

# Should Mitigating Comorbidities Be Considered in Assessing Healthcare Plan Performance in Achieving Optimal Glycemic Control?

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**C**omprehensive diabetes care performance measures were first developed in 1999<sup>1</sup> and have increasingly been used to monitor population health,<sup>2</sup> to compare systems of care,<sup>3,4</sup> and to accredit organizations.<sup>5</sup> The current public reporting measure for glycemic control endorsed by the National Quality Forum<sup>6</sup> is the percentage of individuals in poor control, defined as a glycosylated hemoglobin (A1C) level measurement not performed or greater than 9%. The target level of less than 7% recommended by the clinical practice guideline of the American Diabetes Association<sup>7</sup> has previously been included in quality improvement measure sets and in provider recognition programs.<sup>8,9</sup> More recently, the National Committee for Quality Assurance<sup>10</sup> has approved the addition of a public reporting measure for A1C of less than 7% for all persons with diabetes mellitus (DM) without exclusions to the Health Employer Data Information Set.

However, achieving an A1C level of less than 7% and maintaining it over time have proved difficult even in landmark clinical trials that were able to use a level of resources not typically found in clinical practice.<sup>11-13</sup> Furthermore, multiple clinical guidelines recommend individualization of A1C target values for seniors and acknowledge that less stringent treatment goals may be appropriate for older patients and for individuals with comorbid conditions that result in limited life expectancy in whom the benefits of intensive glycemic control might not be realized or there is increased risk of intensive glycemic control.<sup>14,15</sup>

However, while guidelines are intended to be used by clinicians to assess the relative risk and benefit of an intervention for an individual patient using principles of shared decision making, performance measurement is meant to assess the care of populations of individuals using data abstraction without individual-level context.<sup>16</sup> In the absence of validated risk adjustment models that minimize bias, a key principle of performance measurement development for the purpose of public reporting measures, comparison of plans, or pay for performance is to specify a priori the patient population for whom the intervention is appropriate in almost all instances.<sup>17</sup> Otherwise, the use of the measure may have the unintended consequence of overriding clinical judgment. Consequently, we propose that measuring healthcare system or

**Background:** Whether a public reporting measure for glycosylated hemoglobin (A1C) of less than 7% should apply to all persons with diabetes mellitus is a matter of ongoing controversy.

**Objective:** To evaluate the effect of excluding persons with major medical or mental health conditions on assessment of healthcare system performance in achieving an A1C level of less than 7%.

**Design and Setting:** Retrospective longitudinal administrative data analysis from 144 Veterans Health Administration medical centers.

**Subjects:** Veterans with diabetes mellitus younger than 65 years who were users of Veterans Health Administration healthcare in fiscal years 1999 and 2000.

**Major Outcome Variables:** The proportions, 5-year mortality, and glycemic control of individuals with and without major comorbid conditions, as well as changes in league table rankings of facilities achieving an A1C threshold of less than 7% with and without the inclusion of seriously ill individuals.

**Results:** There were 220 922 subjects identified from 144 facilities. We identified 75 296 individuals (mean  $\pm$  SD facility range of excluded individuals, 33.3%  $\pm$  5.3%) with conditions that would decrease the benefits or increase risks of glycemic control. The 5-year unadjusted mortality was 36.0% in 48 001 subjects (21.7%) excluded for major medical or neurological conditions, 14.9% in 17 515 subjects (7.9%) excluded for major mental health conditions, and 16.5% in 9780 subjects (4.4%) excluded for 2 or more other serious comorbid medical or psychological conditions, compared with 8.8% in the remaining subjects. A comparison of industry league table rankings indicated that 20% of the best and worse facilities changed 1 decile when ranking using exclusion criteria.

**Conclusion:** One in 3 veterans has comorbid conditions that would increase the risks or decrease the benefits of intensive glycemic control. We propose that a public reporting measure for A1C of less than 7% be subjected to exclusion criteria rather than be applied to all persons with diabetes mellitus.

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physician success in achieving “optimal” A1C control (<7%) should be assessed in cohorts of persons with DM for whom the benefits and harms of the intervention can be generalized from the clinical trials from which efficacy was determined.<sup>18</sup>

Our primary objective in this study was to evaluate the prevalence of major comorbid conditions that might alter the risk and benefit for intensive treatment among veterans with DM younger than 65 years receiving care in the Veterans Health Administration (VHA). We evaluated the face validity of our proposed exclusion criteria by determining the 5-year mortality among individuals identified as having serious medical and neurological conditions. Our secondary objective was to evaluate the effects of using a denominator of individuals without significant medical, neurological, or mental health conditions, as opposed to the population without exclusions, on VHA health-care facility rankings based on the proportion of veterans with an A1C level of less than 7%. We hypothesized that there would be significant facility-level differences in the proportions of excluded individuals and that this would affect the identification of best and worst facility-level rankings based on the 2 denominators used for performance measurement.

## METHODS

### Data Sources and Patient Identification

Inpatient and outpatient utilization data and *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes were obtained from the National Patient Clinical Dataset (Austin, Tex), and laboratory data and medication use information were provided by the Veterans Affairs Healthcare Analysis Information Group as previously described.<sup>19</sup> We identified veterans having DM in fiscal year 1999 (October 1, 1998, to September 30, 1999) if they had any hospitalization DM ICD-9-CM code (codes 250, 357.2, 362.0, and 366.41), more than 1 DM code associated with outpatient care on separate calendar days, or any diabetes-specific medication prescription (insulin, sulfonylureas, biguanides, or thiazolidinediones). We ascertained deaths among these subjects from October 1, 1999, through September 30, 2004, using Veterans Affairs death registries.<sup>20</sup>

### Exclusion Criteria for the Denominator of a Public Reporting Measure for A1C of Less Than 7%

Multiple guidelines, including the American Diabetes Association, recommend individualization of A1C target values for individuals 65 years and older because the benefits and the risks of optimal glycemic control are not well defined in the geriatric population.<sup>7,14,15</sup> Consequently, we limited our analysis to individuals younger than 65 years. Clinical practice

guidelines of the American Diabetes Association note that individuals with a limited life expectancy or with coexisting conditions may warrant less stringent A1C goals, but explicit criteria are not provided.<sup>7</sup> Therefore, we developed a hierarchy of medical and mental health conditions that would attenuate the benefits or increase the risks of hypoglycemia based on inclusion and exclusion criteria for and results from major trials of intensive glycemic control. Individuals were considered to have a contradiction to intensive glycemic control if they had 2 face-to-face visits on different days or 1 inpatient admission with a primary ICD-9-CM diagnostic code or procedure code (such as for amputation) listed in **Appendix A** at [www.ajmc.com](http://www.ajmc.com).

An iterative process was used to develop a schema of populations with decreased life expectancy. We operationalized decreased life expectancy as a high likelihood of death within 10 years based on the mean duration of follow-up in the United Kingdom Prospective Diabetes Study (UKPDS).<sup>13</sup> This category included individuals with cancer (except basal and squamous skin cancers) and end-stage hepatic disease. Because intensive glycemic control has not been demonstrated to affect outcomes of persons who have sustained advanced complications of DM, we excluded individuals with end-stage renal disease, prior amputations, and advanced retinopathy (proliferative disease, prior laser treatment, retinal detachment, macular edema, vitreous hemorrhage, and diabetic blindness). We also identified major comorbid conditions that would exclude the use of oral antiglycemic agents while increasing the risk for hypoglycemia due to insulin use or that would impair a subject’s ability to comply with intensive treatment regimens. These included medical conditions such as stroke and congestive heart failure, disabling neurological diseases (dementia, Parkinson’s disease, gastroparesis, and autonomic neuropathy), and stage 3, 4, or 5 chronic kidney disease (creatinine clearance, <60 mL/min per 1.73 m<sup>2</sup> [ $<1.00$  mL/s per 1.73 m<sup>2</sup>]) ascertained using the estimated glomerular filtration rate based on 2 measurements at least 90 days apart to exclude transient creatinine elevations.<sup>21</sup> We defined major mental health conditions (major depression, schizophrenia, bipolar disorder, and substance abuse) as previously described.<sup>22</sup>

Finally, we excluded individuals without 1 of the prior conditions who had at least 2 of the following additional serious medical or mental health disorders: ischemic heart disease, arrhythmias, peripheral vascular disease, chronic pulmonary disease, asthma, transient ischemic attacks, anxiety disorders, and posttraumatic stress disorder. We did not consider hypertension or dyslipidemia as comorbid conditions for the purpose of this analysis. The specificity of administrative code diagnoses for cardiovascular, pulmonary, and chronic kidney

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disease compared with medical record review has been reported to be greater than 0.9 using 2 or more ICD-9-CM codes<sup>23</sup>; the specificity for stroke was reported to be 87%.<sup>24</sup>

### Data Analysis

At the population level, we placed each individual subject into a single domain of contraindications based on the mutually exclusive hierarchical categories previously described. We then sequentially excluded each domain of contraindications, noting the percentage of patients excluded and their 5-year unadjusted mortality rate. We then determined the last A1C measurement performed in fiscal year 2000 in an ambulatory setting and reported the proportion of each group of subjects in mutually exclusive categories of A1C level (<7%, 7%-8%, and >8%). Because we used administrative data and would be unable to determine if an A1C test performed in the private sector rather than in the VHA was recorded by the clinician in the medical record,<sup>25</sup> we did not include individuals without an A1C test in the denominator.

At the facility level, we determined the variation in the proportion of the population excluded on the basis of reasonable contraindications to a stringent A1C measure of less than 7%. We then determined facility adherence to an A1C level of less than 7% for all patients who were alive at the beginning of fiscal year 2000. We used Spearman's rank order coefficient to measure agreement between facility-level rankings using a denominator of the entire population versus a denominator of individuals without major contraindications to intensive glycemic control excluded. Because the use of best and worst decile rankings is an industry standard for identifying best and worst plans,<sup>5</sup> we ranked Veterans Affairs facilities into deciles and used league tables (rank order performance) to determine the degree of ranking movement for facilities in the best and worst 2 deciles. The degree of ranking movement was calculated as the number of facilities that stayed in the same decile versus the number that changed deciles and the magnitude of the change.

## RESULTS

We identified 220 922 individuals with DM younger than 65 years at 144 facilities (see [Appendix B](#) at [www.ajmc.com](http://www.ajmc.com)). The cohort had a mean age of 53.87 years, was 97.2% male, and was 61.0% white, 21.0% African American, 6.8% Hispanic, and 11.2% of other or missing race/ethnicity. Serious medical and mental health conditions were common; for example, 13.0% of individuals were identified as having renal disease based on ICD-9-CM codes or on 2 estimated glomerular filtration rates diagnostic of stage 3, 4, or 5 chron-

ic kidney disease, and 11.1% had a major mental health disorder. The mean Charlson index score (excluding DM) was 1.99, and the unadjusted 5-year mortality was 15.6%. Compared with individuals aged 25 to 44 years, individuals aged 55 to 64 years were more likely to be white (67.5% vs 45.7%), less likely to be taking insulin (30.3% vs 41.1%), and more likely to have a higher burden of medical illness (mean Charlson index score, 2.21 vs 1.53).

Our population had an overall 5-year mortality of 15.6%, and our schema demonstrated a declining mortality gradient among medical, neurological, and mental health conditions ([Table 1](#)). We identified 65 516 individuals (29.7%) with at least 1 major medical (decreased life expectancy, advanced complications, or major medical conditions), neurological, or mental health contraindication to intensive glycemic control. Individuals had a mean 5-year mortality of 36.0% for major medical and neurological conditions and 14.9% for major mental health conditions. We identified an additional 9780 individuals (4.4%) who had 2 or more other serious comorbid cardiovascular, pulmonary, anxiety, or posttraumatic stress-related conditions; these individuals had a 5-year mortality of 16.5%.

Therefore, we identified 145 626 individuals (65.9% of the original cohort) for whom intensive glycemic control would be a reasonable goal (intensive glycemic control cohort) ([Table 2](#)). Compared with the excluded subjects, subjects in this denominator were the same age (53.4 vs 54.8 years) and had comparable A1C levels (8.00% vs 7.85%). However, they had substantially lower 5-year mortality (8.8% vs 28.6%) and a lower percentage of individuals prescribed insulin (28.3% vs 39.6%).

Within the cohort of subjects for whom less than 7% appeared to be a reasonable A1C target because of the absence of serious or multiple conditions ([Table 2](#)), all age strata had a comparable illness burden based on the mean Charlson index scores. Overall, 16.4% of the cohort had coexisting cardiovascular and pulmonary disease, and an additional 2.9% had anxiety or posttraumatic stress disorder. Among the cohort, 8.3% were hospitalized in fiscal year 1999, and 12.7% were hospitalized in fiscal year 2000. Compared with individuals aged 55 to 64 years, individuals aged 25 to 44 years had a higher mean A1C value (8.57% vs 7.74%) and greater use of insulin (41.4% vs 24.9%), perhaps reflecting a greater proportion of individuals with type 1 DM.

The facility-level range of excluded individuals was 16.8% to 53.5% (mean  $\pm$  standard deviation, 33.3%  $\pm$  5.3%). The mean facility performance in the proportion of subjects achieving an A1C threshold of less than 7% was 34.7% (facility range, 19.1%-49.1%) using the entire population as a

■ **Table 1.** Sequential Exclusion of Individuals With Contraindications to Intensive Glycemic Control

Variable	Population Excluded, No. (%)	Remaining Subjects, No.	Age, Mean ± SD	Taking Insulin, %	Charlson Index Score, Mean ± SD	5-y Mortality, %	A1C Test Result in Fiscal Year 2000, %		
							<7	7-8	>8
Denominator without exclusions	(N = 220 922)	220 292	53.87 ± 7.39	32.2	1.98 ± 1.61	15.6	35.06	24.20	40.74
<b>Characteristics of Excluded Population</b>									
<b>(A) Major comorbidity</b>									
Decreased life expectancy	8568 (3.9)	212 354	57.08 ± 6.19	32.9	5.38 ± 2.55	45.0	43.57	23.21	33.22
Advanced complications	7889 (3.6)	204 465	55.81 ± 6.31	62.8	3.47 ± 2.02	35.7	28.32	23.93	47.75
Major medical conditions	27 730 (12.6)	176 735	56.47 ± 6.20	44.6	3.29 ± 1.81	35.0	38.49	24.16	37.36
Major neurological conditions	3814 (1.7)	172 921	54.29 ± 7.43	32.1	2.53 ± 1.49	24.2	44.11	22.01	33.87
<b>(A) Total major comorbidities</b>	48 001 (21.7)	172 921	56.30 ± 6.36	44.5	3.63 ± 2.15	36.0	37.98	23.81	38.21
<b>(B) Major mental health conditions</b>	17 515 (7.9)	155 406	50.24 ± 6.99	30.7	1.72 ± 1.26	14.9	40.48	19.74	39.78
<b>(A + B) Total major comorbidities, including major mental health</b>	65 516 (29.7)	155 406	54.68 ± 7.06	40.8	3.12 ± 2.12	30.4	38.64	22.74	38.62
<b>(C) Other comorbidities</b>									
≥2 Other medical or mental health comorbid conditions	9780 (4.4)	145 626	55.51 ± 6.43	31.3	2.73 ± 1.26	16.5	35.22	25.74	39.04
<b>(A + B + C) Total excluded population</b>	75 296 (34.1)	145 626	54.79 ± 6.99	39.6	3.07 ± 2.04	28.6	38.15	23.17	38.68
<b>Characteristics of Remaining Population</b>									
Denominator after excluding A and B	65 516 (29.7)	155 406	53.53 ± 7.50	28.5	1.51 ± 1.00	9.3	33.64	24.78	41.58
Denominator after excluding A, B, and C	75 296 (34.1)	145 626	53.40 ± 7.55	28.3	1.43 ± 0.93	8.8	33.53	24.71	41.76

SD indicates standard deviation; A1C, glycosylated hemoglobin.

denominator and 33.4% (facility range, 18.8%-47.2%) using the intensive glycemic control cohort as a denominator.

To assess the effect of excluding individuals with serious medical and mental health conditions on healthcare system performance, we assessed facility rankings for an A1C threshold of less than 7% for the entire population and for the intensive glycemic control cohort. For the ranking analysis, we excluded 7 stations having fewer than 100 people. There was high correlation between facility rankings (Spearman's rank order coefficient, 0.97). Overall, 30 (21.7%) of 138 facilities changed decile by at least 1 decile and 9 facilities (6.5%) by at least 2 deciles. Of the best-performing facilities (n = 28) using the entire population, 5 facilities changed 1 decile when ranked using the ideal cohort. Similarly, of the worst-

performing facilities (n = 28), 6 facilities changed 1 decile when ranked using the ideal cohort.

## DISCUSSION

Findings from our study indicate that about 1 in 3 veterans younger than 65 years with DM receiving healthcare in the VHA has major or multiple coexisting medical or mental health conditions that would attenuate the benefits or potentially increase the risk of harms of hypoglycemia from insulin use in pursuit of intensive glycemic control. In addition to the face validity of our classification schema, the high mortality among individuals excluded for medical and neurological conditions suggests predictive validity as well, although formal

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**Table 2.** Characteristics of the Denominator for Intensive Glycemic Control\*

Variable	Final Cohort (n = 145 626)	Age Group, y		
		25-44 (11.7%)	45-54 (41.9%)	55-64 (46.4%)
<b>Age, y</b>	53.40 ± 7.55	39.10 ± 4.93	50.25 ± 2.55	59.83 ± 3.00
<b>Sex</b>				
Male	141 632 (97.3)	92.5	97.3	98.4
Female	3994 (2.7)	7.5	2.7	1.6
<b>Race/ethnicity</b>				
White	85 211 (58.5)	44.5	55.4	64.9
African American	28 755 (19.8)	29.5	21.3	15.9
Hispanic	10 174 (7.0)	6.5	7.2	6.9
Other	2262 (1.6)	1.5	1.7	1.5
Missing	19 224 (13.2)	18.0	14.4	10.9
<b>Treatment</b>				
Taking insulin	41 228 (28.3)	41.4	28.5	24.9
Charlson index score	1.43 ± 0.93	1.27 ± 0.93	1.38 ± 0.92	1.51 ± 0.92
5-y Mortality	12 881 (8.8)	4.4	7.9	10.8
<b>Glycosylated hemoglobin level</b>	8.00 ± 1.92	8.57 ± 2.27	8.15 ± 2.01	7.74 ± 1.70
<b>Other Serious Comorbid Conditions</b>				
<b>Medical</b>				
Ischemic heart disease	23 838 (16.4)	5.0	13.1	22.2
Ischemic heart disease	13 921 (9.6)	2.3	7.9	12.9
Transient ischemic attack	197 (0.1)	0.1	0.1	0.2
Peripheral vascular disease	4932 (3.4)	1.4	2.7	4.5
Chronic obstructive pulmonary disease	3464 (2.4)	0.9	1.8	3.3
Arrhythmia	1324 (0.9)	0.4	0.6	1.4
<b>Psychological</b>				
Anxiety	4268 (2.9)	1.6	5.1	1.3
Anxiety	1092 (0.8)	0.9	0.9	0.6
Posttraumatic stress disorder	3176 (2.2)	0.7	4.2	0.8

\*Data are given as mean ± SD, number (percentage), or percentage.

validation would be necessary. Although the ages, insulin use, mean A1C values, and proportions achieving an A1C threshold of less than 7% were clinically comparable in the excluded population and in the remaining subjects considered candidates for intensive glycemic control, 19.6% of the best-performing and worst-performing facilities changed 1 decile when ranked using the ideal cohort. Given the current healthcare environment in which public reporting measures are becoming the norm, our findings raise concerns about the application of “excellent glycemic control” to large numbers of individuals for whom the benefits and the risks of intensive glycemic control may not be generalizable from landmark randomized clinical trials.<sup>11-13</sup>

Our criteria for exclusion from the denominator of an A1C threshold of less than 7% for a public reporting measure are consistent with the exclusion criteria from major randomized controlled trials. Based on the UKPDS,<sup>13</sup> which is the primary evidence justifying intensive glycemic control for type 2 DM, a mean reduction in A1C level from 7.9% to 7.0% during 10 years of observation resulted in an absolute reduction in a composite clinical end point of 41 versus 46 events per 1000 patient-years, primarily due to a reduction in photocoagulation treatment of retinopathy. In other words, 20 patients with type 2 DM would need to be treated for 10 years to avert 1 adverse microvascular or macrovascular event. However, the 10-year unadjusted mortality rate of 18.2% in the UKPDS was

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about half of the unadjusted 5-year mortality rate of 36.0% in patients excluded from our study because of major medical or neurological conditions. It is likely that the 10-year mortality among these individuals will approach 60% to 70%. Consequently, these patients who would have been excluded from the UKPDS would be less likely to incur the long-term complications of DM and would receive less benefit from intensive glycemic control than subjects in the UKPDS. Individuals with major mental health conditions could be candidates for intensive glycemic control, especially if they were in remission. However, individuals with active symptoms or with abuse of alcohol or drugs may have difficulty in adherence to treatment for intensive glycemic control or may have increased risk of hypoglycemia from insulin use. Finally, individuals with 2 or more cardiovascular, pulmonary, or mental health disorders were excluded because treatment for these conditions could reasonably compete with priorities for intensive glycemic control. We specifically did not exclude individuals who only had cardiovascular disease but note that the absolute benefit of intensive glycemic control on macrovascular disease is under investigation in the Action to Control Cardiovascular Risk in Diabetes trial.<sup>26</sup> Individuals in the control arm can have an A1C target of between 7.0% and 7.9%, with an expected median of 7.5%.

The relevant policy issue is not whether individual physicians and persons with DM should negotiate A1C target values of 7% or greater based on individual circumstances and patient preferences. Rather, it is whether results of clinical trials that excluded such individuals should be generalized to all persons with DM aged 18 to 75 years for the purpose of comparing health plan performances or paying physicians. There are potential unintended consequences to healthcare based on poorly designed measures; these could include adverse selection biases, unnecessary treatment, adverse outcomes (such as hypoglycemia), and disregard of patient preferences.<sup>27</sup>

Indeed, individuals in the cohort considered candidates for intensive glycemic control were not free of other conditions. One in 6 individuals had cardiovascular, pulmonary, anxiety, or posttraumatic stress-related conditions, and almost 1 in 5 was hospitalized during a 2-year period. We did not evaluate the use of medications (such as  $\beta$ -blockers) or the psychotropic treatment of mental health conditions (such as anxiety and stress) that could reasonably warrant an A1C target goal of 7% or higher, especially if that could only be achieved through the use of insulin. In such individuals, application of the concept of patient-centered care indicates that target goals need to be individualized based on the principles of evidence-based medicine and shared decision making.<sup>28,29</sup> Although several widely available risk engines are now

available to assist practitioners and persons with DM in setting target goals, especially for intensive glycemic control, they do not adjust life expectancy for noncardiac or DM-related complications. Consequently, clinical judgment will still be paramount in individual risk communication.

We did not exclude individuals with coexisting hypertension, dyslipidemia, musculoskeletal or rheumatologic disorders, chronic hepatitis, or gastrointestinal disorders. In addition, we did not attempt to identify individuals with severe or repeated hypoglycemic episodes or with social circumstances (such as extreme poverty or lack of social support) that would be beyond healthcare plan control yet would affect adherence to intensive glycemic control regimens.

It is not surprising that a significant proportion of persons with DM in a large national healthcare system had major health conditions that would preclude generalization of results from the landmark randomized trials establishing the efficacy of intensive glycemic control.<sup>11-13</sup> In an evaluation of the quality of care provided to Medicare enrollees (>65 years) who had sustained acute myocardial infarction, only 15.2% were ideal candidates for angiotensin-converting enzyme inhibitor therapy, 17.6% for  $\beta$ -blocker use, and 47.7% for aspirin treatment on discharge.<sup>30</sup> The development of an excellent glycemic control measure that does not address issues of case mix may not only result in unfair evaluation of clinician or plan performance<sup>31</sup> but also result in unintended consequences such as shifting of sicker patients by physicians.<sup>32</sup> One in 5 of the best-performing and worst-performing facilities shifted 1 decile when ranked using the ideal cohort. Consequently, it is not inconceivable that a performance measure, especially in the context of pay for performance or public report cards, could result in treatment of more individuals at greater risk for hypoglycemia. Based on population studies in Sweden<sup>33</sup> and England,<sup>34</sup> it is possible that severe hypoglycemia could have significant societal harms if all persons with DM were considered candidates for intensive glycemic control. In a study<sup>35</sup> of older drivers, the use of antidiabetes drugs (insulin monotherapy or a combination of sulfonylurea and metformin) was associated with a small but significant risk of motor vehicle crash. Given the inability of the healthcare system to readily identify such events if they did not result in emergency department visits or hospitalizations, such harms are likely to go unnoticed at the population level.

Strengths of our study include a well-defined cohort of persons with DM and the availability of longitudinal laboratory, administrative, and mortality records. Although administrative coding for common medical conditions has been validated with acceptable sensitivity and specificity compared with medical record review,<sup>21-24</sup> reliance on administrative data remains a

study limitation. In addition, we were unable to assess the severity of specific conditions (eg, congestive heart failure or chronic obstructive lung disease) because of the unavailability of physiological data. We also recognize that the VHA population has a far greater medical and mental health illness burden than the general US population,<sup>36</sup> although the disease burden may be comparable to that of other social systems of care such as Medicaid<sup>37</sup> and the Indian Health Service.<sup>38</sup> Consequently, the proportion of patients excluded from consideration in system performance measurement might be considerably smaller in private sector indemnity healthcare plans.

In conclusion, our findings indicate that a significant proportion of persons with DM in the VHA might not be candidates for intensive glycemic control based on coexisting medical and mental health conditions that could attenuate the likelihood of benefit or increase the probability of harm. We emphasize that these findings are not meant to deny any patient the potential benefits of intensive glycemic control based on the principle of shared patient-physician decision making. Rather our findings suggest caution in generalizing glycemic control guideline recommendations to a public reporting measure of excellent glycemic control applicable to all persons with DM enrolled in healthcare systems. In contrast, identification of reasonable candidates for intensive glycemic control would enable healthcare plans and clinicians to focus resource-intensive efforts on persons most at risk for long-term complications of DM, as well as possibly to more fairly compare plan results. Finally, we recommend consideration of measurement strategies other than dichotomous thresholds that are more consistent with the clinical epidemiology of glycemic control. For example, assessing progress toward an A1C goal of less than 7% using continuous weighted measures rather than a dichotomous threshold<sup>39</sup> could better reflect the more heterogeneous case mix of patients in practice as opposed to those in randomized clinical trials.

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Dr Pogach had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis for this study.

### Take-away Points

- It is controversial whether a public reporting measure for glycosylated hemoglobin (A1C) of less than 7% should apply to all persons with diabetes mellitus (DM) or should be subjected to exclusion criteria.
- Measuring facility success in achieving optimal A1C control should be assessed among cohorts of persons with DM for whom the benefits and harms of the intervention can be generalized from the clinical trials from which efficacy was determined.
- As an alternative to a dichotomous threshold, the use of continuous weighted measures could better reflect progress toward an A1C goal among a heterogeneous case mix of patients in practice.

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