

# Substantial Differences in the Diagnostic Criteria Used by Diabetes Experts

*Kelly M. West, M.D., Oklahoma City*

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## SUMMARY

A survey of twenty diabetologists revealed that they employ diagnostic criteria differing quite substantially. In some populations, including the general population of the United States, these disparities would result in very major differences in the rates of "diabetes." Under certain common circumstances, some diabetologists would classify as normal more than half of the one- and two-hour values considered to be abnormal by other well-qualified diabetologists. *DIABETES* 24:641-44, July, 1975.

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The American Diabetes Association has recently released a guide for physicians for designing and interpreting glucose tolerance tests.<sup>1</sup> Two other reports have appeared in this journal that reflect attempts of expert groups to transmit to practitioners a consensus of informed judgment with regard to diagnostic procedures for diabetes.<sup>2,3</sup> The report of Dr. Meinert invited comments concerning the recommendations of the Committee on Statistics of the American Diabetes Association.<sup>3</sup> The groups that conceived these three reports were quite aware of the existence of a considerable degree of disagreement and uncertainty among authorities in this field, but no attempt was made to study systematically the degree and character of these differences of opinion. Some of these problems have, however, been discussed by Unger,<sup>4</sup> Andres,<sup>5,6</sup> O'Sullivan,<sup>7-9</sup> Keen and Jarrett,<sup>10</sup> Hayner,<sup>11</sup> this author,<sup>12,13</sup> and others.

The purpose of this report is not to review this complex subject or to promulgate judgments about "proper" diagnostic criteria. Rather, it is simply to describe some of the differences that currently exist among criteria used by experts in this field and to explore certain of the implications of these differences.

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From the Department of Medicine, University of Oklahoma College of Medicine, 800 Northeast 13th Street, Oklahoma City, Oklahoma 73190.

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## METHODS

An informal survey was made of the diagnostic criteria currently employed by twenty physicians with a special interest in diabetes. There were two subgroups. Eleven diabetologists who are cooperating in a multinational study on vascular lesions of diabetes sponsored by the World Health Organization were sent a questionnaire. Nine responded. Specifically, the respondents were P.Z. Zimmet of Melbourne, Jean Pirart of Brussels, J.M. Malins of Birmingham, England, Vinod Kumar of New Delhi, F. Krolewski of Warsaw, Harry Keen of London, John Jarrett of London, Peter Bennett of Phoenix, and O.M. deAcosta of Havana. This group will be referred to as the international group. The second group of eleven American physicians was selected at random; ten of these were encountered consecutively at the 1973 scientific meeting of the American Diabetes Association. Eleven of twelve who were invited to do so completed a questionnaire provided by me. The respondents were Joseph Shipp of Omaha, Frederick Goetz of Minneapolis, Charles Shuman of Philadelphia, Stuart Soeldner of Boston, Reubin Andres of Baltimore, Holbrooke Seltzer of Dallas, Clifford Gastineau of Rochester, Minnesota, W.W. Pote of Turlock, California, John Colwell of Charleston, South Carolina, M.L. Sievers of Phoenix, and Kelly West of Oklahoma City. Both groups included some practicing physicians with special competence in diabetes but with no publications on diagnostic criteria, and some physicians with special academic interest in glucose tolerance tests.

In four of the twenty instances, the views of the experts were known to me prior to the survey through publications, conversations, etc. In sixteen instances, however, I had no prior knowledge of the criteria employed by these clinicians and scientists. The shortcomings of these informal sampling methods are acknowledged. It is not claimed that the frequency

distribution of responses of these diabetologists reflects perfectly those that would be obtained using more elaborate and sophisticated sampling methods in the entire community of diabetes experts. Nevertheless, I believe that the spectrum of responses in these arbitrarily selected groups are of interest and that they probably reflect fairly well the spectrum of criteria currently employed by diabetologists.

The written questionnaires were somewhat lengthy and will not be repeated in their entirety, particularly because they included additional aspects of this matter not covered by this report. The respondents were asked to interpret *plasma* glucose values (Auto-Analyzer method) obtained during a hypothetical oral glucose tolerance test performed under standardized circumstances on an asymptomatic middle-aged woman with mild obesity who had been observing an unrestricted diet. The age of the subject described to the American experts was fifty-one years and the one described to the international group was forty-eight, but otherwise conditions were the same. A hypothetical glucose load of 75 gm. was administered in the morning in the fasting state. The respondents were asked to indicate the lowest two-hour *plasma* value they would regard as "clearly abnormal," and the highest two-hour value they would consider to be "clearly normal." The American group were also asked for their criteria in interpreting fasting and one-hour values. The international group was also told to assume that the one-hour value was found to be consistent with the two-hour value, being 30 mg. per 100 ml. higher than the two-hour value.

## RESULTS

Variations in criteria for the two-hour value are shown in figure 1. In both groups the criteria employed were very similar, with respect to the mean, the range, and the frequency distribution. The means of these criteria are also quite consistent with the standards recently promulgated by the American Diabetes Association.<sup>1</sup> It is interesting, however, that in both groups the responses reflect a consensus that a broad range of borderline values is appropriate. For example, on the average, the American group allowed for a difference of 20 mg. per 100 ml. between the "highest value clearly normal" and the "lowest value clearly abnormal." The international group allowed, on the average, for a borderline range of 29 mg. per 100 ml.

The most interesting aspect of these responses is the rather considerable range in the criteria employed.

Interindividual differences in criteria up to 70 or 80 mg. per 100 ml. were occasionally observed, and differences of more than 20 mg. per 100 ml. were quite common. The Americans were also asked for their standards with respect to the interpretation of the fasting and one-hour values. The frequency distribution of one-hour values was again quite wide, ranging from 160 to 209 for "highest value clearly normal" and from 186 to 250 for "lowest fasting value clearly abnormal." Criteria for "highest fasting value clearly normal" ranged from 105 to 120, and for "lowest fasting value clearly abnormal" 120 to 160.

The data in figure 1 were examined to see whether the spectrum of results was significantly different between those with a special academic interest in glucose tolerance and those of the other diabetes experts. In both subgroups, the spectrum of responses was wide, and no difference was apparent in the levels of the criteria in these two small subgroups. For example, the two highest values were given by a scientist with publications on glucose tolerance and a practicing diabetologist with no such publications; and the values below the mean were provided by both "glucose tolerance scholars" and diabetologists with no special academic interest in diagnostic procedures. The eleven American diabetologists were asked whether they would have responded differently if the hypothetical subject were thirty-one instead of fifty-one years of age. Seven would have employed the same criteria, while four would have used criteria for one- and two-hour values that were on the average 10 mg. per 100 ml. lower.

## DISCUSSION

In certain populations, variations in diagnostic

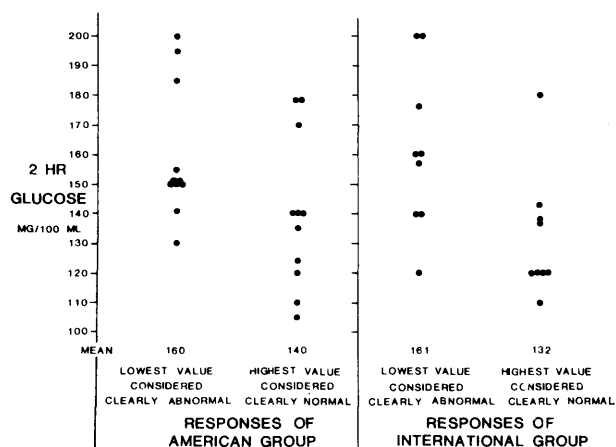


FIG. 1. Diagnostic criteria employed by diabetologists in interpreting two-hour values in a middle-aged subject.

criteria even of this degree would not result in many disagreements in classification. For example, our data from East Pakistan in 606 adults from the general population separated nicely into those that were clearly normal by any of these criteria and those that were clearly abnormal by any of these criteria.<sup>14</sup> Less than 1 per cent of these latter two-hour values would have been the subject of disagreement among any of these twenty diabetologists. But in the more affluent populations things are usually quite different, particularly in groups of subjects over thirty years of age. Differences in diagnostic criteria of modest degree result in disagreements of classification involving huge numbers of people. When, for example, these variations of criteria ranging from 110 to 200 (figure 1) are applied to the data of the population studied by Andres,<sup>5</sup> the following results are obtained: At age fifty the approximate prevalence of two-hour plasma values over 200 mg. per 100 ml. was 2 per cent; the frequency of values over 180 was 6 per cent, over 160 was 17 per cent, over 140 was 37 per cent, over 120 was 62 per cent, and over 110 was 73 per cent. Even when the lowest and highest diagnostic criteria in figure 1 are omitted entirely from consideration, these differences of criteria result in very large differences in the frequencies with which values would be classified as normal or abnormal. Thus, one of these remaining eighteen physicians would classify only about 2 per cent of these values from the population of Andres as "clearly abnormal," while another would have considered about 62 per cent "clearly abnormal"! Consider the implications, however, of even the more modest variations in criteria of, say, 20 mg. per 100 ml. About 20 per cent of the population at this age level studied by Andres had values from 140 to 160 mg. per 100 ml. Thus, even this modest difference would change the rate at which values were classified as abnormal from about 17 per cent to about 37 per cent.

These observations showing a high frequency of values in the "zone of contention" are not at all peculiar to the data of Andres. For example, in a group of women forty-five to fifty-four years of age from a representative sample of the United States population, 16 per cent had venous *whole-blood* values between 150 and 169 mg. per 100 ml. one hour after a glucose load of only 50 gm.<sup>15</sup> In women from sixty-five to seventy-four, 34 per cent had whole-blood values between 150 and 179. Similar analysis of the data of Hayner<sup>11</sup> from a general population (Tecumseh, Michigan) yielded comparable results. Most of the American diabetologists who responded to my survey on one-hour values would have classified more than 25

per cent of the values in the middle-aged people of Tecumseh as clearly abnormal, while some would have classified less than 10 per cent as clearly abnormal. By standards of some of these diabetes specialists, less than 10 per cent of Americans over thirty years of age have "clearly abnormal" two-hour values or "clearly abnormal" one-hour values, while others use criteria that would classify more than one third of both values as "clearly abnormal."

As has been previously pointed out, the "criteria problem" becomes increasingly important with advancing age of the population tested.<sup>6,9-12</sup> One reason for this is that small differences in criteria may in these older groups account for very large differences in rates of diabetes, as noted above. This problem is not peculiar to the United States. By certain conventional criteria about half of the elderly in the general population of Bedford, England, have abnormal tolerance; and in segments of that population over forty years of age, modest differences in diagnostic criteria produce very large differences in rates of abnormality.<sup>16</sup>

There are some reasons to believe that differences among countries in the diagnostic criteria typically employed are probably less than differences among diabetologists who participated in this survey. For example, I asked our international group of respondents to give their impressions as to how their own criteria compared with those of their domestic and foreign colleagues. These responses will not be presented in detail, but they suggested that in six of seven countries typical diagnostic criteria were thought to be close to the mean of the responses in figure 1. These latter responses also suggested that the wide departures from the mean were not the result of ignorance of the opinions and practices of other experts. Before they knew the results of the survey, all four of those who used the highest criteria correctly predicted that most of their foreign and domestic colleagues would recommend lower criteria. On the other hand, each of three diabetologists who used the lowest criteria did think that his foreign colleagues would use criteria that were about the same as his own. It should be pointed out, however, that with one possible exception the values used by these three diabetologists are within the range of those that have been traditionally employed. Most of the spread in the values is seemingly attributable to the use, by some, of the criteria that are higher than those that have been traditionally promulgated. The results in figure 1 suggest that the "traditionalists" who use lower values are still in the majority both in the United States and abroad, although it would appear that the number

who are using higher values is increasing.<sup>12</sup>

The limitations of this survey are acknowledged. Several other factors not measured in this survey would determine the effect of these differences in criteria on purported rates of prevalence of "diabetes." These would include the frequency of diagnostic and screening procedures, criteria of selection of subjects for screening and diagnostic tests, the methods of testing employed, and other factors. There are also several other interindividual variables of significance that were not measured in this survey. These include variations in the number and character of other indices that these respondents may employ in decision making (e.g. plasma glucose values at ninety or 180 minutes) and the relative weights they may assign to the results of determinations at the various intervals. For these and other reasons, it is not possible to determine precisely the comparative frequency with which the respondents would make or exclude the diagnosis of diabetes in a given population. The data do suggest, however, that these differences would be quite substantial in middle-aged and older segments of most Western societies.

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