Rapid A1c Availability Improves Clinical Decision-Making in an Urban Primary Care Clinic

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OBJECTIVE — Failure to meet goals for glycemic control in primary care settings may be due in part to lack of information critical to guide intensification of therapy. Our objective is to determine whether rapid-turnaround A1c availability would improve intensification of diabetes therapy and reduce A1c levels in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — In this prospective controlled trial, A1c was determined on capillary glucose samples and made available to providers, either during ("rapid") or after ("routine") the patient visit. Frequency of intensification of pharmacological diabetes therapy in inadequately controlled patients and A1c levels were assessed at baseline and after follow-up.

RESULTS — We recruited 597 subjects. Patients were 79% female and 96% African American, with average age of 61 years, duration of diabetes 10 years, BMI 33 kg/m^2, and A1c 8.5%. The rapid and routine groups had similar clinical demographics. Rapid A1c availability resulted in more frequent intensification of therapy when A1c was ≥7.0% at the baseline visit (51 vs. 32% of patients, $P = 0.01$), particularly when A1c was >8.0% and/or random glucose was in the 8.4–14.4 mmol/l range (151–250 mg/dl). In 275 patients with two follow-up visits, A1c fell significantly in the rapid group (from 8.4 to 8.1%, $P = 0.04$) but not in the routine group (from 8.1 to 8.0%, $P = 0.31$).

CONCLUSIONS — Availability of rapid A1c measurements increased the frequency of intensification of therapy and lowered A1c levels in patients with type 2 diabetes in an urban neighborhood health center.

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Although diabetes is a common disease that can lead to significant morbidity and mortality (1,2), there is strong evidence that achieving good glycemic control can delay or prevent complications of both type 1 and type 2 diabetes (3–6). However, many patients continue to have high levels of glucose and A1c (7–9) and remain at risk for end-organ damage.

The reasons for failure to achieve the American Diabetes Association (ADA) goals for glycemic control are not well understood. Patient-related factors such as income, age, years of education, occupation, and literacy (10–12), as well as failure to keep appointments (13), poor adherence to prescribed hypoglycemic medications (14), and lack of understanding of diabetes and the importance of good glycemic control (15), can limit the effectiveness of management. However, provider-related factors may be even more important, since providers often fail to intensify diabetes therapy appropriately when patient glycemic control is poor (16,17). Such "clinical inertia" (18,19) slows the process of achieving therapeutic targets and could compromise the ability of health care systems to reduce the morbidity, mortality, and costs associated with diabetes. Moreover, interventions aimed at overcoming clinical inertia can improve glycemic control in a municipal hospital setting, where many patients are affected by poverty and limited literacy (18).

Clinical inertia might be due in part to lack of information available to providers. For example, patients may not monitor their blood glucose levels at home (20) or bring monitoring records to their clinic appointments. Also, while A1c values are the standard indicators for glycemic control, it is often inconvenient for patients to have laboratory tests before office visits in order to have recent A1c measurements available at the time of the visit. As an alternative, the development of A1c assays that can be performed within minutes in a clinic setting could potentially give providers the information they need to guide clinical decision-making. The use of rapid A1c determinations has been shown to improve patient management in specialty diabetes clinics (21,22) and to improve A1c values in some patient populations (22,23). However, although >90% of office visits of patients with diabetes are to primary care providers (24), there has been little experience with the use of rapid A1c measurements in primary care settings. We conducted a prospective controlled trial in a neighborhood health center to determine whether the availability of A1c values at the time of a patient's visit would increase the frequency of intensification of diabetes therapy by providers and improve A1c values at follow-up.

RESEARCH DESIGN AND METHODS

Setting

The study was conducted at the Dekalb/Grady Health Center in Atlanta, GA, a neighborhood primary care clinic affiliated with the Grady Health System and

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

Table 1—*Baseline patient characteristics*

	All patients			Patients with at least 1 follow-up visit			Patients with 2 follow-up visits		
	Routine	Rapid	*P*	Routine	Rapid	*P*	Routine	Rapid	*P*
n	280	317		211	229		134	141	
Age (years)	61.0 ± 0.7	61.0 ± 0.7	0.93	61.5 ± 0.9	61.8 ± 0.7	0.79	62.3 ± 1.0	61.2 ± 0.9	0.44
Diabetes duration (years)	9.6 ± 0.6	10.2 ± 0.5	0.44	10.0 ± 0.7	10.7 ± 0.6	0.41	10.1 ± 0.9	10.7 ± 0.8	0.61
BMI (kg/m^2)	33.0 ± 0.5	32.7 ± 0.5	0.68	33.2 ± 0.6	32.2 ± 0.6	0.28	33.4 ± 0.8	33.1 ± 0.8	0.76
Female (%)	78.6	78.8	0.97	79.6	79.5	0.97	83.6	80.4	0.50
African American (%)	97.4	95.1	0.19	96.6	95.4	0.34	96.5	94.3	0.41
Days between follow-up and previous visit	NA	NA	NA	109 ± 3	108 ± 3	0.75	99 ± 3	97 ± 3	0.66
RBG at baseline (mg/dl)	191 ± 6	195 ± 6	0.72	187 ± 7	190 ± 7	0.76	182 ± 8	191 ± 9	0.44
A1c at baseline (%)	8.4 ± 01	8.5 ± 0.1	0.84	8.2 ± 0.1	8.5 ± 0.1	0.23	8.1 ± 0.2	8.4 ± 0.2	0.24
A1c >7.0% (%)	72.1	67.8	0.25	70.6	69.4	0.79	70.9	68.8	0.70

Data are mean ± SE. RBG, random blood glucose.

supported by faculty from the Emory University School of Medicine. The clinic is staffed by three family practitioners, two general internists, and three nurse practitioners. Approximately 750 patients are seen in the clinic each month, and ~27% have diabetes. Patients with diabetes routinely have capillary glucose determinations (Advantage Accu Data System; Roche, Basel, Switzerland) before seeing their providers.

Design

The study was designed as a controlled trial and approved by the Emory University Institutional Review Board. Before the start of the study, the providers were given a brief review of the evidence justifying good diabetes control, as well as strategies for patient management in routine use at the Grady Diabetes Clinic. This included both glucose and A1c goals as well as use of different hypoglycemic agents in implementing a stepped care program tailored to meet the needs of different patients (18,25). Specifically, providers were encouraged to advance pharmacological therapy for patients with A1c ≥7.0% to achieve the ADA goal of A1c <7.0% (26).

From 1 February 1999 through 31 October 1999, patients with type 2 diabetes of at least 6 months' duration were enrolled in the study. The 6-month criterion was used to allow the patients and providers the opportunity to improve glycemic control through diet and exercise alone. During each visit, patients with diabetes had an A1c level measured with a DCA 2000 instrument (Bayer, West Haven, CT) (normal range 3.4–6.2%; intra-assay coefficient of variability 0.6–2.4%, interassay coefficient of variability 4.3%). The DCA 2000 is a NGSP (National Glycohemoglobin Standardization Program)-certified instrument. For convenience, patients whose baseline visits fell on an even numbered day of the month were assigned to the "rapid" group, and their A1c values were revealed to the provider at the time of the visit. Patients whose baseline visits fell on an odd numbered day of the month were assigned to the "routine" group, and their A1c values were made available to the provider after the patient had left the clinic (similar to routine practice). Therefore, the providers acted as their own control, seeing patients in both groups. A similar alternate day or block randomization scheme has been used in other studies (21,27).

Study visits included a baseline and two follow-up visits 2–4 months apart. However, not all patients had two follow-up visits; of 597 patients who had a baseline visit, 440 patients had only one follow-up visit and 275 patients had two follow-up visits. Such loss to follow-up has been observed in our clinic before (13) and is also common in other settings (28). Follow-up visits were scheduled on the same even/odd day assignment as the baseline visit to prevent contamination between the arms of the study. Providers used a data collection sheet to record whether patients brought blood glucose–monitoring records home, patient diabetes medications, and any changes that were made during each visit. All data were entered into a computerized database after each visit.

Intensification of diabetes therapy was defined as an increase in the dosage of hypoglycemic agents that the patient was taking at the time of the baseline visit or the addition of a new agent. Frequency of intensification was expressed as the percent of poorly controlled patients who had therapy intensified, relative to the number of patients who needed intensification. Based on the ADA goal of A1c <7.0% (26), intensification of diabetes therapy was considered necessary if the A1c level was ≥7.0%. The amount of intensification was determined as milligrams of oral agents or units of insulin. Hypoglycemic agents available through the Grady Health System formulary at the time of the study included sulfonylureas (extended-release glipizide and glyburide), metformin, and insulin, and intensification of therapy involved these agents exclusively.

We examined the effect of rapid A1c availability on both frequency of intensification and amount of intensification in all 597 baseline patient visits to determine whether availability of the current A1c value would change provider behavior. The frequency of intensification of therapy was evaluated in patient groups with different levels of A1c. We also determined the frequency of intensification of therapy in relation to random (nonfasting) capillary glucose at the baseline visit because we have previously found that providers tend to intensify therapy in response to elevated random glucose levels (16,29). In addition, we examined the ef-

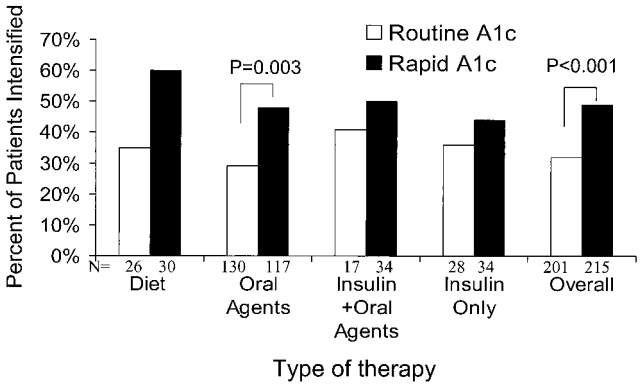

Figure 1—*Intensification of therapy at baseline visit in patients with A1c ≥7.0%.*

fect of rapid A1c availability on A1c levels in the subsets of patients who returned for follow-up.

Statistical analysis

Averages are expressed ±SE. χ^2 test and/or two-tailed unpaired *t* test were used to determine differences in baseline characteristics, frequency of treatment intensification between groups, and the amount of dosage adjustment between groups. Paired *t* tests were used to evaluate changes in A1c values. Multiple logistic regression analysis was used to examine factors contributing to the decision of whether therapy should be intensified. A *P* value <0.05 was considered significant. StatView version 5.0 (SAS Institute, Cary, NC) was used for the analyses.

RESULTS — A total of 597 patients were enrolled in the study (routine, n = 280; rapid, n = 317). Their average age was 61 years, BMI 33 kg/m^2 (data available for n = 431), diabetes duration 10.0 years, and A1c 8.5%. The majority of patients were African American (96%, data available for n = 498) and female (79%). At the baseline visit, 22% of patients were being managed with diet alone (average A1c 7.6%), 54% were using oral agents alone (A1c 8.6%), 10% were using insulin in combination with oral agents (A1c 9.0%), and 14% were using insulin alone (A1c 8.6%); 24% of the patients brought in home glucose–monitoring data. Among patients in the routine group, 28% had a A1c <7.0%, as compared with 32% in the rapid A1c group (P = 0.25). Demographics did not differ between the routine and rapid A1c groups in the full set of 597 patients with a baseline visit, the 440 patients with one follow-up visit, or the 275 patients with two follow-up visits (Table 1). We also compared the characteristics of patients with at least one follow-up visit with those with no follow-up visits. There was no difference in diabetes duration, BMI, sex, or race between the two groups, but there were minimal differences between patients with and without follow-up in age (61.7 vs. 58.8 years, respectively, P = 0.01), random blood glucose (208 vs. 188 mg/dl, P = 0.04), and A1c (8.3 vs. 8.9%, P = 0.009).

Intensification at the baseline visit

Approximately two-thirds of patients in the rapid and routine groups had A1c ≥7.0% at the baseline visit and were considered eligible for intensification of therapy. Among these patients, providers intensified diabetes therapy in 51% of the rapid patients vs. 32% of the routine patients (P = 0.0003). Patients managed with oral agents alone were intensified more frequently if they were in the rapid A1c group (48 vs. 29%, P = 0.003), and a similar but nonsignificant trend was noted for the patients managed with other approaches (Fig. 1).

There was little tendency of providers to intensify therapy if the A1c level was <8.0%, when therapy was intensified in 12% of patient visits on average (Fig. 2). The increased frequency of intensification conferred by availability of A1c levels became apparent and significant when A1c was 8.0–8.9% (rapid group 51% vs. routine group 23%, P = 0.007) and remained so at A1c levels ≥9.0% (rapid group 65% vs. routine group 46%, P = 0.006).

Since the majority of patients (80%) were not fasting at presentation, we also analyzed the intensification in relation to random capillary glucose levels (n = 258 and n = 221 for the rapid and routine groups, respectively). When random capillary glucose levels were >300 mg/dl, intensification of therapy occurred in ~60% of patient visits in both groups, but intensification was less frequent when glucose levels were lower (Fig. 3). The tendency of A1c availability to increase intensification was significant for patients with random capillary glucose 151–200 mg/dl (rapid group 54% vs. routine group 10%, P = 0.001), or glucose 201–250 mg/dl (rapid group 67% vs. routine group 37%, P = 0.04).

Multiple logistic regression analysis was used to determine factors contributing to the decision to intensify diabetes therapy in those patients with elevated A1c levels. After correction for age, race, sex, duration of diabetes, BMI, and glucose levels, both higher baseline A1c (P < 0.001) and the availability of rapid A1c levels (P = 0.026) increased the likelihood of intensification of therapy by providers. Age, race, sex, duration of

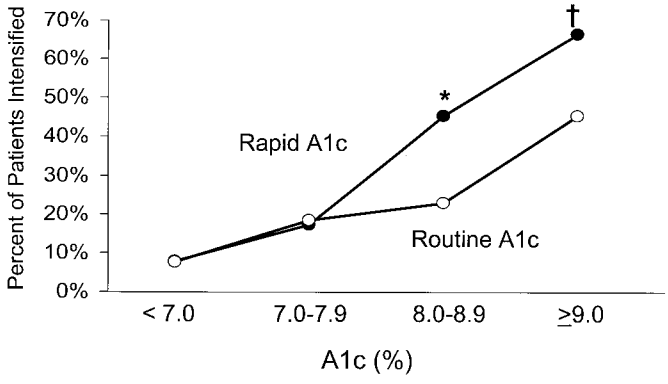

Figure 2— *Intensification of therapy at baseline visit according to A1c level. ○, routine A1c; ●, rapid A1c.* *P = *0.032;* †P = *0.002.*

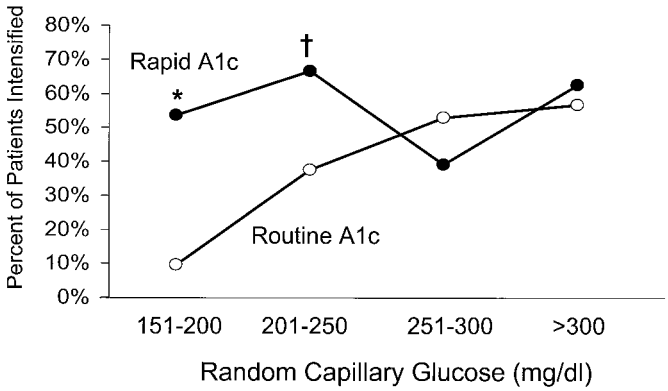

Figure 3— *Intensification of therapy at baseline visit according to random capillary blood glucose level. ○, routine A1c; ●, rapid A1c.* *P < *0.001;* †P = *0.012.*

diabetes, BMI, and capillary glucose levels did not influence the decision to intensify after adjustment for A1c levels (Table 2). Since the majority of our patients were African American, we reran the logistic regression excluding race as a factor; however, it did not affect the significance of baseline A1c (odds ratio 1.36, CI 1.15–1.61) and A1c availability (2.03, 1.10–3.74) in determining intensification of therapy. Availability of home blood glucose records did not influence intensification of therapy; however, only 24% of patients brought in records, and the completeness and time frame of these records were not documented (data not shown).

Amount of intensification

There were no significant differences between the rapid and routine groups in the amount of change in dosage of sulfonylurea, metformin, or insulin. For example, in patients treated with insulin alone and having an A1c ≥7.0%, average A1c was 9.5% and average insulin dosage was 51 units/day (0.59 units · kg^{-1} · day^{-1}); only 32% of patients had any increase in insulin dosage, averaging 8.5 units or 0.11 units/kg (11.1 units in the rapid group vs. 4.6 units in the routine group, $P = 0.19$).

Changes in A1c

A1c levels did not change significantly in either group at the first follow-up visit (average time between visits 108 ± 3 days). The average A1c level decreased from 8.5 ± 0.1 to 8.3 ± 0.1% in the rapid group ($P = 0.13$) and from 8.2 ± 0.1 to 8.1 ± 0.1% ($P = 0.56$) in the routine group. However, there were major differences in A1c responses between patients in whom therapy was advanced and those in whom it was not. If baseline A1c was ≥7.0% and therapy was not intensified, A1c did not change from the baseline visit to the first follow-up visit (8.7 ± 0.1 vs. 8.7 ± 0.1%, routine and rapid groups combined, $n = 178$). For patients whose therapy was intensified, A1c fell from 9.7 ± 0.3 to 9.1 ± 0.3% in the routine group ($P = 0.02$) and from 10.1 ± 0.2 to 9.1 ± 0.2% in the rapid group ($P <$ 0.001), but the changes in A1c did not differ significantly between the routine and rapid groups (Fig. 4).

Since the impact of intensification of therapy would be expected to be cumulative, we also examined changes in A1c in the 134 routine and 141 rapid patients who had two follow-up visits. They had an average interval of 98 days between the baseline and first follow-up visit and 90 days between the first and second follow-up visit, and these values did not differ between groups. Intensification of therapy in poorly controlled patients occurred in 55% of the rapid and 29% of the routine patients at the baseline visit ($P <$ 0.001), as well as in 43% of the rapid and 32% of the routine patients at the first follow-up visit ($P = 0.11$). The A1c level decreased in the rapid group (from 8.4 ± 0.2 to 8.1 ± 0.1% $P = 0.04$) but did not change significantly in the routine group (8.1 ± 0.2 to 8.0 ± 0.1%, $P = 0.31$). However, despite these improvements, 73% of patients in the routine and 70% of patients in the rapid group remained inadequately controlled with A1c levels ≥7.0%.

Table 2—*Logistic regression: factors predicting intensification of therapy*

Variable	Odds Ratio (95% CI)	*P*
Constant	0.24	
Age per year	0.98 (0.95–1.01)	0.19
Male sex	0.87 (0.38–1.95)	0.73
African-American race	0.30 (0.07–1.39)	0.12
Diabetes duration, per year	1.00 (0.96–1.04)	0.86
BMI per kg/m^2	0.99 (0.95–1.02)	0.43
Random blood glucose per mg/dl	1.00 (1.00–1.01)	0.21
A1c at baseline (per 1% increase)	1.39 (1.16–1.65)	<0.001
Rapid A1c available	1.98 (1.06–3.71)	0.03

CONCLUSIONS — There are three major findings of our study. First, in patients with A1c ≥7.0%, glycemic control did not improve if therapy was not intensified, whereas A1c levels improved significantly if therapy was intensified. Second, availability of rapid A1c determinations led to more frequent intensification of therapy in inadequately controlled patients. Finally, availability of rapid A1c determinations was also associated with modest but significant decreases in A1c levels in patients who returned for two follow-up visits.

Interestingly, we found that availability of rapid A1c determinations enhanced intensification of therapy if patients had modest elevation in capillary glucose levels (random glucose 151–250 mg/dl) or substantial elevations in A1c (>8.0%). Our findings suggest that providers are more likely to advance pharmacological therapy in patients exhibiting mild hyperglycemia if a rapid A1c level is available. Our results also show that knowing that an A1c level is high makes it more likely that therapy will be advanced, although there was no difference in intensification of therapy between the two groups for patients having a A1c in the 7.0–7.9% range. Therefore, availability of rapid A1c is likely to change provider behavior significantly in patients with moderate-to-severe hyperglycemia (A1c >8.0%), but may not change their decision-making for

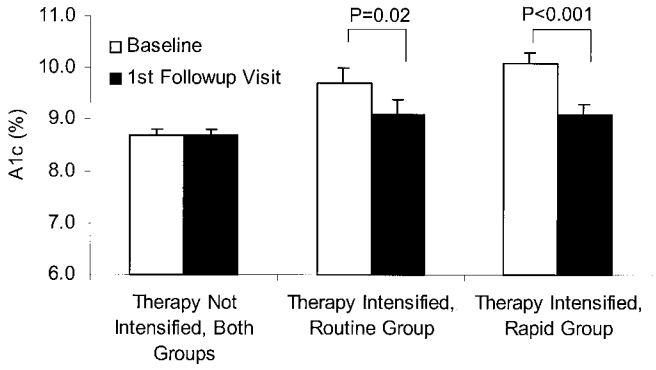

Figure 4— *Baseline and first follow-up A1c levels in patients with A1c ≥7.0% according to whether pharmacological therapy was or was not intensified.*

patients with mild-to-moderate hyperglycemia. It could be argued that such behavior is consistent with ADA guidelines, which suggest action only when A1c levels exceed 8.0%. However, we believe that therapy should be intensified for A1c ≥7.0% because the ADA goal is a A1c level <7.0% (26) and because micro- and macrovascular damage is already occurring when A1c is at 7.0% (30).

It seems likely that the limited impact of rapid A1c availability on glycemic control reflects the low frequency of intensification of therapy and possibly the use of increments of medications that were too low. For patients treated with insulin alone and having an A1c ≥7.0%, the average dose of insulin was 51 units/day (0.59 units · kg^{-1} · day^{-1}) but only 32% had any increase in insulin dosage. Moreover, when the insulin dose was increased, the increment averaged 8.5 units (0.11 units/kg) and the average A1c only decreased from 9.9% at baseline to 9.7% at the first follow-up visit ($P = 0.71$). Previous studies have suggested that higher dosages of insulin are needed in order for insulin therapy to be effective in patients with type 2 diabetes. In a study using intensive insulin therapy for type 2 diabetes, Henry et al. (31) found that the average daily insulin dose required to achieve glycemic control was 100 units at 6 months of follow-up; patients in that study had an average BMI of 31.4 kg/m^2. Although the study by Henry et al. indicates that typical insulin needs for good control may be on the order of 1 unit · kg^{-1} · day^{-1}, the dose of insulin used in the present study was <60% of this amount. These findings suggest that our study patients would have benefited from an increase in both the frequency and amount of intensification of pharmacologic therapy.

The added benefit of rapid A1c measurements may be modest in settings where intensification of therapy is already aggressive. A previous study of the utility of rapid A1c determinations failed to show an impact of rapid A1c on intensification in the Grady Diabetes Clinic (21), largely because providers had already been targeted by quality improvement efforts aimed at overcoming "clinical inertia" (19) and intensifying therapy in patients with elevated glucose levels (16–18). In another study, Cagliero et al. (23) found in their diabetes specialty clinic that rapid A1c availability led to decreased A1c values at follow-up, but the difference in change in A1c between groups was not statistically significant. In a preliminary study, Marrero et al. (22) reported that rapid A1c availability in a primary care setting improved glycemic control over a 6-month period in insulin-treated patients and improved decision-making for non–insulin-requiring patients with A1c >9.0%. Consistent with their report, we also found a greater impact in patients with higher A1c levels.

One limitation of this study is that the majority of patients are African Americans; however, we feel that it should not affect generalizability to other ethnic groups. Another limitation was length of follow-up, which may have affected both provider behavior and effect on glycemic control. Although lack of resources precluded a longer study, a longer time interval would have given providers more of an opportunity to see the outcomes of their decisions. If the providers recognized that lack of intensification was associated with continued high A1c levels, and that use of small therapeutic increments was followed by only limited improvements in glycemia, they might have been prompted to intensify therapy both more frequently and aggressively. Moreover, it seems likely that the impact of A1c availability on glycemic control would be cumulative; modest decrements in A1c at each visit would be more significant after 12 months of care, similar to the benefit of increased frequency of intensification of therapy in the Grady Diabetes Clinic (18). In addition, we were unable to collect data on the impact of the intervention on the frequency of hypoglycemia. While findings from specialty clinics indicate that severe hypoglycemia should be rare in patients with type 2 diabetes (23,32), and utilization of rapid A1c determinations should reduce hypoglycemia by limiting intensification of therapy in patients with A1c <7.0%, the UKPDS (U.K. Prospective Diabetes Study) experience (4) indicates that improvement in glycemic control will probably be associated with some increase in symptomatic hypoglycemia.

The present study shows that rapid A1c availability can improve the frequency of intensification when glucose levels are elevated. However, the reduction in A1c may be modest unless technological innovation is accompanied by measures to help ensure that primary care providers will take full advantage of the added information. Thus, attainment of better diabetes control nationwide is likely to demand the complementation of technological and pharmacotherapeutic advances with strategies that enhance providers' clinical decision-making.

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