

Public Health Implications of Recommendations to Individualize Glycemic Targets in Adults With Diabetes

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OBJECTIVE—To estimate how many U.S. adults with diabetes would be eligible for individualized A1C targets based on 1) the 2012 American Diabetes Association (ADA) guideline and 2) a published approach for individualized target ranges.

RESEARCH DESIGN AND METHODS—We studied adults with diabetes ≥ 20 years of age from the National Health and Nutrition Examination Survey 2007–2008 ($n = 757$). We assigned A1C targets based on duration, age, diabetes-related complications, and comorbid conditions according to 1) the ADA guideline and 2) a strategy by Ismail-Beigi focused on setting target ranges. We estimated the number and proportion of adults with each A1C target and compared individualized targets to measured levels.

RESULTS—Using ADA guideline recommendations, 31% (95% CI 27–34%) of the U.S. adult diabetes population would have recommended A1C targets of $< 7.0\%$, and 69% (95% CI 66–73%) would have A1C targets less stringent than $< 7.0\%$. Using the Ismail-Beigi strategy, 56% (51–61%) would have an A1C target of $\leq 7.0\%$, and 44% (39–49%) would have A1C targets less stringent than $< 7.0\%$. If a universal A1C $< 7.0\%$ target were applied, 47% (41–54%) of adults with diabetes would have inadequate glycemic control; this proportion declined to 30% (26–36%) with the ADA guideline and 31% (27–36%) with the Ismail-Beigi strategy.

CONCLUSIONS—Using individualized glycemic targets, about half of U.S. adults with diabetes would have recommended A1C targets of $\geq 7.0\%$ but one-third would still be considered inadequately controlled. Diabetes research and performance measurement goals will need to be revised in order to encourage the individualization of glycemic targets.

Diabetes Care 36:84–89, 2013

For nearly a decade, diabetes care guidelines from the American Diabetes Association (ADA) have recommended that the goal of glycemic control should be to lower the A1C to $< 7.0\%$ for adults living with diabetes (1). This recommendation currently motivates diabetes public health programs and diabetes care translational research. All of these efforts have the overall intention of shifting the national distribution of A1C levels downward in order to improve diabetes outcomes and may lead to overtreatment of A1C levels in certain diabetes populations.

Although the standard A1C target of $< 7.0\%$ is probably the best-known feature

of the ADA guidelines, the ADA guidelines also recommend that A1C targets should be based on individual clinical circumstances. Similar recommendations for individualized targets have been supported by the Veterans Health Administration-Department of Defense (VA-DoD), American Geriatric Society, American College of Physicians (ACP), and American Association of Clinical Endocrinologists (AACE) (2–5). Recommendations to individualize targets are based on major type 2 diabetes trials that found different levels of benefit, and even harm, from lower A1C levels depending on diabetes population characteristics (e.g., duration of diabetes, age, and comorbidity) (6–10). According to the ADA, lower A1C

targets are recommended for patients with a short duration of diabetes, long life expectancy, and no significant cardiovascular disease (1). Conversely, higher A1C targets are recommended for patients with longstanding diabetes, advanced age, limited life expectancy, a history of macrovascular or advanced microvascular complications, extensive comorbidities, or a high risk for severe hypoglycemia (1–5). Although guidelines have identified these special populations, recommendations on how to set individualized A1C targets have been open to interpretation.

Recently, a formal strategy for individualizing targets was published by Ismail-Beigi et al. (11). Similar to diabetes care guidelines, this strategy was based on expert interpretation of outcomes from prominent diabetes trials, including the U.K. Prospective Diabetes Study (UKPDS), Action to Control Cardiovascular Risk in Diabetes (ACCORD), Action in Diabetes and Vascular Disease: Preterax and Diamicon Modified-Release Control Evaluation (ADVANCE), and Veterans Affairs Diabetes Trial (VADT) (6–10). The Ismail-Beigi strategy used the same clinical characteristics proposed in previous guidelines from the VA-DoD, American Geriatric Society, and ACP (e.g., age, duration of diabetes, history of macrovascular and microvascular complications, comorbidity, and psychosocioeconomic context). Based on their strategy, only adults 20–44 years of age with no history of diabetes-related complications would be recommended an A1C target of $\leq 6.5\%$, and several populations are recommended individualized A1C targets above the conventional ADA threshold of $< 7.0\%$, including adults 45–65 years of age with established macrovascular or advanced microvascular complications, adults > 65 years of age with longstanding diabetes or established macrovascular or advanced microvascular complications, and all adults with advanced age. Additionally, because the Ismail-Beigi strategy suggested ranges of glycemic targets (i.e., ~ 7 , 7.0–8.0, or $\sim 8.0\%$), there exists the potential that some patients who could

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Received 2 December 2011 and accepted 3 July 2012.

DOI: 10.2337/dc11-2344

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safely tolerate lower glycemic targets may be undertreated in order to stay within range.

These recent calls for greater individualization of A1C targets raise fundamental public health questions. The degree to which the individualization of diabetes care is regarded as important depends on how many U.S. adults with diabetes may be candidates for A1C targets more or less stringent than the conventional target of $<7.0\%$. Previous assessments of diabetes care quality have used population-level A1C thresholds to judge the quality of care (12–14); however, the diabetes care quality may differ from previous reports using these newer standards of individualization (15). In order to understand the potential impact of the individualization of glycemic targets on diabetes care quality, we characterized the U.S. adult diabetes population by clinical variables that have been proposed as reasons to individualize A1C targets. We then operationalized the ADA and Ismail-Beigi strategies for individualization to estimate 1) the distribution of the U.S. adult diabetes population across each individualized A1C target and 2) the size of the population who have measured A1C levels that are at or below their recommended individualized A1C target.

RESEARCH DESIGN AND METHODS

We used data collected from the National Health and Nutrition Examination Survey (NHANES) 2007–2008, a nationally representative sample of the U.S. civilian, noninstitutionalized population. The NHANES sample was obtained using a stratified, multistage probability design with planned oversampling of older adults and minority groups. The NHANES used in-home interviews to obtain sociodemographic characteristics and medical and family history. Clinical examinations were conducted at mobile examination centers. Detailed descriptions of the design and data collection of NHANES have been published previously (16).

Between 2007 and 2008, 8,082 individuals 20 years of age or older completed the household interview. The interview included questions on sociodemographic characteristics, medical history, and diabetes history. Diabetes history was based on a question that asked, "Other than during pregnancy (in women), have you ever been told by a doctor or health professional that you have diabetes or sugar diabetes?" For this study, we analyzed

data from 757 respondents 20 years of age and older who reported a diagnosis of diabetes. In analyses comparing recommended individualized A1C targets to actual A1C levels, we only studied the 672 respondents who had measured A1C levels.

Clinical variables

From NHANES 2007–2008, we identified the clinical variables used in the ADA guideline and Ismail-Beigi strategy, specifically duration of diabetes, age, history of macrovascular or microvascular complications, and comorbid conditions. Duration of diabetes was calculated as the difference between each respondent's age and their age when they reported that they were diagnosed with diabetes. Short duration of diabetes was defined as <5 years for the ADA guideline and ≤ 10 years for the Ismail-Beigi strategy. We used different definitions of short duration because the Ismail-Beigi strategy does not have a conventional target, and thus, the A1C target for each individual should be definable by clinical characteristics. However, if short duration is defined as ≤ 5 years, in the Ismail-Beigi strategy, there would be a diabetes population who would not have a recommended A1C target (adults >45 years of age, diabetes for 5–10 years, and no history of complications). A long duration of diabetes was defined as >10 years for both strategies based on clinical recommendations and the characteristics of recent trial populations (6–8,11). Advanced age was defined as ≥ 75 years of age.

Macrovascular disease was identified based on self-reported diagnoses of congestive heart failure, coronary heart disease, angina, myocardial infarction, or stroke. Advanced microvascular complications were defined based on self-reported receipt of dialysis in the past 12 months or measured macroalbuminuria. Both urine albumin and creatinine were measured at a central laboratory. Urine albumin was measured using a solid-phase fluorescent immunoassay. Urine creatinine was analyzed using a Jaffé rate reaction and measured with a CX3 analyzer. The details of urine collection and processing are described elsewhere (16). Urine macroalbuminuria was defined as a urine albumin-to-creatinine ratio of >300 mg/g. Advanced microvascular complications did not include blindness, severe neuropathy, or amputation because these data were not available in NHANES 2007–2008.

For comorbid conditions, we calculated the weighted combined Charlson Comorbidity Index score for each respondent based on the comorbid conditions available in the NHANES 2007–2008 (chronic pulmonary disease, rheumatoid arthritis, leukemia, lymphoma, liver disease, renal disease, malignant solid tumor, diabetes, and diabetes-related end organ damage). The combined index scores in this study are conservative estimates since several conditions (acquired immunodeficiency syndrome, dementia, hemiplegia, peripheral vascular disease, and ulcer disease) and disease severity were not queried in the NHANES 2007–2008. The combined index score incorporates age and has been validated for use to estimate long-term survival. A weighted combined index score of ≥ 4 points was used to define a history of extensive comorbid conditions, because a score of ≥ 4 points is associated with an estimated 53% 10-year mortality (17). Although the ADA guideline also recommends consideration of hypoglycemia unawareness, we were not able to assess this variable.

Statistical analysis

To understand the implications of individualizing glycemic targets using the ADA guideline, we characterized the size of the U.S. adult diabetes population by duration of diabetes, age, macrovascular or advanced microvascular complications, and comorbidity. We then applied the ADA strategy for individualization. The ADA guideline recommends A1C goals more stringent than $<7.0\%$ (e.g., $<6.5\%$) be considered for patients with a short duration of diabetes and no history of significant macrovascular disease, and A1C goals less stringent than $<7.0\%$ (e.g., $<8.0\%$) for patients with longstanding diabetes, advanced age, a history of macrovascular or advanced microvascular complications, or extensive comorbid conditions.

Second, we applied the Ismail-Beigi strategy for individualization (11). We simplified their strategy by creating mutually exclusive categories of individualized A1C targets. Age categories were defined to be mutually exclusive (20–44, 45–65, 66–75, and >75 years). We assigned an individualized A1C target (≤ 6.5 , 6.5–7.0, ~ 7.0 , 7.0–8.0, and $\sim 8.0\%$) according to each respondent's age, duration of diabetes, and history of macrovascular or advanced microvascular complications. Details about the

individualized A1C target assignment are presented in Table 2.

Additionally, we compared recommended individualized A1C targets to measured levels in order to provide an estimate of the current use of individualized A1C targets in U.S. adults with diabetes. We defined the A1C targets ~7.0% and ~8.0% to have a 1.0% range, i.e., 6.5–7.5% and 7.5–8.5%, for analyses comparing individualized targets to measured A1C levels. For all analyses, sampling weights were used to provide estimates that are representative of the U.S. population (16). Statistical analyses were performed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

RESULTS

Respondent characteristics

There were an estimated 18.5 million U.S. adults in 2007–2008 with self-reported diabetes. The mean age of U.S. adults with diabetes was 60 years (Table 1) and average A1C was 7.2%. The mean duration of diabetes was 12 years and about one-third had a history of macrovascular or advanced microvascular complications. The mean weighted combined Charlson Comorbidity Index score for the adult diabetes population was 4.0 points.

Individualization of glycemc targets based on the ADA guideline

Using the ADA guideline, an A1C target more stringent than the conventional A1C of <7% (e.g., <6.5%) would apply to 19% (95% CI 15–22%), whereas the conventional A1C target of <7% would apply to 12% (8–16%), of the U.S. adult diabetes population (Table 2). An A1C target that is set at or above 7.0% (e.g., <8.0%) would apply to 69% (66–73%) of the U.S. adult diabetes population.

Individualization of glycemc targets based on Ismail-Beigi et al.

Using the Ismail-Beigi strategy, 12% (95% CI 9–15%) of the U.S. adult diabetes population would have a recommended A1C target of ≤6.5%, and 44% (39–49%) would have a recommended A1C target that is set at or above 7.0%. Specifically, 18% (13–23%) would have an individualized A1C target of 7.0–8.0%, and 26% (23–28%) would have an A1C target of ~8.0%. The remaining 44% (39–49%) would have intermediate A1C targets of 6.5–7.0 or ~7.0%.

Table 1—Characteristics of U.S. adults with diabetes, NHANES 2007–2008*

n	757
Female	53 (46–60)
Age, mean (SD), years	59.5 (0.4)
20–44	13 (10–16)
45–65	50 (45–55)
66–75	21 (17–25)
>75	16 (13–19)
A1C, mean (SD)†	7.2 (0.1)
A1C ≥7.0%†	47 (41–54)
Diabetes duration, mean (SD), years	11.9 (0.6)
<5	32 (28–36)
>10	39 (35–43)
Macrovascular or advanced microvascular complications	35 (29–40)
Macrovascular only	26 (20–32)
Advanced microvascular only	5 (3–7)
Macrovascular and advanced microvascular	4 (2–7)
Weighted combined Charlson Comorbidity Index, mean (SD)	4.1 (0.1)
≥4 points	52 (47–57)

*Data are expressed as percent (95% CI) unless otherwise indicated. †Results based on 672 participants (weighted population 16,662,539) who had A1C testing.

Comparing individualized glycemc targets to measured glycemc levels

Using the ADA guideline or the Ismail-Beigi strategy, about one-third of the U.S. adult diabetes population would be considered inadequately controlled (ADA, 30% [95% CI 26–35%]; Ismail-Beigi, 31% [27–36%]), as compared with 47% (41–54%) using a conventional A1C target of <7.0%. Based on the Ismail-Beigi strategy, 45% (40–51%) of adults with diabetes have glycemc control tighter than individualized targets, and 23% (20–27%) have glycemc control within individualized A1C targets.

The distributions of measured A1Cs for respondents with the highest and lowest individualized A1C targets are presented in Fig. 1. The subpopulation advised to pursue the highest targets had a similar proportion with A1C levels of <7.5% (ADA, e.g., <8%: 66% [95% CI 60–73%]; Ismail-Beigi, 7.5–8.5%: 72% [63–82%]) as the subpopulation advised to pursue the lowest A1C target (ADA, e.g., <6.5%: 74% [61–86%]; Ismail-Beigi, ≤6.5%: 59% [43–76%]).

CONCLUSIONS—The intended effect of recommendations to individualize glycemc targets in diabetes populations is to maximize the population-level health benefits of glycemc control while reducing the risk of harm. According to strategies for individualizing glycemc targets from the ADA guideline and Ismail-Beigi et al. (11), 44–70% of the U.S. adult diabetes population should have recommended A1C targets set at or above

7.0%. Despite this dramatic change in glycemc target assignment, one-third of the diabetes population would still be considered uncontrolled using individualized targets instead of a conventional A1C target of <7.0%. Thus, individualizing glycemc control targets will not obviate the need for continued population-level improvements in glycemc control.

Calls to individualize glycemc targets have grown in recent years, in part because of the increasing recognition that the U.S. diabetes population has a high prevalence of long-standing diabetes, advanced age, and diabetes-related complications, all variables that potentially reduce the benefits and elevate the risks of traditional glycemc control goals. These population-level characteristics raise serious questions about what the goals of diabetes translational and quality improvement research should be. Most diabetes translational and quality improvement research currently aims to move the population toward the glycemc control target of an A1C <7.0% (18). For example, a recent study found that primary care providers could significantly increase the number of diabetes patients with an A1C level <7.0% by increasing their encounter frequency to every 2 weeks (18). However, if individualization is desirable, then diabetes research efforts should ideally move different segments of the population toward different targets. Diabetes translational research could incorporate individualized targets in a number of ways. An intervention designed to lower blood sugars in a clinic population could

Table 2—Size of U.S. diabetes population recommended for each individualized A1C target based on ADA guidelines and Ismail-Beigi et al., NHANES 2007–2008*

Source	Individualized A1C target (%)	Patient characteristics				Weighted population		
		Age (years)	Duration (years)	Diabetes complication	Comorbidity	N = 18,462,471	% (95% CI)	
ADA	More stringent than <7.0% (e.g., <6.5%)	Any	<5	No	No	3,441,996	19 (15–22)	
	<7.0%	≤75	5–9	No	No	2,183,715	12 (8–16)	
	Less stringent than <7.0% (e.g., <8.0%)†		>75	Any	Any	Any	12,710,527	69 (66–3)
			Any	≥10	Any	Any	2,936,251	23 (18–28)
			Any	Any	Yes	Any	7,184,474	57 (51–62)
			Any	Any	Yes	Yes	6,397,569	50 (44–57)
Ismail-Beigi et al. (11)	≤6.5	20–44	Any	No	—	9,599,516	76 (69–82)	
	6.5–7.0	45–65	<10	No	—	2,155,528	12 (9–15)	
	6.5–7.5	20–44	Any	Yes	—	4,110,538	22 (19–26)	
		45–65	≥10	No	—	226,508	1 (0.1–2)	
	7.0–8.0	66–75	<10	No	—	2,387,578	13 (10–16)	
		45–65	Any	Yes	—	1,369,166	7 (4–11)	
	7.5–8.5	66–75	≥10	No	—	2,672,886	15 (10–19)	
		66–75	Any	Yes	—	695,671	4 (2–5)	
	>75	Any	Any	—	1,782,112	10 (6–13)		
					2,936,251	16 (13–19)		

*Diabetes complications included macrovascular disease (congestive heart failure, coronary heart disease, angina, myocardial infarction, and stroke) and advanced microvascular complications (receipt of dialysis and macroalbuminuria). Comorbidity was defined by a weighted combined Charlson Comorbidity Index score ≥4 points. †Column percentages for subcategories of “less stringent than <7.0%” do not total 100% because of overlap among the subcategories of >75 years of age, duration ≥10 years, diabetes complications, and comorbidity.

still use standard quality improvement tools (e.g., plan-do-study-act cycles, disease registries, and population management), but patients would be assigned to different glycemic control targets. Alternatively, diabetes translational interventions could focus solely on individuals with a common glycemic target, such as healthy younger patients with newly diagnosed diabetes or older diabetes patients with significant comorbidities (19). Interventions for these populations may not only need specific glycemic targets but they may also need specialized components that account for the unique clinical and behavioral needs of these targeted populations.

These findings also have important implications for diabetes quality performance measurement. Typically, dichotomous thresholds have been used to rapidly judge appropriate diabetes care for an organization or practice (20). The difficulty is that dichotomous thresholds may incentivize providers to oversimplify the process of glycemic goal-setting, which can lead to unintended consequences. For example, dichotomous thresholds may penalize clinicians who care

for an older diabetes population and choose appropriately high glycemic targets. Furthermore, diabetes quality of care that is measured using universal dichotomous thresholds does not incentivize or reward clinicians for setting individualized targets. The National Committee for Quality Assurance (NCQA) has partially addressed this issue by adding the A1C target of <8% in 2009 to the A1C target of <7% and the measure of A1C poor control >9% (20,21). Although this additional A1C target measure will likely lead to decreased overtreatment of A1C levels, it may also lead to undertreatment in other groups. The unintended consequences of glycemic control-based performance measures could be eliminated with various methods, including using a composite measure or allowing clinicians to set individualized A1C targets to define diabetes care quality (22).

Interestingly, our study found that measured A1C levels did not correspond with their recommended A1C targets, using two different individualization strategies. There may be several explanations for such findings. Individualized

targets may not correspond with measured levels because the achievement of any glycemic target is dependent on many clinical factors, including disease severity and adherence to medications. It is also possible that some clinicians routinely individualized glycemic targets but were using variables not included in this study (e.g., psychosocioeconomic context). Additionally, there may be slow adoption of individualized glycemic targets due to lack of awareness of the guideline recommendations for individualization. The AACE recommends an A1C target of ≤6.5% for most people with diabetes (3), whereas the ADA and ACP recommend an A1C target of <7% for the general population (1,5). The AACE, ADA, and ACP also recommend that targets should be individualized (1,3,5). In contrast, the VA-DoD recommends only individualized targets (4). Because these guidelines recommend using life expectancy to set targets and include language that may be subject to interpretation (e.g., “extensive comorbid conditions” or “advanced microvascular complications”), it may be challenging to individualize glycemic targets in clinical practice, as

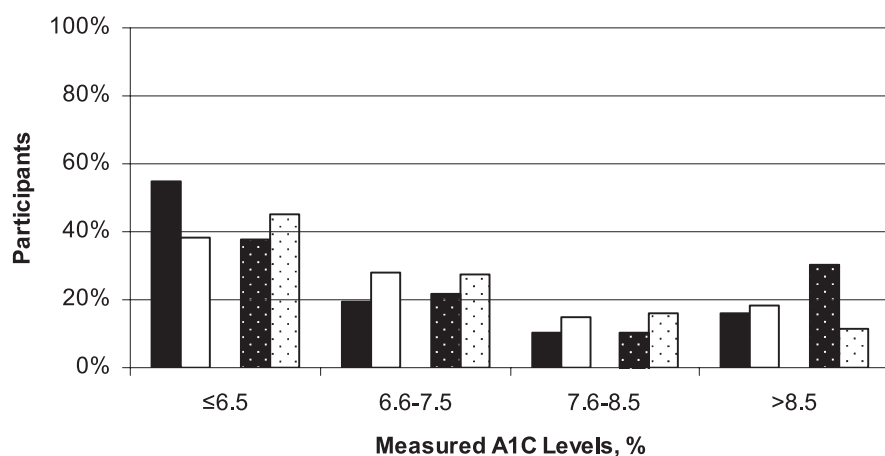


Figure 1—Distribution of measured A1C levels in the U.S. adults with the highest and lowest individualized targets. Black bar, ADA: more stringent A1C target (<math>< 6.5\%</math>); white bar, ADA: less stringent A1C target (<math>< 8.0\%</math>); black bar with white dots, Ismail-Beigi: target A1C $\le 6.5\%$; white bar with black dots, Ismail-Beigi: target A1C = 7.5–8.5%.

opposed to aiming for an A1C target of <math>< 7\%</math>. Additionally, clinicians and practices are likely driven to meet the standards set by the NCQA performance measures, which, for this study population, included the A1C <math>< 7\%</math> performance measure. This performance measure was amended in 2008 to apply only to patients <math>< 65</math> years of age and those without cardiovascular disease (20). As more organizations, like the VA-DoD and NCQA, and experts (23–26) emphasize the importance of individualized targets, future evaluations of the state of diabetes care may demonstrate greater individualization of glycemic targets.

There are several limitations to this study. It is important to acknowledge that there is no universally accepted approach to individualizing diabetes care and that the approaches studied herein are based on current expert opinion. For the purposes of illustration, we only considered two recommended strategies and recognize that there are others (2,4). In carrying out our assignment of individualized targets, we did not have all recommended variables in NHANES. We included patients with self-reported diabetes, which may lead to a selection bias of patients with long-standing diabetes and trend toward individualized A1C targets that are higher. The rates of diabetes-related complications may be underestimated because we relied on self-report. Full capture of advanced microvascular complications would likely increase the number of adults who would have recommended individualized glycemic targets set at or above 7.0%. Similarly,

including hypoglycemia, life expectancy, or failed attempts at intensifying glycemic treatment with insulin would likely increase the population who are recommended less stringent A1C targets. Additionally, because the data are cross-sectional and population-level, we were not able to interpret each respondent's glycemic levels in their clinical context or include their psychosocioeconomic context in the assignment of individualized targets. Also, we defined the targets of ~ 7.0 or $\sim 8.0\%$ with a 1% range, which may be too wide and overestimate the proportion of adults who are being treated to individualized glycemic targets. Additionally, measured A1C levels were used as a marker of quality of diabetes care; however, there is known bias in the A1C levels measured at the NHANES laboratory (-0.10 to $+0.02\%$) from the National Glycosylated Hemoglobin Standardization Program (NGSP) central primary reference laboratory (16). In clinical practice, A1C levels can vary by as much as 1% from NGSP-measured levels because of laboratory imprecision and bias (26). Even in high-quality clinical laboratories, a measured A1C of 7% may actually range $\pm 0.5\%$, and point-of-care A1C tests may be more imprecise (27). Lastly, it is important to acknowledge that A1C levels may differ by race and ethnicity (28), which is not accounted for in the current recommendations for individualized glycemic targets.

The notion that the goals of diabetes should be individualized is not new to experienced practicing clinicians, but has been less commonly discussed in public

health circles. Divergent findings from major clinical trials of glycemic control have led to very prominent recommendations to individualize glycemic control targets. These recommendations have the intended goals of maximizing population-level benefits, reducing harms of therapy, and improving the cost-effectiveness of clinical diabetes care. Our study results show that strategies to individualize glycemic targets do not eliminate the need to intensify diabetes management. If anything, the new strategies may complicate our approaches to quality improvement and performance measurement. Future studies are needed to study the long-term effects of implementing individualized glycemic targets in adults with diabetes.

Acknowledgments—This work was supported by a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Ruth L. Kirschstein National Research Service Award (F32-DK-089973 to N.L.), an NIDDK Diabetes Research and Training Center grant (P60-DK-20595 to N.L., P.M.J., A.G.N., and E.S.H.), and the NIDDK Chicago Center for Diabetes Translational Research (P30-DK-092949 to N.L., P.M.J., A.N., and E.S.H.).

No potential conflicts of interest relevant to this article were reported.

N.L. researched data, contributed to discussion, and wrote, reviewed, and edited the manuscript. P.M.J., A.G.N., and E.S.H. contributed to discussion and reviewed and edited the manuscript. N.L. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Parts of this study were presented at the Society of General Internal Medicine Midwest Regional Meeting, Chicago, Illinois, 15–16 September 2011, and at the 72nd Scientific Sessions of the American Diabetes Association, Philadelphia, Pennsylvania, 8–12 June 2012.

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