

# Impact of the 2020 China Diabetes Society Guideline on the Prevalence of Diabetes Mellitus and Eligibility for Antidiabetic Treatment in China

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**Purpose:** This study aimed to estimate the impact of the 2020 China Diabetes Society's (CDS) guideline on the prevalence of diabetes mellitus and eligibility for antidiabetic treatment in China.

**Material and Methods:** Baseline data from the China Health and Retirement Longitudinal Study (CHARLS, 2011–2012) were used to estimate the prevalence of diabetes mellitus and compare the recommendations for antidiabetic medication and intensification of therapy between the 2017 and 2020 CDS guidelines.

**Results:** According to the 2017 CDS guideline, the prevalence of diabetes mellitus was 12.56% among Chinese adults who were  $\geq 45$  years of age. However, according to the 2020 CDS guideline, 0.65% (0.35%, 1.20%), or 3.54 (2.50, 4.57) million Chinese adults who were  $\geq 45$  years would additionally be diagnosed with diabetes mellitus. Among Chinese adults not taking antidiabetic medications, 1.06% (0.87%, 1.28%), or 5.37 (4.36, 6.38) million Chinese adults with diabetes mellitus were recommended to start antidiabetic medication according to the 2017 CDS guideline, while 1.27% (1.01%, 1.58%), or 6.44 (5.29, 7.60) million Chinese adults with diabetes would be recommended to initiate antidiabetic medication according to the 2020 CDS guideline. Among Chinese adults taking antidiabetic medication, 51.59% (44.19%, 58.93%), or 18.35 (15.58, 21.12) million Chinese adults with diabetes received antidiabetic treatment but had a hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) level higher than that mentioned in the 2017 and 2020 CDS guidelines.

**Conclusion:** The addition of HbA<sub>1c</sub> in the 2020 CDS guideline will result in a modest increase in the number of Chinese adults who are diagnosed with diabetes and diabetes patients recommended for antidiabetic medication; however, the 2020 CDS guideline does not affect the number of diabetes patients eligible for intensification of treatment.

**Keywords:** China Diabetes Society, diabetes, glycated hemoglobin A<sub>1c</sub>

## Introduction

China has the largest population of patients with diabetes mellitus worldwide.<sup>1</sup> Prior studies have estimated that diabetes mellitus is associated with a high risk of cardiovascular disease (CVD) events and mortality.<sup>2,3</sup> Uniform diagnostic criteria are crucial to obtain real data on the prevalence of diabetes mellitus.

The China Diabetes Society (CDS) recently released their "Guideline for the prevention and treatment of type 2 diabetes mellitus in China (2020 edition)".<sup>4</sup> One of its important amendments was to include glycated hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels  $\geq 6.5\%$  as another diagnostic criterion for diabetes mellitus. Furthermore, this

guideline recommends that in laboratories with strict quality control, HbA<sub>1c</sub> levels  $\geq 6.5\%$ , measured by a standardized test, may be used as a supplementary diagnostic criterion for diabetes. From 2003 to 2018, CDS had issued five editions of guidelines for the prevention and treatment of diabetes mellitus in China. In the 2017 CDS guideline, fasting blood glucose (FBG) levels  $\geq 7.0$  mmol/L, random blood glucose (RBG) levels  $\geq 11.1$  mmol/L and 2-h blood glucose after oral glucose tolerance test (OGTT) levels  $\geq 11.1$  mmol/L from venous plasma glucose were included in the diagnostic criteria for diabetes. The 2020 CDS guideline recommends that pharmacological antidiabetic treatment be initiated in adult patients with diabetes if they have an average HbA<sub>1c</sub> level  $\geq 7.0\%$ . The therapeutic goal of HbA<sub>1c</sub>  $< 7.0\%$  is recommended for most non-gestational adults with diabetes and is the same as that in the 2017 CDS guideline.

The impact of this addition to the 2020 CDS guideline on the identification and treatment of Chinese adults remains unclear, although this would certainly increase the prevalence of diabetes. Therefore, our present study aimed to estimate the impact of the adoption of the 2020 CDS guideline on the prevalence of diabetes and eligibility for antidiabetic treatment in Chinese adults. To achieve these goals, nationally representative data from the China Health and Retirement Longitudinal Study (CHARLS) were included.

## Materials and Methods

### Data Sources and Study Population

Baseline data from CHARLS (2011–2012) were used to estimate the impact of the 2020 CDS guideline on the prevalence of diabetes and compare the eligibility for antidiabetic treatment and recommendation for intensification of therapy with that in the 2017 CDS guideline. The profile and data quality of CHARLS had been previously reported.<sup>5,6</sup> In brief, CHARLS is an ongoing nationally representative cohort in China. Participants who were aged  $\geq 45$  years during 2011–2012 were selected using the multistage probability sampling method and were weighted to obtain national estimates. CHARLS data that supported the results of this study were extracted from <http://charls.pku.edu.cn/index/en.html>.

All individuals included in CHARLS provided their written informed consent, and the protocol was approved by the relevant institutional review board. This study was approved by the Human Research Ethics Committee of the Xi'an Jiaotong University Health Science Center (No: 2021-6).

## Blood Glucose Measurement and Definition

Venous blood was collected from each participant by a medically trained staff, following a standard protocol. Participants were required to have fasted overnight. Blood glucose and HbA<sub>1c</sub> levels were measured using the blood specimens collected. HbA<sub>1c</sub> assays were conducted at the Youanmen Center for Clinical Laboratory of Capital Medical University. Patients were considered to have diabetes mellitus if they had at least one of the following criteria: a self-reported history of diabetes, current use of diabetic medications, FBG levels  $\geq 7.0$  mmol/L, or RBG levels  $\geq 11.1$  mmol/L. When estimating the impact of the 2020 guideline in comparison to the 2017 guideline, the criteria above, in addition to having hemoglobin A<sub>1c</sub> levels  $\geq 6.5\%$  were used. Both the 2017 and 2020 guidelines recommended initiating antidiabetic medications for patients with HbA<sub>1c</sub>  $\geq 7\%$  to achieve the treatment goal of HbA<sub>1c</sub>  $< 7\%$ .

## Assessment of Covariables

Definitions of categorical variates included: age (45–55, 55–65,  $\geq 65$  years), gender (male or female), educational attainment (illiterate, primary school, middle/high school, bachelor or above), marital status (married, never), registered residence (rural, urban), self-reported health in excellent/very good condition (yes, no), smoking status (non-smoker, current smoker, ex-smoker), drinking status (non-drinker, drinker), and history of CVD, hypertension, cancer and chronic kidney diseases (CKD) (yes, no). Body mass index was calculated as weight (in kilograms) divided by height (in meters) squared. We defined the following parameters: a history of CVD as a reported coronary heart disease, stroke, or heart failure; CKD as a reported CKD or eGFR rate  $< 60$  mL/min/1.73 m<sup>2</sup> (calculated using the 2009 CKD Epidemiology Collaboration equation); hypertension as a self-reported history of hypertension, the current use of antihypertension medications, systolic blood pressure (SBP)  $\geq 140$  mmHg, or diastolic blood pressure (DBP)  $\geq 90$  mmHg, and cancer reported as cancer.

## Statistical Analyses

Using CHARLS sampling weights extrapolated to the Chinese population aged  $\geq 45$  years, the difference in diabetes prevalence and the eligibility for pharmacologic treatment according to the 2017 and 2020 CDS guidelines were compared. First, the percentage and number of

Chinese adults with diabetes defined by the 2017 and 2020 CDS guidelines were estimated, respectively. Second, among those not taking antidiabetic treatment, the percentage and number of Chinese adults with diabetes who would be recommended to take antidiabetic medication according to the 2017 and 2020 CDS guidelines were calculated separately. Finally, among those taking antidiabetic medication, the percentage and number of Chinese adults with diabetes who would be recommended for intensive treatment according to the 2017 and 2020 CDS guidelines were calculated separately. The percentage of Chinese adults who had concordant and discordant definitions of diabetes, recommended for antidiabetic medication, and above goal HbA<sub>1c</sub> levels by the 2017 and 2020 CDS guidelines were further calculated.

Baseline characteristics of participants in the CHARLS study were described by 2017 and 2020 CDS guidelines. Overall groups were expressed as mean  $\pm$  standard deviation for continuous variables, and n (%) for categorical variables. Stata 16.0 software (StataCorp, College Station, TX 77845, USA) was used for data analysis.

## Results

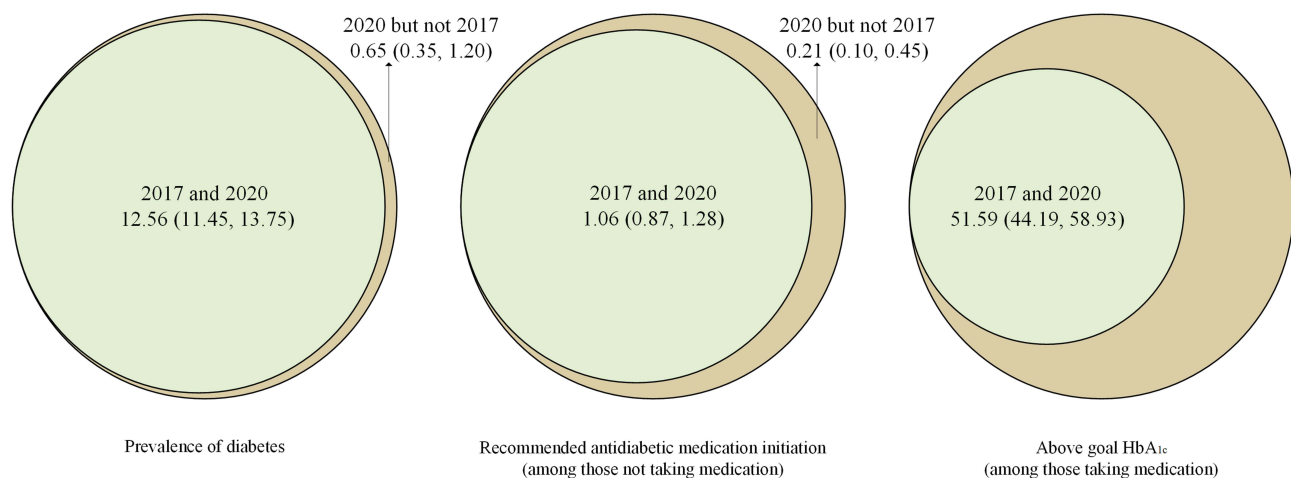
### Prevalence of Diabetes

According to the 2017 CDS guideline, 2051 Chinese adults from the CHARLS 2011–2012 baseline survey, representing 12.56% (95% CI 11.45%, 13.75%) of the Chinese adults who were aged  $\geq 45$  years nationally, or

68.34 (95% CI 62.42, 74.25) million Chinese adults were classified as suffering from diabetes. An additional 94 people, representing 0.65% (0.35%, 1.20%) of the Chinese adults, or 3.54 (2.50, 4.57) million Chinese adults would be additionally labeled as having diabetes based on diagnostic criteria recommended in the 2020 CDS guideline. Therefore, according to the 2020 CDS guideline, 13.21% (12.04%, 14.47%), or 71.87 (65.89, 77.85) million Chinese adults would be classified as suffering from diabetes (Figure 1, left panel and Figure 2, left bar). Compared to Chinese adults with diabetes on the basis of the 2017 CDS guideline, those newly classified as diabetes based on the 2020 CDS guideline were likely to be female (64.89% vs 52.75%), reside in a rural area (77.66% vs 70.75%), be a non-drinker (81.52% vs 70.52%), concomitantly have CKD (15.22 vs 12.52), have less proportion of hypertension (59.57 vs 64.65), and have a lower FBG ( $5.74 \pm 0.70$  vs  $8.94 \pm 3.61$ ) and RBG ( $9.18 \pm 1.09$  vs  $13.91 \pm 6.64$ ) levels (Table 1).

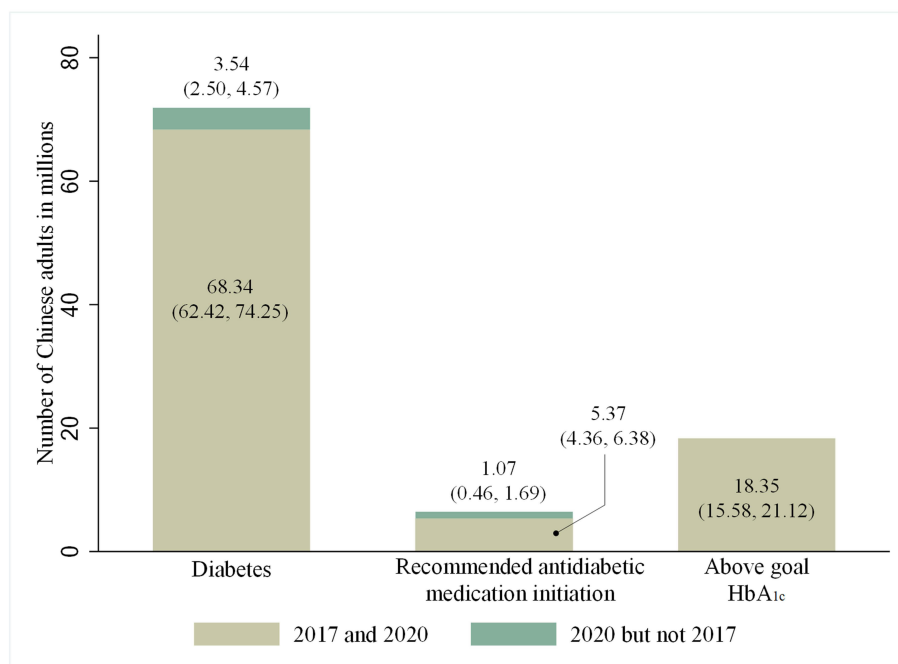
### Eligibility for Antidiabetic Treatment

According to the 2017 CDS guideline, among Chinese adults not taking antidiabetic medication, 1.06% (95% CI 0.87%, 1.28%), or 5.37 (95% CI 4.36, 6.38) million Chinese adults with diabetes were eligible for treatment and yet did not receive it. However, according to the 2020 CDS guideline, Chinese adults not taking antidiabetic medication included 1.27% (1.01%, 1.58%) of the population, or 6.44 (5.29, 7.60) million people. Furthermore,



**Figure 1** Percentage of Chinese adults who had diabetes (left panel), who were recommended to initiate antidiabetic medication among those not taking antidiabetic medication (middle panel), and who with above goal HbA<sub>1c</sub> among those taking antidiabetic medication (right panel). Data used for estimating were from CHARLS 2011–2012 baseline survey.

**Abbreviation:** HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>.



**Figure 2** Number of Chinese adults who had diabetes (left bar), who were recommended to initiate antidiabetic medication (middle bar), and who with above goal HbA<sub>1c</sub> (right bar). Data used for estimating were from CHARLS 2011–2012 baseline survey.

**Abbreviation:** HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>.

0.21% (0.10%, 0.45%), or 1.07 (0.46, 1.69) million increase was estimated in the number of Chinese adults with diabetes requiring the initiation of antidiabetic treatment compared to that according to the 2017 CDS guideline (Figure 1, middle panel and Figure 2, middle bar). Among Chinese adults taking antidiabetic medication according to the 2017 CDS guideline, 51.59% (44.19%, 58.93%), or 18.35 (15.58, 21.12) million Chinese adults with diabetes received antidiabetic treatment but had elevated HbA<sub>1c</sub> levels (Figure 1, right panel and Figure 2, right bar). The treatment goal for HbA<sub>1c</sub> levels suggested by the 2020 CDS guideline was the same as that suggested in the 2017 CDS guideline. Therefore, the application of the 2020 CDS guideline did not increase the number of patients who required intensification of treatment. Under the 2017 and 2020 CDS guidelines, the remaining 1.69 (1.00, 2.38) and 4.15 (3.12, 5.18) million Chinese adults who were aged  $\geq 45$  years would have diabetes and require lifestyle modifications, respectively, because they had an HbA<sub>1c</sub> level of 6.5–7%.

## Discussion

Our study revealed a 0.65% (95% CI 0.35%, 1.20%) increase in the number of Chinese adults who were aged  $\geq 45$  years and diagnosed with diabetes, according to the 2020 CDS guideline. In addition, 1.07 (0.46, 1.69) million

Chinese adults were recommended for antidiabetic medication based on the 2020 CDS guideline compared to that in the 2017 CDS guideline; however, the new recommendations of the 2020 CDS guideline did not cause an increase in the number of patients who required intensification of antidiabetic treatment.

A large national survey<sup>7</sup> in China in 2017 indicated that the prevalence of diabetes in adults aged  $\geq 18$  years increased from 11.2% (according to the 1999 World Health Organization [WHO] criteria) to 12.8% (according to the 2018 American Diabetes Association's criteria, which included measuring HbA<sub>1c</sub> levels), which was similar to our findings. Furthermore, a survey conducted in 2010<sup>8</sup> revealed that the prevalence of diabetes in China was 9.7% among people who were aged  $\geq 18$  years. According to a report on chronic disease risk factor surveillance in China in 2013,<sup>9</sup> the prevalence of diabetes among people who were aged  $\geq 18$  years was 10.4%. Both studies aforementioned used the 1999 WHO criteria. However, the prevalence of diabetes found in our study was higher than those in the three studies listed above due to the higher average age of the study population. Based on data from the National Health Interview Surveys from 2011 to 2015, 9.5% of American adults who were aged  $\geq 20$  years were diagnosed with diabetes using HbA<sub>1c</sub>/FBG levels, which was lower than the levels reported in

**Table I** Characteristics of Overall Chinese Adults and Chinese Adults with Diabetes According to the 2017 CDS Guideline and the 2020 CDS Guideline but Not the 2017 CDS Guideline

	2017 CDS Guideline	2020 CDS Guideline Minus 2017 CDS Guideline	Overall
Number of participants	2051	94	18,245
Age, years	60.97±9.71	61.04±9.77	59.17±9.86
Age, %			
45–55 years	28.96	27.66	36.99
55–65 years	40.27	39.36	37.93
≥65 years	30.77	32.98	25.08
Gender, %			
Male	47.25	35.11	49.46
Female	52.75	64.89	50.54
Educational attainment, %			
Illiterate	26.47	38.3	26.33
Primary school	40.27	31.91	41.35
Middle/high school	30.47	25.53	29.98
Bachelor or above	2.78	4.26	2.35
Marital status, %			
Never	0.68	1.06	0.9
Married	99.32	98.94	99.1
Registered residence, %			
Urban	29.25	22.34	22.51
Rural	70.75	77.66	77.49
Self-reported health			
Excellent/very good, %			
No	97.03	97.87	96.77
Yes	2.97	2.13	3.23
Smoking status, %			
Non-smoker	61.97	62.77	62.01
Current smoker	27.01	30.85	30.22
Ex-smoker	11.02	6.38	7.77
Drinking status, %			
Non-drinker	70.27	81.52	67.14
Drinker	29.73	18.48	32.86
History of disease, %			
CVD	22.48	22.34	13.2
Hypertension	64.65	59.57	55.43
Cancer	1.43	1.09	1.03
CKD	12.52	15.22	8.36
BMI, kg/m <sup>2</sup>	24.76±3.86	24.03±4.04	23.44±3.73
Fasting blood-glucose, mmol/L	8.94±3.61	5.74±0.70	5.74±0.70
Random blood glucose, mmol/L	13.91±6.64	9.18±1.09	9.18±1.09
HbA <sub>1c</sub> , %	6.15±1.58	7.05±1.00	5.26±0.82

**Abbreviations:** CDS, China Diabetes Society; CVD, cardiovascular disease; CKD, chronic kidney diseases; BMI, body mass index; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>.



this study.<sup>10</sup> All of these studies had revealed that China had a high prevalence of diabetes, which continues to increase.

Early intervention plays an important role in preventing diabetes and delaying its progression; however, its early diagnosis is an important prerequisite to achieve early intervention. The ideal diagnostic modality for diabetes should consider not only the sensitivity and specificity of the test but also be fast, simple, economical, and easily interpreted by examinees. Diagnosis of diabetes had long been based on blood glucose levels, including FBG, RBG, and 2-h post glucose (2-h PG) level in China. However, these methods have certain limitations in practice. First, blood glucose reflects the level of immediate glucose metabolism, which is affected by various factors, potentially leading to false negatives or positives, with regard to diagnosis of diabetes.<sup>11</sup> Second, although OGTT is the internationally recognized gold standard for diabetes diagnosis, it has a complicated process, high cost, large variability, and poor reproducibility. Thresholds for FBG and 2-h PG in the diagnosis of diabetes were determined based on the association between blood glucose and retinopathy shown in epidemiological surveys.<sup>12</sup> Studies have confirmed that there is also a strong correlation between retinopathy and HbA<sub>1c</sub> levels.<sup>13</sup> Moreover, several studies have shown that reducing HbA<sub>1c</sub> levels significantly reduces the incidence of diabetes-related cardiovascular events.<sup>14,15</sup>

Unlike FPG level, determining the HbA<sub>1c</sub> level is advantageous in diagnosing diabetes because it does not require fasting, is conveniently detected, and has low variation in terms of results.<sup>16</sup> Moreover, HbA<sub>1c</sub> reflects the average blood glucose level for the past 120 days, which may reflect the chronic hyperglycemic state of diabetes patients. In 2011, the WHO recommended that HbA<sub>1c</sub> should be used to diagnose diabetes in countries or regions where relevant resources were available and suggested the diagnostic threshold to be HbA<sub>1c</sub> levels  $\geq 6.5\%$ .<sup>17</sup> In 2019, WHO announced that HbA<sub>1c</sub> could be used for the clinical diagnosis of diabetes.<sup>18</sup> Moreover, the “Standards of Medical Care in Diabetes – 2010” released by the American Diabetes Association recommended the use of HbA<sub>1c</sub> for the diagnosis of diabetes.<sup>19</sup> Over the past 10 years, China has continuously promoted the standardization of HbA<sub>1c</sub> assay, and in 2020, this indicator was officially added to the diagnosis and screening guidelines for diabetes. However, it has several limitations, including a relatively high cost, limited development due to the lack of standardization in some areas and the incomplete

correlation between HbA<sub>1c</sub> levels and blood glucose in some individuals. In addition, anemia,<sup>20</sup> race,<sup>21</sup> and other factors would affect the detection of HbA<sub>1c</sub> levels. Although the diagnostic cut-off value has been recommended in the 2020 CDS guideline, several studies have reported the sensitivity, specificity, and accuracy of HbA<sub>1c</sub> for the diagnosis of diabetes.<sup>22,23</sup> The sensitivity and specificity of the cut-off value for HbA<sub>1c</sub> level  $\geq 6.5\%$  in the Chinese population still need further verification. Moreover, the effectiveness of this indicator as a general screening tool also needs further evaluation. Nonetheless, the new criteria would better identify patients at risk, and allow early detection, prevention, and treatment of the disease. However, the cost-effectiveness of this new criterion requires further evaluation. In summary, measuring HbA<sub>1c</sub> levels is a powerful diagnostic and screening tool for diabetes mellitus and this should be added to the 2020 CDS guideline.

This study had several limitations. First, the HbA<sub>1c</sub> assay was not appropriate for participants with diseases affecting hemoglobin conditions such as anemia; however, this was not considered in our study due to limited data, which could have led to potential bias. Second, the 2020 CDS guideline recommended that HbA<sub>1c</sub> control targets for diabetic patients should follow be individualized, which should consider age, disease course, life expectancy, and other complications. However, due to the lack of data on these factors, we used the broad target of HbA<sub>1c</sub> levels  $< 7\%$  for all populations in this study. Third, the data used in this study were from a survey conducted from 2010 to 2011, which may underestimate the current status in China. Finally, the national assessment was limited to adults aged  $\geq 45$  years due to the age of the study population.

## Conclusion

The addition of measuring HbA<sub>1c</sub> levels to the 2020 CDS Guideline will result in a modest increase in the number of Chinese adults who are diagnosed with diabetes mellitus and diabetes patients requiring initiation of antidiabetic treatment. However, the guideline does not affect the number of diabetes patients requiring intensification of treatment.

## Data Sharing Statement

The CHARLS data that support the findings of this study are available upon application from <http://charls.pku.edu.cn/index/en.html>.

## Ethics Approval and Consent to Participate

This study was approved by the Human Research Ethics Committee of the Xi'an Jiaotong University Health Science Center (No: 2021-6). All individuals from CHARLS obtained participants' written informed consent and approved by institutional review board approval.

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## Disclosure

The authors report no conflicts of interest in this work.

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