Making Outpatient Care of Diabetes More Efficient: Analyzing Noncompliance

Steven B. Leichter, MD, FACP, FACE

Two recent brief articles[1,2] in this "Business of Diabetes" department focused on common issues that may worsen clinical outcomes of outpatient diabetes care and make the care process more prolonged and complex. These issues were depression and borderline personality disorder, and both are examples of a multitude of problems that result in the failure of diabetic patients to adhere to the medical prescription for their condition. The effort to deal with the negative consequences of noncompliance prolongs the outpatient visit and makes service more complex.

Perhaps no aspect of outpatient diabetes care seems as frustrating to primary care providers as the problems that result in nonadherence. In our program, we have developed a menu of brief, simple assessments to identify the factors that contribute to this overall problem.

"Nonadherence" Versus "Noncompliance"

Some years ago, diabetes educators argued that the term "adherence" be used preferentially instead of "compliance," and the term "nonadherence" be substituted for "noncompliance."[3] The rationale for this proposal was that the term "noncompliance" implies a series of negative value judgments about patients as people. Instead, the term "nonadherence" was thought to imply a description of a failure to follow the medical prescription without any bias toward the patient as a person. Most authorities have endorsed this view.[4] In addition, specific studies have noted that nonadherence may entail various components that may relate to flaws in the process of care and that do not entail a failure on the part of the patient.[5,6]

However, much of the medical community has never adopted this concept, and in many other areas of clinical practice, the term "noncompliance" remains the standard description of this adverse patient behavior.[7,8] In diabetes care, the concept of "noncompliance" with associated innuendoes, remains prevalent.[9,10] It is widespread knowledge that primary care providers in active clinical practice also still use the term "noncompliance."

Regardless of whether concern about the descriptive terms for this clinical situation is appropriate, concern about the clinical issue itself is very important. If primary practitioners and diabetes care professionals had an effective and efficient menu of assessments to analyze noncompliance, the care process and outcomes might improve significantly. Patients who did not adhere to the medical prescription might receive a detailed assessment to determine *why* they did not adhere, rather than a dismissive label of "noncompliant." What is needed is an efficient and effective protocol for making this assessment in the outpatient setting.

Recognized Components of Noncompliance

Multiple issues contribute to whether a diabetic patient adheres to the prescribed treatment. These influences are similar to those for other chronic diseases, such as dyslipidemias,[11] hypertension,[12] mental disorders,[13] and asthma.[14] Some of the determinants are shown in Table 1.

Some issues that affect patient compliance (or apparent compliance) actually are not directly determined by the patient. Cost is one. A recent article on noncompliance to drug therapies for dyslipidemias emphasized that cost is an important determinant of patient adherence.[11] The ability to afford care may also be an important determinant in the compliance of pediatric patients with type 1 diabetes.[15,16]

Whether the treatment prescribed appears to the patient to be having a positive effect may also influence compliance.[17] In part, how patients perceive the relevance of suggested therapies describes how the treatments conform to their "health beliefs model."[5] Conveying information about suggested treatments to patients in terms that are meaningful to them (i.e., that fit with their health beliefs model) is important. At times, prejudgment by health professionals about what patients can or cannot accomplish based on their age, education, or socioeconomic status may lead

Table 1. Determinants of Noncompliance in Diabetic Patients

- Presence of depression
- Personality disorder
- Failure to fulfill patient health beliefs model
- Cost of therapy
- Dosing frequency of medications
- Underinsurance
- Adverse family dynamics, including excessive codependency
- Poor provider-patient relationship
- Drug abuse
- Older age

to unnecessary, negative outcomes.[18] The frequency or complexity of prescribed medical therapies is also an important determinant of compliance. This is true for the treatment of type 1 diabetes with insulin[19] and of type 2 diabetes with oral hypoglycemic agents.[20,21] The inverse effect of dosage frequency on treatment compliance in diabetic patients is consistent with a very large body of data in patients with other chronic conditions.[20] The quality of the provider-patient relationship also influences compliance,[22,23] and so does the adequacy of insurance coverage for the care of diabetes.[15]

Issues related intrinsically to the patient also influence compliance. Depression,[1] personality disorder,[2] or any other psychiatric disorder[24] may have a primary impact. A history of drug abuse negatively influences compliance.[25] Older age may impair compliance in diabetic patients,[20] as it appears to do in patients with dyslipidemias.[11] Adverse family dynamics or other psychosocial disruptions play a role.[15]

The effect of the educational level or sophistication of the patient, independent of problems communicating effectively with people of lower educational achievement, is unclear. We reported no significant effect of educational level in patients learning home glucose monitoring.[18] In contrast, Ronsin et al.[26] noted an adverse effect of lower educational level on the use of insulin pumps.

Effects of Noncompliance on Clinical Outcomes

However valid the judgmental perceptions of treating health providers are about noncompliant patients, their underlying concerns about relationships between noncompliance and poor clinical outcomes are quite well founded. Compliance influences glycemic control.[27] A wide variety of studies demonstrate that patients who fail to adhere to prescribed clinical regimens have very poor outcomes.[15,25,28–30] The likelihood of recurrent diabetic crises is related in part to patient noncompliance.[15,29,31] In diabetes care, noncompliance may represent an important component of unnecessary health care costs, especially hospital costs.[21,32] Thus, the development of effective and efficient methods to assess the possible contributors to noncompliance in the outpatient setting appears very desirable.

A Checklist for Noncompliance

The consideration that a patient may intentionally fail to adhere to the treatment prescription should be applied without pejorative judgment to patients with clinical characteristics that raise specific and objective clinical "flags." In our center, the characteristics shown in Table 2 constitute the most common flags that may trigger our assessment for noncompliance. These include dietary nonadherence or ongoing weight gain, persistent elevation of hemoglobin A_{1c} (A1C), failure to keep multiple office appointments, or multiple episodes of diabetic crisis. We also consider issues related to other disease states, such as lipid disorders and hypertension. Therefore, persistence of abnormal lipid levels, despite the prescription of lipid-lowering agents, or persistence of uncontrolled hypertension, despite the provision of antihypertensive agents, is considered. While persistently poor clinical outcomes may suggest noncompliance, they do not *prove* poor adherence.

Table 2. Clinical Flags That Encourage Assessment for Noncompliance

- Persistent elevation of A1C
- Erratic fluctuations of blood glucose
- Frequent missed office appointments
- Repeated failure to carry out recommended clinical testing
- Repeated failure to do suggested glucose self-monitoring or present results at office visits
- Persistent weight gain
- Dietary nonadherence
- Frequent episodes of diabetic crisis
- Excessive or repeated demands for extraordinary services or other considerations

Whenever a patient triggers a compliance assessment, we attempt to carry the assessment out during our triage check-in process. Much of our assessment is designed to allow the patient to provide the desired information by self-reporting during our triage process. We use quick written assessments and questionnaires to determine if these screens suggest noncompliance. Our assessments are listed in Table 3. When coupled with the flags we use to trigger assessments, these evaluations give us substantial clinical information about whether we should more actively pursue questions regarding noncompliance during the office visit, and they guide us as to which aspects should be emphasized.

A number of our assessments relate to psychological issues. We test for the possibility of depression using a depression index. We observe certain behavioral traits to consider whether the patient may have a personality disorder that might be influencing the success of diabetes care.[2] We administer a self-reported questionnaire to learn what patients have eaten during the 3-day

Table 3. Rapid Office Assessments of Patient Adherence

- Review of home blood glucose testing to determine whether fluctuations of glucose are erratic
- Three-day dietary intake
- Depression scale testing
- Daily schedule and activity assessments
- Laboratory screens for drug abuse
- Assessment of patient behavior toward office staff
- Explanation of frequent missed appointments
- Review of costs of prescribed treatments
- Assessment of reliability of adherence to medication regimen
- Consideration of provider-patient relationship

period before the office visit. We believe that excessive codependency in family dynamics may be an adverse influence on compliance, though there is little comment on this in the literature. Codependency is usually grouped with other behavioral issues in assessments of family dynamics in diabetes.[33] Therefore, we screen for signs of excessive codependency in family relationships.

We are very conscious of the possible adverse influences of excessively costly or complex treatment regimens on our patients. We have learned to estimate the costs of the drugs we frequently use by calling our local pharmacies rather than accepting information on this aspect of treatment from pharmaceutical company representatives. Quite often, the costs of drugs as presented by the pharmaceutical representatives are very much understated compared to what we learn our patients will actually pay at the local pharmacy. To reduce daily pill counts and dosage frequency, we prefer combination medications where applicable.[21] Finally, we attempt to present information in terms our patients understand in order to fulfill their health beliefs model. As part of that effort, we use instructional materials that are written at a reading and comprehension level appropriate for most of our population.[34]

Improving Patient Adherence

The original objection by diabetes educators to the use of the term "noncompliance" was that its application to patients included judgmental innuendoes about their personal values or character.[3,4] In fact, this concern is quite valid in clinical practice. In many clinical situations, "noncompliance" is not a nonspecific description of obstacles that patients may have to therapeutic success; it is a diagnosis. And it is in applying the term to a patient as a diagnosis that, commonly, the problem with the usual clinical approach to this issue occurs, for applying the term as a diagnosis freezes all other considerations of the issue.

Therefore, the first priority for practicing physicians is to *evaluate* why a patient may be noncompliant rather than to complete an assessment with that conclusion. In our center, we consider how the patient has interacted with all members of the staff from the receptionist to the physician. Staff members are encouraged to notify the treating health professional if the patient has given the impression that there may be issues in the interaction or has complained about aspects of the services provided. This sort of behavior may reflect valid dissatisfaction or it may suggest underlying psychosocial questions.

Similarly, we watch the dynamics of the entire family in interacting with us and with each other. We wish to see if there is evidence of dysfunction or codependency. When we find patients with such issues, we refer them to our clinical psychologist. We suggest that each clinical practice that focuses on diabetes develop an active relationship with a clinical psychologist for these and other patients. We have previously published a description of how this relationship may occur within a diabetes practice.[35]

Health providers should review each aspect of the patient's self-care to determine whether there are specific issues that will affect compliance. Such inquiry should consider whether patients understand the specific self-care task and whether they believe it is important to their health. Whether patients can afford the task and whether the task requires the overall treatment to become much more complex should also be examined.

Finally, we suggest that providers confront evidence of patient dissatisfaction with services directly, in a professional manner. In our experience, patients who are exhibiting dissatisfaction in nonverbal ways usually have two sorts of dissatisfaction. One relates to our customer service, and the other relates to real or perceived grievances against a member of the medical staff. We consider these questions with the patient. If the issues have validity, we seek to satisfy them. If not, we endeavor to resolve them with the patient. If we cannot, such a problem would be a reason to sever the patient-provider relationship.

Whatever approach providers take, it is important that they have some protocol of assessment of noncompliance. There may be other items providers wish to include in their evaluations. But in the end, providers should have an idea about *why* their patients are noncompliant, not just whether they are noncompliant. That is the first step to improved adherence.

REFERENCES

[1]Leichter SB, See Y: Problems that extend the visit time and cost in diabetes care. 1. How depression may affect the efficacy and cost of diabetes care. *Clin Diabetes* 23:63–64, 2005

[2]Leichter SB, Dreelin E: Borderline personality and diabetes: a potentially ominous mix. *Clin Diabetes* 23:101–103, 2005

[3]Boehm S, Schlenk EA, Funnell MM, Powers H, Ronis DL: Predictors of adherence to nutrition recommendations in people with non-insulin-dependent diabetes mellitus. *Diabetes Educ* 23:157–165, 1997

[4]Lutfey KE, Wishner WJ: Beyond "compliance" is "adherence." *Diabetes Care* 22:635–639 1999

[5]Pham DT, Fabienne F, Thibaudeau MF: The role of the health belief model in amputees' self-evaluation of adherence to diabetes self-care behaviors. *Diabetes Educ* 22:126–132, 1996

[6]Tillotson LM, Smith S: Locus of control, social support, and adherence to the diabetes regimen. *Diabetes Educ* 22:133–139, 1996

[7]Elkins G, Whitfield P, Marcus J, Symmonds R, Rodriguez J, Cook T. Noncompliance with behavior recommendations following bariatric surgery. *Obese Surg* 15:546–551, 2005

[8]Nelson MR, Ryan P, Willson K, Reid C, Beilin LJ, Jennings GL, Johnston CI, McDonald GJ, Marley JE, McNeil JJ, Morgan TO, West MJ, Wing LM: Predictors of failure to initiate randomized treatment in a large trial of antihypertensive drug therapy in the aged. *Am J Hypertens* 18:885-888, 2005

[9]Schaepelynck-Belicar P, Dufaitre-Patouraux L, Lassmann-Vague V: What could be the reasons for giving up the implanted insulin pump? *Diabetes Metab* 31:87-89, 2005

[10]Yu YN, Howard CP: Improper insulin compliance may lead to hepatomegaly and elevated hepatic enzymes in type 1 diabetic patients. *Diabetes Care* 27:677–680, 2004

[11]Schultz JS, O'Connell JC, McDonough KL, Sasane R, Meyer J: Determinants of compliance statin therapy and low-density lipoprotein goal attainment in a managed care population. *Am J Manag Care* 11:306–312, 2005

[12]Iskedjian M, Einarson TR, MacKeigan LD, Shear N: Relationship between daily dose fre-

quency and adherence to antihypertensive pharmacotherapy: evidence from a meta-analysis. *Clin Ther* 24:302–316, 2002

[13]Lundberg I, Darnstrom Thakker K, Hallstrom TS, Forsell Y: Determinants of non-participation, and the effects of non-participation on potential cause-effect relationships, in the PART study on mental disorders. *Soc Psychiatr Epidemiol* 40:475–483, 2005

[14]Lacasse Y, Archibald H, Ernst P, Boulet LP: Patterns and determinants of compliance with inhaled steroids in adults with asthma. *Canad Resp* J 12:211–217, 2005

[15]Rewers A, Chase HP, Mackenzie T, Walravens P, Roback M, Rewers M, Hamman RF, Klingensmith G: Predictors of acute complications in children with type 1 diabetes. *JAMA* 287:2511–2518, 2002

[16]Poette JD, Heisler MA, Wagner TH: Problems paying out-of-pocket medication costs among older adults with diabetes. *Diabetes Care* 27:384–391, 2005

[17]Schwartz S, Sievers R, Strange P, Lyness WH, Hollander P: Insulin 70/30 mix plus metformin versus triple oral therapy in the treatment of type 2 diabetes after failure of two oral drugs: efficacy, safety, and cost analysis. *Diabetes Care* 26:2238–2243, 2003

[18]Barr B, Leichter SB, Taylor L: Bedside capillary glucose monitoring in the general hospital. *Diabetes Care* 7:261–264, 1984

[19]Paes AH, Baker A, Soe-Agnie CJ: Impact of dosage frequency on patient complance. *Diabetes Care* 20:1512–1517, 1997

[20]Leichter SB, Thomas S: Combination medications in diabetes care: an opportunity that merits more attention. *Clin Diabetes* 21:175–178, 2003

[21]Kuo YF, Raji MA, Markedes KS, Ray LA, Espino DV, Goodwin JS: Inconsistent use of diabetes medications, diabetes complications, and mortality in older Mexican Americans over a 7-year period. *Diabetes Care* 26:3054–3060, 2003

[22]Winnick S, Lucas DO, Hartman AL, Toll D: How do you improve compliance? *Pediatrics* 115:e718–e724, 2005

[23]Chapman RH, Benner JS, Petrilla AA, Tierce JC, Collins SR, Battleman DS, Schwatrz JS: Predictors of adherence with antihypertensive and lipid-lowering therapy. *Arch Intern Med* 165:1147–1152, 2005

[24]Kovacs M, Mukerji P, Iyengar S, Drash A: Psychiatric disorder and metabolic control in IDDM youths. A longitudinal study. *Diabetes Care* 19:318–323, 1996

[25]Laing SP, Jones, ME, Swerdlow AJ, Burden AV, Gatling W: Psychosocial and socioeconomic risk factors for premature death in young people with type 1 diabetes. *Diabetes Care* 28:618–623, 2005

[26]Ronsin O, Jannot-LaMottte MF, Vague P, Lassman-Vague V: Factors related to CSII compliance. *Diabetes Metab* 31:90–95, 2005

[27]Chen H-S, Jap T-S, Chen R-L, Lin H-D: A prospective study of glycemic control during holiday time in type 2 diabetic patients. *Diabetes Care* 27:326–330, 2004

[28]Lin EH, Katon W, Von Korff M, Rutter C, Simon GE, Oliver M, Ciechanowski P, Ludman EJ, Bush T, Young B: Relationship of depression and diabetes self-care, medication adherence, and preventive care. *Diabetes Care* 27:2154–2160, 2004

[29]Skinner TC: Recurrent diabetic ketoacidosis: causes, prevention and management. *Horm Res* 57:78–80, 2002

[30]American Diabetes Association: Hyperglycemic crisis in diabetes (Position Statement). *Diabetes Care* 27:S94–S102, 2004

[31]Gill G, Lucas S: Brittle diabetes characterized by recurrent hypoglycaemia. *Diabetes Metab* 25:8–11, 1999

[32]Maldonado MR, Chong ER, Oehl MA, Balasubramanyam A: Economic impact of diabetic ketoacidosis in a multiethnic indigent population. *Diabetes Care* 26:1265–1269, 2003

[33]Bryden KS, Peveler RC, Stein A, Neil A, Mayou, RA, Dunger DB: Clinical and psychological course of diabetes from adolescence to young adulthood. *Diabetes Care* 24:1536–1540, 2001

[34]Leichter SB, Neimann JA, RW Moore, Collins P, Rhodes A: Readability of self-care instructional pamphlets for diabetic patients. *Diabetes Care* 4:627–630, 1981

[35]Leichter SB, Dreelin E, Moore S: Integration of clinical psychology into the comprehensive diabetes care team. *Clin Diabetes* 22:129–131, 2004

Steven B. Leichter, MD, FACP, FACE, is co-director of the Columbus Research Foundation and president of Endocrine Consultants, PC, in Columbus, Ga. He is a professor of medicine at Mercer University School of Medicine in Macon, Ga.