The Potentially Poor Response to Outpatient Diabetes Care in Urban African-Americans

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OBJECTIVE — HbA_{1c} levels can be reduced in populations of diabetic patients, but some individuals may exhibit little improvement. To search for reasons underlying differences in HbA_{1c} outcome, we analyzed patients managed in an outpatient diabetes clinic.

RESEARCH DESIGN AND METHODS — African-Americans with type 2 diabetes were categorized as responders, intermediate responders or poor responders according to their HbA_{1c} level after 1 year of care. Logistical regression was used to determine baseline characteristics that distinguished poor responders from responders. Therapeutic strategies were examined for each of the response categories.

RESULTS — The 447 patients had a mean age and disease duration of 58 and 5 years, respectively, and BMI of 32 kg/m^2. Overall, the mean HbA_{1c} level fell from 9.6 to 8.1% after 12 months. Mean HbA_{1c} levels improved from 8.8 to 6.2% in responders, and from 9.5 to 7.9% in intermediate responders. In poor responders, the average HbA_{1c} level was 10.8% on presentation and 10.9% at 1 year. The odds of being a poor responder were significantly increased with longer disease duration, higher initial HbA_{1c} level, and greater BMI. Although doses of oral agents and insulin were significantly higher among poor responders at most visits, the acceleration of insulin therapy did not occur until late in the follow-up period.

CONCLUSIONS — Clinical diabetes programs need to devise methods to identify patients who are at risk for persistent hyperglycemia. Whereas patient characteristics explain some heterogeneity of HbA_{1c} outcome (and may aid in earlier identification of patients who potentially may not respond to conventional treatment), insufficient intensification of therapy may also be a component underlying the failure to achieve glycemic goals.

Diabetes Care 24:209–215, 2001

Recent studies have established that complications of diabetes can be delayed by reducing hyperglycemia (1–3). Structured treatment programs—which typically include elements of patient education, use of nurse case managers, and stepped-care algorithms to guide pharmacological management—have been shown to accomplish the goal of improving glycemic control (4–7). Such approaches to managing diabetes may have applicability in a number of health care delivery settings. For instance, we have shown that glucose control can be achieved in type 2 diabetic patients who are followed in an outpatient clinic of a large municipal hospital (8,9).

Although structured care is clearly beneficial when applied to a cohort of patients, with improvement in the group average HbA_{1c} level generally being the basis for defining program success (4–9), some individuals may still exhibit little improvement in hyperglycemia. Because these individuals are at greater risk for complications, clinical programs must establish methods for self-evaluation that recognize these patients so that treatment protocols can be analyzed and modified to further improve management. In addition, defining those patient characteristics associated with a poor HbA_{1c} outcome could both allow practitioners to identify possible poor responders earlier and prompt them to accelerate therapy in these patients. Whereas some studies have identified variables associated with glycemic outcome (10–13), none have included a large number of minority patients, for whom improving care should be a priority given their tendency for poor glucose control and greater prevalence of complications (14,15).

Notwithstanding the overall improvement in HbA_{1c} levels achieved in our clinic, which serves primarily African-Americans with type 2 diabetes, a substantial proportion may still fail to achieve the HbA_{1c} level that is the currently recognized goal, despite 1 year of intensive follow-up care (9). The objective of this analysis was to further examine differences in HbA_{1c} outcomes in a group of patients who were previously shown to have overall improvement in hyperglycemia after participation in an outpatient treatment program. Specifically, response categories were defined, a search was undertaken for baseline patient variables that may distinguish potential poor responders to the clinical intervention, and an examination of therapeutic strategies was performed.

RESEARCH DESIGN AND METHODS

Treatment program

Our standard program included six return visits within the first 6 months after the intake visit (8,9,16). A return visit was also scheduled at 12 months, with at least one intervening visit scheduled between 7 and 12 months; thus, a total of eight follow-up

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Received for publication 22 May 2000 and accepted in revised form 27 October 2000.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

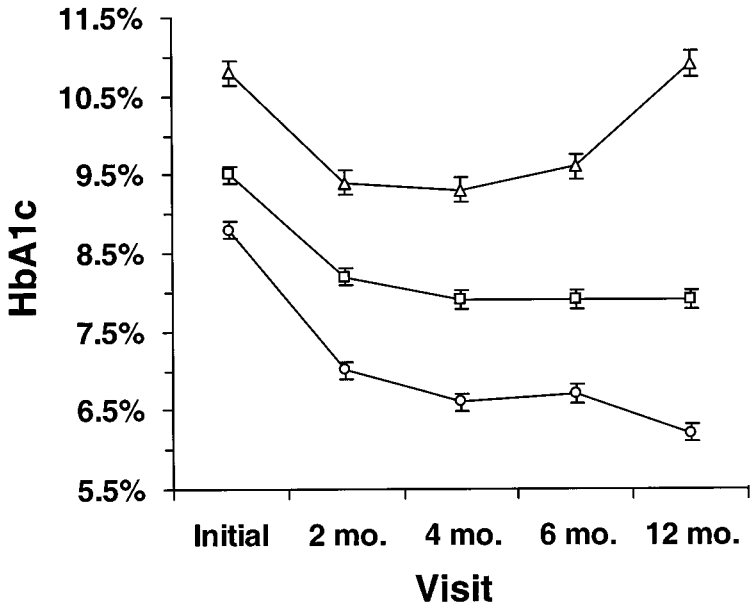

Figure 1—*Mean ± SEM HbA_{1c} values at the initial, 2-, 4-, 6-, and 12-month visits according to treatment response category. △, Poor responders* (n = *123); □, intermediate responders* (n = *158); ○, responders* (n = *166).*

visits were anticipated over the course of 1 year. In type 2 diabetic patients presenting without symptomatic hyperglycemia, medications were traditionally reduced or discontinued (regardless of the presenting HbA_{1c} value) to permit an intensive 2-month trial of nonpharmacological management. If glycemic goals ($HbA_{1c} \leq 7.0\%$) were not met by the end of this 2-month period, pharmacological therapy was reinstituted or advanced.

Patient selection

Patients were selected from an on-site patient registry if they had type 2 diabetes, had initial visits between 1 January 1992 and 31 December, 1996, and returned for scheduled follow-up appointments at 2, 4, 6, and 12 months; these return visits represented times when HbA_{1c} values were typically obtained (9). As previously reported (9), other than being slightly older, the characteristics (e.g., presenting BMI, HbA_{1c} levels, and diabetes duration) of those meeting the above criteria were comparable with patients in the registry who did not meet the selection requirements.

Treatment response categories

Patients were stratified into three categories using the HbA_{1c} level at their 12-month visit. They were classified as responders if their 12-month HbA_{1c} values were ≤7.0%. This cutoff point was approximately one-half of the SD below the group mean, and thus it included those who achieved nationally recognized targets for glycemic control (17). Poor responders were defined as those whose 12-month HbA_{1c} was >9.0%. This cutoff was approximately one-half of the SD above the group average HbA_{1c} level at 1 year, and it represented patients with the poorest glycemic control. Finally, individuals whose 12-month HbA_{1c} level was >7.0 and ≤9.0% were classified as intermediate responders, thus encompassing a group of patients who did not meet the target level, but who may have shown some improvement in hyperglycemia.

Data analysis

Multiple logistical regression analyses were used to identify baseline characteristics that might distinguish intermediate and poor responders from responders. A multiple linear regression was conducted to identify variables predictive of HbA_{1c} change occurring between baseline and 1 year. Because a quality improvement initiative was introduced into the program in 1995, analyses were adjusted for the year of initial visit. Therapeutic strategies that were applied to each of the response categories were determined by examining the proportion of patients prescribed diet, sulfonylureas, or insulin. Between 1992 and 1996, sulfonylureas were the only oral hypoglycemic agents available though our health system.

Statistical differences were evaluated using the Kruskal-Wallis test (across group comparisons) or Wilcoxon's signed-rank test (for paired comparisons). As differences in glycemic outcome might be influenced by appointment-keeping behavior (18,19), the number of return visits was determined. χ^2 tests of association were used to compare proportions across groups.

RESULTS

General patient characteristics

For the 506 individuals meeting the selection criteria, 90% (447) were African-American; therefore, further analyses focused only on these patients. The average BMI was 32 kg/m^2, the average patient age and self-reported duration of disease were 58 and 5 years, respectively, and 65% were women. Mean HbA_{1c} values were 9.6, 8.1, 7.8, 8.0, and 8.1%, respectively, at the initial, 2-, 4-, 6, and 12-month visits. The initial HbA_{1c} level was not statistically different between men and women or across age-groups (<45, 45–54, 55–64, and >65 years). HbA_{1c} levels declined an average of 1.5% after 1 year of care ($P < 0.001$, 12-month versus initial visit); comparable declines were seen in men versus women and across age-groups.

HbA_{1c} changes according to response category

The 12-month HbA_{1c} level was used as the basis in defining patients as responders (n = 166), intermediate responders (n = 158), or poor responders (n = 123) to the treatment program. The percentage who were poor responders was 26, 38, and 38% for patients with first visits in 1992, 1993, and 1994, respectively; however, the percentage declined to 18 and 13% among those with initial visits in 1995 and 1996. Responders constituted 35, 30, and 30% of patients with first visits in 1992, 1993, and 1994; however, the percentage increased to 39 and 58% among those with initial visits in 1995 and 1996 (not shown). These changes were consistent with the timing of our quality improvement initiative, which emphasized increased intensification of diabetes therapy.

A significant ($P < 0.001$) decrease in HbA_{1c} occurred by 2 months in all groups (Fig. 1), and the declines (1.8% in responders, 1.4% in intermediate responders, and 1.4% in poor responders) were comparable ($P = 0.50$). The average HbA_{1c} level of the

responders was 8.8% at the first visit and 6.2% at 12 months; for intermediate responders, the average was 9.5% at the intake visit and 7.9% at 1 year ($P < 0.001$ for both, 12-month versus initial visit). The mean HbA_{1c} level of the poor responders was 10.8% at presentation and 10.9% at 12 months ($P = 0.32$). Comparing HbA_{1c} values at 12 and 2 months, the responders showed additional improvement ($P < 0.001$), poor responders showed deterioration ($P < 0.001$), and intermediate responders showed no change ($P = 0.17$) in glycemic control (Fig. 1).

Table 1—*Presenting characteristics and return visits of African-Americans with type 2 diabetes according to treatment response category*

	Responders	Intermediate responders	Poor responders	*P*
Age (years)	57 ± 13	60 ± 11	56 ± 10	0.005
Diabetes duration (years)	0.25 (0–33)	2.0 (0–43)	4.5 (0–41)	<0.001
Sex (female)	64	66	64	0.99
BMI (kg/m^2)	31.7 ± 7.6	32.1 ± 7.4	33.6 ± 7.4	0.04
Blood pressure (mmHg)				
Systolic	127 ± 18	133 ± 18	130 ± 18	0.003
Diastolic	76 ± 9	80 ± 11	79 ± 10	0.01
HbA_{1c} (%)	8.8 ± 2.6	9.5 ± 2.4	10.8 ± 2.2	<0.001
Lipids (mmol/l)				
Total cholesterol	5.3 ± 1.3	5.8 ± 1.2	5.8 ± 1.6	0.003
LDL	3.6 ± 1.2	3.9 ± 1.0	4.0 ± 1.2	0.08
HDL	1.1 ± 0.4	1.2 ± 0.3	1.2 ± 0.3	0.30
Triglycerides	1.5 ± 0.8	1.9 ± 1.5	1.98 ± 2.2	0.04
C-peptide (nmol/l)	0.89 ± 0.47	0.91 ± 0.54	0.79 ± 0.36	0.06
Return visits				
12-month total	8.5 ± 1.0	8.7 ± 1.1	8.9 ± 1.4	<0.01
First 6 months	6.6 ± 0.9	6.6 ± 0.8	6.5 ± 1.1	0.71
Between 7 and 12 months	1.9 ± 0.5	2.0 ± 0.7	2.4 ± 1.1	<0.01

Data are means ± SD, median (range), or %. All *P* values were determined by Kruskal-Wallis tests (for continuous variables) or χ^2 (for sex comparison).

Patient characteristics according to response category

Age, self-reported duration of diabetes, BMI, systolic and diastolic blood pressures, total cholesterol, and triglycerides were significantly different between groups at the time of their initial visit (Table 1). A comparable percentage of patients in all three categories were women. The HbA_{1c} level at the time of the initial visit was significantly different across groups, with the highest levels found among the poor responders. C-peptide levels were the lowest among poor responders, and there was a trend towards significance across groups. The total number of visits for the 12-month period was statistically different across groups. The number of visits during the first 6 months was comparable, indicating that our selection criteria identified patients who kept the anticipated number of visits during the most intensive phase of our program. In contrast, there was a slight but significant difference in the number of return appointments between 7 and 12 months, with poor responders having the most visits (Table 1).

Variables associated with intermediate and poor response

Multiple logistical regression analyses were used to determine which presenting patient characteristics could potentially distinguish an intermediate or poor responder from a responder (Table 2). Compared with responders, the probability of being an intermediate responder was significantly greater with longer self-reported disease duration, higher initial HbA_{1c} level, and greater diastolic blood pressure at presentation ($R^2 = 0.18$). The initial BMI did not significantly increase the odds of becoming an intermediate responder. The likelihood of being an intermediate responder declined according to year of initial visit, but this was significant only for those patients with first visits in 1996.

Compared with responders, poor responders also had longer self-reported durations of diabetes and higher HbA_{1c} levels at the time of the first visit (Table 2); in addition, greater BMI values significantly raised the odds of becoming a poor responder to the treatment program ($R^2 = 0.34$). The likelihood of being a poor responder after 1 year of care decreased markedly for patients with initial visits in 1995 and 1996. Other variables recorded at the first visit (patient age, sex, therapy for hyperglycemia, lipids, blood pressure, and C-peptide level) did not significantly increase the likelihood of being an intermediate or a poor responder. In comparing poor responders with intermediate responders plus responders (i.e., poor responders versus all others in the data set; not shown), we found that self-reported duration of disease, initial HbA_{1c} level, and BMI remained significant predictors ($R^2 = 0.18$). In addition, the odds of being a poor responder decreased with increasing C-peptide levels (odds ratio 0.74, 95% CI 0.57–0.95, $P = 0.02$). A multiple linear regression, adjusted for the same variables, also demonstrated that disease duration, initial HbA_{1c} levels, and BMI were significant predictors of the change in HbA_{1c} occurring between the baseline and 12-month visit.

Therapeutic management

At the initial visit, 25, 31, and 44% of the responders were being managed with diet, sulfonylureas, and insulin (Fig. 2). For intermediate responders, the percentages were 21, 47, and 32%; and for poor responders, they were 17, 43, and 40%. By 2 months the proportion of patients on diet alone was higher in all three groups relative to their initial visit, consistent with attempts to deintensify therapy (Fig. 2). Use of diet remained highest among the responders (52% at 1 year), with sulfonylureas increasing from 20 to 31% and insulin use decreasing to 16%. For intermediate responders, by 12 months the use of diet decreased to 24%, sulfonylurea therapy increased to 44%, and insulin use ranged from 30 to 32%. Between 2 and 12 months, poor responders experienced a decrease in management with diet alone (from 27 to 6%) and an increase in the use of insulin (41 to 59%); sulfonylurea use remained at 36% at the 4-, 6-, and 12-month visits (Fig. 2).

The average prescribed doses of sulfonylureas for responders, intermediate responders, and poor responders, respectively, were 9, 10, and 12 mg at 2 months and 9, 12, and 17 mg at 12 months (Fig. 3*A*). Sulfonylurea doses were significantly different between response groups at 4, 6, and 12 months. At 12 months, intermedi-

Table 2—*Relationship between presenting patient characteristics and 12-month HbA_{1c} outcome*

	Odds ratio (95% CI)	*P*
Intermediate responders vs. responders*		
Diabetes duration (years)	1.09 (1.04–1.14)	<0.001
HbA_{1c} (%) at initial visit	1.16 (1.04–1.29)	0.009
BMI (kg/m^2) at initial visit	1.01 (0.98–1.05)	0.48
Diastolic blood pressure	1.03 (1.00–1.06)	0.024
Year of initial visit (vs. 1992)		
1993	0.96 (0.40–2.31)	0.93
1994	0.88 (0.37–2.06)	0.76
1995	0.87 (0.39–1.92)	0.73
1996	0.38 (0.15–0.96)	0.04
Poor responders vs. responders†		
Diabetes duration (years)	1.15 (1.08–1.21)	<0.001
HbA_{1c} (%) at initial visit	1.47 (1.28–1.69)	<0.001
BMI (kg/m^2) at initial visit	1.07 (1.02–1.12)	0.007
Diastolic blood pressure	1.03 (0.99–1.06)	0.11
Year of initial visit (vs. 1992)		
1993	1.10 (0.40–3.04)	0.86
1994	1.38 (0.52–3.69)	0.52
1995	0.45 (0.16–1.25)	0.13
1996	0.18 (0.05–0.66)	0.009

Odds ratios correspond to a one-unit increase in continuous variables or a comparison (in the case of year of initial visit) of the designated group to the reference group. Analyses are adjusted for sex (women versus men), mode of therapy at presentation (sulfonylurea versus diet, insulin versus diet), age, lipids (LDL, HDL, and triglycerides), and C-peptide. *R^2 = 0.18; †R^2 = 0.34.

ate and poor responders were on higher doses of these agents than at 2 months ($P <$ 0.001), whereas responders only exhibited a trend (P = 0.06) for being on greater doses. The average total daily doses of insulin prescribed for responders, intermediate responders, and poor responders, respectively, were 22, 27, and 31 U at 2 months and 26, 33, and 39 U at 12 months (Fig. 3*B*). Differences in insulin doses between response groups were not statistically different until the 12-month visit. Total daily doses of insulin at 1 year compared with 2 months were significantly higher for intermediate responders (P = 0.001) and poor responders ($P <$ 0.001) but not for responders (P = 0.83).

CONCLUSIONS — Recent studies confirm the importance of controlling hyperglycemia to reduce the risk of complications (1–3), making it essential for practitioners to strive for optimal glucose control. Moreover, current guidelines, supported by clinical trial data (1–3), provide a clear HbA_{1c} target as an objective of care (17). Although HbA_{1c} levels improved for the group of patients analyzed, closer examination revealed that a substantial proportion (the poor responders) still had levels >9.0% despite frequent follow-up. After the initial comparable decrements in HbA_{1c} levels achieved by all three groups by the second month, differences began to emerge. When comparing the 12-month with the second-month visit, responders showed an additional reduction in HbA_{1c}, intermediate responders had no further change, and poor responders experienced a worsening of hyperglycemia to a level comparable with their initial visit.

Multiple logistical regression analysis showed that higher initial HbA_{1c}, longer self-reported duration of disease, and greater diastolic blood pressure were variables that might distinguish an intermediate responder from a responder. Longer duration of disease, higher initial HbA_{1c} level, and greater BMI increased the odds of being a poor responder. On the other hand, these variables accounted for only a small part of the variability in HbA_{1c} outcome and may not allow development of a model that provides simultaneously acceptable sensitivity and specificity to predict those who will have persistent hyperglycemia. The lack of success in reducing HbA_{1c} levels among the poor responders does not indicate that those patients received no benefit from the treatment program; lifestyle changes, detection of undiagnosed complications, or education in other preventive behaviors that improved their overall quality of life may have occurred.

With these considerations, we would categorize individuals with the above predictors as representing individuals at risk for a poor HbA_{1c} response. Once recognized, these potentially poor responders could be channeled into alternative treatment protocols. The characteristics identified here are easily obtainable for practitioners and could serve as clues as to who may require more aggressive treatment.

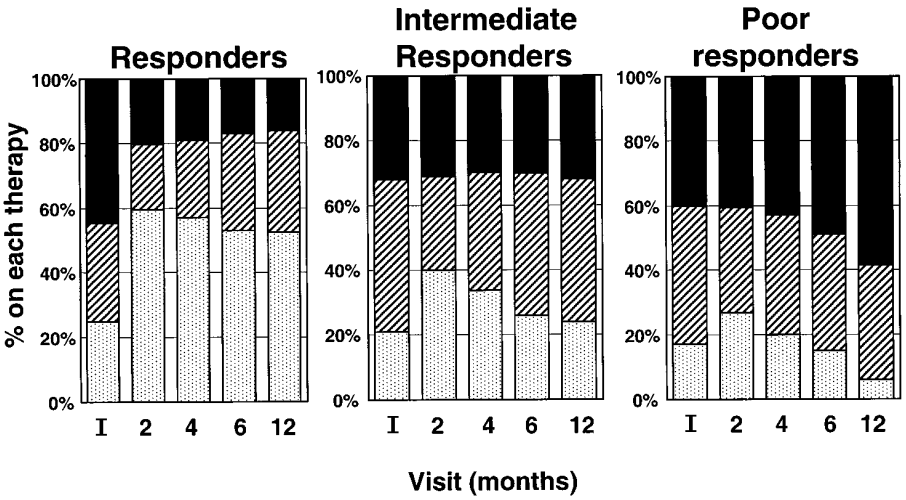

Figure 2—*Percentage of responders, intermediate responders, and poor responders on diet, insulin, and sulfonylurea treatments at the initial (I), 2-, 4-, 6-, and 12-month follow-up visits. ⬚, Diet; ▨, sulfonylurea; ■, insulin.*

Taking into account both the variables that were associated with glycemic outcome in our study and recent findings that it is possible to identify, with high probability, those who need pharmacological therapy (20), it should now be possible to make revisions in our management approach to further improve HbA_{1c} outcomes.

Our results may be compared with other work. A longer duration of disease as a predictor of glycemic control has also been reported in some studies (10–12), but not in others (13). The U.K. Prospective Diabetes Study findings that glycemic control worsens over time (3) are consistent with our data showing that the poor responders had the longest self-reported duration of disease. A recent study found that among type 2 diabetic patients on insulin, younger age, lower BMI, and female sex were predictors of glycemic control; those results are in contrast to the observations made here, where a greater BMI was significant, but age and sex were not (13). Initial HbA_{1c} level as a significant predictor of glycemic control has been noted in one study of patients with type 1 diabetes (10). Between-study differences may be explained by the choice of variables examined (10–13) or the study population analyzed (type 1 versus type 2 diabetes). These considerations all underscore the need for a standardized approach for defining factors that affect HbA_{1c} outcome in clinic populations.

Whereas the clinical importance of the small differences in return visits between groups is unclear, the data indicate that a smaller number of visits among the poor responders was therefore not the explanation for their poorer HbA_{1c} outcome. More visits by the poor responders may have been initiated by the patient and/or practitioner in response to the recognition of persistent hyperglycemia.

Pharmacological management differed for each of the patient groups. A high percentage of responders had medications successfully discontinued. The use of diet alone decreased among intermediate responders, with intensification of therapy occurring principally through reinstitution of sulfonylureas. Poor responders also had a decrease in dietary therapy alone, and the management was intensified by both advancing the sulfonylurea dose and increasing the proportion of patients on insulin. Whereas these observations suggest that providers were advancing therapy according to glycemic status, the data hint that our practitioners may not have been aggressive enough. Among poor responders, increased insulin use did not appear until late in follow-up, the total daily dose of insulin seemed modest given the degree of hyperglycemia, and some individuals remained on oral agents or even diet alone despite evidence of suboptimal control.

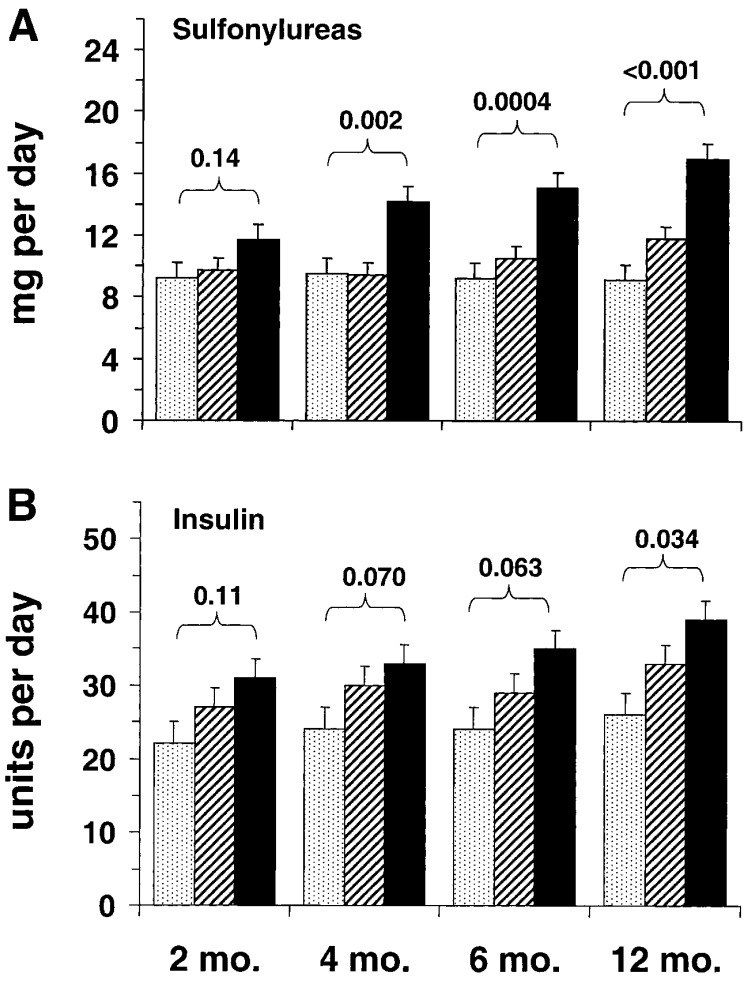

Figure 3—*Mean ± SEM daily doses of sulfonylureas (A) and insulin (B) prescribed to responders, intermediate responders, and poor responders at 2-, 4-, 6-, and 12-month visits. Statistical analysis was performed using the Kruskall Wallis test.* ▨, *Responders;* ▨, *intermediate responders;* ■, *poor responders.*

Although delayed or insufficient action on the part of the practitioners might explain why some patients were poor responders, the retrospective nature of this study precludes development of a predictive model that incorporates provider decision-making. The patterns of treatment seen here were complex and will likely make it difficult to deconstruct the relationship between therapy and outcome. We have previously demonstrated that a quality improvement effort beginning in 1995 that was targeted at providers (21,22) resulted in further improvement in HbA_{1c} levels during 1995–1996 than during 1992–1994 (9). Our observation of the decreased prevalence of poor responders among patients with initial visits in 1995 and 1996 also shows the impact of this initiative. This trend suggests that programmatic changes geared toward practitioner behavior may have a significant influence on glycemic outcome, even among patients with the most severe disease characteristics.

Several limitations of this analysis warrant discussion. Because returning for scheduled visits may affect the 1-year HbA_{1c} levels in our population (18), we selected patients who represented a group that was highly compliant with keeping appointments. Therefore, the variables shown to be predictors of response may not apply to the larger set of diabetic patients in our registry. However, even

among these patients, who had a number of return visits that exceeded current recommendations (17), a large percentage still had a high HbA_{1c} level at 1 year, indicating other factors were influencing the outcome. Although we could not assess this, worsening hyperglycemia among the poor responders between 6 and 12 months could have been caused by declining adherence to treatment recommendations. Although current data suggest that socioeconomic factors do not predict glucose control (11–15,23), differences in educational levels, incomes, or literacy could explain some of the heterogeneity in HbA_{1c} outcome (24–26). Furthermore, the role of comorbid illnesses, which preliminary data indicate do not appear to affect the ability to reduce HbA_{1c} (27), needs to be further explored. These considerations need to be accounted for when designing future studies aimed at examining the contribution of the patient versus that of the provider to glycemic outcome. Examining patients who cross over (those with characteristics of one group but with an outcome similar to another) may provide additional information that would help clinical decision-making.

Diabetes disease management programs should include strategies for the identification of patients who do not respond to conventional treatment algorithms. Because a decline in average HbA_{1c} may simply reflect the successful treatment of easier patients (in our case the responders), identifying and reducing the percentage of those with persistent hyperglycemia should be incorporated as a quality-of-care indicator, in conjunction with the group mean HbA_{1c} level. Prospective analyses incorporating the assessment of patient characteristics and practitioner behavior are needed to better define the determinants of failure to meet glycemic goals. Additional data on socioeconomic variables (e.g., income and educational status) and other individual-level characteristics that might affect patient adherence will need to be gathered. Further testing, refinement, and validation of these models and their generalizability to other clinical settings are necessary, and such studies are particularly urgent in systems that deliver diabetes care to populations carrying the highest burden of disease.

Acknowledgments — This work was supported by awards from the Agency for Healthcare Research and Quality (HS-09722; C.B.C., R.H.L., L.S.P., I.E.-K., D.C.Z., D.L.G.) and the National Institutes of Health (DK-33475 and DK-48124; L.S.P.).

We wish to thank Tammy V. Brown for her assistance in preparing the manuscript.

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