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Implications of the new definition of diabetes for health disparities

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Abstract

In July 2009, an international committee announced a new diagnostic criterion for diabetes based on hemoglobin A1c (HbA1c) values. Our objective was to estimate how the new diabetes diagnostic criterion will affect the prevalence of diabetes among different race, age, and gender subpopulations, compared to the previously used Fasting Plasma Glucose (FPG) criterion.. We analyzed nationally representative data from The National Health and Nutrition Examination Survey (NHANES), aggregated from 1999 – 2006. We estimated the prevalence of known diabetes (prevalence static across either diagnostic criterion), and unknown and no diabetes (prevalence variable by criterion). We tested statistical significance of prevalence differences for unknown diabetes between the prior diagnostic criterion, FPG 126 mg/dl, and the new diagnostic criterion, HbA1c 6.5%, using conditional logistic regression. We further tested the association of these differences with demographic factors. The new HbA1c diagnostic criterion differentially affects different racial/ethnic groups. For Non-Hispanic Whites the prevalence of undiagnosed diabetes was more than halved from 2.6% (95%CI 2.2, 3.1) with FPG diagnosis to 1.3% (95%CI 1.0, 1.7), $P<0.001$ with HbA1c diagnosis. For Hispanics and Non-Hispanic Blacks, the differences in prevalence by the two criteria were smaller and non-significant. Racial differences by diagnostic criteria were most pronounced among people over 55 years of age. Overall, the new definition of diabetes differentially affects ethnic groups, especially for older

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people. If the new criterion is widely adopted, over time we may see an apparent widening of racial/ethnic disparities in diabetes prevalence.

Keywords

Diabetes; Diagnosis; Disparities

Introduction

The diagnosis of diabetes has traditionally been based on a fasting blood glucose or oral glucose tolerance test. For the fasting blood glucose (FPG) criterion, individuals with fasting glucose levels 126 mg/dl or greater on two occasions are considered to have diabetes¹. The choices of diagnostic cutpoints for these tests have been based on what are thought to be normal fasting or post-prandial glucose levels. While these tests have been the gold standard for diagnosing diabetes, their use has frequently been cumbersome in practice due to the requirement of subject fasting.

In July of 2009, the International Expert Committee on the Diagnosis and Classification of Diabetes recommended that the testing methodology for diagnosing diabetes shift from the fasting blood glucose and oral glucose tolerance tests to glycosylated hemoglobin (HbA1c). The committee's recommendation to shift the test methodology was based on improved standardization of glycosylated hemoglobin measurement and the fact that the test can be obtained without fasting. The committee also selected a diagnostic cutpoint of HbA1c 6.5% based on the epidemiological association of baseline glycosylated hemoglobin with future complications². Following the publication of the new diagnostic recommendation, there has been active debate regarding its validity and implications³⁻⁵. The use of the HbA1c diagnostic criterion was recently incorporated into the 2010 American Diabetes Association Standards of Medical Care in Diabetes.

The new diagnostic criterion raises important questions for population level studies of diabetes prevalence and trends. A study using National Health and Nutrition Examination (NHANES) data concluded that the new HbA1c criterion has reasonable agreement with the fasting glucose criterion for diagnosing diabetes, and yields the same results for 97.7% of US adults⁶. Another paper by Cowie and colleagues characterized the diabetes population under the HbA1c criteria and found lower prevalence compared to the FPG criteria, and that minorities and older adults continue to carry an increased burden of disease⁷. However, a number of previous studies have found that HbA1c levels differ by gender⁸, race⁹⁻¹², and age^{8, 13, 14} at the same blood glucose levels regardless of diabetes status. These studies raise the potential for a differential impact of the new HbA1c criterion on diabetes prevalence by subpopulation. In particular, will racial disparities by diabetes prevalence widen over the long-term with the new criterion? We systematically examine the changes in prevalence estimates of diabetes for gender, race, and age subgroups using the new HbA1c definition as compared to the fasting glucose criterion in a nationally representative sample.

Methods

We used data from the fasting subsample of the National Health and Nutrition Examination Survey (NHANES) from 1999 through 2006. NHANES collects health and nutrition data on a nationally representative sample of the non-institutionalized, civilian population of the United States, with oversampling of racial/ethnic minorities and people over the age of 60¹⁵, and measures fasting plasma glucose on a random subsample of the total sample.

We defined known diabetes as self-reported diagnosis of diabetes by a medical professional, and/or taking insulin or glucose-lowering medication. Based on this definition, we excluded individuals from the total 8-year NHANES fasting subsample of 12,773 individuals, successively as follows: 611 pregnant at the time of interview, 909 with non-fasting plasma glucose (fasting < 8 hrs), 8 with incomplete information on self-reported diabetes status, and 18 without HbA1c measurement, yielding an analytic sample of 11,227 people (N), comprised of 681 individuals with known diabetes (N₁) and 10,546 without known diabetes (N₂). We used sample weights provided by NHANES, specific to the fasting subsample so that prevalence estimates presented here are for the United States population.

Among the individuals without known diabetes (N₂), we classified those with FPG ≥ 126 mg/dl as having unknown diabetes by the FPG criterion, and those with HbA1c $\geq 6.5\%$ as having unknown diabetes by the HbA1c criterion. Using the total analytic sample (N), we calculated population-level estimates of the prevalence of known diabetes, unknown diabetes (based on FPG ≥ 126 mg/dl or HbA1c $\geq 6.5\%$), and no diabetes. These prevalences were also estimated by gender, race/ethnicity, and age groups (<18, 18 – 39, 40 – 54, 55 – 64, 65 – 74, 75). We performed an age-stratified analysis for individuals <55 years of age and ≥ 55 years of age. This age cutpoint was selected to allow for sufficient numbers to draw conclusions in the older subgroup. For the race/ethnicity comparisons, we combined the “other Hispanic” group with Mexican Americans to form the Hispanic subgroup. We did not include the “other” racial group in age-stratified analysis due to insufficient numbers. We tested statistical significance of prevalence differences between the FPG and A1c criteria, and the association of these differences with demographic factors, among participants without known diabetes (N₂). For this purpose, we used conditional logistic regression, which accounts for the pairing of FPG and A1c measurements within individuals, with diabetes status (unknown, none) as the dependent variable.

Because people with known diabetes are likely taking steps to lower their blood glucose levels, we did not evaluate the HbA1c levels of these individuals. All analyses accounted for the NHANES survey sampling design through incorporation of sampling strata and clusters as well as sampling weights. We performed all analyses in Stata Version 10 (College Station, TX).

Results

We describe diabetes status (known diabetes, unknown diabetes, and no diabetes) for the entire population (N=11,227) and stratified by age (Table 1). The prevalence of known diabetes was 6.1% (95% CI: 5.5, 6.8). Using the original fasting glucose criterion, 2.5% (95% CI: 2.1, 2.9) of the population had unknown diabetes and 91.4% (95% CI: 90.6, 92.1) had no diabetes. Using the new HbA1c criterion, the estimated prevalence of undiagnosed diabetes was significantly lower at 1.5% (95% CI: 1.2, 1.8), $P < 0.001$. Among the 10,546 individuals without known diabetes, 321 met one or both of the criteria for unknown diabetes; for this group, 174 people, 54%, had discrepant diagnostic results – that is, they met only one of the two criteria. Among those with discrepant results, 79% met the FPG criterion alone.

As observed in the overall population, the prevalence of undiagnosed diabetes was significantly lower with the new criterion for most demographic subgroups. However, the extent to which demographic characteristics were significantly associated with a change in prevalence by diagnostic criteria varied. The difference in prevalence of undiagnosed diabetes between the two test criteria was not significantly associated with gender or age. However, we found that race was significantly associated with the difference in prevalence; the net result was an effective widening of racial disparities under the HbA1c criterion ($P =$

0.01). Among Non-Hispanic Whites, the prevalence of unknown diabetes was significantly lower using the HbA1c criterion (1.3% (95% CI: 1.0, 1.7)) as compared to the FPG criterion (2.6% (95% CI: 2.1, 3.1)), while differences by criteria were smaller and non-significant for both Hispanics and Non-Hispanic Blacks.

We further examined prevalence estimates for gender and race stratified by age and found distinct results by age strata. For individuals under 55 years, the prevalence of unknown diabetes was significantly lower using the HbA1c criterion compared to the FPG criterion, but prevalence differences for the two criteria were not significantly associated with gender or race/ethnicity.

For people 55 years and older, the prevalence of unknown diabetes was also lower using the HbA1c criterion; differences in diabetes status by gender under the FPG criterion were not present under the HbA1c criterion, and differences in diabetes prevalence by race/ethnicity noticeably widened under the new HbA1c criterion. For Non-Hispanic Whites over age 55, the prevalence of undiagnosed diabetes was more than halved from 5.8% (95%CI: 4.8, 7.1) with FPG diagnosis to 2.5% (95%CI: 1.7, 3.5) with HbA1c diagnosis ($P < 0.001$); for older Hispanics, the difference in prevalence by the two criteria was smaller but still statistically significant (5.8% vs. 4.7%, HbA1c, $P = 0.04$), while prevalence for older Non-Hispanic Blacks was not significantly different under the two criteria (6.8 vs. 6.7 % FPG vs. HbA1c).

Discussion

The estimated prevalence of unknown diabetes decreased using the new HbA1c criterion as compared to the original fasting plasma glucose criterion. The overall estimate of diabetes prevalence declined from 8.6% to 7.6% which translates into a change in the number of people with diabetes from 26.4 million to 23.3 million people in the United States, a decrease of 3.1 million people¹⁶. The reduction in undiagnosed prevalence occurred for all subgroups, although the drop was largest for Non-Hispanic Whites and older people. The differential effect of the HbA1c criterion among different racial/ethnic groups led to an apparent widening in the racial/ethnic disparities in diabetes prevalence, particularly among people over the age of 55. In the future, this differential effect of the HbA1c cutpoint will lead to a decreased incidence of diabetes among older Non-Hispanic Whites.

There are at least two potential explanations for the differential effect of the HbA1c criterion by race/ethnicity. First, the finding may reflect previous observations of increased HbA1c levels in older populations^{8, 13, 14} and minority ethnic groups^{9–12} despite similar FPG levels. These observations have been attributed to potential differences in the glycosylation process by age and race/ethnicity. A second explanation is that higher HbA1c levels among undiagnosed minority participants compared to Non-Hispanic Whites may reflect differences in access to health services. As a result of historic differences in access, the time from disease onset to diagnosis may differ by race, with a longer time lapse for minorities. Therefore, the higher prevalence of undiagnosed diabetes for minority populations with the HbA1c criterion may reflect a more advanced stage of disease than that of Non-Hispanic Whites.

Apart from our new findings on subgroup differences, our analysis yielded slightly different results for the overall population-prevalence for diabetes than a previous report by Carson, which noted the undiagnosed diabetes prevalence would decline from 3.6% under the FPG diagnosis to 2.3% with the HbA1c diagnosis⁶. The difference in prevalence estimates is due to differences in which the analytic populations were defined. Our analysis included all people between 0 and 85, excluded people who had fasted for <8 hours before giving their

blood glucose, and excluded all pregnant women, while the analysis by Carson and colleagues included people 20 – 85, and excluded those who had fasted for <9 hours ⁶.

There are some limitations to this study. First, under the FPG diagnostic criterion, diabetes status should be determined with two FPG measurements; however, NHANES only collects one measurement. It is possible that some people in our study classified as having diabetes based on a single FPG have impaired glucose tolerance rather than diabetes. As a result, the baseline prevalence of undiagnosed diabetes using FPG criterion may be lower and thus the decline in prevalence using the new HbA1c criterion may be less dramatic. Second, we did not adjust for conditions that could affect hemoglobin levels, such as anemia or hemoglobinopathies. Third, our study does not address how the new diagnostic criterion might affect individuals with existing diabetes, who have been diagnosed by a variety of criteria including different fasting glucose cutpoints over time. Among this population, there are likely to be a number of individuals diagnosed with diabetes, who never had an untreated HbA1c above 6.5%.

Despite these limitations, the prevalence of diabetes will decrease over time under the new diagnostic criterion, particularly among older non-Hispanic Whites, causing racial disparities in diabetes prevalence to widen. As the relative burden of diabetes for minorities grows, efforts to reduce racial/ethnic disparities in health and healthcare will become increasingly important ¹⁷. Patients, physicians, researchers and public health officials will need to remain vigilant as the new criterion is implemented to ensure treatment of patients is equitable.

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Prevalence of Known, Unknown, and No Diabetes Where Unknown Diabetes is Determined by Either a Fasting Plasma Glucose or Hemoglobin A1c Measure, US Population, 1999 – 2006.

Table 1

	Known Diabetes	FPG Criterion			HbA1c Criterion			FPG vs HbA1c	
		Unknown Diabetes	No Diabetes	Unknown Diabetes	No Diabetes	P-value ^a	P-value ^b		
	% (95% CI)	%(95% CI)	%(95% CI)	%(95% CI)	%(95% CI)				
Entire Population									
Overall	6.13(5.51, 6.81)	2.46(2.12, 2.85)	91.41(90.62, 92.14)	1.47(1.20, 1.81)	92.4(91.56, 93.16)				< 0.001
Gender									
Men	5.96(5.17, 6.86)	3.09(2.53, 3.78)	90.94(89.88, 91.91)	1.76(1.33, 2.31)	92.28(91.19, 93.25)		0.12		< 0.001
Women	6.29(5.48, 7.20)	1.85(1.47, 2.32)	91.87(90.87, 92.76)	1.20(0.91, 1.58)	92.51(91.45, 93.45)				< 0.001
Race									
White, non-Hispanic	5.32(4.59, 6.15)	2.58(2.16, 3.09)	92.10(91.13, 92.97)	1.27(0.96, 1.69)	93.41(92.42, 94.28)		0.01 ^d		< 0.001
Black, non-Hispanic	8.18(6.86, 9.74)	2.47(1.90, 3.22)	89.35(87.69, 90.80)	2.19(1.72, 2.78)	89.63(88.05, 91.02)				0.34
Hispanic	7.44(5.74, 9.59)	2.19(1.53, 3.13)	90.37(87.96, 92.35)	1.83(1.19, 2.81)	90.73(88.34, 92.67)				0.09
Other	9.53(6.53, 13.71)	1.43(0.48, 4.19)	89.04(84.42, 92.41)	1.80(0.56, 5.63)	88.67(83.39, 92.42)				--
Age, y									
<18	0.66(0.24, 1.81)	0.19(0.06, 0.63)	99.15(98.06, 99.63)	0.18(0.05, 0.63)	99.15(98.06, 99.63)		0.70		--
18 – 39	1.86(1.41, 2.46)	0.71(0.41, 1.23)	97.43(96.75, 97.97)	0.58(0.34, 0.98)	97.56(96.94, 98.06)				0.42
40 – 54	6.69(5.41, 8.24)	2.48(1.74, 3.50)	90.84(89.08, 92.33)	1.56(1.06, 2.28)	91.75(90.19, 93.09)				0.01
55 – 64	12.34(10.25, 14.77)	4.58(3.33, 6.26)	83.09(80.15, 85.66)	2.86(1.89, 4.29)	84.81(82.03, 87.22)				0.005
65 – 74	16.32(13.70, 19.32)	7.61(5.80, 9.93)	76.07(72.09, 79.65)	3.69(2.49, 5.42)	80.00(76.73, 82.91)				0.002
>=75	12.68(10.19, 15.68)	5.75(4.29, 7.67)	81.57(78.8, 84.05)	3.01(1.84, 4.89)	84.30(81.73, 86.57)				0.003
Age, y									
<55	3.47(2.90, 4.14)	1.28(0.92, 1.79)	95.25(94.44, 95.95)	0.88(0.63, 1.24)	95.65(94.91, 96.30)		0.14		0.008
>=55	13.65(12.00, 15.48)	5.79(4.86, 6.89)	80.57(78.44, 82.53)	3.15(2.44, 4.06)	83.20(81.14, 85.09)				< 0.001
Age < 55 years									

	Known Diabetes %(95% CI)	FPG Criterion		HbA1c Criterion		FPG vs HbA1c	
		Unknown Diabetes	No Diabetes	Unknown Diabetes	No Diabetes	P-value ^d	P-value ^b
		%(95% CI)	%(95% CI)	%(95% CI)	%(95% CI)		
Gender							
Men	3.62(2.90, 4.53)	1.76(1.20, 2.59)	94.62(93.35, 95.65)	1.24(0.82, 1.88)	95.14(94.05, 96.04)	0.84	0.03
Women	3.30(2.54, 4.28)	0.79(0.49, 1.28)	95.91(94.89, 96.73)	0.51(0.30, 0.86)	96.19(95.17, 97.00)		0.10
Race							
White, non-Hispanic	2.69(2.05, 3.54)	1.21(0.75, 1.94)	96.10(95.05, 96.93)	0.77(0.47, 1.25)	96.54(95.66, 97.25)	0.73	0.05
Black, non-Hispanic	5.12(3.83, 6.80)	1.46(0.96, 2.22)	93.43(91.66, 94.84)	1.14(0.75, 1.74)	93.74(92.10, 95.07)		0.32
Hispanic	4.62(3.01, 7.02)	1.53(0.92, 2.52)	93.85(91.24, 95.73)	1.31(0.75, 2.27)	94.07(91.53, 95.89)		0.29
Age 55 years							
Gender							
Men	13.50(11.24, 16.14)	7.40(5.96, 9.14)	79.10(76.25, 81.69)	3.42(2.33, 5.00)	83.08 (80.06, 85.73)	0.04	< 0.001
Women	13.76(11.57, 16.30)	4.49(3.36, 5.97)	81.75(78.95, 84.25)	2.93(2.11, 4.05)	83.31(80.58, 85.72)		0.001
Race							
White, non-Hispanic	11.52(9.78, 13.52)	5.83(4.77, 7.12)	82.65(80.34, 84.74)	2.47(1.73, 3.51)	86.01(83.80, 87.97)	0.01	< 0.001
Black, non-Hispanic	21.36(17.65, 25.62)	6.82(4.70, 9.80)	71.82(66.99, 76.19)	6.70(4.74, 9.39)	71.93(67.45, 76.02)		0.91
Hispanic	22.64(18.36, 27.57)	5.75(3.09, 10.43)	71.62(66.36, 76.35)	4.65(2.19, 9.58)	72.71(67.35, 77.49)		0.04

Abbreviations: CI, Confidence Interval; FPG, Fasting Plasma Glucose; HbA1c, hemoglobin A1c

^a P-value for association between variable and differences in prevalence of unknown diabetes by the two criteria.

^b P-value for difference in unknown diabetes prevalence between the two criteria. Note that differences may be statistically significant even when confidence intervals overlap.

^c P-value for association of variable with diabetes status (known diabetes, unknown diabetes, no diabetes)

^d P = 0.003 if 'Other' race excluded