

## REPORT OF THE GLOUCESTER DIABETES STUDY

# Evaluation of a Method of Self-Testing for Diabetes

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A need exists for a practical and economical method of identifying the numerous, undiscovered cases of diabetes mellitus. It has been estimated that in the United States there are approximately one million diabetics with the disease undiagnosed.<sup>1</sup> To discover these cases in their incipiency requires organized case-finding programs. Such programs usually are expensive undertakings, since they require special equipment and trained professional personnel. For this reason, a relatively simple, inexpensive procedure has been sought which could be used satisfactorily as a mass case-finding method.

Self-testing of urine is used successfully by certain groups of lay individuals. For the most part, these are persons with diagnosed diabetes mellitus who have been trained to employ a self-test method and to interpret correctly the results of their tests as an integral part of a regime for therapeutic control. Whether or not this same technique of self-testing may be employed successfully in communities as a case-finding technic has never been satisfactorily established.

The purpose of this communication is to report the results of a study designed to answer these questions: Is

it possible for large groups of lay individuals to perform accurately the self-test for sugar in urine samples? If so, do those whose tests indicate the presence of excess sugar in their samples seek further diagnostic studies? These were the basic questions which apparently had to be answered, in order to justify the use of the self-test method for mass surveys in diabetes detection. It must be emphasized that the study, conducted in Gloucester, Massachusetts over a two-month period, was not intended to locate new cases, but rather to measure the ability of a large group of people to perform a specific technique, to interpret correctly the results of their tests, and to act upon these results.

Gloucester is a community of approximately 28,000 persons. Its area of 26 square miles includes several distinct villages separated from each other by a few miles of roads. Racially, the community is divided into four groups—Italian, Portuguese, Finnish, and "Old Gloucester Yankee" stock. Although in the summer months a substantial income is derived from a large influx of tourists, fishing is the principal year-round industry.

This project was undertaken by the Massachusetts Department of Public Health, the Diabetes Control Section of the United States Public Health Service and the Diabetes Committee of the Massachusetts Medical Society, with the cooperation of the medical staff of the Addison-Gilbert Hospital, in Gloucester. Through a grant from the Nordisk Insulin-fund to the American Diabetes Association, funds were provided to assist in carrying out the survey. This grant was secured through the interest and cooperation of Dr. Elliott P. Joslin.

#### METHOD OF STUDY

The Gloucester study was not a case-finding program but an evaluation of a community's ability to perform a specific procedure, i.e., the self-test for urine sugar. The first step was to secure public interest in and understanding of the program. For this purpose, a Citizens' Committee, composed of representatives of various racial, religious, social, labor, business and professional groups of Gloucester, was organized. Public interest in the program was stimulated by numerous newspaper articles, both on diabetes mellitus and on the proposed study, by programs on the local radio station, and by a film on diabetes control, exhibited at a Gloucester theatre. Moreover, a letter explaining the study was prepared and mailed by the Committee to the 8,000 householders of the city.

Concurrent with this publicity, an interviewing team (which was to conduct follow-up studies on those who participated in the program) received indoctrination re-

garding diabetes mellitus. A pretested 41-line questionnaire was designed for these subsequent studies. The interviewing team gained experience in its use by conducting a pretest on 100 individuals employed in a Boston office. The completed questionnaires on 2911 survey participants provide the source material for all analyses contained in this report.

With the cooperation of the Gloucester drugstores, self-testing kits were made available for public distribution. Each kit contained sufficient material to perform two urine tests and included printed instruction for the collecting and testing of specimens, with advice to report any "suspicious" findings to a physician. As these kits had been donated by a private firm for research purposes, no charge was made for them.\* However, each person had to go to a drugstore and register by name, address and date, in order to obtain the kit. By means of this registry, the interviewing team was able to contact survey participants for follow-up studies regarding the use of the test material. It is appreciated that, had a charge been made for procuring the kits, not only the number and characteristics of the individuals in the cooperating group but also their responses might have differed from the present findings. Within four days following the appearance of the self-test kits in the drugstores the entire supply was exhausted.

#### EXTENT OF COMMUNITY PARTICIPATION

An accounting for the distribution of 3252 kits was obtained from the registration cards made out in the drugstores. The kits were distributed primarily to residents of Gloucester, and only about 5 per cent were received by the summer visitors. It is estimated that the surveyed population comprised about 20 per cent of the Gloucester population in the age groups 20 to 65, but the percentage was less under and over this age group.

The 1950 census was not available, but the population of Gloucester recorded in the four preceding censuses has not differed greatly, ranging from 24,046 to 24,862. The surveyed population probably included a somewhat smaller percentage of males than the Gloucester population. In 1940, males comprised 48.7 per cent of the Gloucester population, while they made up 46.6 per cent of the surveyed population.

In Table 1 is shown the distribution, by type of performance, of the 3252 persons responding to the community campaign to participate in the self-testing program.

\* Assistance given by the Ames Company, Inc., of Elkhart, Indiana, is gratefully acknowledged.

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TABLE 1 DISTRIBUTION OF REGISTRANTS—BY TYPE OF PERFORMANCE

Total number of individuals who registered for and accepted kits		3252
Number performing self-tests	1730	} 2911
Number not performing self-tests	1181	
Number of "lost persons" who could not be located for interview"		341

From the above table it may be seen that complete information could be obtained from 2911 persons relative to use or non-use of the self-test. Of this group 1730 (59 per cent) actually performed the test whereas 1181 individuals (41 per cent) failed to perform the test once they had obtained the material. Reasons for this failure are discussed later.

With the test employed in this study, sugar in the urine amounting to more than 0.2 per cent resulted in color changes ranging from green, olive green, tan, orange to brown, depending upon the amount of glycosuria.

The following instructions for interpreting and acting upon the results of the self-test were given in the instruction sheet included with each kit:

1. Blue means "negative"—no sugar.
2. Any other color means "positive," "suspicious," or sugar present.
3. If the color change was anything beyond green, the examinee was advised to report his findings to his physician in order that the cause of the glycosuria might be determined.
4. With a single green result, the examinee was advised to repeat the test on a second urine sample.

5. If the second test resulted in a color change of any sort, that is, if it was other than blue, the examinee was urged to notify his physician.

In a community-wide undertaking in which self-testing is employed as a screening device, the technical instructions must of necessity be brief, simple and definite. The categories of "suspicious" and "negative" results presented in Table 2 conform with the criteria used by the participants in this self-testing program.

RESULTS OF SELF-TESTING

Of the 1730 individuals known to have performed the test, 1526 persons, or 88 per cent, had results classified as "negative," and 98 persons, or 5.6 per cent had "suspicious" findings. The remaining 106 persons, or 6.2 per cent, could not be classified in either of the above categories (Table 2). The majority of this category were those who, after obtaining a green reaction with the self-test, failed to follow instructions, i.e., to repeat the test on a second urine sample.

The self-testing urine procedure, as well as any detection method based upon a single determination, appears to have certain inherent weaknesses. Even mild glycosuria should not be lightly passed over by the clinician. Some persons with this finding may appear at first to be nondiabetic, but upon long-term follow-up are found to have diabetes, as has been shown by Joslin, Root, and others.<sup>2</sup> Moreover, the single negative determination should not be used for the exclusion of diabetes, as has been pointed out by Beaser<sup>3</sup> and Harting.<sup>4</sup> These weaknesses are recognized as existing in the self-testing procedure as it has been employed here.

TABLE 2 RESULT OF SELF-TESTING BY 1730 INDIVIDUALS ACCORDING TO COLOR REACTIONS OBTAINED

Color Reaction		Known Diabetics No. Persons	Other Examinees No. Persons	Totals	
Test 1	Test 2			Number	Per Cent
<b>Negative Group</b>					
Blue	(Blue)	33	1405	1438	} 1526 88.2
Green	Blue	1	87	88	
<b>Undetermined Group</b>					
Green	—	0	98	98	} 106 6.2
Green	Unknown	0	1	1	
Unknown	—	0	7	7	
<b>Suspicious Group</b>					
Green	Green	8	67	75	} 98 5.6
Yellow, Orange or Brown		5	18	23	
<b>Totals</b>		<b>47</b>	<b>1683</b>	<b>1730</b>	<b>100.0</b>

TABLE 3 DISTRIBUTION OF "SUSPICIOUS" CASES SEEKING MEDICAL ADVICE BY RESULTS OF SELF-TESTING

Color Reaction		Cases with Suspicious Findings			Suspicious Cases Seeking Medical Advice	
Test 1	Test 2	Known Diabetics	All Others	Total Number	Number	Per Cent
Green	Green	8	67	75	18	24.0
Yellow, orange or brown		5	18	23	5	21.7
Totals		13	85	98	23	23.5

However, it is obvious that the self-testing procedure could be used more effectively if all those having results classified as "suspicious" (i.e., green, yellow, orange or brown reductions) secured diagnostic studies from physicians. The fact that the population under study failed in this respect is illustrated in Table 3.

Of a total of 98 persons with suspicious findings (and including 13 known diabetics) only 23 or 23.5 per cent visited their physicians for diagnostic follow-up studies; in other words, over three-fourths of this group, 76.5 per cent, failed to seek further advice. The inclusion of diagnosed cases of diabetes in these figures is a condition which could not be avoided, as no selectivity was employed in the choice of individuals wishing to participate in the survey.

#### INTERPRETATION

One of the most interesting aspects of the survey was the manner in which the examinees interpreted the results of their tests (Table 4). These interpretations were obtained in response to the interviewers, question: "What does the color result of your test mean to you?"

A negligible number of those who had had "negative" reactions believed they had diabetes. However, of the group of 98 persons with "suspicious" findings, 35

per cent interpreted their test results as indicating that they had either no diabetes or no sugar in blood or in urine, and only 23.5 per cent interpreted their positive tests as indicating a need for obtaining diagnostic studies to determine the cause of the glycosuria.

Another finding of interest, which also pointed up the inability of the population under study to perform mass self-testing successfully, was found within the group of 262 individuals each of whom had obtained a green reduction with the self-test. Ninety-eight (37 per cent) of those obtaining a green reduction failed to examine a second specimen as instructed.

Apparently a relationship exists between the number of examinees correctly interpreting their suspicious findings and the number of physician referrals. Only 23 (23.5 per cent) of those in whom the presence of diabetes should have been seriously suspected interpreted their results as indicating the need for further studies by a physician. The same number (23.5 per cent) did make a visit to their physicians because of their suspicious findings. It should be mentioned that within this group of 23 individuals, two were known diabetics who believed that because of these positive findings, further medical advice was required.

#### COMPARISON OF PERFORMERS AND NON-PERFORMERS

Of the 2911 individuals on whom complete follow-up studies were obtained, it was found (Table 1) that 1730 (59 per cent) performed the self-test while 1181 (41 per cent) failed to use the kits they had obtained. A comparison of these two groups was undertaken in an effort to determine what similarities and differences characterized performers when compared with non-performers.

With respect to age and academic levels, there was no significant difference. Forty-four per cent of the performers were males, as compared with 49 per cent of the non-performers. The two groups differed in respect to the reasons given for having secured the kit. Of those who actually self-tested, a larger percentage claimed

TABLE 4 INTERPRETATION OF RESULTS OF SELF-TESTS BY 1730 EXAMINEES

Interpretation of Results by Examinees	Neg. Results No. Persons	Unconfirmed Results No. Persons	Suspicious Results	
			No. Persons	Per Cent
"No disease" or "No sugar"	1518	49	34	34.7
Might have diabetes	1	6	22	22.4
Sugar in urine or blood	0	8	17	17.3
Repeat the test	2	36	0	—
See my physician	0	4	23	23.5
No opinion	5	3	2	2.0
Totals	1526	106	98	99.9

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they obtained the kits because of a willingness to participate in a community endeavor, a fear of the disease, or the presence of diabetes mellitus in the family, than was found in the group who failed to perform the test. On the other hand, a smaller percentage of participants than of non-participants secured the kits because of family advice (Table 5).

TABLE 5 REASONS FOR SECURING KITS

	Non-Performers Per Cent	Performers Per Cent
Diabetes in self or family	8.2	11.1
Worry	5.6	9.3
Civic response	10.6	15.6
Recommended by physician, druggist or other individual	7.8	5.4
Recommended by family	27.8	16.0
Preventive measures	30.3	34.1
Curiosity	7.8	7.9
Other reasons	1.8	0.7
Totals	99.9	100.1

Apparently those who accepted the kits and performed the test actually had a closer association with diabetes than did those who did not use the kits. That is, a higher percentage of diabetes in their own or their spouses' families was found to exist in the group of individuals who performed the test (Table 6).

TABLE 6 PRESENCE OF DIABETES IN FAMILY OR SPOUSE'S FAMILY

	Non-Performers Per Cent	Performers Per Cent
Acceptor had diabetes	1.2	1.9
Acceptor had diabetes, and diabetes in family	0.2	0.8
Acceptor had diabetes, and diabetes in spouse's family	0.0	0.2
Diabetes in own family and in spouse's family	0.8	1.4
Diabetes in own family only	15.4	17.9
Diabetes in spouse's family only	6.5	8.2
No diabetes	76.0	69.7
Totals	100.1	100.1

Those performing the test also had a larger number of friends afflicted with diabetes than did those failing to self-test, the respective rates being 57 and 46 per cent.

When the 1181 individuals were questioned regarding their failure to use the kits, the most frequent answer was that they had "lost interest" in performing the tests. Nearly a third stated that they still intended to use the kits, but since these individuals were interviewed two to four weeks after the kits had been obtained,

it is doubtful that they were or ever will be used. The next most frequent reason given for failure to use the kits was that they had mechanical or other hindrances. These hindrances included broken test tubes and droppers, and lost tablet reagents, but the primary hindrance was repeated failure to remember to do the test at the proper time after a meal. Slightly over 20 per cent gave some reason of this kind. Six individuals stated that they lost courage to perform the test. This small number would indicate that among those who obtained the kits, phobia was a negligible factor (Table 7).

TABLE 7 REASONS FOR NOT USING THE KITS AMONG 1811 INDIVIDUALS

Reason	No. Persons	Per Cent
Lost interest	485	41
Procrastinated	340	29
Had mechanical or other hindrances	242	20
Had recent test	75	10
Threw kit away	20	
Gave kit away	13	
Lost courage	6	
Totals	1811	100

Among the 1730 persons who self-tested, approximately 75 per cent reported no difficulty in performing the test strictly according to instructions; 8.2 per cent admitted having difficulties, mainly in respect to recognizing the color, following the instructions or interpreting the results; and 16.9 per cent experienced no difficulty but admitted they did not follow the explicit instructions, particularly in regard to the time of collection of urine in relation to their meals (Table 8).

TABLE 8 DIFFICULTIES NOTED BY 141 SELF-TESTERS

Difficulties Encountered	Number
Determination of color	70
Following instructions	30
Interpretation of results	16
Performance of test	6
Use of equipment	4
Color and interpretation of results	4
Collection of urine sample	2
Instructions and color	2
Instructions and collection of sample	2
Equipment and determination of color	1
Performance of test and use of equipment	1
Interpretation of results and performance of test	1
Color, performance of test and use of equipment	1
Instructions and performance of test	1
Total	141

Of the group of 3252 studied, 242, as shown in Table 7, did not do the test because of mechanical or

other hindrances, and 141, as shown in Table 8, actually experienced technical difficulties in the performance of the test. The total number having difficulty of some kind was greater than 10 per cent. Therefore, the question of technical difficulties cannot be considered a negligible factor in the failure of the population to use such self-test procedures successfully.

At least four factors influencing the success of a self-testing program seem to stand out significantly in this study. The first is the loss of interest by the participants; the second is procrastination in performing the test; the third is inaccurate interpretation of the test; and the fourth is the failure of the majority of those with suspicious results to seek medical advice.

#### DISCUSSION

Few attempts have been made to approach any important health problem by distributing equipment and instructions *en masse* for carrying out in the home the technical procedures for diagnosing disease. Therefore, this study in Gloucester, Massachusetts, represented a new departure, the prime purpose of which was to ascertain whether or not a sample of the American population is ready to accept such material, to carry out the procedure and then to take necessary further steps in the direction of medical care. This is a question of basic importance, not only in the field of detection of diabetes but in other fields of preventive medicine and health protection. For example, in time of national emergency it might be desirable to distribute technical equipment and information with instructions to large groups of the population. Such a distribution might have importance in the field of nutrition and nursing as well as in the care of injuries in such an emergency.

An important need exists for early diagnosis of diabetes in order that the patient may be brought under prompt continuous medical care. The great bulk of diabetic patients develop the disease in middle life, and the condition then often exists for many months or even years without the patients' suffering marked and recognized symptoms. Lack of control of diabetes during this period may leave serious sequelae in the retinae and the cardiovascular-renal system, many of which might have been prevented or postponed had the patient received adequate medical care and in particular adequate instruction in the care of the skin and the feet, and the proper use of diet and insulin.

The interest of the public in this field has tremendously increased during the last 25 years. Indeed, in Gloucester the fact that every test kit was picked up

within 4 days after the announcement date confirms this impression.

The fact that of the group with positive or suspicious findings only 23.5 per cent sought medical advice seems discouraging. However, certain facts must be taken into consideration not only in interpreting these results, but in attempting to draw conclusions which might be of value to others who may consider similar studies. In the first place the distribution of this technical equipment was not accompanied by any personal advice as might have been accomplished if the distribution had been in the hands of family physicians. Obviously a distribution by family physicians would not have satisfied the objectives of this particular study, which were intended to ascertain the responsiveness of the general public to a program without such personal influence. However, in order to secure the widest possible distribution and highest rate of performance of the test in future distributions of equipment for a medical study, great advantage might accrue if the distribution were made through family physicians as well as through public facilities. The physician might answer questions at the time of the distribution which would aid the recipients in securing better understanding. Another factor probably affecting both distribution and use of the self-testing kit was that of lack of cost. It seems logical to contend that an article which has a purchase price will be more slowly distributed than if it were free. Contrariwise, a purchased article would more likely be used.

A third of the 98 patients whose tests really were suspicious interpreted the results as "no disease" or "no sugar." Twenty-two per cent simply reported that they interpreted the result as meaning that they might have diabetes. Twenty-three of the 98 patients consulted their physicians. The implications of such results make clear that a great increase in efforts to disseminate health information to the public is needed. Although the information should be distributed in such a manner as not to arouse needless fears, it should be expressed in terms that will bring the problem home to the individual.

This study indicates the existence of a wide community interest in any attempt to prevent health disorders by early detection. New methods must be developed which will be more effective. The active participation of all physicians as well as of all public health and educational agencies is necessary in any community program which has for its objective a wide and well-planned health education program which will bring under prompt and continued medical supervision all patients discovered to have diabetes.

## SUMMARY

1. The results of a study designed to evaluate the self-testing method of discovering glycosuria in a diabetes detection program have been presented.

2. With adequate community organization providing advance publicity, good acceptance of the program by the public was obtained.

3. An analysis of follow-up studies on 2911 individuals who had obtained self-test kits revealed that 59 per cent performed the self-test and that 41 per cent failed to use the equipment. A comparison of these two groups revealed reasons for performance and non-performance.

4. The majority of those who did not test their urine either lost interest in the project or procrastinated in carrying out the procedure.

5. Among those who performed the test there was found more fear of the disease and a close association with diabetes in family, among friends, or in spouse's family.

6. In the group which performed self-tests, 88 per cent had negative results, 5.6 per cent had positive results, and 6.2 per cent had undetermined results (single green tests).

7. Only 24 per cent of those with positive results interpreted these findings as indicating a need for medical advice, while 36 per cent of the positive group believed that their positive tests indicated that they had no disease or no sugar in their blood or urine.

8. Of those with positive results, 76 per cent failed to obtain medical advice.

9. To obtain a high degree of performance of even as simple a test as the test for glycosuria, maximal cooperation, including participation, of all physicians as well as all public health agencies is desirable.

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## ACETONE IN THE BREATH

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