

# Mitigating Case Mix Factors by Choice of Glycemic Control Performance Measure Threshold

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**OBJECTIVE** — Performance measures are tools for assessing quality of care but may be influenced by patient factors. We investigated how currently endorsed performance measures for glycemic control in diabetes may be influenced by case mix composition. We assessed differences in A1C performance measure threshold attainment by case mix factors for A1C >9% and examined how lowering the threshold to A1C >8% or >7% changed these differences.

**RESEARCH DESIGN AND METHODS** — Using data from the 1999–2002 National Health and Nutrition Examination Survey for 843 adults self-reporting diabetes, we computed the mean difference in A1C threshold attainment of >9, >8, and >7% by various case mix factors. The mean difference is the average percentage point difference in threshold attainment for population groups compared with that for the overall population.

**RESULTS** — Diabetes medication was the only factor for which the difference in threshold attainment increased at lower thresholds, with mean differences of 5.7 percentage points at A1C >9% (reference), 10.1 percentage points at A1C >8% ( $P < 0.05$ ), and 14.1 percentage points at A1C >7% ( $P < 0.001$ ).

**CONCLUSIONS** — As 87% of U.S. adults have A1C <9%, a performance measure threshold of >9% will not drive major improvements in glycemic control. Lower thresholds do not exacerbate differences in threshold attainment for most factors. Reporting by diabetes medication use may compensate for heterogeneous case mix when a performance measure threshold of A1C >8% or lower is used.

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The implementation of performance measures to provide public accountability and financial incentive for quality health care represents a major shift in the approach to improving population health within the U.S. (1). The movement to measure quality diabetes care involves establishing standards related to glycemic control, eye and foot examinations, urine protein screening, and management of lipids and blood pressure (2). The performance measure threshold for glycemic control has been controversial. More stringent measures may encourage overzealous treatment of individuals to which more general guidelines do not apply. Conversely, providers

may mistake less stringent performance measures for guidelines that have been carefully developed by a number of medical organizations to assist physicians in setting therapeutic targets for their patients (3).

The most commonly cited guidelines are those of the American Diabetes Association (ADA), which state that although certain patient groups (e.g., elderly patients or those with comorbidity) may not benefit from stringent glycemic targets, maintaining A1C <7% is a reasonable goal for individuals with diabetes (4). After decades in which less than half of Americans reached the target of A1C <7% (5), national data have shown im-

proved glycemic control in those with diabetes with 56% achieving A1C <7% in 2003–2004 (6,7). Even before these improvements, some stakeholders questioned whether linking pay for performance programs to a >9% threshold would encourage adequate glycemic control for individual patients or propel declines in A1C at the national level (8). With only 13% of Americans with diagnosed diabetes having a A1C of >9% in 2003–2004, a performance measure of >9% may have limited ability to drive population-wide quality improvement.

In contrast to clinical practice guidelines for glycemic control, such as the ADA guideline, which address goals for individual patients, performance measures are designed to indicate overall health care quality delivered across a population of patients (9). An A1C performance measure for holding providers accountable may foster improvement in population-level glycemic control, although experts debate how to define an optimal measure of health care quality (10,11). This debate has led to different thresholds established by different organizations and used for different purposes. The National Diabetes Quality Improvement Alliance (NDQIA), a consortium of stakeholders interested in diabetes care, has established two categories of performance measures. The first category of measures is intended for quality improvement efforts within an organization and describes A1C values across the range of <6.0 to >10.0%. The second set of measures is that to which providers and health plans will be accountable for public reporting and on which performance-based reimbursements will be based. The glycemic control performance measure that the NDQIA recommends for public reporting is A1C >9% to indicate poor control (12). The NDQIA has a good control measure of A1C <7% under “active consideration” but stated that “before such a measure can be put forward, appropriate means for considering case mix must be specified.” The National Quality Forum (NQF), whose mission is to improve health care quality through national performance standards, has

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adopted the NDQIA benchmarks, including the A1C >9% threshold for public reporting. In contrast, the National Committee for Quality Assurance adopted a Health Plan Employer Data and Information Set measure of A1C <7% for public accountability (13). This measure has undergone scrutiny (10,11) because not all patients should achieve this goal. Clinical guidelines state that individual goals are to be tailored according to age, life expectancy, comorbidity, risk of hypoglycemia, and patient preferences (4).

Part of the challenge of implementing an A1C performance measure is preventing unintended consequences, such as penalizing physicians who treat low-income patients or patients with medically complicated diabetes in whom A1C may be more difficult to control. In its rationale for the >9% threshold, the NDQIA stated that [performance] measures “must account for differences in individual patient conditions and preferences.” This wording suggests that the NDQIA is adopting a lenient threshold to diminish differences in threshold attainment that are due to heterogeneity in case mix.

Differences in glycemic control across age, BMI, duration of diabetes, and diabetes medication use (6,14) indicate that these case mix factors are likely to influence performance measure attainment. Differences in glycemic control by race/ethnicity have also been reported (15) but may be a function of access to care (16). Education and income level may influence measures of diabetes care independent of access to care (16). Determining the effect of threshold choice on the magnitude of case mix factor differences is important for the careful selection of a performance measure. Using representative data from individuals with diabetes in the U.S. and considering A1C thresholds of >9, >8, and >7%, we computed estimates of differences in threshold attainment for various patient factors and determined how the magnitude of differences is affected by choice of threshold.

## RESEARCH DESIGN AND METHODS

Data for this cross-sectional analysis come from the 1999–2002 National Health and Nutrition Examination Survey (NHANES). This ongoing survey conducted by the National Center for Health Statistics uses a stratified, multistage, probability cluster design that results in a nationally representative sample of the noninstitu-

tionalized, civilian U.S. population. The sampling design oversamples non-Hispanic blacks, Mexican Americans, individuals aged  $\geq 60$  years, and low-income individuals to provide more precise estimates for these specific groups. We included 843 adults aged  $\geq 20$  years with valid measures of A1C who were not pregnant and who reported during an interview that a health care professional had told them they have diabetes. The NHANES 1999–2002 underwent institutional review board approval, and written informed consent was obtained from participants.

## Measures

Sociodemographic characteristics and information on diabetes, health, and insurance status were ascertained during interviews. Age-groups were based on approximate quintiles of the analytic sample. Race/ethnicity was based on self-identified race and Hispanic origin. Income-to-poverty ratio was defined as the ratio of reported total family income to the U.S. Census Bureau poverty threshold. Diabetes medication was categorized as use of insulin (with or without oral agents), use of oral agents only, and no use.

Weight and height were measured during a physical examination. BMI was calculated as weight in kilograms divided by the square of height in meters, and weight status was categorized as underweight or normal weight, overweight, obese, and severely obese with BMI cut points of <25, 25–29.9, 30–39.9, and  $\geq 40$  kg/m<sup>2</sup> (17). A1C was assessed by boronate affinity high-performance liquid chromatography using Primus CLC330 and Primus CLC 385 (Primus, Kansas City, MO), and values were standardized according to the method of the Diabetes Control and Complications Trial (18,19), yielding interassay coefficients of variation of <3.0%.

## Data analysis

The mean difference provides a measure of disparity among different groups within a population (20). We used the mean difference to assess differences in A1C threshold attainment by various population groups within potential case mix factors. For each factor, we calculated a mean difference to provide a summary of the difference in proportion of people with diabetes whose A1C was >7, >8, and >9%. The mean difference is expressed in percentage points, across any

number,  $p$ , of population groups. The referent for each threshold,  $r_{\text{ref}}$ , was selected as the proportion exceeding the threshold among the overall population. These referent proportions are constant at a given threshold and provide an intuitive standard from which to gauge differences across groups. For each population group,  $j$ , we calculated the proportion,  $r_j$ , exceeding the threshold, and the absolute difference in that proportion from that of the referent,  $r_{\text{ref}}$ . For each factor, the mean difference was calculated using Equation 1.

$$\text{Mean difference} = \frac{\sum_{j=1}^p |(r_j - r_{\text{ref}})|}{p} \quad (1)$$

All calculations were made with Wesvar (version 5; Westat, Rockville, MD) using the 4-year examination sample weights to account for the sample design and nonresponse. Sampling variance was calculated using the jackknife procedure, appropriate for the complex, multistage sample design (21), and 95% confidence limits were calculated by taking the natural logarithm of the mean difference, estimating the standard error of the transformed estimate, deriving confidence limits, and back-transforming the confidence limits via exponentiation. This transformation results in asymmetric confidence limits but improves their validity (22). Student's  $t$  tests were used to test whether the differences between the mean differences for the 7 and 8% thresholds relative to the 9% threshold were equal to 0.

**RESULTS**— The proportion of individuals whose A1C concentrations were >9, >8, and >7% are presented by various patient factors (Table 1). Frequency distributions for each factor across the overall population are provided for reference. Of the overall (unstratified) population, 18.4% exceeded an A1C threshold of 9%, 32.8% exceeded an A1C threshold of 8%, and 52.6% exceeded the ADA recommended target A1C of 7%. These proportions provide the referent to which subgroup threshold attainment is compared. We first present differences in threshold attainment within factors and then describe the effects of lowering the A1C threshold on these differences.

## Sociodemographic factors

For sociodemographic factors, important differences existed across groups of age,

## Choice of A1C performance measure threshold

**Table 1—Weighted frequency distribution of sociodemographic and health status factors, the proportion of each group exceeding three A1C thresholds, and the mean difference across groups**

	Frequency distribution	Proportion exceeding A1C threshold		
		>9%	>8%	>7%
Overall population	100.0	18.4	32.8	52.6
Sociodemographic factors				
Age				
20–44 years	17.4	32.7	45.7	63.5
45–54 years	21.5	23.7	37.9	52.3
55–64 years	23.2	16.4	32.8	51.1
65–74 years	21.9	13.4	28.0	55.5
75+ years	16.0	5.8	18.2	39.4
Mean difference		7.8 (4.4–13.9)	7.5 (3.7–15.1)	5.7 (2.9–11.4)
Race/ethnicity				
Non-Hispanic white	62.7	13.5	28.7	48.4
Non-Hispanic black	15.2	25.6	38.8	60.7
Mexican American	7.0	26.8	41.9	61.4
Other race, other Hispanic, multiracial	15.2	27.8	39.2	57.8
Mean difference		7.4 (4.7–11.9)	6.4 (3.5,11.8)	6.6 (3.4–12.8)
Income-to-poverty ratio				
≤0.8	10.7	32.4	40.2	58.0
0.8–2	36.1	14.9	29.5	51.1
2–4	30.6	17.5	34.5	51.2
>4	22.6	15.1	27.1	51.1
Mean difference		5.4 (3.0–9.8)	4.5 (1.7–12.2)	2.5 (0.7–9.0)*
Insurance status				
Uninsured	10.3	38.0	50.6	59.4
Private insurance	39.9	21.3	34.3	57.7
Public or government insurance	32.0	12.6	28.4	45.7
Both public and private insurance	17.9	11.5	25.9	49.3
Mean difference		8.8 (5.2–15.0)	7.6 (3.7–15.6)	5.6 (2.1–14.9)
Sex				
Male	50.5	20.2	32.8	54.8
Female	49.5	16.7	32.7	50.3
Mean difference		1.8 (0.3–9.7)	0.0 (0.0–)†	2.2 (0.4–11.3)
Education				
<High school	36.4	21.4	34.7	54.8
High school Graduate	25.1	15.9	33.2	48.2
>High school	38.6	17.3	30.6	53.3
Mean difference		2.2 (0.4–12.0)	1.5 (0.1–16.3)	2.4 (0.4–15.8)
Health status factors				
Diabetes medication				
Use of insulin	26.1	27.5	48.3	71.4
Use of oral agents only	55.5	16.0	29.2	52.0
No use of medications	18.4	13.0	21.5	27.7
Mean difference		5.7 (2.3–13.8)	10.1 (6.5–15.7)*	14.7 (10.8–20.1)‡
Diabetes duration				
<5 years	35.4	15.9	29.1	46.7
5 to <10 years	20.8	25.5	39.8	58.4
10 to <15 years	13.5	22.3	39.8	62.8
15 to <20 years	7.5	23.6	38.2	62.6
≥20 years	22.8	12.5	27.0	48.4
Mean difference		4.9 (2.2–11.1)	5.8 (2.7–12.3)	7.2 (4.2–12.3)
Weight status				
Underweight or normal weight	16.6	25.0	36.6	54.6
Overweight	31.5	19.1	28.6	50.8
Obese	38.1	17.0	38.8	54.9

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Table 1—Continued

	Frequency distribution	Proportion exceeding A1C threshold		
		>9%	>8%	>7%
Severely obese	13.9	13.8	22.5	53.7
Mean difference		3.3 (1.0–11.3)	6.1 (3.3–11.3)	1.8 (0.1–27.9)
Self-reported health				
Excellent or very good	18.8	9.8	25.6	46.9
Good	36.6	20.0	31.4	49.7
Fair or poor	44.6	20.8	36.9	57.4
Mean difference		4.2 (2.0–9.1)	4.2 (1.3–14.0)	4.5 (1.4–14.3)
Number of prescription medications				
0–1	19.4	25.6	39.5	55.5
2–3	27.4	17.0	31.0	52.2
4–6	29.7	16.3	28.6	49.0
≥7	23.5	16.7	34.3	54.7
Mean difference		3.1 (0.8–11.9)	3.5 (1.0–12.6)	2.2 (0.4–11.3)
Number of health care interactions				
0–1	10.2	23.7	36.0	48.8
2–3	22.4	24.0	37.9	61.1
4–9	39.1	13.6	30.1	50.5
≥10–12	28.3	19.0	31.4	50.5
Mean difference		4.1 (1.5–11.1)	3.1 (0.4,22.0)	4.1 (1.5–11.7)
Hospitalization in last year				
Yes	24.4	21.6	35.1	54.8
No	75.6	17.4	32.0	51.9
Mean difference		2.1 (0.1–34.5)	1.6 (0.1–25.3)	1.4 (0.0–†)

Data are % or mean difference (95% confidence limits). Mean difference (expressed in percentage points) indicates absolute differences between the proportion of the group and that of the total population exceeding the threshold. \* $P < 0.05$  for comparison to mean difference estimate for A1C >9%. †Calculation of upper confidence limit results in value above theoretical maximum. ‡ $P < 0.001$  for comparison to mean difference estimate for A1C >9%.

race/ethnicity, and insurance status at each of the A1C thresholds, whereas differences across sex and education were minor. The proportion with A1C >9% declined steadily with increasing age, such that 32.7% of those aged 20–44 years but only 13.4% of those aged 65–74 years and only 5.8% of those aged ≥75 years surpassed the threshold. The age gradient was not explained by a shorter reported duration of diabetes or a lower proportion of insulin use among elderly individuals (data not shown). In comparing each of the five age-groups to the overall population, the mean difference in the proportion with A1C >9% was 7.8 (95% confidence limits 4.4–13.9) percentage points. The difference across race/ethnic groups was of a magnitude similar to that for the age difference at this threshold. Among race/ethnic groups, the proportion exceeding any threshold was much lower for non-Hispanic whites than for any minority race/ethnic group. Almost one-third of those most economically disadvantaged (income-to-poverty ratio ≤0.8) had A1C >9%, but the proportions of individuals in the other income-to-poverty ratio cat-

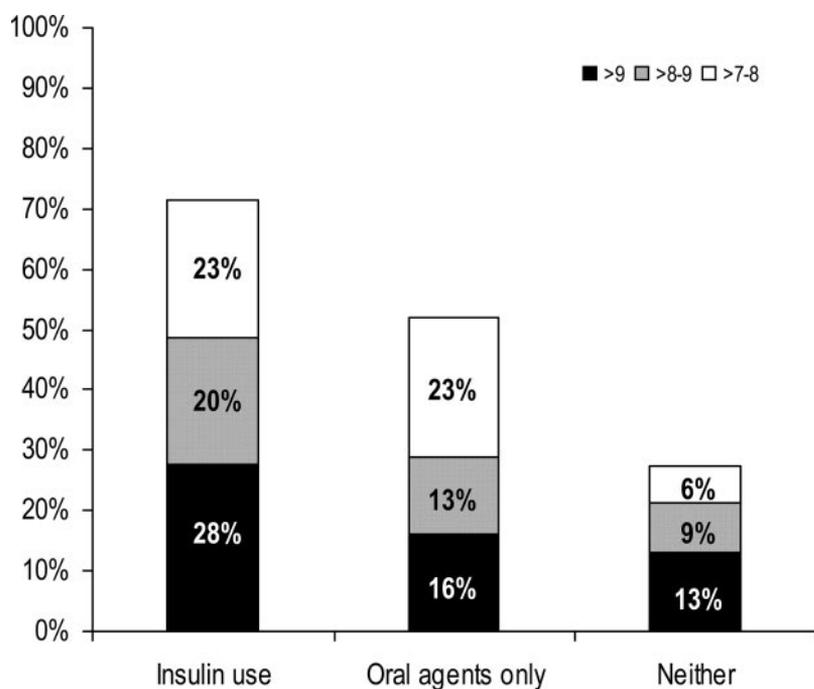
egories with A1C >9% were much lower and ranged from 14.9 to 17.5%, resulting in a mean difference of 5.4 (3.0–9.8) percentage points. Uninsured individuals were more likely to have A1C >9% than those with any insurance. The lower proportion with A1C >9% among those with public insurance (and among those with additional private insurance) appears to be explained by the Medicare eligibility of individuals aged ≥65 years, who have a lower probability of poor control (data not shown).

Lowering the threshold to A1C >8 or >7% did not significantly affect most sociodemographic disparities. The age gradient persisted, and mean differences across age and insurance status were modestly reduced as the threshold was lowered from >9 to >7%. Mean differences across race/ethnic groups at the lower thresholds remained substantial. Lowering the threshold to A1C >8% did not significantly reduce the disparity across income-to-poverty groups, but lowering the threshold to A1C >7% reduced the mean difference to 2.5 (95% confidence limits 0.7–9.0) percentage points, a significant decline from the esti-

mate at >9% ( $P < 0.05$ ). Although our analysis was framed in terms of the effect on the mean difference across various groups of lowering the threshold for poor control, the results are similar if framed in terms of raising the A1C threshold for good control.

### Health status factors

Among health status factors, the largest difference at the >9% threshold was found across diabetes medication categories. Compared with 18.4% overall, more than one-quarter of individuals taking insulin, 16% of those taking oral medications, and 13% of those using no medications had concentrations above this level, yielding a mean difference of 5.7 (95% confidence limits 2.3–13.8) percentage points. The relation of poor glycemic control by diabetes duration was U-shaped, as a lower proportion among those with duration of diabetes <5 and at least 20 years had A1C >9%; the mean difference was 4.9 (2.2–11.1) percentage points. The mean difference for weight status was small at 3.3 (1.0–11.3) percentage points. Only 9.8% of individuals who reported good or excellent health



**Figure 1**—Proportion of people with A1C >9, >8–9, and >7–8% by diabetes medication use.

had A1C >9%, whereas 20% of those reporting good or fair to poor health had concentrations above the threshold, yielding a mean difference of 4.2 (2.0–9.1) percentage points for self-reported health. At A1C >9%, mean differences across categories of number of prescription medications and number of health care interactions and hospitalization in the last year were small, at 3.1 (0.8–11.9), 4.1 (1.5–11.1), and 2.1 (0.1–34.5) percentage points, respectively.

Lowering the threshold to A1C >8 or >7% had a large and significant effect on the mean difference across categories of diabetes medication. Compared with 32.8%

of the overall population, nearly half of those who used insulin had A1C >8%, and compared with 52.6% overall, >70% of insulin users had A1C >7%. Mean differences were 10.1 (95% confidence limits 6.5–15.7) percentage points at A1C >8% and 14.7 (10.8–20.1) percentage points at A1C >7% ( $P < 0.05$  and  $P < 0.001$ , respectively, compared with A1C >9%). The increase in the mean difference for diabetes medication categories at sequentially lower A1C thresholds reflects a differential increase by type of medication in the proportion exceeding the lower thresholds (Fig. 1). When the threshold is lowered to A1C >8%, the proportion of insulin users ex-

ceeding the threshold increased by 20 percentage points (to include those with A1C >8–9%), compared with increases of 13 and 9 percentage points for those taking oral agents and those not using medication, respectively. When the threshold is lowered to A1C >7%, the increase in the proportion above this threshold was 23 percentage points for the insulin users and those taking oral agents (after including those with A1C >7–8%), but only 6 percentage points for those using no medication. The mean differences for the remaining health status factors were not significantly affected by lowering the A1C to >8 or >7%.

In Table 2, patient factors were ranked by mean differences at each A1C threshold. Considering a mean difference of  $\geq 5$  percentage points as noteworthy, important disparities were consistently observed across all three A1C thresholds for age, race/ethnicity, insurance, and diabetes medication, but their rank varied by threshold. At A1C >9%, insurance, age, and race/ethnicity contributed the greatest mean differences in threshold attainment. At lower thresholds, diabetes medication exhibited the greatest disparity with mean differences of 10 and almost 15 percentage points. The average mean difference across all factors was consistent (4.7–4.8) among all thresholds.

**CONCLUSIONS** — This study demonstrates the extent to which disparities in glycemic control by patient subgroups are mitigated or exacerbated by choice of A1C thresholds of >9, >8, and >7%. For 11 of the 13 factors examined, choice of A1C threshold did not significantly affect the magnitude of population subgroup

**Table 2**—Sociodemographic and health status factors ranked by their mean difference according to A1C threshold

Rank	>9%	MD	>8%	MD	>7%	MD
1	Insurance status	8.8	<b>Diabetes medication use</b>	10.1	<b>Diabetes medication use</b>	14.7
2	Age-group	7.8	Insurance status	7.7	Years since diagnosis	7.2
3	Race/ethnicity	7.5	Age-group	7.5	Race/ethnicity	6.6
4	<b>Diabetes medication use</b>	5.7	Race/ethnicity	6.4	Age-group	5.8
5	<b>Income-to-poverty ratio</b>	5.4	Weight status	6.1	Insurance status	5.6
6	Years since diagnosis	4.9	Years since diagnosis	5.8	Self-reported health	4.5
7	Self-reported health	4.2	<b>Income-to-poverty ratio</b>	4.5	No. of health care interactions	4.1
8	No. of health care interactions	4.1	Self-reported health	4.2	<b>Income-to-poverty ratio</b>	2.5
9	Weight status	3.3	No. of prescription medications	3.5	Education	2.4
10	No. of prescription medications	3.1	No. of health care interactions	3.1	No. of prescription medications	2.3
11	Education	2.2	Hospitalization in last year	1.6	Sex	2.2
12	Hospitalization in last year	2.1	Education	1.5	Weight status	1.8
13	Sex	1.8	Sex	0.0	Hospitalization in last year	1.4
Average MD		4.7		4.8		4.7

Factors in bold are those for which the mean difference (MD) changed significantly with the change in A1C threshold.

differences in glycemic control. For example, we observed pronounced race/ethnicity differences in achievement of glycemic control at all three thresholds, a finding consistent with previous research (23). We found no evidence, however, that establishing a lower A1C cutoff as a performance measure would exacerbate this disparity or that selecting a less stringent threshold would obviate the disparity.

Diabetes medication is the major patient factor for which differences in threshold attainment would be exacerbated by lowering the current NDQIA and NQF glycemic control performance measure of A1C >9%. The importance of diabetes treatment for good (A1C <7%) glycemic control has been shown to be independent of sociodemographic characteristics, abdominal obesity, and health care access and utilization (15). The magnitude of this difference at the lower thresholds has implications for pay for performance quality improvement models being considered by the Centers for Medicare & Medicaid Services and other payers. Practices that include a greater proportion of patients receiving insulin may have proportionately more patients exceeding A1C thresholds. A quality improvement system that includes an incentive to achieve a performance measure for glycemic control may not recognize appropriate care given by physicians whose practice includes a larger proportion of people needing insulin for glycemic control, unless the system accounts for this factor. Reporting performance measure attainment specific to diabetes medication use, and insulin use in particular, might be one means to account for this difference in case mix, although implementing this recommendation may not currently be practical under most systems. As health systems move forward with electronic medical records, however, capturing information on medication use will be more feasible. Although automated review of electronic medical records may not consistently capture data on prescription medications (24), performance measures stratified by prescription medication may be a viable solution as long as measures receive adequate field testing (25).

Differences across other patient health factors examined (self-reported health, number of prescription medications taken, and history of hospitalization) were not greatly influenced by the choice of glycemic control performance

measure threshold. Of the 13 factors studied, only socioeconomic status (as measured by the income-to-poverty ratio) had a reduced disparity in threshold attainment with a lower A1C threshold.

We observed a sizable difference in threshold attainment by age, with improved glycemic control across increasing age-groups. The effect may be one of survivorship bias whereby life-threatening complications are reduced among individuals with well-controlled diabetes or may reflect milder disease with more  $\beta$ -cell function in elderly individuals. The poorer control in younger patients is ominous as they will have a longer duration of diabetes and thus greater risk of complications. Our findings also suggest that the current NDQIA and NQF performance measure of A1C >9% is unlikely to drive major improvements in glycemic control in the Medicare population as only 13.4% of those aged 65–74 and 5.8% of those aged  $\geq 75$  had A1C >9%.

Our analysis of these national data offers a response to a specific health policy question being debated among groups committed to establishing national health care quality measures. Nonetheless, we acknowledge several limitations. Recent evidence suggests that differences in A1C by race may reflect physiological differences such as rates of glycation and erythrocyte survival (26). Fair implementation of threshold-based performance measures will depend on determining whether small differences in A1C threshold attainment truly indicate differences in quality diabetes care after adjustment for case mix. Diagnosed diabetes status was assessed with a validated question that nonetheless has a sensitivity of  $\sim 81\%$  and a positive predictive value of  $\sim 89\%$  (27). Another limitation is that our analysis relied heavily on self-reported case mix factors. The NHANES surveys are designed to result in a representative sample of the noninstitutionalized U.S. population but may underrepresent noninstitutionalized persons with mental health and substance abuse conditions, a group shown to have poor glycemic control (28).

We conclude that implementing an A1C performance measure to indicate poor control that is more stringent than the current measure of A1C >9% would not increase disparities across most patient factors including age, race/ethnic group, and socioeconomic status. To account for a case mix that includes more insulin users, however, stakeholders con-

sidering the selection of a performance measure threshold for glycemic control that is  $\leq 8\%$  should consider reporting of threshold attainment specific to diabetes medication use. Stratified reporting would allow more rigorous goals for glycemic therapy in groups for whom a benefit has been established. In so doing, lowering the A1C performance measure threshold may advance the overall quality of diabetes care, without magnifying overall differences among population groups and without discouraging physician acceptance of insulin-requiring patients whose diabetes is more difficult to manage.

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