An Intervention to Overcome Clinical Inertia and Improve Diabetes Mellitus Control in a Primary Care Setting

Improving Primary Care of African Americans With Diabetes (IPCAAD) 8

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Background: Although clinical trials have shown that proper management of diabetes can improve outcomes, and treatment guidelines are widespread, glycated hemoglobin (HbA1c) levels in the United States are rising. Since process measures are improving, poor glycemic control may reflect the failure of health care providers to intensify diabetes therapy when indicated—clinical inertia. We asked whether interventions aimed at health care provider behavior could overcome this barrier and improve glycemic control.

Methods: In a 3-year trial, 345 internal medicine residents were randomized to be controls or to receive computerized reminders providing patient-specific recommendations at each visit and/or feedback on performance every 2 weeks. When glucose levels exceeded 150 mg/dL (8.33 mmol/L) during visits of 4038 patients, health care provider behavior was characterized as did nothing, did anything (any intensification of therapy), or did enough (if intensification met recommendations).

Results: At baseline, residents did anything for 35% of visits and did enough for 21% of visits when changes in therapy were indicated, and there were no differences among intervention groups. During the trial, intensification increased most during the first year and then declined. However, intensification increased more in the feedback alone and feedback plus reminders groups than for reminders alone and control groups (P<.001). After 3 years, health care provider behavior in the reminders alone and control groups returned to baseline, whereas improvement with feedback alone and feedback plus reminders groups was sustained: 52% did anything, and 30% did enough (P<.001 for both vs the reminders alone and control groups). Multivariable analysis showed that feedback on performance contributed independently to intensification and that intensification contributed independently to fall in HbA1c (P<.001 for both).

Conclusions: Feedback on performance given to medical resident primary care providers improved provider behavior and lowered HbA1c levels. Similar approaches may aid health care provider behavior and improve diabetes outcomes in other primary care settings.

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Type 2 diabetes mellitus is a major public health problem. The lifetime risk of diabetes has recently been projected at 33% and 38% for American men and women born in 2000, with accompanying decrease in life expectancy. Diabetes is now the sixth leading cause of death in the United States, and accounted for about 11% of total US health care expenditures in 2002. Although better metabolic control can reduce costs, recent analyses indicate that glycated hemoglobin (HbA1c) levels are getting worse rather than better; in the NHANES surveys, the average HbA1c level in patients with diagnosed diabetes mellitus rose from 7.8% in 1988-1994 to 8.1% in 1999-2000.

Despite the persistence of inadequate metabolic control, how best to rectify the problem is not well understood. Glycemic control is clearly affected by poor patient adherence to treatment regimens, such as failure to keep appointments or to take medications as recommended, but such measures of patient engagement have been relatively constant in our large diabetes specialty care site over the past 12 years. Moreover, the rise in HbA1c level is occurring despite improvement in process measures. Accordingly, it is more likely that poor glycemic control reflects

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contributions from the failure of health care providers to initiate or intensify therapy appropriately—clinical inertia. Clinical inertia appears to hinder control of hypertension\textsuperscript{13} and dyslipidemia\textsuperscript{14} as well as diabetes\textsuperscript{15-19} but may be less of a problem for diabetes specialists than for primary care physicians.\textsuperscript{17,19} To the extent that clinical inertia is a limiting problem, interventions aimed at improving health care provider behavior—reducing clinical inertia—might lead to better diabetes management in the primary care setting.

This hypothesis has been tested in the Improving Primary Care of African Americans with Diabetes (IPCAAD) study,\textsuperscript{20} a controlled trial in which primary care physicians (internal medicine residents) were randomized either to be controls or to receive interventions aimed at reducing clinical inertia. We now report the impact of these interventions on health care provider behavior and its relation to changes in HbA1c levels over the 3-year period of the study.

**METHODS**

**SETTING**

The IPCAAD study\textsuperscript{20} was approved by the Emory University institutional review board for conduct without consent forms and was based in the Grady Medical Clinic, the largest site of primary care in the Grady Health System. The patients were predominantly African American and economically disadvantaged.\textsuperscript{21} The Grady Medical Clinic has roughly 60,000 patient visits per year and is staffed by residents, nurse practitioners, physician assistants, and attending physicians, with support from pharmacists, nutritionists, health educators, and social workers. The IPCAAD study focused on patients with type 2 diabetes mellitus treated by internal medicine residents who were supervised by Emory Division of General Medicine faculty members.

**STUDY PROCEDURES**

The IPCAAD study has been described in detail elsewhere.\textsuperscript{20} Briefly, beginning in July 1999, the visits of all patients with type 2 diabetes mellitus included interactions with study personnel who measured capillary glucose levels and blood pressure and recorded the incoming and outgoing medications. From January 1, 2000, through December 31, 2002, residents were randomized either to be controls (usual care) or to receive interventions aimed at reducing clinical inertia. We now report the impact of these interventions on health care provider behavior and its relation to changes in HbA1c levels over the 3-year period of the study.

health care provider actions or outcomes specific to the patients seen by that provider. Emphasis was placed on achieving American Diabetes Association goals\textsuperscript{31} and on acting appropriately when values were abnormal during patient visits (eg, when random capillary glucose level exceeded 150 mg/dL [8.33 mmol/L]). We have found that such glucose values are highly predictive of HbA1c levels higher than 7%\textsuperscript{32} and that intensification of therapy based on such values is associated with very little risk of severe hypoglycemia.\textsuperscript{33}

**ASSESSMENTS**

Clinical and laboratory data from all visits were captured manually and via electronic transfer and maintained in a relational database (Oracle, Redwood City, Calif). Hemoglobin A1c was measured with the Hitachi 717 analyzer (Boehringer Mannheim, Indianapolis, Ind) and capillary glucose with the Medisense Precision PCX Point-of-Care System (Abbott Laboratories, Bedford, Mass). Capillary glucose measurements were defined as random if they occurred less than 5 hours after the last meal and fasting otherwise. To simplify the analysis, 25 mg/dL (1.39 mmol/L) was added to fasting glucose levels to render them comparable to random glucose levels; the relationship between HbA1c and random glucose levels is almost identical to the relationship between HbA1c and the following quantity: fasting glucose level + 25 mg/dL (1.39 mmol/L).\textsuperscript{34}

**STATISTICAL ANALYSIS**

Based on publications in the literature, we used a glucose algorithm\textsuperscript{35} to transform changes in therapy made by the residents into “steps”; one step was intended to reduce the HbA1c level by approximately 1%. Since a random glucose level of 150 mg/dL (8.33 mmol/L) corresponds to an HbA1c level of about 7%, and a difference of 50 mg/dL (2.78 mmol/L) corresponds to a difference in HbA1c level of about 1%,\textsuperscript{36} steps of therapy needed to reduce HbA1c level to about 7% at a given visit were arbitrarily expressed, using milligrams per deciliter, as (random glucose level - 150)/50. For visits in which the random glucose level was higher than 150 mg/dL (8.33 mmol/L), management was categorized as did nothing (no steps taken), did anything (some steps taken), or did enough (steps taken ≥ steps needed). Management was also assessed for visits in which random glucose level was stratified as 151 to 199, 200 to 249, 250 to 300, and higher than 300 mg/dL (8.38-11.04, 11.10-13.82, 13.88-16.65, and >16.65 mmol/L). The analysis of the impact of the interventions on health care provider behavior and the impact on change in HbA1c levels was hierarchical, or multilevel, in that providers were the unit of randomization to interventions, but the data were patient-level. Thus, “patients nested within providers” was included as a random effect in all models. Analysis of the impact of the interventions on health care provider behavior used ordinal logistical regression in which provider behavior was categorized as an ordinal outcome: 0, did nothing; 1, did anything; 2, did enough. Analysis included the patient’s age, body mass index (BMI) (calculated as weight in kilograms divided by the square of height in meters), sex, race, random glucose levels, and duration of diabetes as well as the resident’s postgraduate year (PGY) (1, 2, or 3) and length of exposure to the intervention (follow-up time) as covariates in the models. Patients within residents within half-day clinic modules (2 geographically contiguous units with separate waiting areas, examination rooms, rooms, equipment, and staff) was also included as a random effect in the regression models to account for potential clustering effects due to exposure to different endocrinologists and medical clinic faculty members. Based on the logistical regres-
sion models, a predicted percentage of health care provider behaviors when random glucose level exceeded 150 mg/dL (8.33 mmol/L) was calculated at baseline and at the end of each of the next 6 successive 6-month intervals during the 3 years of the active intervention. A predicted percentage of health care provider behaviors for the various categories of elevated glucose level was also calculated at baseline and at the end of the first, second, and third (last) year of the active intervention. Adjusted percentages of health care provider actions were calculated for a “typical” patient, ie, the mean of the patient characteristics and resident’s PGY level.

The impact of the interventions and health care provider intensification behavior on change in HbA1c levels over the study period was analyzed by linear mixed effects models for repeated measures data. This analysis also accounted for clustering, the multilevel nature of the data (patients nested within residents within half-day clinics with different but overlapping groups of attending physicians), and the behavior of the patients (who did not always have laboratory tests as scheduled, dropped out, and/or returned on days when their assigned intervention was not being conducted). Although 95% of the study patient visits were with residents and 70% of study visits were within the assigned intervention arm, only 42% of patients saw only their assigned resident at all of their visits. Accordingly, the analysis used all available patient data for which there were at least 2 visits, and the data were structured such that patient outcomes at a given time were associated with the previous visit (resident [intervention assignment] and the behavior of that resident) because health care provider actions at a given visit could only affect outcomes following the visit. The regression model included as covariates (1) patient characteristics of age, sex, race, BMI, duration of diabetes, number of medical clinic visits, and number of diabetes clinic visits and (2) resident characteristics of duration of exposure to the intervention and intensification of treatment. For this analysis, intensification was defined simply as either did enough or not.

Analysis of health care provider behavior used the ologit routine in Stata, version 7 (StataCorp, College Station, Tex). Analysis of HbA1c level used the lme routine in S-Plus, version 6 (Insightful Inc, Seattle, Wash). Both models included a random effects component to account for the nested (multilevel) design of the study, and in addition, both models accounted for the longitudinal aspect of the study—resident participation from 1 to 3 years.

RESULTS

Resident and patient characteristics

As reported previously,30 the mean±SD age of the 345 residents who participated in the study was 27±3 years; 35% were women, 58% were non-Hispanic white, and 8% were African American; there was no difference in PGY distribution among the intervention arms (P>.20 for all). The mean age of entire group of 4038 patients who were seen during the study was 59 years; 8% were African American; there was no difference in sex or PGY of the residents (P>.20 for all).

Impact of the interventions

The initiation of the active interventions was followed by a significant increase in the tendency to intensify therapy during visits (Figure 1 and Figure 2). However, throughout the 3-year period of the study, health care provider behavior improved significantly more for both of the feedback intervention groups for each 6-month time period than for either the reminders-only or the control groups (P<.001 for all). The improvements in health care provider behavior were greatest during the first 6 to 12 months of the study, and then they decreased. During the last 6 months, intensification of therapy remained above baseline levels for both of the feedback groups (P<.02 for both groups) but was no longer above baseline for either the reminders-only or the control groups (P>.20 for both). Beginning approximately 1 year after the intervention was initiated, intensification of therapy was significantly higher in both feedback groups than in the reminders-only and control groups (P<.001).
To illustrate the impact of the interventions, Figure 3 and Figure 4 show the model-predicted behavior of the health care providers when patients exhibited progressive elevation in glucose levels. All results were adjusted for differences in age, race, sex, BMI, duration of diabetes, and duration of follow-up. Throughout the study, whether measured as did anything or did enough, health care providers tended to intensify more often when random capillary glucose level rose from the 8.38 to 11.04 mmol/L range to 201 to 250, 251 to 300, and 300 mg/dL or higher (from the 8.38-11.04 mmol/L range to 11.10-13.82, 13.88-16.65, and >16.65 mmol/L) (P < .001). At baseline, there were no significant differences in health care provider behavior among the intervention groups (P > .70). After 1 year of the intervention, intensification of therapy increased in all 4 groups. However, the increases were significantly greater in both the feedback-only and feedback + reminders groups than among controls (P < .001 for both), but not in the reminders-only group compared with controls (P = .06). By the end of the 3-year intervention, the behavior of the health care providers in the control and reminders-only groups had returned to baseline levels. While there was also a reduction in intensification of therapy for both the feedback-only and feedback + reminders groups, their behavior remained significantly above both baseline levels (P < .005 for both) and the control and reminders-only groups (P < .02 for all).

During the intervention period, residents with more experience tended to intensify therapy more (P = .005 for PGY). Residents also intensified therapy more with younger patients (P < .001) and patients with higher BMI (P = .01). However, after adjusting for other factors, the feedback intervention significantly and independently increased the likelihood of intensification of therapy (Table 1); in contrast, reminders had no significant independent impact and did not affect the impact of feedback (interaction term nonsignificant).
A multivariable linear mixed effects analysis was used to determine whether intensification by health care providers contributed independently to lower HbA1c levels. For this analysis, we examined health care provider behavior only as did enough, since such an assessment includes an inherent adjustment for glucose and HbA1c levels, and the analysis is not confounded because of the tendency of providers to intensify more often when patients have poor control. As summarized in Table 2, BMI, sex, race, and the number of medical clinic visits had no independent impact on HbA1c level. Levels of HbA1c tended to be higher in patients who had longer duration of disease and higher baseline HbA1c levels and lower in patients who had more visits to the diabetes clinic. (In this “real-world” study, it would have been inappropriate to prevent visits to the diabetes clinic.) After adjustment for covariates, intensification by health care providers was independently associated with a reduction in HbA1c levels. However, the effect of assignment to a feedback intervention also remained significant (P = .003), indicating that the benefit of the feedback intervention cannot be attributed solely to improvement of health care provider behavior as measured by the tendency to do enough when glucose levels are elevated.

**COMMENT**

In the present study, a feedback on performance intervention given by endocrinologists to physicians in training improved health care provider behavior and levels of HbA1c in patients with type 2 diabetes mellitus. When patients’ glucose levels were elevated, intensification of therapy improved in all groups during the first year of the study, presumably due in part to contamination, the Hawthorne effect—altered behavior from recognition of being monitored—and recommendations for aggressive management, which may have been perceived as “new.” Over the next 2 years, management in the control and reminders-only groups returned to baseline levels. Health care provider behavior improved significantly more in the feedback on performance groups than in the other intervention arms during the first year, and improvements persisted above baseline levels for the duration of the study. Interestingly, the change in behavior in the feedback groups was apparent at both higher (>200 mg/dL [>13.88 mmol/L]) and lower (151-199 mg/dL [8.38-11.04 mmol/L]) glucose levels—a change in both responsiveness and sensitivity. The impact of the feedback on performance intervention on health care provider behavior withstood adjustment for demographic and other patient-related factors, and this intervention contributed independently to improvement in HbA1c levels.

Assessment of doing enough includes an intrinsic adjustment for glucose levels (intensification at least as great as that recommended by a “glucose algorithm,” (see the “Methods” section)), and our evaluation of intensification by this criterion, summarized in Table 2, showed that both intensification per se and the feedback on performance intervention had independent effects to lower HbA1c level. However, comparison of

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**Table 1. Ordinal Logistical Regression Analysis of Effect of the Interventions on Therapy Intensification**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Regression Coefficient</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Random capillary glucose category</td>
<td>0.2266</td>
<td>&lt;.001</td>
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<tr>
<td>Age (10-y increments)</td>
<td>-0.1291</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Female sex</td>
<td>0.0220</td>
<td>.66</td>
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<tr>
<td>African American</td>
<td>-0.0197</td>
<td>.65</td>
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<tr>
<td>BMI (increments of 10)</td>
<td>0.0666</td>
<td>.01</td>
</tr>
<tr>
<td>Duration of disease (10-y increments)</td>
<td>-0.0146</td>
<td>.58</td>
</tr>
<tr>
<td>PGY</td>
<td>0.0718</td>
<td>.005</td>
</tr>
<tr>
<td>Follow-up time (12-mo increments)</td>
<td>-0.1503</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Reminders only</td>
<td>0.0908</td>
<td>.18</td>
</tr>
<tr>
<td>Feedback only</td>
<td>0.4812</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Feedback X reminders†</td>
<td>0.0125</td>
<td>.89</td>
</tr>
</tbody>
</table>

**January 1, 2000, Through December 31, 2002**

<table>
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<tr>
<td>Random capillary glucose category</td>
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<td>Age (10-y increments)</td>
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<tr>
<td>Female sex</td>
<td>0.0220</td>
<td>.66</td>
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<tr>
<td>African American</td>
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<td>BMI (increments of 10)</td>
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<td>.01</td>
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<tr>
<td>Duration of disease (10-y increments)</td>
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<td>.58</td>
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<tr>
<td>PGY</td>
<td>0.0718</td>
<td>.005</td>
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<td>&lt;.001</td>
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<tr>
<td>Reminders only</td>
<td>0.0908</td>
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<tr>
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<td>0.4812</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Feedback X reminders†</td>
<td>0.0125</td>
<td>.89</td>
</tr>
</tbody>
</table>

**Table 2. Multivariable Mixed Model Analysis of Impact of Therapy Intensification on Change in HbA1c Level**

<table>
<thead>
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<th>Characteristic</th>
<th>Regression Coefficient</th>
<th>P Value</th>
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</thead>
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<td>Age, y</td>
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<tr>
<td>BMI</td>
<td>0.0058</td>
<td>.08</td>
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<tr>
<td>Duration of disease, y</td>
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<td>Female sex</td>
<td>-0.0477</td>
<td>.43</td>
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<tr>
<td>African American</td>
<td>0.1322</td>
<td>.28</td>
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<tr>
<td>Medical clinic visits, No.</td>
<td>-0.0009</td>
<td>.86</td>
</tr>
<tr>
<td>Diabetes clinic visits, No.</td>
<td>-0.0265</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Baseline HbA1c</td>
<td>0.4348</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Treatment intensification (did enough)</td>
<td>-0.1911</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Follow-up, y</td>
<td>-0.0659</td>
<td>.02</td>
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<tr>
<td>Reminders only</td>
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<td>.39</td>
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<tr>
<td>Feedback only</td>
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<td>.003</td>
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<tr>
<td>Feedback X reminders†</td>
<td>0.0808</td>
<td>.46</td>
</tr>
</tbody>
</table>

**Abbreviations:** BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); PGY, postgraduate year.

†Interaction term between feedback only and reminders only.

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Figure 4 with Figure 3 shows that health care providers often intensified therapy less than recommended (did anything in 25%-65% of visits vs did enough in 10%-35% of visits). Apparent suboptimal performance might be due in part to a variety of clinical contraindications, but the frequency of both did anything and did enough findings in our study remained less than those in our diabe-
tes clinic (data not shown). To the extent that feedback on performance might improve HbA1c levels independent of changes in intensification, the mechanism could involve a change in health care provider attitudes (since we have shown that perceived barriers to management were reduced significantly by this feedback intervention, but not in the control or reminders-only groups). 38

In the present study, feedback on performance altered health care provider behavior (intensified diabetes therapy), and it is reasonable to conclude that the altered behavior improved clinical outcomes (HbA1c levels). It is well recognized that health care providers often do not adhere to medical guidelines13-19,30-42—although diabetes specialists may do somewhat better than generalists27,19—but changing provider behavior is difficult, and providers are poorly responsive to traditional continuing medical education lectures.43 The interventions tested in the present study—reminders and feedback on performance—were selected because such approaches have improved health care provider adherence to guidelines in other settings.22-29 However, most previous studies have focused mainly on process measures (eg, ordering laboratory tests, immunizations, or recommended antibiotics44) rather than complex clinical decision making. It is possible that process measures might be easier to influence than diabetes management, which might explain the limited impact of reminders in our study; in fully-adjusted models (Table 1 and Table 2, Figure 3 and Figure 4), the reminders had mildly positive effects on both behavior and change in HbA1c level, although the trends were not significant. Alternatively, the reminders might have been more effective if the health care providers had been “forced” to respond to them45; in our paradigm, providers were free to ignore the reminders, but they could not ignore the feedback on their performance.

Our study has several limitations. Contamination was unavoidable both from resident-resident discussions and presentation of the “message” in lectures, but such contamination should only have decreased the between-group differences, which remained significant. It is possible that the residents would have intensified therapy more often if the criterion for action had been elevated HbA1c rather than glucose level. However, provision of rapid turnaround results for HbA1c levels had only modest impact on behavior and HbA1c levels in another Grady Health Systems primary care setting,46 and most of the patients in the present study had HbA1c levels that were often over 7%. We also do not know whether feedback would be as effective if provided by individuals who are not endocrinologists. In this study, feedback also improved health care provider attitudes,38 which might not be comparably affected by other feedback strategies. Finally, we do not know whether the impact of feedback is fully generalizable and would have been similar with recipients who had completed training in other settings. Further studies will be required to resolve these issues, but our results should at least be generalizable to the large number of municipal teaching hospitals serving the minority populations, which are at high risk of receiving less health care and having worse health outcomes than nonminority populations.

Our study demonstrates (1) that individualized feedback on performance given face-to-face by endocrinologists to internal medicine physicians in training improves health care provider behavior as measured by the tendency to intensify therapy for patients with type 2 diabetes mellitus who have high glucose levels and (2) that such improvements in provider behavior are associated independently with a reduction in levels of HbA1c. To the extent that limitations in health care provider behavior—clinical inertia—constitute a major barrier to diabetes management, our model may have broad application to improve patient outcomes and to decrease the clinical and economic impact of diabetes in the primary care setting.

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REFERENCES