Compliance and Chronic Disease

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SUMMARY The shifting demographics of the population and increasing skill in treatment of chronic disease in this country have combined to make compliance a topic of greater salience than ever before. General issues of compliance are a necessary background to specific issues of compliance with regimens for single diseases such as hypertension. The definition of compliance continues to be modified, and examination of past work reveals certain consistencies in studies of compliance. Noncompliance is higher in chronic conditions, in activities requiring change in life-style, and in clinician-initiated visits. Noncomprehension of instructions is held to be the most frequent cause of noncompliance. Noncompliance is a threat to the course of treatment, increases unnecessary diagnostic procedures, and confounds evaluation of effectiveness. Factors related to compliance have been identified with regard to certain patient and disease characteristics, amount of support in the immediate environment, and the nature of the doctor-patient relationship. Older patients are often at greater risk in understanding regimens because clinicians educate this group less often, because symptoms are misunderstood by both patient and provider, and because of greater complexity in both conditions that are being treated and number of drugs and other aspects of treatment required. Methods of improving the doctor-patient relationship have been urged most recently as a means through which compliance can be increased. (Hypertension 11 [Suppl II]: II-56-II-60, 1988)

KEY WORDS • compliance • elderly • chronic disease • doctor-patient relationships

THE formidable success of the health care system in the control of infectious disease makes it certain that ongoing emphasis will be on the improvement, maintenance, rehabilitation, and palliation of chronic conditions. Further, this particular focus in health care will be relevant for an increasing number and proportion of the population and over longer periods of time. The changing epidemiological picture ensures that we will continue to keep a greater number of chronically ill people alive for longer periods. 1-3 This has implications not only for clinical practice but for research, teaching, and policy and planning. In clinical practice and in research, particularly, the accelerating concentration on chronic disease and its treatment makes the consideration of compliance unavoidable as a crucial issue in care and its evaluation.

This report, in reviewing general issues in compliance, serves as the background necessary for more specific applications of compliance, that is, compliance in hypertension therapy. With this as an objective, an overview is presented of the past work on compliance in general, including discussion of the different aspects or discrete elements of the concept. In the process, some support will be offered for the assertion that compliance is an essential part of chronic disease treatment.

Definition of Compliance

There has been dissension over the word compliance, and it is disliked by many clinicians, researchers, and patients because of the authoritarian ambience it radiates. Sackett and Haynes 4 in their landmark work on compliance comment on this but in the end reject the broader "therapeutic alliance" because they feel it is cumbersome. Despite the recognized controversy, they suggest that a working definition of compliance should be and is in their work "the extent to which the patient's behavior (in terms of taking medications, following diets or executing other life-style changes) coincides with the clinical prescription." They added "no matter how it was generated." 5 But there is an additional dimension to compliance considered essential by many, and that includes some concept of joint responsibility, and this dimension has been in evidence increasingly over the years that followed the McMaster's Conference, 6 which gave birth to the Sackett and Haynes work on compliance cited previously. Whether this change, adding mutuality to responsibility, has been fueled by the increasingly litigious nature of medical practice is certainly a question that might be raised. However, this is not the only impetus to this compliance in general, including discussion of the different aspects or discrete elements of the concept. In the process, some support will be offered for the assertion that compliance is an essential part of chronic disease treatment.
addition since clinical experience dictates consideration of a broader definition.

If such a dimension were added, a definition of compliance might be changed as follows: the degree of cooperation and agreement between clinician and patient in the management of regimens, characterized by the patient's understanding of and adherence to these regimens, including appropriate reporting back to the clinician. Further, to achieve this level of adherence, the clinician will take responsibility for education around existing conditions, preparation for the nature of ongoing treatment, and monitoring of that treatment over time. This last segment is not truly part of compliance but rather a hypothesized correlate.

One appeal of the first definition besides its parsimony (always a desired attribute) is the greater ease with which that compliance can be measured and evaluated. The second expanded definition has "softer" aspects, and there is less confidence that once its elements have been measured the outcome will reflect a true picture. Not that the earlier definition is without such problems and in their review of studies of compliance, Sackett and Haynes attest to this. Nevertheless, the challenge to those laboring to understand and make use of the concept of compliance and its effect on treatment of disease is to find rigorous measures for defining compliance as a phenomenon that is a joint responsibility of patient and clinician. Substantial support for this argument can be found in current work. In a critique of the state of the art of compliance studies, Levensthal maintains that studies of compliance require a systems approach based on a theoretical position that draws heavily on patient-provider interaction. To understand patient reaction to illness and subsequent behavior, it is essential to understand the way illness and treatment are handled with the patient by the clinician since this is a very powerful influence on what follows in compliance with any regimen.

This has been a relatively lengthy discourse on definition, but it gives some idea of the degree of accord or lack of it in the field. Moving beyond definition, there are areas of concern and interest in compliance that have been receiving attention and that in a sense make up the content as well as strategy for change. The balance of this discussion will focus on the following: 1) levels of noncompliance and their effect, 2) the factors that make up compliance and implications for treatment of chronic disease, and 3) strategies for improving compliance.

In the process of investigating each of these areas, past work in the field will be reviewed in a summary fashion along with problems in the method of studying compliance that surface on examination.

**Extent of Noncompliance**

There appears to be general agreement among clinicians and researchers that the level of noncompliance is high. Estimates as high as 50% of noncompliance with medications prescribed and 20 to 50% in appointment keeping have been made. Rates of noncompliance vary by type of setting studied and by the methods used for the study. Even so, this agreement on the levels of noncompliance is not without its problems. First, there appears to be little concordance between perceptions of clinicians and the evidence gathered independently on the compliance of patients so that data gathered in this fashion require much caution in interpretation. But more serious than the validity of clinician perception (which can be explained in many ways) is the fact that it is not clear what appropriate compliance, or at least compliance to achieve a specific end, might mean. One position is that compliance should be defined in terms of therapeutic efficacy. For example, in hypertension, 80% compliance with medications may be sufficient to achieve the desired outcome and about one third of conventionally prescribed amounts of medication provides some protection against the recurrence of rheumatic fever. This kind of concern, as well as issues, for example, of how to juxtapose not taking medications for 2 weeks against taking two thirds of the medication prescribed for 2 months, causes considerable pause. These caveats are raised to reflect some of the problems involved. What is known and more or less agreed upon concerning noncompliance is as follows: 1) There is more noncompliance in preventive behavior than in treatment behavior of established illnesses and conditions. 2) Behaviors with greatest noncompliance are those requiring changes in overall life-style, such as smoking and weight loss. 3) Asymptomatic patients and those with appointments that are provider initiated rather than patient initiated are more likely to fail their appointments. 4) It is believed and to some extent demonstrated that noncomprehension of instructions is the single most frequent cause of noncompliance. There is also general agreement on the potential for harm in noncompliance, a harm for patients as well as to the system of health care. These are 1) disruption of the course of treatment, 2) unnecessary diagnostic and treatment procedures, 3) questions by patients about the efficacy of treatment, 4) confounding of evaluation of treatment effectiveness, and 5) confounding of clinical trials that test outcomes of specific treatment regimens.

Discussion of noncompliance and its effects can be generalized to all types of treatment. It remains to support the original contention that with chronic disease these concerns are increased geometrically.

**Factors in Compliance: Effect on Treatment of Chronic Disease**

Over roughly the past 2 decades, there have been more than 700 studies, about 35 each year, that have examined variables that could be demonstrated as predictive of adherence to various medical regimens. The factors most often hypothesized in these studies as powerfully predicting compliance are characteristics of both the disease and the patients. Under certain circumstances, these have shown a correlation with compliance but not consistently and often not at a significant level. Factors most often cited as contributing significantly to compliance are 1) the nature of
the patient-provider interaction, 2) specific psychological and social characteristics of the patient, and 3) the amount and type of support given the patient in his or her environment.

These last two qualify as types of patient characteristics earlier referred to as not consistently important in compliance. However, when patient characteristics are referred to as a general category, what is usually meant are education, income, age, and other basic sociodemographic markers.

This overview of the most recent studies highlights an increasingly frequent leitmotif in compliance discussions—the importance of the doctor-patient relationship. 15 16 This relationship figures prominently in the argument that compliance is particularly significant in the process and content of treatment of chronic disease, and therefore, it deserves pride of place in discussion of influences on compliance.

Thirty years ago a psychiatrist and an internist proposed a model to illustrate different levels of patient involvement necessary for adequate and potentially successful medical treatment. 17 In this heuristic approach, Szasz and Hollander placed the comatose, delirious, or emergency patient at the lower end of a continuum of patient-clinician cooperation, while the nonpsychotic psychiatric patient was placed at the other. Chronic disease patients fell close to the upper end, immediately below the psychiatric patient. It was hypothesized that for chronic disease patients, while treatment might proceed (as it could not for psychotherapeutic patients) without the intense involvement of the patient, it was not likely to go well unless the patient was as knowledgeable as possible and willing to cooperate with the treatment in an active fashion, including taking appropriate responsibility for the overall regimen. Other cogent and well-argued positions urging involvement of patients had been made earlier, but the Hollander-Szasz model, which interestingly had been designated as an issue in the philosophy of medicine, represented something of a benchmark in discussions—the importance of the doctor-patient relationship.

This overview of the most recent studies highlights the importance of the doctor-patient relationship in compliance. It may be helpful to elaborate on this concept since in fact it consists of many elements and often changes because of shifts in either provider or patient, in the disease and condition, or in the life situation of the patient outside the treatment setting (or all three). In the broadest terms, when denoting a doctor-patient relationship, we may be referring to the nature of the means of communication, the level of trust engendered, specific education about the conditions present and about the treatment regimens, and the supervision of the ongoing situation, which includes assessing compliance, assessing changes in the condition, or monitoring side effects of regimens. Obviously this is a cyclical process so that changes occur, adjustments are made, and appropriate education and ongoing monitoring are repeated. The interactive behaviors that make up the doctor-patient relationship are greatly influenced by the delivery system within which care is given. The setting provides the ambience and often dictates the rhythm of the practice. The setting also influences how accessibility to care is perceived by patients. The nature of the setting can influence time available during a visit, prescribing patterns, and other contents and processes of the care given. Which of these many elements, as well as their interaction, influence compliance is only beginning to be understood.

Is there support to the original statement that for chronic disease, compliance has heightened significance? Earlier descriptions of studies regarding noncompliance and the factors affecting it provide strong evidence that in caring for chronicities, clinicians must be particularly concerned regarding levels of adherence. 15 16 Findings that illustrate this are as follows: 1) Preventive behaviors have higher levels of noncompliance than direct-care behaviors. Any regimens for
individuals with chronic conditions are not, in the strict sense of the term, preventive. However, since these regimens are aimed at keeping the condition from getting worse and avoiding secondary complications, these actions can be said to be secondary or tertiary prevention. The nomenclature is not rigorously or universally agreed upon. Directions that fall into this secondary or tertiary prevention are common in care for chronic conditions. It has been demonstrated that such direction is more difficult to comply with than other types of regimens, and this substantiates the particular burden of compliance in chronic disease care. 2) Conditions of long duration are associated with less compliance. The meaning of this factor for treatment of chronic disease is self-evident. 3) Complex treatment regimens, multiple conditions, and many drugs are all associated with noncompliance. This description of characteristics of a population fits most patients with chronic disease and is further evidence supporting the importance and difficulties of compliance for patients with chronic conditions.

These three examples emphasize the importance of patient compliance for those delivering health care and for those investigating the content and process of care. There are additional issues that are receiving attention of late, and these refer particularly to the older population. There is some evidence that older individuals may actually be overcompliers. One basis for this belief is that the elderly have many vague and overlapping symptoms and misread their implications. These often go unreported by the patient who may categorize such signs and symptoms as related to the so-called normal changes of aging. Secondly, there are many concerns older individuals have at any visit to a clinician, and since the time available with the clinician is limited, a priority setting takes place, and issues that have less salience for the patient are low on the list, often omitted from discussion. An additional influence on less reporting of symptoms and side effects of any regimen is that many older individuals presume that this is to be borne as part of the treatment for their conditions. All of these hypothetical views of behavior of patients with chronic conditions lend weight to the crucial importance of the doctor-patient relationship. That this powerful relationship may be the keystone to compliance, overall treatment and the design of intervention strategies has impressive support. A better understanding of the process of that influence requires attention and systematic investigation.

Conclusion

This discussion has centered on compliance, its definition, and its importance in the treatment of chronic disease and the factors that predict successful or unsuccessful compliance. Ongoing work has been narrowing differences in definition and has been identifying with increasing success elements in the patient, clinician, and disease that influence compliance. There are varying estimates of the degree of failure in adherence and recognized problems of measurement. There are, however, some commonalities that do emerge. There is evidence that noncompliance is higher in preventive than in treatment behaviors, in regimens requiring change in lifestyle (such as smoking cessation or weight loss), and in clinician-initiated appointments. Studies have shown that specific patient and provider characteristics, as well as the nature of the disease or condition being treated, influence the level of compliance. In addition, the nature of support within the patient's environment has been correlated with compliance. One area thought to be the single most frequent cause of noncompliant behavior is that of the misunderstanding by patients of regimens being prescribed. This has particular importance for the older population since there is parallel evidence that clinicians are less likely to discuss regimens at any length with older patients and far less likely to discuss potential side effects of drugs. The older population represents a crucial group in the consideration of compliance. They are at greatest risk for chronic disease that requires life-long compliance with a variety of regimens. They are the least likely to be involved in close patient-provider relationships around treatment regimens, particularly in the case of prescribed drugs. Not only will it be essential to continue investigations into the nature of compliance and strategies to increase adherence to treatment, but attention must be directed to methods of increasing the interaction between older patients and their providers.

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Compliance and chronic disease.

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Hypertension. 1988;11:I156
doi: 10.1161/01.HYP.11.3_Pt_2.I156

Hypertension is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0194-911X. Online ISSN: 1524-4563

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