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Imprecision of New Criteria for the Oral Glucose Tolerance Test

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Summary. Subjects selected from a centre specializing in diabetes detection have been classified using nine different methods of diagnosis including the recent criteria of the National Diabetes Data Group and the World Health Organization. The applicability of these two new criteria have been evaluated and compared with seven other previous criteria. The agreements and discrepancies between these criteria have been assessed. Application of the new criteria result in a major redistribution of subjects with abnormal glucose tolerance into a rare category of diabetes mellitus and a large category of 'impaired glucose tolerance'. An important percentage of our population (33%) is excluded from the three clinical classes circumscribed by the criteria of the National Diabetes Data Group. Among these subjects, two-thirds correspond to the subjects named 'non-diagnostic' by these authors and one-third are not classifiable. The need to allow for all possible oral glucose tolerance test responses is emphasized.

Key words: Diabetes, diagnostic criteria, oral glucose tolerance test.

The diagnosis of diabetes in the asymptomatic subject remains difficult. The need to standardize the definition and classification of diabetes in relation to other biological parameters (e.g. obesity and pregnancy) and the procedure of the oral glucose tolerance test (GTT) have been reviewed in detail [1]. Recently, two groups (the National Diabetes Data Group [2] and the World Health Organization [3]) have discussed these problems and have proposed two new sets of criteria. At first glance, these two criteria seem to express a certain amount of agreement as to definition and some technical details, such as size of the glucose load and blood glucose limits. The importance of these two criteria therefore led us to study whether they were practically applicable, to compare them with each other and the results given by them with those of seven other widely used international criteria, which we have discussed in detail previously [4].

Subjects and Methods

For the first visit the subjects came to the Diabetes Screening Centre of the Hôtel Dieu Hospital, Paris. They did so either voluntarily following an educational campaign about diabetes screening or because they were suspected to be diabetic and sent by their physician. Pregnant and post-partum women, as well as those taking contraceptive pills, were excluded. A total of 543 subjects participated in this study after giving informed consent. After a preliminary examination in conditions similar to those recommended by the World Health Organization [5] and the Committee on Statistics of the American Diabetes Association [6], which consisted of a (simplified) 0–2 h oral GTT where blood samples were taken at 0 and 2 h and where glycosuria was measured semi-quantitatively, subjects were selected as follows. Those subjects with symptoms of diabetes or with a fasting blood glucose level of > 7.3 mmol/l and 2-h blood glucose level of > 8.4 mmol/l were classified as diabetic and were sent for treatment. Subjects without glycosuria and with a fasting blood glucose level < 5.6 mmol/l and a 2-h blood glucose level < 6.7 mmol/l were considered as normal and were asked to come for a second screening if they wished. Those with values between these two extremes were asked to return for a second test. This consisted of blood samples taken at ½, 1, 2 and 3 h after ingestion of glucose. The procedure for both oral GTTs was as follows. The diet during the 3 days preceding the test included at least 200 g of carbohydrate daily. Between 08.00 and 08.30 h, after an overnight fast, each subject ingested 75 g of glucose in 150 ml of water in less than 5 min. Subjects were resting and did not smoke. The blood glucose was measured (within 12 h) by the glucose oxidase method on whole venous blood (Boehringers reactant TCM2). Characteristics of the subjects including sex, age, height, weight, family history of diabetes, and pregnancy were noted during the first test. The body mass index was calculated according to the formula:

$$100 \left(\log \frac{\text{weight (kg)}}{\text{height}^2 \text{ (m)}} - 1\right) [7].$$

The percentage of difference from ideal weight was taken from those given by the Society of Actuaries [2]: 0%, +10%, +20% and +30% correspond to mean body mass indices of 37.0, 40.0, 43.0 and 47.0 respectively for men, and 32.0, 36.0, 40.0 and 44.0 for women. A man was classified as obese if his body mass index was > 43 ($> 20\%$ over ideal weight) and a women if her index was > 40 ($> 20\%$ over

Table 1. Glucose criteria for diagnosis of diabetes

Author(s)	Reference	Procedure of oral GTT		Diabetic if:	Normal if:	Impaired glucose tolerance if:
		Glucose load	Analysis			
United States Public Health Service	[14]	100 g	Glucose-oxidase	$BG_0 \geq 6.1$ and $BG_3 \geq 6.1$ or $BG_0 \geq 6.1$ and $BG_1 \geq 9.5$ and $BG_2 \geq 6.7$ or $BG_1 \geq 9.5$ and $BG_2 \geq 6.7$ and $BG_3 \geq 6.1$	others	no
Wilkerson	[10]	100 g	Somogyi-Nelson	$BG_0 \geq 6.1 \rightarrow 1$ point; $BG_1 \geq 9.5 \rightarrow ½$ point (6.4) (9.2) $BG_2 \geq 6.7 \rightarrow ½$ point; $BG_3 \geq 6.1 \rightarrow 1$ point (6.4) Sum of points > 2	others	no
Fajans & Conn	[9]	1.75 g/kg ideal weight	Ferri-cyanide Somogyi-Nelson	$BG_1 \geq 8.8$ and $BG_{1½} \geq 7.8$ and $BG_2 \geq 6.7$ (8.6)	others	no
World Health Organization 1965	[5]	50 g or 100 g	Ferri-cyanide	$BG_2 \geq 7.2$ (7.5)	$BG_2 < 6.1$ (6.4)	$6.1 < BG_2 < 7.2$ (6.4) (7.5)
British Diabetes Association	[11]	50 g	Glucose-oxidase	$BG_{Int} \geq 8.8$ and $BG_2 \geq 6.1$ (10.0) (6.7)	others	no
University Group Diabetes Program	[12]	30 g/m^2 body surface	Ferri-cyanide	$BG_0 + BG_1 + BG_2 + BG_3 \geq 27.8$ (26.4)	others	no
European Study Group of Diabetes Epidemiology	[13]	50 g	Glucose-oxidase	$BG_{Int} \geq 12.2$ and $BG_2 \geq 8.3$	$BG_{Int} < 8.8$ and $BG_2 < 6.7$	others
National Diabetes Data Group	[2]	75 g	Glucose-oxidase	2 successive $BG_0 \geq 6.7$ or ($BG_{Int} \geq 10.0$ and $BG_2 \geq 10.0$) twice	$BG_0 < 5.6$ and $BG_2 < 6.7$ and $BG_{Int} < 10.0$	$BG_0 < 6.7$ and $BG_{Int} < 10.0$ and BG_2 {6.7, 10.0}
World Health Organization 1980	[3]	75 g	Glucose-oxidase	$BG_{Int} \geq 10.0$ and $BG_2 \geq 10.0$ or $BG_2 \geq 10.0$ and ($BG_0 \geq 6.7$ or $BG_2 \geq 10.0$)		$BG_0 < 6.7$ and BG_2 {6.7, 10.0}

BG_s indicate the blood glucose values (mmol/l) at time s (h); the glucose limits are those initially proposed by the authors.
BG_{Int} is for intermediate blood glucose values ($BG_{½}$ or BG_1 or $BG_{1½}$).
The values in parentheses are those which would correspond to a 75 g glucose load on whole venous blood measured by glucose oxidase method

Table 2. Characteristics of the population studied

	Men	Women
Number of subjects	374	169
Percentage with family history of diabetes	27	34
Obese subjects (%)[a]	29	29
Age (years)	44 ± 12	43 ± 13
Height (cm)	170 ± 7	159 ± 6
Weight (kg)	74 ± 12	64 ± 13
Body mass index[b]	39 ± 7	39 ± 8

Results are expressed as mean ± SD. [a]Obese if the body mass index is > 43 for men and > 40 for women (see text); [b] Body mass index [7] calculated according to $100 \left(\log \frac{\text{weight (kg)}}{\text{height}^2 \text{ (m)}} - 1\right)$

ideal weight). Using the simple formula of weight (kg)/height^2 (m) would give corresponding indices for obesity of 27 for men and 25 for women [8].

Nine methods of diagnosis were used to classify the population: those of Fajans and Conn [9], the Wilkerson Point System [10], World Health Organization recommendations of 1965 [5], British Diabetic Association [11], University Group of Diabetes Program [12], European Study Group of Diabetes Epidemiology [13], United States Public Health Service [14], National Diabetes Data Group [2] and the 1980 World Health Organization recommendations [3].

The first seven methods used differing glucose loads, methods of blood glucose assay and blood or plasma samples. Using the same techniques as previously [4], we have therefore standardized all the limit values to those which would be obtained after a 75 g glucose load using an assay by the glucose oxidase method on whole venous blood. These standardized criteria are shown in Table 1 together with the initial values. All the subjects were classified on the complete 0–3-h oral GTT and, when two oral GTTs were necessary for National Diabetes Data Group (NDDG) [2] and World Health Organization (WHO) [3] criteria, we have used the data of the simplified 0–2-h test and of the 0–3-h oral GTT.

The different criteria recognize two or three diagnostic classes: 'normal', 'diabetic' and 'impaired glucose tolerance'. The NDDG includes a fourth category of 'non-diagnostic'. We have classified the population in two, three and four classes accordingly. In the epidemiological situation we have studied, we cannot know whether a subject is actually 'diabetic' or not. Strictly speaking, we cannot therefore assess the specificity and sensitivity (as defined by Remein and Wil-

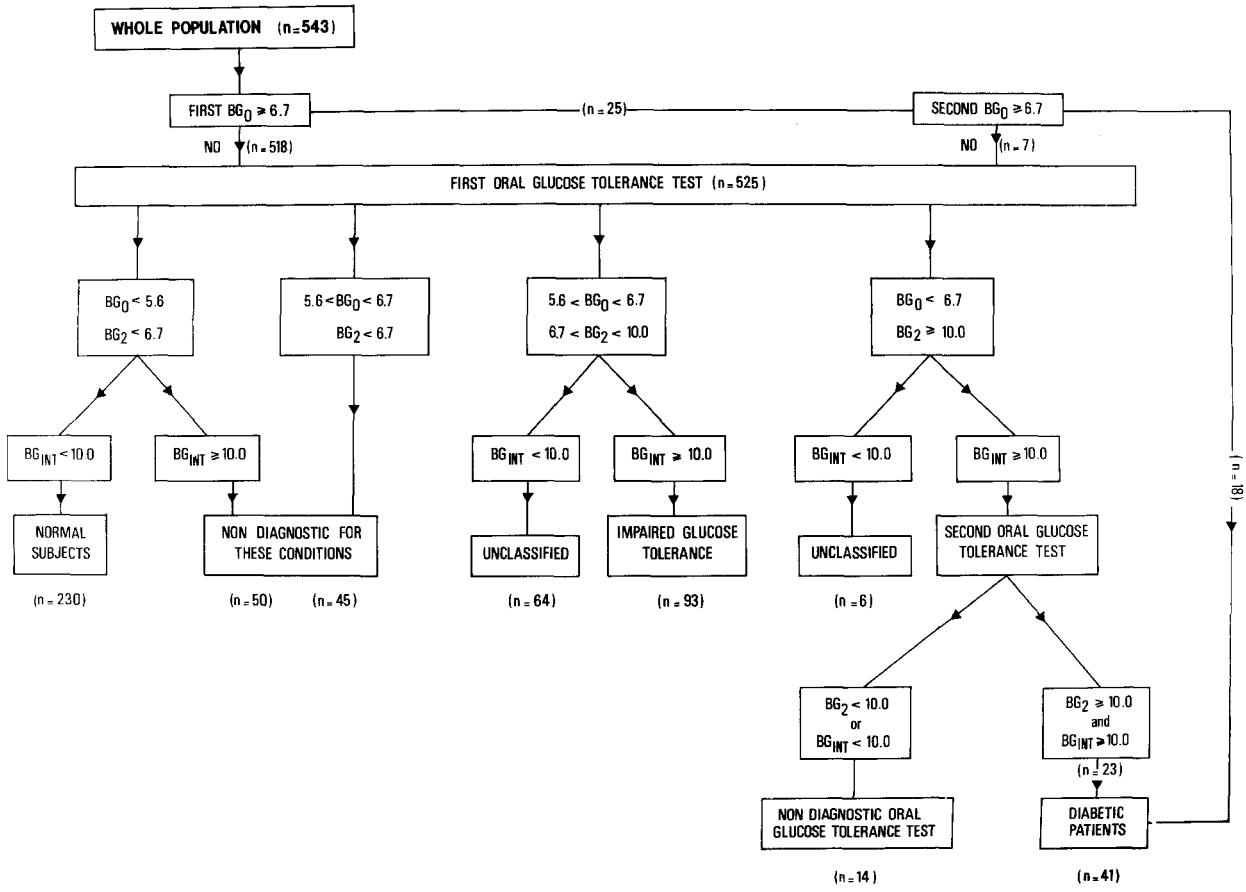

Fig. 1. Classification of the population by the National Diabetes Data Group Criteria. BG_s = Whole venous blood glucose at time s (h) in mmol/l, e.g. BG_0 = basal value. BG_{Int} is for intermediate blood glucose values, e.g. $BG_{½\,h}$ or BG_{1h} or $BG_{1½\,h}$ (n = number of subjects)

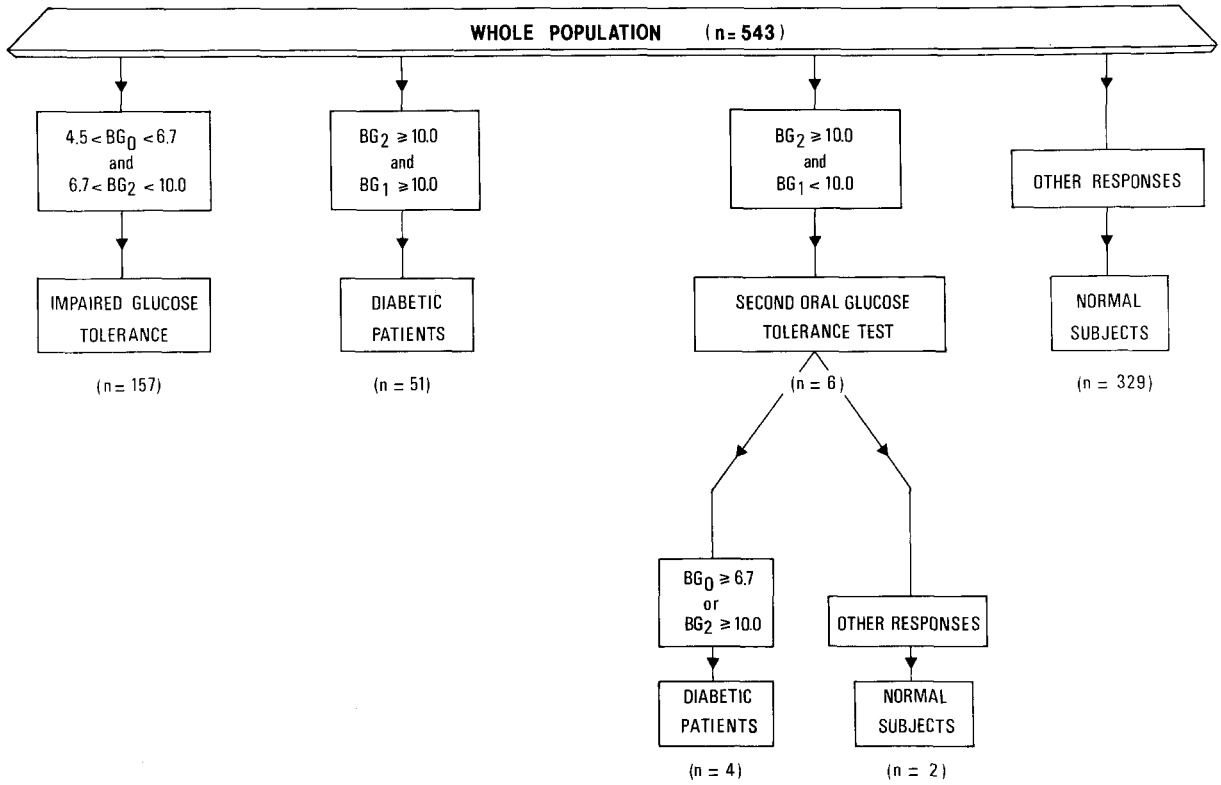

Fig. 2. Classification of our asymptomatic population by World Health Organization criteria (1980). BG_s = Whole venous blood glucose value (mmol/l) at time s (h) e.g. BG_2 = glucose at 2 h after ingestion. (n = number of subjects)

Table 3. Classification of the subjects by nine different methods for diagnosis of diabetes

Author(s)	Reference	'Diabetic' subjects (%)	'Normal' subjects (%)	'Impaired glucose tolerance' (%)	Unclassifiable subjects (%)
Fajans and Conn	[9]	35	65	–	–
Wilkerson	[10]	11	89	–	–
British Diabetes Association	[11]	41	59	–	–
University Group Diabetic Program	[12]	35	65	–	–
United States Public Health Service	[14]	15	85	–	–
World Health Organization 1965	[5]	28	55	17	–
European Study Group of Diabetes Epidemiology	[13]	10	37	53	–
National Diabetes Data Group	[2]	8	42	17	33
World Health Organization 1980	[3]	10	52	30	–

kerson [15]) of the diagnostic procedures we study here. We have therefore observed whether a subject classified as diabetic or normal by criteria A is or is not so classified by criteria B. To evaluate the different criteria by paired comparison, we have calculated for each method the percentage of subjects considered as diabetic by method A among subjects classified as diabetic by method B and the percentage of subjects considered as normal by method A among subjects classified as normal by method B. This technique was used in a previous study [4] where these percentages have been called 'relative specificity' and 'relative sensitivity'.

Results

Characteristics of the population studied are shown in Table 2. Approximately two-thirds were men and one-third were women. A family history of diabetes was present in about 30% of patients and obesity in 29% of patients.

Figure 1 is a flow diagram of the NDDG classification with the various sets of blood glucose values which may be encountered. In our population, 41 subjects were classified as 'diabetic' (of which 18 had two successive fasting blood glucose levels > 6.7 mmol/l), 93 were classified as having 'impaired glucose tolerance', 230 were classified as 'normal', 95 subjects were considered as 'non-diagnostic', and 14 were considered as 'non-diagnostic OGTT' because their second oral GTT responses were not diabetic. Notwithstanding this class, the blood glucose responses of 70 subjects could not be classified by the NDDG criteria. These 70 subjects had intermediate blood glucose levels of < 10.0 mmol/l. No allowance for such combinations of 0, intermediate and 2-h values was made by the NDDG procedures and this led us to exclude 64 of these subjects from the 'impaired glucose tolerance' group and six from the second oral GTT.

Figure 2 is the flow diagram of the WHO criteria [3]. Only two diagnostic classes in asymptomatic subjects are recognized: 'diabetes mellitus' and 'impaired glucose tolerance'. When we applied these criteria to our population, 157 were classified as having 'impaired glucose tolerance', 55 were classified as 'diabetic' (51 on their first oral GTT and four with a second test). All the others (331) were accordingly considered as 'normal'.

Intercomparison

The different classifications of the subjects using the nine sets of criteria which we standardized are shown in Table 3. The percentage of diabetic subjects ranged from 8 to 41 and the percentage of normal subjects ranged from 37 to 89. It is notable that the percentage of subjects recognized as diabetic by the recent WHO (1980) criteria was three times less than the percentage given by their 1965 criteria.

Four of the methods include a third class of subjects neither 'normal' nor 'diabetic'. These subjects, called 'borderline' in the European Study Group of Diabetes Epidemiology [13] and the WHO (1965) recommendations [3] were those excluded from the normal or diabetic classes and did not strictly correspond to the 'impaired glucose tolerance' class as defined by NDDG and WHO (1980) criteria. As noted above, 33% of the subjects do not enter into the three NDDG classes of 'normal', 'diabetic' or 'impaired glucose tolerance'. Among these 33%, 20% correspond to subjects classified by NDDG as 'non-diagnostic'. It is, again, worthy of note that the remaining 13% correspond to subjects in whom no classification at all is made, not even the so-called 'non-diagnostic'.

Table 4 shows the discrepancies in the definition of normal subjects between the nine methods. The discrepancies between NDDG and the WHO (1980) criteria are also great since only 69 'normal' subjects by WHO standards were recognized as 'normal' by NDDG. However, all subjects classified as 'normal' by NDDG are also classified as such by WHO.

Table 5 shows the discrepancies in the definition of diabetic subjects between the nine methods. The recent criteria never recognize as 'diabetic' more than 72% and sometimes as few as 18% of the subjects classified as 'diabetic' by the previous methods (Table 5, first seven columns). The population of subjects classified as 'diabetic' by the new methods are not always recognized as such by previous methods (Table 5, columns 8 and 9). Even using the same numerical limits, these discrepancies remain between the new methods since, of 100 'diabetics' by the new WHO criteria only 67 are 'diabetic'

Table 4. Relative percentage of subjects considered as 'normal'

Author(s)	Reference	Fajans and Conn [9]	Wilkerson [10]	British Diabetes Association [11]	University Group Diabetes Program [12]	United States Public Health Service [14]	World Health Organization 1965 [5]	European Study Group of Diabetes Epidemiology [13]	National Diabetes Data Group [2]	World Health Organization 1980 [3]
Fajans and Conn	[9]	–	72[a]	97	91	76	100	100	100	97
Wilkerson	[10]	100	–	100	100	100	100	100	100	98
British Diabetes Association	[11]	89	66	–	86	70	93	100	95	87
University Group Diabetes Program	[12]	91	72	94	–	76	94	100	99	90
United States Public Health Service	[14]	99	95	100	100	–	100	100	100	98
World Health Organization 1965	[5]	86	62	87	80	65	–	95	93	90
European Study Group of Diabetes Epidemiology	[13]	57	41	62	57	43	63	–	78	59
National Diabetes Data Group	[2]	65	47	68	65	50	71	90	–	69
World Health Organization 1980	[3]	93	67	90	86	71	100	100	100	–

Among 100 subjects classified as 'normal' by the criteria in column, number of subjects classified also as 'normal' by the method in row
[a] e.g. among 100 subjects classified as 'normal' by Wilkerson only 72 are classified as such by Fajans and Conn

Table 5. Relative percentage of subjects considered as 'diabetic'

Author(s)	Reference	Fajans and Conn [9]	Wilkerson [10]	British Diabetes Association [11]	University Group Diabetes Program [12]	United States Public Health Service [14]	World Health Organization 1965 [5]	European Study Group of Diabetes Epidemiology [13]	National Diabetes Data Group [2]	World Health Organization 1980 [3]
Fajans and Conn	[9]	–	100	83	83	99	93	100	100	100
Wilkerson	[10]	30[a]	–	26	30	71	36	58	83	67
British Diabetes Association	[11]	95	100	–	90	100	95	100	100	100
University Group Diabetes Program	[12]	83	100	78	–	100	92	100	100	100
United States Public Health Service	[14]	42	100	37	43	–	49	74	88	76
World Health Organization 1965	[5]	72	93	64	71	89	–	100	97	100
European Study Group of Diabetes Epidemiology	[13]	30	57	26	30	51	38	–	73	74
National Diabetes Data Group	[2]	21	58	18	21	44	27	53	–	67
World Health Organization 1980	[3]	28	64	25	29	51	37	72	90	–

Among 100 subjects classified as 'diabetic' by the criteria in column, number of subjects classified also 'diabetic' by the method in row
[a] e.g. among 100 subjects classified as diabetic by Fajans and Conn only 30 are classified as such by Wilkerson

according to NDDG, and, of 100 'diabetics' by NDDG standards, 90 are classified as 'diabetic' by the WHO.

Discussion

We shall focus our discussion on the two new criteria, both in general terms and in consideration of our own results.

The new criteria lead to lower percentages of 'diabetic' and 'normal' subjects, with a higher percentage of subjects with 'impaired glucose tolerance'; this continues a tendency started 10 years ago.

The blood glucose limits for the diagnosis of diabetes have been raised by the NDDG and the 1980 WHO criteria, while the criteria for normality have not been substantially lowered. The levels adopted by NDDG are based on the characteristics of the blood

glucose distribution in the Pima Indians [16], the Nauruan populations [17] and on the results of several long-term prospective studies [18–22], which have shown that the blood glucose standards commonly used as diagnostic criteria for diabetes may have been set too low and that the creation of an intermediate group of 'impaired glucose tolerance' may be justified. If glucose intolerance and hyperglycaemia are now defined rather as having higher risks of developing specific micro- and macrovascular complications than as a specific disease, recent studies concerning microvascular complications suggest that these limits might well be too low [23–26].

If the general tendency has been to agree with the blood glucose limits proposed by the NDDG [27–31], the creation and their strict definition of a intermediate group of 'impaired glucose tolerance' is more controversial [25, 31–33]. In particularly, Dix and Cohen [33] deplored that the 'non-diagnostic oral GTT' cannot be considered as 'impaired glucose tolerance' because of the strict definition of this class.

Apart from certain combinations of GTT values which are recognized as 'non-diagnostic' by the NDDG, we have found numerous others that have not been taken into account and for which no classification can be made. This is evident when considering our results of the different situations that can occur (Fig. 1). A procedure of diagnosis serving, as the authors of NDDG claim, 'to plan and to conduct clinical research in diabetes' should 'a priori' include all situations that might occur. This criticism was endorsed by Köbberling and Creutzfeld [25], who also observed undefined combinations when a two-dimensional graph of the NDDG criteria (based on the 1 and 2-h values) was plotted. They concluded that the NDDG criteria are too loose and too complicated and suggest criteria simply based on the addition of the 1 and 2-h values.

Both NDDG and WHO criteria are aimed to take into account, at least partly, the lack of reproducibility of the GTT even under standard conditions [34, 35]. To do so, they define as 'diabetic' a subject having at least two 'elevated' blood glucose values, either during two successive oral GTTs [2], or at 2 h and one other time during a single test [3]. The lack of reproducibility is not taken into account for 'normal' subjects. We have determined that in this population, 25% of the subjects classified as 'normal' according to their first GTT have a abnormal second one. These subjects had a 2-h blood glucose level > 6.7 mmol/l and approximately one-third of them had a fasting blood glucose level > 5.6 mmol/l. This makes it clear that the lack of reproducibility should also be taken into account in defining the 'normal' subject. However, the fact that an oral GTT is expensive, inconvenient and stressful for the patient has been noted [33].

Despite the fact that the WHO claims the NDDG recommendations as an inspiration, we found important discrepancies (Table 3). The estimated prevalence of 'diabetes' when assessed by WHO criteria (1980) will be greater than that recognized by the NDDG criteria. This is explained by the differences between the numbers of blood glucose values required for the diagnosis (e.g. two successive abnormal values for the WHO, and two successive abnormal oral GTTs with 2 h and two intermediate blood glucose values for the NDDG criteria). On the other hand, the WHO report considers as 'normal' all subjects who have neither 'impaired glucose tolerance' nor 'diabetes': for this reason there is no 'non-diagnostic' group. If we agree with this attitude in a diagnostic situation, we would emphasize the great heterogeneity of those subjects who have neither 'impaired glucose tolerance' nor 'diabetes' according to these criteria. Indeed the oral GTT responses of such subjects show an important percentage (16%) of subjects with fasting hyperglycaemia. The two other subjects with a first 'diabetic' value have second oral GTT responses clearly showing 'impaired glucose tolerance'. As emphasized in the WHO report, such subjects should not be labelled as normal and returned to the community by default. It is therefore necessary that future WHO recommendations should be given explicitly to avoid any subjective interpretations.

Another flaw, which is partly computational, can also be found. The report expressed the limit values both in mg/dl and in mmol/l (by using a conversion factor of 18 from mg to mmol and rounding the final figures of mmol). This has more consequences than might be thought at first sight. Indeed, if we assume that the fasting blood glucose level is normally distributed in a population with a mean of 5.6 and a standard deviation of 0.8 mmol/l, 5% of the subjects range between 6.7 mmol/l (120 mg/dl) and 7 mmol/l (126 mg/dl) and 4.5% have a blood glucose value above 7 mmol/l. Therefore, the prevalence (percentage of subjects classified as diabetic) obtained with limits expressed in mmol/l values would be much smaller than with the mg/dl values.

In conclusion, the application of the new criteria results in a major redistribution of these asymptomatic subjects with abnormal glucose tolerance into a relatively uncommon category of 'diabetes mellitus' and a large category of 'impaired glucose tolerance'. Apart from the 'impaired glucose tolerance' class, a significant part of the population remains unclassified. The elaboration of a flow diagram with the recognition of all the possible blood glucose combinations (even those which might be been assumed 'surprising' from pathophysiological considerations) could avoid this problem and better permit the recommendations to be used in practice. From a methodological point of view, a systematic quantitative evaluation, such as we present here, could be undertaken whenever new criteria are proposed to high-light the areas of divergence from other criteria so that they may be intelligently argued and clarified.

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