Management of Patient Compliance in the Treatment of Hypertension

Report of the NHLBI Working Group

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SUMMARY Low patient cooperation erodes many of the proven benefits of antihypertensive therapy. Over the last few years, there have been important advances in our understanding of the nature and management of patient compliance in hypertension and other chronic illnesses. In this article we review the theoretical foundation of compliance behavior; methods of measuring compliance; established and promising approaches to managing compliance; ethical considerations in measuring, improving, and researching compliance; the current state of implementation of compliance techniques in practice settings; and the efforts to disseminate information on compliance through undergraduate and continuing health professional education programs.

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THE benefits of antihypertensive therapy have been well documented in both selected populations and the general community. However, demonstrations of the efficacy of blood pressure lowering required circumventing patient compliance as a problem by disqualifying non-compliers from entering the study or utilizing extraordinary measures to improve compliance that would be difficult to apply en block in the usual delivery of medical care.

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Under common conditions of medical practice, the extent to which low patient compliance undermines the effectiveness of antihypertensive therapy is truly staggering. At each step from detection through long-term follow-up, large numbers of patients fall out of care: up to 50% fail to follow through with referral advice; over 50% of those who begin treatment drop out of care within 1 year; and only about two-thirds of those who stay under care consume enough of their prescribed medication to achieve adequate blood pressure reduction. It is no wonder that studies have repeatedly shown that only 20% to 30% of individuals who know themselves to be hypertensive are under good control. Achieving and maintaining high compliance with antihypertensive therapy thus present challenges that must be met if we are to realize the benefits of modern medical therapy for high blood pressure.
Because it has been only a decade since the first convincing demonstration of the efficacy of antihypertensive treatment, it is hardly surprising that innovative approaches to improving patient acceptance of this therapy are of recent vintage. Our understanding of compliance and of ways to improve low compliance has grown considerably during the last few years. This article is a concise summary of the theory, research, ethics, and application of compliance management methods in the treatment of hypertension as viewed by an interdisciplinary group of clinicians and researchers convened by the National Heart, Lung, and Blood Institute for the purpose of reviewing current developments in compliance research.

**Definition of Compliance**

Compliance is the extent to which a person's behavior (in terms of keeping appointments, taking medications, and executing life-style changes) coincides with medical advice. Although this definition of compliance is nonjudgmental, for many the term implies patient sin and servitude. Terms that can be used synonymously include "adherence" and "defaulting," with the former term having perhaps fewer negative connotations.

**Theories of Compliance Behavior**

### Historical Background

The study of compliance behavior holds fascination for those who wish to understand it (without necessarily attempting to modify it) as well as those who wish to modify it (without necessarily understanding it). Theory provides an organizational framework through which research can be conducted in an orderly fashion to satisfy both these perspectives.

Theories of compliance behavior have developed in an expected fashion from simplistic to relatively sophisticated. Early theories held that compliance was related to easily tested characteristics of patients or their social environments such as age, sex, marital status, education, intelligence, religion, and socioeconomic status. Empirical testing of these "structural models" failed to reveal consistent relationships between these variables and compliance, however. Studies on "situational barriers," such as inconvenient clinics and complex regimens, were somewhat more fruitful but still failed to explain more than a fraction of the compliance problems, and it followed that compliance was not much affected by simply making treatments easier to follow and treatment visits more convenient.

### Educational Model

A major theory of compliance behavior holds that patients generally lack sufficient knowledge of their illness and treatment to comply properly and that thorough instruction will therefore result in better compliance. This appears to have merit for short-term treatments (less than 2 weeks in duration) but has very limited value for chronic disease regimens.

### Health Belief Model

The health belief model is perhaps the commonest "motivational model" of compliance. Simply stated, it holds that an individual's cooperation with health advice depends upon the extent to which that person perceives that he or she is susceptible to the disease, that the disease is serious, that the treatment is efficacious, and that the barriers to compliance are possible to overcome. A cue to action has also been built into the model to account for the influence of external factors. Tests of the model show that it does have predictive value for at least some preventive and short-term therapeutic health actions but that the...
magnitudes of its predictive value is modest at best.\textsuperscript{39–41} Furthermore, communications that influence health attitudes may have no observable effect on compliance,\textsuperscript{42–44} making the model of less interest from a clinical perspective.

### Emotional Drive Model

The emotional drive model is related to the health belief and educational models in that it attempts to achieve compliance through information about the illness to which is added some form of motivational appeal. Generally, the motivating part of the message seeks to arouse fear in the patient about dire consequences of failing to comply. A graded effect on behavior has sometimes been demonstrated, with stronger threat messages effecting greater compliance,\textsuperscript{42, 45} but other studies have shown no such gradient.\textsuperscript{43, 44, 46} Most of the studies of this model have been of once-only or short-term compliance; threats and fear arousal appear to have little long-term influence.\textsuperscript{47, 48}

### Behavioral Learning Model

The behavioral learning model provides a more powerful explanation of why people comply and how compliance can be improved. Operant learning theory, as originally developed by Skinner,\textsuperscript{49} suggests that behavior is solely the result of environmental cues and rewards. More recently, cognitive learning theory or social learning theory\textsuperscript{50, 51} has been developed to account for the interaction of environmental events with a person's perception of them. This model departs from operant learning theory in two important ways. First, it holds that the individual's interpretation of the environment determines what is reinforcing and what is not. Second, it postulates that it is possible to teach someone when and how to respond, without rewarding him or her for performing the response, especially through "modeling" the behavior, that is, by having the person observe someone execute the desired behavior. Thus, both the person and his or her environment have an important effect on a given behavior, with the person perhaps holding the balance of power. Rather than competing with the models described earlier, social learning theory can be seen as a broad frame of reference that encompasses them.

### Self-Regulation Model

The final theoretical construct of relevance is that of self-regulation. This model attempts to describe, within the framework of social learning theory, the role and method of acting of an individual when presented with health advice. It comprises the following components: 1) extracting information from the environment; 2) generating a representation of the illness danger to oneself; 3) planning and acting, which involves imagining response alternatives to deal with the problem and taking selected actions to achieve specific effects; and 4) monitoring how ones coping reactions affect the problem and oneself.\textsuperscript{48–50} At present this model holds promise for both understanding and modifying a person's compliance, but it has had only preliminary empirical testing in the health sphere.

### Measuring Compliance

The efficient management of patient compliance requires accurate and available methods of measurement.

#### Monitoring Attendance

Because up to 50\% of hypertensive patients simply drop out of care within 1 year of its beginning,\textsuperscript{7–9} monitoring attendance at appointments is critical. This is not as obvious a technique as it sounds, as many primary care practitioners do not make definite follow-up appointments for their patients or fail to note when patients miss appointments. Furthermore, attendance at appointments is not a substitute for medication compliance, as about one-third of patients who remain in care fail to follow the prescribed treatment.\textsuperscript{16, 11}

#### Clinical Judgment

The commonest method of assessing medication compliance is probably clinical judgment. This is intuitively attractive to clinicians and easily applied, but it has been shown repeatedly that clinicians cannot reliably predict the compliance of their patients\textsuperscript{46–50} even when they feel confident of their predictions.\textsuperscript{46, 50} Thus, clinicians should avoid depending upon their subjective impressions in monitoring compliance.

#### Patient Self-Reports

When patients are asked directly about their compliance they tend to overestimate the amount of medication they are taking.\textsuperscript{51–55} However, about half of noncompliant patients will admit to missing at least some medication and the ease with which this information can be obtained makes it very valuable. The value of self-reports can be augmented by self-monitoring through regular recording by the patient or by special medication dispensers that perform this task automatically.\textsuperscript{54, 60} Self-monitoring is one of the few ways that one can determine the pattern of medication consumption as distinguished from the quantity consumed.
Pill Counts

Pill counts provide a quantitative estimate of compliance over a period of time. This method is relatively reliable if performed at the patient's home and with scrupulous attention to bookkeeping, but these requirements make it largely impractical for clinical settings. Although it has not been demonstrated empirically, it is generally felt that pill counts are unreliable when they are performed on pills that patients bring with them to clinic visits — non-compliant patients may bring only some of their unused pills, or forget to bring their pills with them, or fail to attend the appointment entirely. In general, the pill count gives higher estimates of compliance than biological assays and lower compliance than patient self-reports.

Drug Level Measurement

Drug level determinations can be useful, particularly for drugs that have a sufficiently long half-life to have minimal fluctuation in plasma concentration during usual clinical dosing intervals. For example, digoxin and phenytoin plasma levels can provide information on compliance which can be used to guide compliance interventions. However, their interpretation is subject to the foibles of individual variation in drug absorption, metabolism, and excretion. Further, drug level assessments are not routinely available for antihypertensive drugs.

Biological Effects Assessment

In contrast to the direct measurement of drug levels, the biologic effects of drugs have not been found to correlate well with compliance. For example, thiazide diuretics lower blood pressure and serum potassium and raise serum uric acid; but none of these effects provides as good an indication of compliance as simply asking the patient. Nevertheless, in clinical practice it would improve efficiency to focus concern about compliance on only those patients who fail to achieve the therapeutic goal despite prescription of usually adequate doses of treatment.

Patient Reactivity

All methods of assessing patient compliance are susceptible to “reactivity.” That is, if patients become aware of the purpose of the assessment, they may alter their compliance. Generally, one would expect any change in compliance to be in a favorable direction, and thus this is a potentially useful phenomenon clinically. For research, it is clearly a hazard if the purpose of the measurement is solely to document rather than alter compliance.

While no single method of assessing compliance is wholly satisfactory, many of the measures provide more information than guessing and sequential combinations of the measures can minimize the amount of effort required. For example, in routine patient care, compliance need not be considered a problem unless the patient fails to respond to usually adequate treatment. When the treatment response is judged inadequate, the patient can be asked about compliance. If the patient reports less than complete compliance, the clinician can proceed with compliance interventions. If the patient reports full compliance, problems with the treatment itself can be considered along with application of more sophisticated methods of measuring compliance.

Improving Compliance

From the perspective of compliance, optimum control of hypertension in the community will only be achieved if four aims are met. First, screening programs must gain the full cooperation of citizens; second, referral from screening must be successful; third, appointments for those in care must be attended regularly; and finally, medication must be taken as prescribed. These four steps require somewhat different tactics, but research into compliance has generated successful methods of dealing with each of them. All of the following methods have been subjects of controlled clinical trials unless otherwise stated.

Screening Programs

The yield of screening programs can be increased by home visits, especially if executed outside usual working hours. However, most screening programs reach no more than 25% of the population; and then only for the duration of the program. Inasmuch as 70% of the people visit a physician within a given year, it would seem logical to shift the site of hypertension screening to the physician's office. Whether physicians will take up this task, however, remains to be seen.

Referral from Screening

The success of referral from screening can be augmented by counseling and by assisting patients to make and keep appointments. Although not evaluated in controlled trials of compliance strategies which would perhaps be unnecessary with the results obtained, virtually complete referral success has been achieved in two studies in which patients were followed until at least one appointment had been kept.

Medication and Follow-Up

Once the patient is under care for hypertension, additional efforts are usually required to prevent the
patient from dropping out of treatment and to promote full compliance with prescribed therapy. Unfortunately, there does not appear to be as yet a single-dose or single-modality cure for noncompliance. Indeed, none of the following methods has improved compliance when tested as the only intervention: special learning packages\textsuperscript{17} and pamphlets;\textsuperscript{28} counseling about medication and compliance by a health educator;\textsuperscript{24} home visits;\textsuperscript{49} increased convenience of care at the worksite;\textsuperscript{17, 70} self-monitoring of blood pressure;\textsuperscript{49, 71} tangible rewards;\textsuperscript{71} group discussions;\textsuperscript{71} and counseling by nurses.\textsuperscript{71}

In contrast to the lack of effect of unimodal interventions, several controlled trials have shown statistically and clinically significant increases in compliance from combinations of interventions, including some that have not worked in isolation. All of these approaches are characterized by interactions between providers and patients, leading to the general conclusion that the level of supervision of and attention to ongoing care is a key factor.\textsuperscript{75} Within this framework, there appears to be a variety of effective options for interaction. These include feedback of the blood pressure response to the patient, through blood pressures taken by either the provider\textsuperscript{10, 75} or the patient;\textsuperscript{74, 75} rewarding the patient for improved compliance and/or lowered blood pressure;\textsuperscript{28, 71, 74} tailoring of medications to daily schedules to decrease forgetting and inconvenience;\textsuperscript{48, 74} encouraging family support;\textsuperscript{24} engendering self-help through group support and discussion;\textsuperscript{46, 75} negotiating a brief written contract with the patient for improvements in health behavior;\textsuperscript{48} and calling back patients who miss appointments.\textsuperscript{79}

Although a provider is present in all of the successful interactions, the type of provider does not appear to be important. Physicians,\textsuperscript{10} nurses,\textsuperscript{6, 23, 48} pharmacists,\textsuperscript{10} health educators,\textsuperscript{48} psychologists,\textsuperscript{78} and even individuals with no formal health training\textsuperscript{14} have played the key role in successful interventions. In a similar vein, although a place for provider and patient to meet is required, the specific site does not appear to be important. Compliance with antihypertensive treatment has been increased in community clinics,\textsuperscript{75} general medical clinics,\textsuperscript{10} hypertension clinics,\textsuperscript{25, 24, 70} pharmacies,\textsuperscript{10} worksites,\textsuperscript{70, 74} and patients' homes.\textsuperscript{6}

While most interventions were applied directly to the patient or the patient's family, one study reported a beneficial effect of tutorials for house staff and attending staff in a general medical clinic.\textsuperscript{78} This study has important implications for the education of health professionals.

New Directions in Improving Compliance

The comments in the section above are based on controlled clinical trials of compliance improvement strategies which provide us with the most reliable information available on how to improve compliance; they indicate that several methods are worthwhile. Nevertheless, our understanding of compliance remains incomplete and the ways of improving compliance tested to date are both personnel intensive and less than fully effective. Thus, we must continue to seek better understanding of compliance and better ways to manage it. Two promising avenues of approach to these goals are studies of the clinician-patient relationship and the role of social support in compliance.

Clinician-Patient Relationship

Research into the interactions between clinicians and patients can be broadly classified into four categories. Studies in the first category deal with the pedagogical techniques employed by practitioners to inform patients about their prescribed treatment. These studies are both correlational\textsuperscript{77-80} and experimental\textsuperscript{82-84} in their design and suggest that greater provider explicitness regarding needed patient behaviors is associated with better patient follow-through.

The second category of studies addresses the extent to which clinicians and patients share the same expectations about their interactions and the effect of this on subsequent patient compliance ("mutuality of expectations"). Studies on this topic are difficult to perform and remain descriptive at present. They indicate that when patients' expectations are not fulfilled (for tests they feel should be ordered, and for treatments and advice they feel should be rendered), compliance is likely to be low.\textsuperscript{62-64}

The third category includes investigations into patients' acceptance of responsibility for following their prescribed therapy, a procedure suggested by the self-regulation theories described above. Shulman\textsuperscript{85} has found that compliance is better among patients who feel that they are actively involved in their own care. While no study has yet isolated patient responsibility from other elements of the therapeutic process, several studies show that negotiating care with the patient, rather than simply dictating or prescribing it, results in better compliance.\textsuperscript{11, 66-68} Roter\textsuperscript{60} also found that attendance at appointments improved when patients were encouraged to take greater responsibility by asking more questions of their physicians. Finally, Nessman et al.\textsuperscript{79} found that blood pressures were better controlled and compliance was higher among patients randomly allocated to monitor their own blood pressures at home and choose their own medications in group sessions, according to a standard step-wise regimen.

The last category concerns the affective tone of the patient-clinician encounter. The social learning theory described above suggests that liked and powerful others would be more influential. This, again, has proven a difficult matter to study, and no interventional studies have been reported. Studies in which the clinician-patient interaction has been observed directly support the concept that approachability and friendliness of the clinician to the patient are positively correlated with compliance.\textsuperscript{80, 91}
Social Support

The second promising new direction for understanding and managing patient compliance is that of social support, that is, the help that patients receive from their family and friends to carry on with their treatments. It has been well documented that patients from disrupted or isolated social circumstances are less likely to be good compliers than those with stable families and/or helpful friends.\cite{92, 99} Only recently, however, have there been systematic studies of attempts to engender or direct social support in order to improve compliance with antihypertensive therapy.\cite{94, 100} These studies have not shown an independent effect on compliance of attempting to promote social support, but their results must be regarded as preliminary. Both social learning and self-regulation theories point to a number of complex ways that social support could enhance compliance.

Ethical Concerns in Applying Compliance Strategies

When attempts are made to improve compliance in medical practice, rather than in research, the ethical practitioner should consider the following guidelines.\cite{101, 102} First, the diagnosis must be correct. Second, the therapy must be of established efficacy. Third, neither the illness nor the proposed treatment can be trivial. Fourth, the patient must be an informed and willing partner in any attempts to alter his compliance behavior. Finally, the strategy to be employed to improve compliance must also be of established merit. Of course, the practitioner must tailor these guidelines to fit the circumstances of the individual patient: therapies and compliance interventions that benefit most patients are not suitable for all.

In research, the focus of intent shifts from benefit to the individual patient to the testing of a hypothesis in order to develop new knowledge. The compliance considerations are somewhat different in this context and depend on whether the object of the research is testing a new treatment or a new method of improving compliance. If the former, the compliance maneuver used should, itself, be of established merit, and we should be able to say that its application will result in more adequate testing of the new treatment than could be achieved without the compliance maneuver. Arrangements should be specified in such studies for detecting harm to patients to permit their prompt removal from the study, as an effective compliance maneuver would increase the rate at which harm occurs and potentially the severity of any harm.

When the object of research is to test the safety and/or efficacy of a compliance intervention itself, say in increasing compliance to a standard antihypertensive regimen, there must be good cause to believe that the compliance intervention is worth testing. This would include an adequate theoretical base as well as a protocol for testing that details an adequate research design. In both this and the previous research situation, the anticipated harms and benefits must be disclosed to the prospective research subject who will be the final arbitor of the favorability of the balance of harms and benefits, and thus reach a decision concerning participation in the project.\cite{103, 104}

Monitoring patient compliance also poses ethical problems because some of the most powerful methods of measuring compliance require deception in order to maintain validity. While this matter merits more discussion than can be provided in this article, the basic ethical principles that must be observed are that patients and research subjects must be aware of the fact, if not the details, of measurement and must agree to its execution. Practitioners and investigators should avoid circumstances that create the necessity for "deceptive debriefing" or "inflicted insight" which are harms incurred by informing patients about compliance monitoring after the fact.\cite{105}

Ethical issues may seem to be insurmountable barriers to the execution of at least some compliance research: in particular cases there may be serious tensions between the demands of scientific design and obligations to be respectful of the rights and welfare of human subjects. However, the guidelines above are not absolute but rather enter into a more general consideration of benefit versus harm in the decision to execute a research project. Furthermore, it is usually possible to negotiate resolutions of such tensions that all concerned will find satisfactory.

Utilization of Strategies to Increase Compliance

Just as the availability of antihypertensive drugs does not ensure that they will be prescribed optimally, the demonstration that various methods of promoting compliance are effective does not mean that practitioners will or do apply them to advantage or that students of the health sciences will be taught them. We attempted to ascertain the extent of utilization of compliance promotion in the public and private health care delivery sectors and teaching of compliance management in schools of medicine, nursing and pharmacy. Sources of information included published literature and direct contact with medical associations, schools, clearing houses, and organizations concerned with blood pressure control and education activities. This informal survey, the details of which are related elsewhere,\cite{106} leads us to a few general conclusions.

First, there is a vigorous effort being made, particularly through the National High Blood Pressure Education Program, under the National Heart, Lung, and Blood Institute, to disseminate information about management of compliance and long-term follow-up of hypertensive patients, and to organize at the state level various intervention programs. Through this process and others, several practical strategies are in common use including streamlined services, patient
tracking, instruction, and counseling. However, it is noteworthy that the most frequently used techniques, such as public and patient instruction, are not those shown to be the most effective in well-designed controlled trials. Second, research in this area continues to grow rapidly. Third, compliance management is beginning to be taught as a subject in some medical and other health professional schools. Finally, and unfortunately, the private practice sector, in which the majority of hypertensives are treated, appears as yet little affected by new information about the management of patient compliance.

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