Potential Overtreatment of Diabetes Mellitus in Older Adults With Tight Glycemic Control

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IMPORTANCE In older adults with multiple serious comorbidities and functional limitations, the harms of intensive glycemic control likely exceed the benefits.

OBJECTIVES To examine glycemic control levels among older adults with diabetes mellitus by health status and to estimate the prevalence of potential overtreatment of diabetes.

DESIGN, SETTING, AND PARTICIPANTS Cross-sectional analysis of the data on 1288 older adults (≥65 years) with diabetes from the National Health and Nutrition Examination Survey (NHANES) from 2001 through 2010 who had a hemoglobin A1c (HbA1c) measurement. All analyses incorporated complex survey design to produce nationally representative estimates.

EXPOSURES Health status categories: very complex/poor, based on difficulty with 2 or more activities of daily living or dialysis dependence; complex/intermediate, based on difficulty with 2 or more instrumental activities of daily living or presence of 3 or more chronic conditions; and relatively healthy if none of these were present.

MAIN OUTCOMES AND MEASURES Tight glycemic control (HbA1c level, <7%) and use of diabetes medications likely to result in hypoglycemia (insulin or sulfonylureas).

RESULTS Of 1288 older adults with diabetes, 50.7% (95% CI, 46.6%-54.8%), representing 3.1 million (95% CI, 2.7-3.5), were relatively healthy, 28.1% (95% CI, 24.8%-31.5%), representing 1.7 million (95% CI, 1.4-2.0), had complex/intermediate health, and 21.2% (95% CI, 18.3%-24.4%), representing 1.3 million (95% CI, 1.1-1.5), had very complex/poor health. Overall, 61.5% (95% CI, 57.5%-65.3%), representing 3.8 million (95% CI, 3.4-4.2), had an HbA1c level of less than 7%; this proportion did not differ across health status categories (62.8% [95% CI, 56.9%-68.3%] were relatively healthy, 63.0% [95% CI, 57.0%-68.6%] had complex/intermediate health, and 56.4% [95% CI, 49.7%-62.9%] had very complex/poor health (P = .26). Of the older adults with an HbA1c level of less than 7%, 54.9% (95% CI, 50.4%-59.3%) were treated with either insulin or sulfonylureas; this proportion was similar across health status categories (50.8% [95% CI, 45.1%-56.5%] were relatively healthy, 58.7% [95% CI, 49.4%-67.5%] had complex/intermediate health, and 60.0% [95% CI, 51.4%-68.1%] had very complex/poor health; P = .14). During the 10 study years, there were no significant changes in the proportion of older adults with an HbA1c level of less than 7% (P = .34), the proportion with an HbA1c level of less than 7% who had complex/intermediate or very complex/poor health (P = .27), or the proportion with an HbA1c level of less than 7% who were treated with insulin or sulfonylureas despite having complex/intermediate or very complex/poor health (P = .65).

CONCLUSIONS AND RELEVANCE Although the harms of intensive treatment likely exceed the benefits for older patients with complex/intermediate or very complex/poor health status, most of these adults reached tight glycemic targets between 2001 and 2010. Most of them were treated with insulin or sulfonylureas, which may lead to severe hypoglycemia. Our findings suggest that a substantial proportion of older adults with diabetes were potentially overtreated.

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Diabetes mellitus is highly prevalent among older persons (≥65 years), yet optimal glucose management in this population remains ill-defined. For younger, healthier adults, the American Diabetes Association (ADA) recommends glycemic control to achieve a hemoglobin A₁c (HbA₁c) level of less than 7% (to convert to proportion of total hemoglobin, multiply by 0.01), while the American Association of Clinical Endocrinologists (AACE) recommends an HbA₁c level of less than 6.5% to reduce the risk of microvascular complications. However, older persons, particularly those with complex medical problems, may derive less benefit from intensive strategies to lower glucose levels and are more susceptible to hypoglycemia and its consequences compared with younger, healthier persons.

Recent studies suggest that hypoglycemia, in particular, poses significant health threats to older adults. Glucose-lowering agents have been implicated in one-fourth of emergency hospitalizations for adverse drug events in older US Medicare beneficiaries. In addition, hypoglycemia has admissions for hypoglycemia surpass those for hyperglycemia among Medicare beneficiaries. In addition, hypoglycemia has emerged as a dominant complication of diabetes in older adults with a longer duration of the disease.

Current recommendations for diabetes management, including The 2012 ADA and American Geriatrics Society (AGS) consensus statement, endorse higher glycemic targets for older patients with multiple comorbidities, functional impairments, established diabetic complications, or limited life expectancy. The reasons for higher glycemic targets in these persons are 2-fold: intensive glycemic control is unlikely to result in a benefit, but it is associated with a risk for harm. Yet, most US adults have an HbA₁c level of less than 7%, including those who are 65 years or older. Some adults may reach these targets through lifestyle modification alone, which may not incur the risk of harm. However, some adults attain tight glycemic control with medications that increase the risk of adverse effects, including hypoglycemia. For older adults with complex comorbidities and limited life expectancy, the risks of harm likely exceed any benefit. The use of a treatment that is unlikely to result in benefit, and may cause harm, indicates potential overtreatment. To determine whether there is evidence for potential overtreatment, we used nationally representative National Health and Nutrition Examination Survey (NHANES) data to assess the health status and treatment patterns among older participants with diabetes who attain tight glycemic control (HbA₁c level, <7%).

Methods

Study Source
We analyzed data from NHANES years 2001-2002, 2003-2004, 2005-2006, 2007-2008, and 2009-2010. The NHANES uses stratified, multistage, probability-cluster techniques to ensure that sample populations are representative of the nation’s noninstitutionalized civilians. Data are collected from household interviews and standardized medical examinations and blood sample collections are performed in mobile examination centers.

This study was deemed exempt from further review by the University of California, San Francisco, Institutional Review Board because it used only deidentified secondary data.

Study Population
We included adults from the NHANES who were 65 years or older, reported a diagnosis of diabetes from a health professional, and had an HbA₁c measurement. We used interview responses to classify participants in terms of age, sex, and race or ethnic group.

Health Status
We classified older adults with diabetes into 3 health status categories endorsed by the ADA/AGS framework for considering treatment goals for glycemia. The 3 categories include those who are relatively healthy, those with complex medical histories for whom self-care may be difficult, and those with a very significant comorbid illness and functional impairments, many of whom may have limited life expectancy. Participants were categorized as having very complex/poor health status if they were receiving dialysis or had 2 or more activities of daily living (ADL) impairments. We could not determine the presence of other indicators of very complex/poor health status per the ADA/AGS framework, including end-stage (stage III-IV) congestive heart failure, oxygen-dependent lung disease, uncontrolled metastatic cancer, or severe cognitive impairment. Participants were categorized as having complex/intermediate health status if they had 3 or more chronic conditions or 2 or more instrumental ADL impairments. We included chronic illnesses identified by the ADA/AGS framework, including arthritis, congestive heart failure, lung disease, chronic kidney disease, coronary heart disease, stroke, or urinary incontinence, but we did not have information on active cancer, clinical diagnosis of depression, or falls. We also did not include hypertension because it is highly prevalent and usually not considered a serious chronic illness. Finally, we categorized participants as relatively healthy if they did not meet these criteria.

We used interview responses to identify chronic conditions (congestive heart disease, lung disease [emphysema, chronic bronchitis, or asthma], coronary heart disease [myocardial infarction or angina pectoris], stroke, or arthritis). Urinary incontinence status was based on a series of questions about leakage of urine with or without activity like coughing, lifting, or exercise and with or without preceding urge or pressure to urinate. We considered urinary incontinence to be a chronic condition if it occurred at least a few times a week. Chronic kidney disease was identified based on an estimated glomerular filtration rate of less than 60 mL/min/1.73 cm², calculated using the Chronic Kidney Disease Epidemiology Collaboration equation (http://www.ncbi.nlm.nih.gov/pubmed/19414839).

Functional limitations were assessed based on a series of questions designed to measure participants’ functional status. These questions were phrased to assess the individual’s level of difficulty in performing the task without using any special equipment. Patients who reported some or much difficulty or were unable to perform ADL were categorized as hav-
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Glucotoxic Control
We categorized glycemic control, based on the measured HbA1c level, as tight (HbA1c level, <7%), moderate (7%-8.9%), and poor control (≥9%). In additional analyses, we examined very tight control (HbA1c level, <6.5%). During 2001-2010, there were 3 laboratory instruments for measuring HbA1c and 2 laboratories used in the NHANES. Measurement of HbA1c was performed in the first laboratory using the Primus CLC330 and Primus CLC85 (Primus Corp) (from 2001-2004) and then in the second laboratory on the Tosoh A1C G7 (Tosoh Medics, Inc) (from 2005-2006). From 2007-2010, HbA1c testing was performed in the second laboratory on the Tosoh A1C G7. Laboratory method crossover studies were conducted at the time of each of the laboratory instrument changes. Both laboratories that analyzed NHANES HbA1c data from 2001-2010 were standardized by participating in the National Glycohemoglobin Standardization Program, and no adjustment across years for the HbA1c assay has been recommended.

Glucose-Lowering Treatment
Participants were asked to report prescription medications they had taken in the past 30 days and to bring medication bottles to the examination, where the information was documented. Receipt and type of oral glucose-lowering treatment was based on review of medications brought in to the examination; insulin use was based on review of medications brought in or self-reported use of insulin, because participants may not always bring vials or pens to the examination.

Statistical Analysis
We calculated the weighted proportions of survey participants with glycemia that was poorly (HbA1c level, ≥9%), moderately (7%-8.9%), or tightly (<7%) controlled across health status categories. In addition, we calculated the weighted proportions of survey participants whose glycemia was tightly controlled and were treated with either insulin or sulfonylureas across health status categories. We conducted logistic regression analyses to assess linear trends in proportions of participants with tightly controlled glycemia, their health status, and patterns of treatment during the 5 NHANES surveys. To preserve statistical power in these trend analyses, we combined participants with complex/intermediate and very complex/poor health status into 1 category. All analyses incorporated a complex survey design using NHANES-recommended methods to produce nationally representative estimates. All data, except where otherwise noted, show annualized estimates of the number of US adults with the outcome of interest based on the mean of values across the 10 study years. Analyses were performed using SAS, version 9.3 (SAS Institute, Inc) and Stata SE, version 12 (StataCorp). We considered 2-sided P < .05 to be statistically significant.

Results
During the 10-year study period, we identified 6667 adults 65 years or older, of whom 1373 (20.6%) reported a diagnosis of diabetes (eFigure in the Supplement). For this analysis, we included 1288 participants who had an HbA1c measurement during the survey period (94.7 of participants with diabetes, representing 4.4 million-7.5 million older adults during each 2-year survey period). The characteristics of the study sample are presented in Table 1. The mean (SD) age was 73.2 (5.7) years, and 20.8% were 80 years or older. More than one-third of older adults reported at least 1 ADL impairment; similarly, more than one-third reported at least 1 instrumental ADL impairment. In the study sample of older adults with diabetes, 50.7% (95% CI, 46.6%-54.8%), representing 3.1 million (95% CI, 2.7-3.5) US adults, were relatively healthy, 28.1% (95% CI, 24.8%-31.5%) (1.7 million; 95% CI, 1.4-2.0) had complex/intermediate health, and 21.2% (95% CI, 18.3%-24.4%) (1.3 million; 95% CI, 1.1-1.5) had very complex/poor health. About one-fourth and one-third of older adults with complex/intermediate and very complex/poor health status, respectively, were 80 years or older compared with only 13.6% of those who were relatively healthy.

Among older adults with diabetes, 61.5% (95% CI, 57.5%-65.3%) had an HbA1c level of less than 7% (3.8 million; 95% CI, 3.4-4.2), 32.2% (95% CI, 28.7%-35.9%) had an HbA1c level of 7% to 8.9% (2.0 million; 95% CI, 1.6-2.3), and 6% (95% CI, 5.0%-8%) had an HbA1c level of 9% or greater (0.4 million; 95% CI, 0.3-0.5). A total of 41.9% (95% CI, 37.9%-46.1%) of older adults had an HbA1c level of less than 6.5% (2.6 million; 95% CI, 2.2-2.9) and 19.6% (95% CI, 17.0%-22.6%) had an HbA1c level of 6.5% to 7% or less (1.2 million; 95% CI, 1.0-1.4). There were no significant differences in the proportions of patients who attained tight (HbA1c level, <7%), moderate (HbA1c level, 7%-8.9%), or poor (HbA1c level, ≥9%) glycemic control across health status categories (P = .43) (Figure 1). Specifically, 62.8% (95% CI, 56.9%-68.3%) of adults who were relatively healthy, 63.0% (95% CI, 57.0%-68.6%) of those with complex/intermediate health, and 56.4% (95% CI, 49.7%-62.9%) of those with very complex/poor health had an HbA1c level of less than 7% (P = .26). Notably, 44.9% (95% CI, 38.7%-51.3%) and 37.9% (95% CI, 32.2%-44.0%) of patients with complex/intermediate and very complex/poor health had an HbA1c level of less than 6.5%, respectively.

Among older adults with an HbA1c level of less than 7%, 54.9% (95% CI, 50.4%-59.3%) were treated with either insulin or sulfonylureas (4.0% were treated with both; eTable in the Supplement). This proportion did not differ by health status: 50.8% (95% CI, 45.1%-56.5%), 58.7% (95% CI, 49.4%-67.5%), and 60.0% (95% CI, 51.4%-68.1%) of participants with relatively healthy, complex/intermediate, and very complex/poor health status received insulin or sulfonylurea, respectively (P = .14) (Figure 2). Similarly, large proportions of participants with HbA1c levels of less than 6.5% were treated with insulin or sulfonylureas across health status categories (43.9% [95% CI, 36.8%-51.3%] of relatively healthy, 52.3% [95% CI, 40.4%-64.0%] with complex/intermediate health, and 56.3% [95% CI, 44.1%-67.8%] with very complex/poor health).
During the 10 years, there were no significant trends in the proportion of older adults with diabetes who had an HbA1c level of less than 7% (P = .34) or the proportion with an HbA1c level of less than 7% who had complex/intermediate or very complex/poor health (P = .27). Among participants with an HbA1c level of less than 7% who were relatively healthy, the proportion treated with insulin or sulfonylureas decreased over time (P = .05). However, among participants with an HbA1c level of less than 7% who had complex/intermediate or very complex/poor health, treatment with insulin or sulfonylureas remained stable over time (P = .65) (Table 2).

### Discussion

In a nationally representative sample of noninstitutionalized adults from 2001 through 2010, a total of 62% of older participants with diabetes had an HbA1c level of less than 7%, corresponding to 3.8 million US persons. Despite unproven benefits and potential harms of tight glycemic control in older persons with extensive comorbidities, most older adults with complex/intermediate and very complex/poor health had an HbA1c level of less than 7%, corresponding to 1.8 million persons. Moreover, approximately 60% (or 1.0 million) of adults with complex or very complex medical problems were treated with insulin or sulfonylureas to achieve tight glycemic targets, which may lead to severe hypoglycemia. We did not find significant changes in treatment patterns across health status over time. Our findings suggest that a substantial proportion of older adults with diabetes in the United States were potentially overtreated.

Consistent with our findings, studies based on national surveillance data from 1999 through 2010 that assessed trends in risk-factor control among US adults with diabetes suggest that most older adults met stringent glycemic control goals during this time.14-17 However, although individualized glycemic targets were considered to some extent in 1 of these studies,17 the authors did not take into account achieved glycemic targets that may be too low. Similarly, current performance metrics for glycemic control in diabetes focus exclusively on

### Table 1. Characteristics of Older Adults With Diabetes From 2001 Through 2010 by Health Status

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N = 1288)</th>
<th>Relatively Healthy (n = 665)</th>
<th>Complex/Intermediate (n = 332)</th>
<th>Very Complex/Poor (n = 291)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>73.2 (5.7)</td>
<td>72.0 (5.2)</td>
<td>74.0 (5.8)</td>
<td>74.9 (6.0)</td>
</tr>
<tr>
<td>Age, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65-69 y</td>
<td>33.4</td>
<td>40.7</td>
<td>26.2</td>
<td>25.4</td>
</tr>
<tr>
<td>70-79 y</td>
<td>45.8</td>
<td>45.7</td>
<td>48.5</td>
<td>42.5</td>
</tr>
<tr>
<td>≥80 y</td>
<td>20.8</td>
<td>13.6</td>
<td>25.3</td>
<td>32.1</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>45.0</td>
<td>52.5</td>
<td>38.5</td>
<td>35.7</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>74.2</td>
<td>72.8</td>
<td>80.2</td>
<td>69.3</td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>12.0</td>
<td>11.9</td>
<td>10.5</td>
<td>14.2</td>
</tr>
<tr>
<td>Mexican American</td>
<td>5.2</td>
<td>5.5</td>
<td>3.2</td>
<td>7.1</td>
</tr>
<tr>
<td>Other Hispanic</td>
<td>3.3</td>
<td>4.6</td>
<td>1.5</td>
<td>2.4</td>
</tr>
<tr>
<td>Other/multiracial</td>
<td>5.4</td>
<td>5.2</td>
<td>4.6</td>
<td>7.1</td>
</tr>
<tr>
<td>BMI, mean (SD)</td>
<td>30.9 (6.5)</td>
<td>30.0 (5.6)</td>
<td>31.4 (6.0)</td>
<td>32.6 (8.4)</td>
</tr>
<tr>
<td>No. of comorbidities, mean (SD)</td>
<td>2.2 (1.4)</td>
<td>1.2 (0.7)</td>
<td>3.3 (1.0)</td>
<td>2.9 (1.4)</td>
</tr>
<tr>
<td>Comorbidities, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>40.0</td>
<td>23.6</td>
<td>60.9</td>
<td>51.3</td>
</tr>
<tr>
<td>Congestive heart disease</td>
<td>17.2</td>
<td>2.7</td>
<td>32.2</td>
<td>32.5</td>
</tr>
<tr>
<td>Lung disease</td>
<td>18.9</td>
<td>10.2</td>
<td>27.6</td>
<td>28.4</td>
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<tr>
<td>Coronary heart disease</td>
<td>30.4</td>
<td>15.2</td>
<td>55.6</td>
<td>33.2</td>
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<tr>
<td>Stroke</td>
<td>15.8</td>
<td>2.8</td>
<td>29.7</td>
<td>28.4</td>
</tr>
<tr>
<td>Arthritis</td>
<td>58.4</td>
<td>41.7</td>
<td>73.9</td>
<td>77.5</td>
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<tr>
<td>Urinary incontinence</td>
<td>36.5</td>
<td>25.4</td>
<td>52.9</td>
<td>41.2</td>
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<tr>
<td>≥1 ADL impairment, %</td>
<td>36.7</td>
<td>13.1</td>
<td>32.8</td>
<td>98.5</td>
</tr>
<tr>
<td>≥1 IADL impairment, %</td>
<td>39.3</td>
<td>17.1</td>
<td>48.7</td>
<td>81.7</td>
</tr>
<tr>
<td>Diabetes mellitus treatment, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>26.9</td>
<td>20.5</td>
<td>31.2</td>
<td>36.5</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>40.4</td>
<td>38.9</td>
<td>45.4</td>
<td>37.6</td>
</tr>
<tr>
<td>Metformin hydrochloride</td>
<td>36.0</td>
<td>42.3</td>
<td>32.9</td>
<td>24.9</td>
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<tr>
<td>Thiazolidinediones</td>
<td>15.6</td>
<td>17.0</td>
<td>16.0</td>
<td>11.9</td>
</tr>
<tr>
<td>Other oral medications</td>
<td>10.1</td>
<td>9.9</td>
<td>10.1</td>
<td>10.5</td>
</tr>
<tr>
<td>No pharmacotherapy</td>
<td>15.3</td>
<td>16.9</td>
<td>13.5</td>
<td>13.8</td>
</tr>
</tbody>
</table>

**Abbreviations:** ADL, activities of daily living; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IADL, instrumental activities of daily living.

*All percentages were calculated taking into account complex survey design. Raw numbers were omitted because they do not directly correspond to the percentages. Percentages of types of treatment add up to greater than 100 because many participants were treated with more than 1 type of medication. Health status categories are defined in the Methods section.*
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Tight glycemic control, such as an HbA1c level of less than 7% (or even <6.5%) may be appropriate in patients who are relatively healthy, with a long life expectancy, in whom long-term benefits of glycemic control are more likely to materialize. Tight glycemic control may also be appropriate in patients with complex/intermediate or very complex/poor health, if it is consistent with patient goals of care and achieved through lifestyle modification or low-risk medications, such as metformin hydrochloride. However, intensive glycemic control strategies markedly increase the risk of hypoglycemia. In turn, hypoglycemia has been associated with poor outcomes, such as increased mortality, cardiovascular disease, falls and accidents, dementia, and low health-related quality of life. Therefore, intensive strategies to lower glucose levels may result in more harm than benefit, particularly among older, sicker patients.

Our study suggests that a substantial number of older adults with diabetes were potentially overtreated. We incorporated the presence of chronic comorbidities and functional impairments to determine participant health status, according to a framework developed jointly by the ADA and AGS, to guide glycemic treatment targets among older adults. Based on this framework, we estimated that approximately 1 million older adults with diabetes attained tight glycemic control with the use of insulin or sulfonylureas, despite complex/intermediate or very complex/poor health, indicating potential overtreatment. Given incomplete information on all comorbidities in our study, it is likely that we underestimated the complexity of health status, and thus, true estimates of adults who are potentially overtreated may be even higher.

To motivate improvements in quality, Pogach and Aron have proposed an overtreatment measure to minimize treatment that is unlikely to provide benefit and may result in harm. Based on electronic health records, this measure would identify patients with diabetes with an HbA1c level of less than 7% who are at high risk for hypoglycemia, including all persons 75 years or older. The measure would then prompt physicians and other health care professionals to reevaluate therapy. Our findings suggest that such a measure might identify a substantial proportion of older adults with diabetes whose therapy requires careful reassessment.

Our study has some limitations. We combined NHANES data from 2001 through 2010 to increase our sample size, but our study may have been underpowered to detect more subtle changes in treatment patterns over time. The ADA has only recently endorsed individualized glycemic targets, and it is possible that undertreatment is actually more common than we estimated.

Studies from the Department of Veteran Affairs also suggest a high prevalence of potential overtreatment among adults with diabetes. In a study, the prevalence of potential overtreatment, defined as an HbA1c level of less than 7%, treatment with insulin or sulfonylurea medications, and coexisting risk factors for hypoglycemia (age >75 years; elevated creatinine level of ≥2 mg/dL [to convert to micromoles per liter, multiply by 88.4]; or cognitive impairment or dementia), was approximately 50%. These results indicate that a substantial proportion of veterans received intensive treatment despite a high risk for serious hypoglycemia. Our research supports and extends these findings in several ways. We used nationally representative samples (with equal numbers of men and women) served by different health systems that are more generalizable to the US population at large. In addition, we incorporated functional impairments, which are an important risk factor for adverse outcomes in diabetes treatment but are not captured in administrative records such as those used in the study by Tseng et al. Finally, we were able to detect changes in potential overtreatment over time.

Tight glycemic control, such as an HbA1c level of less than 7% (or even <6.5%) may be appropriate in patients who are relatively healthy, with a long life expectancy, in whom long-term benefits of glycemic control are more likely to materialize. Tight glycemic control may also be appropriate in patients with complex/intermediate or very complex/poor health, if it is consistent with patient goals of care and achieved through lifestyle modification or low-risk medications, such as metformin hydrochloride. However, intensive glycemic control strategies markedly increase the risk of hypoglycemia. In turn, hypoglycemia has been associated with poor outcomes, such as increased mortality, cardiovascular disease, falls and accidents, dementia, and low health-related quality of life. Therefore, intensive strategies to lower glucose levels may result in more harm than benefit, particularly among older, sicker patients.

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Our study has some limitations. We combined NHANES data from 2001 through 2010 to increase our sample size, but our study may have been underpowered to detect more subtle changes in treatment patterns over time. The ADA has only recently endorsed individualized glycemic targets, and it is possible that undertreatment is actually more common than we estimated.

Studies from the Department of Veteran Affairs also suggest a high prevalence of potential overtreatment among adults with diabetes. In a study, the prevalence of potential overtreatment, defined as an HbA1c level of less than 7%, treatment with insulin or sulfonylurea medications, and coexisting risk factors for hypoglycemia (age >75 years; elevated creatinine level of ≥2 mg/dL [to convert to micromoles per liter, multiply by 88.4]; or cognitive impairment or dementia), was approximately 50%. These results indicate that a substantial proportion of veterans received intensive treatment despite a high risk for serious hypoglycemia. Our research supports and extends these findings in several ways. We used nationally representative samples (with equal numbers of men and women) served by different health systems that are more generalizable to the US population at large. In addition, we incorporated functional impairments, which are an important risk factor for adverse outcomes in diabetes treatment but are not captured in administrative records such as those used in the study by Tseng et al. Finally, we were able to detect changes in potential overtreatment over time.

Tight glycemic control, such as an HbA1c level of less than 7% (or even <6.5%) may be appropriate in patients who are relatively healthy, with a long life expectancy, in whom long-term benefits of glycemic control are more likely to materialize. Tight glycemic control may also be appropriate in patients with complex/intermediate or very complex/poor health, if it is consistent with patient goals of care and achieved through lifestyle modification or low-risk medications, such as metformin hydrochloride. However, intensive glycemic control strategies markedly increase the risk of hypoglycemia. In turn, hypoglycemia has been associated with poor outcomes, such as increased mortality, cardiovascular disease, falls and accidents, dementia, and low health-related quality of life. Therefore, intensive strategies to lower glucose levels may result in more harm than benefit, particularly among older, sicker patients.

Our study suggests that a substantial number of older adults with diabetes were potentially overtreated. We incorporated the presence of chronic comorbidities and functional impairments to determine participant health status, according to a framework developed jointly by the ADA and AGS, to guide glycemic treatment targets among older adults. Based on this framework, we estimated that approximately 1 million older adults with diabetes attained tight glycemic control with the use of insulin or sulfonylureas, despite complex/intermediate or very complex/poor health, indicating potential overtreatment. Given incomplete information on all comorbidities in our study, it is likely that we underestimated the complexity of health status, and thus, true estimates of adults who are potentially overtreated may be even higher.

To motivate improvements in quality, Pogach and Aron have proposed an overtreatment measure to minimize treatment that is unlikely to provide benefit and may result in harm. Based on electronic health records, this measure would identify patients with diabetes with an HbA1c level of less than 7% who are at high risk for hypoglycemia, including all persons 75 years or older. The measure would then prompt physicians and other health care professionals to reevaluate therapy. Our findings suggest that such a measure might identify a substantial proportion of older adults with diabetes whose therapy requires careful reassessment.

Our study has some limitations. We combined NHANES data from 2001 through 2010 to increase our sample size, but our study may have been underpowered to detect more subtle changes in treatment patterns over time. The ADA has only recently endorsed individualized glycemic targets, and it is possible that undertreatment is actually more common than we estimated.
Overtreatment of Diabetes in Older Adults

We were not able to de-

izedadults,ourfindingsdonotapplytoolderadultswholive

erd of questions about ADL and instrumental ADL impair-

participantsaccordingtohealthstatusbasedonalimitednum-

mephenytoin or sulfonylureas. We categorized

takes into account dementia or cognitive impairment;
to the extent possible, we have followed the ADA/

countries with hypoglycemia and life expectancy than others;

drugs usedtocategorizehealthstatusmayhavestrongeras-

treatment. Some combinations of comorbid conditions

glycemic treatment. We found that nearly two-thirds of older

ingly attained tight glycemic control. These vulnerable

tions from treatment, such as hypoglycemia and other adverse
effects. Recognition of both the harms and benefits of glyce-
ic control is critical for patients and physicians and other

health care professionals to make informed decisions about

glucose-lowering treatment.

Table 2. Changes in Glycemic Control and Treatment of Diabetes Mellitus Among US Adults From 2001-2002 Through 2009-2010

<table>
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<tbody>
<tr>
<td>Less than 7% Overall</td>
<td>57.3 (48.4-65.7)</td>
<td>68.0 (62.5-73.0)</td>
<td>66.3 (52.8-77.6)</td>
<td>56.3 (47.4-64.9)</td>
<td>59.5 (52.7-65.9)</td>
<td>.34</td>
</tr>
<tr>
<td>Complex/intermediate or very complex/poor</td>
<td>39.2 (29.3-51.5)</td>
<td>46.8 (34.1-59.9)</td>
<td>50.8 (35.2-66.4)</td>
<td>49.9 (39.2-60.7)</td>
<td>50.6 (39.3-61.8)</td>
<td>.27</td>
</tr>
<tr>
<td>Relatively healthy</td>
<td>48.5 (36.9-60.2)</td>
<td>61.9 (48.9-73.5)</td>
<td>58.3 (39.3-75.1)</td>
<td>36.2 (26.1-47.7)</td>
<td>47.2 (38.7-55.7)</td>
<td>.05</td>
</tr>
<tr>
<td>Complex/intermediate or very complex/poor</td>
<td>72.8 (45.3-89.7)</td>
<td>44.3 (30.9-58.5)</td>
<td>61.4 (48.5-72.8)</td>
<td>64.0 (50.3-75.8)</td>
<td>60.8 (49.4-71.1)</td>
<td>.65</td>
</tr>
</tbody>
</table>

Abbreviation: HbA1c, hemoglobin A1c.

a Health status categories are defined in the Methods section.

Conclusions

Using a nationally representative sample of US adults, we

harm, such as hypoglycemia. Achieved HbA1c level is a poor

predictor of self-reported serious hypoglycemia, although

multiple randomized trials showed that intensive glycemic con-

tional framework, which does not distinguish between these

combinations. Since NHANES is a study of noninstitutional-

ized adults, our findings do not apply to older adults who live

in nursing homes or other facilities. We were not able to de-

termine whether potential overtreatment directly resulted in

ARTICLE INFORMATION

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Author Contributions: Dr Steinman 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.

Study concept and design: Lipska, Steinman.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Lipska.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Miao.

Administrative, technical, or material support: Steinman.

Study supervision: Steinman.

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REFERENCES