# Barriers to Treatment Adherence in Patients with Type 2 Diabetes: A Review

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Given that effective control of diabetes usually requires concerted efforts on the part of patients, adherence to prescribed therapies has a profound effect on the disease course. These authors examine the latest research on factors that influence patient adherence in the primary care setting.

iabetes mellitus is a chronic disease with multiple associated illnesses. Between 1980 and 2007, the crude incidence of diagnosed diabetes increased 136% from 3.3 to 7.8 per 1,000 population.1 The effects of uncontrolled diabetes on multiple organ systems results in health, financial, and social burdens to patients, families, and society. Keeping blood glucose levels as close to normal as possible, however, has been shown to slow the onset and progression of such microvascular complications as eye, kidney, and nerve diseases.<sup>2</sup>

In order to achieve this level of glycemic control, patients with diabetes must commit to daily self-management and lifestyle modifications.<sup>3</sup> As a result of these demands, the most serious obstacle to effective diabetes management may be inadequate patient adherence. Patient adherence—a phrase used essentially interchangeably with the term "patient compliance" in medical literature—generally is defined as the extent to which a patient is consistent in implementing an agreed-upon treatment plan. It is related to clinical measures of diabetes control and must be considered when there is poor outcome or lack of improvement.<sup>4</sup> In fact, adherence to diabetes regimens—which frequently involve complex, intrusive, and inconvenient tasks<sup>5</sup>—may be poorer than adherence to regimens for many other conditions.<sup>6</sup>

Multiple research studies have assessed adherence among patients with type 2 diabetes. These studies have identified numerous factors that appear to be associated—positively or negatively—with adherence in these patients, including the quality of the provider-patient relationship,<sup>7,8</sup> the patient's health beliefs, the social environment of the family,<sup>7</sup> depression,<sup>9,10</sup> stress, self-esteem, diabetes knowledge,<sup>11</sup> medication costs, complexity of the regimen,<sup>12</sup> and adverse effects of medication.<sup>13</sup>

These studies were conducted in a variety of settings (including inpatient, primary care, specialty care, and community settings), however, and barriers to adherence may differ from one setting to another. In order to examine those barriers found specifically among patients with type 2 diabetes being treated in the primary care setting, therefore, we conducted a review of relevant studies published over the past decade. Here, we present the results of this review. We also explore how these findings fit within the larger context of diabetes literature and discuss interventions with the potential to address the adherence barriers that have been identified.

# STUDY IDENTIFICATION AND SELECTION

In our review, we attempted to determine the most prevalent barriers to treatment adherence among patients with type 2 diabetes in primary care. To find research addressing this question, we searched the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, MEDLINE, and PubMed databases for all relevant studies published between October 30, 1997 and October 30, 2007. Search terms focused on the following key words and title phrases: "type 2 diabetes mellitus," "type 2 diabetes" AND "adherence," "patient adherence," "patient compliance," and "barriers to adherence."

All results of the database searches were assessed for relevance to the review, based on the information provided in the title, abstract, and National Library of Medicine Medical Subject Headings (MeSH). In order to be included in the review, articles had to describe research (exploratory

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descriptive studies; cohort studies; cross-sectional studies; or randomized, controlled trials), be written in English, and be published in a peerreviewed journal. For the purpose of this review, we considered the primary care setting to be inclusive of general practice. Therefore, we included in our review studies that were performed in primary care or general practice settings. We also included studies of data drawn from medical claims databases when the distinction was made that patients had been newly diagnosed with diabetes or had been newly started on diabetes therapy. We excluded studies conducted in all other settings (such as diabetes specialty clinics and inpatient units). Other inclusion criteria were: study population that was composed exclusively or predominantly of patients with type 2 diabetes and assessment of patient adherence to nonpharmacologic or pharmacologic treatments.

All studies that met the inclusion criteria were retrieved for a full report. References of search results also were searched manually for additional studies relevant to the review. In total, our search yielded 11 studies (Table).<sup>7,9,13–21</sup> Each author of this article reviewed the full reports of these studies independently before we discussed them together. In addition, each author abstracted data from the studies independently.

#### Assessing adherence

In reviewing the study findings, we considered all the factors reported to play a role in preventing patients with type 2 diabetes from adhering to pharmacologic or nonpharmacologic treatments. Currently, there is no gold standard method for measuring patient adherence. It can be measured directly or indirectly by several validated methods, such as self-reports, pill counts, pharmacy record reviews,<sup>22–25</sup> questionnaires, assessment of patients' clinical response, and electronic medication monitoring.<sup>22,24</sup> Choice of method may depend on the situation, the type of adherence being assessed, the precision required, and the application of the results.<sup>25</sup> In the studies we reviewed, methods of assessment included patient self-reports and questionnaires, focus groups, electronic monitoring, pill counts, and pharmacy record reviews.

#### **BARRIERS TO ADHERENCE**

#### **Psychological barriers**

Psychological problems are reported commonly as barriers to diabetes treatment adherence in the primary care setting. Four of the studies we reviewed found depression to be a barrier to medication adherence.<sup>9,14–16</sup> In two of these studies, participants with depressive symptoms also exhibited lower adherence to self-care.<sup>9,14</sup>

Ciechanowski and colleagues stratified 367 patients with type 1 or type 2 diabetes into depression severity groups according to results from a self-report instrument and then assessed their adherence to oral hypoglycemic agents (OHAs) and self-care activities.9 They found that patients in the high-severity depression group had a higher percentage of days of nonadherence to OHAs (15%) than did those in the low-severity depression group (7%; P = .04). Patients in both the medium- and high-severity groups were significantly less adherent to dietary recommendations than patients in the low-severity group.

In a cross-sectional survey that utilized both patient questionnaires (to assess depression and self-care) and pharmacy refill data (to assess medication adherence), Lin and colleagues found that patients with major depression had a higher percentage of nonadherent days compared with those who were not depressed (24.5% versus 18.8%, respectively).<sup>14</sup> Depressed individuals also were less adherent to self-care activities than were nondepressed individuals.

The other two studies that found depression to be linked to lower adherence concentrated on medication adherence. In Kalsekar and colleagues' retrospective study of Medicaid claims data on 1,326 patients newly diagnosed with type 2 diabetes, a multivariate analysis showed that the 471 depressed patients were 3% to 6% less adherent to OHAs than the 855 patients who were not depressed.15 In assessing the association between depression and diabetes medication adherence among 203 older patients (mean age, 67 years) with type 2 diabetes, Kilbourne and colleagues found the self-reported rate of diabetes medication adherence to be only 42% among the 19 patients who were depressed, compared with 67% among the 184 nondepressed patients (P = .03).<sup>16</sup> Notably, while pharmacy refill data also showed a lower median percentage of days with adequate medication coverage among the depressed patients versus the nondepressed patients, there was no association between depression and nonadherence when the latter was assessed by provider reports or by data from electronic monitoring caps issued to patients for 30 days.<sup>16</sup>

In three of the studies we reviewed, patients self-reported forgetfulness as a reason for nonadherence.<sup>13,17,18</sup> Hill-Briggs and colleagues used structured interviews to assess medication adherence among 181 urban African American patients with type 2 diabetes and found that 35% reported forgetting to fill prescriptions for diabetes medications and 26% reported forgetting to take their medications.<sup>17</sup> Using a pharmacist-administered, telephone questionnaire in which 128 patients

Table. Studies included in review of barriers to adherence among patients with type 2 diabetes in the primary care setting <sup>7,9,13-21</sup>						
Primary author and year	Patient sample and age	Method/design	Data collection instrument(s)	Findings		
Vinter-Repalust 2004 <sup>7</sup>	49 patients with type 2 diabetes, aged 44–83 years	Explanatory, descriptive focus groups	Group discus- sions (audio- taped and transcribed)	Factors identified as important to patient adherence: health be- liefs; quality of provider-patient relationship; social environment of the family, workplace, and health system; and quality of information from health profes- sionals and media		
Ciechanowski 2000 <sup>9</sup>	367 patients with type 1 or type 2 diabetes (96% type 2), aged > 18 years	Cross-sectional	Questionnaires, pharmacy refill data	Patients with a high severity of depression were less adherent to diet and medication regi- mens than patients with a low severity of depression		
Grant 2003 <sup>13</sup>	128 patients with type 2 diabetes; mean (SD) age, 66 (12) years	Survey	Pharmacist- administered questionnaire, electronic medical records	Barriers to adherence identified: adverse effects of medication, difficulty remembering to take all doses, and medication cost; perception of benefit of medi- cation also had an impact on adherence		
Lin 2004 <sup>14</sup>	4,463 patients with type 1 or type 2 diabetes (96% type 2); mean (SD) age, 63.3 (13.4) years	Cross-sectional survey	Questionnaire, pharmacy refill data	Patients with major depression showed less adherence to med- ication and self-care activities (less physical activity, unhealthy diet) than patients without major depression		
Kalsekar 2006 <sup>15</sup>	1,326 patients newly diagnosed with type 2 diabetes, aged < 65 years	Retrospective cohort	Medicaid claims database, pre- scription refill data	Depressed patients had signifi- cantly lower adherence to oral hypoglycemic agents than non- depressed patients		

were asked to assess their medication adherence over the past week, Grant and colleagues found that the second most common reason given for less than perfect adherence to a particular medication was not remembering to take all doses (12 of 51 "problem" medications, or 23%).<sup>13</sup> Forgetfulness also was a recurring theme in a focus group interview of 24 patients with type 2 diabetes, conducted by Nagelkerk and colleagues, on the topic of perceived barriers to medication adherence.<sup>18</sup>

#### **Psychosocial issues**

Several of the studies we reviewed identified various psychosocial factors—such as family support, life-style, health beliefs, and social environment—as influencing patients' adherence to both nonpharmacologic and pharmacologic therapies for diabetes. In a focus group study by Vijan and colleagues involving both urban and suburban patients with type 2 diabetes, support and family issues and quality of life and lifestyle issues emerged as common barriers to dietary adherence.<sup>19</sup> These researchers

Table. Studies included in review of barriers to adherence among   patients with type 2 diabetes in the primary care setting <sup>7,9,13-21</sup> (continued)						
Primary author and year	Patient sample and age	Method/design	Data collection instrument(s)	Findings		
Kilbourne 2005 <sup>16</sup>	203 patients with type 2 diabetes; mean age, 67 years	Longitudinal survey	Questionnaires, electronic moni- toring, phar- macy refill data	Depression associated with de- creased medication adherence as assessed by patient self- report and pharmacy refill data; no association with adherence as assessed by provider reports or electronic monitoring		
Hill-Briggs 2005 <sup>17</sup>	181 patients with type 2 diabetes, aged 35–75 years	Cross-sectional survey	Self-report, questionnaire	Barriers to adherence identified: running out of medication (fi- nancial problems), forgetting to refill prescriptions, forgetting to take medication		
Nagelkerk 2006 <sup>18</sup>	24 patients with type 2 diabetes	Exploratory, de- scriptive focus groups	Group discus- sions (audio- taped and transcribed)	Barriers to adherence identified: medication—forgetting to take it, difficulty keeping track of it, not having it, cost, not under- standing reason for change in regimen; diet—lack of knowl- edge and understanding of diet plan		
Vijan 2005 <sup>19</sup>	446 patients with type 2 diabetes (197 in focus groups); mean age, 61 years	Survey and focus groups	Self-adminis- tered question- naire, group discussions	Barriers to adherence identified (diet only): cost, portion size, social and family support, qual- ity of life and lifestyle issues, provider-patient communica- tion, rigid schedule		
Farmer 2006 <sup>20</sup>	121 patients with type 2 diabetes, aged 57–75 years	Exploratory, survey	Self reports, questionnaire	Belief that taking diabetes med- ication would lead to weight gain and belief that changes in daily routine would make it more difficult to take medication regularly both associated with reduced medication adherence		
Hertz 2005 <sup>21</sup>	6,090 patients newly treated for type 2 diabe- tes, aged 18–64 years	Retrospective, cohort	Administrative claims data- base, medica- tion possession ratios	Nonpersistence in filling pre- scriptions and 12-month dis- continuation associated with initial treatment with insulin or $\alpha$ -glucosidase inhibitors		

also reported that participants at the urban site highlighted difficulties with dietary adherence encountered during holidays and special occasions.19

Vinter-Repalust and colleagues found similar obstacles to nonpharmacologic treatment adherence in a descriptive, focus group study that ex-

plored patients' attitudes, thoughts, and fears about diabetes; expectations of the health care system; and problems with therapy adherence.<sup>7</sup> Specifically, patients identified lack of willingness, lack of motivation, and difficulties during family celebrations as barriers to dietary adherence, and they identified lack of motivation and willpower, laziness, and time pressures as barriers to exercise. Patients also said it was difficult to follow the treatment regimen, particularly the recommended diet, while working. Other psychosocial factors identified as important to both pharmacologic and nonpharmacologic adherence were patients' health beliefs (such as the recognition that they are the most responsible for their own health status) and the social environments of the family, workplace, and health care system.

Farmer and colleagues mentioned another psychosocial barrier in their exploratory survey of 121 patients aged 40 years or older who had type 2 diabetes. The authors found a significant association between reduced medication adherence and patients' belief that changes in daily routine would make it more difficult for them to take their diabetes medication regularly (P < .001).<sup>20</sup>

#### **Characteristics of therapy**

Our review revealed that patients frequently identify aspects of the diabetic regimen or the treatments themselves that make adherence difficult. The rigid schedule of diabetic diets and limitations on portion sizes, for instance, were both implicated as contributing to patient nonadherence in the focus group study by Vijan and colleagues.<sup>19</sup>

In a retrospective, cohort study analyzing medical claims data on 6,090 patients with type 2 diabetes, Hertz and colleagues found that early nonpersistence (defined as not filling a second antihyperglycemic prescription) and 12-month treatment discontinuation were both significantly more likely to occur when patients were treated initially with insulin (odds ratio [OR], 3; 95% CI, 2.31 to 3.10) or an  $\alpha$ -glucosidase inhibitor (OR, 2.07; 95% CI, 1.11 to 3.84).<sup>21</sup>

Two studies we reviewed mentioned adverse effects of medication as barriers to adherence.13,20 The exploratory survey by Farmer and colleagues found that 32.8% of patients felt that taking diabetes medication would lead to "unpleasant side effects" and 13.9% believed specifically that medication would cause weight gain.<sup>20</sup> The latter of these beliefs was significantly associated with reduced medication adherence (P < .01).<sup>20</sup> And in Grant and colleagues' telephone survey, the most commonly reported barrier to medication adherence was adverse effects (cited for 29 of 51 problem medications, or 58%).13

This study also found patients' self-reported days of adherence to be significantly fewer for medications they felt were not improving their health (6.1 versus 6.9 days out of 7; P < .001).<sup>13</sup> Similarly, Nagelkerk and colleagues' focus group study identified patients' frustration with lack of glycemic control and continued disease progression despite adherence to the medication regimen to be one of the most frequently reported barriers to ongoing adherence.<sup>18</sup>

#### **Financial issues**

Three studies found cost to be a barrier to medication adherence,<sup>13,17,18</sup> and two found cost to be a barrier to dietary adherence.<sup>7,19</sup> In Grant and colleagues' study, cost was the third most common reason cited for having a problem with medication (four of 51 problem medications, or 8%).<sup>13</sup> Hill-Briggs and colleagues' study of African American patients found that financial difficulty was the most commonly reported reason for running out of medication (51.7%).<sup>17</sup> Medication cost also was reported as a barrier to adherence in Nagelkerk and colleagues' study.<sup>18</sup>

In Vinter-Repalust and colleagues' focus group study, one patient cited financial problems as a reason for being unable to follow dietary recommendations.<sup>7</sup> And each of the six focus groups on dietary adherence conducted by Vijan and colleagues reported cost as a major concern.<sup>19</sup>

#### **Knowledge deficit**

Gaps in patients' knowledge of diabetes and its management were identified in three of the studies we reviewed.7,18.19 Vinter-Repalust and colleagues identified "knowledge about illness" as one of the eight major themes that emerged from their focus groups.<sup>7</sup> They found that the patients in their study "were not sufficiently aware of the importance of following a diet" and "did not know how to prepare their meals, which food to choose for a proper diet, or how to carry out physical activities correctly."7 Moreover, some patients felt that because the disease is so common in older patients, it did not need to be treated at all.7

Nagelkerk and colleagues reported that lack of knowledge and understanding of a specific diet and lack of knowledge of medication action, adverse effects, administration schedule, and dosage adjustments were perceived barriers to adherence reported in their focus groups.<sup>18</sup> In the study by Vijan and colleagues, patients reported confusion over food choices, indicating gaps in their knowledge of the recommended diet.<sup>19</sup>

#### **Provider-patient relationship**

The quality of the relationship between the provider and patient—including the ease and effectiveness of their communication—emerged as themes in the focus groups of both the Vinter-Repalust and colleagues and Vijan and colleagues studies.7,19 In the former study, "relation to health professionals" was one of the eight major themes identified, with patients commenting that support and closeness with the practitioner was important as it "made them feel more like partners than patients" and helped them manage their condition more thoughtfully.7 Vijan and colleagues reported that patients in the urban focus group noted more difficulties communicating with their providers about diet and social circumstances compared with those in the suburban focus groups.19

#### THE LARGER CONTEXT

This systematic review explored the published evidence concerning barriers and interventions that facilitate adherence among patients with type 2 diabetes being treated in the primary care (or general practice) setting. Studies reviewed used a variety of methods to evaluate adherence to pharmacologic and nonpharmacologic modalities. The collective identification, in these studies, of multiple barriers to treatment adherence is not surprising given that diabetes is a complex disease that requires combined treatment modalities. It's important to note, however, that some of the studies assessed patients' perceptions, rather than actual adherence behavior, which may have contributed to the relatively high number of barriers reported.

In the studies reviewed, depression was the most commonly reported barrier to pharmacologic and nonpharmacologic adherence in the primary care setting. Findings also indicated that the magnitude of depression may affect the level of adherence. In an outpatient, specialty care setting, Park and colleagues also found higher scores for depression to be associated with poor self-care behaviors—but only marginally with poor medication adherence.<sup>10</sup> Recent research into antihypertensive medication adherence lends further support for depression as a predictor of nonadherence.<sup>26</sup>

Our review also identified forgetfulness as a potential barrier to antidiabetic medication adherence in the primary care setting. Similarly, a randomized, controlled trial assessing adherence to primary prevention regimens among patients with impaired glucose tolerance found forgetting to take medication to be a major barrier.<sup>27</sup> Other psychological barriers have been identified in studies that were not necessarily confined to the primary care setting. Anxiety, high levels of stress, low self-esteem, and burnout, for instance, have been reported in various studies as barriers to diet and exercise adherence among diabetic patients.11,28

Psychosocial issues emerged in several studies as adherence barriers-particularly with regard to diet and exercise regimens. In a study that used structured questionnaires to examine adherence to dietary and exercise recommendations among Kuwaiti patients with diabetes, hypertension, or both, the patients reported unwillingness to follow dietary regimens, difficulty adhering to individual diets that are different from those of the rest of the family, social gatherings with lack of time to prepare food, coexisting disease, and adverse weather conditions as adherence barriers.<sup>29</sup> Other research has linked diabetic patients' belief in conventional medicine,4 inflexible family control,30 time constraints,<sup>31</sup> and the competing demands of other health problems (such as chronic pain<sup>32</sup>) to lack of adherence.

Various aspects of the treatment regimens—including dietary limitations, rigidity of scheduling, medication adverse effects, and perceived effectiveness of treatments—were identified in the review as contributing to nonadherence in the primary care setting. Outside of this setting, complexity of the medication regimen has been reported as a barrier to adherence. For instance, studies conducted in community and outpatient settings have demonstrated that patients taking one pill were more adherent to their treatment regimen than those taking two or more pills.<sup>33–36</sup> Interestingly, this finding was not confirmed in the study of polypharmacy and medication adherence by Grant and colleagues included in the current review.13

Cost emerged in several studies as a barrier to both dietary and medication adherence-particularly among urban and African American populations. This finding is supported by a study of barriers to medical nutrition therapy among black women with type 2 diabetes.<sup>31</sup> This study also found knowledge deficit to be a barrier to dietary adherence<sup>31</sup>—a finding echoed in several of the studies we reviewed. Finally, the connection between the strength of the provider-patient relationship and adherence identified in our review was explored in more depth by Ciechanowski and colleagues in a study that used the conceptual model of attachment theory.8 In this study of 367 patients with type 1 and type 2 diabetes, the researchers found that patients who exhibited the signs of "dismissing attachment" (in which a distrust of others leads the individual to be "compulsively selfreliant") and rated patient-provider communication as poor had particularly low levels of medication adherence—as well as worse glycosylated hemoglobin levels.8

#### INTERVENTIONS TO PROMOTE ADHERENCE

In studies both within and outside our review criteria, interventions rec-

ommended to improve adherence include prescribing generic or preferred medications within a therapeutic class,37 psychological intervention with exercise,38 efforts to foster closeness between the patient and provider,7 encouragement, and support.18 One study conducted in a community health center found that a pharmacist-administered educational intervention, which tailored information on medication use (such as adverse effects and mechanisms of action) to the individual patient, did not reduce adherence barriers or improve selfreported adherence.39 It's important to note, however, that patient-reported rates of medication adherence in this study were already quite high prior to the intervention.39

A recent systematic review reported that, while once-a-day dosing appears to help increase adherence to OHAs, the question of whether any intervention significantly enhances adherence to treatment recommendations in type 2 diabetes remains unanswered.<sup>40</sup> Clearly, more research into this area is necessary.

#### **IN SUMMARY**

For optimal control of diabetes and delay of associated complications, it is imperative that both health care providers and patients adhere to established standards of care and treatment guidelines—such as those put forth by the American Diabetes Association. Various health care organizations have taken on the responsibility of assessing provider adherence to standards of care. Assessment of patient adherence, however, is the domain of the individual providers.

Our review of studies assessing barriers to adherence to pharmacologic and nonpharmacologic treatments among patients with type 2 diabetes in the primary care setting suggests that psychological support is essential for patients to perform effective self-management. Given the strong connection between depression and nonadherence to diabetes treatments, we recommend that all patients with diabetes should be screened for depression in the primary care setting. Results of this screening should then be used for planning and monitoring of care. Exercise programs, medication regimens, and dietary recommendations should be as simple as possible, customized to the individual patient's lifestyle, and developed through a collaborative approach between the primary care provider and the patient. Finally, primary care providers must partner with their diabetic patients to identify and address individual barriers to treatment adherence and to monitor and adjust therapies as needed to achieve optimal outcomes-both in terms of disease and quality of life.

#### Author disclosures

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