Self-Monitoring of Capillary Blood Glucose: Changing the Performance of Individuals with Diabetes

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Standard reflectance meters were modified by the addition of memory chips capable of storing 440 glucose determinations with corresponding time and date. These modified reflectance meters (MR) were given to 20 individuals with type I diabetes in an effort to determine the level of reliability and accuracy they could achieve on a self-monitoring regimen. During a 6-wk period these subjects measured their capillary blood glucose and recorded the results in a logbook (LB). At 2-wk intervals they visited the clinic. Data from the MR was offloaded onto an Apple IIe microcomputer (Apple Computer, Inc., Cupertino, California) and presented to the subjects in a graphic format, depicting the level of metabolic control over the previous 2 wk. The performance of subjects for the 6-wk period showed that they averaged 7 omissions from the LB for every 100 MR recordings; 1 added value in the LB for every 200 MR recordings; and 1 error in accurately copying the test value for every 100 determinations. In comparison with subjects who participated in an earlier study in which they were unaware of the memory function of the reflectance meter, performance during the current study improved in all categories. It was also observed that consistency in reliable and accurate record keeping did not diminish throughout the study period. Despite these positive changes in performance, no alteration in glycemic control was found. DIABETES CARE 1985; 8:207–13.

Current approaches to the treatment of insulin-dependent diabetes (IDDM) require a substantial involvement of the individual with diabetes in the monitoring of glycemic control and clinical decision-making.[1,2] This is most evident with respect to regimens based on multiple injections of mixed insulins or continuous subcutaneous insulin infusion.[3,4] Because the individual's performance is central to these regimens, compliance has been a major focus of concern. Many recent studies have attempted to analyze those factors that contribute to adherence, examining health beliefs,[5,6] treatment environment,[7,8] family interaction,[9] education,[10–14] complexity and duration of the regimen,[15–18] and knowledge of the disease process and severity of the illness.[19–21] They have, however, been unable to develop a consistent explanation for noncompliant behavior. Other investigators have tried to develop a psychosocial profile of noncompliant individuals in an effort to provide an easy method of identification before the behavior occurs and to find appropriate intervention strategies.[22–24] Despite these and other studies,[25] no composite profile of the noncompliant person has emerged.

In two recent studies of individuals with IDDM, we attempted to address the question of their adherence to complex regimens requiring multiple injections of insulin with frequent self-monitoring of capillary blood glucose (SMBG).[26,27] While we were unable to identify the specific psychosocial characteristics of those individuals who consistently adhered to their regimen versus those who did not, we were able to identify the nature of noncompliant behavior and to measure it using specially modified reflectometers with memory chips (MR) capable of storing glucose readings with time and date. In these studies, the subjets were unaware of the reflectometer modification and were instructed to use the meter in conjunction with logbook (LB) recordings. When we compared the data stored in the MR with the data recorded in the subjects' LBs we found that the subjects reported significantly (P = 0.0001) lower blood glucose values in their LBs than had actually been recorded in the MR. The pattern of noncompliance consisted of adding fabricated test scores to the logbook, and omitting or lowering actual test values. This resulted in the omission of hyper- and hypoglycemic events from the LB records, with serious consequences for clinical

TABLE 1
Subject performance during the 6-wk study period

Subject no.	Age/sex	Duration of diabetes	$\bar{X}$ Tests/day	$\bar{X}$ MR	$\bar{X}$ LB	%UR*	%OR†	%PR‡
1	22/M	7	6.0	82	83	0	0	100
2	41/M	13	3.4	83	84	7	0	98
3	18/F	2	1.6	110	110	31	0	100
4	14/F	3	4.0	114	112	5	0	91
5	32/F	6	5.5	120	121	0	0	100
6	30/F	14	4.2	131	138	2	0	98
7	34/F	10	8.0	136	136	22	0	100
8	28/F	5	4.4	140	139	0	0	100
9	30/M	7	3.6	146	148	5	3	100
10	29/F	2	3.7	156	157	0	1	99
11	24/F	4	5.9	158	159	2	0	98
12	28/F	15	5.3	178	178	0	0	100
13	34/F	6	3.8	178	178	0	0	100
14	34/F	8	4.6	186	189	1	0	100
15	21/F	11	4.0	190	193	9	5	99
16	29/F	11	4.8	194	196	42	0	98
17	41/F	28	5.3	209	209	0	0	100
18	27/F	10	4.6	219	220	11	0	98
19	23/F	11	2.9	254	254	0	0	100
20	23/F	11	3.3	315	312	0	0	100

Measures of reliability and accuracy:[27]
*% Underreporting = [number of MR readings − (number of corresponding MR and LB readings)]/[number of MR readings] × 100.
†% Overreporting = [number of LB readings − (number of corresponding MR and LB readings)]/[number of LB readings] × 100.
‡% Precision = [number of identical MR and LB readings]/[number of corresponding MR and LB readings] × 100.

decision-making for both the person with diabetes and the health care provider.

In the current investigation, the subjects were informed about the memory function in the reflectometers and were provided with a microcomputer-based feedback system that facilitated analysis of self-generated blood glucose data. The fourfold purpose was: (1) to determine to what degree performance could be altered by informing the subject about the memory capability of the reflectometer and by providing direct feedback about performance from the memory recordings; (2) to measure the maximum level of precision achievable by the subject using the MR; (3) to gauge the consistency in accuracy and reliability that could be attained by the subject over the course of the study; and (4) to determine the extent to which metabolic control was affected by self-monitoring behavior.

METHODS

Twenty individuals (see Table 1) with type I diabetes volunteered to enter this study. All subjects were treated on a regimen of multiple injections (two or more per day) of mixed insulin with SMBG using a Glucometer (Ames, Elkhart, Indiana). As part of the standard treatment regimen, subjects were instructed to record capillary blood glucose data, insulin dose and type, diet, exercise, and symptoms of hypo- and hyperglycemia in an LB that was to be available at each clinic visit. The subjects ranged in age from 14 to 41 yr, with an average age of 28.1 ± 1.5 yr (mean ± SE). There were 17 female and 3 male subjects, whose average duration of diabetes was 9.2 ± 1.4 yr. All subjects attended high school; 11 attended college. The subjects came from the New York metropolitan area, equally divided between urban and suburban residences.

Six standard reflectometers, modified by the addition of a memory chip, were used in this study.[27] Each instrument is able to store 440 glucose readings along with the corresponding time and date of the test. These reflectometers are directly linked through an RS-232 interface to an Apple IIe microcomputer for offloading. A data management program designed for the Apple IIe is used to analyze the data. It produces both instant screen and print formats. These displays include all glucose determinations by date with the corresponding time, aggregation of glucose readings into one modal day with mean and standard deviation values for all determinations (provided at 15-min time intervals), and the mean blood glucose levels calculated for the study period (see Figure 1).

For this study, the subjects were instructed to use the MRs in conjunction with the maintenance of LB records. Individuals were to enter the glucose value with the corresponding time and date in their LB. The subjects were specifically informed about the data storage and reporting capabilities of the MR. They were requested to continue their regimen as before and not to change either the testing frequency or timing during the study period. To insure the subjects' performance, study participants demonstrated SMBG procedures before an observer. Additionally, each instrument was tested against both laboratory determinations and other reflectance meters.

At three 2-wk intervals, the subjects returned to the unit with both the LB and MR. Data from the MRs were offloaded onto the Apple IIe computer, and printouts containing the raw test values as well as summarized values were shown to the subjects by a member of the health care team. At these clinic visits, the health care providers encouraged the subjects to study their data to help them gauge their level of metabolic control. Simultaneously, LB data (consisting of the glucose value with corresponding time and date, and insulin dose with type, time, and date) were directly entered into the Apple IIe, but not presented to the subjects. During this experiment, feedback about the consistency between LB and MR data was not given to the subjects.

Measures of the accuracy and reliability of the subjects' performance were calculated using MR data as the standard against which LB recordings would be evaluated. We used three measures (Table 1) from our previous study: overreporting, underreporting and precision.[27] Overreporting was calculated by determining the percentage of LB recordings that had no corresponding MR reading. Underreporting was calculated by determining the percentage of MR readings that were omitted from the LB records. Precision was the percent of LB recordings that were identical in value to recordings in the MR taken at the corresponding time. Paired *t*-tests were used to determine whether there was a significant difference in the subjects' performance at specified time points.[28]

RESULTS

Twenty subjects completed the study as designed. The average duration of participation was 40 days, ranging from 28 to 55. The mean number of determinations made by these subjects was 182, ranging from 44 to 283, with an average of 4.6 each day. The mean blood glucose level for the 6-wk study period determined from the MR data was 165 mg/dl, and the average blood glucose level calculated from the LB records for the same period was 167 mg/dl.

Subject performance (see Table 1) during the study period revealed that underreporting, a measure of the degree of omission of true reflectometer readings from the LB, occurred in 11 cases (nos. 2, 3, 4, 6, 7, 9, 11, 14, 15, 16, and 18). This resulted in an overall average score of 6.8% (or 7 of every 100 MR recordings was not recorded in the LB), with a range of 0–42%. In contrast, for all 20 subjects, the mean overreporting score, a reflection of the willingness of subjects to add unconfirmed recordings to their LB records, was less than 0.5% (or 1 per 200 LB recordings was not corroborated by an MR reading). Three subjects (nos. 9, 10, and 15) were discovered to have added values. Precision, a measure of the degree to which the subject accurately recorded the test results at a time corresponding to the test, averaged at 99%. No subject achieved a score of less than 91% on this dimension. In no instance did the level of inaccuracy lead to a substantial

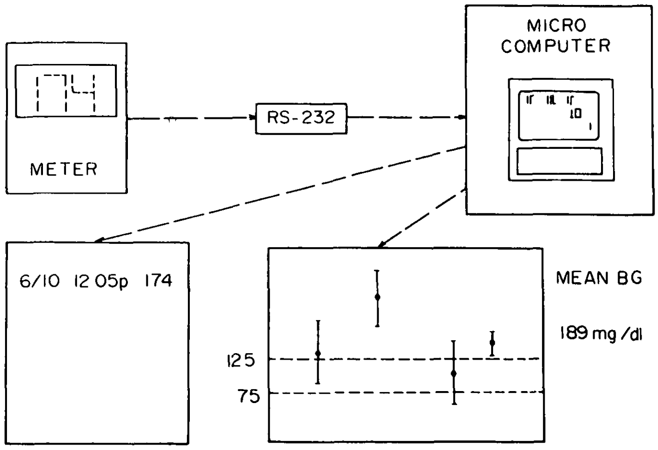

FIG. 1. Computer-based patient management system. Glucose readings are entered into the reflectance meter's memory as they appear in the meter's window. The time and data corresponding to the reading are also entered. The meter connects through an RS-232 interface to the Apple IIe microcomputer. A program to enter the data onto a subject file is activated. Once in the computer, the data can be stored on a disk, displayed on a screen, or printed. The formats are menu-driven.

difference in the reported (LB) level of glycemic control and that found in the MR. Twelve subjects recorded the results of the capillary blood tests with 100% precision.

To determine whether performance during the 6-wk study period varied in terms of overall reliability and accuracy, we compared mean overreporting, underreporting, and precision scores (not shown) at the three 2-wk intervals (corresponding to clinic visits) of the study period. The scores on these dimensions did not differ significantly from interval to interval.

Next, the differences in performance between subjects participating in the current study with those of the previous study (when they were unaware of the memory capability of the reflectometer) were examined (see Table 2). Of the 20 subjects who participated in the current study, 13 took part in the earlier 2-wk study. The mean scores for overall reliability and accuracy were different when they were compared with the current study: (1) underreporting, 10% versus 7% (P = NS); (2) overreporting, 34% versus 1% ($P = 0.0027$); (3) precision, 72% versus 99% ($P = 0.0037$).[20] During the current study underreporting reduced from 2% to 23% (with the exception of subject no. 16, whose score increased by 42%); overreporting reduced from 1% to 82% compared with the 2-wk period, and precision increased by 1–98%. These changes occurred without any significant (P = NS) alteration in the frequency of testing between the earlier study (2 wk) and the current study (6 wk) among those who participated in both studies.

On an individual basis, a substantial change in performance was recorded when these subjects knew about the reflectometer modification. For example, subject no. 12 (see Figure 2) improved in overall reliability and accuracy, with a 12% decrease in underreporting, a 37% decrease in overreporting,

TABLE 2
Subject performance during the blind study versus the informed study

Subject no.	Previous blind study without memory feedback				Current study with memory feedback			
	X̄MR	%UR	%OR	%PR	X̄MR	%UR	%OR	%PR
1	113	0	0	87	82	0	0	100
2	144	10	82	0	83	7	0	98
3	94	54	70	54	110	31	0	100
8	146	6	12	62	140	0	0	100
9	156	0	2	85	146	5	3	100
10	154	2	0	98	156	0	1	99
12	186	12	37	84	178	0	0	100
13	202	8	55	45	178	0	0	100
14	145	14	53	84	186	1	0	100
15	190	3	8	98	190	9	5	99
16	221	0	61	65	194	42	0	98
17	266	8	0	100	209	0	0	100
20	313	10	56	77	315	0	0	100

and a 16% increase in precision. The pattern observed during the earlier study, where actual high glucose test results were reported in the LB as lower readings, was not repeated during this investigation. Previously, severe hyperglycemia had gone unreported when the subject was unaware of the MR capability, resulting in an LB mean glucose of 165 mg/dl. At that time, the MR mean was 186 mg/dl, consistent with the 6-wk pattern (178 mg/dl) uncovered during the current study.

Subject no. 20 (see Figure 3), whose earlier behavior was characterized by a pattern of reporting lower than actual glucose values in her LB during the second half of that study, scored 0% overreporting, 0% underreporting, and 100% precision during the current investigation. This subject's LB calculated mean glucose was more than 100 mg/dl lower than the actual (MR) level during the previous study. The MR and LB mean blood glucose levels were virtually the same (315 mg/dl versus 312 mg/dl) during the current study, corroborating the pattern of hyperglycemia that was uncovered earlier.

Similarly, subject no. 2 (see Figure 4), whose overreporting score of 82% was the highest and precision of 0% the lowest for all subjects in the previous study, scored 0% overreporting and 98% precision during the current investigation. This subject's previous pattern was to test one time per day, lower that result, and add four fabricated readings to the LB; however, when the subject knew of the memory capability of the reflectometer the actual testing was increased to 4 times per day without error in precision, with no overreporting, and with the omission of fewer than 1 in 15 actual glucose determinations from the LB record. This new performance uncovered a blood glucose range of 30–220 mg/dl, with more than $\frac{1}{3}$ of the readings <60 mg/dl. This revealed a pattern of hypoglycemia that had previously gone undetected.

Next, we examined whether the high reliability and ac-

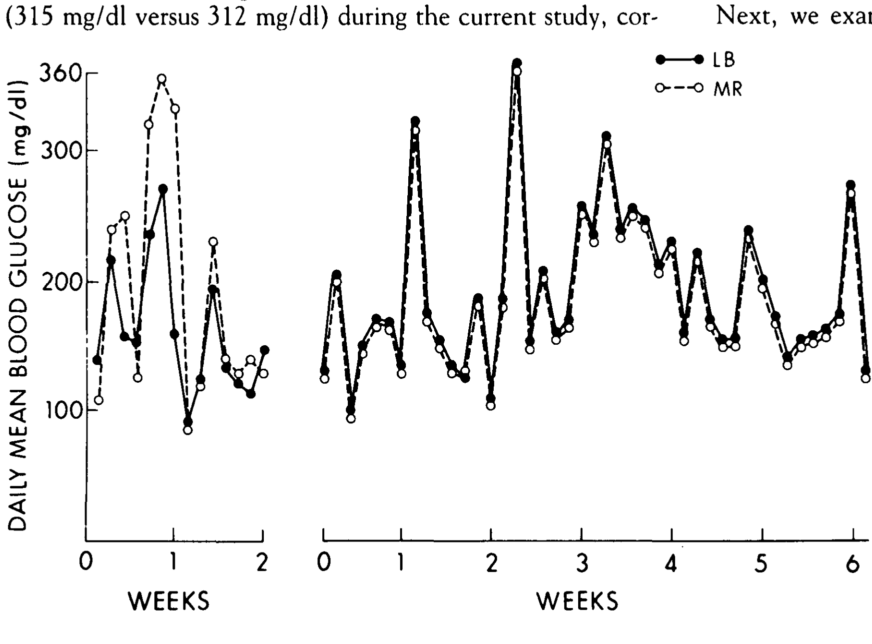

FIG. 2. Individual subject performance: subject no. 12. Each circle represents the daily mean blood glucose. The closed circles and solid lines represent the logbook (LB) recordings; the open circles and broken lines represent the memory reflectance meter (MR) recordings. The left graph depicts the 2-wk blind study, and the right graph illustrates the current study.

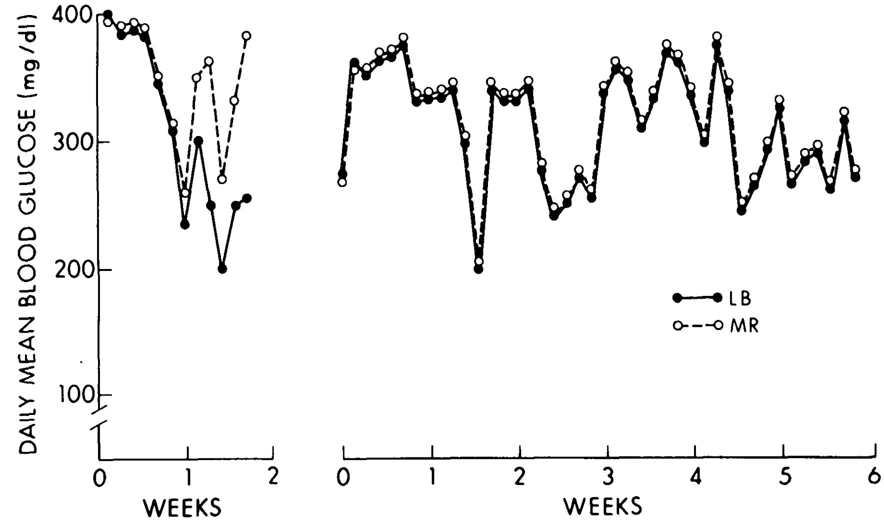

FIG. 3. *Individual subject performance: subject no. 20. Symbols are same as those in Figure 2.*

curacy of all the subjects in the current study had an appreciable impact on their overall metabolic control. Mean MR blood glucose levels were calculated for the three 2-wk intervals (corresponding to patient visits) that comprised the study period. The values of 162 mg/dl, 168 mg/dl, and 164 mg/dl, respectively, were not found to be significantly different from each other, nor from the mean blood glucose level (165 mg/dl) for the entire study period. Additionally, daily mean blood glucose levels (with standard deviations) were determined for each subject. We did not find a significant pattern of improvement in the mean glucose values or the variance in the values as the study progressed. The dose and time of insulin administration was also examined. No particular alteration in insulin administration was observed.

Finally, this analysis was repeated for the 13 subjects who participated in the earlier study. Although an overall decrease of mean blood glucose from 179 ± 16 mg/dl to 167 ± 16 mg/dl was recorded when the two studies were compared, the drop was not significant. While some subjects showed a decrease between current mean glucose values and mean blood glucose values during the blind study, these lower glucose values were present at the outset of the current study.

DISCUSSION

The introduction of new technology to diabetes management has significantly changed the environment in which this disease is treated. The individual with diabetes has moved to the focal point of a unique therapeutic alliance with the health care practitioner. Increasingly, the physician has come to rely on client-generated data as the basis for clinical decision-making. As a result, the individual with diabetes has become more acutely aware of the course of treatment. The introduction of a reflectance meter with the ability of storing self-determined blood glucose levels provided us with an opportunity to characterize the performance of persons with diabetes on complex regimens and determine the extent to which behavior is alterable. In the current study, we followed subjects on this new device for a period of 6 wk to determine the level of accuracy and reliability that could be achieved using the MR. As a basis of comparison, we contrasted their performance with the behavior of subjects who were placed on the same device, but who were unaware of the memory capability of the machine.

We observed a high degree of accuracy and reliability achieved by subjects using MRs when they knew of the memory capability of the device. They were able to reach a level of precision averaging 1 error for every 100 entries into their LBs. Their overall reliability, as determined by the degree to which they omitted true readings (6.8%) and added fabricated values (0.5%), averaged <5 such occurrences in 100 LB entries. In fact, during this study, the practice of adding fabricated test results all but ceased. This level of accuracy and reliability was significantly higher than that achieved by sub-

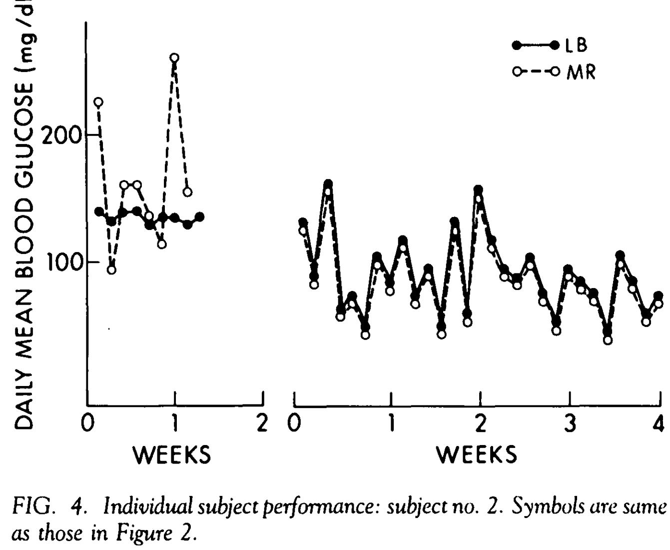

FIG. 4. *Individual subject performance: subject no. 2. Symbols are same as those in Figure 2.*

jects who were unaware of the memory capability of the reflectometer. For the 6-wk study period, we also observed a consistency in performance that did not diminish over time in terms of the level of reliability and accuracy of data recordings, nor did we uncover a diminution in the frequency of self-testing.

Despite these substantial findings and important changes in behavior, we did not observe a significant change in metabolic control either during the 6-wk period or in comparison (for 13 subjects) with the earlier blind study. While it might be expected for the subjects to have altered their insulin regimen or diet because of accurate recording of blood glucose, evidence from behavioral research does not necessarily support this. It has been observed by some investigators[5,18,29–31] that past experiences, the cost of compliance to the regimen versus the immediate benefit, and overall satisfaction with both the treatment and the health care provider are other factors that contribute to compliance. We did not, by introduction of this MR, necessarily impact on these particular factors. Our findings indicate that the impact of the MR was on behaviors directly related to the use of that device. Although SMBG is intended to be used as a part of a more complex therapeutic regimen that is linked to alterations in insulin administration and dietary intake, in this experiment these elements appeared to be disconnected. Improved performance in SMBG was not observed to "spill over" to insulin administration.

This study suggests that direct independent verification of behavior (in this case of self-testing) is a powerful, albeit, limited strategy for altering adherence. However, it also suggests that the changed behavior is so closely dependent on the means of verification, that steps to improve glycemic control need to link the positive behavior fostered by the MR with appropriate behavior regarding insulin administration and dietary regulation. These results point to the need for both cognitive- and attitude-related interventions as a means of fostering a linkage between SMBG and insulin and dietary regulations. It is conceivable that the connection between self-testing behavior and clinical decision-making concerning insulin administration and diet is not understood by the person with diabetes and that even if the individual understands the connection he has not developed the appropriate skills to facilitate it. Finally, it is probable that currently held health-related attitudes do not necessarily support behaviors that foster glycemic control. Thus, it seems that educational and behavioral interventions that concentrate on positive attitude development and clinical decision-making skills are needed if the linkage between SMBG and metabolic control is to be completed.

The current study focused primarily on determining whether performance could be significantly altered by making it apparent to the subject that an independent means of verification of the accuracy and reliability of self-generated data was in use. We have shown that significant, positive change was possible. The second purpose was to measure the level of precision that was achievable by subjects using the reflectance meter. We found that the majority of subjects were able to accurately record each reflectometer reading with no significant error in time or glucose value. The third aim was to determine the extent to which the subjects' performance could be sustained. We found that performance as measured by accuracy and reliability was consistent throughout the 6 wk of the study. The fourth goal was to evaluate the impact of performance on metabolic control. We observed no significant alteration in glycemic control as a result of the high level of accuracy and reliability of subject performance.

These conclusions should be considered within the limits of the study design. The subjects were followed for a 6-wk period, and although they may continue their behavior indefinitely, they may also revert to the earlier, less reliable performance. Additionally, the subjects' frequent self-monitoring, although not excessive, may have placed them in the category of "motivated" participants, which may in turn impact on their overall performance. However, since during the blind period many of these subjects maintained a similar schedule, we do not think that the frequency in testing had a significant impact on the study outcome. Finally, while their precision in recording test results was high, except for an observed demonstration of testing technique, we cannot be certain that the subjects maintained a high level of SMBG skills throughout the study period. Nevertheless, the use of the MR did serve to uncover patterns of metabolic control (i.e., hypo- and hyperglycemia) that were not apparent from self-generated data when no means of verification was in use. Although the high level of accuracy and reliability did not appear to impact on the subjects' metabolic control, this form of self-generated glucose data promises to provide information that would be of great use to the health care practitioner. More importantly, if linked to the development of clinical decision-making skills for the person with diabetes, it could foster better use of such data by the individual who is attempting to achieve near-normal levels of glycemic control.

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