.M.)

ENTRY AND FOLLOW-UP QUESTIONNAIRE

1. During the two-week period prior to your last visit to the center, did you have *(Check one for each):*

a.	Headaches	___ Yes	___ No	___ Sometimes
b.	Dizzy spells	___ Yes	___ No	___ Sometimes
c.	Blurred vision	___ Yes	___ No	___ Sometimes
d.	Difficulty in breathing or shortness of breath	___ Yes	___ No	___ Sometimes
e.	Swelling of your legs	___ Yes	___ No	___ Sometimes
f.	Pain or discomfort in your legs	___ Yes	___ No	___ Sometimes
g.	Or, did you have to limit your exercise or activity?	___ Yes	___ No	___ Sometimes

h. Did you have any problems I haven't mentioned?
___ Yes ___ No→*(If "No," go to Question 2.)*

i. Could you tell me what they were? *(Write in description of <u>each</u> problem.)* (What kind of trouble was it?)

Other: Specify _____

_____

Other: Specify _____

_____

2. During your most recent visit to the center, did someone take your blood pressure? *(Check one.)*
___ Yes ___ No→*(Go to Question 3.)*

a. What did that person tell you the blood pressure was at that time? *(Check one.)*

___

b. What was it? *(Write in.)*

_____

_____

_____

___No ___ Don't remember

c. Were you ever told anything about your blood pressure?
___Yes ___No *(Go to Ques. 3.)*

d. What were you told? *(Write in.)*

_____

_____

3. What is normal blood pressure for a person your age? *(Write in.)*

_____

_____

4. Now, when people come to the center, often lab tests are done. When you were at the center two weeks ago, did you have any tests? *(Check one.)* For example, blood tests or x-rays?

___ Yes ___ No → *(Go to Question 5.)*

↓

a. What tests were done? *(Write in. If you do not know which tests, write in "Don't know.")*

_____

_____

b. Do you know what the test(s) was (were) for? *(Check one.)*

___ Yes ___ No → *(Go to "d".)*

↓

c. What was (were) it (they) for? *(Write in.)*

_____

_____

d. Did you know what would happen to <u>you</u> during the test(s)? *(Check one.)*

___ Yes ___ Some ___ No

e. Do you know the results of the test(s)? *(Check one.)*

___ Yes ___ Some ___ No

↓ ↓ ↓

f. What were the restuls of the test(s)? *(Write in.)*

_____

_____

_____

g. Were you not told or don't you remember? *(Check one.)*

___ Wasn't told

___ Don't remember

5. List name of one medicine that you have taken in past two weeks *(describe if you don't know the name)*. After you have answered Question 5 for all the medicines you take, please go to Question 6.

   MEDICINE #1: _____

   a. How long have you taken the above listed medicine?
      _____ (two weeks, a month, or how long?)

   b. What is the purpose of the above listed medicine? What does it do for you? _____
      _____

   c. Are there any precautions with that medicine? *(What are the side effects?)* _____

   d. How often do you take the above listed medicine?
      ___ 1 time a day
      ___ 2 times a day
      ___ 3 times a day
      ___ 4 times a day
      ___ or how often? (specify)

   e. How many do you take each time?
      ___ one ___ three ___ or how many? (specify)
      ___ two ___ four

   f. Do you take the medicine ___ all of the time?
      ___ none of the time? ___ some of the time?

   g. Would you say you take the medicine
      ___ more than 1/2 of the time?
      ___ 1/2 of the time?
      ___ seldom?

   h. Do you feel the above listed medicine has ___ improved?
      ___ worsened?
      ___ no effect?
      ___ not enough time to see effect?

   i. Do you have negative effects from the above-listed medicine?
      ___ Yes (specify) _____
      ___ No

MEDICINE #2: _____

a. How long have you taken the above listed medicine?
_____ (two weeks, a month, or how long?)

b. What is the purpose of the above listed medicine? What does it do for you? _____
_____

c. Are there any precautions with that medicine? *(What are the side effects?)* _____
_____

d. How often do you take the above listed medicine?
___ 1 time a day
___ 2 times a day
___ 3 times a day
___ 4 times a day
___ or how often? (specify)

e. How many do you take each time?
___ one ___ three ___ or how many? (specify)
___ two ___ four

f. Do you take that medicine ___ all of the time?
___ none of the time?
___ some of the time?

g. Would you say you take the medicine
___ more than 1/2 of the time?
___ 1/2 of the time?
___ seldom?

h. Do you feel the above listed medicine has ___ improved?
___ worsened?
___ no effect?
___ not enough time to see effect.

i. Do you have negative effects from the above listed medicine?
___ Yes (specify) _____
___ No

MEDICINE #3: _____

a. How long have you taken the above listed medicine?
_____ (two weeks, a month, or how long?)

b. What is the purpose of the above listed medicine? What does it do for you? _____
_____

c. Are there any precautions with that medicine? *(What are the side effects?)* _____
_____

d. How often do you take the above listed medicine?
___ 1 time a day
___ 2 times a day
___ 3 times a day
___ 4 times a day
___ or how often? (specify)

e. How many do you take each time?
___ one ___ three ___ or how many? (specify)
___ two ___ four

f. Do you take that medicine ___ all of the time?
___ none of the time?
___ some of the time?

g. Would you say you take the medicine
___ more than 1/2 of the time?
___ 1/2 of the time?
___ seldom?

h. Do you feel the above listed medicine has ___ improved?
___ worsened?
___ no effect?
___ not enough time to see effect.

i. Do you have negative effects from the above listed medicine?
___ Yes (specify) _____
___ No

MEDICINE #4: _____

a. How long have you taken the above listed medicine?
_____ (two weeks, a month, or how long?)

b. What is the purpose of the above listed medicine? What does it do for you? _____
_____

c. Are there any precautions with that medicine? *(What are the side effects?)* _____
_____

d. How often do you take the above listed medicine?
___ 1 time a day
___ 2 times a day
___ 3 times a day
___ 4 times a day
___ or how often? (specify)

e. How many do you take each time?
___ one ___ three ___ or how many? (specify)
___ two ___ four

f. Do you take that medicine ___ all of the time?
___ none of the time?
___ some of the time?

g. Would you say you take the medicine
___ more than 1/2 of the time?
___ 1/2 of the time?
___ seldom?

h. Do you feel the above listed medicine has ___ improved?
___ worsened?
___ no effect?
___ not enough time to see effect.

i. Do you have negative effects from the above listed medicine?
___ Yes (specify) _____
___ No

MEDICINE #5: _____

a. How long have you taken the above listed medicine?
_____ (two weeks, a month, or how long?)

b. What is the purpose of the above listed medicine? What does it do for you? _____
_____

c. Are there any precautions with that medicine? *(What are the side effects?)* _____
_____

d. How often do you take the above listed medicine?
___ 1 time a day
___ 2 times a day
___ 3 times a day
___ 4 times a day
___ or how often? (specify)

e. How many do you take each time?
___ one ___ three ___ or how many? (specify)
___ two ___ four

f. Do you take that medicine ___ all of the time?
___ none of the time?
___ some of the time?

g. Would you say you take the medicine
___ more than 1/2 of the time?
___ 1/2 of the time?
___ seldom?

h. Do you feel the above listed medicine has ___ improved?
___ worsened?
___ no effect?
___ not enough time to see effect.

i. Do you have negative effects from the above listed medicine?
___ Yes (specify) _____
___ No

6. Have you stopped taking any of the medicines your doctor told you to take? *(Check one.)*
___ Yes *(Please fill in boxes below for each medicine you have stopped taking.)* ___ No *(Go to Question 7.)*

	Medicine #1 stopped	Medicine #2 stopped	Medicine #3 stopped	Medicine #4 stopped	Medicine #5 stopped
a. What are the names of the medicines? *(Write in name or description under medicine #1-5.)*					
b. When did you stop taking _____? *(Name of medicine(s).)*	__wk. ago __2 wk. ago __mo. ago __more than 1 mo. ago __other how long	__wk. ago __2 wk. ago __mo. ago __more than 1 mo. ago __other how long	__wk. ago __2 wk. ago __mo. ago __more than 1 mo. ago __other how long	__wk. ago __2 wk. ago __mo. ago __more than 1 mo. ago __other how long	__wk. ago __2 wk. ago __mo. ago __more than 1 mo. ago __other how long
c. Why did you stop taking the medicine? *(Write in reason in appropriate column.)*					

Now, I'd like to ask you a few general questions about high blood pressure. There is no one right answer; we only are interested in your opinion.

7. What is high blood pressure: That is, what does the term high blood pressure mean to you? *(Write in.)* _____
_____

8. What do you think is the single most important cause of high blood pressure? *(Write in.)* _____
_____

9. And what helps control high blood pressure? *(Write in. What do you think has to be done to control it?--Medicines, diet, activity restrictions, or what?)* _____

_____

10. What can you personally do to help keep your blood pressure under control? *(Write in.)* _____

_____

11.1. When you were at the center, did the doctor suggest a special diet?

___ Yes ___ No *(Go to Question 11.2)* ___ Don't know

a. What type of diet did the doctor suggest?
___ reducing diet
___ low salt
___ both
___ other (specify) _____

b. Has it been difficult for you to follow?
___ Yes ___ No ___ Somewhat ___ Don't know

c. Would you say you follow it
___ all the time?
___ some of the time?
___ none of the time?
___ don't know.

d. What effect do you feel it has on your health?
___ improved.
___ worsened.
___ no effect.

11.2. When you were at the center, did the doctor restrict your activity.

___ Yes ___ No *(Go to Question 11.3)* ___ Don't know

a. In what way did he restrict your activity? *(Write in.)* _____

_____

b. Has it been difficult for you to follow?
___ Yes ___ No ___ Somewhat ___ Don't know

c. Would you say you follow it?
___ all the time?
___ some of the time?
___ none of the time?
___ don't know.

d. What effect do you feel it has on your health?
___ improved.
___ worsened.
___ no effect.

11.3. When you were at the center, did the doctor suggest you change your work habits?
___ Yes ___ No *(Go to Question 11.4)* ___ Don't know

a. In what way did he suggest you change your work habits?
(Write in.) _____

b. Has it been difficult for you to follow?
___ Yes ___ No ___ Somewhat ___ Don't know

c. Would you say you follow it
___ all the time?
___ some of the time?
___ none of the time?
___ don't know.

d. What effect do you feel it has on your health?
___ improved.
___ worsened.
___ no effect.

11.4. When you were at the center, did the doctor suggest you change <u>any</u> of your habits? *(Example: smoking, drinking, etc.)*
___ Yes ___ No *(Go to Question 12)* ___ Don't know

a. In what way did the doctor suggest you change your habits?
(Write in.) _____

b. Has it been difficult for you to follow?
___ Yes ___ No ___ Somewhat ___ Don't know

c. Would you say you follow it
___ all the time?
___ some of the time?
___ none of the time?
___ don't know.

d. What effect do you feel it has on your health?
___ improved.
___ worsened.
___ no effect.

12. Have you lost any weight during the past month? *(Check one.)*

___ Yes

a. How many pounds have you lost? *(Write in.)*

_____ pounds

___ No

b. Have you gained any weight during the last two weeks? *(Check one.)*

___ No
___ Yes

c. How many pounds have you gained? *(Write in.)*

_____ pounds

FOR ALL THOSE WHO WORK, ANSWER: QUESTIONS 13, 14, and 15.

FOR ALL THOSE WHO DO NOT WORK, GO TO QUESTION 16.

13. Do you feel your blood pressure has affected your job situation? *(Check one.)*

___ Yes ___ No

14. Have you had to be away from work because of your blood pressure? *(Check one.)*

___ Yes ___ No *(If "No," go to Question 16.)*

15. How much time have you lost from work in the past month because of your blood pressure? *(Write in.)* _____

_____

16. How often does the doctor expect you to come back to see him? *(Write in: one week, one month, six months.)* _____

_____

17. Could you tell me what some typical symptoms of high blood pressure are? *(Write in.)* _____

_____

_____

18. Is your high blood pressure presently under control? *(Check one.)*

___ Yes ↓

a. What do you feel is the main reason it is under control? *(Check one.)*

___ Followed doctor's recommendations.
___ Understood the doctor's recommendations.
___ Condition wasn't that severe
___ The doctor's ability
___ Or, is there some other reason? (specify)

_____
_____

___ No ↓

b. What do you feel is the main reason it is not under control? *(Check one.)*

___ Failure to follow doctor's recommendations.
___ Didn't understand the doctor's recommendations.
___ Severity of your condition
___ The doctor's ability
___ Or, is there some other reason? (specify)

_____
_____

19. Do you believe someone can be cured of high blood pressure or must treatment always be continued? *(Check one.)*

___ usually cured.
___ continue treatment.
___ not sure.

20. Below are some things people sometimes say about doctors. I'd like to know whether you personally think they are true about your doctor(s), or not. *(Continue reading through list. Check one for each statement.)*

	True	Not True	Don't Know
a. They give you a chance to tell them exactly what your trouble is.	___	___	___
b. They take enough personal interest in you.	___	___	___
c. They tell you enough about your condition; they explain just what the trouble is.	___	___	___
d. They tell you enough about your medicine; they explain the importance of the medication.	___	___	___
e. Their treatments or medicines often make you feel worse than before you started taking it.	___	___	___
f. They rush too much when they examine you.	___	___	___

21. How satisfied are you with your doctor? *(Write in.)* _____

_____

_____

22. What problems would cause you to seek immediate medical attention? *(Write in.)* _____

_____

_____

Finally, just a few general questions.

23. Of the following diseases which do you consider very serious for someone your age? Do you consider that very serious, fairly serious, or not serious for someone your age? *(Check one for each disease.)*

	Yes, Very Serious	Yes, Fairly Serious	No, Not Serious
a. Cancer	___	___	___
b. A stroke	___	___	___
c. A heart condition	___	___	___
d. Diabetes	___	___	___
e. High blood pressure . . .	___	___	___
f. Ulcers	___	___	___

24. And, in terms of your general health, would you say it was: *(Read alternatives. Check one.)*

___ Excellent
___ Good
___ Fair
___ Poor

Thank you very much for your cooperation. We will ensure that your answers are never identified with you personally but used to try and improve the care to our patients.

FOLLOW-UP INTERVIEW FORM

SURVEY OF PATIENTS WITH HYPERTENSION

RESPONDENT I.D. #_____

TELEPHONE #_____

INTERVIEWER:_____

RECORD OF CALLS:	1	2	3	4	5
DATE:					
TIME OF CALL:	AM PM	AM PM	AM PM	AM PM	AM PM

RECORD OF PERSONAL CONTACTS:	1	2	3
DATE:			
TIME OF CONTACT:	AM PM	AM PM	AM PM

INTERVIEW STATUS:

____ Completed Interview

____ Partial Interview (specify)_____

_____

____ Refusal (specify)_____

_____

____ Unable to contact after _____ attempts.

____ Other (specify)_____

_____

(MARK TIME INTERVIEW STARTED: _____ A.M. OR P.M.)

Hello, I'm _____, and I'm working with Dr. Simoni of St. Joseph's Family Practice Center. We are calling you again to see how you have been since our last call to you. You will recall our questions concerned care you received for high blood pressure and that we need answers to some questions so that we can try to improve the care for other patients with high blood pressure.

Is this _____ (name of respondent)? *(Remove identifying name when editing questionnaire.)*

(If the person answering the phone is the respondent, proceed. If the person answering the phone is not, repeat the introduction when the respondent comes to the phone.)

I'm going to be asking you questions about your health and your recent status since my last contact. Let's start with your health during the last week.

MEDICAL HEALTH STATUS

1. During the last week period, did you have: *(Read alternatives and check one for each.)*

a.	Headaches?	___ Yes	___ No	___ Sometimes	___ NA
b.	Dizzy spells?	___ Yes	___ No	___ Sometimes	___ NA
c.	Blurred vision?	___ Yes	___ No	___ Sometimes	___ NA
d.	Difficulty in breathing or shortness of breath	___ Yes	___ No	___ Sometimes	___ NA
e.	Swelling of your legs	___ Yes	___ No	___ Sometimes	___ NA
f.	Pain or discomfort in your chest	___ Yes	___ No	___ Sometimes	___ NA
g.	Did you have to limit your exercise or activity	___ Yes	___ No	___ Sometimes	___ NA

h. Did you have any problems I haven't mentioned?

___ Yes ___ No → *(If "No," go to Question 2.)*

↓

i. Could you tell me what they were? *(Write in description of <u>each</u> problem. PROBE: WHAT KIND OF TROUBLE WAS IT?)*

Description of Problem: _____

_____

j. Description of Problem: _____

_____

k. Description of Problem: _____

_____

MEDICAL HEALTH STATUS

2. When people come to the center, often lab tests or other procedures are done. The last time you were at the center, did you have any tests?

___ Yes ___ No → *(Go to Question 4.)*

a. What tests were done? *(Write in. If respondent does not know which tests, write in "DK. Blood tests not enough.)*

_____

_____

_____

b. Do you know what the test(s) was (were) for? *(Check one.)*

___ Yes ___ No

c. What was (were) it (they) for? *(Write in.)*

_____

_____

_____

d. Do you know the results of the test(s)? *(Check one.)*

___ Yes

e. What were the results of the test(s)? *(Write in.)*

_____

_____

_____

_____

___ No

f. Were you not told or don't you remember? *(Check one.)*

___ Wasn't told

___ Doesn't remember

Question 3	Medicine #1	Medicine #2	Medicine #3	Medicine #4	Medicine #5
Can you tell me what medicine you have taken in the last two weeks? *(Write in name of medicines or description in columns 1-5. If more than five medicines, prepare a second sheet and re-number columns. PROBE: Any others?)*					
a. What is the purpose of (name of med.)? *(PROBE: What does it do for you? Write in purpose for each medicine in appropriate column.)*					
b. Are there any precautions with this (name of medicine)? What are the side effects? *(Write in precautions for each medicine in appropriate column.)*					
c. How often do you take (name of med.)? *(Read alternatives and check one for each medicine.)*	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often (Specify):	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often (Specify):	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often (Specify):	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often (Specify):	___ 1 x/day ___ 2 x/day ___ 3 x/day ___ 4 x/day ___ or how often (Specify):
d. How many (medicine) do you take each time? *(Read alternatives and check one for each medicine.)*	___ One ___ Two ___ Three ___ Four ___ Or how many? (Specify):	___ One ___ Two ___ Three ___ Four ___ Or how many? (Specify):	___ One ___ Two ___ Three ___ Four ___ Or how many? (Specify):	___ One ___ Two ___ Three ___ Four ___ Or how many? (Specify):	___ One ___ Two ___ Three ___ Four ___ Or how many? (Specify):
e. Do you take (medicine) all the time, some of the time, or none of the time? *(Check one for each medicine.)*	___ All the time ___ None of the time ___ Some of the time	___ All the time ___ None of the time ___ Some of the time	___ All the time ___ None of the time ___ Some of the time	___ All the time ___ None of the time ___ Some of the time	___ All the time ___ None of the time ___ Some of the time
f. Would you say you take (name of med.) more than 1/2 the time, 1/2 the time, or seldom? *(Check one for each medicine.)*	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom	___ More than 1/2 time ___ 1/2 time ___ Seldom
g. Do you feel (medicine) has improved your health, worsened your health, or had no effect on your health in the past few months? *(Check one for each medicine.)*	___ Improved ___ Worsened ___ No effect ___ No time to see effect	___ Improved ___ Worsened ___ No effect ___ No time to see effect	___ Improved ___ Worsened ___ No effect ___ No time to see effect	___ Improved ___ Worsened ___ No effect ___ No time to see effect	___ Improved ___ Worsened ___ No effect ___ No time to see effect
h. Do you have any negative effects from (medicine)?	___ No ___ Yes (Specify):	___ No ___ Yes (Specify):	___ No ___ Yes (Specify):	___ No ___ Yes (Specify):	___ No ___ Yes (Specify):

4. Have you stopped taking any of the medicines your doctor told you to take? *(Check one.)*

___ Yes *(For each medicine stopped, ask:)* ___ No → *(Go to Question 7.)*

	Medicine #1	Medicine #2	Medicine #3	Medicine #4	Medicine #5
a. What are the names of the medicines? *(Write in name or description in Columns 1-5. If more than five medicines, prepare a second sheet and re-number columns. PROBE: Any others?)*					
b. When did you stop taking _____ (name of medicine(s))? *(Write in appropriate columns. PROBE: A week ago, a month ago, or how long ago?)*					
c. Why did you stop taking _____ (name of medicine(s))? *(Write in reason in appropriate columns.)*					

Now, I'd like to ask you a few general questions about high blood pressure.

5. What is high blood pressure? That is, what does the term high blood pressure mean to you?
(Write in) _____

6. What do you think is the single most important cause of high blood pressure? *(Write in)*

7. And what helps control high blood pressure? *(Write in. PROBE: What do you think has to be done to control it? If respondent does not answer, suggest: medicines, diet, activity restrictions, or what?)*

8. What can you personally do to help keep your blood pressure under control? *(Write in)*

Question 9	Special Diet Restrictions	Activity Restrictions	Changes in Work Habits	Changes in Habits
Since we last called, did the doctor suggest you follow a special diet? --restrict your activity in any way, or change your work habits? Do you work? Did he ask you to change any of your habits? *(PROBE: For example, smoking? Check one in each column.)* *(For all doctor recommendations answered "no", ask: Has the doctor ever suggested you _____ (recommendation) ?)* *(Check one.)*	___Yes (Ask a, e, f, g) ___No ___DK	___Yes (Ask b, e, f, g) ___No ___DK	___Yes (Ask c, e, f, g) ___No ___DK ___Doesn't work ___Works part time	___Yes (Ask d, e, f, g) ___No ___DK ___Doesn't smoke
a. What type of diet did the doctor suggest? *(Read alternatives. Check one.)*	___Reducing diet ___Low salt diet ___Both ___Other (Specify): _____	N.A.	N.A.	N.A.
b. In what way did the doctor suggest you restrict your activity? *(Write in.)*	N.A.		N.A.	N.A.
c. In what way did the doctor suggest you change your work habits? *(Write in.)*	N.A.	N.A.		N.A.
d. In what way did the doctor suggest you change your habits? *(Write in.)*	N.A.	N.A.	N.A.	
For ALL recommendations answered "Yes," ask e, f, g:				
e. Has it been difficult for you to follow _____ (recommendation) ? *(Check one in appropriate columns.)*	___Yes ___No ___DK ___Somewhat	___Yes ___No ___DK ___Somewhat	___Yes ___No ___DK ___Somewhat	___Yes ___No ___DK ___Somewhat
f. Would you say that you follow _____ (recommendation) all of the time, some of the time, or none of the time? *(Check one in appropriate columns.)*	___All the time ___Some of the time ___None of the time ___DK	___All the time ___Some of the time ___None of the time ___DK	___All the time ___Some of the time ___None of the time ___DK	___All the time ___Some of the time ___None of the time ___DK
g. Do you feel _____ (recommendation) has improved, worsened, or had no effect on your health? *(Check one in appropriate column.)*	___Improved ___Worsened ___Had no effect	___Improved ___Worsened ___Had no effect	___Improved ___Worsened ___Had no effect	___Improved ___Worsened ___Had no effect

10. Have you lost any weight during the past month? *(Check one.)*

___ Yes
↓
a. How many pounds have you lost? *(Write in.)*

_____ pounds

___ No
↓
b. Have you gained any weight during the last two weeks? *(Check one.)*

___ No *(Go to instructions.)*

___ Yes
↓
c. How many pounds have you gained? *(Write in.)*

_____ pounds

FOR ALL THOSE WHO WORK, ASK: QUESTIONS 11, 12, and 13.

FOR ALL THOSE WHO DO NOT WORK, GO TO QUESTION 14.

11. Do you feel your blood pressure has affected your job situation? *(Check one.)*

___ Yes ___ No

12. Have you had to be away from work because of your blood pressure? *(Check one.)*

___ Yes ___ No → *(Go to Question 14.)*
↓
13. How much time have you lost from work in the past month because of your blood pressure? *(Write in.)* _____

_____

14. How often does the doctor expect you to come back to see him? *(Write in. PROBE: For specific intervals?)* _____

_____

15. Could you tell me what some typical symptoms of high blood pressure are? *(Write in.)*

_____

_____

16. a. What do you feel is the main reason it is under control? *(Read alternatives. Check one.)*

___ Followed doctor's recommendations.
___ Understood the doctor's recommendations.
___ Condition wasn't that severe.
___ The doctor's ability.
___ Or, is there some other reason? (Specify):_____

_____

b. What do you feel is the main reason it is not under control? *(Read alternatives. Check one.)*

___ Failure to follow doctor's recommendations.
___ Didn't understand doctor's recommendations.
___ Severity of your condition.
___ The doctor's ability.
___ Or, is there some other reason? (Specify):_____

_____

17. Do you believe someone can be cured of high blood pressure or must treatment always be continued? *(Check one.)*

___ Usually cured
___ Continue treatment
___ Not sure

12. Now I'm going to read some things people sometimes say about doctors. I'd like to know whether you personally think they are true of your doctor(s), or not. For example, *(Read "a").*--Do you think that's true of your doctor(s), or not? *(Continue reading through list. Check one for each statement.)*

	True	Not True	Don't Know
a. They give you a chance to tell them exactly what your trouble is.	____	____	____
b. They take enough personal interest in you.	____	____	____
c. They tell you enough about your condition; they explain just what the trouble is.	____	____	____
d. They tell you enough about your medicine; they explain their importance to you.	____	____	____
e. Their treatments or medicines often make you feel worse than before you started taking it.	____	____	____
f. They rush too much when they examine you.	____	____	____

19. How satisfied are you with your doctor? *(Write in.)* _____

_____

20. What problems would cause you to seek immediate medical attention? *(Write in.)* _____

_____

_____

_____

21. And finally, in terms of your general health, would you say it was *(Read alternatives. Check one.)*

___ Excellent
___ Good
___ Fair
___ Poor

Thank you very much for your cooperation.

(MARK TIME INTERVIEW ENDED: _____ A.M. OR P.M.)

APPENDIX E

INSTRUCTION BOOKLET FOR INTERVIEWERS AND INTERVIEWER REPORT FORMS

INSTRUCTION BOOKLET FOR INTERVIEWERS

SURVEY OF PATIENTS WITH HYPERTENSION

St. Joseph's Family Practice Center
Flint, Michigan
Winter 1974

Perhaps the main reason useful data can be obtained from respondents is that they are assured that all their answers will be kept confidential--that they will never be identified with them as individuals but used only for statistical purposes and as bases for general statements. As an interviewer, it is your responsibility to ensure this confidentiality. You must never repeat to anyone the information that is given to you by a respondent.

A. Introductory Procedures

1. Before you call a respondent, fill in his/her I.D. number, telephone number and name on the first page of the questionnaire. (Make sure to remove the respondent's name when editing questionnaire. See section on editing below.)

2. Have all the materials you will need at hand: pencils or pens; questionnaires; paper on which to record information when a respondent amplifies her answers.

When you dial a number, give the person you are calling time to answer by waiting a minute--about 10 rings. You'll often save another call by doing this.

3. All of the people you are being asked to call already have been contacted by letter; the purposes of this study have been explained to them and hopefully, they consider it important and worthwhile enough to give you their cooperation.

The introductory remarks on the first sheet of the questionnaire tell the respondent who you are, what organization you represent, and why you are calling. Most respondents will accept this explanation and allow you to proceed with the interview. Some people, however, may be reluctant to be questioned for some or all of the following reasons:

a. The confidential nature of the information being asked for: Assure the respondent that her answers will be kept completely confidential and that they will be used only for statistical purposes and never identified with them or their family;

b. Uncertainty about the purposes of the study: Explain why the study is being conducted and its importance; i.e., to identify the problems of people with high blood pressure in order to give them more and better

health services. If you are asked questions about the study, by all means answer them. Try to be as brief and unspecific as possible, however. You do not want to influence the respondents to answer your questions in a certain way;

c. Why they were chosen: Explain that they were selected because they have high blood pressure. We are trying to evaluate the care given to determine what aspects of care could be improved. Assure the respondent (R) that nothing they say will ever be identified with her/him as an individual;

d. The interview will take too long: Explain that usually the interview takes only about 10 minutes and suggest that you start out. Usually the sooner you start the interview, the less questions you will be asked.

If a respondent says that they cannot talk with you at that time, or if the respondent is not at home, find out when you can call back to complete the interview.

B. Beginning the Interview

It is important to remember that good interviews are based on your telephone manner. The respondent cannot see you; they "hear" the way you look. They like what they hear if you sound natural, pleasant, and interested. Do not allow your interest to interfere with your role as an interviewer, however. Combine an interested attitude with a businesslike manner.

When we talk with a person we often receive "cues" about them or their thinking by their mannerisms, e.g., a smile, shrug of the shoulders, and so on. You will not be receiving such cues. Therefore, you must be extremely alert. Some general rules to follow are:

1. Prepare in advance: Know the questionnaire and what you are expected to say. This frees your mind for listening;

2. Concentrate: Focus your mind on what the respondent says. Practice shutting out outside distractions;

3. Turn off your own worries: Personal worries or problems not connected with contact form a kind of "static" that can blank out the respondent's message.

C. Asking the Questions

Your goal is to obtain accurate and complete information by using the questionnaire. It has been devised so that it will provide standardized data which can be analyzed and compared with other data. Therefore, *all respondents must be asked the same questions in the same way*. The analyst must be sure that differences in the data reflect differences in respondents and not differences in the interviewers.

Sentences or words in italics are instructions for you and are not to be read to the respondent.

Words in parentheses such as (it/they) represent alternative ways of wording questions. You should choose the appropriate word to use.

Some general rules to follow are:

1. Ask all questions as they are worded and in the sequence in which they are presented in the questionnaire. Respondent's answers are influenced by the wording and order of questions. This rule is not sacred, however. If you find you have skipped a question, go back and ask that question;

2. Every question in the questionnaire should be asked--unless it is a follow-up question which is not relevant because of a negative answer to an earlier "screening" question;

3. *Remain neutral.* Nothing you say should affect the way in which the respondent answers the questions. Do not indicate a personal opinion about the answers you receive by your tone of voice.

D. Probing

The questionnaire with which you will be working contains both "close-ended" and "open-ended" questions (that is, questions in which we ask a respondent to give us his ideas in his own terms). Close-ended questions usually do not require anything more on your part than checking the space next to the appropriate answer which the respondent has chosen from all those suggested to him.

Open-ended questions, however, require "work" and you will use two techniques in working with these questions--verbatim recording and probing.

By probing we mean that technique which is used by an interviewer to stimulate discussion and obtain more information. Probes are used when the interviewer wants the respondent to enlarge, clarify or explain the reasons for what he has said. They also are used when the respondent gives a vague, incomplete or irrelevant answer which does not fulfill the requirements of the question asked.

The important point to remember in using probes, however, is that you must not question a respondent's answers. You do not want to appear to be confronting the respondent with a contradiction in his answers or implying to him that his answer is not right. You are using probes so that the analyst will have clear and rich data with which to work.

There are many different kinds of probes. Perhaps the most neutral and natural are: (1) brief remarks of interest and understanding such as "uh-huh" or "I see" or "Yes" or "that's interesting" and (2) the "pregnant pause." In this probe, silence conveys to the respondent that you believe he has more to say. This technique should not be overused, however, since sometimes a respondent has "run out" of answers and you do not want to embarrass him/her. Your own sensitivity will help you determine when to use this technique.

Sometimes a respondent does not seem to understand a question, misinterprets it, seems unable to make up his mind or has strayed from the subject. When this happens, you can repeat the question as a probe, emphasizing those points which he seems to have missed. This usually will help the respondent realize what kind of answer is needed. At other times, you may want to stimulate further thought by the respondent. In such cases, you can simply repeat what he has said as soon as he stops talking. This can be done as you are writing.

Frequently you can use certain neutral questions or comments to stimulate thought or obtain clearer and fuller responses. Such phrases as the following are commonly used by interviewers.

"Could you tell me why you feel that way?"

"Why do you think that is so?"

"Will you tell me what you have in mind?"

"Is there anything else?"

Sometimes it is a good technique to intimate to the respondent that you have not understood his answer. For example, you might say, I'm not quite sure I know what you mean by that, could you tell me a

little more? This technique should not be overused to the extent that the respondent feels you do not understand him. But it may be used to encourage him to clarify or enlarge upon his answer.

Finally, there may be times when you want to get a respondent "back on the tract," when you know he has given you a full or complete answer or when he is digressing at length about a subject not related to the question. In order to regain control of the interview in such situations, you might say, "Oh, that's interesting. We cover that later in the interview. Shall we move on to . . . or, you might say, "I know you have a busy schedule and we have so much more to cover, shall we move on to. . . .

E. Recording Responses and Editing the Interview

Up to this point we have discussed how to ask questions and obtain responses. Both of these are extremely important jobs. However, if you fail to record the answer properly, the analyst will not have the data he needs to work with and your efforts will have been to no avail.

In most cases you only will be required to check the appropriate space next to the answer chosen. In those cases where a respondent elaborates on her answer, you should record this information *verbatim* in the space next to the question. If you require more room, use an extra sheet of paper. Just remember to note the respondent number and question's number which you are recording so that the answers can be coded accurately.

In order to record the respondent's answer as completely as possible, write as the patient is talking. (If you later try to remember what was said, valuable information may be lost.) Jot down key words and phrases. If you omit articles, prepositions and pronouns, however, you must put them in later when you edit the questionnaire. Do not paraphrase what the respondent has said; record the respondent's *own words*.

Sometimes, of course, the respondent will have to wait as you record her answers. In such a case you might say, "I don't want to miss anything," or, "I want to get this all down." Or you may repeat the last few phrases of the answer as you are writing. This tells the respondent that you are listening to what she has said and also may serve as a probe to stimulate her to enlarge on her answer.

When you edit your questionnaire you should include everything that the respondent has said that pertains to the questions. Sometimes, however, a respondent will talk at length about something that has no direct bearing on the subject. If you are *certain* that her answer is irrelevant, then you may summarize her statements, noting on the questionnaire what you have done.

When you edit the questionnaire, you must account for each question. Sometimes questions will not be answered because you have been instructed to skip them because of the respondent's earlier answers. In such a case, draw a slash mark (/) through the spot where the answer would have appeared had the question been asked. If a respondent has refused to answer a question, despite your probing, mark it "no answer," abbreviated *NA*. A "don't know" answer should be marked *DK*.

If you have made an error in recording an answer, do *not* erase. Place a slash mark (/) through the incorrect answer, note "my error," and check (✓) the correct answer. If a respondent changes her answer, place a slash mark (/) through her first response, note "R changed answer," and check (✓) her new choice.

Use a black pencil or black or blue pen to edit the questionnaire. Only your comments and remarks should be put in parentheses, not the respondent's.

F. The Questionnaire

Cover Page

Respondent I.D. #.--The same I.D. number must be written on all questionnaires used for one respondent. If you use more than one questionnaire for a respondent, you must copy this number on the cover page of every questionnaire used. This number also should be written in the lower right hand corner of the last page of the questionnaire. This number will be the patient's record number for the center.

You will be given a set of identification numbers for all respondents you are to call.

Record of Calls.--In this space write in the date and time of day for each separate phone call you make to the respondent. Enter this information even when there is no answer; this will help you remember when you were not able to find anyone at home. Do not repeatedly call a household at the same time day after day; try calling a few times in the morning; a few times in the afternoon; and a few times in the evening.

Interview Status.--When you have completed the interview, check the most appropriate line below the words "interview status."

A check in the "completed interview" space indicates that all the appropriate questions were asked and answered for all members of the household. If the respondent (R) refused to answer a few questions but gave you most of the information you asked for, check (✓) the "completed interview" space.

A check in the "partial interview" space indicates you were able to get some but not *all* of the information asked for. Explain why you were not able to get all the required information.

When a person refuses to be interviewed, e.g., she objects to being questioned, mark the appropriate space and explain the reason given.

If you are unable to reach anyone at the telephone number, check "no answer after ____ attempts," writing in the number of times you called the household.

A phone may have been disconnected and you will be unable to reach one of the households you have been assigned. In this case, check the "other" space and explain the situation.

INTERVIEWER REPORT FORM

1. In general, how do you think respondents felt about being interviewed?

2. Do you think respondents told you accurately about the medical problems and care they have had?

   a. Which questions do you think they didn't answer accurately?

   b. Why do you think they didn't?

3. What questions do you think were most difficult for the respondents to answer?

   a. Why do you think these were difficult to answer?

4. Which questions do you think were easiest to answer?

   a. Why do you think these were easy to answer?

5. What kind of things do you find most successful in getting respondents to do the interview?

Date:

Interviewer:

Name:_____

Social Security #:_____

DAILY WORK RECORD

DATE	# HOURS SPENT		ACTIVITY
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	Morning		
	Afternoon		
	Evening		
	TOTAL HOURS:		

APPROVED:_____

PROCESSED:_____

APPENDIX F

PROCESS CRITERIA

LITERATURE SOURCES FOR PROCESS CRITERIA

	AYERS (Emcro) (1973)	HARE & BARNOON (1973)	BROOK (1973)	DUSTAN (1973)	GIFFORD (1974)
I. DIAGNOSTIC PROCESS:					
A. History					
1. Family history of hypertension	x	x	x	x	x
2. Family history of death or disability from stroke or heart attack	x		x		x
3. History of renal or urinary tract disease	x	x		x	x
4. Duration of hypertension	x		x		x
5. Ingestion of estrogen preparation	x		x	x	x
6. Smoking habits (risk)	x				x
7. History of:					
headache	x	x	x		x
palpitations--tachycardia	x		x	x	x
tremor		x			x
anxiety			x		x
external dyspnea	x	x	x	x	x
orthopnea	x	x	x		x
pedal edema	x	x		x	x
8. Previous antihypertensives	x	x	x	x	x
effectiveness	x	x		x	x
side effects	x	x			x
9. End organ effect					
S&S of CHF	x	x	x	x	x
coronary artery disease	x	x	x	x	x
renal status	x	x	x	x	x
B. Physical Examination					
1. Blood pressure measurement					
both arms	x	x	x		x
supine	x	x	x		x
standing	x	x	x		x
2. Optic fundus	x	x	x	x	x
3. Cardiac pulmonary examination					
hypertrophy	x	x	x	x	x
4. Peripheral arteries					
carotid--subclavian	x	x	x	x	x
aortic	x			x	x
renal	x	x		x	x
femoral--popliteal and pedal	x	x	x	x	x
5. Neurological examination	x	x	x	x	x
6. Abdominal examination (liver-aorta)	x	x		x	x
C. Laboratory and Roentgenographic Exams					
1. Complete blood count	x	x	x		x
2. Routine urinalysis	x	x	x	x	x
3. Serum creatinine or blood urea nitrogen	x	x	x	x	x
4. Uric acid	x	x	x	x	
5. Serum cholesterol and triglycerides		x	x	x	x
6. Chest x-ray (heart)	x	x	x	x	x
7. Electrocardiogram	x	x	x	x	x
8. Blood sugar	x		x	x	x
9. Serum potassium	x	x	x	x	x
10. Serum chloride				x	
11. Serum sodium			x	x	
12. Intravenous pylogram	x	x	x	x	x
13. VMA	x	x	x		x

LITERATURE SOURCES FOR PROCESS CRITERIA--CONTINUED

	AYERS (Emcro) (1973)	HARE & BARNOON (1973)	BROOK (1973)	DUSTAN (1973)	GIFFORD (1974)
II. THERAPEUTIC PROCESS					
A. Medications					
1. Antihypertensive	x	x	x	x	x
vasodilators	x	x	x	x	x
sympathetic inhibiting agents	x	x	x	x	x
diuretics	x	x	x	x	x
2. Sedatives and tranquillizers	x	x			
B. Diet					
1. Lo sodium	x	x	x		
2. Obesity (weight loss)	x	x	x		x
C. Activity					
1. Rest	x		x		
2. Exercise restriction			x		
D. Habit					
1. Tobacco prohibited					x
E. Continuity					
1. Check compliance--keep record	x	x	x		x
2. Patient education	x	x			x
3. Followed up visits					
every two-three weeks until stabilized	x	x	x		x
then every three months	x	x	x		x
4. Activities for follow-up visit					
cardiovascular status	x	x	x		x
renal status	x	x			
blood pressure	x	x	x		x
evaluate side effects of medications	x	x	x		x
adjust medications if need	x	x	x		x
neurological status	x	x	x		x
5. Follow-up diagnostic tests (every three months)					
BUN (or uric acid)	x	x	x	x	x
serum K	x	x	x	x	x
glucose (FBS)	x		x		x
6. Automatic follow-up--for cancels and failure to keep appointments					x
7. Evaluating number of physicians providing care		x			
8. Recording of recommendation	x	x	x		
9. Evaluation changes in signs and symptoms	x	x	x	x	x

SPECIFIC PROCESS CRITERIA USED FOR STRUCTURED DATA COLLECTION GUIDE

I. Screening
   A. Indications for Ambulatory Treatment of Hypertension
      1. Diastolic Blood Pressure--above 95 mm Hg

II. Diagnosis
   A. History
      1. Past History of Hypertension
      2. Family History of Hypertension
      3. Cardiovascular History
         a. CHF
         b. Ischemic Heart Disease
      4. Peripheral Vascular Disease
      5. Renal History
         a. Past History of Renal Disease
         b. History of Present Symptoms
      6. CNS Symptoms
         a. Headaches
         b. Dizzy Spells
         c. Blurred Vision
         d. Cerebrovascular Complications
      7. Cardiovascular Symptoms
         a. Difficulty in Breathing
         b. Chest Pain
      8. History of Previous Medications
      9. Length of Signs and Symptoms
   B. Physical Examination
      1. Blood Pressure
         a. Multiple Pressure Observations
            1) Lying, Sitting, Standing
            2) Both Arms
      2. Weight
      3. Examination of Carotid Pulses and Bruits
      4. Jugular Veins and Renal Artery Bruits
      5. Examination of Ocular Fundus
      6. Examination of the Heart
      7. Examination of the Lungs
      8. Examination of the Abdomen
      9. Examination of Extremities
         a. Pulses
         b. Edema

C. Laboratory and Radiographic Examination
   1. Urinalysis
   2. BUN or Creatinine
   3. Serum Potassium
   4. VMA
   5. Uric Acid
   6. Cholesterol or Triglycerides
   7. Blood Sugar
   8. Intravenous Pylogram
   9. Electrocardiogram

III. Therapeutic Regimen and Management
   A. Explanation of Disease or Regimen
   B. Dietary Restrictions
   C. Physical Restriction (activity and work)
   D. Resources Used
   E. Medications Ordered
   F. Evaluation of Need for Medication Change
   G. Psychosocial Management and Support (fears, anxieties, stresses)
   H. Habit Alteration

IV. Follow-Up and Continuity
   A. Frequency of Visits
      1. Every Two to Three Weeks if Hypertensive Drugs Till Stable
      2. Every Three Months After Stable
   B. Therapeutic Recommendations Documented
   C. Effects of Drug Evaluated
   D. Multiple Blood Pressures
   E. Evaluation Activities (at least for three months)
      1. Cardiovascular, Renal, and Neuro Status
      2. Laboratory Tests to Include BUN, K, FBS
   F. Number of Physicians Seeing Patients
   G. Change in Signs and Symptoms Evaluated

V. Compliance
   A. Adherence to Medical Regimen (drugs)
   B. Adherence to Recommended Diet and Habits
   C. Adherence to Activity Restrictions
   D. Adherence to Follow-Up Recommendations (re-visits and return)

VI. Patient Education
   A. For Drugs and Therapeutic Regimen
   B. Hypertension and Control.

APPENDIX G

PROCESS DATA COLLECTION FORM

Record No._____

Patient Name_____ Age_____

Address_____ Sex_____

Phone No._____

PROBLEM LIST

	Problems	Date of Onset	Follow-Up for Episode					
			One	Two	Three	Four	Five	Six
A								
B								
C								
D								
E								

MEDICATION LIST

	Medication	Date Ordered	Dosage	Frequency	Date Change	Dosage	Frequency
A							
B							
C							
D							
E							
F							

RETURN VISITS ORDERED FOR:	Visit I	Visit II	Visit III	Visit IV	Visit V	Visit VI
One Week						
Two Weeks						
Four Weeks						
Not Specified						

MEDICAL AUDIT PROCESS OF CARE MEASURES

DIAGNOSTIC PROCESS (from record)

I. HISTORY

	Yes	No	Not Mentioned
A. Past History of Hypertension	___	___	___
B. Family History of Hypertension	___	___	___
C. Cardiovascular History			
CHF Ischemic Heart Disease	___	___	___
Peripheral Vascular Disease	___	___	___
D. History of Significant Meds			
Antihypertensive Agents to Include Diuretics, Sedatives, and Tranquilizers But Not Sympathomimetic Agents	___	___	___
Both Antihypertensives and Sympathomimetics	___	___	___
Sympathomimetic Agents But Not Antihypertensives	___	___	___
Other Significant Meds	___	___	___
List:			
E. Renal History			
Past History of Renal Disease	___	___	___
History of Present Symptoms	___	___	___
F. Length of Symptoms	___	___	___

- No Symptoms ___
- 0-3 Days ___
- 3-7 Days ___
- 8-14 Days ___
- 3 Weeks ___
- 4 Weeks ___
- More Than 4 Weeks ___

II. PHYSICAL EXAM (from record)

A. General Appearance ___ Well ___ Acutely ___ Chronic

B. Observations		Contact One	Contact Two	Contact Three
1. BP	Single measurement/contact	___	___	___
BP_____ recording	Multiple measurement/contact	___	___	___
2. BP lying	normal	___	___	___
	elevated	___	___	___
	not recorded	___	___	___
3. BP sitting	normal	___	___	___
	elevated	___	___	___
	not recorded	___	___	___
4. BP standing	normal	___	___	___
	elevated	___	___	___
	not recorded	___	___	___
5. BP Right arm	normal	___	___	___
	elevated	___	___	___
	not recorded	___	___	___
6. Left arm	normal	___	___	___
	elevated	___	___	___
	not recorded	___	___	___
7. Carotid pulses	normal	___	___	___
	abnormal	___	___	___
	not recorded	___	___	___
8. Carotid bruits	present	___	___	___
	absent	___	___	___
	not recorded	___	___	___
9. Renal artery bruits	present	___	___	___
	absent	___	___	___
	not recorded	___	___	___
10. Jugular veins	normal	___	___	___
	reflux filling	___	___	___
	no filling	___	___	___
	not recorded	___	___	___

			Contact One	Contact Two	Contact Three
11.	Ocular fundus	normal	___	___	___
		hypertensive retinopathy	___	___	___
		other abnormalities	___	___	___
		not recorded	___	___	___
12.	Heart	normal	___	___	___
		cardiomegaly	___	___	___
		other abnormalities	___	___	___
		not recorded	___	___	___
13.	Lungs	normal	___	___	___
		abnormal	___	___	___
		not recorded	___	___	___
14.	Abdomen	normal	___	___	___
		abnormal	___	___	___
		not recorded	___	___	___
		bruits--present	___	___	___
		bruits--absent	___	___	___
15.	Extremities	pulses	___	___	___
		edema	___	___	___
		not recorded	___	___	___
C.	Lab Procedure				
1.	Urinalysis	a. ordered	___	___	___
		not ordered	___	___	___
		ordered not done	___	___	___
		b. normal	___	___	___
		proteinuria	___	___	___
		albuminuria	___	___	___
		other abnormalities	___	___	___
2.	BUN or creatinine	a. ordered	___	___	___
		not ordered	___	___	___
		patient not comply	___	___	___
		b. elevated	___	___	___
		borderline	___	___	___
		normal	___	___	___

			Contact One	Contact Two	Contact Three
3.	K+	a. ordered	___	___	___
		not ordered	___	___	___
		patient not comply	___	___	___
		b. normal	___	___	___
		elevated	___	___	___
		low	___	___	___
4.	VMA (Urine 24 hr.) or Catecholamine	a. ordered	___	___	___
		not ordered	___	___	___
		patient not comply	___	___	___
		b. normal	___	___	___
		elevated	___	___	___
5.	Uric acid	a. ordered	___	___	___
		not ordered	___	___	___
		patient not comply	___	___	___
		b. normal	___	___	___
		elevated	___	___	___
6.	Blood sugar	a. ordered	___	___	___
		not ordered	___	___	___
		not done	___	___	___
		b. normal	___	___	___
		elevated	___	___	___
D.	Radiology				
1.	IVP	a. ordered	___	___	___
		not ordered	___	___	___
		not comply	___	___	___
		b. normal	___	___	___
		c. abnormal	___	___	___
2.	Chest x-ray	a. ordered	___	___	___
		not ordered	___	___	___
		patient not comply	___	___	___
		b. normal	___	___	___
		cardiomegaly	___	___	___
		other abnormalities	___	___	___
3.	EKG	a. ordered	___	___	___
		not ordered	___	___	___
		patient not comply	___	___	___
		b. normal	___	___	___
		abnormal	___	___	___

III. PROCESS OF CARE--THERAPEUTIC REGIME AND MANAGEMENT

A. Actual		Contact One	Contact Two	Contact Three
Actual treatment done in office	yes	___	___	___
	no	___	___	___
Actual medication in office	yes	___	___	___
	no	___	___	___
Explanation of disease	yes	___	___	___
	no	___	___	___
B. Recommendations				
1. Diet restriction				
Both low Na and weight reducing started		___	___	___
Weight reducing without low Na started		___	___	___
Low sodium without weight reduction		___	___	___
Not mentioned		___	___	___
Initiated at which contact		___	___	___
2. Physical activity restriction				
Not ordered		___	___	___
Exercise limited only		___	___	___
Bedrest only		___	___	___
Activities of daily living		___	___	___
Work and job restrictions				
Not work		___	___	___
Full (no restrictions)		___	___	___
Part time		___	___	___
Initiated at which contact		___	___	___
3. Resources used				
None used		___	___	___
Physician specialist		___	___	___
Dietitian		___	___	___
Social service		___	___	___
Public health nurse		___	___	___
Other		___	___	___
4. Medications				
None indicated		___	___	___
Initiated at which contact		___	___	___
Type of Meds:				
Antihypertensive agents (to include diuretics, sedatives and tranquilizers)		___	___	___
Other cardiovascular medications exclusive of above (e.g., dig.)		___	___	___
Both antihypertensive and cardiovascular drugs		___	___	___
Other medications only		___	___	___

		Contact One	Contact Two	Contact Three
5.	Personal support by physician to patient			
	None indicated	___	___	___
	Encouraged about condition	___	___	___
	Re-explained condition	___	___	___
	Other evidence (smoking, weight) education	___	___	___
	Express fears and concerns	___	___	___
6.	Alteration of habits (ex., smoking)			
	Recommended	___	___	___
	Not recommended	___	___	___
	Not recorded	___	___	___
7.	Return visit specified (1 week, 2 wks, 4 wks., other) yes	___	___	___
	no	___	___	___
8.	Medication effectiveness evaluated yes	___	___	___
	not mentioned	___	___	___
	changed	___	___	___
9.	Recommendations recorded yes	___	___	___
	none mentioned	___	___	___
10.	Psychosocial management yes	___	___	___
	no evidence	___	___	___
11.	Evidence that compliance evaluated yes	___	___	___
	no evidence	___	___	___

Other data

____ Number of doctors seen in five months.

____ Number of cancelled or broken appointments.

____ History and physical done.

APPENDIX H

OTHER DATA

Table H1

Data Collected from Medical Record--Diagnostic Process

History				
Historical Feature	Total Number of Charts With Comments (%)	Findings According to Documentation		
		Positive (%)	Negative (%)	No Answer (%)
Duration of hypertension	92.2	82.5	9.7	7.8
Family history of hypertension	37.9	26.4	11.5	62.1
History of central nervous system symptoms	62.1	51.5	10.6	37.9
History of cardio-vascular symptoms	65.0	55.3	9.7	35.0
History of genito-urinary symptoms	24.3	17.5	6.8	75.7
History of peripheral vascular symptoms	36.9	28.2	8.7	63.1

Table H2

Data Collected from Medical Record--Diagnostic Process

Physical Examination				
Physical Finding	Total Number of Charts With Comments (%)	Findings According to Documentation		
		Positive (%)	Negative (%)	No Answer (%)
Description of optic fundi	41.8	24.3	17.5	58.2
Description of lung findings	76.7	41.7	35.0	23.3
Description of cardiac findings	97.1	32.1	65.0	2.9
Ankle edema	45.7	24.3	21.4	54.3
Extremity femoral pulse	9.7	6.8	2.9	90.3
Abdominal bruit	12.6	11.6	1.0	87.4
Carotid	9.7	5.8	3.9	90.3

Table H3

Data Collected from Medical Record--Diagnostic Process

Laboratory Studies				
Laboratory Study	Total Number of Charts With Comments (%)	Findings According to Documentation		
		Positive (%)	Negative (%)	No Answer (%)
Urinalysis	97.1	50.5	46.6	2.9
BUN +/or creatinine	53.4	49.5	3.9	46.6
Blood glucose	64.1	52.4	11.7	35.9
Roentgenogram of chest	63.1	32.0	31.1	36.9
Electrocardiogram	53.4	39.8	13.6	46.6
Any test for pheochromocytoma VMA or catecholemene	8.7	6.8	1.9	91.3
Intravenous pyelogram	36.9	30.1	6.8	63.1
Uric acid	46.6	41.7	4.9	53.4

Table H4

Data Collected from Medical Record--Therapeutic Process

Therapeutic Process	Total Number of Charts with Comments (%)	Yes (%)	No (%)
Explanations	27.2	5.8	21.4
Resources used	86.4	13.6	86.4
Medications			
Side effects of medications	80.6	50.5	29.1
Personal support	40.5	40.5	49.5
S & S there but not followed up	82.5	71.8	10.7
Evidence that compliance evaluated	37.9	37.9	62.1
Mention of psychiatric aspects	44.7	44.7	55.3
Obesity control	47.5	29.1	18.4
Low Na diet if on diuretic	94.2	50.5	43.7
Recommended therapy for drug regimen and status	100.0	87.4	12.6
Supplementary drug therapy needed	100.0	26.0	74.0

Table H5

Change in Reported Drug Compliance from Beginning to End of Study[a] (N = 97)[b]

	Level I 0-34%	Level II 35-66%	Level III 67-99%	Row Total
Level I 0-34%	4	2	2	8
Level II 35-66%	6	4	6	16
Level III 67-99%	12	12	49	73
Total	22	18	57	97

[a]Summary of change: Improved, 10; No Change, 57; Worsened, 30.

[b]Six patients--no data.

Table H6

Change in Reported Overall Compliance from Beginning to End of Study[a] (N = 97)[b]

	Level I 0-34%	Level II 35-66%	Level III 67-99%	Row Total
Level I 0-34%	4	4	2	10
Level II 35-66%	5	12	14	31
Level III 67-99%	9	14	33	56
Total	18	30	49	97

[a]Summary of change: Improved, 19; No Change, 50; Worsened, 28.

[b]Six patients--no data.

Table H7

Change in Overall Knowledge From Beginning to End of Study[a] (N = 97)[b]

	Level I 0-48%	Level II 49-73%	Level III 74-99%	Row Total
Level I 0-48%	8	2	1	11
Level II 49-73%	9	52	7	68
Level II 74-99%	1	14	3	18
Total	18	68	11	97

[a]Summary of change: Improved, 10; No Change, 63; Worsened, 24.

[b]Six patients--no data.

Table H8

Change in Knowledge About Drugs from Beginning to End of Study[a] (N = 97)[b]

	Level I 0-48%	Level II 49-73%	Level III 74-99%	Row Data
Level I 0-48%	7	2	2	11
Level II 49-73%	12	17	8	37
Level III 74-99%	10	19	20	49
Total	29	38	30	97

[a]Summary of change: Improved, 12; No Change, 44; Worsened, 41.

[b]Six patients--no follow-up data.

Table H9

Summary Table of Changes in Knowledge and Compliance from Beginning to End of Study (N = 97)

	Improved	Worsened	No Change	Total
Drug knowledge	12	41	44	97
Overall knowledge	10	24	63	97
Drug compliance	10	30	57	97
Overall compliance	19	28	50	97

APPENDIX I

RELIABILITY MEASURES

RELIABILITY MEASURES

Indices used in data collection for process items and outcome parameters of knowledge and perception were analyzed for reliability to evaluate the accuracy and precision of the indices. Computations were carried out and a Pearson product moment correlation coefficient was obtained. Each index of therapeutic process, patient compliance, knowledge and understanding, and perception of health and care was divided into two sets of scores so that the split half technique could be applied. A correlation coefficient was computed for the two sets of scores to determine the internal consistency. Table II presents the results obtained.

Table II

Pearson Product Moment Correlations for Split Half Reliability of Indices (N = 103)

Indices	Correlation
Pre knowledge	.60*
Pre compliance	.72*
Pre perception	.68*
Diagnostic process	.46*
Therapeutic process	.45*
End knowledge	.74*
End compliance	.61*
End perception	.85*

*Significant at .001 level.

As can be seen from the table, the patient components of knowledge and compliance had correlations higher than the physician performance indices. All of the patient components correlated above .60. The provider components of diagnostic process and therapeutic process correlated at .46 and .45, respectively. The correlations can be affected by the range in scores. The comprehensiveness of the scores was low for both diagnostic and therapeutic process components and thus, this homogeneous range may account for the lower reliability coefficients.

To determine the estimated reliability of a full length test of the Process and Outcome Indices the split-half reliability correlations were adjusted. Results of the estimated reliability can be found in Table I2.

Table I2

Estimated Reliability of Full Length Test on Process and Outcome Indices (N = 103)

Indices	Correlation
Pre knowledge	.75*
Pre compliance	.84*
Pre perception	.81*
Diagnostic process	.63*
Therapeutic process	.62*
End knowledge	.85*
End compliance	.76*
End perception	.91*

*Significant at .001 level.

Pearson product moment correlations were conducted between the components of the Medical Status Indices. These correlations are presented in Table I3.

Table I3

Pearson Product Moment Correlations of Medical Status Indices (N = 103)

	Correlation
Post functional status and post severity	.09
Post functional status and systolic blood pressure	.26*
Post functional status and diastolic blood pressure	.24*
Post severity index and systolic blood pressure	.73*
Post severity index and diastolic blood pressure	.68*
Post systolic blood pressure and post diastolic blood pressure	.87*

*Significant at .001 level.

From the above correlations one can see that the medical health status (severity indices) and blood pressure recordings were significantly correlated. Functional status was not correlated with severity index or blood pressure probably due to the lack of variation in functional status scores. The reader will recall, however, that actual patient changes in functional status with the blood pressure recordings and severity index were similar.

BIBLIOGRAPHY

BIBLIOGRAPHY

Aday, LuAnn and Ronald Anderson. *Development of Indices of Access to Medical Care.* Ann Arbor: Health Administration Press, 1975.

Aday, LuAnn and Ronald Anderson. "The Structural Approach to Physician Distribution: A Critical Evaluation." *Health Services Research* 9 (Fall 1974): 195-207.

Akpom, A., S. Katz, and P. Densen. "Methods of Classifying Disability and Severity of Illness in Ambulatory Care Patients." *Medical Care Supplement* 11 (March-April 1973): 125-130.

Ayers, Carlos, A. Slaughter, Harvey Smallwood, Frank Taylor, and R. Wertzman. "Standards for Quality Care of Hypertensive Patients in Office and Hospital Practice." *The American Journal of Cardiology* 32 (September 20, 1973): 533-544.

Beaumont, G., D. Feigal, R. M. Magraw, E. DeFoe, and J. Carey. "Medical Auditing in a Comprehensive Clinic Program." *Journal of Medical Education* 42 (1967): 359-367.

Blackwell, B. "Drug Therapy Patient Compliance." *New England Journal of Medicine* 289 (August 2, 1973): 249-252.

Blankenhorn, M. A. "Standards of Practice of Internal Medicine and Methods of Assessing the Quality of Practice in Hospitals." *Annals of Internal Medicine* 47 (April 1957): 367-374.

Bonnar, John, A. Goldberg, and J. Smith. "Do Pregnant Women Take Their Iron?" *Lancet* 1 (March 1, 1969): 457-458.

Brook, R. H., and R. L. Stevenson. "Effectiveness of Patient Care in an Emergency Room." *New England Journal of Medicine* 283 (1970): 904-907.

Brook, R. H., F. A. Appel, C. Avery, M. Orman, and R. L. Stevenson. "Effectiveness of Inpatient Follow-Up Care." *New England Journal of Medicine* 285 (December 30, 1971): 1509-1514.

Brook, Robert. *Quality of Care Assessment: A Comparison of Five Methods of Peer Review.* Washington, D.C.: U.S. Department of HEW, Public Health Services, Health Resources Administration, Bureau of Health Services Research and Evaluation, July, 1973.

Brook, R. H., and F. A. Appel. "Quality of Care Assessment: Choosing a Method for Peer Review." *New England Journal of Medicine* 288 (November 1973): 1323-1329.

Brook, R. H. "Quality Assurance: The State of the Art." *Hospital Medical Staff* 74 (March 1974): 15-26.

Cayten, C. G. "Directions in Surgical Care Appraisal." *Bulletin of American College of Surgeons* 73 (January 1973): 9-13.

Charney, E., and Eldridge D. Bynum. "How Well Do Patients Take Oral Penicillin? A Collaborative Study in Private Practice." *Pediatrics* 40 (August 1967): 188-195.

Cheitlin, Melvin. "The Physician and Hypertension." *Journal of American Medical Association* 228 (July 3, 1974): 1249-1250.

Clark, T. "The Periodic Health Examination: Evaluation of Routine Tests and Procedures." *Archives of Internal Medicine* 54 (June 1961): 1209-1222.

Clute, K. F. "The Quality of General Practice." In *The General Practitioner*. Toronto: University of Toronto Press, 1963, pp. 262-340.

Codman, E. A. *A Study in Hospital Efficiency: The First Five Years*. Boston: Thomas Todd Company, 1916.

Cohn, Jay. "Hypertension 1974." *Archives of Internal Medicine* 133 (June 1974): 911-913.

Corcoran, A. C., H. Dustan, I. Page, and R. Schnecklothe. "Management of Hypertensive Disease." *American Journal of Medicine* 17 (1954): 383.

Daily, E. F., and M. A. Morehead. "A Method of Evaluating and Improving the Quality of Health Care." *American Journal of Public Health* 46 (1956): 848-854.

Davis, M. S. "Physiologic, Psychological and Demographic Factors in Patient Compliance with Doctor's Orders." *Medical Care* 5 (March-April 1968): 115-122.

_____. "Predicting Non-Compliant Behavior." *Journal of Health and Social Behavior* 8 (December 1967): 265-271.

_____. "Variations in Patients' Compliance with Doctors' Advice: An Empirical Analysis of Patterns of Communication." *American Journal of Public Health* 58 (February 1968): 274-288.

_____. "Variations in Patients' Compliance with Doctor's Orders: Analysis of Congruence Between Survey Responses and Results of Empirical Investigations." *Journal of Medical Education* 41 (November 1966): 1037-1048.

_____ and R. L. Eickhorn. "Compliance with Medical Regimens: A Panel Study." *Journal of Health and Human Behavior* 4 (Winter 1963): 240-249.

Degeyndt, W. "Five Approaches for Assessing the Quality of Care." *Hospital Administration* 15 (Winter 1970): 21-42.

Deniston, O., I. Rosenstock, M. Welch, and V. Getting. "Evaluation of Program Efficiency." *Public Health Reports* 83 (July 1968): 219-239.

Densen, Paul. "Public Accountability and Reporting Systems in Medicare and Other Health Programs." *New England Journal of Medicine* 289 (1973): 401-406.

_____. "The Quality of Medical Care." *Yale Journal of Biology and Medicine* 37 (June 1965): 523-532.

_____. "Some Practical and Conceptual Problems in Appraising the Outcomes of Health Care Services and Programs." Paper presented at Health Services Outcomes Convention, Los Angeles, California, December 1, 1969.

Denton, J. C., A. B. Ford, R. E. Liske, and S. Weiner. "Predicting Judged Quality of Patient Care in General Hospitals." *Health Service Research* 2 (1967): 26-33.

Donabedian, A. "Evaluating the Quality of Medical Care." *Milbank Memorial Fund Quarterly* 44, Part 2 (1966): 166-206.

_____. "Promoting Quality Through Evaluating the Process of Patient Care." *Medical Care* 6 (May-June 1968): 181-202.

Dreyfus, E. G., R. Minson, J. A. Sbarbaro, and D. L. Cowen. "Internal Chart Audits in a Neighborhood Health Program: A Problem-Oriented Approach." *Medical Care* 9 (September-October 1971): 449-454.

Dustan, H., R. Schneckloth, A. Corcoran, and Irvine Page. "The Effectiveness of Long-Term Treatment of Malignant Hypertension." *Circulation* 18 (October 1958): 644-651.

_____. "Clinical Approaches to Hypertension." *Modern Medicine*, November 26, 1973, pp. 34-41.

Edwards, Joseph C. *Management of Hypertensive Disease*. St. Louis: C. V. Mosby Company, 1960.

Eisele C., V. Slee, and L. Hoffman. "Can the Practice of Internal Medicine Be Evaluated? *Annals of Internal Medicine* 44 (1956): 144-161.

Eisele, C. Westley. "The Medical Audit in Continuing Education." *Journal of Medical Education* 44 (April 1969): 263-265.

Elinson, J., H. Freeman, and S. Levine. *Handbook of Medical Sociology*. 2nd. edition. Englewood Cliffs, N.J.: Prentice-Hall, 1972, Chapter 20.

Elinson, J., and R. E. Tressel. "Some Factors Relating to Degree of Correspondence for Diagnostic Information as Obtained by Household Interviews and Clinical Examinations." *American Journal of Public Health* 47 (1957): 310-315.

Elling, Ray, R. Whitmore, and Morris Green. "Patient Participation in a Pediatric Program." *Journal of Health and Human Behavior* 1 (Fall 1960): 183-191.

Ellwood, P. M. "Quantitative Measurement of Patient Care Quality." *Hospitals* 40 (December 1966): 42-63.

Falk, I. E., H. Shonfeld, B. R. Harris, and P. Lavieties. "Development of Standards for Audit and Planning of Medical Care." *American Journal of Public Health* 57 (July 1967): 7.

Fessel, W. J., and E. E. Van Brunt. "Assessing Quality of Care from the Medical Record." *New England Journal of Medicine* 286 (January 1972): 134-138.

Finnerty, F. "New Techniques for Improving Patient Compliance." In *The Hypertension Handbook* . Merck, Sharp and Dohme, 1974.

Fitzpatrick, T. B., D. C. Riedel, and B. C. Payne. *Character and Effectiveness of Hospital Use, Project 2, Hospital and Medical Economics*. Edited by W. J. McNervey. Chicago: Hospital Research and Educational Trust, 1962, pp. 361-592.

Francis, Vida, B. Korsch, and M. Morris. "Gaps in Doctor-Patient Communication; Patients' Response to Medical Advice." *New England Journal of Medicine* 280 (March 6, 1969): 535-540.

Freis, E. D. "The Clinical Spectrum of Essential Hypertension." *Archives of Internal Medicine* 133 (August 1974): 982-987.

Frey, Charles, Richard J. Hinds, Richard W. Dow, and Jeremiah H. Turocotte. "From Emergency Room to Emergency Department: An Evaluation of the Emergency Department." *U. M. Medical Center Journal* 36 (1971): 62-64.

Frohlich, Edward D., C. Emott, J. Hammerstem, M. Linehan, D. Pollack, and A. William Horsely. "Evaluation of the Initial Care of Hypertensive Patients." *Journal of the American Medical Association* 218 (November 15, 1971): 1036-1038.

Gersten, H., and Robert Gray. "Patient Non-Compliance Within the Context of Seeking Medical Care for Arthritis." *Journal of Chronic Disease* 26 (November 1973): 689-698.

Gifford, Ray. "Current Views on Diagnostic Evaluation." In *The Hypertension Handbook.* West Point, Pa.: Merck, Sharpe and Dohme, 1974, pp. 67-79.

_____. "A Practical Guide to Medical Management." (Prepared in cooperation with the National High Blood Pressure Education Program.) In *The Hypertension Handbook.* West Point, Pa.: Merck, Sharpe and Dohme, 1974, pp. 83-111.

Given, C. Functional Status Indices. Unpublished paper, 1973.

Goldberg, G. A. "Medical Care Evaluation Studies." *Journal of the American Medical Association* 220 (April 1972): 372-375.

Goldman, Arthur G., Paul D. Varady, and Stanley S. Franklin. "Body Habitus and Serum Cholesterol in Essential Hypertension and Renovascular Hypertension." *Journal of American Medical Association* 221 (July 24, 1972): 378-383.

Goldsmith, Seth. "A Reevaluation of Health Status Indicators." *Health Services Reports* 88 (December 1973): 937-941.

_____. "The Status of Health Status Indicators." *Health Services Reports* 97 (March 1972): 210-220.

Gonnella, J. S., J. J. Goran, J. W. Williamson, and N. Cotsonas. "Evaluation of Patient Care." *Journal of American Medical Association* 214 (December 14, 1971): 2040-2043.

Goran, Michael J., J. W. Williamson, and J. S. Gonnella. "The Validity of Patient Management Problems." *Journal of Medical Education* (February 1973): 171-179.

Hagner, S., V. LoCicero, and W. Steiger. "Patient Outcomes in a Comprehensive Medicine Clinic." *Medical Care* 6 (March-April 1968): 144-156.

Hare, R. L., and S. Barnoon. *Medical Care Appraisal and Quality Assurance in Office Practice of Internal Medicine.* San Francisco: American Society of Internal Medicine, July 1973.

Health Services Research Study, Institute of Medicine, National Academy of Sciences. "Development of Methodology for Evaluation of Neighborhood Health Centers." U.S. Department of Health, Washington, D.C., February 1972. Contract No. HEW-OS-70-130.

Heinzelman, F. "Factors in Prophylaxis Behavior in Treating Rheumatic Fever, An Exploratory Study." *Journal of Health and Human Behavior* 3 (1962): 73-81.

Helfer, R. E. "Estimating the Quality of Patient Care in a Pediatric Emergency Room." *Journal of Medical Education* 42 (1967): 244-248.

Hernandez, M., and T. P. Hackett. "Problem of Non-Adherence to Therapy in the Management of Duodenal Ulcer Recurrences." *American Journal of Digestive Disease* 7 (December 1962): 1047-1060.

Hulka, B., and J. Cassel. "The AAFP-UNC Study of the Organization, Utilization and Assessment of Primary Medical Care." *American Journal of Public Health* 63 (June 1973): 494-501.

Hulka, B., L. Kupper, and J. Cassel. "Medication Use and Misuse: Physician-Patient Discrepancies." *Journal of Chronic Disease* 28 (1975): 7-21.

Hulka, B., S. Zyzanski, and J. C. Cassel. "Scale for Measurement of Attitudes Toward Physicians and Primary Medical Care." *Medical Care* 8 (1970): 429.

Hulka, Barbara S., Lawrence L. Kupper, and John C. Cassel. "Determinants of Physician Utilization: Approach to a Service-Oriented Classification of Symptoms." *Medical Care* 10 (1972): 300-309.

Hulka, Barbara S., Lawrence L. Kupper, John C. Cassel, and Shirley J. Thompson. "A Method for Measuring Physicians' Awareness of Patients' Concerns." *HSMHA Health Reports* 86 (August 1971): 741-751.

Huntley, R. R., R. Steinhauser, and K. L. White. "The Quality of Medical Care: Techniques and Investigation in the Outpatient Clinic." *Journal of Chronic Disease* 14 (1961): 630-642.

Hyman, Martin D. "Social Psychological Factors Affecting Disability Among Ambulatory Patients." *Journal of Chronic Disease* 28 (1975): 199-216.

Jackson, H., and J. Cooper. "Streptococcal Pharyngitis in Rural Practice: Rational Medical Management." *Journal of the American Medical Association* 197 (1966): 385-388.

Katz, S., A. Ford, and C. Akpom. "Prognosis After Strokes, Part II: Long-Term Course of 147 Patients with Fractures of the Hip." *Surgery, Gynecology and Obstetrics* 124 (1967): 1219-1223.

Katz, S., and B. Jackson. "Studies of Illness in the Aged: The Index of ADL, A Standardized Measure of Biological and Psychological Function." *Journal of the American Medical Association* 185 (September 21, 1963): 914-919.

Katz, S., B. A. Jackson, and M. Jaffee. "Multidisciplinary Studies of Illness in Aged Persons; Comparison Study of Rehabilitated and Non-Rehabilitated Patients with Fractures of Hip." *Journal of Chronic Disease* 15 (1962): 979-984.

Kerr, M., and D. J. Trantow. "Defining, Measuring and Assessing the Quality of Health Services, Perspectives and a Suggested Framework." *Public Health Reports* 84 (May 1969): 415-424.

Kessner, D. M., C. E. Kaik, and J. Singer. "Assessing Health Quality--The Case for Tracers." *New England Journal of Medicine* 288 (January 25, 1973): 189-194.

Koch-Weser, Jan. "Correlation of Pathophysiology and Pharmacotherapy in Primary Hypertension." *American Journal of Cardiology* 32 (1973): 499-510.

Korsch, Barbara M., V. Francis, and M. Morris. "Gaps in Doctor-Patient Communication, I: Doctor-Patient Interaction and Patient Satisfaction." *Pediatrics* 42 (November 1968): 855-871.

Kroeger, H. H., I. Altman, D. A. Clark, A. Johnson, and C. G. Sheps. "The Office Practice of Internists, 1: The Feasibility of Evaluating Quality of Care." *Journal of American Medical Association* 193 (August 2, 1965): 371-376.

Laragh, John H. "Symposium on High Blood Pressure: Mechanism and Management--Introduction." *American Journal of Cardiology* 32 (1973): 497-498.

Lashoff, J., and L. Turner. "Periodic Evaluation of Out Patients." *Archives of Environmental Health* 8 (April 1964): 531-538.

Lebow, Jay. "Consumer Assessments of the Quality of Medical Care." *Medical Care* 12 (April 1974): 328-337.

Lee, J. A. H., S. L. Morrison, and J. N. Morris. "Fatality from Three Common Surgical Conditions in Teaching and Non-Teaching Hospitals." *Lancet* 2 (1957): 785-790.

Lembcke, P. A. "Evaluation of the Medical Audit." *Journal of the American Medical Association* 199 (February 20, 1967): 111-118.

_____. "Measuring the Quality of Medical Care Through Vital Statistics Based on Hospital Service Areas." *American Journal of Public Health* 42 (1952): 276-286.

_____. "Medical Auditing by Scientific Methods." *Journal of the American Medical Association* 162 (1956): 646-655.

Lewis, C. "The State of the Art of Quality Assessment--1973." *Medical Care* 12 (October 1974): 799-806.

Lewis, C., B. Resnik, G. Schmidt, and D. Waxman. "Activities, Events and Outcomes in Ambulatory Patient Care." *New England Journal of Medicine* 280 (1969): 645-649.

Longest, Beaufort. "Relationships Between Coordination, Efficiency and Quality of Care in General Hospitals." *Hospital Administration* 19 (Fall 1974): 65-86.

Maddock, R. K. "Patient Cooperation in Taking Medicines; A Study Involving Isoniazine and Aminosalicylic Acid." *Journal of the American Medical Association* 199 (January 16, 1967): 169-172.

Makover, H. B. "The Quality of Medical Care; Methodology of Survey of the Medical Groups Associated with the Health Insurance Plan of New York." *American Journal of Public Health* 41 (1951): 824-832.

Marston, Mary Vesta. "Compliance with Medical Regimes: A Review of the Literature." *Nursing Research* 19 (July-August 1970): 312-323.

_____. "Compliance with Medical Regimens as a Form of Risk Taking in Patients with Myocardial Infarctions." Ph. D. dissertation, Boston University, 1969.

McKillop, W. "Assessing Quality of Medical Care." *Hospital Administration* 19 (Fall 1974): 20-43.

_____. "Is High-Quality Care Assessable?" *Hospitals*, January 16, 1975, pp. 43-47.

Medalie, J. H., and K. J. Mann. "Evaluation of Medical Care; Methodological Problems in a 6-Year Follow-Up of a Family and Community Health Center." *Journal of Chronic Disease* 19 (1965): 17-33.

Mohler, D. N. "Studies in the Home Treatment of Streptococcal Disease; I. Failure of Patients to Take Penicillin by Mouth as Prescribed." *New England Journal of Medicine* 252 (June 30, 1955): 1116-1118.

Morehead, Mildred A. "Evaluating Quality of Medical Care in the Neighborhood Health Center Program of the Office of Economic Opportunity." *Medical Care* 8 (1970): 118-131.

_____. "The Medical Audit as an Operational Tool." *American Journal of Public Health* 57 (September 1967): 1643-1656.

Morehead, Mildred, Rose Donaldson, and Mary Seravalli. "Comparison Between O.E.O. Neighborhood Health Centers and Other Health Care Center Providers of the Quality of Health Care." Paper presented at Medical Care Section of American Public Health Association, Houston, Texas, 1970.

Muller, C. "Medical Review of Prescribing." *Journal of Chronic Disease* 18 (1965): 689-696.

Payne, B. C. *Hospital Utilization Review Manual.* Ann Arbor: University of Michigan School of Medicine, 1968.

Pender, Nola. "Patient Identification of Health Information Received During Hospitalization." *Nursing Research* 23 (May-June 1974): 262-267.

Peterson, O. L., L. P. Andrews, R. S. Spain, and B. Greenberg. "An Analytical Study of North Carolina General Practice 1953-1954." *Journal of Medical Education* 31, Part 2 (December 1956): 1-165.

Pohl, M. L. "Teaching Activities of the Nursing Practitioner." *Nursing Research* 14 (Winter 1965): 4-11.

Preston, D. "The Tuberculosis Outpatients' Defection from Therapy." *American Journal of Medical Science* 247 (January 1965): 21-25.

Reader, G. G., L. Pratt, and M. C. Mudd. "What Patients Expect from Their Doctors." *Modern Hospital* 89 (1957): 83-94.

Reiss, Mark D., Joseph J. Brookstein, and Kenneth H. Bleifer. "Radiological Aspects of Renovascular Hypertension, Part 4: Arteriographic Complications." *Journal of American Medical Association* 221 (July 24, 1972): 374-378.

Roemer, Milton I. "Evaluation of Health Service Programs and Levels of Measurement." *HSMHA Health Reports* 86 (September 1971): 839-848.

Rosenberg, E. William. "What Kind of Criteria?" *Medical Care* 13 (November 1975): 966-975.

Rosenfeld, L. S. "Quality of Medical Care in Hospitals." *American Journal of Public Health* 47 (July 1957): 856-865.

Roth, H. P., and D. G. Berger. "Patients' Belief About Peptic Ulcer and Its Treatment." *Annals of Internal Medicine* 56 (January 1962): 72-80.

Sanazaro, P. J. "Assessing the Quality of the Delivery of Health Care." Speech given at mid-winter session, Massachusetts Society of Internal Medicine, 1971.

Sanazaro, P. J., R. Goldstein, J. Roberts, D. Maglott, and J. McAllister. "Research and Development in Quality Assurance--The Experimental Medical Care Review Organization Program." *New England Journal of Medicine* 287 (November 30, 1972): 1125-1131.

Sanazaro, P. J., and J. W. Williamson. "End Results of Patient Care: A Provisional Classification Based on Reports by Internists." *Medical Care* 6 (March-April 1968): 123-130.

Schonfeld, H. K. "Standards for the Audit and Planning of Medical Care: A Method for Preparing Audit Standards for Mixtures of Patients." *Medical Care* 8 (1970): 287-298.

Schonfeld, H. K., I. S. Falk, P. H. Lavieties, J. Landwirth, and L. S. Krassner. "The Development of Standards for the Audit and Planning of Medical Care." *American Journal of Public Health* 58 (November 1968): 2097-2110.

Schulberg, H. S., A. Sheldon, and F. Baker (eds.). *Program Evaluation in the Health Fields*. New York: Behavioral Publications, 1969.

Shapiro, S., L. Werner, and P. Densen. "Comparison of Prematurity and Perinatal Mortality." *American Journal of Public Health* 48 (1958): 170-185.

Shapiro, S. "End Result Measurement of Quality of Medical Care." *Milbank Memorial Fund Quarterly* 45, Part 1 (April 1967): 7-30.

Shapiro, S., L. Weiner, H. Jacobziner, and P. Densen. "Further Observations on Prematurity and Perinatal Mortality in a General Population and in a Population of a Prepaid Group Practice, Medical Care Plan." *American Journal of Public Health* 50 (1960): 1304-1317.

Shapiro, S. D., J. J. Williams, A. S. Yerby, P. Densen, and L. Weiner. "Patterns of Medical Use by the Indigent Aged Under Two Systems of Medical Care." *American Journal of Public Health* 57 (May 1967): 784-790.

Sheard, M. H. "Influence of Doctor's Attitude on the Patient's Response to Antidepressant Medication." *Journal of Nervous and Mental Disorders* 136 (June 1963): 555-560.

Sheps, M. C. "Approaches to the Quality of Hospital Care." *Public Health Reports* 70 (September 1955): 877-886.

Sherman, Samuel. "Quality Health Care: What Is It?" Paper presented at the 1968 National Health Forum, Quality in Health Care, Los Angeles, California, March 15-17, 1968.

Shortridge, M. "Quality of Medical Care in an Outpatient Setting." *Medical Care* 12 (April 1974): 283-300.

Simmonds, S. K. "The Educational Care of Patients with Congestive Heart Failure." *Health Educational Journal* 25 (1967): 131-141.

Stapleton, J. F., and J. A. Zwerneman. "The Influence of an Intern-Resident Staff on the Quality of Private Patient Care." *Journal of the American Medical Association* 194 (1965): 877-882.

Starfield, B. "Measurement of Outcome: A Proposed Scheme." *Milbank Memorial Fund Quarterly* 52 (1974): 39-50.

_____. "Health Services Research: A Working Model." *New England Journal of Medicine* 289 (July 19, 1973): 132-136.

_____. "Effectiveness of Pediatric Care on the Relationship Between Process and Outcome." *Pediatrics* 49 (1972): 547-552.

Stewart, R. B., and L. E. Cluff. "A Review of Medication Errors and Compliance in Ambulant Patients." *Clinical Pharmacological Therapy* 13 (Fall 1972): 463-468.

Suchman, E. *Evaluative Research: Principles and Practice in Public Service and Social Action Programs*. New York: Russell Sage Foundation, 1967.

Sullivan, D. "Conceptual Problems in Developing an Index of Health, Vital and Health Statistics." National Center for Health Statistics, Series 2, No. 17, Public Health Service Publication No. 1000, 1966.

_____. "A Single Index of Morality and Morbidity." *HSMHA Health Reports* 86 (April 1971): 347-354.

Tenny, J., K. White, and J. Williamson. "National Ambulatory Medical Care Survey: Background and Methodology." U.S. Department of HEW, Public Health Services, DHEW Pub. No. HRA 74-1335, 1974.

Thompson, J. D., D. B. Marquis, R. L. Woodward, and R. C. Yeomans. "End-Result Measurements of the Quality of Obstetrical Care in Two U.S. Air Force Hospitals." *Medical Care* 6 (March-April 1968): 131-143.

Trussell, R. E., M. P. Morehead, J. Ehrlick, and R. Donalson. *The Quantity, Quality and Costs of Medical and Hospital Care Secured by a Sample of Teamster Families in the New York Area.* New York: Columbia University School of Public Health and Administrative Medicine, 1962.

U.S. Congress. Public Law 92-603, 92nd Congress, Social Security Amendments of 1972. Second Session, House of Representatives, October 30, 1972, pp. 110-117.

Varady, Paul D., and Morton H. Maxwell. "Assessment of Statistically Significant Changes in Diastolic Blood Pressures." *Journal of the American Medical Association* 221 (July 24, 1972): 365-368.

Vincent, Pauline. "Factors Influencing Patient Non-Compliance: A Theoretical Approach." *Nursing Research* 20 (November-December 1971): 509-515.

Watts, M. S. M. "The Price of Quality in Medical Care." *California Medicine* 119 (July 1973): 1205-1210.

Williams, T. F., D. Martin, M. Hagan, J. Watkins, and E. Ellis. "The Clinical Picture of Diabetic Control, Studied in Four Settings." *American Journal of Public Health* 57 (March 1967): 441-451.

Williamson, J. "Evaluating Quality of Patient Care, A Strategy Relating Outcome and Process Assessment." *Journal of the American Medical Association* 218 (October 25, 1971): 564-569.

Williamson, J., M. Alexander, and J. Miller. "Continuing Education and Patient Care Research: Physician Response to Screening Tests Results." *Journal of the American Medical Association* 201 (September 18, 1967): 938-942.

Williamson, J. W., M. Alexander, and G. E. Miller. "Priorities in Patient-Care Research and Continuing Medical Education." *Journal of the American Medical Association* 204 (1968): 303-308.

Williamson, J. W., J. H. Mitchell, and S. D. Kreider. "Assessing Outcomes of Medical Care: A Study of Heart Failure Among Emergency Room Hypertensives." Mimeograph, 1970.

Wood, J., E. Fries, W. Kukendal, and H. Williamson. "Guidelines for Detection, Diagnosis and Management of Hypertensive Populations." *Circulation* 44 (November 1971): 263-272.