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Determinants of Compliance to Ocular Occlusion Therapy Among Pediatric Amblyopia Patients

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DETERMINANTS OF COMPLIANCE TO
OCULAR OCCLUSION THERAPY AMONG
PEDIATRIC AMBLYOPIA PATIENTS

by

Hans Joachim Wolff

A Dissertation Submitted to the Faculty of the Graduate School
of Loyola University of Chicago in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Philosophy

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VITA

Hans Joachim Wolff was born in Bad Waldsee, Germany on April 27, 1951. His elementary education was obtained at Saint Isaac Jogues in Niles, Illinois. His secondary education was completed at Notre Dame High School in Niles, Illinois where he graduated in 1969.

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In 1983, Hans co-authored a paper on measurement in medical education and presented a paper on pediatric compliance at the Midwest Regional Meeting of Orthoptists in May of the same year.

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CHAPTER I

INTRODUCTION

The treatment of medical problems has traditionally been the sole responsibility of medical professionals. It has been generally accepted that the typical role of the physician has been superordinate, authoritative, and active, whereas the role of the patient has been subordinate, respectful, and passive. This model of medical care was sufficient during the era of acute externally caused diseases where intervention, when successful, was quick and decisive. However, the last four decades have experienced an increasing number of patient care problems which are chronic, rather than acute. Chronic illnesses such as cancer, arthritis and hypertension require long-term therapy and behavioral readjustment.

A less prevalent but equally difficult to manage disease is amblyopia in pediatric patients. The treatment of this condition requires patching of the dominant eye and a commitment of both parent and child to the patching regimen. The responsibility for treatment success in this instance is equally shared by the parent, patient, and physician and is largely dependent upon the degree of adherence to the therapy.

BACKGROUND

This new focus on patient responsibility for health care has brought an increasing need to understand why and under what conditions

people take action to prevent, detect, and treat diseases; hence, the emergence of health psychology and behavioral medicine disciplines. The main emphasis of these emerging disciplines is on health behavior. The health behavior which plays a critical role in treatment success is patient compliance. Patient compliance is defined as the degree to which the patient adheres to the treatment regimen prescribed by the physician. Treatment regimens usually involve a variety of therapeutic actions, some of which require the taking of medications while others require more pervasive changes such as diet restrictions, increasing or decreasing of daily activities and alterations in life-style. It is more accurate to view the phenomenon not as a dichotomous, all-or-none occurrence, but as a continuum along which increasing degrees of compliance lie.

The most important problem caused by patient noncompliance is failure to reach the treatment goal. This deprives patients of optimal health and may lead to additional medical problems when noncompliance occurs but is not suspected (e.g., the effectiveness of the treatment is misjudged; inappropriate medications are prescribed; unnecessary tests are ordered; other forms of treatment such as surgery are recommended; and unnecessary hospital admissions are required).

The reported magnitude of noncompliance is alarmingly high. According to Ashburn's review of the literature (1980), in roughly two-thirds of the studies on compliance, 25 to 50 percent of outpatients fail to take their medications properly. Robbins (1980) studied pill taking behavior of hypertensive patients and found

noncompliance to be greater than 50 percent. Compliance rates for pediatric patients in general, range from 7 to 89 percent, with rates of 50 percent or lower found in pediatric clinic settings (Shope, 1981). To date, there have been no studies which have investigated the degree of compliance to ocular occlusion therapy (patching). It is possible, however, that adherence to an eye patching regimen among pediatric patients is as low as that found in other studies due to the amount of behavioral change it entails. While the particular measurement or definition of compliance has varied among investigators, reviewers agree (Blackwell, 1973; Stimson, 1974) that at least one-third of the patients in most studies fail to follow the physician's prescriptions.

Amblyopia

Amblyopia is a functional decrease in visual acuity in an eye not correlated with any structural pathology. It may result from an interference with use of the eye during the critical period when cortical visual connections normally become fixed (Parr, 1976). A more common form of amblyopia, sometimes referred to as suppression amblyopia, occurs secondary to misalignment of the eye (strabismus amblyopia) or a significant difference in refraction between the two eyes (anisometropia amblyopia). Amblyopia does not occur significantly after the age of seven and can be treated only in childhood. If left untreated, it lasts for life, even if the sight in the other eye is lost. The prevalence of this disease in children is about 1-2 percent. The degree of visual defect is largely determined by the age of onset: the younger the child when normal seeing is

interfered with, the more profound will be the loss of vision. The likelihood of recovery of vision with treatment is largely determined by the duration (i.e. the longer the amblyopia has been present, the less effective the treatment will be) (Parr, 1976).

Strabismus is that condition in which the visual axis of one eye (the squinting eye) is not directed to the object being looked at by the other eye (the fixing eye). In other words, this condition is caused by a failure of the two eyes to look at the same object simultaneously. This results in two different images being received by the brain. The infant is able to suppress the images arising from one of the eyes, thereby preventing the poorer of the two images from reaching consciousness. In many children it is always the same eye which is suppressed. The vision of this suppressed eye therefore fails to develop normally or in the case of acquired strabismus, deteriorates in the young child. When a child is hypermetropic (the eye is too short or the refraction is too weak), to see clearly the child must accommodate more than is normally required both for distant and for near vision. As a result of the linkage of convergence with accommodation (for near vision, the two occur together and it is impossible to converge without accommodating, and vice versa), this excess accommodation gives rise to excessive convergence and results in a convergent squint.

To be diagnosed, amblyopia must be specifically looked for, since with normal vision in one eye, the child with amblyopia exhibits normal visual behavior. Several methods of estimating the vision of the small child are reliable enough for screening purposes since it is

not so much the absolute level of visual acuity which is required as it is the comparison of the vision of the two eyes. Referral for formal ophthalmic investigations is indicated if the difference in the levels reached by a pair of eyes is two lines or more on a test chart, or if the vision of either eye is worse than 6/12 for children less than four years of age or worse than 6/9 for children between four and five years.

Treatment for amblyopia is based on the simple idea of forcing the child to use his/her amblyopic eye. The most common method is correction with glasses of any significant refractive errors and total light-tight occlusion (patching) of the normally used eye. The duration of the treatment depends on the age of the child and the depth of the amblyopia. With prompt treatment a few weeks may suffice in infants but in the older child, more than one year may be needed. According to Raab (1982), if there is no improvement after three months of conscientious occlusion, there will probably not be any thereafter.

Statement of the Problem

The generally high rates of noncompliance reported in various studies appear to reflect a lack of understanding of this health care problem. The results of research efforts have generated a multiplicity of findings which can be characterized as unsystematic, often contradictory, and inadequate in providing an explanation of compliance. The various determinants which have been investigated are not generally agreed upon nor have they been organized into a cohesive framework for understanding compliance. This is at least partly due

to the difficulties encountered with measuring a behavior as subjective and elusive as patient compliance and submitting it to "hard" data analysis. Therefore, before the specific problem of patching compliance can be addressed, a systematic analysis of these alleged determinants and techniques for assessing compliance appears warranted.

Once a general framework for the study of compliance is in place, the main problem then becomes one of specifying those variables which exert an influence on adherence to patching regimens. This would then involve the further investigation of two problematic aspects which are critical for a complete understanding of the process and dynamics of patching behavior.

(1) The determinants of adherence to eye patching regimens are not currently known. Therefore an understanding of the phenomena is clearly absent.

(2) A far more complex problem lies in the effects of the relationships among these determinants.

The multitude of factors which function as determinants of patching are not only related to compliance but are almost always correlated with each other as well. It is rare that the study of one independent variable, in isolation from all other influences, will yield conclusive results. This second problem then involves the difficulty in untangling the effects of the alleged correlates on the dependent variable in order to elucidate the interrelationships among the compliance correlates.

In summary, the two problematic aspects of studying adherence to

patching regimens involve the multiplicity and correlation among patching correlates. First, the sheer multitude of possible factors influencing compliance presents a problem of specifying which factors will be included. Second, these same factors are interrelated in seemingly complex ways. These problems need to be systematically addressed if adherence to patching is to be studied in a comprehensive context and as part of an overall dynamic treatment process.

Purpose

The main goal of this investigation is to construct a comprehensive framework for understanding the dynamics involved in determining adherence to an occlusion regimen in amblyopia patients. In order to develop this framework, it will be necessary to systematize the various determinants of patching compliance and to provide an explanation of the variability in patching behavior. Thus, the primary purpose of this study is to identify variables associated with adherence to ocular occlusion (patching) regimens. The inclusion of all theoretically relevant variables is critical for a complete understanding of patching compliance. In the case where a pertinent variable may have been neglected, such as family functioning, the result would be an overestimation of the effects of those variables which are under investigation, thus leading to false conclusions regarding their relationship with the dependent variable, compliance. For this reason, patching compliance will be studied as a multifaceted phenomenon which has both psychosocial and behavioral correlates. The selection of variables for this study will thus be guided by both theoretical considerations and related research findings.

The second purpose is to elucidate the interrelationships among the select determinants and their effect upon adherence to patching. This involves determining the effects of a particular factor on adherence while taking into account the influences of the other factors. The variance uniquely contributed by each variable can then be estimated along with its relationship to other variables. Explanations of variance in patching regimens provide an understanding of behavior, and understanding involves determining the relative and absolute contributions of pertinent factors to the dependent variable, patching. In summary, the two purposes of this study are: (1) adequate specification of the variables associated with patching, and (2) elucidation of the interrelationships among these variables and their effect on compliance with patching.

Method of Statistical Analysis

In this present investigation the independent variables associated with adherence to patching regimens will be assessed by questionnaires administered to parents/guardians of amblyopia patients, physician data, and standardized measures. Due to the complexity of patching compliance and the presumed multiplicity and correlation among variables, multiple regression analysis will be the method of choice. By estimating the magnitude of different sources of influence and by analyzing the interrelationships among the determinants of patching, multiple regression will be utilized to reveal the amount of compliance which is presumably due to the independent variables. Multiple regression will also give some idea of the relative amounts of influence of these variables and will

provide tests of statistical significance of combined influences of these variables and of the separate influence of each independent variable. In summary, multiple regression facilitates, with relative precision, the study of complex interrelationships between independent and dependent variables, and thus helps to "explain" the presumed phenomenon represented by the dependent variable, patching compliance.

Limitations

Although this study has striven to investigate the influences of all pertinent variables, it is realized that other variables which are currently unknown may also contribute to our understanding of patching compliance. Inadequate specification of all relevant factors may result in a specious over-estimation of the effects of those variables which are included.

A second limitation of this study is its reliance upon an accurate assessment of pediatric compliance to the patching regimen. Compliance is an entirely subjective experience and does not lend itself to "hard" data analysis. Compliance is typically determined by the parent and/or patient and occurs in circumstances where it cannot usually be observed directly. In addition, its appraisal depends upon what the parent decides to do and what to report. The paradox is that the quality of the inferences which can be made can be no better than the compliance method employed. This is a critical challenge to all compliance research.

A third limitation is posed by the instability of the measures used to measure the independent variables. The problem exists that chance fluctuations which are independent of the phenomenon, patching,

may erroneously suggest either the absence or presence of an attribute. In this study, the variables which are of ultimate interest and which form the theoretical foundation for this investigation can only be indirectly and imperfectly measured. In assessing psychosocial constructs, this problem is even more acute. The reason for this is that subjects' responses may tend to be distorted to the extent that they can discern and choose the "socially desirable" and/or "appropriate" responses. This could then result in a discrepancy between measured attitudes and subsequent behavior related to that particular attitude, thus questioning the validity of that instrument. A related issue involves the construct validity of the instruments. Although it may be appropriate in some circumstances to assess the validity of the measures solely by their success in predicting patching compliance, the larger issue of why the measure succeeds remains elusive. Knowledge of the true "meaning" of the instruments and the variance they explain will require additional empirical support.

Implications

Hopefully, the identification of pertinent variables, their interrelationships, and their association with patching will contribute to a more complete understanding of this health behavior. With a better grasp of the dynamics involved in patching, the physician will be sensitized to the influences which both facilitate and inhibit its occurrence. With this information, potential noncompliers can be more readily identified a priori, thus alerting eye care specialists to the possibility of treatment failure due to

nonpatching. The ability to predict the occurrence of noncompliance is thus one implication of this study.

More important than mere prediction, however, is the need for explanation. This is best illustrated with an example.

In order for a patching regimen to be effective, the patch must be worn for a specified number of hours. The act of compliance typically begins with the parent. He/she must first remember to use the patch, then apply it correctly, and then supervise the child in wearing it properly, and only remove it after the specified time has elapsed. The typical child will find the patch uncomfortable, refuse to wear it, make numerous attempts to tear it off, modify his/her daily activities around the patch, and contend with insensitive peers and family members.

Successful patching thus entails effective communication between parent and child, family understanding, patience, parents' belief in the efficacy of the treatment, and constant negotiation over patching. A complete explanation of this behavior thus involves the elucidation of the interrelationships among the compliance correlates with a focus on patching as a continuous and multifaceted process. Only after this framework is provided, will health providers have sufficient information and knowledge necessary for developing efficacious interventions and compliance-improving programs.

Summary

The primary responsibility for patient care and treatment success is becoming increasingly shared by both physician and patient. This emphasis on patient involvement has brought a need to understand why and under what conditions patients will comply with treatment regimens. The focus of this investigation is on compliance with ocular occlusion (patching) regimens among pediatric amblyopia patients.

The state of the field in compliance research is muddled at best and does not adequately explain the problem of noncompliance. It is necessary therefore to begin this investigation with an analysis of the alleged determinants of compliance along with an examination of the various techniques for assessing compliance. With this framework in place, the two main aspects of this study can then be addressed. These are: (1) The determinants of compliance to patching regimens are not known, and (2) These determinants are interrelated in complex ways.

In order to develop a comprehensive framework and to begin to address the two previously stated aspects of this study, it will be necessary to focus on two purposes. These are: (1) to specify those variables which are associated with compliance to patching regimens, and (2) to elucidate the interrelationships among these variables and their relationship to patching. In this way patching will be studied as a multifaceted behavior which has both psychosocial and behavioral correlates.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

This chapter is designed to provide a systematic and critical examination of two areas of research literature pertinent to the study at hand (variables which are allegedly associated with compliance and methodological issues related to the measurement of compliance). According to Davidson (1980), there is a limited amount of information available related to patient compliance in ophthalmology. Furthermore, there are no studies to date which have specifically investigated the problem of non-adherence to an ocular occlusion (patching) regimen. However, it is possible that adherence to a patching regimen among pediatric patients is as low as that found in other studies (Davis, 1966; Blackwell, 1973) due to the amount of behavioral change it entails. It is also probable that the very same factors which allegedly help determine compliance in more general studies (Ashburn, 1980; Haynes, 1979) are also influencing adherence to patching. For this reason, variables associated with successful compliance will be discussed within the context of general studies of compliance to provide a framework in which to anchor both theoretical and research-related variables of interest to the present investigation. This literature review will thus form the basis for the selection of those variables which are pertinent to the present

investigation. An adequate specification of these factors would appear to be critical for a complete understanding of this health behavior. The second section focuses on the problem of measurement of compliance behavior. Of course, the quality of this investigation and the validity of the inferences that can be made are limited by the precision of the instrumentation employed to measure compliance.

Determinants of Compliance

The phenomenology of compliance according to Haynes (1979), is riddled with contradictions. A review of the literature will clarify the point that compliance is one of the least understood and most elusive topics in health care. The results of the studies, frequently inconclusive and contradictory, do not adequately explain the problem of noncompliance.

Zisook (1980) has identified variables which contribute to noncompliant behavior and has grouped them under the following categories: features of the disease; features of the treatment regimen; patient-physician interaction factors; and patient characteristics. The majority of factors associated with compliance can be classified under one of these headings. In the case of pediatric compliance, an additional set of factors must be added. Compliance among children is often dependent upon the behavior and attitudes of their "responsible other". This control over the child's health behaviors has been well documented for actions such as obtaining immunizations (Tyroler, 1965), taking medications (Becker, 1974), and dental care (Freeman, 1965). In addition to the influence of the responsible other, features of the entire family of the

pediatric patient have been associated with compliance (Becker, 1972). For these reasons, a category which includes family characteristics and family-patient-child interactions is critical for a complete understanding of patient compliance.

Table 1 summarizes the current research related to the particular variables under study. The right-hand columns indicate both the number of studies cited and their alleged association with the dependent variable, patient compliance. These data do not exhaust the multitude of possible factors but represent a summary of the variables from the majority of the most recent, relevant investigations.

It is important to bear in mind that although each of these determinants may have some relationship to compliance, there are many factors impinging on the compliance outcome which may either negate or enhance the interpretability of this relationship. Shope (1981) states that a breakdown of factors serves at least two purposes. It clearly demonstrates that compliance is not simply determined or explained, and it demarcates some of the components of the compliance process which may serve as targets for compliance-improving strategies.

The first category of variables describes the relationship between patient compliance and the features of the disease. These features can be further subdivided into the following: severity; number of symptoms; degree of disability; and duration of the disease. It is apparent from Table 1 that less than one-half of these investigations found significant correlations. Studies of disease

Table 1

Summary Description of Determinants of Compliance

	<u>Association with Compliance</u>		Zero
	Positive	Negative	
1) Features of the Disease			
a) severity	Murthy (1974) Thawrani (1975)	Bonnar (1969) Brand (1974) Brand (1977) Davis (1968)	Bloch (1977) Carpenter (1976) Charney (1967) Diamond (1968) Hulka (1975) Moon (1976) Nelson (1975)
b) symptoms		Baekeland (1973) Hurtado (1973)	Charney (1967) Heinemann (1976)
c) degree of disability	Donabedian (1964) Heinzelman (1962) Hertroijs (1974)	Baekeland (1973) Spaeth (1970)	
d) duration			Baekeland (1976) Bloch (1977) Haynes (1979)
2) Features of Treatment Regimen			
a) number of medications/ complexity	Moon (1976)	Brand (1977) Francis (1969) Gatley (1968)	

Table 1 (continued)

	<u>Association with Compliance</u>		
	Positive	Negative	Zero
b) degree of behavioral change required		Donabedian (1964)	
c) cost	Cody (1977)	Brand (1977) Davis (1977)	Lima (1976)
d) duration		Bergman (1963) Blackburn (1977) Farley (1975) Haynes (1979) Ludy (1977)	
3) Patient-Clinician Interaction			
a) communication	DiMatteo (1980) Finnerty (1973) Houston (1972) Joyce (1969) Ley (1967) Zisook (1980)		Geersten (1973)
b) patient satisfaction	Becker (1972) Davis (1968) Diamond (1968) Francis (1969) Kincey (1975) Korsch (1968)		
c) patient expectations met	Benfari (1981) Blackwell (1976) Francis (1969)		

Table 1 (continued)

	<u>Association with Compliance</u>		Zero
	Positive	Negative	
4) Patient Characteristics			
a) demographic			
educational level	Ewalt (1972)		Arnhold (1970) Becker (1972) Bloch (1977) Borkman (1976) Madden (1973) Vannecelli (1976)
number of children		Gordis (1969)	
age	Becker (1977) Levav (1976)		Bloch (1977) Carpenter (1976) Madden (1973) Russel (1976)
sex			Arnhold (1970) Barnum (1974)
socio-economic status	Jacobs (1972)		Latiolais (1969) Miller (1977)
b) personality			Caine (1976) Carr (1968) Haynes (1976)

Table 1 (continued)

	<u>Association with Compliance</u>		Zero
	Positive	Negative	
c) locus of control (internal)	Balch (1975) James (1965) MacDonald (1970) Weaver (1972)	Key (1975)	Lowery (1981) Marston (1970)
d) health beliefs	Becker (1972) Becker (1977) Cerkoney (1980) Ley (1979)		Andreoli (1981) Taylor (1979)
5) Family Characteristics			
a) family stability	Elling (1960) Mattar (1974)		Aron (1976) Gordis (1979)
b) family functioning	Alpert (1964) Korsch (1978) Pless (1972)		

severity have for the most part found no correlation with compliance. Six of thirteen studies did find a correlation but were inconsistent in that two studies found a positive correlation while four found a negative correlation. Consistent with the negative correlations, Davis (1968) found that patients with more severe problems were less likely to comply than were patients with less severe disorders. Several explanations for these results were hypothesized by Hingson (1977). First, a more severe disorder may require a more complex treatment regimen. Second, patients with more severe disorders may have more difficulty complying due to limitations imposed by their illness. Third, these same patients may have experienced prior lack of success with previous regimens, thereby making them less confident in the present program.

Most studies investigating the relationship between the severity of the disorder and compliance have not controlled for the difficulty or complexity of the regimen. Thus the literature suggests that the severity of the disorder may not always affect the extent to which patients are compliant, but the reasons for this are unclear. In conclusion, knowing the severity of a particular disease gives us little or no information as to the degree of compliance for that disease. Haynes (1979) agrees that disease factors are relatively unimportant as determinants of patient compliance.

Similarly, not a single study has found that having a greater number of symptoms encourages compliance with the treatment regimen. On the contrary, four investigations found a negative association. This implies that patients who are constantly reminded of their

disease via their symptoms are less likely to comply than those patients with fewer symptoms.

The degree of disability produced by a disease state does appear to influence compliance in a positive direction. The greater the degree of disability produced by the illness, the greater the likelihood that the patient will adhere to the treatment program (Heinzelman, 1962). Two studies (Baekeland, 1973; Spaeth, 1970) showing a negative correlation imply that this association may possibly reverse after the degree of disability reaches a critical level. In other words, once a disease becomes extremely debilitating, the patient may lose faith in the efficacy of the treatment and cease complying.

The duration of the disease does not appear to influence compliance. A review of the literature on dropout rates in alcoholism treatment found that rates of attrition were independent of duration of the drinking (Baekeland, 1976). Haynes (1979), in his review of the literature, states that previous experience with a disease, including its duration and prior hospitalization, are not associated with compliance.

In summary, features of the disease do not appear to be important determinants of patient compliance. The only possible exceptions may be that increased disability may be associated with increased compliance and that increasing symptoms may be accompanied by decreasing compliance. Rather than the disease features per se, the attitudes and beliefs reflecting the patient's perception of his disease are emerging as likely determinants of compliance. These

beliefs are the basis of the Health Belief Model which will be discussed later.

The features of the treatment regimen apparently have a powerful effect on patient compliance. Regimens usually involve a variety of components, some of which require changes in life-style (modifying diets, exercise, activity), whereas others entail the taking of medications. The therapeutic program's degree of complexity relates to noncompliance, in that an inverse relationship exists between the number of directions given and the degree to which patients follow those directions (Francis, 1969). Patients are more likely to take one medication daily than two or three medications each day. Gatley (1968) found a steep decline in compliance as the frequency of dosing increased from once a day to four times a day. Surwit (1983) claims that the treatment demands placed upon patients with insulin-dependent diabetes set the stage for problems with adherence to the prescribed regimens. These findings can be attributed to patient reactions to the regimen including the inability to keep track of multiple medications, lack of confidence with medications which must be taken for a long period of time, and a lack of understanding the necessity to complete the course of treatment even though the symptoms have abated.

Another variable related to compliance is the degree of behavioral change required by the therapy (Donabedian, 1964). Patients who must change life-long habits such as smoking or drinking are more unlikely to comply than patients who are required to make less drastic changes. Typically, attitude change precedes behavioral

change and therefore, patients whose attitudes are less than optimal toward the medical regimen are even less likely to change behaviors.

The influence of the cost of treatment on compliance is not well documented. Two studies (Brand, 1977; Davis, 1977) imply that cost is an important issue for at least some patients.

A final variable, duration of the treatment regimen, is directly related to compliance (Bergman, 1963). The longer a patient is required to participate in a therapeutic program, the less likely he/she is to adhere to that program. Haynes (1979) found that 12 of 15 compliance studies report a similar inverse relationship. In summary, the characteristics of the treatment regimen appear to be inversely related to adherence with the treatment regimen. As the duration, complexity, and amount of behavioral change required increases, the degree to which the patient complies decreases.

The therapeutic relationship can contribute significantly to the process of behavioral change. A positive interaction between the patient and physician facilitates behavioral change by promoting a communication of understanding and caring for the purpose of increasing client self-understanding and motivation. According to Korsch (1972), the common neglect of these psychological factors by doctors may account in part for the flourishing of quacks and faith healers whose main attraction for sick people is their skill in furnishing emotional support. More than one-half of a physician's working time is spent on problems involving primarily psychological factors, and hence the need for interpersonal skills rather than for technical knowledge. Consequently, the investigation of factors

associated with a positive patient-physician relationship is critical for the improvement of the delivery of health care.

The quality of this relationship also plays an important role in influencing patient compliance. Physicians in the past have attributed noncompliance to the patient's uncooperative personality (Davis, 1966) and inability to understand their instructions (Ley, 1967), and have therefore laid the blame for noncompliance on the patient's doorstep. Increasingly however, there is a trend toward relationships which assume that the patient is a more equal partner in determining his plan of care. According to Hingson (1977), in the medical setting, under the pressure of illness, one cannot expect all patients to behave in a fully rational manner. For realistic progress to be made, initiatives to identify and resolve those problems in the patient-physician relationship which might affect compliance clearly are the responsibility of professional medical personnel, not patients. A more moderate view and one which is more widely accepted is advanced by Zola (1977). He states that the issue of compliance is the responsibility of the physician as well as the patient and advocates an equal sharing of responsibility for compliance.

Although all of the elements of a "good" patient-physician relationship have not yet been fully defined, several main components do emerge. These include the quality of the communication (Finnerty, 1973), patient satisfaction (Alpert, 1964), and the meeting of the patient's expectations regarding the clinic visit (Caine, 1976). General studies in educational psychology indicate the important role played by the transmitter of information in influencing subjects'

attitudes and behaviors. According to DiMatteo (1980), effective communication about illness and treatment contributes to the patients' feelings of being cared for and enhances their perception of the health care.

Zola (1977) speculates that there are certain structural barriers in the treatment situation which specifically impede communication. First, the patient-physician encounter is perhaps the most anxiety-laden of all lay-expert encounters. Delay of the visit is usually the norm. While some anxiety has been found to be conducive to learning (Hilgard, 1975), the amount present at the typical clinic visit is surely in excess.

Second, there is a problem of data overload. In contrast to most teaching situations, the patient is not typically given instructional aids and techniques to help with comprehension and memory. Ley and Spelman (1967) reported on three groups of medical outpatients and found that within 10 to 80 minutes of seeing the physician, the outpatients could not recall 39 percent of what they were told. Similar findings were presented by Joyce et al. (1969) who investigated two series of patients attending a rheumatology clinic and found that 52 percent of all information was forgotten. In addition, Houston and Pasanen (1972) found that the patients' subjective perception of the amount of information provided rather than the actual amount was predictive of compliance and satisfaction. These studies point to the importance of both objective and subjective factors in determining adherence.

Third, there is the manner of communication. This is the

situation in which the physician attempts to distill in several minutes the knowledge and experience accumulated in decades. When this communication is so faulty that the patient never learns, understands or remembers the regimen, compliance is highly unlikely (Zisook, 1980).

Fourth, there appears to be a clash between what patients want to know and what physicians believe they should know. Most patients want to know as much as possible about their illness even if the illness is likely to be fatal (Ley and Spelman, 1967). It is common however for doctors to believe that patients should not be told that they are dying (Fletcher, 1973). Therefore, in addition to anxiety, data overload, and manner, communication is further hampered by physicians' beliefs regarding what the content of their message should include.

It is apparent from the research that patients are selective as to what they attend to during the clinic visit. This includes the information they receive from the physician along with communications from other health professionals. It also appears that physicians, in at least some circumstances, are selective as to what they choose to communicate to the patient. It is understandable then that patients tend to deviate from treatment regimens.

The second component which appears to be critical to the patient-physician relationship is patient satisfaction. Francis (1969) found that mothers who were dissatisfied with the doctor's friendliness, his ability to understand their concerns, and his desire to carry out conversation with them were highly unlikely to comply

with the physician's orders. Mothers were more likely to give their children a prescribed medication not on the basis of time spent with the physician or on their perceptions of his competence but rather based on the mother's feeling that the doctor had praised her as a mother and had established friendly and easy communication with her. Mothers who reported high satisfaction were "highly" compliant 53 percent of the time while mothers who reported "low" satisfaction were "highly" compliant only 17 percent of the time. This finding is similar to that in Davis' (1968) study which found a similar relationship between noncompliance and malintegrative behavior (poor rapport). In other words, the more the interaction is characterized by poor rapport, the less likely it is that the patient will follow the physician's advice.

A finding which adds significance to these studies is the high incidence of dissatisfaction with medical care. In a study by Korsch (1968), based on investigations of 800 consultations at a walk-in emergency clinic at Children's Hospital of Los Angeles, the researcher found that 40 percent of the patients were assessed as highly satisfied with their visit, 36 percent as moderately satisfied, 11 percent as moderately dissatisfied, and 13 percent as very dissatisfied. In a more recent study, Kinsey et al. (1975) found a positive relationship between satisfaction and compliance among a sample of mothers of children seen by a pediatrician. It is apparent from these studies that the strong association between satisfaction and compliance becomes even more important in light of the high incidence of dissatisfaction with medical care.

A third important determinant of compliance is reported to be whether or not the patient's expectations regarding the clinic visit were met. According to social psychology, people who bring noncomplementary expectations to the interpersonal encounter are likely to experience conflict (Turner, 1978). This conflict can result in dissatisfaction, unhappiness, and failure to take action. The patient-physician relationship plays a critical role in preparing the patient for action, i.e., adherence to the treatment. Patients tend to have preconceived ideas and expectations regarding their clinic visit. If these expectations are disparate with what actually occurs, cognitive dissonance could occur and subsequent compliance would be less likely. Goldstein (1962) posits that the generating of positive expectations for success is an important motivator for behavioral change.

Benfari (1981) states that the presentation of "preparatory structures" has important implications for increasing patient compliance. Blackwell (1976) found that patients whose expectations had been met were more likely to adhere to the treatment program. Similarly, Francis (1969) reported that mothers who expected to learn the diagnosis and cause of their child's illness and did not, were less likely to comply with advice than were those who had their expectations fulfilled. These studies demonstrate that an accurate perception of what will take place during the visit and after therapy can facilitate the course of treatment. When pediatric patients are involved, it is the expectations of the parent or guardian which are critical in determining the degree of compliance of the child. In

summary, the effectiveness of the patient-physician communication, the satisfaction of the patient with this interaction, and the meeting of the patient's expectations regarding the clinic visit are allegedly associated with patient compliance with the treatment regimen.

Patient characteristics have also been investigated as correlates of compliance. At this point however, there are many theories but little agreement on how personal characteristics interact with the intervention environment to affect adherence to the therapeutic program. According to Haynes (1979), socio-demographic factors such as age, sex, race, religion, and socio-economic factors do not appear to have any effect on compliance. Matthews and Hingson (1977) have similarly observed that studies which report no relationship between demographic variables and compliance outnumber those which do by nearly three to one. The credibility of these studies is enhanced by the fact that this lack of relationship between these variables and compliance has been studied for a variety of illnesses, in a variety of settings, and with a variety of compliance measures.

Despite this impressive evidence negating the importance of demographic factors, a substantial number of studies do exist which indicate a fairly strong association between select factors and compliance. Ewalt (1972) found that the educational level of the mother was positively correlated with her child's adherence to a medical regimen. Another variable, number of children, was reported by Gordis (1969) to be negatively associated with compliance of children to long-term antistreptococcal prophylaxis. This finding

suggests that in families with many children the mothers may be too overwhelmed with responsibility for the children to pay particular attention to one child. Finally, although the age of adult patients is not predictive of compliance, Becker (1977) found that the age of the pediatric patient was significantly associated with adherence to a diet program. Older children were more likely to adhere to a weight loss regimen than were younger children. This however, may be due more to the types of pressures that older children typically encounter rather than to age itself (e.g., peer pressure and greater awareness of their body image). This lack of agreement among researchers regarding the influence of demographic factors points to a need for clarification and a systematic analysis of their association with patient compliance.

Few studies have investigated the role of personality factors in influencing compliance. According to Haynes (1976), there is no personality profile of the noncompliant patient. Similarly, other studies (Carr, 1968; Caine, 1976) have also found no association. In general, there is little or no evidence supporting the further investigation of personality factors as determinants of patient compliance.

A psychological construct which appears to offer considerable promise as a determinant of patient compliance is locus of control. The concept of health locus of control has its origins in social learning theory (Rotter, 1966). This theory posits that "the potential for a behavior to occur in any specific psychological situation is a function of the expectancy that the behavior will lead

to a particular reinforcement in that situation and the value of that reinforcement" (Rotter, 1975, p. 57). Individuals who tend to expect reinforcement to come from their own behavior have been defined as "internals", while individuals who tend to expect reinforcement or outcomes to relate to forces outside themselves (e.g., luck, fate) have been defined as "externals" (Lewis, 1978). The construct of locus of control represents points along a continuum of internality and externality rather than a dichotomy.

In its original form locus of control was designed as a global measure of reinforcement expectancy and not as a specific measure of health related behavior. According to Wallston (1976), knowledge of locus of control expectancies should theoretically contribute to the prediction of health behavior. This has been shown to be the case in numerous studies. The utility of locus of control beliefs has contributed to our understanding of smoking reduction (James, 1965), birth control use (MacDonald, 1970), and health information seeking (Toner, 1979). Balch and Ross (1975) reported that internal beliefs were predictive of adherence to an overweight reduction program. Similarly, Weaver (1972) found that internal locus patients with severe kidney disorders who were using dialysis machines to stay alive were significantly more likely to comply with diet restrictions than were their matched externals. These studies point toward the utility of locus of control assessments as determinants of patient compliance to treatment regimens.

Although these studies hold promise for future research, other investigations have been reported which show contradictory results.

Lowery (1981) reports that in many studies, locus of control has failed to predict the dependent variable. Marston (1970) for example found no relationship between locus of control and compliance among myocardial infarction patients, and Key (1975) found greater compliance among externals in a study of predominantly black, female, working class hypertension patients. From both a theoretical and an empirical perspective, locus of control beliefs are not straight forward predictors of health behaviors. There appear to be limitations to their predictive power, some of which may be due to methodological considerations. According to Wallston (1976), a misunderstanding of the interactive nature of locus of control with other constructs, such as perceived values of outcomes, has caused many investigators to adopt relatively unsophisticated approaches to method and analysis. This fact may help to account for the lack of a clear understanding of the relationship between locus and compliance. In general however, there appears to be sufficient evidence to warrant the further investigation of the locus of control construct as an aid to our understanding of compliance.

A related construct, health beliefs, provides a general theoretical framework for explaining the likelihood of an individual adhering to a recommended health care plan and is represented by the Health Belief Model (HBM) (Maiman and Becker, 1974). This theory is based on the decision-making concepts of valence and subjective probability. The theory purports that whether or not an individual will comply with a recommended treatment regimen is dependent upon that individual's perceptions of: (1) level of personal

susceptibility to the particular illness; (2) the degree of severity of the consequences which might result from contracting the condition; (3) the health action's potential benefits or efficacy in preventing or reducing susceptibility and/or severity; and (4) physical, psychological, financial, and other barriers or costs related to continuing or initiating the advocated behavior (Becker, 1977). The HBM also stipulates that a "cue to action" must trigger the appropriate behavior by making the individual aware of his feelings about the health threat. These cues include internal (perception of symptoms) and external (mass media) reminders or indicators of health. The Health Belief Model is based on the individual's subjective perception rather than on the actuality of the disease. In other words, the patient's belief regarding the severity of the disease is the focus rather than the actual clinical severity.

The pertinence of health beliefs to this study is reflected by their association with patient compliance. Cerkoney (1980) found a correlation of .5 between diabetic patients' overall compliance levels and a composite of their level of health belief motivation. This indicates that health beliefs accounted for 25% of the variation in the compliance group. Ley (1979) reviewed recent studies on health beliefs and found that over one-half of these investigations reported a positive relationship with compliance.

Becker and Maiman (1975) have since revised this model for pediatric compliance. For most children, according to Becker (1975), the relevant health beliefs of the "responsible other" are often the primary determinants of the degree to which the child adheres to the

treatment plan. Mechanic (1964) supports this idea through his findings that the child's attention to symptoms is related to the mother's interest in health matters. Litman (1974) has shown that the mother's influence was the primary determinant of the child's food habits and attitudes. Becker (1972) studied children with otitis media and found the following mother characteristics to be predictive of the child's compliance: mother was concerned about the child's health and present illness; illness was considered to be a substantial threat to the child; mother had a satisfactory experience at the clinic; mother was better able to manage life's problems; and the mother engaged in preventive health behaviors. In a related study, Becker (1977) found that the mother's perception of how easily her child gets sick (index of susceptibility) was found to be highly correlated ($.504, p < .01$) with both weight loss and appointment keeping. The overall score for general "perceived severity of the disease" was also a good predictor of weight loss ($.525, p < .01$) (Becker, 1977). This study indicates that significant predictions about weight loss can be made just by knowing about the mother's perceived severity of the child's illness and her beliefs regarding the child's susceptibility to the illness. Also, the mother's belief in the efficacy of the treatment, although not significant in this study, was correlated highly enough to also deserve additional attention.

Not all studies, however, support the utility of health beliefs as determinants of compliance. Andreoli (1981) concluded that in male hypertensive patients, health beliefs are not different in those who

comply with prescribed therapy than in those who do not comply. Taylor (1979) found that health beliefs related to hypertension and its treatment that were assessed before the initiation of drug treatment did not predict compliance six and twelve months later. However, health beliefs expressed six months after the initiation of treatment were consistent with compliance measured at the same point in time and also predictive of compliance at twelve months. It appears from these data that health beliefs develop along with compliance behavior rather than preceding or determining it. This suggests that health beliefs may become congruent with actual compliance as well as the reverse of this. Despite these limitations, the majority of investigations point to a need to focus on parents' perceptions of health when attempting to assess the likelihood of noncompliance among children.

The final set of factors which appear to be particularly pertinent to pediatric patients are family characteristics. The bulk of the literature emphasizing the importance of the family in illness has concentrated upon either the way in which illness may be an outcome of certain aspects of family life (e.g., childrearing patterns; parental attitudes; mother-child relationships) or on the effects of a member's illness on the family (Vincent, 1963). A growing body of evidence, however, suggests an important role for the family in enhancing pediatric compliance (Donabedian, 1964; Oakes, 1970).

Most studies describing family characteristics have dealt with structural aspects of the family unit. These have traditionally

included: the marital status of the parents; family size; working mothers; and family member involvements with the police. Mattar (1974) found that patients with stable families evidenced better compliance than those from unstable families. Korsch (1978), in her study of noncompliance in children with renal transplants, found that noncompliant patient families had more fatherless households than compliant families. Similarly, Elling, Whittemore, and Green (1960) reported a relationship between poor participation in a rheumatic fever prevention program and family situations reflecting stresses such as marital separation, conflicts involving the police, and recent changes in residences.

Although these studies emphasize the importance of stability as a determinant of compliance, other investigations have not found similar relationships. Gordis (1969) for example studied compliance with physicians' instructions to children on oral penicillin prophylaxis and found no significant relationship between noncompliance and either one- or two-parent households. Gordis also grouped four subjective items into a scale of family tension and instability and again found no relationship. More recently, Aron (1976) reported no relationship between dropping out of a drug treatment program and family stability.

A reason for these seemingly contradictory findings has been proposed by Wingert (1968). He speculates that in many families which outwardly appear to be unstable, there exist hidden sources of stability which enable parents to adequately manage their children's health problems. This would help account for the lack of association between family stability measures and pediatric noncompliance. The

relationship between family characteristics and pediatric compliance may be more fruitfully studied within a dynamic, interaction framework.

There are three main reasons according to Becker (1975), for approaching the study of compliance within a framework of family interactions. First, groups such as children and the aged depend upon other family members assuming responsibility for their adherence to the treatment regimen. Mattar and Yaffee (1974) have emphasized that parents play a vital role in determining the extent to which their children comply with therapeutic regimens. Second, the separate roles found within the family unit have important consequences for health care. For example, the mother, through her role as food provider, has the most impact upon diet restrictions of the child. Third, the family's influence upon compliance may take the form of pressure to adhere, intersperse concordance on the necessity for health action, and attitudes of family members. Mabry (1964) suggests that attitudes and behavior patterns in the family may sometimes interfere with compliance, especially in cases where members do not understand the treatment requirements. It appears then that the family serves as an intervening variable in these situations and may therefore be best conceptualized as a dynamic, functioning unit.

Family functioning can be defined to represent the dynamics of everyday life; the way in which the family operates as a unit across multiple dimensions (Pless, 1972). Its intended use, to assess the strength of relationships and life-style taken as a whole, focusses on intrafamily communications, cohesiveness, and the dynamics of family

interactions. Alpert (1964) reports that pediatric clinic appointments were most often broken by patients from poorly functioning and disorganized families. Children from families which emphasized togetherness and family activity tended to keep their scheduled appointments. Korsch, Fine, and Negrete (1978) found that renal transplant patients who were noncompliant tended to come from families with poor communication, i.e., interactions between family members were characterized as lacking empathy and utilizing double messages and other nonfacilitative communications. Families which experience difficulty communicating are also unlikely to offer supportive comments regarding the disease and treatment regimen. Although the construct of family functioning is imprecise and not well documented in compliance research, it offers a means by which to investigate the compliance process as it occurs or fails to occur in the family unit.

The present review related to determinants of compliance has focused on the total process through which patient compliance to therapeutic regimens may or may not occur. The major components of this process reportedly include the particular disease which the patient is experiencing, the treatment prescribed by the physician, the patient-physician interaction, and patient and family characteristics. According to Shope (1981), these components do not necessarily occur in sequence, nor do they function independently of each other. They do however point to a need to study the phenomenon of compliance in a comprehensive framework, as part of a dynamic and complex process involving to some extent, all of these components.

Measures of Compliance

There are critical challenges in research related to compliance measurement. According to Gordis (1979), there has thus far been too little interest in methodology and perhaps too much emphasis on premature applications. Enlund (1982) states that the absence of a definitive framework for studying compliance is at least partly due to the inadequacies of the designs and methods of the studies. It therefore seems appropriate that a major focus of the present study should be on the methodological aspects of measuring compliance. For this reason, a review of the literature on methods appears warranted and is presented in what follows.

Table 2 summarizes specific methods available for measuring patient compliance along with their respective advantages and disadvantages. The first set of methods presented in Table 2 are the direct measures (Gordis, 1979). These methods involve the measuring of medication in blood and urine levels. Although they are generally accurate and amenable to quantification, they are not without disadvantages. There are questions regarding the sensitivity of the detection instrument along with its specificity as a method of detection. There also exist pharmacokinetic variations which reflect individual differences in rates of absorption, distribution, metabolism, and excretion of drugs. Lindenbaum (1971) showed marked variations in the biologic availability of digoxin from four preparations. Brodie (1952) reported significant interindividual variations in how bisacouacetate was metabolized by eight normal subjects after a single intravenous dose of 20 mg/kg. The form in

Table 2

A Summary Description of Measures of Compliance

	<u>Advantages</u>	<u>Disadvantages</u>
1) Direct Methods		
a) blood and urine levels	accuracy, amenability to quantification	questionable sensitivity, pharmacokinetic variation
b) observation	objectivity	impracticality
2) Indirect Methods		
a) therapeutic outcome	useful when directed towards those who fail to reach therapeutic goal	lack of direct relationship between outcome and treatment
b) patient interview	practicality	inaccuracy of interview data
c) pill count	moderate validity, objectivity	overestimation of compliance
d) physician assessment		lack of relationship between physician estimate and compliance
e) appointment keeping	easily recorded	based on single event
f) filling of prescriptions	controls effects of physician/researcher	little value for short-term therapy
g) medication monitor	accuracy	cost, impractical for most clinics
h) metabolic consequences		pharmacokinetic variations

which the drug is administered, whether in capsule or tablet, will also have a major effect on its absorption. These findings clearly show that any study of compliance using these methods must take into account a number of characteristics related to pharmacokinetic variations among patients and also other variables related to the drug itself.

An additional method which can be classified as direct is observation. This method has been employed for diabetic self-care (Malone, 1976), stroke rehabilitation (Diamond, 1968), and seat belt use (Robertson, 1975). Although this method has value as a direct, objective technique, it is more practical for inpatients than for outpatients due to the problem of obtaining observations over extended periods of time. For this reason, direct observation of patient compliance has not been used extensively and therefore is not well documented in the research literature.

The second class of measures are the indirect methods. The first of these is therapeutic outcome. At face value this would seem to be a reasonable technique. Several studies document a relationship between therapeutic effectiveness and noncompliance. Markowitz (1970) found that patients complying less than one-third of the time had a higher risk of streptococcal infection than did the remaining full-complying patients. Kutt (1966) found that in twelve of sixteen patients with epilepsy who were not responding to diphenylhydantoin, noncompliance was a significant problem; when the medication was administered to them under rigidly monitored conditions, adequate blood levels of the drug were achieved and a good therapeutic response

resulted.

The main problem of using outcome as a measure of compliance is that there rarely exists a simple, direct relationship between therapy and outcome. Gordis (1979) states that not all components of effective medical care are mediated through compliance. Patients on antihypertensive medication may also receive support from the physician and family, resulting in stress reduction and a decrease in blood pressure. Thus, the outcome may be due to the external conditions as well as to the therapy. The multitude of existing environmental factors, psychological variables, and psychosocial influences makes it difficult to screen out the unique effects of treatment adherence. Thus, the relationship between compliance and outcome becomes increasingly blurry and complex. Given this perspective, it becomes apparent that outcome is a result of a complex set of interactions in which compliance is only one of many factors relating to improved health. Viewed within this framework, differences in outcome, in general, are of limited value as measures of compliance.

The fourth method for measuring patient compliance is the patient interview. The obvious question is whether or not patients give valid estimates of their adherence to the therapeutic regimen. Feinstein (1959) compared compliance rates in children on penicillin prophylaxis by interview and pill count. Although there was good agreement between the two methods among those classified as poor compliers, there was a considerable discrepancy among those classified as good compliers. Other studies comparing interview data and objective data

on medication compliance indicate that underreporting of noncompliance is pervasive (Bergman, 1963; Hecht, 1974). Even when the interviewer is not a member of the staff, thus making the patient feel less threatened, underreporting of noncompliance was the norm. Of 73 patients interviewed, only four percent reported missed doses, whereas monitor records showed that 33 percent of the patients missed doses (Norell, 1981).

Research also shows that parents, when interviewed regarding their children's compliance, give poor estimates of compliance. Bergman and Werner (1963) reported on the failure of children to receive penicillin by mouth. Children were to be treated by oral penicillin for ten days and tested with urine assays for penicillin and pill counts. Therapy compliance results showed that only 44 percent of the children were receiving penicillin on the third day, 29 percent on the sixth day, and 18 percent on the ninth day. Despite these alarming facts, 83 percent of the parents stated that all medications were given. It is apparent from these results that both patient and parent reports of compliance tend to be grossly overestimated.

The pill count has frequently been used as a measure of compliance. Pill count is measured by comparing the amount of medication remaining in the patient's dispenser with the amount that should have remained if he had adhered to the prescription. According to Enlund (1982), the pill count method usually involves asking the patient to bring their leftover drugs with them to the next appointment, or making unannounced visits to the homes of the

patients. He states that this procedure may be feasible in a 10-day antibiotic trial, but is not realistically possible for most regimens. This method is also affected by those who forget to take their medication with them to the clinic visit and by the possibility that other family members may also be taking the same medication.

Bergman and Werner (1963) presented data on both urine tests and pill counts in their study of children on ten-day penicillin therapy for streptococcal pharyngitis. They found that by the ninth day of the treatment plan, on the basis of urine tests, only eight percent of the population were taking penicillin, whereas on the basis of pill count, 18 percent would have been considered compliant. This finding suggests that pill counts may overestimate compliance thereby raising doubts regarding its validity as an adequate measure of compliance.

Physician estimates of patient compliance have been investigated by Caron and Roth (1968). Their study showed that physicians could not estimate patient compliance any better than they might have by chance alone. Mushlin and Appel (1977) reported that residents' predictions of which patients returned for follow-up appointments were accurate for only 14 of the 40 patients who failed to return after an initial appointment. Although physician estimates of compliance have not been extensively investigated, the available data do not support its use as a reliable measure of patient compliance.

Appointment keeping as a measure of compliance has value as a practical method. A patient is considered in compliance when he/she shows up for the scheduled appointment. According to Sackett (1979) this is the most common form of noncompliance. A patient who does not

attend is lost to the system without even getting in the door. This method requires the researcher to establish a prior criteria for classifying patients who cancel and reschedule and those who cannot attend for appropriate reasons. For example, would a patient be considered in noncompliance if he breaks his appointment due to illness or death in his family? An additional disadvantage is that appointment keeping is based on a single event and does not take into account the degree of compliance, i.e., appointment keeping treats compliance as a discrete, dichotomous variable.

A promising approach to compliance measurement is the evaluation of prescription filling patterns (Enlund, 1982). The patient is usually not aware that his compliance is being assessed. This enhances the validity of the measure by controlling for the effects of the physician and/or researcher on the compliance reporting of the patient. An additional advantage is that the pharmacist can project when patients should refill their prescriptions, thus giving him a readily accessible, noninvasive method for estimating compliance. Solomon (1974) reported that the incidence of potential therapeutic problems which pharmacists detected by using prescription refilling patterns was 5.8%, compared to a rate of only 0.1% detected without this information.

This method however is not without its disadvantages. First, it has limited value for measuring compliance with single-prescription or short-term therapy (McKenney, 1979). Second, it assumes that all medications which are dispensed are consumed by the patient. Third, the process of collating the prescription-filling data can be very

laborious and is more feasible in countries where prescription information is stored centrally, using either manual or EDP-systems (Enlund, 1982).

The most accurate method for measuring compliance, although it is also the most expensive and least practical for most clinics, is the medication monitor described by Yee (1974). The daily use of the monitor is recorded by an electronic memory system, provided that the patient replaces the medication bottle into a plastic container each time it is used. The monitor records the date and hour each time that the bottle is opened. The capacity of the monitor is limited to three weeks and therefore the intervals between clinic visits will be shorter than usual for most patients (Norell, 1981). The medication monitor is useful mainly for research purposes on a relatively small scale. Its value lies in its utility as a validating instrument for other more practical methods.

The final method reviewed here pertains to the metabolic consequences associated with compliance. This measure is based upon the absence of pharmacologic effects or side-effects. Some regimens produce clear-cut pharmacologic effects, the absence of which suggests low compliance (e.g., urinary frequency with diuretics or dry amount with anti-cholinergics) (Sackett, 1979). Alward and Wilensky (1981) studied compliance among glaucoma patients who were prescribed carbonic anhydrase inhibitors for reducing elevated intraocular pressure. They hypothesized that serum CO₂ levels could indicate regular acetazolamide use by reflecting inhibition of carbonic anhydrase in the renal cortex. They found that patients who were

taking the drug regularly could be distinguished from those using it intermittently by noting their serum CO₂ value. The problem always exists, however, that high compliance with an adequate regimen (or with a poorly absorbed medication) can result in neither side-effects nor achievement of the treatment goal. This method has the same limitations as the therapeutic outcome method with the additional disadvantage that it is not coterminus with the treatment goal.

From what is reported above related to compliance methodology it is clear that currently available methods of measuring compliance leave much to be desired. The need exists to maintain a good balance between generality, realism, and precision (Enlund, 1982). Although compliance as a variable may lack great scientific appeal due to methodological problems related to the use of hard data analysis, it appropriately reflects the degree of complexity inherent in any truly human phenomenon.

Summary

The determinants of patient compliance which have emerged from the literature reviewed here can be classified into five major categories. These include: features of the disease; features of the treatment regimen; patient-physician interaction variables; patient characteristics; and family characteristics. Features of the disease such as severity, symptoms, degree of disability, and duration have been implicated in influencing compliance although the findings have not yielded consistent results. Features of the treatment regimen such as duration, complexity, cost, and amount of behavioral change appear to be inversely related to compliance. In other words, an

increase in these variables is associated with a decrease in adherence. Patient-physician factors have been shown to be highly related to compliance. The quality of the communication between patient and doctor, patient satisfaction, and the meeting of the patient's expectations reportedly influence the degree to which patients will comply with doctor's orders. Demographic characteristics of patients have been well documented but their influence on patient behavior remains unclear. Although personality variables as a whole have not added to our understanding of compliance behavior, two constructs which appear to offer promise are locus of control and health beliefs. The final category of variables, family characteristics, appears to be especially pertinent to pediatric studies. Pediatric compliance has been shown to be related to family functioning and stability. It would seem that in order to understand the rather complex dynamics involved in determining pediatric compliance to patching regimens, a systematic investigation of the five categories of determinants presented above (Features of the Disease, Features of the Treatment Regimen, Patient-Clinician Interaction, Patient Characteristics, and Family Characteristics) needs to be carefully addressed within the context of a field experimental setting.

The second part of the literature review focused on the conceptual and methodological problems involved in assessing the extent of patient noncompliance. The method of measuring blood and urine levels for the presence of the prescribed drug is very precise but is also highly influenced by pharmacokinetic variability in the

patient population. Unfortunately, direct observation, although objective and easily measured, appears to be very impractical for most research studies. Therapeutic outcome has intuitive appeal but is hindered by the fact that the relationship between outcome and treatment is not always apparent. Patient reports tend to overestimate compliance although they do appear to be accurate when patients admit to noncompliance. Pill counts are the most widely used method of estimating compliance, although they are dependent on the patients return of their medication containers. Also, the number of medications remaining cannot always be assumed to indicate the number of pills actually taken by the patient. Physician estimates have been shown to be no better than chance although they tend to be more accurate in cases of gross noncompliance. Appointment keeping is both practical and objective but is based on a single event which may or may not be directly related to medication adherence. Prescription filling patterns have little use in short-term therapy. The medication monitor may be the most accurate measure but is also the most costly and therefore most impractical for most research purposes. In summary, available methods for assessing patient compliance have both strengths and weaknesses, and no single method has emerged to date which combines practicality, generality, and precision.

CHAPTER III

PROCEDURE

The purpose of the present study was first to identify those factors associated with adherence to a patching regimen and second to explicate the nature of their interrelationships. In the first part of this chapter the factors identified as relating to compliance are organized and presented, together with the specific hypotheses which evolved from these factors. In the second part, instrumentation, data collection and analysis are described.

Pertinent research questions to be answered are as follows:

- 1) Do the factors identified as relating to compliance in general, influence patching compliance?
- 2) Which specific factors contribute the most to our understanding of patching compliance?
- 3) What are the interrelationships among the alleged factors and how do these effect compliance?

PART I

Identification of Factors Related to Compliance

The review of the literature of general compliance studies attempted to identify those variables which contribute to understanding patient compliance. Since this particular study is concerned only with those variables which may be associated with patching compliance, a subset of the original set needed to be

specified. Two criteria were therefore established to guide the selection of possible patching determinants. First, the independent variable in question was either documented by empirical findings or based upon intuitive or theoretical considerations. Second, the variable was directly or indirectly related to some corresponding aspect of amblyopia, patching regimen, parent-ophthalmologist interaction, characteristics or behaviors of the parent, or of the amblyopic patient. Variables which met both of these criteria are presented in Table 3. These are organized into five major categories: (1) Features of the disease; (2) Features of the treatment regimen; (3) Parent-clinician interaction; (4) Parent-child characteristics; and (5) Family characteristics.

Features of the disease which were selected are severity, duration, and presence of symptoms. Disease severity (defined as the acuity of the amblyopic eye) was chosen for further investigation due to the existence of at least two studies (Murthy, 1974; Thawrani, 1975) supporting its importance. Despite the fact that the majority of studies do not support these results, the existence of contrary data warrants its further study.

Duration of the disease (defined as being either congenital (present at birth) or acquired (absent at birth)) was chosen despite the lack of empirical support from more general studies. It was felt that with a chronic disease such as amblyopia, duration would be inversely related to compliance due to the persistent long-lasting nature of the condition.

The presence of symptoms [defined as the presence of a noticeable

Table 3

Summary of the Results of the Variable Selection Process and the Corresponding Assessment Instruments

<u>Variable Related to Patient Compliance</u>	<u>Assessment Instrument</u>
1) Features of the Disease	Physician Questionnaire:
a) Acuity of the amblyopic eye	H.O.T.V., E-Game, Snellen Chart
b) Congenital or Acquired	Age of Onset
c) Presence of a cosmetic condition	Noticeable ocular imbalance
2) Features of the Treatment Regimen	Physician Questionnaire:
a) Duration of the patching regimen	Number of weeks of previous patching
b) Frequency of patching	Number of daily patching hours prescribed by the physician
3) Parent-Clinician Interaction	
a) Satisfaction	Satisfaction Scale (DiMatteo, 1980)
b) Communication	Communication Scale (DiMatteo, 1980)
c) Expectations	Learning the Diagnosis/Progress of the Patient (Korsch, 1968)
4) Parent-Child Characteristics	
a) Demographic Data: parent education, public aid status, age and sex of child, number of children at home, one- or two-parent household	Parent Interview Questionnaire
b) Locus of Control	Health Locus of Control Scale (Lau, 1981)

Table 3 (continued)

<u>Variable Related to Patient Compliance</u>	<u>Assessment Instrument</u>
c) Health Beliefs	Health Belief Indices (Becker, 1977)
5) Family Characteristics	
a) Family Functioning	Family Functioning Index (Pless and Satterwhite, 1973)
	Parent Judgement Regarding a Particular Child Scale (Itkin, 1952)
6) Appointment Keeping	Attendance at the subsequent appointment

(cosmetic) ocular imbalance] was also included for further investigation, although its importance in determining compliance in general studies is not well supported. The reason for its inclusion is that the presence of an ocular imbalance may be of no direct consequence to the child, however, it may function as a constant reminder/cue to the parent of the necessity for patching. Under these circumstances, we might expect differences in adherence between patients who have noticeable imbalances and those who do not.

The degree of disability was not included as a variable since it does not appear to be related to patching compliance due to the fact that the patient is able to suppress poor images and therefore retain acceptable vision (Parr, 1978).

Features of the treatment regimen which were selected are duration and complexity. The importance of both treatment duration and complexity/number of medications as determinants of compliance have received considerable support from general studies (Ludy, 1977; Haynes, 1979; Brand, 1977; Francis, 1969). For the purpose of this investigation, the variable, complexity/number of medications, has been defined to represent frequency of patching.

The variables, cost and amount of behavioral change, were considered idiosyncratic to medical regimens and life-style change regimens and were therefore not included for further investigation. Only treatment duration and frequency of patching were selected as possible patching determinants.

All three components of the patient-clinician interaction (communication, satisfaction, and meeting of expectations) were

selected for further study. The research literature strongly supports their role as compliance determinants in the majority of studies and they appear to be pertinent to all settings involving patient-physician interactions (Ley, 1976; Haynes, 1979; Zisook, 1980).

The category, patient characteristics, was expanded to include both parent and pediatric patient factors. The following demographic variables were selected for further analysis: educational level of the mother; socio-economic status (defined as whether or not the parent is currently receiving public aid); age and sex of the child; number of children at home; and number of parents at home (i.e., one- or two-parent household). Characteristics of the parent such as educational level, socio-economic status, and number of parents at home have been found to be significantly related to pediatric compliance (Ewalt, 1972; Jacobs, 1972; Mattar, 1974). Similarly, patient characteristics such as age, sex, and number of children have also been reported to relate to pediatric compliance (Becker, 1977; Arnold, 1970; Gordis, 1969). For these reasons, all six of the demographic variables were selected.

Locus of control was selected in order to determine if the parents' locus of control beliefs are related to their child's adherence to the patching regimen. Although there is no research to date which has investigated this particular relationship, it is possible that parents' beliefs, due to their involvement with child care, would be reflected in their approach to the patching program. Studies (Balch, 1975; Weaver, 1972) do report a relationship between

locus of control beliefs of patients and their compliance with therapy. Whether or not this relationship exists for pediatric compliance warrants further investigation.

The role of health beliefs in determining compliance has received considerable empirical support (Becker, 1974; Ley, 1979; Becker, 1977). Although the majority of studies have investigated compliance in acute diseases, an increasing number have found that health beliefs also help to explain compliance in chronic diseases such as diabetes (Cerkoney, 1980). Health beliefs also appear to be useful in the explanation and prediction of a mother's adherence to a diet regimen prescribed for her child (Becker, 1977). Since this study is concerned with both a chronic disease (amblyopia) and pediatric patients, further investigation of health beliefs is especially warranted.

Personality variables were not selected due to the myriad of inconclusive and contradictory findings (Caine, 1976; Carr, 1968; Haynes, 1976) which reportedly exist. In summary, parent-child characteristics were represented by both demographic data and beliefs related to locus of control and health.

The family characteristic which was selected for further study is family functioning. Family functioning is critical to this study because the family is the primary social unit for virtually every aspect of child health care. It is reasonable therefore, to speculate that family functioning is also an important intervening variable in pediatric patching compliance. Since family functioning represents a comprehensive, process approach to pediatric compliance, the related

variable, family stability, was subsumed under the former.

The final variable selected was appointment keeping. Although appointment keeping lacks the empirical validity to justify its use as a measure of patching, it does have appeal as an objective, easily obtained piece of data. The worth of this data source in enhancing understanding of compliance may be better realized by examining it in a different light. Granted, no evidence exists which indicates that keeping an appointment is positively related to other aspects of the treatment regimen. However, this is not to say that not keeping an appointment is unrelated to compliance. In fact, Ramsay (1983) has shown that habitual failure to keep appointments is predictive of lower compliance. In her study of dropouts from a hypertension control program, she found significantly higher rates of noncompliance among dropouts than for patients continuing in the program. In this light, appointment keeping would appear to be a necessary, although not sufficient, condition for compliance, and thus warrants further investigation.

In summary, the variables summarized in Table 3 represent those determinants which are both supported by empirical findings or intuitive considerations, and which are especially pertinent to the study of patching compliance among pediatric amblyopia patients. These factors thus form the basis for the further investigation of those particular variables which exert an influence on patching adherence.

Statistical Hypotheses

These hypotheses evolved from the first part of this study and

from the factors identified as relating to compliance which were organized and presented there.

Hypothesis 1

There is no linear relationship between the constellation of disease features (acuity, age of onset, presence of cosmetic condition) and patching compliance.

Hypothesis 2

No variable, in isolation, within the constellation of disease features accounts for unique variance in patching compliance once the effects of treatment, parent-clinician interaction, parent-child characteristics, and family characteristics have been held constant.

Hypothesis 3

There is no linear relationship between the constellation of treatment features (duration of the patching regimen, frequency of patching) and patching compliance.

Hypothesis 4

No variable, in isolation, within the constellation of treatment features accounts for unique variance in patching compliance once the effects of disease, parent-clinician interaction, parent-child characteristics, and family characteristics have been held constant.

Hypothesis 5

There is no linear relationship between components of the parent-physician interaction (parent satisfaction, communication, and meeting of expectations) and patching compliance.

Hypothesis 6

No component, in isolation, of the parent-physician relationship

accounts for unique variance in patching compliance once the effects of disease, treatment, parent-child characteristics, and family characteristics have been held constant.

Hypothesis 7

There is no linear relationship between the constellation of parent-child characteristics (demographic, locus of control, health beliefs) and patching compliance.

Hypothesis 8

No variable, in isolation, within the constellation of parent-child characteristics accounts for unique variance in patching compliance once the effects of disease, treatment, parent-physician interaction, and family characteristics have been held constant.

Hypothesis 9

There is no linear relationship between family functioning and patching compliance.

Hypothesis 10

Family functioning, in isolation, accounts for no unique variance in patching compliance once the effects of disease, treatment, parent-physician interaction, and parent-child characteristics have been held constant.

PART II

The research generated by the hypotheses is presented in the following sequence. First, the instruments which appear in Table 3, utilized to measure the selected variables are described, followed by the method used in data collection, experimental design, and analysis.

Instrumentation: Description and Use

The following were used to collect data related to features of the disease and of the treatment regimen. Three instruments were used to measure acuity. All yield acuity values ranging from 20/20 (excellent vision) to 20/400+ (poor vision). (Appendix B).

H.O.T.V. Chart

This instrument measures the acuity of the amblyopic eye in children under three years of age.

E-Game

This instrument measures the acuity of the amblyopic eye in children between the ages of three and six.

Snellen Letter Chart

This instrument measures the acuity of the amblyopic eye in children over the age of six.

Physician Questionnaire

This questionnaire, designed by the researcher and completed by the physician, was used to record both disease and treatment features. The following information was elicited by the questionnaire: whether the amblyopia was congenital or acquired; presence of a cosmetic condition; duration of the patching regimen (weeks of previous patching); and frequency of prescribed patching (hours per day) (Appendix C).

The quality of the parent-physician relationship was assessed by measuring three related components. These were parent satisfaction with the physician, parent-physician communication, and the meeting of the parent's expectations. The following three instruments were

utilized to measure these components of the parent-clinician interaction.

Satisfaction Scale

Parent satisfaction was measured by the Satisfaction Scale (Appendix D). This scale represents a subset of the Satisfaction Questionnaire developed by DiMatteo (1980) for use to determine patient satisfaction. It was originally developed by an a priori grouping of the items based upon the work of Ware (1978). The Satisfaction Scale consists of five statements, each requiring an agree-disagree response on a five-point Likert scale. Each item is worded as a statement of opinion and is associated with a five point response scale ranging from "strongly agree" (precoded as 1) to "strongly disagree" (precoded as 5). Items marked with an (*) were reversed before scoring (i.e., "strongly agree" = 5). The item scores are summed to yield a total score. The higher the score, the greater the parent's satisfaction with the physician. Cronbach's alpha for the entire 25-item Satisfaction Questionnaire is 0.92 (n=287). Test-retest reliability is 0.63 (n=22). Cronbach's alpha for the five-item subtest is 0.76 (n=287) and test-retest reliability is 0.60 (n=23).

One criticism of satisfaction surveys in general is that they are not valid because they reflect preferences of individual patients and their general life sentiments more than the actual structure, process, and outcome of medical care (Ware, 1977). This argument states that value preferences and the way people feel about life in general, substantially determine how they evaluate the medical care they

receive. Ware (1977) feels however, that this influence of preferences and general sentiments on patient satisfaction ratings is not large enough to invalidate satisfaction surveys. Patient satisfaction is best predicted from measures of what happens to patients when they seek care and from measures of how patients are treated by physicians.

A second concern regarding validity is that differences in the results of satisfaction surveys when items differ in referent (i.e., focus on satisfaction with your own physician as opposed to physicians in general) do exist (Ware, 1977). In other words, respondents tend to indicate greater satisfaction with personal medical care experiences than with care in general. However, according to Ware (1977), satisfaction ratings for care personally received and for care received by other people in general, do not differ in reliability; the two kinds of measures also have the same predictive validity.

Communication Scale

Parent-physician communication was assessed by the Communication Scale (Appendix D), which represents a second subset of the Satisfaction Questionnaire developed by DiMatteo (1980). These items measure the parent's perception of their physician's proficiency at communicating and listening to details of the illness and treatment. This scale focusses on the patient's subjective assessment of the quality of this interchange. Support for the validity of these types of questions is provided by Kinsey et al. (1975). They found that patients who perceived the patient-physician interchange to be characterized by good communication tended to be better compliers.

The Communication Scale consists of four statements, each requiring an agree-disagree response on a five-point Likert scale. Each item is worded as a statement of opinion and is associated with a five point response scale ranging from "strongly agree" (precoded as 1) to "strongly disagree" (precoded as 5). Items marked with an (*) were reversed before scoring (i.e., "strongly agree" = 5). The item scores are summed to yield a total score. The higher the score, the better the patient's perception of the communication between parent and physician. Cronbach's alpha for the four-item Communication Scale subtest is 0.75 (n=287) and the test-retest reliability is 0.66 (n=23).

Learning the Diagnosis/Progress of the Child Question

The assessment of the extent to which parents' expectations regarding the clinic visit had been met was measured by a single question requiring either a "yes" or "no" response. The question related directly to the parent's expectation of learning their child's diagnosis. (Note: For parents returning to the clinic with prior knowledge of the diagnosis, a modified question related to the expectation of learning about the child's progress, was substituted). According to Korsch (1968), in her study of 800 pediatric clinic visits, learning their child's diagnosis was the primary expectation of the mothers. Fifty-six percent of the mothers who felt that the physician had not met this expectation were grossly noncompliant.

Parent-child characteristics were measured by the following three paper-and-pencil instruments designed specifically for this study.

Parent Interview Questionnaire

This instrument (Appendix E) was designed to elicit the following pertinent demographic data from parent responses: parent education, socio-economic status, age and sex of the child, number of children at home, and number of parents at home. The educational level of the parent who brought the child to the clinic was assessed as the highest grade completed in school (eight = 8, first year high school = 9, etc.). Socioeconomic status was defined dichotomously as either receiving ("yes") or not receiving ("no") public aid. Age and sex of the child was provided by the parent along with the number of children currently living at home. One- or two-parent household was assessed as either "yes", the spouse was living at home, or "no", the spouse was not living at home.

Health Locus of Control Scale

Locus of control beliefs were measured by two subscales of the Health Locus of Control Scale (Appendix F) developed by Lau and Ware (1981). This scale is a modification of the original scale developed by Rotter (1966). This modification was based upon the hypothesis that locus of control perceptions are situation-specific and are therefore better assessed by a health-specific scale rather than by a general scale (Lau, 1981).

Four dimensions of health-specific locus of control beliefs comprise this scale. They are: Chance Health Outcomes ; General Threat to Health ; Provider Control Over Health ; and Self-Control Over Health . Correlations among these scales are weak and insignificant (0.20-0.27). This implies that each scale makes an

independent contribution to predictive models of health behaviors. This independence among the scales allows for the use of individual scales rather than the entire battery.

The two subscales selected to assess locus of control were the Self-Control Over Health Subscale and the Chance Health Outcome Subscale. Self-control over health is associated with the rejection of chance and health threat in determining health outcomes, and reliance on self in maintaining health. Chance health outcomes are associated with more general chance and controllability measures. These particular two subscales were selected because they appear to assess beliefs related to self-care and self-responsibility for health; two critical components of compliance with treatment regimens.

A total of 14 questions are based on the two selected subscales. Six questions assess self-control over health beliefs and eight questions assess chance health outcome beliefs. Each item is worded as a statement of opinion and is associated with a five point response scale ranging from "strongly agree" (precoded as 1) to "strongly disagree" (precoded as 5). Items marked with an (*) are reversed (i.e., "strongly agree" = 5) before scoring. All items are summed in order to yield one total score which assesses the parent's overall locus of control. The higher the score, the more external are the parent's beliefs regarding health matters.

Reliability estimates based on internal consistency and test-retest methods appear to be satisfactory. The Self-Control Over Health Subscale has an internal consistency of 0.65 and a test-retest reliability of 0.71. The Chance Health Outcome Subscale has an

internal consistency of 0.71 and a test-retest reliability of 0.69.

A preliminary test of validity was based on construct validation. The two scales correlated with rotated factors in a manner consistent with the interpretation implied by the names assigned to the scales. Chance outcome measures correlated significantly with the rotated factor which defined belief in chance both in general and with respect to health outcomes. Self-control over health measures correlated highest with the factor which defined belief in the role of chance. Consistent with theory, persons believing in personal control over health tended not to believe that health outcomes are due to chance (Lau, 1981). In summary, these two health locus of control subscales (Chance Health Outcome Subscale and Self-Control Over Health Subscale) would appear to be useful in distinguishing parents who are unlikely to take personal responsibility for their child's patching from those parents who prefer to take more responsibility for the patching regimen.

Health Belief Indices

Becker's Health Belief Indices (1977) provided the measures of the health beliefs. Health beliefs corresponding to the various dimensions of the Health Belief Model (HBM) (Becker, 1975) were assessed by seven single questions designed for this study (Appendix G). According to Mikhail (1981), although the Health Belief Model has provided theoretical definitions for the major constructs, agreement on the meaning of these constructs and difficulties in operationalizing some of them are still encountered. In other words, no standard set of questions has been developed which is agreed upon

by all researchers.

The questions which were used in this study parallel the types of questions developed by Becker (1975). They were slightly modified in order to more specifically assess health beliefs for parents of pediatric amblyopia patients. According to Becker (1975), for groups such as children, the relevant health beliefs and attitudes of the "responsible others" are often the primary determinants of the degree to which the dependent patient follows the treatment program. The questions were selected from questionnaires used in previous studies (Becker, 1977; Jette, 1981), retaining the original wording whenever possible. Since Becker's (1975; 1977) studies deal specifically with parent beliefs and their effect upon pediatric compliance, his questions were given greater consideration.

The entire questionnaire consists of seven statements, each requiring an agree-disagree response on a five-point Likert scale. Each item is worded as a statement of opinion and is associated with a five point response scale ranging from "strongly agree" (precoded as 5) to "strongly disagree" (precoded as 1). Each statement assesses one of the following unique health belief dimensions: general health motivation; susceptibility to illness; severity of the illness; and perceived barriers. The higher the score, the stronger is the parent's belief regarding that dimension. Although single-item measures have been criticized (Ware, 1977) for limiting construct dimensions, the purpose here is to delimit specific parent beliefs. These particular seven statements were chosen because they correlated highest with pediatric compliance both with a prescribed diet (Becker,

1977) and also with a medical regimen for asthma (Becker, 1977).

The General Health Motivation Scale (statements 1, 3, and 4) assesses the parent's concern about the child's general health and that related specifically to the child's amblyopia. This health motivation index has been found to be highly correlated with compliance (.514, $p < .01$) (Becker, 1977). The Susceptibility Scale (statement 2) assesses the parent's perception of the child's susceptibility to contracting an illness. The mother's perception of how easily her child gets sick has also been found to be highly related to compliance (.491, $p < .01$) (Becker, 1977). The Severity Scale (statement 5) measures the degree of emotional arousal created by the thought of an illness as well as the difficulties the parent believes the illness will create. This component, along with the susceptibility scale, have strong cognitive undertones wherein knowledge, in part, leads to action. This perceived severity is also highly correlated with compliance. Correlations are typically in the range of .614 to .640 (Becker, 1977; Cerkoney, 1980). The Perceived Barriers Scale (statement 6) assesses the parent's confidence in adhering to the patching regimen. In Becker's study (1977), this variable was unassociated with compliance. However, his question was directed at the mother's influence on her child's diet, whereas, in the present study, the question is directed specifically at the mother's assessment of her ability to get her child to wear the patches. For this reason, the preceding question was included.

Research relating to the Health Belief Model in general, provides empirical evidence of the model's utility in predicting adherence to

therapeutic regimens (Becker, 1974; Becker, 1977; Cummings, 1979). Although the HBM model has been used extensively for predicting various health behaviors, until recently little attention was given to important methodological issues such as the reliability and validity of the measures of the health belief dimensions. Using factor analysis, Jette et al. (1981) found empirical support for the assumption that the HBM dimensions are sufficiently distinct to be considered different beliefs. General measures of perceived susceptibility to illness, perceived severity of illness, and perceptions of barriers to health actions were conceptually distinct from condition-specific measures of these beliefs. This suggests that it may be less valid to mix general and specific items within the same questionnaire when measuring specific beliefs.

Becker (1977) found that the internal consistency of the indexes, assessed by calculating a consistency coefficient (Kerlinger, 1973) ranged from .47 to .96. Measures of general health threat achieved the highest reliabilities (.72-.77). Although not all indices have been shown to be consistently related to compliance, in combination they appear to account for substantial variance.

Family functioning was assessed by the following two instruments: The Family Functioning Index and Parent's Judgment Regarding a Particular Child Scale.

Family Functioning Index (FFI)

The FFI was developed by Pless and Satterwhite (1973) (Appendix H) as a simple, easily administered test to reflect the functioning of family interaction. The FFI consists of 15 questions tapping such

areas of family interaction as marital satisfaction, frequency of disagreement, communication, and feelings of happiness and closeness. The veracity of individual responses is supported by studies suggesting that most respondents are able and willing to describe some aspects of family life truthfully, either in the course of an interview or in a brief questionnaire (Rutter, 1966; Locke, 1959). The variable "functioning" is defined as the strength of relationships and life style of the family as a whole.

The index was developed initially as part of a semi-structured interview schedule used in a study of the adjustment of children with chronic physical illnesses (Pless, 1971). It was administered to the parents of 399 children of school age, all of whom were part of a one percent random sample of families in Monroe County, New York (Roghamann, 1970). Two hundred nine of these children had chronic disorders at the time of the study and the remainder were healthy. The psychological adjustment of all children, sick and well, was assessed within a few months of the household interview through a series of tests and ratings obtained from the subjects themselves, their parents, peers and teachers. Sixteen questions asked at the end of the interview with the mother formed the basis of the original index. The choice of questions was made to reflect the multi-dimensional nature of the construct being assessed. The choice was essentially eclectic and was based on both theoretical and empirical considerations. For example, the questions dealing with "decision making" were those used by Blood and Wolfe (1960) as an "Index of Decision Power" - a dimension of probable significance in a

situation where the mother was likely to be forced to assume a dominant role to meet the medical needs of her sick child. Similarly, the marital satisfaction component, also based on the work of Blood and Wolfe (1960) was of obvious relevance in families under stress. Questions relating to "happiness", "closeness", and "frequency of disagreements" each had face validity and were supported by the findings of Bossard and Boll (1955).

The scoring of the responses is deliberately simple. Zero, one or two points are assigned to each response depending on the degree to which the response is congruent with presumed optimal functioning. The total score is obtained by the addition of scores for each question. The range of possible scores is from 0 to 35, with higher scores indicating more desirable levels of functioning. Families in which a spouse was missing were analyzed separately by the test designers using only those items which were applicable.

Two means of validation were established by Pless and Satterwhite (1973). The index was adapted for self-administration and was given to new registrants at three professional family counseling agencies to be completed by husbands and wives independently. The results were not disclosed to the case worker, who was requested to rate the family on a five-point scale designed to reflect the content of the index. It was assumed that the case worker's assessment of the family was a valid estimate of the level of functioning. Table 4 shows the correlation between both parent's FFI scores and those of the case worker.

Table 4

Correlation* Between Index Score and Independent Ratings

	<u>Caseworkers' ratings</u>		
	N	r	p
Mother's FFI Scores	43	0-48	0.01
Father's FFI Scores	39	0-35	0.013

*Pearson product moment correlation.

A second validation incorporated similar independent ratings made by six non-professional counselors who had been assigned to families of children with chronic physical disorders (Pless, 1972). In each instance, the counselor had known the family for at least one year. Using the same five point scale, the mother's FFI score was compared with the counselor's independent rating. A correlation of 0.39 ($p < 0.001$) was obtained for the 65 families in the program.

An important qualification of any screening instrument, if it is to be used with confidence, is its stability. The test-retest reliability over a five year period of the Family Functioning Index of 0.83 provides this added dimension. This together with the previous high correlation between scores of respondents and case workers suggests that the use of the FFI in the assessment of family dynamics in a wide variety of settings, particularly in those in which highly skilled/trained assessors are not readily available, may be of considerable value. The FFI appears to be an adequate instrument for assessing the overall functioning of the patient's family.

Parent's Judgment Regarding a Particular Child Scale

According to Mechanic (1964) and Litman (1974), it is the mother who plays the most pervasive role in the health care of the child. For this reason, it seemed desirable to also include a measure of the relationship between the mother and child as part of the overall functioning index. The measure selected was the Parent's Judgment Regarding a Particular Child Scale (Appendix I) developed by Itkin (1952). Five multiple choice items were selected from the total scale of 35 items. These particular items were selected because they assess the parent's attitude toward the child rather than the child's personality; the former being an aspect of family functioning. Each item is followed by five possible responses (scored 1 through 5 depending upon the degree to which it reflects a favorable attitude toward the child). The possible range of scores is from 1 to 25. A high score indicates a favorable attitude toward the child. Split-half reliability was found to be .903, based upon the responses of 412 parents. Validity scores of parents (N=68) for the entire scale were found to correlate $-.623$ with self-ratings.

Measures of Compliance

An accurate assessment of patching compliance was a critical aspect of this study. The validity of the inferences which could be made were dependent not only upon the independent measures but also on the reliability and validity of the dependent variables. A main problem stems from the fact that compliance is reportedly an entirely subjective and human phenomenon. According to Feinstein (1979), "the degree of compliance is determined by the patient; the act of

compliance usually occurs in circumstances where it cannot be observed directly by the researcher; and its appraisal depends upon what the patient decides to do and what he reports" (p. 311). These distinguishing characteristics of compliance make hard data collecting both difficult and undesirable. The paradox exists that the quality of the research and the validity of the inferences can be no better than the design of the research and the compliance measures employed (Gordis, 1979).

Enlund (1982) states that the need exists to maintain a good balance between generality, realism, and precision. This type of balance, according to Sackett (1979), is best achieved by the use of multiple methods. Multiple methods refers to the use of more than one instrument to measure the same phenomenon. In this way, the selected instruments are utilized in a way which maximizes their strengths and minimizes their weaknesses. Thus, the assessment of various aspects of patching behavior should provide a more complete understanding and more accurate measure of this health behavior. For these reasons, the following three methods/instruments were used: Patch Box Data ; Parent Estimate ; and Verbal Patch Usage .

Patch Box Data

The most objective of the three measures was Patch Box Data (Appendix J). This instrument was designed to maximize the strengths of both observational techniques and pill count measures and was used in all cases where the patch box was returned. Observational methods according to Hersen (1976), provide an objective assessment of compliance and are clearly superior to less direct methods. Recording

patch usage requires parents to observe and record the number of hours that each patch is worn by the patient. The patch box contains 20 ocular occlusion patches (either Coverlet or Opticlude) and the following directions attached to the box: Please record, on the box, the total number of hours that each patch is used. If the patch is used for only one hour and is never used again, record one hour on the box. If you use this particular patch again for an additional number of hours, please add the total number of hours together for that patch. Please bring your box with you to your next visit. We will return the remaining patches to you. If your supply of patches runs out, please record that date on the box but still bring the empty box with you. This data provides an estimate of the average number of hours per day that patching occurred.

Additional information is provided by counting the number of patches remaining in the box. This can be used to corroborate the reporting of patch usage. In this way, patch count provides additional evidence regarding patch usage and the consistency of parent reporting. In addition, patch count also provides a means by which unrecorded patch use can be estimated. In other words, mean substitution can be utilized to estimate the patching hours of patches which were not returned and not recorded. For example, when a discrepancy exists between the number of patches recorded and the number missing, the discrepant patch hours can be estimated based on the mean of the recorded hours. However, as the number of discrepant patches increases, the reliability of their estimates decreases.

There are possible threats to the validity of patch box measures

which need to be addressed. These include observer bias, instrument reactivity, and accuracy of the recorded data. First, parents are not typically casual, unobtrusive observers of their children's behavior. For this reason, their observations may tend to be biased, since poor compliance may reflect unfavorably on their role as parents. In order to minimize this source of bias, the parent was kept unaware of the purpose of these measures and was focussed instead on the patches and problems with them (e.g., not sticking, irritation, etc.). With parent's attention focussed upon specifics of the patches, the suggestion that the parents are to blame for poor compliance was hopefully minimized. This should increase the validity of the recorded data and provide a more accurate picture of actual patching behavior.

A second potential problem was the possibility that the act of recording patch use would in itself influence subsequent patching behavior. This may have occurred if parents were cued or reminded to patch their children by the act of recording the patch hours. In this instance, the patch data would not only have functioned as a measure of compliance but also as a compliance-improving intervention and would thus have compromised the objectivity and validity of the instrument. In an effort to minimize the possibility of this type of reaction, an attempt was made to keep the act of recording as simple and unobtrusive as possible and thus to minimize feedback effects.

A third problem with this instrument was the possibility that parents may have failed to keep accurate records and/or attempted to fill in records long after the fact. These potential threats to the

validity of Patch Box Data have been addressed in the following ways. First, the recordkeeping chart was attached to the patch box and should therefore have provided a reminder cue to record the patch hours whenever a patch was removed. Second, the removal of a patch from the child's eye was hopefully an additional reminder to either record or mentally note the number of hours that the patch was used.

The patch box method, by incorporating the qualities of direct observation and pill count measures was designed to provide an estimate of the actual patching hours completed by the patient. By utilizing parent observations and patch counts, the validity and accuracy of the recorded data was hopefully maximized.

Parent Estimate

In the case where the patch box was not returned, the Parent Estimate of patching compliance was used only in those instances where their estimate of the number of hours actually patched was less than 25 percent of the number of prescribed hours (based on an estimate of the minimal level of compliance required for improved visual acuity in the amblyopic eye). The parent's estimate of the average number of daily hours patched was recorded on the Parent Interview Questionnaire II (Appendix K). This estimate was purposefully preceded by a list of problems (e.g., not sticking, skin irritation) typically associated with the patches, and required parents to identify those problems they had similarly encountered. This was done in an effort to enhance the veracity (and thus the validity) of the parent estimates by implying that noncompliance is due more to inherent problems with the patches themselves rather than

with any deficiency on the parents' part.

Although parents tend to overestimate their children's compliance, the accuracy of these estimates is further enhanced when parents admit to low or noncompliance. Gordis (1979) states that there is little evidence to suggest that complying patients misrepresent themselves as noncompliers, nor is there evidence that those who profess noncompliance are lying. In the case of major compliance defaults, Park and Lipman (1964) found that parent estimates tended to correspond to pill counts. For this reason, parental estimate of patching compliance failures was accepted as reasonably reliable when major compliance failures were reported.

Verbal Patch Usage

The least objective of the three measures was Verbal Patch Usage because of its reliance on recall of data. This method was designed to question the parents regarding their recall of the number of patches remaining in the patch box and was used in those remaining cases where patching compliance could not be assessed by either Patch Box Data or Parent Estimate. The parents were also asked to estimate the number of hours that the average patch lasted. In doing so, an estimate of the average number of hours per day of patching completed was made. Despite its limitation of relying on recall data, Verbal Patch Usage would appear to be at least as accurate as parent estimates with the added advantage of obscuring the true purpose of the study. In addition, this method was only used when the box was not returned and subsequently when the parent estimated high patching compliance (greater than 25%).

Table 5 summarizes the procedure for instrument selection.

Table 5

Summary of the Procedure for the Selection of Appropriate Compliance Measure

<u>Status of Patch Box</u>	<u>Status of Parent Estimate</u>	
	<u>< 25%</u>	<u>> 25%</u>
Patch Box Returned	Patch Box Data	Patch Box Data
Patch Box Not Returned	Parent Estimate	Verbal Patch Usage

For example, a parent who returned the patch box with the chart information had patching compliance assessed by Patch Box Data. A parent who failed to return the box had patching compliance assessed by either Parent Estimate (when this estimate was less than 25%), or by Verbal Patch Usage, in the remaining cases. Every method thus yielded a single measure of patching compliance represented as a percent of the total prescribed patching hours. These three methods are mutually exclusive and exhaustive. In summary, the most appropriate method for measuring patching compliance was determined by the type of data available and the assumed accuracy of that data.

METHOD

Sample selection and description, data collection, statistical design and analyses of data follow:

Subjects

Parents of 30 pediatric amblyopia patients who attended the

motility clinic of the Eye and Ear Infirmary of a major university during a four month period were selected for the study. Selection was limited to those patients who were currently patching or beginning a patching program (ocular occlusion) and whose condition was uncomplicated by other eye diseases. Table 6 presents a description of parent and child characteristics.

Table 6

Patient/Parent Characteristics

Characteristics		N
Sex	Male	18
	Female	12
Public Aid	Yes	11
	No	19
Number of Parents at Home	One	10
Number of Parents at Home	Two	20
Number of Years of Schooling Completed by Parent	Eight	1
	Ten	6
	Twelve	16
	Fourteen	1
	Sixteen	3
Number of Children at Home	One	4
	Two	13
	Three	7
	Four	3

Table 6 (continued)

Characteristics		N
Number of Children at Home	Five	1
Who Brought the Child	Mother	24
	Father	5
	Both	1
Age of the Patient	0 to 2	5
	3 to 4	8
	5 to 6	9
	7 to 8	3
	9 and older	5

Male patients tended to outnumber females. The majority of patients were not on public aid and came from two-parent households. Typically, the mother brought the child to the clinic, had herself completed high school, and had less than four children at home. The ages of the patients varied from one to nine with the majority falling between three and six years of age. All parents who were asked to participate did so and signed permission forms prior to their scheduled appointment.

Data Collection

The data collection was conducted in the following manner. Parents/guardians of amblyopic subjects were interviewed and asked to

complete questionnaires at three different times. Table 7 represents the time table for the collection of the data. Prior to Appointment I (Time A), the following instruments were administered: Health Locus of Control Scale; Health Belief Indices; Parent Judgement Regarding a Particular Child Scale; Parent Interview Questionnaire; and the Family Functioning Index. (Note: for some patients, Appointment I represented the initial appointment while for others, it represented different points in time along a continuing regimen).

Table 7

Time Table for Data Collection and Administration of Instruments

<u>Times</u>	<u>Instruments</u>
A (Immediately prior to Appointment I)	1) Health Locus of Control Scale 2) Health Belief Indices 3) Parent Judgment Regarding a Particular Child Scale 4) Parent Interview Questionnaire 5) Family Functioning Index 6) Physician Questionnaire
B (Immediately following Appointment I)	7) Satisfaction Scale 8) Communication Scale 9) Expectation Question 10) Parents Receive the Patch Box
C (Immediately prior to Appointment II)	11) Appointment Keeping

Table 7 (continued)

<u>Times</u>	<u>Instruments</u>
C (Immediately prior to Appointment II)	12) Patch Box Data, Parent Estimate, or Verbal Patch Usage

During Appointment I, the physician assessed the features of the disease and treatment regimen and completed the Physician Questionnaire. This included: administering the appropriate acuity instrument (H.O.T.V., E-Game, or Snellen Chart); determining if the amblyopia was congenital or acquired; noting the cosmetic condition of the eye; and noting the duration and frequency of the regimen.

Immediately following Appointment I (Time B), the parent/guardian completed the Satisfaction and Communication Scales and the question regarding their expectations. Also at this time, the parent received the box of ocular patches and instructions to record on the chart attached to each box the total number of hours that each patch was used.

The time interval between Time B and Time C varied (1-12 weeks) depending upon the depth of the amblyopia and the age of the patient. Parents were instructed to return the Patch Box at Time C (immediately prior to Appointment II). During this time, data regarding whether or not the patient had kept the previous appointment (appointment

keeping) was recorded. Also recorded at this time were either Patch Box Data, Parent Estimate, or Verbal Patch Usage, depending upon the availability of data.

Upon completion of the data collection, the instruments were hand scored. Instruments which yielded continuous and scaled scores are listed in Appendix A along with their corresponding range of values. Also included are those variables which are discrete in nature together with their corresponding code values. The next step involved the analysis of the data and the obtaining of a single continuous score which would represent the dependent variable, patching compliance.

Design and Statistical Analysis

The behavioral sciences inherited from the older branches of science the simple paradigm: vary a single presumed causal factor and its effects on the dependent variable, while holding constant other potential factors. This design is appropriate for the physical sciences, but it does not appear to address the complexity of human behavior such as compliance to therapeutic regimens. Issues related to health actions studied by health educators and psychologists are extremely intricate in nature and occur in naturalistic rather than in experimental settings. In such naturalistic settings, it is difficult to exert the same kinds of strict controls (e.g., random sampling) that one might achieve in a laboratory. Rather, research in natural settings must often rely on statistical controls to separate specious correlations from true causal influences (i.e., estimating the unique influence of one or more independent variables while holding constant

the influence of others).

Since it was necessary to measure the independent variables before their influences on patching compliance could be controlled statistically, the design of this study became increasingly complex and involved a large number of independent and potentially confounding variables. What was needed to adequately address these research issues was a data-analytic approach of considerable flexibility and power which would permit the testing of complex theoretical models in such a way that the data analyses were responsive to hypotheses rather than being limited by inflexible analytic techniques. For this reason, Multiple Regression Analysis was chosen as the statistical tool by which patching compliance could be systematically studied as a function of, or in relationship to, the specified independent variables (determinants of compliance). More specifically, it was used to reveal the amount of compliance which was presumably due to the independent variables and to give some idea of the relative and absolute amounts of influence of these factors.

Stepwise multiple regression was the primary analytic procedure used. The 26 independent variables were entered into the primary analysis using patching compliance as the dependent criterion variable. The R^2 increase was used to estimate both the contribution of the entire set of independent variables and the contribution of each variable to the explained variance in patching. Standardized partial regression coefficients (beta weights) were used as estimates of the unique contribution of each variable with the influence of all other variables held constant. The general form of the

(unstandardized) regression is:

$$Y_1 = A + B_1 X_1 + B_2 X_2 + \dots + B_K X_K$$

where Y_1 represents the estimated value for the dependent variable (patching compliance), A is the intercept, and the B 's are regression coefficients.

As previously discussed, the dependent variable, patching compliance, was assessed by one of three instruments (Patch Box Data, Parent Estimate, Verbal Patch Usage) depending upon the type of data available and the assumed accuracy of that data.

Patch Box Data was analyzed by counting the number of patches missing from the box and comparing this to the number which were recorded on the chart to determine if any patches were used but not recorded. If this were the case, the number of hours that these patches were used was estimated by substituting the mean hours of the recorded patches. By using mean substitution, a more accurate estimate of the total patching time could be determined.

Secondly, the average daily number of patch hours was then obtained by summing the individual patch hours recorded and dividing by the number of days since the last appointment (in the case where the supply of patches ended prior to the next appointment, the number of days between their last appointment and the day on which the supply ended, was calculated).

$$\frac{\text{(recorded patch hours)}}{\text{number of days}} = \text{average number of daily patching hours}$$

Since the number of prescribed hours varied depending upon the age of the patient, a more accurate estimate of compliance was obtained by

calculating the proportion of prescribed hours actually patched.

$$\frac{\text{average number of} \\ \text{daily patching hours}}{\text{average number of} \\ \text{daily patching hours prescribed}} = \text{patching compliance (\%)}$$

Parent estimate of the average daily patching hours was also obtained by dividing it by the average number of daily patching hours prescribed to yield patching compliance (%).

$$\frac{\text{parent estimate of} \\ \text{daily patching hours}}{\text{average number of} \\ \text{daily patching hours prescribed}} = \text{patching compliance (\%)}$$

In the case of Verbal Patch Usage, the number of patches reported to be remaining was subtracted from 20, the original number of patches, to obtain an estimate of the number of patches used. This estimate was then multiplied by the parent estimate of longevity (of the patches) to obtain a total patching hours estimate. This total patching hours estimate was then divided by the number of days (based upon the same criteria used with Patch Box Data) to yield an estimate of the average number of daily hours patched. Again, for a more accurate estimate of patching compliance, the average number of daily hours was divided by the average number of daily hours prescribed to obtain the dependent measure, patching compliance.

$$(\text{20 patches remaining}) \times (\text{longevity}) = \text{average number of daily} \\ \text{patching hours}$$

$$\frac{\text{average number of} \\ \text{daily patching hours}}{\text{average number of} \\ \text{daily patching hours prescribed}} = \text{patching compliance (\%)}$$

Summary

This chapter dealt with the statistical hypotheses, subject selection and description, data collection, instrumentation, and the statistical methods of the study. The ten hypotheses dealt with the relationship between the independent variables and patching compliance.

The subjects were 30 parents and their amblyopic children. Each parent completed the following instruments: Health Locus of Control Scale; Health Belief Indices; Parent Judgment Regarding a Particular Child Scale; Family Functioning Index; Satisfaction and Communication Scales; Expectations Question; and the Parent Interview Questionnaire. The physician completed the Physician Questionnaire.

The dependent variable, patching compliance, was assessed by one of three instruments depending upon the availability and accuracy of the information. Patch Box Data was used to assess patching compliance in all cases where the patch box and the recorded patch usage information were returned. Parent Estimate was the method of choice in those remaining cases where the estimate was less than 25 percent. The remaining cases were assessed by Verbal Patch Usage.

Multiple Regression Analysis was used to study patching compliance as a function of, or in relationship to, the specified independent variables.

CHAPTER IV

RESULTS

The purpose of the present study was first to identify those factors associated with adherence to a patching regimen and second to explicate the nature of their interrelationships. In the first part of this chapter, variables are presented and discussed descriptively, and a strategy for reducing the number of factors is developed. In the second part, the final set of reduced variables is analyzed using stepwise multiple regression.

PART I: IDENTIFICATION OF COMPLIANCE VARIABLES

The descriptive statistics pertaining to the independent and dependent variables' associated with compliance are summarized in Tables 8 and 9. Table 8 displays the means and standard deviations of the variables under investigation. The distributions of the majority of variables approximated normal curves, with the majority of cases falling between one standard deviation above and below the means.

Weeks of patching however was positively skewed (2.236), indicating that the majority of cases fell along the lower values for this variable. There tended to be restriction at the low end of the distribution due to the fewer number of subjects who had been patching for a long period of time.

Table 9 displays the correlation coefficients among the

Table 8

Descriptive Statistics of Independent and Dependent Variables

Variable	Mean	Standard Deviation
Congenital (Duration)		
Severity	2.00	.87
Cosmetic		
Weeks of Previous Patching	44.97	67.44
Present Hours of Patching	7.4	3.15
Locus of Control	34.20	5.01
HB 1 (General Health Motivation)	4.30	.65
HB 2 (Susceptibility)	2.60	1.13
HB 3 (Specific Health Motivation)	2.60	1.10
HB 4 (Specific Health Motivation II)	4.43	.50
HB 5 (Severity)	3.43	1.14
HB 6 (Perceived Barriers)	2.87	1.14
HB 7 (Treatment Efficacy)	4.27	.64
Family Functioning	61.57	25.81
Attitude Toward the Child	8.53	5.75
Age of Child	5.4	2.82
Sex of Child		
Number of Children	2.27	1.14
Parent Education	11.27	3.52
Public Aid		
Spouse (Parents in Household)		

Table 8 (continued)

Variable	Mean	Standard Deviation
Parent Satisfaction	17.60	5.20
Communication	14.93	3.49
Appointment Keeping		
Patching Hours Completed	64.13	32.28 (Dependent Variable)

Table 9

Correlation Matrix (Intercorrelations of Variables)

	Cong	Seve	Cosm	Week	Pres	Locu	HB 1	HB 2	HB 3	HB 4	HB 5	HB 6	HB 7	Famf	Accl	Age	Sex	Numb	Educ	Aid	One-	Satl	Coun	Appo	Hour	
Congenital (Duration)		.069	-.153	.136	-.046	-.039	.204	.181	-.033	-.112	-.050	-.471*	-.214	-.040	.089	-.308	-.170	-.067	-.124	-.007	-.168	.330	.312	.026	.106	
Severity			.277	.066	-.214	-.182	-.061	.140	-.395	-.471*	.035	.104	.186	-.051	-.048	.168	.318	-.208	-.292	-.070	-.083	.221	.249	.085	.150	
Cosmetic				.203	-.299	.051	-.019	-.128	-.460*	-.367	-.216	-.113	.214	.052	-.288	.479*	.048	-.067	-.218	.007	.042	-.074	.068	.104	-.168	
Weeks of Previous Patching					-.283	-.028	.116	.344	.213	.161	.002	.146	-.347	-.095	.048	.285	-.023	-.244	.119	-.161	.243	.045	.026	.077	-.240	
Present Hours of Patching						.034	.259	.066	.247	.104	.191	-.062	-.021	.190	-.033	-.531*	-.238	-.127	.009	-.150	.229	-.074	.078	.197	-.373	
Locus of Control							-.135	.106	-.353	-.308	-.307	.035	-.211	.005	-.381	.040	-.475*	-.022	-.087	-.235	.273	-.299	-.401	-.100	.075	
HB 1 (General Health Motivation)								.122	.077	.116	.145	.009	.381	-.115	.066	-.311	.255	-.065	-.277	-.102	.110	.077	.282	.148	-.283	
HB 2 (Susceptibility)									.116	.314	.193	.038	.295	.038	.045	.106	-.134	.032	.062	-.171	.254	.089	.167	-.353	.146	
HB 3 (Specific Health Motivation)										.509*	.143	.066	-.036	.104	.334	-.024	-.013	-.049	.179	-.121	.065	.176	.109	.175	-.138	
HB 4 (Specific Health Motivation II)											.384	-.016	.164	-.067	.144	-.053	.110	.092	.302	.076	.095	-.182	-.140	-.279	.026	
HB 5 (Severity)												.207	.025	.064	.148	-.207	.171	.360	.255	.087	.232	-.139	-.036	.137	-.121	
HB 6 (Perceived Barriers)													.193	-.284	.106	.200	.097	.135	.113	-.093	.021	.078	-.054	.013	.057	
HB 7 (Treatment Efficacy)														.036	.129	-.042	.195	.088	-.017	-.051	.375	.054	.224	-.046	-.085	
Family Functioning															.283	-.236	-.310	.108	.299	.417	-.144	.042	.148	.089	.028	
Attitude Toward Child																-.239	.116	.203	.451*	.654*	-.217	.439	.208	.178	.367	
Age of Child																	.054	-.088	-.132	-.189	.051	-.141	-.193	-.042	.068	
Sex of Child																		-.194	-.259	.024	-.000	.091	.055	.059	-.076	
Number of Children																				.247	.237	-.042	-.196	-.160	-.220	.185
Parent Education																					.370	.088	-.109	-.144	-.239	.201
Public Aid																						-.591*	.079	-.067	-.273	.367
Spouse (parents in household)																							-.221	-.069	.154	-.374
Parent Satisfaction																								.840*	-.006	.251
Communication																									.140	.014
Appointment Keeping																										.670*
Patching Hours Completed																										

*p < .01

variables. The coefficients corresponding to the dependent variable are zero-order correlations. The highest correlation coefficient associated with patching hours (%) was appointment keeping ($-.670$, $p < .000$). This may be thought of as the single most important explanatory variable. Since the sign of the coefficient is negative, it indicates that, as scaled (keeping the appointment=1; not keeping the appointment=2), higher scores on patching hours (%) are associated with lower scores on appointment keeping. In other words, keeping the appointment is associated with higher degrees of compliance.

The second highest zero-order coefficient between patching compliance (%) and an independent variable is associated with parents in household ($-.374$, $p < .05$). Since the sign is negative, it indicates that, as scaled (one-parent=2; two-parent=1), higher scores on patching compliance (%) are related to lower scores on parent household. In other words, having two parents at home is associated with higher degrees of compliance than having only one parent at home.

The third highest coefficient is associated with present hours of patching ($-.373$, $p < .05$). This indicates that higher scores on patching compliance (%) are correlated with lower values of present hours of patching. That is, prescribing less patching hours is associated with greater degrees of adherence.

The final two coefficients which were significant are attitude toward child and public aid ($.367$, $p < .05$). In both of these cases higher degrees of patching compliance (%) were associated with a more positive attitude toward the amblyopic child and not being on public aid, respectively. In summary, higher scores on the dependent

variable, patching compliance (%), appear to be significantly related to keeping the appointment, a lower number of prescribed patching hours, two-parent household, a positive attitude toward the child, and not being on public aid.

In addition to the correlations between the independent variables and patching, the interrelationships among the independent variables is also noteworthy. The highest correlation among the independent variables is that between Satisfaction and Communication (.840, $p < .000$). Since the coefficient is positive, it indicates that higher satisfaction values are associated with higher communication values. The strength of this relationship implies that both of these factors may measure the same construct and may therefore lay claim to largely the same portion of variance in the dependent variable. This may present a problem of "multicollinearity" and will be discussed further in a subsequent section.

The second highest intercorrelation is represented by the relationship between attitude toward child and public aid (.654, $p < .01$). This indicates that a more positive attitude toward the child is associated with not being on public aid. As previously reported, both of these factors are also significantly correlated with the dependent variable (.367, $p < .05$). Again the problem of "multicollinearity" may be present, i.e. both variables laying claim to the same variance. Further complication is encountered when examining the correlation between public aid and parents in household (-.591, $p < .01$). This indicates that being on public aid is associated with being part of a one-parent household. This finding

would make sense in light of the fact that aid is more readily available to one-parent than to two-parent families.

The strong negative relationship between present hours and age ($-.531, p < .01$) was expected since older children are typically prescribed less patching hours than are younger children.

Although the majority of the intercorrelations among the health belief dimensions (HB 1,2,3,4,5,6,7) are insignificant, implying independence between measures, the few significant coefficients should be noted. The coefficient between HB 3 (likelihood of losing eyesight) and HB 4 (worry about the eyesight) ($.509, p < .01$) implies that these factors may overlap in what they are assessing. The coefficients for HB 7 (belief in treatment efficacy) and HB 1 (concern about general sickness) ($.381, p < .05$), and HB 5 (severity) and HB 4 ($.384, p < .05$) are also significant although to a lesser degree. Since none of these variables are correlated with patching compliance (%), interpretation of the results was not seriously complicated by these correlations.

Locus of control and sex of the child were also associated ($-.475, p < .008$) in that, an internal locus of control was more often associated with parents of girl patients than with those of boys.

The age of the child was significantly related to both having an amblyopia which was cosmetic ($.479, p < .007$) and to prescribed hours of patching ($-.531, p < .003$). In other words, the older the child, the less likelihood of the presence of a noticeable condition and the greater the number of prescribed patching hours.

HB 6 (parents' belief regarding their ability to adhere to the

patching program) was inversely related to whether or not the amblyopia was acquired or congenital. That is, parents who expressed doubt regarding their child's compliance represented conditions where the amblyopia was acquired after birth rather than present at birth.

HB 4 (parents' concern about the amblyopia) was related to severity of the amblyopia. In other words, greater concern with the child's disease was associated with greater disease severity (poor acuity).

The investigation of 24 independent variables and their relationship to patching compliance presented a problem in the present study. Due to the large number of factors, the validity of the statistical inferences which could be drawn was jeopardized. In other words, the more variables in an investigation, the more hypotheses which need to be tested. Subsequently, the more hypotheses tested, the greater the chance of occurrence of spurious significance (Type I error).

Additionally, another consideration arose. The greater the number of independent variables, the lower was the power of the test on each independent variable. Thus, having more variables when fewer may be possible increased the risks of both finding things that are not so and failing to find things that are. For these reasons, it was desirable to systematically reduce the number of factors in order to enhance the statistical validity, the power, and the clarity of the meaning of the results.

The selection of the final subset of variables was not a straight-forward process but was hampered by the constant presence of

two major problems. First, the multiplicity of influences and their representation in the measures and instruments used made the interpretation of a single factor's influence on the dependent variable difficult and uncertain. Second, the intercorrelation among the independent variables resulted in redundancy among these variables with regard to what they explained. The presence of these problems warranted the use of multiple criteria for determining the selection of pertinent variables.

Three criteria were therefore established which guided the final selection of variables. First, all factors which yielded significant zero-order correlations ($p < .05$) were selected for further analysis. Second, all factors which yielded significant Beta weights ($p < .1$) across multiple analytic strategies (stepwise regression, forward regression, backward regression) were also selected. Finally, those additional variables which have received considerable empirical support (i.e., the majority of published studies reported significant results) also qualified for inclusion. Using these criteria, those variables which yielded moderately significant and consistent results were included for further investigation in the final analysis. Table 10 presents the final subset of variables along with their status on the entry criteria.

PART II: ANALYSIS OF THE REDUCED SET OF VARIABLES

Stepwise regression analysis was used to test the hypotheses on which the second part of the study was based. Those independent

Table 10

Summary of Variables Selected for Further Analysis

Variable	Zero-Order r	Beta Weight (Stepwise Regression)	Beta Weight (Forward Regression)	Beta Weight (Backward Regression)	Empirical Support (majority of studies supporting the variable)
Appointment Keeping	-.67***	-.43***	-.43***	-.65***	--
Present Hours of Patching	-.37**	-.35***	-.35***	-.27*	yes
Spouse (Parents in Household)	-.37**	-.01	-.01	-.92***	no
Attitude Toward Child	.37**	.17	.17	.72***	no
Parent Satisfaction	.28*	.52**	.52**	-.15	yes
HB 1	-.28*	-.09	-.09	-.32**	yes
Weeks of Previous Patching	-.24	-.39***	-.39**	-.73***	no
Parent Education	.201	.04	.04	.25*	no
Locus of Control	.08	.17	.17	.80***	yes

*p < .1

**p < .05

***p < .01

variables which met the entry criteria ($p < .2$) were analyzed according to their contribution to explained variance and were thus entered into the regression equation in the following order: appointment keeping; parent satisfaction; present hours of patching; weeks of previous patching; attitude toward the child; and locus of control.

Table 11 summarizes the results of the regression. Appointment keeping was entered first because of its high zero-order correlation (.670, $p < .000$) with the dependent variable. In other words, it explained the greatest amount of variance in patching compliance (45%). The R^2 (multiple correlation coefficient) in this case is equal to the zero-order correlation (.670) and the F ratio is 22.8 ($p < .000$).

The variable parent satisfaction was entered next into the equation because it made the greatest increment to R^2 (coefficient of multiple determination) (.077), holding appointment keeping constant. The variable which made the next largest contribution over and above that made by the preceding two factors was present hours of patching (.051). The final three variables entered, in order of their increments to the variance left unexplained by the other variables were weeks of previous patching (.081), attitude toward the child (.029), and locus of control (.029). The analysis was terminated because no remaining variables made a significant contribution to R^2 .

The total variance explained with all six factors in the equation was .72 ($p < .000$). The adjusted R^2 represents a more conservative estimate of the percent of variance explained by the independent

Table 11

Summary Table for Stepwise Regression

Variable	Multiple R	R Square	Adjusted R Square	F	Signifi- cance of F	R Square Change	F of R Square Change	Signifi- cance of R Square Change
Appointment Keeping	.670	.449	.429	22.80	.000	.449	22.80	.000**
Parent Satisfaction	.725	.526	.491	14.97	.000	.077	4.38	.046*
Present Hours of Patching	.760	.577	.528	11.81	.000	.051	3.14	.088
Weeks of Pre- vious Patching	.811	.657	.603	11.99	.000	.081	5.88	.023*
Attitude Toward the Child	.829	.687	.621	10.51	.000	.029	2.23	.148
Locus of Control	.846	.715	.641	9.63	.000	.029	2.31	.142

*p < .05

**p < .01

variables and was computed as .64. As indicated by Table 11, R^2 tended to increase at each step of the analysis, though in diminishing amounts. The significance of the increment in R^2 at each step was also analyzed. According to Table 11, only appointment keeping, parent satisfaction, and weeks of previous patching made significant contributions ($p < .05$).

Table 12 displays the b weights and their corresponding standardized beta weights for each of the independent variables on the criterion variable, patching compliance. As the table indicates, appointment keeping, present hours of patching, and weeks of previous patching, were negatively and significantly associated with patching. Parent satisfaction, attitude toward the child, and locus of control, although not significant, did indicate a fairly strong positive association with the dependent variable.

As further indicated in Table 12, neither of the three remaining variables (HB 1 (General Health Motivation), parent education, spouse) had significant associations with patching compliance when the influence of all the other variables were held constant. The multiple regression equation is

$$Y = -35.53X_1 \text{ (appointment keeping)} - 3.54X_2 \text{ (present hours of patching)} - 0.15X_3 \text{ (weeks of previous patching)} + 1.30X_4 \text{ (parent satisfaction)} + 1.47X_5 \text{ (attitude toward the child)} + 1.22X_6 \text{ (locus of control)} + 51.57$$

Thus, in terms of negatively influencing patching compliance, failure to keep the following scheduled appointment was associated with a 35.53 ($p < .000$) unit decrease in the dependent variable. In other

Table 12

Summary of B and Beta Weights for Stepwise Regression

Variable	b	Standard Error of b	Beta	Standard Error of Beta	T	Significance of T	Correlation Zero-Order	Part Correlation	Partial Correlation
Appointment Keeping	-35.53	8.28	-.51**	.12	-4.30	.000	-.6700	-.4775	-.6668
Parent Satisfaction	1.30	.79	.21	.13	1.66	.111	.2813	.1847	.3271
Present Hours of Patching	-3.54	1.23	-.34*	.12	-2.87	.009	-.3735	-.3194	-.5136
Weeks of Previous Patching	-.15	.06	-.31*	.12	-2.68	.013	-.2402	-.2982	-.4878
Attitude Toward the Child	1.47	.75	.26	.13	1.94	.064	.3671	.2162	.3755
Locus of Control	1.22	.80	.19	.12	1.52	.142	.0755	.1692	.3023
HB 1	-4.26	.66	-.09	.13	-.64	.53	-.2832	-.0729	-.1452
Parent Education	.64	1.46	.07	.16	.44	.67	.2007	.0502	.1004
Spouse (Parents in Household)	-17.32	11.95	-.26	.18	-1.45	.16	-.3739	-.1652	.3155

*p < .05

**p < .01

words, patients who missed appointments were also highly likely to exhibit low compliance. Similarly, a one unit increase in present hours of patching was associated with a 3.54 ($p < .01$) unit decrease in compliance. And finally, a one unit increase in weeks of previous patching was associated with a 0.15 decrease in patching, with all other variables held constant.

Similarly, a considerable increase (one full standard deviation) in present hours of patching results in a $-.34$ ($p < .01$) standard deviation decrease in patching compliance. In other words, full-time patchers had a lower rate of compliance than those who were prescribed less hours of patching (part-time). And finally, a one standard deviation increase in weeks of previous patching was associated with a $-.31$ ($p < .01$) standard deviation decrease in patching compliance. That is, patients who had been patching for longer periods of time (e.g. 200 weeks) tended to have lower rates of compliance than those who had not been patching as long (e.g. 5 weeks).

In terms of positively influencing compliance, one unit increases in parent satisfaction, attitude toward the child, and locus of control were associated with 1.30 ($p < .1$), 1.47 ($p < .1$), and 1.22 ($p < .1$) increases in patching compliance. In summary, high compliance was related to keeping an appointment, lower number of prescribed patching hours, fewer weeks of previous patching, parent satisfaction, positive parental attitude toward the patient, and external locus of control.

The relative importance of the independent variables in determining the dependent variable is indicated by their beta weights

(Table 12) which were used to determine the following standardized regression equation:

$$Y = -0.51 X_1 \text{ (appointment keeping)} - 0.34 X_2 \text{ (present hours of patching)} - 0.31 X_3 \text{ (weeks of previous patching)} + 0.21 X_4 \text{ (parent satisfaction)} + 0.26 X_5 \text{ (attitude toward the child)} + 0.19 X_6 \text{ (locus of control)}$$

These beta weights represent the standard deviation change in the dependent variable (patching compliance) associated with a one standard deviation increase in the independent variable.

For example, with the remaining five variables held constant, a one standard deviation change in appointment keeping was associated with a -.51 standard deviation change in patching compliance. That is, hours of patching compliance tended to fall by over one-half standard deviation when the appointment was not kept. In contrast, for the other three factors, increases were more modest but in a positive direction. Considerable increases (one standard deviation) in parent satisfaction, attitude toward the child, and locus of control elicited the following increases in compliance (.21, .26, .19). We can therefore conclude that the impact of appointment keeping, present hours, and past weeks of patching, as measured in standard deviations, was greater than was the impact of satisfaction, attitude, and locus of control. Indeed, it seems that the effect of keeping an appointment on patching compliance was about two times that of parent satisfaction (.51/.21 = 2.4), attitude toward the child (.51/.26 = 2.0), and locus of control (.51/.19 = 2.7).

The residuals were examined in order to check for violations of

the regression model assumptions. The standardized residuals fell between bounds slightly larger than plus or minus two standard deviations and were positively and negatively signed with equal frequency. The probability plot of residuals showed no dramatic departure from normality, although the plot was not unequivocally normal. The pattern of residuals appeared free of abnormalities. The plot of the fit versus the residuals revealed no clear model inadequacies and seemed acceptable on the whole.

Hypotheses one, three, five, seven, and nine were designed to test the null hypothesis of no relationship between select independent variables (classified into five major categories) and patching compliance. Hypotheses two, four, six, eight, and ten were developed to test the null hypothesis that the addition of a particular select variable results in no increase in the explained variance in the dependent variable, patching compliance.

Hypotheses 1 and 2

The features of the disease (severity, congenital (duration), presence of cosmetic condition) yielded no significant correlations with patching compliance. Therefore, the null hypotheses of no relationship were not rejected. Similarly, none of these disease factors resulted in an increase in the explained variance in the dependent variables.

Hypotheses 3 and 4

The features of the treatment regimen (previous weeks of patching, present hours of patching, and appointment keeping) yielded significant relationships with patching compliance. With the

remaining variables held constant, the partial correlations were as follows: appointment keeping (-.667, $p < .00$); present hours (-.514, $p < .01$); previous weeks (-.488, $p < .01$). The null hypothesis of no linear relationship was therefore rejected. Regarding the null hypotheses of no increase in explained variance, both appointment keeping (.449, $p < .00$) and previous weeks (.081, $p < .05$) made significant increases while present hours (.051) fell slightly below the .05 level.

Hypotheses 5 and 6

Neither of the two components of the parent-physician relationship (parent satisfaction, communication) yielded significant relationships with patching compliance once the remaining variables were held constant. The null hypotheses of no linear relationship were therefore not rejected. The variable, parent satisfaction, did however account for a significant increase in the explained variance in the dependent variable (.077, $p < .05$). The null hypothesis that the addition of parent satisfaction results in no increase was therefore rejected.

Hypotheses 7 and 8

There was no relationship between parent-child characteristics (demographic, locus of control, health beliefs) and patching compliance. Therefore, the null hypotheses of no relationship were not rejected. Similarly, none of these factors accounted for an increase in the explained variance in the dependent variable.

Hypotheses 9 and 10

There was no relationship between family functioning (including

parent attitude toward the child) and patching compliance. The null hypotheses of no relationship were not rejected. With all remaining variables controlled, parent attitude was correlated with compliance. However, this correlation fell slightly below the .05 level of significance (.376, $p < .06$). Neither of these two factors resulted in an increase in explained variance.

Summary

Since the large set of independent variables under investigation increased the risk of Type I and II errors, a strategy was developed for reducing the number of factors. Three criteria (zero-order correlation, across model consistency, and empirical support) were established to guide the selection of the final set of nine variables: appointment keeping; parent satisfaction; present hours of patching; weeks of previous patching; attitude toward the child; locus of control; HB 1 (General Health Motivation); parent education; and spouse (number of parents at home).

Stepwise multiple regression was utilized in order to investigate the effects of the above selected factors on patching compliance. Variables were selected for entry into the regression equation based upon entry criteria ($p < .2$). The coefficient of multiple determination (R^2) was .715 ($p < .000$), indicating that the six variables which met the entry criteria together accounted for 72% of the variance in patching compliance. The following variables made unique contributions to R^2 : appointment keeping (45%, $p < .001$), parent satisfaction (8%, $p < .05$), and weeks of previous patching (8%, $p < .05$).

In terms of prediction, appointment keeping had the greatest influence on patching, with the other variables controlled (Beta: $-.51$). That is, a one standard deviation increase in appointment keeping was associated with a one-half standard deviation decrease in patching compliance. The next two most important predictors were present hours of patching (Beta: $-.34$) and weeks of previous patching (Beta: $-.31$). It was also noted that parent satisfaction was much less useful than originally suspected in explaining variance when the contributions of the remaining variables were considered.

CHAPTER V

DISCUSSION

This study was designed to determine those factors associated with adherence to a patching regimen and to explicate the specific nature of the interrelationships among the identified factors. In this chapter within the context of the original five categories of compliance determinants, results, implications for improving compliance and suggestions for further research are presented.

Features of the Disease

In this study features of the disease (acuity of the amblyopic eye, presence of an ocular (cosmetic) imbalance, and onset of amblyopia) were not found to be associated with patching compliance. These findings are consistent with Haynes' (1979) review of the literature which indicates that disease features were not determinants of compliance. It is particularly noteworthy, however, to examine the relationships between these factors and two of the health belief dimensions. As previously indicated by Table 10, the severity of the amblyopia was inversely related to both HB 3 and HB 4 (measures of the parents' belief regarding the severity of the amblyopia). This indicates that the actual severity of the amblyopia was consistent with the parents' belief regarding its severity. This has not, however, always been found to be the case. At least one study (Becker, 1979) has reported a discrepancy between actual severity

of diseases and patients' perceived severity. The fact that this discrepancy does not exist in this particular clinic implies that parents are receiving information which is accurate regarding disease severity.

Another finding which deserves special attention is the significant relationship found between these same two health belief dimensions and the presence of a noticeable (cosmetic) ocular imbalance. This finding indicates that having a noticeable symptom is associated with stronger parental beliefs regarding disease severity. It is probable then, that the imbalance served as a constant reminder to the parents of the presence of amblyopia and facilitated their strong belief in the severity of the disease. Intuitively, we might suspect that the presence of this symptom would "cue" both parent and child into better adherence since it would serve as a constant reminder of the need to patch. This however, was not found to be the case in the present study. It may be fruitful for future studies to further investigate the role of symptoms in health care.

Features of the Treatment Regimen

Features of the treatment regimen (present hours, previous weeks of patching, and appointment keeping) were found to be strongly correlated with patching compliance. The results indicated that appointment-keeping was most strongly associated with adherence to the patching regimen. In fact, it was highly likely that parents and patients who failed to keep their subsequent appointments were either not patching at all or were patching too little to benefit from the regimen. Since keeping an appointment is a form of compliance, it

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Features of the Treatment Regimen

Features of the treatment regimen (present hours, previous weeks of patching, and appointment keeping) were found to be strongly correlated with patching compliance. The results indicated that appointment-keeping was most strongly associated with adherence to the patching regimen. In fact, it was highly likely that parents and patients who failed to keep their subsequent appointments were either not patching at all or were patching too little to benefit from the regimen. Since keeping an appointment is a form of compliance, it

seems that low compliance for one aspect of a regimen may indicate low compliance for other aspects, and vice versa. It seems unlikely therefore, that patients who miss their appointments are complying with other aspects of the regimen. All things considered, it appears that appointment keeping is a good predictor of patching compliance. In fact, knowledge of this one variable may allow physicians to make reasonably reliable guesses as to which patients are not improving due to noncompliance. Appointment keeping also helps explain patching behavior. That is, 45% of the variability in patching compliance can be accounted for by appointment keeping. This does not mean, however, that a causal relationship exists. In fact, since compliance is recorded prior to the assessment of appointment keeping, the case for a causal explanation is even less tenable.

At least two possibilities exist for explaining this strong relationship between keeping an appointment and adherence to the patching regimen. First, if parents knew ahead of time that they were not going to keep the next appointment, patching compliance could be adversely affected. Support for this view is provided by Ashburn (1980) who found that the use of eyedrops for glaucoma therapy increased prior to clinic visits. If this finding can be generalized to patching therapy, then parents who know ahead of time that they will not be keeping their next appointment will not increase their patching behavior as a result of the appointment. Although this explanation is tenable, it fails to explain the patching behavior of those who kept their scheduled appointments and still failed to comply. Second, it may be the case that the same underlying factor or

construct is responsible for both behaviors. In this case it would be incorrect to say that appointment keeping "explained" patching since the same factor would actually be responsible for both. Although appointment keeping is a powerful predictor of noncompliance, it does not completely explain this behavior.

Present hours of patching (the number of hours prescribed by the physician) was found to be inversely related to patching compliance. In other words, full-time patchers patched proportionately less than those patients who were prescribed fewer hours. At least two explanations may help to account for these results. First, a part-time patching regimen (two to six hours) allows for some flexibility. In this case, the times when the patching is actually done can, to some extent, be negotiated between parent and child and this in itself may facilitate patching compliance. With full-time patchers, there is no opportunity for negotiation since all waking hours are typically patched.

Second, age of the patient was highly negatively correlated with present hours of patching ($r = -.531, p < .01$). This finding is not unexpected since due to the demands of the disease and the difficulty in getting patients to patch in school, younger children (less than five years of age) are usually prescribed more hours than are older patients. Studies (Becker, 1977; Levav, 1976) have shown that older children tend to have higher compliance rates than younger ones. This may help explain why fewer prescribed hours, since they are generally associated with older patients, have higher compliance rates.

Whatever the explanation is for the relationship between present hours

of patching and compliance, it is clear that high rates of patching compliance are more difficult to obtain for patients who are prescribed larger numbers of patching hours.

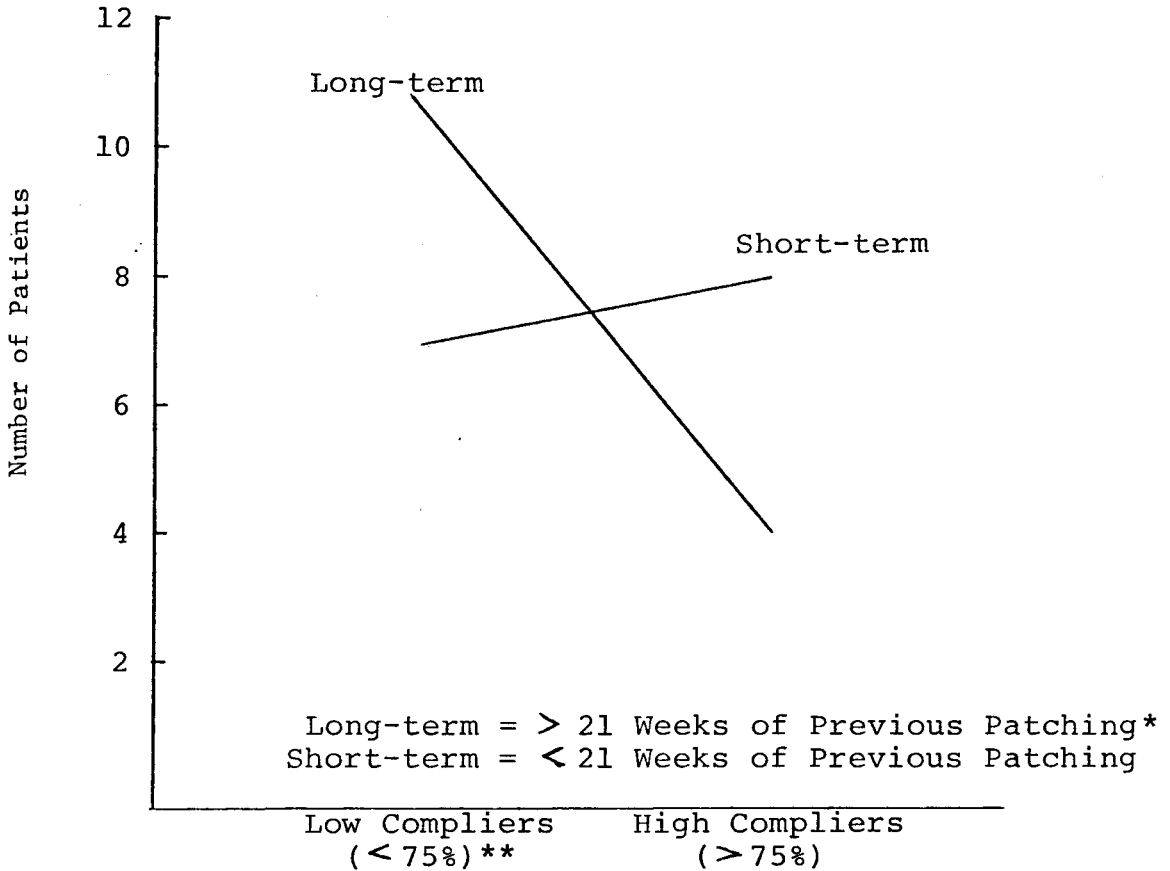
Weeks of previous patching is also an important correlate of patching compliance. Patients who have been patching for a long period of time tended to have lower rates of compliance.

Figure 1 presents a graph which represents compliance among long-term (patients who have been patching for longer than 21 weeks) and short-term patchers (patients who have been patching for less than 21 weeks). As indicated by the graph, the long-term group tends to be overrepresented by low compliers, whereas the short-term group appears to be evenly divided between high and low compliers. In effect, knowing that a patient has been patching for a short period of time is not helpful in determining his rate of compliance. However, knowing that the patient has been patching for an extended period of time is predictive of noncompliance.

It could be that weeks of previous patching is partially the result of poor compliance since patients who do patch consistently are likely to improve and terminate the regimen. On the other hand, some patients who currently report non-adherence may be those who have been on the patching regimen for a longer period of time primarily as a result of this noncompliance. The importance of this variable then is in its use as a predictor of chronic noncompliance rather than as an explanation of patching behavior.

Parent-Clinician Relationship

The influence of the parent-clinician interaction factors (parent



* This value is based on the median in order to minimize the influence of extreme values.

** This value is based on the physician's estimate of a cut-off value, above which, good compliance will likely occur.

Figure 1. Patching compliance among long-term and short-term patients.

satisfaction, communication) on patching compliance is less clear than previous studies have indicated. Although parent satisfaction was the second most important variable in the stepwise analysis, its influence was considerably reduced when other variables were taken into account. This implies that satisfaction is related to and influenced by a number of other factors. In fact, Ware (1977) found that numerous characteristics of physicians and medical care services influence patient satisfaction. Some of these include doctor friendliness, cost, and clinic atmosphere.

In this particular study, the quality of the communication experienced by the parent was highly related to satisfaction ($r = .84$, $p < .000$). In fact, communication accounted for a full 76% of the variability in parent satisfaction. This strongly implies that the clarity of the physician's instructions and the degree to which the doctor is willing to listen to parents and carry on an active exchange with them, influences parent satisfaction and subsequent compliance.

Similarly, parent satisfaction was also found to be related to an internal locus of control ($r = -.30$). That is, parents who reportedly felt they had control over most health matters were more likely to express satisfaction with their physician. Although this is not to imply causality, it is reasonable to assume that believing in one's control of the environment (and especially their child's health) could result in a greater satisfaction with physicians. Other factors which were moderately correlated with satisfaction include: whether or not the condition was present at birth ($r = .33$); having a spouse at home ($r = .22$); and having a positive attitude toward the child ($r = .44$,

$p < .05$). It would appear then, that parent satisfaction is multidimensional in nature and is influenced by numerous factors, both general and specific. Ware's (1977) report that patient satisfaction ratings are directly related to general life outlook and economic sentiment as well as to factors inherent in the patient-physician relationship lends support to the results of this study. The direction of causality in these relationships, however, is not known, and there are probably plausible arguments for effects in both directions.

This is not to say, however, that parent satisfaction is unimportant. It is fair to say that satisfaction does influence subsequent patching compliance but that it may not be entirely determined by the quality of the patient-physician relationship. It may in fact be equally as important to examine background and experiential factors of parents of amblyopic children in order to sensitize physicians to variables which may either facilitate or debilitate the parent-physician relationship. Some of the variables supported by this investigation include: the degree to which parents perceive that they have control over their child's health (locus of control); the support system parents have at home; and the parent's attitude toward their child and life in general. In this way, the focus on enhancing patient compliance will include not only parent-physician interaction factors, but life and family factors as well.

In summary, parent satisfaction initially appeared to account for a significant amount of variance in patching compliance. Although

this is still the case, a closer examination of the interrelationships among the satisfaction correlates reveals parent satisfaction to be more complex than originally thought. Instead of perceiving satisfaction to be totally determined by the quality of the parent-physician relationship, it now appears to be multidimensional in nature, and it would therefore be unfair to hold medical personnel totally accountable for parent dissatisfaction.

The variable communication, as previously discussed, was found to be only weakly associated with patching compliance. Its value, however, lies in its strong association ($r = .84$) with parent satisfaction. Communication appears to be one of the major factors influencing parents' reported satisfaction or dissatisfaction with the physician. The parents' perception of whether or not the physician provided them with adequate information, answered their questions, and actively listened to their concerns, was used as the criterion variable because it tended to be more comprehensive than reported in most other studies. Most studies of communication have tended to focus only on the transfer of information from the physician to the patient and the amount of information retained by the patient after the clinic visit. Previous investigations have not typically assessed the listening skills of physicians and the degree to which the patient and physician carried on a two-way conversation. Since this type of interchange would tend to be more conversational in nature and involve the patient to a greater degree, it would also seem as if it should enhance overall satisfaction with the physician. It is not surprising then that communication and satisfaction were found to be highly

related in the present investigation. In summary, it seems that communication between parent and physician is an important component of parent satisfaction and thus deserves additional attention.

Parent/Child Characteristics

The parent-child characteristics which were investigated included demographic factors, locus of control, and health beliefs. As indicated by the results, demographic variables were not significantly associated with patching compliance. This finding is consistent with those from the majority of past studies. As will be discussed later however, demographic variables do appear to exert an influence on those factors which do affect compliance.

Parent health beliefs on the whole were not associated with patching compliance. These results are similar to the findings reported by Taylor (1979). He found that health beliefs related to hypertension and its treatment that were assessed before the initiation of drug treatment for hypertension, did not predict compliance six and twelve months later. However, health beliefs expressed six months after initiation of therapy were found to be consistent with compliance measured at the same point in time, and also predicted subsequent (twelve-month) compliance. It may be the case then that health beliefs, instead of preceding and determining patching compliance, develop along with compliance behavior as a result of experience with the amblyopia and patching regimen.

Another possible reason for the failure of health beliefs to emerge as determinants of patching adherence is related to the theory upon which the health belief dimensions are based. The Health Belief

Model posits that the individual's psychological state of readiness to take action is determined by the perceived severity of the consequences of contracting the condition. In addition, the model also posits that a stimulus or cue (e.g. a reminder of the presence of the disease or a form of fear arousal) must occur to trigger the appropriate health behavior. In this study, it is possible that the consequence of contracting amblyopia (i.e., loss of acuity) was not perceived as being that severe. In fact, only 23% of the parents stated that they felt that the amblyopia posed a serious threat to their child's vision. Secondly, a cue (in this case a cosmetic condition) was present in only one-half of the patients. Therefore, due to the absence of cues to trigger action and the fact that a child, by using his/her good eye, could still retain acceptable vision despite the loss of acuity of the amblyopic eye, the Health Belief Model may not have been an appropriate framework for explaining patching compliance.

One exception to these nonsignificant relationships is the association between HB 2 (parents' perception of how easily their child gets sick) and appointment keeping. As the results indicated, HB 2 was significantly correlated with appointment keeping ($r = -.353$, $p < .05$), i.e., parents who were more concerned with their child's susceptibility to illness were also more likely to keep their appointments. The fact that HB 2 was related to appointment keeping but not to patching compliance seems to indicate that parents who are concerned with their child's susceptibility will get their child to the physician but will not necessarily comply with treatment

recommendations. It may be the case that at least some of the parents feel that their responsibility for their child's health care ends with bringing the child to the doctor. The commitment of parents to supervise and take responsibility for their child's health care may require stronger beliefs and/or attitudes than can be assessed by an attitude instrument.

Locus of control beliefs among parents were not associated with patching compliance. In fact, the direction of the relationship which was expected, based upon theory, was reversed. That is, an internal locus of control, which has been documented to be associated with higher compliance, was actually related to lower adherence. A possible explanation for this seemingly contradictory result is that the instrument (Health Locus of Control Scale) did not adequately assess the underlying construct. A cursory analysis of the subjects' individual responses to the items revealed some response inconsistencies in the case of negatively worded items. Some parents tended to respond "strongly agree" to a particular item and then also respond "strongly agree" to a similar item which was negatively worded. This strongly implies that the negative wording may have confused at least some of the parents, thus resulting in attitudes/scores which cancelled themselves out. Future studies should improve the validity of this scale and determine better ways to assess locus of control.

Family Characteristics

As the results indicate, family functioning, as measured by the Family Functioning Index (FFI), was not found to be associated with

patching compliance. One possible reason for this lack of significance is the fact that the FFI was standardized on a population consisting almost entirely of two-parent households, whereas one-third of the families in this study represented one-parent households. For this reason, the FFI may not have been sensitive to or designed to assess family functioning in those households with only one parent.

The second aspect of family functioning, parental attitude toward the child (e.g., getting along with the child, deriving enjoyment and satisfaction from the child), fell slightly short ($p < .06$) of the .05 level of significance. This lack of significance was most probably due to its correlation with parent satisfaction (.439, $p < .05$), and the subsequent sharing of common variance. Since parent satisfaction was entered into the equation prior to attitude, the variance it shared with attitude was attributed solely to parent satisfaction. This may have resulted in an underestimation of the "true" contribution of parental attitude toward the child, to patching compliance. Nevertheless, parental attitude, although not statistically significant, appears to play an important role in pediatric compliance.

A mother who feels that she gets along well with her child and derives satisfaction from caring for him/her is more likely to adhere to a patching regimen than is a mother who harbors more negative feelings toward her child. The fact that the mother's attitude is an important determinant of pediatric compliance is not surprising. However, the fact that this attitude plays a more important role in influencing compliance than do demographic factors, disease features,

health beliefs, and family functioning in general, is a tribute to the importance of the mother-child relationship in pediatric health care.

In order to more fully understand the construct, parental attitude toward the child, it is necessary to examine its interrelationships with other relevant variables. In this way, an explanatory framework for studying pediatric health care can begin to develop.

One particularly pertinent variable, parent education, was only weakly correlated with the dependent variable. However, it was significantly related to attitude toward the child. In other words, more years of schooling was positively associated with a more positive attitude and accounted for a significant portion of the variance. This finding is not totally surprising since increased education typically results in the acquisition of life skills such as child care, health care, and interpersonal skills. These acquired skills would therefore tend to enhance the overall mother-child relationship.

A strong relationship also exists between attitude toward the child and receiving public aid ($r = .654, p < .01$). In other words, a positive attitude toward the amblyopic child was highly related to not being on public aid. The finding that an equally strong relationship exists between receiving public aid and being in a one-parent household ($r = -.591, p < .01$) further complicated this relationship. Therefore, receiving public aid was associated both with being from a one-parent household and having a less positive attitude toward the child.

It is not possible to determine causality from these

relationships except in the possible association between number of parents at home and public aid. Since a one-parent household is more likely to qualify for public assistance, a weak causal explanation may exist for at least some cases. Both of these variables could be argued to be at least indirectly related to the parents' economic sentiment and general life outlook, and at least one investigator (Ware, 1977) feels that these sentiments color the way people look at life in general. It would not seem unreasonable to presume then that a poor life condition could affect the way parents feel about their child, and in turn, could help determine patching noncompliance.

Summary

From the findings discussed above, features of the treatment regimen (previous weeks and present hours of patching, and appointment keeping) appear to be powerful predictors of noncompliance. Because these factors reportedly affected compliance behavior as well as being affected by it, the direction of causality is unclear at best. For this reasons, they do not completely explain this health behavior. In addition, because these features are also determined by static attributes such as depth of amblyopia and patients' age, they are typically accepted as nonmanipulable "givens" by health care professionals. This lack of explanatory power and nonmanipulability, makes these treatment variables not amenable to manipulation and intervention.

Parent satisfaction and parental attitude toward the child, on the other hand, are influenced by static factors as well as by factors which are more amenable to modification. Parent satisfaction was

found to be associated with an internal locus of control and good parent-physician communication, while parental attitude appeared to be positively influenced by parent education. In summary, both parental attitude and satisfaction are not simply determined but appear to be influenced by features of the parent-physician interaction as well as by life-circumstances and sentiments.

CHAPTER VI

SUMMARY AND CONCLUSIONS

Amblyopia in pediatric patients is a difficult disease to manage because treatment success is largely dependent upon adherence to an eye patching regimen. Compliance with regimens in general, typically occurs in only one-third of the reported cases. Thus it is important to identify those factors which help determine patching compliance or noncompliance.

This study was concerned with specifying those variables associated with patching compliance, and the elucidation of their interrelationships and their effect on compliance.

Method

The following factors which might be associated with patching compliance were identified from a review of the literature: features of the disease and treatment regimen; features of the parent-physician relationship; and characteristics of the patient, parent, and family. Appropriate instrumentation was selected or designed for data collection relative to this research study.

Parents of 30 pediatric amblyopia patients who attended the motility clinic of the Eye and Ear Infirmary of a major university during a four month period were selected for the study. Selection was limited to those patients who were currently patching or beginning a patching program (ocular occlusion) and whose condition was uncomplicated by other eye diseases.

Each parent completed the following instruments: Health Locus of Control Scale; Health Belief Indices; Parent Judgment Regarding a Particular Child Scale; Family Functioning Index; Satisfaction and Communication Scales; Expectations Question; and the Parent Interview Questionnaire.

The dependent variable, patching compliance, was assessed by one of three instruments depending upon the availability and accuracy of the information. Patch Box Data was used to assess patching compliance in all cases where the patch box and the recorded patch usage information were returned. Parent Estimate was the method of choice in those remaining cases where the estimate was less than 25 percent. The remaining cases were assessed by Verbal Patch Usage.

Stepwise multiple regression was the primary analytic procedure used. The 26 independent variables were entered into the primary analysis using patching compliance as the dependent criterion variable. The R^2 increase was used to estimate both the contribution of the entire set of independent variables and the contribution of each variable to the explained variance in patching. Standardized partial regression coefficients (beta weights) were used as estimates of the unique contribution of each variable with the influence of all other variables held constant.

Results

Due to the large number of variables under investigation, the interpretation of their contribution to explained variance was unduly complicated. Three criteria (zero-order correlation, across model consistency, and empirical support) were therefore established to

reduce the number of factors and guide the selection of the final set of variables. This final set included: appointment keeping; parent satisfaction; present hours of patching; weeks of previous patching; attitude toward the child; locus of control; HB 1 (general health motivation); parent education; and spouse (number of parents at home).

Stepwise multiple regression was utilized in order to investigate the effects of the above selected factors on patching compliance. Variables were selected for entry into the regression equation based upon entry criteria ($p < .2$). The coefficient of multiple determination (R^2) was .715 ($p < .000$), indicating that the six variables which met the entry criteria together accounted for 72% of the variance in patching compliance. The following variables made unique contributions to R^2 : appointment keeping (45%, $p < .001$), parent satisfaction (8%, $p < .05$), and weeks of previous patching (8%, $p < .05$).

In terms of prediction, appointment keeping had the greatest influence on patching, with the other variables controlled (Beta: .51). That is, a one standard deviation increase in appointment keeping was associated with a one-half standard deviation increase in patching compliance. The next three most important predictors were present hours of patching (Beta: $-.34$), weeks of previous patching (Beta: $-.31$) and attitude toward the child (Beta: $.26$). It was also noted that parent satisfaction was much less useful than originally suspected in explaining variance when the contributions of the remaining variables were considered.

Conclusions and Recommendations

Features of the treatment regimen (previous weeks and present hours of patching, and appointment keeping) are powerful predictors of noncompliance. Because these factors affect compliance as well as being affected by it, the direction of causality is unclear at best. For this reason, they do not completely explain this health behavior. In addition, because these features are also determined by static attributes such as depth of amblyopia and patients' age, they are typically accepted as nonmanipulable "givens" by health care professionals. This lack of explanatory power and nonmanipulability, makes these treatment variables not amenable to manipulation and intervention.

Parent satisfaction and parental attitude toward the child, on the other hand, are influenced by static factors as well as by factors which are more amenable to modification. Parent satisfaction is associated with an internal locus of control and good patient-physician communication, while parental attitude is positively influenced by parent education. In summary, both parental attitude and satisfaction are not simply determined but are influenced by features of the parent-physician interaction as well as by life circumstances and sentiments.

Although parent satisfaction with the physician is not solely determined by the therapeutic relationship, the physician does play an important role as a facilitator of pediatric health care. That is, the two factors which appear to directly influence parent satisfaction, internal locus of control and communication, are to some

degree within the physician's control. For example, the parent's perception that the doctor communicated clearly, answered the parent's questions, and indicated a willingness to carry on a conversation with them, is determined primarily by the interpersonal skills of the physician. This would indicate a need to develop interventions designed to facilitate this communication between doctor and parent. Kirscht (1977) and Komaroff (1976) have been fairly successful in enhancing patient-physician communication and point toward a need to equip doctors and medical students with better interpersonal skills vis a vis medical and continuing medical education. The other construct which appears to be amenable to modification is locus of control. Although one's locus is based upon past experiences with expectancies and reinforcement, studies (Schachat, 1975; Green, 1975) have shown locus of control beliefs to be modifiable by direct training and re-education. Parents who are taught to behave more internally in health matters will hopefully take more responsibility for their children's health care. In summary, the physician can positively influence parent satisfaction through his/her role as communicator and teacher and thus enhance overall pediatric compliance.

Future research could benefit pediatric health care by identifying those specific aspects of education which directly influence child health care and which are particularly amenable to instruction and training. Specification of these pertinent aspects could then be implemented into programs designed to enhance not only patching compliance but pediatric compliance in general.

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APPENDIX A

APPENDIX A

Variable Coding

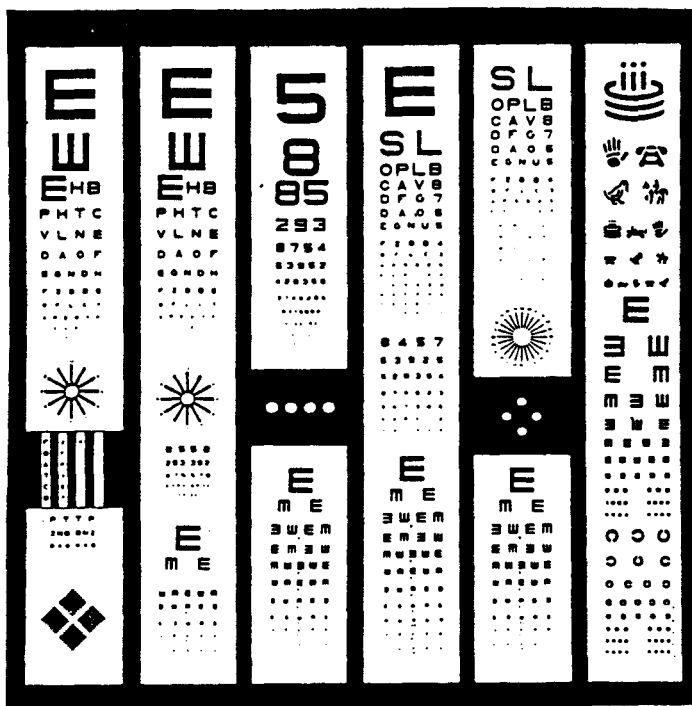
Instrument	Quantification/Coding
H.O.T.V., E-Game, Snellen	20/20-20/40 = Good (code=3) 20/41-20/70 = Fair (code=2) over 20/100 = Poor (code=1)
Age of Onset	Congenital = 2 Acquired = 1
Noticeable Ocular Imbalance	Cosmetic = 1 Not Cosmetic = 2
Number of Weeks of Previous Patching	0 - 250
Number of Daily Patching Hours Prescribed	1 - 12
Satisfaction Scale	5 - 25
Communication Scale	4 - 20
Expectations	Expectations Met = 1 Expectations Not Met = 2
Parent Education (Highest Grade Completed)	0 - 20
Public Aid Status	On Public Aid = 1 Not On Public Aid = 2
Age of Child	0 - 15
Sex of Child	Male = 1 Female = 2
Number of Children at Home	1 - 6
Parent Household	One-parent = 1 Two-parent = 2
Health Locus of Control Scale	13(internal) - 65(external)
Health Belief Indices	7 Indices Each Measured Along a Scale of 1 - 5

Instrument	Quantification/Coding
Family Functioning	0 - 35
Appointment Keeping	Appointment Kept = 1 Appointment Not Kept = 2

APPENDIX B

APPENDIX B

HOTV



Snellen Eye Chart and E-Game

actual size ↓	LETTERS FOR 10 FEET by OTTO LIPPMANN M.D. FOR VERY YOUNG CHILDREN						20 ft. equivalent ↓
$\frac{10}{100}$	O		V				$\frac{20}{200}$
$\frac{10}{50}$	H	V	O	T			$\frac{20}{100}$
$\frac{10}{35}$	T	H	O	V	H		$\frac{20}{70}$
$\frac{10}{25}$	V	O	T	H	O	V	$\frac{20}{30}$
$\frac{10}{20}$	H	T	O	V	T	H	$\frac{20}{40}$
$\frac{10}{15}$	O	H	V	T	H	O	$\frac{20}{30}$
$\frac{10}{10}$	T	V	H	O	V	T	$\frac{20}{20}$

APPENDIX C

APPENDIX C

Physician Questionnaire
Data to be completed
by the Physician

Please check your status First year resident
 Second year resident
 Fellow
 Attending
 Orthoptist

Acuity of the Amblyopic eye _____

Is this condition _____ congenital or _____ acquired?

 If acquired, what is the age of onset? _____

Does this patient have Strabismus _____ (yes or no)?

Is it cosmetic _____ (yes or no)?

Number of weeks of previous patching _____

Number of hours of patching per day prescribed at this visit _____

APPENDIX D

APPENDIX D

Satisfaction and Communication Scale

FOR EACH STATEMENT PLEASE CIRCLE THE RESPONSE WHICH MOST CLOSELY REFLECTS YOUR OPINION

SA (strongly agree) A (agree) N (neither agree/disagree)
D (disagree) SD (strongly disagree)

1) I don't think I would recommend this doctor to a friend.

SA A N D SD

2) I really like this doctor a great deal.

SA A N D SD

3) I don't like this doctor very much as a person.

SA A N D SD

4) This doctor is the nicest person I have ever known.

SA A N D SD

5) I wish I could stay with this doctor and never have to change.

SA A N D SD

6) This doctor explained perfectly to me everything I could ever want to know about my child's medical condition.

SA A N D SD

7) During the examination, this doctor hardly ever tells me what he/she is doing.

SA A N D SD

8) This doctor doesn't give me a chance to say what is on my mind.

SA A N D SD

9) This doctor listened to everything I had to say.

SA A N D SD

PLEASE ANSWER NUMBER 10 IF THIS IS YOUR FIRST VISIT REGARDING THIS PROBLEM, OTHERWISE ANSWER NUMBER 11.

10) I expected to learn the nature or cause of this problem.

SA A N D SD

IF YOU ANSWER NUMBER 10 PLEASE RESPOND (YES OR NO) TO THE FOLLOWING QUESTION: Did you learn the nature or cause of this problem?_____

11) I expected to learn the progress that was made since my last appointment.

SA A N D SD

IF YOU ANSWER NUMBER 11 PLEASE RESPOND (YES OR NO) TO THE FOLLOWING QUESTION: Did you learn the progress that was made since your last appointment?_____

APPENDIX E

APPENDIX E

Parent Interview Questionnaire

PLEASE COMPLETE THE FOLLOWING INFORMATION

Your relationship to this child _____ (for example, mother, guardian)

Age of child attending this clinic _____

Sex of child _____ (boy or girl)

Number of children living at home _____

Highest grade completed by you _____ (for example, 8th grade, 9th grade)

Are you receiving public aid? _____ (yes or no)

Is your spouse living at home? _____ (yes or no)

IF YOU ANSWERED "no" TO THE LAST QUESTION, PLEASE ANSWER ONLY THE QUESTIONS MARKED WITH A *.

IF YOU ANSWERED "yes" TO THE LAST QUESTION, PLEASE ANSWER ALL QUESTIONS ON PAGES 5 THROUGH 8.

PLEASE TURN TO THE NEXT PAGE AND
AND BEGIN ANSWERING THE QUESTIONS

APPENDIX F

APPENDIX F

Health Locus of Control Scale

FOR EACH STATEMENT PLEASE CIRCLE THE RESPONSE WHICH MOST CLOSELY REFLECTS YOUR OPINION.

SA (strongly agree) A (agree) N (neither agree nor disagree)
D (disagree) SD (strongly disagree)

1) Staying well has little or nothing to do with chance (luck).

SA A N D SD

2) Anyone can learn a few basic health rules that can go a long way in preventing illness.

SA A N D SD

3) People's ill health results from their own carelessness.

SA A N D SD

4) There is little one can do to prevent illness.

SA A N D SD

5) I have a lot of confidence in my own ability to cure myself once I get sick.

SA A N D SD

6) Whether or not people get well is often a matter of chance (luck).

SA A N D SD

7) When it comes to health, there is no such thing as "bad luck."

SA A N D SD

8) In the long run, people who take good care of themselves stay healthy and get well quick.

SA A N D SD

9) Recovery from illness has nothing to do with luck.

SA A N D SD

10) Healthwise, there isn't much you can do for yourself when you get sick.

SA A N D SD

11) "Taking care of yourself" has little or no relation to whether you get sick.

SA A N D SD

12) If I get sick, it's really my own fault.

SA A N D SD

13) Good health is largely a matter of luck.

SA A N D SD

APPENDIX G

APPENDIX G

Health Belief Indices Scale

FOR EACH STATEMENT PLEASE CIRCLE THE RESPONSE WHICH MOST CLOSELY REFLECTS YOUR OPINION

SA (strongly agree) A (agree) N (neither agree/disagree)
D (disagree) SD (strongly disagree)

1) I am very concerned about the possibility of my child getting sick.

SA A N D SD

2) My child gets sick easily.

SA A N D SD

3) It is very likely that my child could lose his/her eyesight.

SA A N D SD

4) I worry about my child's eyesight.

SA A N D SD

5) My child's eye condition is very serious.

SA A N D SD

6) It will be very difficult to get my child to wear the patch.

SA A N D SD

7) I believe that patching the eye will improve my child's eyesight.

SA A N D SD

APPENDIX H

APPENDIX H

Family Functioning Questionnaire

*1. What sorts of things do you do as a family

a. In the evenings-

b. On the weekends-

c. On vacations-

(Put a check in the box corresponding to your choice)

*2. How do you think the children get along together compared with other families? (Disregard if only one child.)

better same worse

3. Do the children find it easy to talk to their father about their problems?

yes sometimes no

4. Do you find your husband an easy person to talk to when something is troubling you?

yes sometimes no

5. Is your husband able to spend a lot of time with the children in the evening?

yes sometimes no

6. Is your husband able to spend a lot of time with the children on the weekend?

yes sometimes no

*7. Would you say, all in all, that your family is happier than most others you know, about the same, or less happy.

happy same less
happy

*8. What would you say was the most important problem you as a family had to deal with this last year?

a. Was a solution arrived at?

yes no

b. Did you discuss the problem with your husband?

yes no

c. Was everyone satisfied with the solution?

yes no

FOR EACH QUESTION BELOW (a-h), SELECT A RESPONSE FROM THE FOLLOWING CHOICES:

- 1=Husband always
- 2=Husband more than wife
- 3=Husband and wife exactly the same
- 4=Wife more than husband
- 5=Wife always

- a. Who usually makes the final decision about what kind of car to get?_____
 - b. Whether or not to buy some life insurance?_____
 - c. What house or apartment to take?_____
 - d. What job your husband should take?_____
 - e. Whether or not you should go to work or quit work?_____
 - f. How much your family can afford to spend per week on food?_____
 - g. What doctor to have when someone is sick?_____
 - h. Where to go on vacation?_____
10. Thinking of marriage in general which one of these five things would you say is the most valuable part of marriage? (Write in the number corresponding to your choice, using each number only once.)

- 1=The chance to have children
- 2=The standard of living - the kind of house, clothes, car and so forth
- 3=The husband's understanding of the wife's problems and feelings
- 4=The husband's expression of love and affection for the wife
- 5=Companionship in doing things together with the husband

- a. the most valuable part in marriage
- b. the next most valuable
- c. third most valuable
- d. fourth most valuable
- e. fifth most valuable

11. Of course, most couples differ sometimes over things, when you and your husband differ about something, do you usually give in and do it your husband's way or does he usually come around to your point of view? Husband's way 50/50 Wife's way
- *12. Would you say disagreements in your household come up more often, about the same, or less often than in other families you know? More Often Same Less Often
- *13. Would you say that compared to most families you know, you feel less close to each other, about the same or closer than other families do? Less Close Same Closer
- *14. The following are some feelings you might have about certain aspects of marriage. (Write in the number corresponding to your choice.)
- 1=Pretty disappointed. I'm really missing out on that
2=It would be nice to have more
3=It's all right, I guess - I can't complain
4=Quite satisfied - I'm lucky the way it is
5=Enthusiastic - it couldn't be better
- a. How do you feel about your standard of living, the kind of house, clothes, car and so forth?
- b. How do you feel about the understanding you get of your problems and feelings?
- c. How do you feel about the love and affection you receive?
- d. How do you feel about the companionship of doing things together?
15. When your husband comes home from work, how often does he talk about things that that happened there? Very Often Sometimes Never

APPENDIX I

APPENDIX I

Parent's Judgment Regarding a Particular Child Scale

Please place a check in front of whichever of the alternative choices most nearly resembles your own feeling regarding the child attending this clinic.

1) It is necessary to punish this child...

- Very Frequently
- Quite Often
- Sometimes
- Seldom
- Never

2) I find myself becoming angry at this child...

- Very Frequently
- Quite Often
- Sometimes
- Seldom
- Never

3) I feel that I get along with this child...

- Very Well
- Well
- Fairly Well
- Not Very Well
- Poorly

4) This child gets on my nerves...

- Frequently
- Quite Often
- Sometimes
- Seldom
- Never

5) I get...

- Very much satisfaction from this child
- Considerable satisfaction from this child
- Some satisfaction from this child
- Very little satisfaction from this child
- No satisfaction from this child

APPENDIX J

APPENDIX J

PATCH BOX DATA

Please record, on the other side, the total number of hours that each patch was used. If the same patch was used at different times, record the total number of hours that patch was used. Please bring this box to your next appointment. We will return the remaining patches to you at no charge. If your supply of patches runs out, record that data, but still bring your box with you to your next visit.

Please record the total number of hours each patch is used

Date your supply of patches ran out _____

APPENDIX K

APPENDIX K

Parent Interview Questionnaire II

PLEASE INDICATE (with a check) WHICH PROBLEMS YOU HAD WITH THE PATCHES.

- Caused skin irritation _____
- Did not stick _____
- Difficult to put on _____
- Child refused to wear _____
- Child tore them off _____
- Difficult to remember to put them on _____
- Supply ran out _____
- Other (please explain) _____
- Other (please explain) _____
- Other (please explain) _____

All problems considered, please estimate the average number of hours per day that the patches were worn by your child _____

How many hours of patching per day were prescribed by your physician? _____

Has your child changed his/her daily activities because of the patches? _____ (yes or no)

If yes, please explain _____

Was the previous appointment kept? _____ (yes or no)

(NOTE: Check this with chart information)

APPROVAL SHEET

The dissertation submitted by Hans Joachim Wolff has been read and approved by the following committee:

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The final copies have been examined by the director of the dissertation and the signature which appears below verifies the fact that any necessary changes have been incorporated and that the dissertation is now given final approval by the Committee with reference to content and form.

The dissertation is therefore accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

December 1, 1983
Date

Anne M. Juhasz
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