Undiagnosed Diabetes in U.S. Adults: Prevalence and Trends

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OBJECTIVE

Confirmatory testing is recommended for diabetes diagnosis in clinical practice. However, national estimates of undiagnosed diabetes are based on single elevated test measures, potentially resulting in overestimation. Our objective was to update trends in undiagnosed diabetes using definitions consistent with clinical practice.

RESEARCH DESIGN AND METHODS

We included 30,492 adults (aged ≥20 years) from the National Health and Nutrition Examination Survey (1988–2020). Among adults without diagnosed diabetes, confirmed undiagnosed diabetes was defined as having both elevated levels of fasting plasma glucose (FPG) (≥126 mg/dL) and elevated glycated hemoglobin (HbA_{1c}; ≥6.5%), and persistent undiagnosed diabetes was defined as having elevated HbA_{1c} or FPG levels, adjusted for the within-person variability in HbA_{1c} and FPG tests.

RESULTS

From the periods 1988–1994 to 2017 to March 2020, there was an increase in the prevalence of diagnosed diabetes (from 4.6% to 11.7%), but no change in prevalence of persistent undiagnosed diabetes (from 2.23% to 2.53%) or confirmed undiagnosed diabetes (from 1.10% to 1.23%). Consequently, the proportion of all undiagnosed diabetes cases declined from 32.8% to 17.8% (persistent undiagnosed diabetes) and from 19.3% to 9.5% (confirmed undiagnosed diabetes). Undiagnosed diabetes was more prevalent in older and obese adults, racial/ethnic minorities, and those without health care access. Among persons with diabetes, Asian Americans and those without health care access had the highest proportion of undiagnosed cases, with rates ranging from 23% to 61%.

CONCLUSIONS

From 1988 to March 2020, the proportion of undiagnosed diabetes cases declined substantially, suggesting major improvements in diabetes screening and detection. Undiagnosed diabetes currently affects 1–2% of US adults; up to 90% of all cases are diagnosed.

Diabetes is a major risk factor for cardiovascular events, microvascular disease, and premature mortality. In 2020, diabetes was the eighth leading cause of death in the U.S. and resulted in >100,000 deaths (1). Diabetes also imposes a substantial economic burden, costing patients and the health care system >$400 billion annually (2).

Accurately estimating the prevalence of diabetes is critical for evaluating public health efforts and developing effective prevention strategies. Prior studies reported a significant increase in the prevalence of diabetes in the U.S. over the past two decades, along with a substantial burden of undiagnosed diabetes (3,4). However,

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existing research relies almost exclusively on single elevated measures of glycated hemoglobin (HbA_{1c}), fasting plasma glucose (FPG) level, or 2-h glucose level to characterize undiagnosed diabetes. In contrast, clinical guidelines uniformly recommend confirming an elevated test with a secondary measurement for the diagnosis of diabetes (5). As a result, the current population prevalence may overstate the burden of undiagnosed diabetes (6).

Using over three decades of nationally representative data, our objective was to update trends in undiagnosed, diagnosed, and total (undiagnosed plus diagnosed) diabetes among U.S. adults. To more accurately characterize the burden of diabetes, we used definitions of undiagnosed diabetes that most closely reflect screening and diagnostic practices used in clinical practice.

RESEARCH DESIGN AND METHODS

Study Population

Using a complex, stratified, multistage probability cluster sampling design, the National Health and Nutrition Examination Survey (NHANES) selected a nationally representative sample of participants from the noninstitutionalized, civilian population in the U.S. Data were collected through in-home interviews and visits to a mobile examination center during each survey cycle. The National Center for Health Statistics (NCHS) institutional review board approved the study protocols, and all participants provided written informed consent. Additional details about the NHANES are available elsewhere (7).

We included participants from the NHANES III (1988–1994), the continuous NHANES (1999–2016), and the prepandemic combined NHANES (2017 to March 2020; hereafter, 2017–2020) who were aged ≥20 years, nonpregnant, and had measures of their diabetes status, HbA_{1c}, and FPG available (*N* = 30,492).

Measures of Hyperglycemia

High-performance liquid chromatography methods were used to measure HbA_{1c} (8), and the hexokinase method was used to measure FPG levels. Because laboratory methods changed over time, we calibrated HbA_{1c} using an equipercentile equating approach, with HbA_{1c} data from the NHANES 2015–2018 as the reference (9,10). We calibrated fasting FPG levels using regression equations recommended by the NCHS (10,11).

Definitions of Diabetes

We defined total diabetes as either having diagnosed or undiagnosed diabetes. We defined diagnosed diabetes as a self-reported diagnosis of diabetes by a physician other than during pregnancy. Among those without diagnosed diabetes, we examined two definitions of undiagnosed diabetes in our main analyses: *1*) confirmed undiagnosed diabetes: elevated HbA_{1c} (≥6.5%) and elevated FPG level (≥126 mg/dL); and *2*) persistent undiagnosed diabetes: elevated HbA_{1c} or FPG levels adjusted for within-person variability in the HbA_{1c} and FPG tests (5). In sensitivity analyses, we examined trends in undiagnosed diabetes with the conventional definition most commonly used in the existing literature (i.e., elevated HbA_{1c} or elevated FPG levels among those without diagnosed diabetes) (3,4).

To define persistent undiagnosed diabetes, we examined data in a subsample of 679 participants in the NHANES III with no diagnosed diabetes and repeated measures of HbA_{1c} and FPG levels (Supplementary Appendix 1). We calculated the proportion of individuals with either an elevated HbA_{1c} or FPG level at the first study visit who also had either an elevated HbA_{1c} or FPG level at their second study visit, conducted approximately 2 weeks later. We assumed this rate (73%; 95% CI 56–85%) represented the persistence of hyperglycemia (elevated HbA_{1c} or FPG level) among adults without diagnosed diabetes. To determine the prevalence of persistent undiagnosed diabetes, we calculated the proportion of adults with no diagnosed diabetes and elevated HbA_{1c} or FPG levels in the main NHANES sample and multiplied estimates by 0.73. This calculation was meant to account for the within-person variability in HbA_{1c} and FPG tests.

We examined the characteristics and prevalence of complications in U.S. adults by diabetes status. For these analyses, we created four mutually exclusive categories to allow for direct comparison: no diabetes, diagnosed diabetes, unconfirmed undiagnosed diabetes (isolated elevated HbA_{1c} or FPG level), and confirmed undiagnosed diabetes (elevated HbA_{1c} and FPG level).

Demographic Characteristics and BMI Categories

During in-person interviews, participants self-reported their age, race/ethnicity (Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Asian, Mexican American, other), sex (male, female), highest level of education (high school or less, some college, and college or more), family income (family income to poverty ratio <130%, 130–349%, ≥350%), health insurance status (uninsured, any health insurance), access to a usual source of care (has access, no access), and recent health care visit (had visit in the past year, no visit in the past year). BMI was calculated as weight in kilograms divided by height in meters squared. Participants were classified into three weight status groups: normal, BMI <25 kg/m^2; overweight, BMI 25–29.9 kg/m^2; or obese, BMI ≥ 30 kg/m^2.

Complications

We defined albuminuria as an albumin to creatinine ratio ≥30 mg/g (12). Retinal photography was performed on both eyes for participants aged ≥40 years in the 2005–2008 NHANES and graded using the Early Treatment Diabetic Retinopathy Study scale. We defined diabetic retinopathy when Early Treatment Diabetic Retinopathy Study score was ≥14 (13). Participants aged ≥40 years in the 1999–2004 NHANES participated in a lower-extremity examination. We defined lower-extremity disease as having peripheral neuropathy (insensate area on the foot identified through monofilament testing), peripheral artery disease (ankle–brachial index<0.9 for either ankle), or a self-reported history of ulcers (14). We defined cardiovascular disease as having a self-reported history of congestive heart failure, stroke, or heart attack.

Statistical Analyses

We estimated trends in the prevalence of diagnosed, undiagnosed, and total diabetes and the proportion of all diabetes cases that were undiagnosed, overall and across subgroups. Per NCHS guidelines (7), we combined the NHANES 2017–2018 and 2019–2020 into a single period in the overall analyses. For subgroup analyses, we pooled survey years into two time intervals (1988–2010 and 2011–2020) to improve the precision of estimates (15). We also age standardized estimates using the age distribution of the 2017–2020 NHANES as the reference

and assessed differences within subgroups using Wald tests. Because the time intervals were unequal, we modeled the midpoint of each survey period as a linear predictor in logistic regression models, as recommended by NCHS analytic guidelines (15).

We compared the demographic and clinical characteristics of U.S. adults by diabetes status. We examined the association between unconfirmed and confirmed undiagnosed diabetes with four major complications (retinopathy, albuminuria, lower-extremity disease, and self-reported cardiovascular disease) using logistic regression models adjusted for age, sex, and race/ethnicity.

We conducted all analyses using Stata, version 17.0 (StataCorp) and recommended sample weights, making our findings representative of the civilian, noninstitutionalized U.S. adult population. We used bootstrap resampling to obtain 95% CIs for persistent undiagnosed diabetes estimates and Taylor linearization for the CIs of other estimates. A two-sided $P < 0.05$ was considered statistically significant. Neither patients nor the public were involved in the design, conduct, reporting, or dissemination plans of our research.

RESULTS

From 1988–1994 to 2017–2020, the prevalence of total diabetes, defined as diagnosed plus persistent undiagnosed diabetes, increased from 6.8% (95% CI 5.9, 7.7) to 14.2% (95% CI 12.5, 15.9) (Table 1). Increases in total diabetes were driven by increasing levels of diagnosed diabetes; the prevalence of persistent undiagnosed diabetes remained stable during the study period (2.23% [95% CI 1.86, 2.60] to 2.53% [95% CI 2.02, 3.04]) (Table 1, Fig. 1). As a result, the proportion of all diabetes cases that were undiagnosed declined from 32.8% (95% CI 27.3, 38.3) to 17.8% (95% CI 14.3, 21.3). Using the more conservative confirmatory definition of undiagnosed diabetes, the prevalence of total diabetes (diagnosed plus confirmed undiagnosed diabetes) also increased, from 5.7% (95% CI 4.9, 6.5) to 12.9% (95% CI 11.3, 14.5). Confirmed undiagnosed diabetes was unchanged (1.10% [95% CI 0.81, 1.39] to 1.23% [95% CI 0.94, 1.52]), and the

Table 1—Trends in the crude prevalence of undiagnosed (confirmed or persistent), diagnosed, and total diabetes among U.S. adults, 1988–2020

	1988–1994 (*n* = 7,392)	1999–2000 (*n* = 1,739)	2001–2002 (*n* = 2,078)	2003–2004 (*n* = 1,874)	2005–2006 (*n* = 1,824)	2007–2008 (*n* = 2,328)	2009–2010 (*n* = 2,582)	2011–2012 (*n* = 2,286)	2013–2014 (*n* = 2,388)	2015–2016 (*n* = 2,244)	2017–2020 (*n* = 3,757)	P for trend‡
Total diabetes (diagnosed plus persistent undiagnosed diabetes)*	6.80 (0.47)	7.62 (0.91)	9.17 (0.73)	9.47 (0.84)	10.05 (0.84)	10.82 (0.71)	10.72 (0.85)	11.28 (1.14)	12.00 (0.88)	13.28 (0.90)	14.20 (0.85)	<0.001
Diagnosed diabetes	4.57 (0.43)	5.63 (0.82)	6.58 (0.67)	7.21 (0.78)	7.88 (0.71)	8.57 (0.67)	8.48 (0.79)	9.20 (1.10)	9.99 (0.84)	11.05 (0.87)	11.67 (0.81)	<0.001
Persistent undiagnosed diabetes	2.23 (0.19)	1.99 (0.38)	2.59 (0.28)	2.26 (0.31)	2.17 (0.46)	2.25 (0.22)	2.24 (0.30)	2.07 (0.32)	2.00 (0.26)	2.23 (0.23)	2.53 (0.26)	0.71
Proportion of total diabetes that is undiagnosed	32.8 (2.8)	26.2 (4.8)	28.3 (3.0)	24.0 (3.2)	21.6 (3.9)	20.8 (2.1)	21.0 (2.8)	18.5 (3.0)	16.7 (2.2)	16.8 (1.8)	17.8 (1.8)	<0.001
Total diabetes (diagnosed plus confirmed undiagnosed diabetes)†	5.67 (0.41)	6.97 (0.96)	7.93 (0.87)	8.44 (0.85)	9.21 (0.87)	9.39 (0.75)	9.77 (0.71)	10.38 (1.30)	11.39 (0.80)	12.36 (0.99)	12.89 (0.83)	<0.001
Diagnosed diabetes	4.57 (0.43)	5.63 (0.82)	6.58 (0.67)	7.21 (0.78)	7.88 (0.71)	8.57 (0.67)	8.48 (0.79)	9.20 (1.10)	9.99 (0.84)	11.05 (0.87)	11.67 (0.81)	<0.001
Confirmed undiagnosed diabetes	1.10 (0.15)	1.34 (0.29)	1.35 (0.33)	1.23 (0.25)	1.33 (0.35)	0.82 (0.15)	1.29 (0.28)	1.18 (0.30)	1.39 (0.36)	1.31 (0.22)	1.23 (0.15)	0.74
Proportion of total diabetes that is undiagnosed	19.3 (2.9)	19.2 (3.4)	17.0 (3.1)	14.5 (2.7)	14.4 (3.1)	8.7 (1.4)	13.2 (3.1)	11.4 (2.1)	12.2 (3.2)	10.6 (1.5)	9.5 (1.2)	<0.001

Data are presented as prevalence estimate (SE) unless otherwise noted. ‡Based on logistic regression with the midpoint of each period modeled as a linear predictor. *Persistent undiagnosed diabetes was defined as having no diagnosed diabetes and an elevated HbA_{1c} (≥6.5%) or FPG level (≥126 mg/dL) after adjusting for within-person variability in HbA_{1c} and FPG measurement. †Confirmed undiagnosed diabetes was defined as having no diagnosed diabetes and an elevated HbA_{1c} (≥6.5%) and FPG level (≥126 mg/dL).

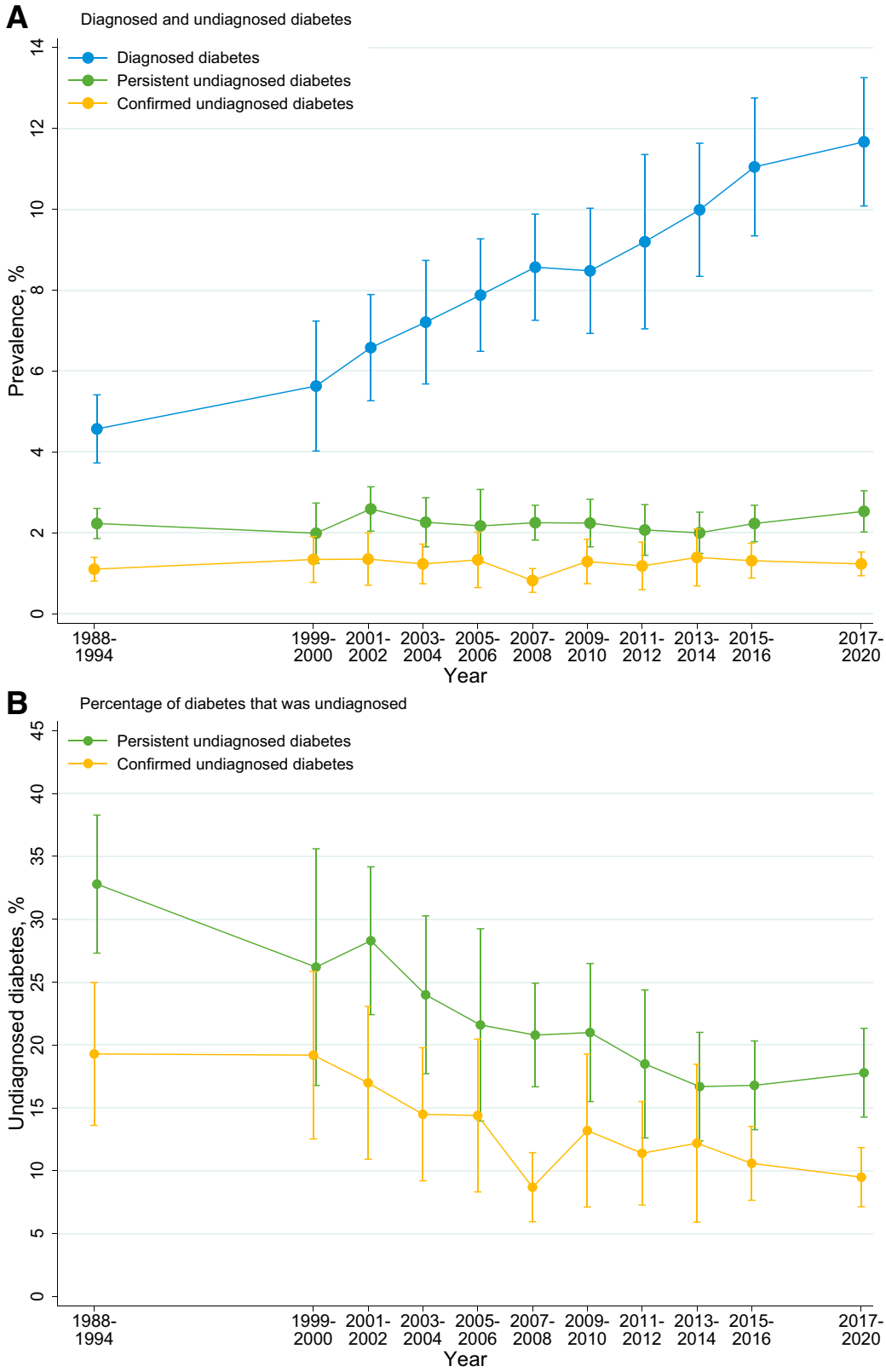

Figure 1—Trends in diagnosed and undiagnosed diabetes among U.S. adults, NHANES 1988–2020. *A*: Diagnosed and undiagnosed diabetes. *B*: Percentage of diabetes that was undiagnosed.

proportion of all undiagnosed diabetes cases declined from 19.3% (95% CI 13.6, 25.0) to 9.5% (95% CI 7.1, 11.9).

From 1988 to 2020, the age-standardized prevalence of persistent and confirmed undiagnosed diabetes was stable across most subgroups (Table 2). However, there were nonsignificant declines in persistent and confirmed

Table 2—Trends in the age-standardized prevalence of confirmed and persistent undiagnosed diabetes, 1988–2020, by subgroup

	Confirmed undiagnosed diabetes*						Persistent undiagnosed diabetes†					
	Prevalence (SE)		P for trend‡	Proportion (SE) of undiagnosed diabetes cases		P for trend‡	Prevalence (SE)		P for trend‡	Proportion (SE) of undiagnosed diabetes cases		P for trend‡
Period	1988–2010	2011–2020		1988–2010	2011–2020		1988–2010	2011–2020		1988–2010	2011–2020	
Age group, years												
20–44	0.44 (0.08)	0.76 (0.11)	0.01	15.6 (2.6)	20.7 (2.6)	0.13	0.81 (0.12)	1.12 (0.14)	0.26	25.4 (3.4)	27.8 (3.2)	0.92
45–64	1.71 (0.20)	1.67 (0.24)	0.01	15.0 (1.6)	11.0 (1.5)	<0.001	2.88 (0.25)	2.94 (0.27)	0.17	22.9 (1.8)	17.8 (1.7)	<0.001
≥65	2.49 (0.30)	1.72 (0.38)	0.52	13.4 (1.5)	7.2 (1.5)	0.01	5.32 (0.41)	3.39 (0.38)	0.16	24.9 (1.7)	13.2 (1.4)	<0.001
Sex												
Female	0.95 (0.10)	1.33 (0.17)	0.18	13.5 (2.1)	14.7 (1.9)	0.38	1.83 (0.15)	2.13 (0.19)	0.58	19.7 (1.5)	18.3 (1.6)	0.07
Male	1.73 (0.19)	1.24 (0.23)	0.05	16.4 (1.9)	14.5 (2.4)	<0.001	3.22 (0.21)	2.34 (0.24)	0.04	28.3 (1.7)	16.2 (1.5)	<0.001
Race/ethnicity§												
Non-Hispanic White	1.01 (0.13)	0.86 (0.16)	0.10	10.9 (1.7)	8.5 (1.7)	<0.001	2.24 (0.16)	1.69 (0.18)	0.12	25.9 (1.7)	15.7 (1.6)	<0.001
Non-Hispanic Black	2.26 (0.27)	1.53 (0.31)	0.14	15.8 (2.6)	14.4 (2.8)	0.01	3.64 (0.28)	2.92 (0.35)	0.02	22.8 (1.7)	16.0 (1.7)	<0.001
Mexican American	2.61 (0.33)	3.31 (0.50)	0.28	24.8 (2.7)	19.5 (3.0)	0.07	3.30 (0.29)	4.08 (0.48)	0.46	18.9 (1.5)	19.4 (2.0)	0.13
Asian American	–‖	2.59 (0.56)	–	–	29.3 (5.5)	–	–	4.03 (0.58)	–	–	24.6 (3.0)	–
BMI category, kg/m^2												
<25.0	0.33 (0.08)	0.53 (0.16)	0.35	8.0 (2.5)	8.2 (2.7)	0.87	1.11 (0.14)	1.04 (0.19)	0.42	21.6 (2.8)	17.6 (3.2)	0.10
25.0–29.9	1.07 (0.14)	0.44 (0.08)	<0.001	15.9 (2.6)	9.0 (2.8)	<0.001	2.09 (0.17)	1.21 (0.16)	0.004	26.3 (2.1)	12.2 (1.6)	<0.001
≥30	2.47 (0.27)	2.56 (0.31)	0.45	15.5 (1.7)	16.7 (1.7)	0.01	4.15 (0.28)	3.96 (0.32)	0.28	23.7 (1.5)	19.8 (1.5)	0.002
Education												
College or more	0.83 (0.19)	0.54 (0.13)	0.39	11.0 (2.6)	12.4 (2.8)	0.02	1.57 (0.23)	1.50 (0.24)	0.93	23.7 (3.2)	16.5 (2.6)	0.09
Some college	0.95 (0.16)	1.57 (0.31)	0.20	11.4 (1.9)	15.4 (2.6)	0.71	2.11 (0.24)	2.05 (0.26)	0.29	21.4 (2.2)	15.7 (1.9)	0.24
High school or less	1.76 (0.18)	1.68 (0.22)	0.68	18.1 (2.1)	14.9 (2.1)	<0.001	3.13 (0.19)	2.98 (0.25)	0.41	25.5 (1.4)	18.6 (1.4)	<0.001
Income to poverty ratio, %												
≥350	0.91 (0.16)	0.77 (0.17)	0.59	12.2 (2.3)	8.3 (1.9)	0.002	1.85 (0.18)	1.57 (0.22)	0.61	26.0 (2.3)	15.3 (2.2)	0.002
130–349	1.58 (0.21)	1.46 (0.21)	0.94	16.1 (2.6)	17.9 (2.4)	0.02	2.91 (0.25)	2.29 (0.25)	0.29	24.0 (1.9)	16.7 (1.7)	<0.001
<130	1.65 (0.25)	1.99 (0.35)	0.78	13.8 (2.3)	16.3 (2.4)	0.16	2.80 (0.24)	3.61 (0.37)	0.71	20.7 (1.7)	19.8 (1.9)	0.17
Health insurance coverage												
Yes	1.16 (0.11)	1.13 (0.14)	0.32	12.3 (1.4)	11.7 (1.4)	<0.001	2.34 (0.14)	2.09 (0.15)	0.24	22.8 (1.3)	16.1 (1.1)	<0.001
No	1.92 (0.34)	2.09 (0.44)	0.32	26.5 (4.1)	24.1 (3.2)	0.24	2.85 (0.39)	3.86 (1.00)	1.00	30.5 (4.1)	28.8 (6.2)	0.07
Last health care visit, years												
≤1	1.17 (0.11)	1.01 (0.11)	0.34	10.9 (1.1)	10.6 (1.2)	<0.001	2.44 (0.15)	2.09 (0.13)	0.20	22.1 (1.2)	15.3 (1.0)	<0.001
>1	2.08 (0.30)	3.95 (1.03)	0.23	57.5 (4.8)	57.6 (5.6)	0.03	2.71 (0.37)	3.99 (0.82)	0.35	54.8 (6.1)	61.3 (6.6)	0.02
Usual source of care												
Yes	1.23 (0.11)	1.19 (0.15)	0.35	11.9 (1.2)	12.1 (1.5)	<0.001	2.46 (0.14)	2.17 (0.16)	0.23	22.7 (1.2)	16.1 (1.1)	<0.001
No	1.70 (0.41)	2.02 (0.41)	0.48	47.8 (5.9)	33.4 (5.6)	0.001	2.32 (0.39)	2.49 (0.37)	0.92	45.6 (6.6)	31.3 (5.6)	<0.001

All estimates are age standardized with the 2017–2020 age distribution as the reference. *Confirmed undiagnosed diabetes was defined as having no diagnosed diabetes and an elevated HbA_{1c} (≥6.5%) and FPG level (≥126 mg/dL). †Persistent undiagnosed diabetes was defined as having no diagnosed diabetes and an elevated HbA_{1c} (≥6.5%) or FPG level (≥126 mg/dL) after adjusting for within-person variability in HbA_{1c} and FPG measurement. ‡Based on logistic regression with the midpoint of each period modeled as a linear predictor. §Adults who self-reported other as their race/ethnicity were included in all analyses. However, we did not report race/ethnicity-specific estimates for this group since it likely combines participants from a variety of different racial/ethnic backgrounds. ‖Nationally representative data for Asian-American adults were unavailable in the NHANES until 2011.

undiagnosed diabetes in adults who were aged ≥65 years and significant decreases in male participants and adults who were overweight. The proportion of undiagnosed diabetes cases declined for most populations, regardless of the definition of undiagnosed diabetes used. However, there was no significant change for adults who were aged <45 years, women, Mexican American, low income, and/or uninsured, and there was an increase among adults without a recent health care visit.

In 2011–2020, the prevalence of persistent and confirmed undiagnosed diabetes was higher among adults older than 65 years (1.72% [95% CI 0.98, 2.46] and 3.39% [95% CI 2.65, 4.13], respectively) compared with those aged 45–64 years (1.67% [95% CI 1.20, 2.14] and 2.94% [95% CI 2.41, 3.47], respectively) and aged 20–44 years (0.76% [95% CI 0.54, 0.98] and 1.12% [95% CI 0.85, 1.39], respectively) (Table 2; Supplementary Appendix 2). Racial/ethnic minorities, including Asian Americans, had a higher age-standardized prevalence of persistent and confirmed undiagnosed diabetes than did non-Hispanic Whites, and obese adults had a higher age-adjusted prevalence than those who were overweight or normal weight. The age-adjusted prevalence of both persistent and confirmed undiagnosed diabetes was approximately 4% for adults without a recent health care visit, compared with 1% and 2%, respectively, for those with a recent visit. Among adults with diabetes, the populations with the highest proportion of cases that were undiagnosed included Asian Americans and those without health insurance, usual access to care, or a recent health care visit.

Trends were similar when using the conventional definition of undiagnosed diabetes (i.e., elevated HbA_{1c} or FPG level) (Supplementary Appendix 3), but prevalence estimates were notably higher. In 2017–2020, the prevalence of undiagnosed diabetes, based on the conventional definition, was 3.5% (95% CI 2.8, 4.1) with 22.9% (95% CI 19.0, 26.8) of all cases being undiagnosed. Estimates were also higher for all subgroups when using the conventional definition compared with a confirmatory or persistence-adjusted definition of undiagnosed diabetes (Supplementary Appendix 4).

The demographic and clinical characteristics of adults with confirmed undiagnosed diabetes differed substantially from those of adults with unconfirmed undiagnosed diabetes (Table 3). Only 37.9% of those with confirmed undiagnosed diabetes had HbA_{1c} <7%, compared with >95.7% of those with unconfirmed undiagnosed diabetes. Adults with confirmed undiagnosed diabetes were also more likely to be Mexican American, obese, have lower income, and/or lack access to care. Compared with unconfirmed undiagnosed diabetes, confirmed undiagnosed diabetes was more strongly associated with retinopathy (odds ratio [OR] 1.49 [95% CI 0.53, 4.21] vs. 3.17 [95% CI 1.34, 7.49], respectively), albuminuria (OR 2.44 [95% CI 1.84, 3.23] vs. 4.06 [95% CI 2.98, 5.53], respectively), and cardiovascular disease (OR 1.31 [95% CI 0.97, 1.77] vs. 1.64 [95% CI 1.14, 2.36], respectively) (Fig. 2).

Table 3—Characteristics of U.S. adults, 1988–2020, by diabetes status

	No diabetes	Diagnosed diabetes	Unconfirmed undiagnosed diabetes*	Confirmed undiagnosed diabetes†
Age group, years				
20–44	52.3 (0.6)	13.9 (0.9)	18.5 (2.1)	21.9 (2.2)
45–64	32.5 (0.5)	46.2 (1.1)	44.2 (2.7)	46.8 (2.6)
≥65	15.2 (0.4)	39.9 (1.2)	37.4 (2.4)	31.3 (2.7)
Sex				
Female	51.7 (0.3)	48.5 (1.2)	43.6 (2.8)	47.1 (3.1)
Male	48.3 (0.3)	51.5 (1.2)	56.4 (2.8)	52.9 (3.1)
Race/ethnicity‡				
Non-Hispanic White	70.5 (0.8)	61.6 (1.7)	67.7 (2.4)	52.6 (3.1)
Non-Hispanic Black	10.6 (0.5)	14.7 (1.0)	14.0 (1.4)	15.8 (1.7)
Mexican American	7.3 (0.4)	9.3 (0.7)	6.4 (1.0)	14.1 (1.7)
Asian American	2.1 (0.2)	2.8 (0.4)	2.9 (0.6)	4.8 (1.2)
HbA_{1c} categories, %				
<5.7	79.6 (0.4)	8.6 (0.7)	20.2 (2.1)	–
5.7 to <6.5	20.4 (0.4)	27.0 (1.1)	51.0 (2.4)	–
6.5 to <7.0	–	16.2 (1.0)	24.5 (2.2)	37.9 (2.9)
7–8	–	23.1 (1.3)	4.0 (0.9)	25.0 (2.4)
>8	–	25.1 (1.1)	0.3 (0.2)	37.1 (2.5)
BMI category, kg/m^2				
<25.0	36.2 (0.5)	13.8 (0.9)	16.4 (1.9)	8.7 (1.4)
25.0–29.9	33.9 (0.4)	28.4 (1.1)	27.7 (2.2)	21.6 (2.2)
≥30	29.9 (0.5)	57.8 (1.2)	55.9 (2.4)	69.7 (2.6)
Education				
College or more	28.1 (0.7)	18.6 (1.1)	19.5 (2.5)	13.4 (2.0)
Some college	29.5 (0.5)	27.9 (1.2)	21.7 (2.0)	26.4 (2.8)
High school or less	42.4 (0.7)	53.6 (1.3)	58.8 (2.7)	60.2 (3.1)
Income to poverty ratio, %				
≥350	42.7 (0.8)	33.3 (1.6)	34.1 (2.7)	27.7 (2.7)
130–349	37.7 (0.6)	41.7 (1.4)	41.5 (2.7)	46.1 (3.2)
<130	19.6 (0.5)	25.0 (1.3)	24.4 (2.1)	26.2 (2.3)
Health insurance coverage				
Yes	83.1 (0.5)	91.1 (0.6)	86.8 (1.9)	79.1 (2.1)
No	16.9 (0.5)	8.9 (0.6)	13.2 (1.9)	20.9 (2.1)
Last health care visit, years				
≤1	81.0 (0.4)	97.0 (0.4)	90.9 (1.1)	75.9 (2.2)
>1	19.0 (0.4)	3.0 (0.4)	9.1 (1.1)	24.1 (2.2)
Usual source of care				
Yes	82.0 (0.4)	96.0 (0.5)	90.6 (1.5)	83.7 (2.0)
No	18.0 (0.4)	4.0 (0.5)	9.4 (1.5)	16.3 (2.0)

Data are presented as percent (SE). *Unconfirmed undiagnosed diabetes was defined as having no diagnosed diabetes and elevated HbA_{1c} (≥6.5%) or FPG level (≥126 mg/dL) but not both. By definition, adults without diabetes had HbA_{1c} <6.5% and those with confirmed undiagnosed diabetes had HbA_{1c} ≥6.5%. †Confirmed undiagnosed diabetes was defined as having no diagnosed diabetes and elevated HbA_{1c} (≥6.5%) and FPG level (≥126 mg/dL). ‡Adults who self-reported other as their race/ethnicity were included in all analyses. However, we did not report race/ethnicity-specific estimates for this group since it likely combines participants from a variety of different racial/ethnic backgrounds.

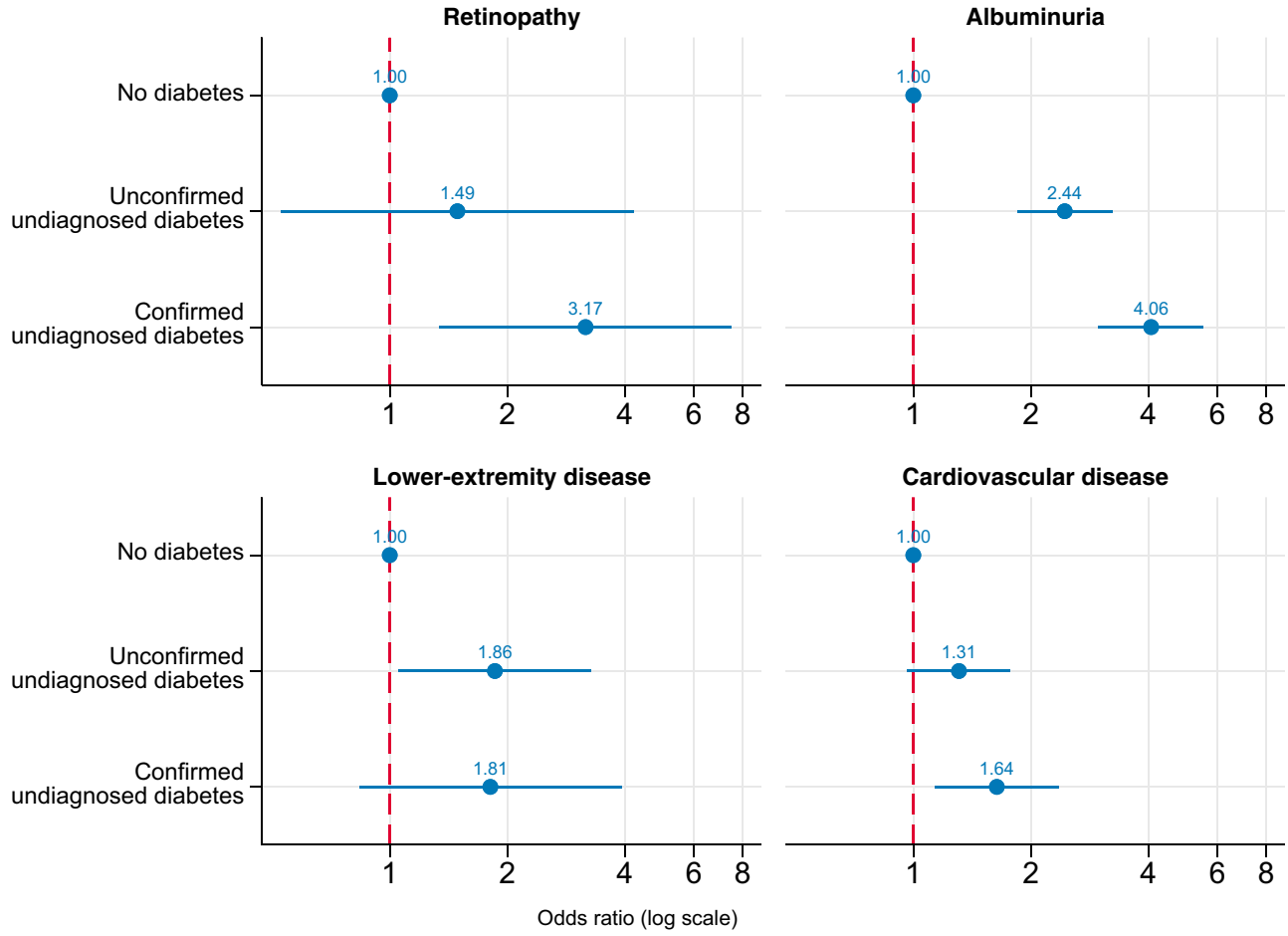

Figure 2—Association between undiagnosed diabetes and prevalence of major complications. ORs are adjusted for age, sex, and race/ethnicity.

CONCLUSIONS

Over the past three decades, the crude prevalence of total diabetes among U.S. adults increased substantially, reaching 12.9% to 14.2% in 2017–2020. This increase was driven by an increase in cases of diagnosed diabetes. The prevalence of undiagnosed diabetes remained stable throughout the study period and ranged from 1.2% to 2.5% in 2017–2020, depending on definition used. Consequently, the proportion of undiagnosed diabetes cases fell sharply, reaching 9.5% to 17.8% in 2017–2020.

Our estimates of undiagnosed diabetes are substantially lower than in prior studies. For example, the Centers for Disease Control and Prevention estimates that the prevalence of undiagnosed diabetes ranges from 3–5%, and that 20–36% of all cases are undiagnosed (3,4). These differences stem from discrepancies in methodology. We used two straightforward approaches to approximate how diabetes is diagnosed in clinical practice (5), resulting in lower estimates of undiagnosed diabetes. The first—based on elevated HbA_{1c} and FPG levels in the same blood sample—is highly specific (16) and is a recommended diagnostic approach (17). The second, which accounts for the within-person variability in HbA_{1c} and FPG level, is a commonly used method to estimate the national prevalence of other conditions that require repeated, confirmatory testing, such as chronic kidney disease (18).

Our results suggest that undiagnosed diabetes in U.S. adults is less common than previously thought and that diabetes detection has significantly improved in the U.S. This interpretation is consistent with findings of studies showing declines in the mean age of diabetes diagnosis and large improvements over time in the health profile of persons with newly diagnosed diabetes (19,20). A growing emphasis on diabetes screening likely contributed to these improvements. Beginning in the late 1990s, professional groups increasingly recommended routine diabetes screening for asymptomatic adults (21–24), resulting in a large increase in testing in the U.S. (25,26). Diagnostic criteria were also changed to enable earlier detection. The diagnostic threshold for fasting glucose was reduced from 140 mg/dL to 126 mg/dL in 1997 (22), and HbA_{1c} $\geq$6.5% was added as a new criterion in 2009, giving providers an additional, convenient diagnostic test (27).

Despite these improvements, undiagnosed diabetes remained high in certain subpopulations. We found that adults who were racial/ethnic minorities in the U.S., including Asian Americans, overweight or obese, low income, or uninsured had the highest prevalence of undiagnosed diabetes. Current guidelines recommend beginning diabetes screenings at age 35 years (28,29), with an emphasis on overweight or obese adults, racial/ethnic minorities, and those with a family history of diabetes. Our results support these recommendations, in particular the focus on overweight and obesity in young adults. However, testing

among some eligible adults remains poor, especially in high-risk groups, such as those who have a low income or lack access to care (26). These findings suggest that reducing undiagnosed diabetes may require expanded health care access and targeted screening efforts for underserved populations.

We found that the prevalence of complications varied considerably across definitions of undiagnosed diabetes. Those with confirmed undiagnosed diabetes (i.e., elevated HbA_{1c} and FPG level) had a higher prevalence of microvascular complications (i.e., retinopathy and albuminuria) compared with those with unconfirmed undiagnosed diabetes (i.e., isolated elevated HbA_{1c} or FPG level). In contrast, the prevalence of macrovascular complications (i.e., cardiovascular disease and lower-extremity disease, which included peripheral artery disease, in this study) were similar across both groups. Hyperglycemia is known to confer greater risk for microvascular (versus macrovascular) disease, and we observed large differences in glycemic control. Greater than 95% of adults with unconfirmed undiagnosed diabetes had HbA_{1c} $<7\%$, compared with only 38% of those with confirmed undiagnosed diabetes. This suggests that confirmed diabetes identifies patients with a higher prevalence of complications specific to diabetes. Existing studies typically combine unconfirmed and confirmed diabetes together, obscuring these differences in complications. Our results underscore that undiagnosed diabetes, as it is normally defined in clinical practice, is associated with major morbidity.

Our study also has implications for global estimates of undiagnosed diabetes. The International Diabetes Federation estimates the global prevalence of undiagnosed diabetes to be 10.5%, with 44.7% of all cases being undiagnosed (30,31). However, these estimates are based on single measures of FPG or 2-h glucose, likely resulting in overestimation. Using a confirmatory definition (e.g., elevated FPG level and 2-h glucose) or adjusting for within-person variability in test measures can produce accurate global estimates and help identify populations at highest risk for complications of diabetes. Adjusting for test variability may be especially valuable in low-resource settings where collecting a second biochemical measure is infeasible.

Our study had several limitations. First, our estimate of persistence was imprecise because it was based on a small sample size. There may be differences in persistence across patient characteristics (e.g., age) and comorbidities that we could not explore, because of small sample size. Second, we applied contemporary diagnostic criteria throughout the study period. The use of consistent definitions allowed for direct comparison of undiagnosed diabetes prevalence over time. However, diabetes diagnosis is more complicated in practice, because diagnostic criteria changed after 1997 (the FPG threshold was lowered) and 2009 (HbA_{1c} criteria were added). Our estimates prior to 2009 may have overstated the burden of undiagnosed diabetes, because some cases of undiagnosed diabetes, based on current diagnostic criteria, would not have been considered diabetes in earlier periods. Third, we were not able to evaluate undiagnosed diabetes based on the 2-h glucose criteria, because these data were not collected in every study period. The absence of this information means we likely underestimated the true prevalence of undiagnosed diabetes. This is important because the oral glucose tolerance test is the most sensitive test and generally identifies the most cases of undiagnosed diabetes. Nonetheless, other than in pregnancy, the oral glucose tolerance test is rarely used for diagnosis of diabetes. Our results reflect undiagnosed diabetes because it is typically defined in contemporary clinical practice. Fourth, diagnosed diabetes was self-reported and not confirmed by medical records review. However, findings of prior studies indicated that this measure is highly specific and reliable (32). Fifth, the cross-sectional design of the NHANES prevented us from directly exploring the potential causes of increasing diabetes prevalence. Sixth, response rates in the NHANES have declined over time. However, our analysis used sampling weights designed by the NCHS to minimize nonresponse bias. Seventh, our analyses were restricted to adult participants and did not examine trends in youth and adolescents.

Our study had several important strengths. We analyzed over three decades of data from nationally representative surveys of U.S. adults. Our definitions of undiagnosed diabetes were based on objective, rigorous, and systematic measures of glycemia and were consistent with clinical practice. Our estimates of persistence were derived from the NHANES III, one of the largest population-based studies with standardized and repeated measures of glycemia collected at two time points separated by $\sim$2 weeks.

Early detection and treatment of diabetes are critical for delaying and preventing serious complications. Over the past three decades, the proportion of all undiagnosed diabetes cases sharply declined, suggesting major improvements in diabetes awareness, screening, and detection in the U.S. Currently, undiagnosed diabetes only affects 1–2% of U.S. adults, and up to 90% of all cases are diagnosed. However, undiagnosed diabetes remains common in high-risk, underserved patients with poor access to health care. Addressing the remaining burden of undiagnosed diabetes will require enhancing health care access and developing targeted screening programs for these populations.

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Author Contributions. M.F., J.C., and E.S. designed the study. M.F. and D.W. conducted the statistical analysis. M.F. drafted the manuscript. J.C. and E.S. guided the statistical analysis and provided critical revisions to the manuscript. All authors approved the final manuscript. M.F. is the guarantor of this work and, as such, 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.

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