Impact of New Diagnostic Criteria for Diabetes on Different Populations

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OBJECTIVE — For epidemiological purposes, it has now been recommended that a fasting plasma glucose value of 7.0 mmol/l can be used to diagnose diabetes, instead of a 2-h value of 11.1 mmol/l. This study assesses the impact of making this change on the prevalence of diabetes and on the phenotype of individuals identified.

RESEARCH DESIGN AND METHODS — Data were collated from nine population-based southern hemisphere studies in which a 75-g oral glucose tolerance test was performed. Comparisons were made between the prevalence derived from fasting values only and the prevalence derived from 2-h values only. Cardiovascular risk was assessed in all individuals.

RESULTS — There were 20,624 subjects in the nine surveys, of whom 1,036 had previously diagnosed diabetes and 1,714 had newly diagnosed diabetes, according to either fasting or 2-h glucose. The differences in prevalence within each population resulting from changing the diagnostic criteria ranged from +30 to −19% (relative difference) and +4.1 percentage points to −2.8 percentage points (absolute difference). BMI was the most important determinant of disagreement in classification. A total of 31% of those individuals who were diabetic on the fasting value were not diabetic on the 2-h value, and 32% of those with diabetes on the 2-h value were not diabetic on the fasting value. Apart from obesity, there were no differences in cardiovascular risk between those identified by the fasting and the 2-h values.

CONCLUSIONS — Changing the diagnostic criteria is likely to have variable and sometimes quite large effects on the prevalence of diabetes in different populations. Furthermore, the fasting criterion identifies different people as being diabetic than those identified by the 2-h criterion.

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The American Diabetes Association (ADA) has recently recommended a change in the diagnostic criteria for diabetes, with a lowering of the fasting plasma glucose (FPG) threshold from 7.8 mmol/l to 7.0 mmol/l (1). The alternative diagnostic threshold, relating to a random plasma glucose or one taken 2-h after a 75-g oral glucose challenge, is unchanged at 11.1 mmol/l. ADA also indicated that the fasting threshold should become the diagnostic measure of choice, and in particular should be used alone for epidemiological studies. The World Health Organization (WHO) has also recently reviewed the same issues (2) and is likely to recommend the same lowered fasting threshold. WHO continues to accept either the fasting or 2-h values for epidemiological purposes.

Over the last decade, most epidemiological studies have followed the WHO's 1985 guidelines (3) and have used the 2-h plasma glucose (2-h PG) alone to diagnose diabetes. Thus, a significant change in the classification is now likely to occur, as researchers shift from the 2-h PG threshold to the new FPG threshold. However, it is not clear how this will affect calculations of the overall prevalence of diabetes, or how many individuals will be reclassified. In a recent analysis of 16 different European populations (4), it was clear that not only was the prevalence affected in different directions in different populations, but that the two different diagnostic thresholds identified different populations: only 28% of all those who were diabetic on either threshold were diabetic on both.

The aim of this study was to ascertain the impact of a change from the 2-h PG threshold to the new FPG threshold, using data we previously collected from nine southern hemisphere population-based studies (5–11) in which an oral glucose tolerance test (OGTT) was used. A secondary aim was to determine if the groups identified by the different diagnostic thresholds differed in their associations with hypertension, hyperlipidemia, and obesity.

RESEARCH DESIGN AND METHODS

— Surveys of southern hemisphere island populations, coordinated from a single center (International Diabetes Institute, Melbourne, Australia), were used for this analysis. Surveys were included if a full 75-g OGTT, including both fasting and 2-h samples, was performed. All surveys were population based and reflected the ethnic mixture of each island's overall population (Table 1). Where more than one survey was available for one location, the largest survey was used.

Diabetes was diagnosed as known diabetes mellitus (KDM) if subjects were on oral hypoglycemic drugs or insulin. These subjects had only an FPG measured, whereas all other subjects had an OGTT. To compare prevalence estimates according to the ADA (1997) and WHO (1985) guidelines, diabetes was determined in all non-KDM subjects according to ADA (1997) epidemiological criteria (FPG ≥ 7.0 mmol/l, irrespective of 2-h PG) and according to WHO (1985) epidemiological criteria (2-h PG ≥ 11.1 mmol/l, irrespective of FPG).

To examine the extent to which individuals are classified differently by the two approaches and to compare phenotypic

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Abbreviations: ADA, American Diabetes Association; DECODE, Diabetes Epidemiology: Collaborative Analysis of Diagnostic Criteria in Europe; FPG, fasting plasma glucose; KDM, known diabetes mellitus; OGTT, oral glucose tolerance test; PG, plasma glucose; WHO, World Health Organization.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Characteristics of study populations*

Survey site	Year	Response rate (%)	*n*	% Men	Age (years)	BMI (kg/m²)	Ethnic groups
Nauru	1994	64	1,423	46	39 ± 11 (19–82)	35.9 ± 7.6	Micronesian
Western Samoa	1991	69	1,777	45	46 ± 14 (25–81)	30.7 ± 6.0	Polynesian
Rodrigues	1992	97	1,530	48	44 ± 11 (25–64)	26.5 ± 4.9	General*
New Caledonia and Wallis Islands	1980	89	1,404	47	40 ± 13 (20–99)	29.3 ± 4.4	Melanesian, Polynesian
Cook Islands	1980	83	2,179	48	42 ± 16 (18–96)	28.1 ± 5.3	Polynesian
Fiji	1980	87	3,046	47	39 ± 14 (20–99)	25.6 ± 5.4	Asian Indian, Melanesian
Kiribati	1981	83	2,864	47	38 ± 14 (20–84)	26.9 ± 4.9	Micronesian
Mauritius	1987	86	4,990	47	43 ± 13 (25–74)	23.5 ± 4.3	Asian Indian, General*, Chinese
Papua New Guinea	1991	80	1,411	43	42 ± 14 (25–88)	26.4 ± 5.0	Melanesian
Overall	—	82	20,624	47	42 ± 14 (18–99)	26.9 ± 6.2	—

Data are %, *n*, or means ± SD (range). *The ethnic group "general" refers to a genetic admixture of African, European, and Malagasy ancestry.

differences between diabetic individuals satisfying different diagnostic criteria, all newly diagnosed diabetic subjects (i.e., those not already taking hypoglycemic drugs) were further classified as "ADA only" (FPG ≥ 7.0 mmol/l and 2-h PG < 11.1 mmol/l), "WHO only" (FPG < 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l) or "both" (FPG ≥ 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l). Any non-KDM subjects who did not have values for both FPG and 2-h PG were excluded from analysis. In all surveys, venous plasma samples were used for the measurement of glucose.

Blood pressure was measured after a 5-min rest, using the first and fifth Korotkoff sounds, recorded to the nearest 2 mmHg. Blood pressure was recorded twice, and the mean value was used. The subjects were considered to be hypertensive on the basis of WHO criteria (systolic blood pressure ≥ 160 mmHg and/or diastolic blood pressure ≥ 95 mmHg) or of self-reported antihypertensive medication taken in the past week. Height and weight were measured in light clothing without shoes, and the BMI was calculated as weight (kg)/height (m)². Waist and hip circumferences were measured twice, and the means were used to calculate the waist-to-hip ratio.

Statistical analysis

The prevalences of diabetes according to ADA or WHO criteria included subjects with previously diagnosed diabetes, and differences in prevalence within each population according to diagnostic criteria were assessed by McNemar's test. The possibility that the observed differences between the nine populations in the performance of the two sets of criteria were due to chance was tested by logistic regression, in which the significance of the interaction term between survey site and diagnostic criteria in predicting diabetes status was determined. Comparisons of variables between the different diabetic groups were made with one-way analysis of variance using Tukey's modification. Cholesterol and triglycerides were measured by different methods in the different surveys. To allow comparisons across the surveys, each lipid value was given a percentile rank representing its rank within the newly diagnosed diabetic population of each of the nine surveys. This generated nine series of values between 0 and 100 for cholesterol and triglyceride, which were analyzed by the Kruskal-Wallis test.

RESULTS — A total of 20,624 subjects were included from the nine surveys, from which there were 1,036 KDM subjects and 1,714 newly diagnosed subjects, according to either ADA or WHO criteria. The basic characteristics of each population are shown in Table 1. The populations were similar to each other with regard to age and sex, but they varied in the levels of obesity and included a number of different ethnic

Table 2—*Prevalence of diabetes according to the criteria on which diabetes is diagnosed*

Survey site	*n*	Prevalence of KDM (%)	Prevalence by ADA criteria (%)	Prevalence by WHO criteria (%)	Change in prevalence (95% CI)
Nauru	1,423	14.3	31.3	27.1*	+4.1 (+2.9 to +5.4)
Western Samoa	1,777	5.7	14.9	11.5*	+3.4 (+2.5 to +4.4)
Rodrigues	1,530	3.9	10.8	9.3*	+1.6 (+0.6 to +2.6)
New Caledonia and Wallis Islands	1,404	4.6	7.8	7.5	+0.3 (−0.4 to +1.0)
Cook Islands	2,179	3.6	7.1	7.1	0.0 (−0.5 to +0.6)
Fiji	3,046	3.8	8.8	8.8	0.0 (−0.7 to +0.7)
Kiribati	2,864	1.2	5.0	6.2*	−1.2 (−1.9 to −0.5)
Mauritius	4,990	5.5	10.9	12.8*	−1.9 (−2.5 to −1.3)
Papua New Guinea	1,411	7.3	17.2	19.9*	−2.8 (−4.0 to −1.6)
Overall	20,624	5.0	11.3	11.4	−0.1 (−0.4 to +0.2)

ADA criteria included KDM plus diabetes diagnosed by FPG ≥ 7.0 mmol/l. WHO criteria included KDM plus diabetes diagnosed by 2-h PG ≥ 11.1 mmol/l. *$P < 0.01$ vs. ADA prevalence.

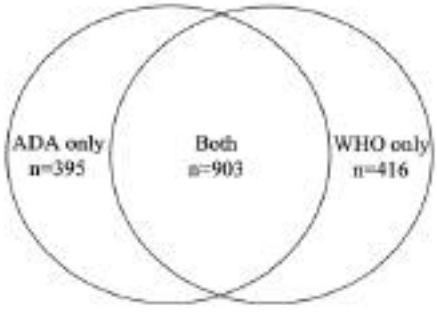

Figure 1—*Number of subjects without previously diagnosed diabetes classified as ADA only (FPG ≥ 7.0 mmol/l and 2-h PG < 11.1 mmol/l), WHO only (FPG < 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l) or both (FPG ≥ 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l).*

groups. The prevalence of diabetes according to the different diagnostic criteria is shown for each survey in Table 2. In three populations, the total prevalence was significantly higher when using the new ADA criteria; in three populations, it was significantly lower; and in the remaining three, there were no significant changes. Logistic regression showed that the interaction term between survey site and diabetes criteria (ADA or WHO) was a highly significant predictor of diabetes status ($P < 0.0001$), confirming that the variability in performance of the two sets of criteria between populations was not due to chance.

Table 2 shows that the absolute change in prevalence varies between +4.1 percentage points and −2.8 percentage points, but when the ADA prevalence is calculated as a percentage of the WHO prevalence, it varies between a 30% increase (Western Samoa) and a 19% decrease (Kiribati).

Figure 1 shows the degree to which the two diagnostic thresholds disagree. Of all subjects with FPG ≥ 7.0 mmol/l, 31% had nondiabetic 2-h values; and of those with 2-h PG ≥ 11.1 mmol/l, 32% had nondiabetic FPG values (<7.0 mmol/l). A total of 53% of all those who were diabetic according to either threshold were diabetic on both. Table 3 shows the differences in classification by survey site. The percentage of newly diagnosed diabetic subjects who satisfied both criteria ranged from 33% in men from New Caledonia and Wallis Islands to 68% in men from Nauru. The change in the number of newly diagnosed subjects that would result from a switch from using the 2-h threshold only to using the fasting threshold only ranged from a 79% increase (Rodrigues men and Western Samoa men) to a 46% reduction (Kiribati women).

Table 4 shows the influence of sex, age, and BMI on the proportions diagnosed by the different criteria. Obese diabetic subjects were much less likely than lean diabetic subjects to have low fasting and high 2-h PG levels, but more likely to have both elevated fasting and 2-h PG. When age was categorized as shown in Table 4, there was no influence, but among those ≥64 years of age (n = 216), 19% were diagnosed as ADA only, 33% as WHO only, and 48% as both. This was different from the distribution in those <64 years of age (P = 0.007), in that older diabetic people were more likely than younger people to be WHO only. Because there was a negative correlation between age and BMI, we looked at the effect of age (divided at 64) in each of the BMI categories. In the two lower BMI categories, a trend for the same effect of age was apparent, but in the highest category (BMI ≥ 30), older people were more likely than younger people to be diagnosed as ADA only. In none of the three BMI categories were the effects of age significantly related to diagnostic categorization.

In Table 5, comparisons between those diagnosed in different categories are made for a number of factors that are associated with diabetes. With regard to differences between ADA only and WHO only, most parameters were similar, except that ADA-only subjects were younger (men only) and more obese (BMI in both sexes, waist-to-hip ratio in women). Those diabetic by both criteria had higher FPG and 2-h PG than either of the other groups and also showed greater abnormalities than the other two groups in cholesterol, triglycerides, and family history of diabetes. The differences for lipids were significant whether the raw values or the rank values were used.

CONCLUSIONS — The data presented in this analysis show a complex effect resulting from a change in the diagnostic thresholds for diabetes. ADA anticipated that changing to the FPG threshold would lead to a slight reduction in the prevalence of diabetes as determined by epidemiological surveys (1), and this was supported by data from the U.S. showing a fall from 14.3 to 12.3% (12). The current study finds a variable effect, with some populations increasing the number of subjects with diabetes by up to 30% and others showing a fall of up to 19%. This variability is in keeping with similar variability seen in the Diabetes Epidemiology: Collaborative Analysis of Diagnostic Crite-

Table 3—*Subjects diagnosed as having diabetes according to ADA or WHO criteria in the different populations*

	Men			Women		
Survey site	ADA only	WHO only	Both	ADA only	WHO only	Both
Nauru	35 (29)	4 (3)	82 (68)	40 (29)	12 (9)	84 (62)
Western Samoa	37 (47)	4 (5)	38 (48)	30 (33)	2 (2)	59 (65)
Rodrigues	25 (47)	3 (6)	25 (47)	17 (24)	15 (21)	40 (56)
New Caledonia and Wallis Islands	6 (33)	6 (33)	6 (33)	9 (23)	5 (13)	25 (64)
Cook Islands	13 (30)	10 (23)	21 (48)	9 (17)	11 (21)	33 (62)
Fiji	28 (30)	23 (25)	42 (45)	32 (27)	37 (31)	49 (42)
Kiribati	32 (29)	38 (34)	41 (37)	5 (7)	34 (50)	29 (43)
Mauritius	34 (16)	81 (39)	95 (45)	24 (11)	73 (35)	114 (54)
Papua New Guinea	13 (13)	21 (21)	64 (65)	6 (6)	37 (37)	56 (57)
Overall	223 (27)	190 (23)	414 (50)	172 (19)	226 (26)	489 (55)

Data are n (%). Percentages are calculated from the total number of subjects newly diagnosed as diabetic by either ADA or WHO criteria within each subpopulation. ADA only criteria included FPG ≥ 7.0 mmol/l and 2-h PG < 11.1 mmol/l. WHOonly criteria included FPG < 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l. Both criteria included FPG ≥ 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l.

Table 4—*Influences of sex, age, and BMI on diagnostic category among diabetic subjects*

	n	ADA only	WHO only	Both	*P* value (χ^2)
Sex					
Male	827	27	23	51	—
Female	887	20	26	54	0.003
Age (years)					
≤40	547	27	24	49	—
41–55	672	22	24	54	—
>55	494	21	25	54	0.11
BMI					
<25	441	21	36	43	—
25–30	503	21	26	53	—
≥30	767	26	16	58	<0.00001

Data are %. ADA only criteria included FPG ≥ 7.0 mmol/l and 2-h PG < 11.1 mmol/l. WHO only criteria included FPG < 7.0 mmol/l and 2-h PG ≥ 11.1 mmol/l. Both criteria included FPG ≥ 7.0 mmol/l and 2-h PG ≥11.1 mmol/l.

ria in Europe (DECODE) Study of different European populations (4) and in other single-population reports, some of which show a higher prevalence according to WHO criteria (12,13), whereas other populations have a higher prevalence according to ADA criteria (14).

Obesity was the most important factor in determining on which criterion diabetes was diagnosed. This was apparent from the finding that the two studies (Nauru and Western Samoa) with the highest mean population BMI also had the highest proportion of diabetic subjects with FPG ≥ 7.0 mmol/l, as well as the analysis of BMI for the whole sample (Table 4). A similar trend was seen in the European study (4). However, this finding was not consistent among all the populations in the current study, suggesting that there are other important factors. It would be difficult to predict the effects of a change in diagnostic criteria for any other population.

The influence of age was not clear-cut and was only significant when comparing those ≥64 years of age with the rest. These older people were more likely to be in the WHO-only group than were younger people. This is in keeping with recent findings in older Americans—in whom 14.8% were diabetic on the 1985 WHO criteria but only 7.7% were diabetic according to the ADA fasting criteria (15)—and data from the Rancho Bernardo study showing that in the elderly, 60% of those with undiagnosed diabetes are only diabetic according to the 2-h and not the fasting value (16). In the DECODE Study (4), of the five data sets focusing on the elderly, WHO diabetes was more common than ADA diabetes in three and less common in two.

Irrespective of changes in the overall prevalence, the classification of individuals was markedly different with the two methods. There was more overlap between the methods in this study than in the European populations—which is probably due to greater obesity leading to a higher proportion of subjects being diabetic on both criteria in our study—but still 24% of all diabetic subjects were WHO only, and a further 23% were ADA only.

The influence of potential reclassification of subjects with previously diagnosed diabetes (KDM) cannot be accurately assessed from this study, though ultimately it is likely to be important. It is probable that KDM subjects represent greater abnormalities of glucose, as many of them would have been symptomatic at diagnosis; indeed, despite being on treatment, their mean FPG was higher than that in newly diagnosed subjects in 7/9 populations. Thus, most of them would probably be diabetic on both criteria. For the calculations of prevalence changes, we assumed that all KDM subjects would be diabetic on both criteria. If any of them only satisfied one set of criteria, this would increase the difference between the prevalences. The analysis of reclassification of individuals (Fig. 1, Table 3) used only newly diagnosed subjects. If we assume that most KDM subjects are diabetic on both criteria, the degree of agreement for the total diabetic population would be higher if KDM subjects were included:

Table 5—*Phenotypic characteristics according to criteria on which diabetes is diagnosed in subjects without previously diagnosed diabetes*

	Men			Women		
	ADA only	WHO only	Both	ADA only	WHO only	Both
n	223	190	414	172	226	489
FPG (mmol/l)	7.7 ± 1.0*	5.8 ± 0.8*	11.3 ± 3.7	7.5 ± 0.8*	5.9 ± 0.8*	11.3 ± 3.8
2-h PG (mmol/l)	7.7 ± 2.0*	12.8 ± 1.8*	17.8 ± 4.8	8.2 ± 1.8*	13.0 ± 2.5*	18.0 ± 5.1
Age (years)	45 ± 12†	50 ± 13	48 ± 12	48 ± 14	48 ± 15	48 ± 12
Diastolic blood pressure (mmHg)	84 ± 16	82 ± 13	83 ± 14	80 ± 15	80 ± 13	82 ± 16
Systolic blood pressure (mmHg)	136 ± 24	134 ± 25	139 ± 24	137 ± 27	137 ± 25	139 ± 27
Cholesterol (mmol/l)	5.0 ± 1.3	5.2 ± 1.7	5.5 ± 1.5†	5.1 ± 1.4	5.3 ± 1.5	5.7 ± 1.4*
Triglycerides (mmol/l)	1.8 ± 1.7	1.5 ± 1.2	2.3 ± 2.4*	1.4 ± 0.9	1.3 ± 0.8	1.9 ± 1.5*
Waist-to-hip ratio	0.91 ± 0.07	0.90 ± 0.06	0.92 ± 0.05‡	0.86 ± 0.07	0.84 ± 0.07§	0.87 ± 0.06
BMI (kg/m²)	30 ± 7	26 ± 6*	30 ± 7	33 ± 9	28 ± 7*	31 ± 7
Family history of type 2 diabetes (%)	25	25	35§	29	25	34‡
Hypertensive (%)	28	26	27	26	27	29

Data are means ± SD or %. Waist-to-hip ratio was only done on 908 of 1,714 subjects. Data on family history of type 2 diabetes were only available for 1,603 of 1,714 subjects. *$P < 0.001$ vs. other two groups. †$P < 0.01$ vs. other two groups. ‡$P < 0.05$ vs. WHO only. §$P < 0.05$ vs. other two groups.

then, up to 71% (instead of 53%) of all diabetic subjects would be diabetic on both fasting and 2-h values.

A degree of caution should be maintained in extrapolating the results of an epidemiological study to individual subjects, because for an individual, hyperglycemia must be confirmed on another day to diagnose diabetes. Nevertheless, there is no evidence to suggest that repeated testing would influence the proportions of subjects who were WHO only or ADA only.

We examined possible phenotypic differences between those selected on fasting criteria and those selected on 2-h criteria by comparing extreme groups (ADA only and WHO only). However, despite comparing the extremes, and in support of the use of the FPG criteria alone, there was no evidence that there were any other differences between ADA-only subjects and WHO-only subjects with regard to their associations with other aspects of the metabolic syndrome, apart from the greater obesity of the former group. The two groups, however, had significantly milder abnormalities than the group that had diabetes by both criteria. The most important associations with end-organ disease in the context of diagnosing diabetes are with microvascular complications. Whereas several studies indicate that both an FPG of 7.0 mmol/l and a 2-h PG of 11.1 mmol/l are equally predictive of diabetic retinopathy (1,17,18), none has reported the risk in subjects diabetic on only one criterion.

In conclusion, this study shows that changing over to using the FPG $\geq$ 7.0 mmol/l cutoff can have variable, unpredictable, and sometimes quite large effects on both the number of people and the specific individuals classified as having diabetes. Furthermore, diabetic subjects defined by the new FPG level, as a group, will be more obese than those identified by the 2-h PG level. Therefore, a major change of diagnostic practice should have very clear justification from a variety of studies that confirm its validity in terms of pathophysiological processes, risk of diabetic complications, and screening strategies.

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