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Epidemiological Ramifications of Diagnosing Diabetes with HbA1c Levels

Mayer B. Davidson and Deyu Pan

Charles R. Drew University, Los Angeles California

Abstract

Aims—To compare the prevalence of diabetes by history and using the fasting plasma glucose (FPG) criterion alone, the HbA1c criterion alone or either one in those not known to have diabetes.

Methods—Analysis of NHANES population 20 years old from 1999 through 2010.

Results—In those diagnosed by laboratory tests, 86% met the FPG criterion and 53% met the HbA1c criterion. The prevalence of diabetes (history or laboratory test) was significantly increased when the FPG criterion was used compared with the HbA1c criterion in the entire (11.5% vs 10.5%, $P = 0.018$) and Caucasian (10.6% vs 9.2%, $P = 0.022$) populations. In contrast, there were no significant differences in the prevalence when only the FPG criterion was used compared with only the HbA1c criterion in Hispanics (12.9% vs 12.1% $P = 0.386$) and African Americans (14.5 vs 14.3%, $P = 0.960$). Using history and either criterion in those not known to have it, diabetes increased by 61% in this 12 year period in adults 20 years old.

Conclusions—Using the FPG rather than the HbA1c criterion to diagnose diabetes in those without a history significantly increased the total prevalence of diabetes in Caucasians but not in African Americans or Hispanics.

Keywords

Diagnosis of diabetes; prevalence of diabetes; HbA1c; fasting plasma glucose; race/ethnicity; NHANES/diabetes

Introduction

The current prevalence of diabetes mellitus in the United States is 8.3% of the total population [1] and 11.5% of those over 20 years of age [2]. Globally, it is estimated to be 6.4% [3] or 6.6% [4] of the total world population. By 2030, the prevalence of diabetes is predicted to increase to 14.5% of people over 20 years in the United States [2] and to 7.7% [3] or 7.8% [4] of the total world population. These estimates and predictions are based on glucose criteria, fasting plasma glucose (FPG) concentrations and/or oral glucose tolerance

Correspondence to: Mayer B. Davidson, MD, Charles R. Drew University, 1731 East 120th Street, Los Angeles, CA 90059, Phone: (323) 357-3439, FAX: (323) 563-4887, mayerdavidson@cdrewu.edu.

Diabetes Prevalence Using HbA1c for Diagnosis

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tests (OGTT). However, the evidence for using glucose criteria for diagnosing diabetes is weak [5]. Recognizing this and the pre-analytic and analytic problems associated with measuring glucose [6], the American Diabetes Association (ADA) recommended in 2010 that diabetes could also be diagnosed by HbA1c levels $\geq 6.5\%$ (48 mmol/mol) but left the glucose criteria in place as well [7].

After the ADA made this recommendation, a number of studies compared the prevalence of diabetes in people not known to have diabetes. Since so few clinicians use the oral glucose tolerance test (OGTT) to screen for or diagnose diabetes [8], this paper will focus on the fasting plasma glucose (FPG) concentration as the glycemic criterion for diagnosing diabetes. Most studies in people not known to have diabetes [9-13], but not all [14-16] showed a greater percent meeting the FPG criterion for diabetes than the HbA1c criterion. These results raise the possibility that the current prevalence and its projection [1,2] might be less if the HbA1c criterion were used instead of the glucose criteria. Alternatively, since the ADA recommended that either the glucose or HbA1c criterion could be used for the diagnosis [7], might there be significantly more people diagnosed with diabetes or possibly even a higher prevalence using the HbA1c criteria in certain populations as was recently shown in Africans from Rodrigues [16]? This paper will track the prevalence of diabetes (both known and unknown) in the National Health and Nutrition Examination Survey (NHANES) data from 1999 through 2010 utilizing the FPG or HbA1c criterion alone or either one in individuals not known to have it to determine if using the HbA1c criterion to diagnose diabetes in those not known to have it affects the total prevalence of diabetes in the United States.

Methods

The study analyzed the participants in the NHANES 1999-2010 data bases conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). NHANES used a highly stratified multistage probability sampling to obtain a representative sample of the civilian, non-institutionalized US population and employed over-sampling of the elderly, non-Hispanic blacks and Mexican Americans. Descriptions of the survey, sampling procedures, and details of the laboratory tests evaluated can be found on the CDC website (<http://www.cdc.gov/nchs/nhanes>).

The data collection protocol was approved by the Centers for Disease Control and Prevention Institutional Review Board. During a home interview, survey participants provided socio-demographic information, such as self-assigned race/ethnicity (non-Hispanic white, African American, Mexican American, other Hispanic, other race), as well as age and sex. Participants were asked whether a doctor or other health care provider had previously diagnosed them with diabetes, and if so, were asked about use of diabetes medications.

We limited the analysis to adults ≥ 20 years old. In addition, we excluded those women with gestational diabetes. The total analytic sample was 12,484 adults for NHANES 1999-2010. Data on diabetes were collected by both self-report, and in those with no history of diabetes, by laboratory tests. Subjects were defined as having a history of diabetes if they answered "yes" to the question, "Have you ever been told you have sugar/diabetes?" In those who

answered “no”, comparisons for the diagnosis of diabetes were made using only FPG ≥ 126 mg/dl (7.0 mmol/L), only HbA1c $\geq 6.5\%$ (48 mmol/mol) or either one. Comparisons among ethnicity/racial populations were limited to Caucasians, Hispanics and African Americans because there were so few in other groups.

Body Mass Index (BMI) was calculated as weight (kg)/height (m)². Lean was defined as a BMI <25.0 , overweight as 25.0-29.9 and obese as ≥ 30.0 .

The Physical Activity (PA) questionnaire data consisted of participants' responses to whether or not they participated in leisure time moderate and/or vigorous physical activities; and if yes, what were the type, frequency and duration of the specific activities participants performed in the past 30 days. Metabolic Equivalent of Task (MET) was summed from the questionnaires from each respondent as MET-minutes per month. Each item was calculated as follows: (duration of activity) $\times$ (frequency of activity during the last 30 days) $\times$ (MET value of activity) [17] based on previously published classification schemes [18]. Only leisure time PA data were used because work-related PA was not assessed in NHANES 1999-2006.

Descriptive statistics were used to characterize the subjects (means for continuous variables and percentages for categorical variables). The statistical differences among the groups during this 12 year period were analyzed by chi-square tests for assessment of the differences of the prevalence of diabetes by race/ethnicity and sex. $P < 0.05$ (2-tailed) was considered statistically significant. Pearson correlation coefficients between prevalence of diabetes and body mass index (BMI) were calculated for estimating the association. Data were analyzed using SAS (Release 9.1.3, 2002; SAS, Inc., Cary, NC). Sample “fasting” weights, provided by the NCHS, were used to correct for differential selection probabilities and to adjust for non-coverage and non-response.

Results

The study characteristics of the NHANES population included in the 12 year period from 1999 through 2010 is shown in Table 1. The total number of individuals ≥ 20 years of age was 12,484, 1,461 whom had a history of diabetes (11.7%) while 11,023 did not. Of the latter, 516 individuals (4.7%) had newly diagnosed diabetes by laboratory tests, 47% of whom met only the FPG criterion (≥ 126 mg/dl [≥ 7.0 mmol/L]), 14% met only the HbA1c criterion ($\geq 6.5\%$ [≥ 48 mmol/mol]) and 39% met both, i.e., overall 53% (14% + 39%) met the HbA1c criterion and 86% (47% + 39%) met the FPG criterion. Thus, in those diagnosed with diabetes by laboratory tests, 47% (100% - 53%) did not meet the HbA1c criterion and 14% (100%-86%) did not meet the FPG criterion.

After appropriate weighting, the BMIs and prevalence of diabetes (diagnosed by history or meeting only the FPG, only the HbA1c or either criteria in those not known to have diabetes) in the entire NHANES populations in three age groups are shown in Table 2 and Figure 1. Since the prevalence of diabetes is so low in the younger age group, further analyses will include the entire adult population (≥ 20 years old) and the older population (≥ 40 years old). The prevalence of diabetes over this 12 year period was significantly higher

if diabetes was diagnosed by FPG compared with HbA1c in those not known to have it in the entire adult (≥ 20 years of age) (11.5% vs 10.5%) and older (≥ 40 years of age) populations 16.6% vs 15.0%) (both $P = 0.018$). Since the ADA has recommended that either the FPG or the HbA1c criteria could be used to diagnose diabetes (if confirmed), it is likely that many individuals would receive both tests. In the older population, if either the FPG or the HbA1c criterion were allowed to diagnose diabetes in those not known to have it, the total prevalence (17.1%) was significantly ($P < 0.0001$) increased. In contrast, in the entire adult population, the prevalence was significantly ($P = 0.001$) increased only when either criteria was compared with HbA1c alone but not with FPG alone ($P = 0.398$). The percent of people with diabetes who did not know that they had it was higher if diabetes had been diagnosed in them by FPG (22%) compared with a diagnosis by HbA1c (13.0%) in the 2 age groups.

The prevalence of diabetes using the history of diabetes or laboratory tests in those not known to have it were compared separately in the three ethnic/racial groups (Table 3). There were significant differences in the prevalence of diabetes over the 12 year period using only the FPG compared with only the HbA1c criterion in both the entire adult Caucasian population (10.6 vs. 9.2, $P = 0.022$) and for the older Caucasian cohort (14.6 vs. 12.7, $P = 0.021$). In contrast, there were no significant differences in the prevalence when only the FPG criterion was used compared with only the HbA1c criterion in both the adult and older Hispanics and African Americans; 12.9% vs 12.1% ($P = 0.386$) for Hispanic adults, 14.5% vs 14.3%, ($P = 0.960$) for African American adults, 23.5% vs 22.5%, ($P = 0.536$) for older Hispanics, and 22.2% vs 22.3% ($P = 0.990$) for older African Americans.

Comparing either test vs each one alone to diagnose diabetes in those not known to have it gave the following results in the three ethnic/racial groups (Table 3). In both age groups of Caucasians, there was no difference with either test compared to the FPG criterion but a significant increase compared to HbA1c alone (both $P = 0.02$). In contrast, the prevalence of diabetes was similar in both age groups of Hispanics and African Americans when either criteria was compared to each one alone ($P > 0.228$).

Using either criteria to diagnose diabetes in those not known to have it, the total prevalence of diabetes (known plus unknown) rose from 8.8% in 1999-2000 to 14.2% in 2009-2010, a 61% increase, in the entire adult population (Table 2). Throughout this period, it rose progressively in both adult and older Caucasians and Hispanics but fell markedly in both adult and older African Americans in 2009-2010 (Table 3). In 2009-2010, the last period in which NHANES data were available, in those ≥ 20 years old, 14.2% of the entire population, 13.3% of Caucasians, 16.6% of Hispanics and 15.5% of African Americans had diabetes. In those ≥ 40 years old, 20.7% of the entire population, 18.6% of Caucasians, 25.8% of Hispanics and 25.9% of African Americans had diabetes.

The BMI along with the prevalence of diabetes among the various groups during this 12 year period are also shown in Tables 2 and 3. As expected, the correlations between the prevalence of diabetes and BMI in these age groups and ethnicities/races were very high, all > 0.8 . Table 4 shows the change in the distribution of weight during this 12 year period. In 1999-2000, 40% of the population were lean and 29% obese; in 2009-2010, 31% were lean

and 36% were obese. The overweight group stayed stable reflecting the shift from lean to overweight and overweight to obese. Yet there was a substantial increase in the prevalence of diabetes in all 3 groups implicating a decrease in physical activity accounting for this rise. To address this question, subjects evaluated during this 12 year period were categorized into tertiles of activity according to their total MET scores per month: tertile 1 (0-514 MET-minutes/month), tertile 2 (515-1468 MET-minutes/month), and tertile 3 (1469 MET-minutes/month). After adjusting for BMI, the prevalence of diabetes was 10.3% in the most sedentary group, 9.6% in the middle group and 8.1% in the most active group ($P=0.06$ for sedentary vs middle, $P<0.0001$ for sedentary vs most active and $P<0.001$ for middle vs most active).

The influence of sex on the prevalence of diabetes is complex (Table 5). It was significantly higher in Caucasian men ($p<0.001$) and African American women ($p=0.047$) and not different in Hispanic men and women ($p=0.596$). Because of the preponderance of Caucasians in the NHANES population, diabetes was statistically more common in men in the United States ($P<0.001$).

Discussion

Many more individuals without a history of diabetes met the FPG criterion for the diagnosis of diabetes (86%) than the HbA1c criterion (53%). This increased sensitivity of the FPG criterion occurred in Caucasians but not Hispanics and African Americans. Since Caucasians are the majority population in the United States, this increased sensitivity of the FPG criterion in those not known to have it accounts for the increased overall prevalence of diabetes using this criterion in the entire adult population. This difference in sensitivity also accounts for the difference in the percent of people with diabetes who were not known to have it using the FPG criterion (22%) vs the HbA1c criterion (13%). The clinical implications of the different sensitivities between the FPG and HbA1c criteria in diagnosing diabetes in Caucasians are unknown at present.

In contrast, there were no differences in FPG and HbA1c criteria in Hispanics and African Americans. This is explained by the demonstration that both Hispanics [19,20] and African-Americans [19-24] are known to have higher HbA1c levels for a given glucose concentration compared with Caucasians. At least three possible reasons have been advanced to account for this finding; differences in glucose transport into erythrocytes, glycation rates, and/or variations in erythrocyte survival (25). Regardless of the reason(s) behind increased HbA1c levels for a given level of glycemia in African Americans, the association between HbA1c levels and retinopathy (26,27) and nephropathy (28)) did not differ by race/ethnicity.

There was a 61% increase in the prevalence of diabetes between 1999-2000 through 2009-2010 in people 20 years of age. A recent analysis of an NHANES population 12 years of age revealed a 75% increase in the prevalence of diabetes during this same period (29). This difference between the two increases reflects the recent increase of diabetes in the adolescent population. In 2009-2010, the prevalence of diabetes in Caucasians, Hispanics and African Americans 20 years of age was 13.3%, 16.6% and 15.5%, respectively (Table

3). In those 40 years of age, it was 18.6%, 25.8% and 25.9%, respectively (Table 3). The prevalence of diabetes has continued to increase progressively in Caucasians and Hispanics but fell considerably in African Americans between 2007-2008 and 2009-2010 (Table 3). It will be of considerable interest to see if this is simply statistical variation or portends a significant favorable trend in this vulnerable population.

Diabetes also increased 33% in the lean population during this 12 year period (Table 4) suggesting that obesity itself could not account for the rise in diabetes prevalence and implicating physical inactivity. Physical inactivity was implicated because when BMI was taken into account, there were significant decreases in diabetes as physical activity increased. The progressive and significant decrease in the prevalence of diabetes as physical activity increased even after adjustments for BMI strongly suggests a protective effect of physical activity independent of obesity. This could be reassuring to the vast majority of people in whom sustained weight loss is so difficult to achieve.

A limitation to this study is that glucose and HbA1c levels were measured only once and not confirmed. However, this is routinely done in epidemiological studies, including all NHANES studies. The strengths of the study are the large number of individuals evaluated and the 12 year history of the prevalence of diabetes in this country.

In conclusion, approximately 5% of adults who did not know that they had diabetes tested positive for it, 86% meeting the FPG criterion and 53%, the HbA1c criterion. Significantly more Caucasians met the FPG criterion than the HbA1c one whereas in Hispanics and African-Americans, there was no difference between the two criteria. The total prevalence of diabetes rose by 61% between 1999-2000 through 2009-2010 with progressive increases throughout for Caucasians and Hispanics but a marked decrease from 2007-2008 to 2009-2010 for African-Americans. In 2009-2010, the prevalence of diabetes in the entire population and in Caucasians, Hispanics and African Americans in people 20 years of age was 14.2%, 13.3%, 16.6% and 15.5%, respectively. In those 40 years of age, it was 20.7%, 18.6%, 27.0% and 25.9%. Increased physical activity, independent of obesity, protects against the development of diabetes.

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Figure 1.

Prevalence of diabetes in NHANES cohorts from 1999-2010 in 3 age groups (20-39, 40 years and 20 years old) in whom diabetes was diagnosed by history and in those not known to have it by only the FPG criterion, only the HbA1c criterion or either one.

Table 1
Characteristics of the NHANES Study Population

Variable	Diabetes Mellitus [*]	Non-Diabetes Mellitus	P-value
Age			
20-39	152 (10.8%)	3839 (41.5%)	<0.0001
40	1827 (89.2%)	6666 (58.5%)	
Gender			
Male	1044 (52.6%)	5138 (48.2%)	0.0022
Female	935 (47.4%)	5367 (51.8%)	
Race/Ethnicity			
Caucasians	841 (65.1%)	5392 (71.9%)	<0.0001
Hispanics	623 (14.0%)	2819 (12.5%)	
African Americans	431 (14.0%)	1880 (10.4%)	
Other	84 (6.9%)	414 (5.2%)	
BMI (mean $\pm$ SD)	32.3 $\pm$ 6.4	27.8 $\pm$ 6.3	<0.0001
Physical activity (METS) (mean $\pm$ SD)	1441 $\pm$ 2098	1663 $\pm$ 2546	0.1995

N (weighted %) unless stated otherwise

* Diagnosed by history of diabetes or either FPG ≥ 126 mg/dl (7.0 mmol/L) or HbA1c $\geq 6.5\%$ (48 mmol/mol) in those not known to have diabetes

Table 2
(%) of Diabetes* in the NHANES Populations from 1999 through 2010

	2001-2002			2003-2004			2005-2006			2007-2008			2009-2010			1999-2010		
	Prevalence	Percent Unknown		Prevalence	Percent Unknown		Prevalence	Percent Unknown		Prevalence	Percent Unknown		Prevalence	Percent Unknown		Prevalence	Percent Unknown	
Type 1 Diabetes	Age 20 Years																	
	2,078			1,874			1,827			2,352			2,615			12,484		
	10.1	26.3		10.5	21.7		12.0	21.8		13.1	22.0		13.7	22.3		11.5	22.4	
	9.0	17.1		9.6	13.8		11.0	15.0		11.8	13.0		12.7	15.9		10.5	13.3	
	10.5	29.3		10.9	24.4		12.3	24.0		13.6	25.0		14.2	24.9		11.9	25.8	
	28.0			28.4			28.8			28.3			28.8			28.4		
Type 2 Diabetes	Age 40 Years																	
	1,526			1,405			1,329			1,801			1,879			9,267		
	15.2	26.1		15.6	20.5		16.3	21.5		18.8	19.1		20.0	19.9		16.6	21.9	
	13.3	14.3		14.0	11.0		15.1	14.4		17.2	11.4		18.5	12.9		15.0	12.9	
	15.8	30.1		16.0	23.1		16.9	24.8		19.6	23.5		20.7	23.6		17.1	25.2	
	28.6			28.7			29.4			28.7			29.2			28.8		
Type 3 Diabetes	Age 20-39 Years																	
	713			631			666			813			899			4,319		
	2.5	17.0		2.5	24.2		4.4	18.6		3.7	38.8		3.1	40.0		3.3	26.9	
	2.5	17.1		2.4	22.4		3.8	6.6		2.6	9.7		2.8	29.0		2.9	17.0	
	2.7	21.9		2.8	36.3		4.4	18.6		3.7	38.8		3.1	40.0		3.4	30.7	
	27.2			28.0			27.9			27.6			28.2			27.6		

PG 126 mg/dl (7.0 mmol/L) only or HbA1c 6.5% (48 mmol/mol) only or either one in those not known to have diabetes

diabetes but subsequently diagnosed by laboratory tests

Table 3

Prevalence of Diabetes (%) and BMI in the NHANES Populations from 1999 through 2010 in Three Race/Ethnicities in All (20 Years) and Older (40 Years) Adults

NHANES Years	Prevalence 1999-2000	Prevalence 2001-2002	Prevalence 2003-2004	Prevalence 2005-2006	Prevalence 2007-2008	Prevalence 2009-2010	Prevalence 1999-2010
Caucasians (20 years)							
N	845	1203	1087	1020	1248	1312	6715
FPG	8.1	9.1	9.4	10.9	12.4	12.9	10.6
HbA1c	6.8	7.7	8.0	9.7	10.8	11.6	9.2
Either *	8.3	9.4	9.7	11.2	12.8	13.3	10.9
BMI	27.3	28.0	28.1	28.7	28.0	28.6	28.1
Hispanics (20 years)							
N	653	557	464	428	760	856	3718
FPG	9.8	11.2	12.2	13.7	13.7	16.1	12.9
HbA1c	9.6	10.7	12.8	12.8	11.7	14.9	12.1
Either	9.9	11.3	12.8	14.0	14.0	16.6	13.2
BMI	28.4	27.9	28.8	28.5	28.8	29.4	28.7
African-Americans (20 years)							
N	378	413	397	461	507	455	2611
FPG	9.2	12.4	13.8	15.8	18.8	14.5	14.5
HbA1c	8.5	12.2	13.6	16.0	19.0	14.4	14.3
Either	9.5	13.9	14.2	16.6	20.8	15.5	15.4
BMI	29.6	29.2	30.6	31.0	30.0	31.4	30.4
Caucasians (40 years)							
N	614	891	785	749	925	949	4913
FPG	10.8	13.3	13.3	14.6	16.7	18.0	14.6
HbA1c	8.9	11.1	11.1	13.0	14.8	16.2	12.7
Either	10.9	13.8	13.4	15.0	17.3	18.6	15.0
BMI	28.0	28.6	28.6	29.2	28.5	29.0	28.7
Hispanics (40 years)							

NHANES Years	Prevalence 1999-2000	Prevalence 2001-2002	Prevalence 2003-2004	Prevalence 2005-2006	Prevalence 2007-2008	Prevalence 2009-2010	Prevalence 1999-2010
N	442	332	310	236	492	530	2342
FPG	20.6	21.5	24.2	24.6	24.9	26.1	23.5
HbA1c	19.9	20.4	24.5	24.0	22.9	24.6	22.5
Either	20.6	21.3	20.2	23.9	23.2	25.8	24.1
BMI	29.2	28.0	29.2	28.5	29.5	29.8	29.1
African Americans (> 40 years)							
N	238	265	251	286	330	306	1676
FPG	13.6	19.0	22.2	24.0	27.3	24.2	22.2
HbA1c	12.1	18.5	22.4	24.8	28.5	24.0	22.3
Either	13.6	20.8	22.9	25.5	30.7	25.9	23.9
BMI	30.2	29.7	30.5	31.7	30.1	32.0	30.8

* Diagnosed by history of diabetes or FPG ≥ 126 mg/dl (7.0 mmol/L) only or HbA1c $\geq 6.5\%$ (48 mmol/mol) only or either one in those not known to have diabetes

Table 4
Distribution of Lean (BMI <25), Overweight (BMI 25.0-29.9) and Obese (BMI ≥30) Individuals and their Prevalences of Diabetes

	1999-2000		2001-2002		2003-2004		2005-2006		2007-2008		2009-2010		Increase *
	%	DM%	%	DM%	%	DM%	%	DM%	%	DM%	%	DM%	
Lean	40.0	3.9	34.3	4.1	33.2	5.0	33.0	4.4	32.9	4.8	30.9	5.2	33%
Over-weight	31.2	6.8	36.9	8.2	34.2	6.8	31.9	8.6	34.6	8.2	32.8	10.1	48%
Obese	28.8	12.8	28.8	15.4	32.6	17.1	35.1	19.1	32.5	22.3	36.3	21.1	65%

DM – Diabetes Mellitus diagnosed by history of diabetes or either FPG ≥126 mg/dl (7.0 mmol/L) or HbA1c ≥6.5% (48 mmol/mol) in those not known to have diabetes

* Percent increase in prevalence of diabetes from 1999-2000 to 2009-2010

Table 5
Comparison of Diabetes* Prevalence (%) in the NHANES Populations from 1999 through 2010 by Sex

NHANES	1999-2000	2001-2002	2003-2004	2005-2006	2007-2008	2009-2010	1999-2010
All							
Men	8.1	10.2	10.1	10.0	12.3	14.2	11.0
Women	7.1	7.8	9.1	12.0	11.3	11.2	10.0
Caucasians							
Men	8.3	9.7	9.4	8.8	11.8	13.4	10.4
Female	5.4	5.7	6.5	10.5	9.9	10.0	8.2
Hispanics							
Male	8.8	9.4	12.9	9.9	12.0	16.9	11.8
Women	10.3	12.1	12.6	16.2	11.4	12.7	12.4
African-Americans							
Men	5.0	8.7	12.2	16.2	18.1	13.4	12.7
Women	11.5	15.0	14.7	15.8	19.8	15.3	15.7

* Diagnosed by history of diabetes or either FPG 126 mg/dl (7.0 mmol/L) or HbA1c 6.5% (48 mmol/mol) (or both) in those not known to have diabetes