SUMMARY Compliance with medical therapy in general is often low, and compliance with blood pressure treatment is no better. Numerous studies have shown that patients frequently drop out of treatment for hypertension. Furthermore, even when patients stay in treatment, they often take their medications in a way quite dissimilar from that prescribed. Identifying noncompliant patients is important but not always easy to accomplish. Pill counts, the "gold standard," are seldom practical in routine clinical practice. Assessing compliance by its biological effect is compromised by physiological diversity among patients. Assessing compliance from patient self-reports is limited in its accuracy but is more useful than many researchers and clinicians appreciate. Compliance behavior is affected by many factors. Complexity of medical regimen has some effect; the presence of drug side effects has surprisingly little. Contrary to what many clinicians think, increased age is often accompanied by increased medication compliance. Features of the doctor-patient relationship likely have an important effect on patient compliance, though our knowledge of these factors is still limited. (Hypertension 11 [Suppl II]: II-61-II-64, 1988)

KEY WORDS • ambulatory medicine • patient education • clinical assessment

COMPLIANCE is a complex topic that becomes no simpler when viewed only in the framework of blood pressure control. Though necessarily limited, the following discussion highlights several key aspects of compliance with hypertension therapy.

How Much Compliance?

A first issue, obviously, is the actual magnitude of patient compliance with hypertension therapy. As noted in Dr. German's review, compliance behavior in general is often suboptimal. Unfortunately, compliance with hypertension therapy is no better. For example, Engelland et al.1 reviewed records from a medical practice in an affluent section of Manhattan and reported that 51% of a sample of hypertensive patients failed to reappear during the year following their initial visit. Similarly, Gillum et al.2 reviewing 2 years of records from a Boston teaching hospital's outpatient clinic, reported that 51% of a sample of hypertensive patients failed to reappear during the year following their initial visit. Johnson et al.,3 in a follow-up study of a community population volunteering for a shopping-center blood pressure screening program, found that 21% of patients had stopped treatment within 1 year. Likewise, 19% of patients in The Australian Mild Hypertension Trial refused to continue with therapy within the first 2 years of the program, often discontinuing during the first few months.4

Thus, these and other studies5-7 confirm that many patients drop out of treatment for hypertension. This is not the only bad news, however, because it turns out that compliance among those staying in treatment is poor also.

For example, Johnson et al.,3 studying their shopping-center screening program, reported that only 60% of the patients remaining in treatment claimed to be fully compliant with their drug regimen. Likewise, Sackett et al.,8 describing their landmark study of Canadian steelworkers enrolled in a randomized trial of antihypertensive treatment, reported that only about 50% of patients complied with at least 80% of their prescribed drug regimen. Data from the Maryland Statewide Hypertension Survey9 revealed that among patients who were actively under treatment (defined as having medication bottles at home) when interviewed, only 60% scored high on a four-point compliance scale.

Clinicians and Their Assessment of Patient Compliance

These and other studies10-12 document that even when patients remain under treatment, compliance in taking medication is often poor. However, when patients remain in treatment, clinicians, at least theoreti-
Methods for Assessing Patient Compliance

As these and other studies16,17 demonstrate, personal assessments by clinicians of patients' compliance are of limited accuracy. Thus, the question is raised as to whether there exist other more accurate means of assessing compliance.

It is easy, of course, to assess dropping out of treatment altogether since the patient is no longer there. However, much harder is the task of assessing how much medication a patient actually consumes relative to how much was prescribed.

Traditionally, the "gold standard" in assessing medication compliance has been pill counts. Though this can be an effective means of assessing compliance in carefully controlled prospective trials, it is of limited utility in the world of everyday practice. Obviously, the typical clinician cannot drop in on his patients at home to count pills. On the other hand, asking patients to bring their pill bottles to the office is not an acceptable alternative since pill count accuracy is easily compromised. For example, patients may forget to bring their pill bottles to the office. Or, if they bring pill bottles to the office, they may forget having divided their medication among several bottles for convenience and bring in only some of the bottles. Of, if they do bring in all bottles, they may first purposely empty out some of the pills so as to not "disappoint" their doctor.

A second means of evaluating medication compliance used at times by both researchers and practicing clinicians has been the measurement of drug levels and the assessment of biological effects of treatment. However, both of these means of assessing compliance are limited. For one thing, drug levels of antihypertensive medications are not routinely available and, even if they were, would not likely be very useful because of physiological variation among individuals in their clearance of these drugs. Similarly, assessing drug compliance by looking at biological effects is limited by physiological variability among patients. For example, although thiazides tend to depress serum potassium levels and raise serum uric acid levels, the magnitude of these effects if too variable for serum levels to be useful in assessing medication compliance. Blood pressure control itself is neither a sensitive nor specific measure of compliance since it is possible for a patient to be compliant but hypertensive (if his medication regimen is inadequate) or, conversely, to be noncompliant but normotensive (if he did not actually need all the medication prescribed).

Self-Report and the Recognition of Noncompliance

Asking patients whether they are compliant with their antihypertensive regimen is another way to assess compliance behavior, though it is a method so simplistic that it has generated little enthusiasm among researchers. However, in light of the fact that it is clinically easy to do and since other means of assessing compliance have shown limited utility, this means of evaluating compliance has recently received increased attention.

For example, Levine et al.18 reported on a four-item compliance scale used in studying three educational interventions aimed at hypertensive ambulatory patients. They found a high degree of consistency in responses among the four items and adequate predictive validity with blood pressure control. Furthermore, Morisky et al.,19 studying these patients at year two, reported 75% of those scoring high on the scale to have adequate blood pressure control compared with 47% scoring low ($p<0.01$).

Similarly, Hershey et al.,20 studying outpatients attending hypertension sessions at The Hospital of the University of Pennsylvania, reported that asking patients whether they took their high blood pressure pills "always, most of the time, some of the time, seldom, or never" was a useful way to assess compliance. Answers proved to be significantly ($p<0.02$) related to hypertension control with 75% of those reporting they always complied, being normotensive, compared with 53% of those reporting they did not. Moreover, patients who reported missing on average more than three pills per week were far less likely ($p<0.01$) to be normotensive than were those who missed none.

Haynes et al.21 compared various means of assessing medication compliance in the control of hypertension among steelworkers involved in a worksite hypertension project. They found that an effective means of assessing medication compliance, even better than measuring serum uric acid levels, serum potassium levels, urine chlorothalidone levels, or urine hydrochlorothiazide levels, was to elicit patients' own assessments of their compliance. Haynes et al. obtained these assessments using an interview instrument carefully crafted to be nonjudgmental. This instrument consisted of an initial section introducing the issue of compliance: "People often have difficulty taking their pills for one reason or another and we are interested in finding out any problems that occur so that we can understand them better." Then the patients were asked whether they ever missed their pills (and, if so, to state the average number of tablets missed per day, week, and month). Using this approach, Haynes et al. reported a 75% rate of agreement between self-reported compliance and pill counts. A self-report of high compli-
Predicting Noncompliance

Successful recognition of noncompliance after it has occurred (whether through pill counts, self-report, etc.) is valuable both so that researchers can take compliance into consideration in assessing new therapies and so that clinicians can understand poor medical outcomes. However, even more useful would be the ability to predict noncompliance ahead of time, thereby giving researchers and clinicians an opportunity to attempt to prevent it in the first place.

For example, it has been suggested that we could develop a profile of the type of individual who is likely to be noncompliant by considering some combination of characteristics of the patient, the treating physician, and the medication regimen itself. If we were successful in this regard, then we could concentrate on targeting compliance promotion programs at those individuals most likely to be noncompliant. Additionally, if one could identify specific aspects of the doctor-patient interaction or specific features of treatment itself that correlate with noncompliance, then we could potentially work to modify these elements and, thereby, increase compliance.

Age and Compliance

One potential determinant of compliance behavior that has been widely discussed in the medical literature over the years has been that of patient age. In particular, much has been written about how there is an especially great problem of medication noncompliance among the elderly. Interestingly, however, when one begins to look closely at these pronouncements, it becomes clear that much of what is referenced is either anecdotal or limited in its applicability. In fact, careful review of the literature suggests that elderly patients on average try especially hard to be compliant, despite some clinicians’ perceptions to the contrary. This seems true for medication use in general as well as for antihypertensive medications specifically.

For example, Haines and Ward, summarizing data from two national surveys sponsored by the National Heart, Lung, and Blood Institute, report that “Younger hypertensives were more likely to discontinue their medication than were older ones.” Similarly, data from the most recent of the Maryland Statewide Hypertension Surveys demonstrate that among those patients who reported in the past being prescribed antihypertensive medications, the most likely (p < 0.001) to be actively taking medications at the time of the survey were the elderly. Additionally, among patients currently taking antihypertensive drugs, the elderly were especially likely (by the four-item compliance scale described previously) to report high compliance (p < 0.0001).

Health Knowledge and Compliance

Health knowledge has often been theorized to be a potentially important determinant of compliance behavior, and consequently, various attempts at promoting compliance through educational maneuvers have been carried out over the years. Though such approaches would seem reasonable, a review of the literature actually reveals relatively little support for a strong relationship between health knowledge and medication compliance. For example, a study of medication compliance among an ambulatory clinic population at a major teaching hospital revealed no correlation (r = 0.00) between medication compliance and knowledge of medication purpose. Similarly, attempts by several researchers to improve compliance with antihypertensive therapy by imparting health knowledge have tended to be unsuccessful. For instance, Sackett et al. randomly assigned patients to an educational program designed to teach them about hypertension, including its effects upon target organs, health, and life expectancy, the benefits of antihypertensive therapy, the need for compliance with medications, and some simple reminders for pill taking. Though this program was effective in increasing knowledge of the group exposed to the educational intervention (at 6 months, 85% of patients in the intervention group had mastered the health information compared with only 18% of the patients in the control group), this learning did not increase compliance. Furthermore, individual compliance rates bore no relation to knowledge about hypertension either at entry into the study (r = -0.03) or at 6 months (r = 0.08).

In a similar way, Levine et al. applied an educational intervention as part of a three-part compliance promotion program. Although participation in the program overall did lead to improved blood pressure control, exposure by itself to the individualized 15-minute counseling session in which the practitioners’ instructions were explained and reinforced did not result in a significant improvement in blood pressure.

Compliance Versus Complexity and Side Effects of Therapy

The relationship between complexity of medication regimen and compliance (both in general and in hypertension therapy specifically) has been much discussed in the medical literature. However, it is not nearly as clear a relationship as is often assumed. Overall, it is true that complexity of medication regimen seems to be inversely related to medication compliance. However, it also appears that it is primarily not how many times a day medications are prescribed but, rather, how many different types of medications are prescribed that is important.

As for the relationship between compliance and side effects of medications, this also is a complex issue. It would seem reasonable to expect to find medication compliance inversely related to side effects. Certainly,
one would not expect patients to be more compliant with their medications because they experience side effects. However, although there is some data supporting such an inverse relationship, a review of data overall actually suggests that this inverse relationship is relatively weak (and, in fact, may actually be of limited clinical importance). For example, a study of 299 randomly selected outpatients from a teaching hospital medical practice revealed very few patients stopping their medications in general because of side effects, which was similar to what was found in the Maryland Statewide Hypertension Survey that concentrated on antihypertensive medications.

Compliance and the Doctor-Patient Relationship

As the preceding brief discussion has attempted to demonstrate, the issue of compliance and blood pressure control is complex and incompletely understood despite the publication of numerous papers exploring medical compliance in general. Dr. German in her review has highlighted aspects of the doctor-patient relationship affecting compliance in general, stressing her belief in their importance. Similarly, it would seem probable that these factors affect compliance with blood pressure therapy specifically. Unfortunately, relatively few studies have addressed this particular issue, thereby limiting our ability to intercede in the doctor-patient relationship to maximize compliance.

Conclusion

The preceding discussion has summarized our knowledge of compliance in the treatment of hypertension. In part, the data are discouraging, revealing large numbers of patients dropping out of treatment as well as low compliance among patients staying in treatment. On the other hand, we have seen that clinicians can use patient self-reports to identify a sizable portion of their noncompliant patients. Thus, there exists a simple and inexpensive means of targeting patients for whom compliance-promoting programs are indicated.

The fraction of our population consisting of individuals 65 years of age and older continues to increase. In this light, it is important to realize that the elderly on average represent a patient group especially likely to strive for medication compliance, even in the face of drug side effects. Finally, it is important to realize that there is still much to be learned about the doctor-patient relationship and its effects on hypertension treatment. Hopefully, studies exploring these relationships will be forthcoming.

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Hypertension. 1988;11:II61
doi: 10.1161/01.HYP.11.3_Pt_2.II61
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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World Wide Web at:
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