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ORIGINAL ARTICLES

Ascensia® WinGLUCOFACTS® Professional Software Improves Diabetes Health Outcomes

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Abstract

Background:

Traditionally, people with diabetes keep handwritten blood glucose (BG) logs. Although a useful, and a necessary component of diabetes management, logbooks can be incomplete, inaccurate and illegible, which may lead to faulty analyses of BG trends associated with meals, medications and daily activities. Ascensia®, WinGLUCOFACTS®, Professional Software (WinGLUCOFACTS) from Bayer HealthCare was developed to assist in diabetes management by providing text and graphic presentations of downloaded data. It has a unique Data Wizard™ tool that automatically identifies BG trends.

Methods:

A one year outcome study was conducted at Baptist Primary Care (Jacksonville, Florida) to investigate whether use of WinGLUCOFACTS would improve BG control, diabetes related behaviors, and patient knowledge and attitudes. The cost effectiveness of this software in a primary care setting was also studied. Two physicians treated both the Test Group (90 subjects) and Control Group subjects (66 subjects). The Test Group subjects' diabetes was managed using WinGLUCOFACTS in conjunction with handwritten logs. The Control Group subjects' diabetes was managed using only handwritten logs. Both groups were scheduled to visit their physician 5 times, at 3 month intervals over the course of the 12 month study.

Results:

Hemoglobin A1C (A1C) dropped by about half a percentage point from baseline for both Control Group (-0.48) and Test Group subjects (-0.58) at the 3 month visit, a clinically significant change. The Control Group's A1C levels, however, increased at each succeeding visit, so that at 9 and 12 months it was statistically indistinguishable from baseline, whereas the Test Group's A1C remained significantly lower than baseline (-0.64 and -0.41; 90% confidence level). Based on published methodologies for calculating cost savings related to such a sustained reduction in A1C, annual cost savings would be $75.04 to $111.54 per patient or $75,040 to $111,540 per 1000 patients. The use of WinGLUCOFACTS also had a positive effect on patients' diabetes related behaviors and on their satisfaction with their care. A majority of Test Group subjects wanted their physician to continue using WinGLUCOFACTS. The physicians expressed satisfaction with this data management system, stating that it helped them to manage the Test Group subjects' diabetes by analyzing BG trends.

continued →

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Abbreviations: (WinGLUCOFACTS) Ascensia® WinGLUCOFACTS® Professional Software, (BG) blood glucose, (SMBG) self-monitoring of blood glucose, (HCP) health care professional, (ADA) American Diabetes Association

Keywords: blood glucose data management software, diabetes, self-monitoring of blood glucose, SMBG, WinGLUCOFACTS

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Abstract cont.

Conclusions:

The use of Ascensia® WinGLUCOFACTS® Professional Software from Bayer HealthCare helped in the management of patients' diabetes. It improved overall glycemic control, increased their knowledge of diabetes, increased SMBG frequency, and their satisfaction with care, and was cost effective. The primary care physicians confirmed the benefit afforded by this software in the real-world management of diabetes.

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Introduction

It is well established that self-monitoring of blood glucose (SMBG) has important clinical benefits for people with both type 1[1] and type 2 diabetes.[2,3,4,5] The maintenance of near normal blood glucose (BG) levels with minimal hypoglycemia can only be achieved with the efficacious use of SMBG. However, frequent SMBG by itself does not influence BG levels; it merely provides data to patients and health care professionals (HCPs) that can be used to modify treatments and behaviors in a timely fashion. This data must be correctly understood, interpreted and acted upon.

Patients are typically advised to maintain written logbooks to keep track of their SMBG results. Although a useful, and a necessary component of SMBG practice, logbooks are often incomplete, inaccurate and illegible.[6,7] Even when SMBG logbooks are meticulously kept, they offer limited help in interpreting what can become an intimidating compilation of data. Thus, people with diabetes are often unable to take full advantage of the information they collect. The task of analyzing logbook data can be daunting to HCPs as well as to patients, preventing the former from providing optimal treatment recommendations, and often discouraging diligent SMBG practices by patients who may perceive no benefit from it.[8,9]

The medical device industry, as well as academic scientists,[9] have responded to such concerns by developing hardware and software tools to facilitate SMBG data management. Properly used, diabetes management software can lead to improved glycemic control in the real-world.[8] Many of the computer programs, such as Ascensia® WinGLUCOFACTS® Professional Software (WinGLUCOFACTS) from Bayer HealthCare, are available to help patients and health care providers analyze and manage blood glucose data more effectively and efficiently. Blood glucose readings and test times stored in WinGLUCOFACTS-compatible meters (e.g., Ascensia® CONTOUR®, Ascensia® BREEZE®, Ascensia® DEX® 2, Ascensia ELITE® XL) can be downloaded to computers running WinGLUCOFACTS.

WinGLUCOFACTS features include: an electronic logbook for storing and organizing downloaded BG data; data displays in textual and graphic forms; analysis of BG and testing frequency time averages; and a Data Wizard™ tool that identifies and interprets BG trends. WinGLUCOFACTS also has the capacity for storing additional information for multiple patients such as medications and laboratory results, and thus can function as an electronic medical record for the patient population of a physician or clinic. This capability for scanning an entire patient database for population trends may aid an institution in complying with established recommendations and guidelines for diabetes care, and could facilitate achieving recognition/certification from various agencies.

Presented here are the results of a year long outcome study with WinGLUCOFACTS in a primary care practice that led to improved glycemic control (i.e., reduction in A1C), increased SMBG frequency, greater satisfaction with care, patients' greater understanding of their diabetes, benefits to the physician, and potential cost savings projected from improved A1C values.

Materials and Methods

Ascensia® WinGLUCOFACTS® Professional Software

SMBG data accumulated in the memory of a WinGLUCOFACTS compatible BG meter can be downloaded periodically to a computer running WinGLUCOFACTS Software. The program stores and organizes the downloaded data, as well as user-entered data (such as meal times, insulin dosage, and other

medications.) WinGLUCOFACTS can display the data in a variety of textual and graphic forms, and can analyze it to provide BG time averages, testing frequency time averages, success at meeting target ranges, and standard deviations in BG levels at particular times. It can correlate BG results with medication doses and time points, meal times and exercise regimens. A salient feature of the program is the Data Wizard™ tool, a suite of analytic functions designed to identify and interpret trends and patterns in the patient's BG management regime that might otherwise be overlooked. The Data Wizard tool incorporates a proprietary technology, *Intelligent Diabetes Data Interpreter*, which uses statistical algorithms to search for temporal trends in BG levels, and presents them in plain language. For example, it can report that average BG was significantly higher during a certain period (such as weekends) than during some other period, or that all episodes of very high BG always occurred, (e.g., at night). It does not explicitly provide clinical recommendations; it creates a series of comments pertaining to relevant parameters, including modal day/week, hyperglycemic/hypoglycemic episodes, and rapid BG swings. WinGLUCOFACTS can also analyze relationships between insulin therapy and BG levels if the appropriate insulin information is entered. Records of medications taken, laboratory results (such as A1C) and behaviors (such as meal times and exercise events) can also be handled. All such clinical information is retained and is available for analysis in a time frame of the user's choosing (e.g., the last 4 months, or 2 years).

Cost Analysis

In this study, subjects' A1C values were the surrogate measurement for effectiveness of diabetes control. It is well established that there is a direct relationship between direct and indirect costs and diabetes control.[1,2,3,4,5] Direct costs include expenses for medicines, in-hospital and home-care. Indirect costs include the potential productivity loss due to the inability to work and other such factors. In general, the better the diabetes control, the lower the A1C and the lower the costs.

Direct and indirect costs have been modeled by Minshall, *et al*[10] based on information from published sources. For a population of 13.3 million people with diabetes, lowering their A1C from 7.0% to 6.5% would result in an estimated cost savings of $7.4 billion and $22 billion over 5 and 10 years, respectively. Therefore, in the current study, the average cost saving rate, R, (i.e., annual dollar savings per subject) would be $111 to $165 when the A1C is reduced by 0.5%. Since the baseline A1C for subjects in this study was 7.4%-7.5%, it is reasonable to use the same average cost saving rate.

Assuming the A1C change in this study is X% and the average cost saving rate is R, then the estimated cost savings in Y years would be S,

$$S=X*(R/-0.5\%)*Y \qquad \text{Eq. (1)}$$

Study Design

An outcome study was conducted at a primary care clinic to investigate whether WinGLUCOFACTS would improve BG control, diabetes-related behaviors, and patients' attitudes toward the disease. WinGLUCOFACTS was used solely on the HCP's computer in this study. Although it can also be used at home on a patient's personal computer, none of the subjects in this study downloaded their meters at home.

Two primary care physicians managed 90 Test Group and 66 Control Group subjects each of whom agreed to participate in the study for 12 months. The subjects in the Test Group and Control Group were matched in terms of demographics, diabetes history, and glycemic control.

The protocol and informed consent document were approved by the Allendale Investigational Review Board (Allendale, NJ). All subjects completed the informed consent process. Subjects were assigned to the Test Group or Control Group based on the type of blood glucose meter they chose to use (i.e., whether or not the meter was able to communicate with the WinGLUCOFACTS software). Subjects were asked if they would like to continue to use their personal meter, be given a new Bayer Elite® Basic meter that is not WinGLUCOFACTS - compatible, or be given a Bayer meter that is WinGLUCOFACTS - compatible. The WinGLUCOFACTS - incompatible meters used by subjects in the study were Roche Accu-Chek®, Lifescan OneTouch®, Medisense Precision Xtra™, and Bayer Elite® Basic meters.

The Control Group subjects were managed using handwritten logs and *Usual Care* procedures for Baptist Primary Care which basically adhered to American Diabetes Association Guidelines. The Test Group subjects were managed using WinGLUCOFACTS along with handwritten logs (in most cases) and *Usual Care* procedures. All subjects had access to diabetes education in place at Baptist Primary Care.

The exception to Usual Care was that an A1C assay was scheduled to be performed on all subjects every 3 months at each scheduled clinic visit. Since this was an outcome study designed to determine the impact of WinGLUCOFACTS in a real-world setting, subjects were only withdrawn from the study and their data not used in the analyses if they missed

multiple clinic visits. Data from subjects who returned for the 9 month and/or 12 month visit were included in the analysis even if they missed 2 prior clinic visits.

Clinic Visits

Both groups of patients were instructed to visit their physician 5 times, at 3 month intervals. At each clinic visit the BG values from Test Group subjects' glucose meters were electronically downloaded into the WinGLUCOFACTS program. Additional subject data was manually entered into the WinGLUCOFACTS as determined by the physicians (e.g., insulin dose, A1C, laboratory results, height, weight). The BG values of Control Group subjects were managed manually; subjects kept written BG logs, which they presented to their physician at each clinic visit.

An A1C assay was performed at baseline, 3, 6, 9, and 12 months at the clinic with a DCA 2000® (Bayer HealthCare LLC). The DCA 2000 A1C assay is CLIA waived, and is approved by National Glycohemoglobin Standardization Program (NGSP).

Similar information was obtained from the Control Group and Test Group. General examinations including weight, blood pressure and other appropriate tests were performed at each clinic visit. All other laboratory tests were performed according to standard practices of the clinic. Patients' knowledge, behaviors and attitudes were assessed immediately after their enrollment into the study and again at 6 months, and at their final study visit. Subjects in the Control Group were given similar surveys except the questions pertaining directly to WinGLUCOFACTS were not included.

At baseline, the physicians were given a survey to assess their knowledge, behaviors and attitudes toward diabetes management software. They were given similar surveys at 6, 9 and 12 months to assess any changes. They also evaluated their experience with the WinGLUCOFACTS system at 6 months and again at the conclusion of the study.

Physicians discussed the WinGLUCOFACTS output (i.e., charts and graphs) with the Test Group subjects during each clinic visit, and used the output to help make therapeutic management decisions. Some subjects also took copies of the WinGLUCOFACTS printouts home for further review and to discuss with their families.

Results

Demographics

Subjects in the Test Group and Control Group were matched in terms of demographics, diabetes history, and glycemic control (**Table 1**).

TABLE 1.
Subject Demographics

	TEST (n=90)	CONTROL (n=66)
Median Age (range) in years	57 (20-88)	52 (32-81)
Male	57%	48%
Female	43%	52%
Type 1	11%	6%
Type 2	89%	94%
Race		
Caucasian	73%	52%
African American	16%	35%
Hispanic	10%	6%
Other	1%	7%
Testing Frequency		
≥4 x/day	14%	11%
2-3x/day	46%	56%
1x/day	20%	14%
≤3x/wk.	20%	19%

Hemoglobin A1C

The mean baseline A1C for the Control Group and Test Group was 7.4% ±1.6%, and 7.5% ±1.7%; respectively. Hemoglobin A1C dropped by about half a percentage point from baseline for both Control Group (-0.48) and Test Group subjects (-0.58) at the 3 month visit, a clinically significant change. The Control Group's A1C levels, however, increased at each succeeding visit, so that at 9 and 12 months it was statistically indistinguishable from baseline, whereas the Test Group's A1C remained significantly lower than baseline (-0.64 at 9 months, and -0.41 at 12 months; 90% confidence level) throughout the study (**Figure 1**).

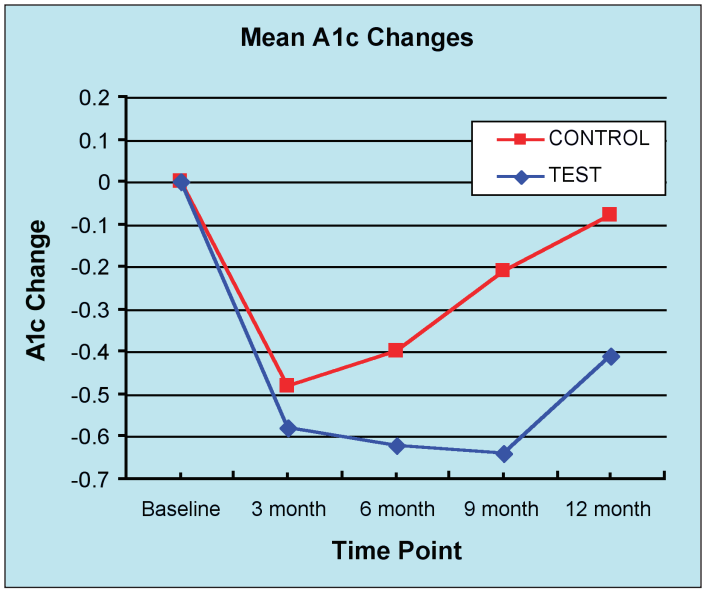

Figure 1: Change in A1C for the TEST and CONTROL subjects at each clinic visit. The change in A1C was calculated as the value of A1C at each clinic visit minus the baseline value. The mean A1C differences are plotted (y-axis) for each time point (x-axis).

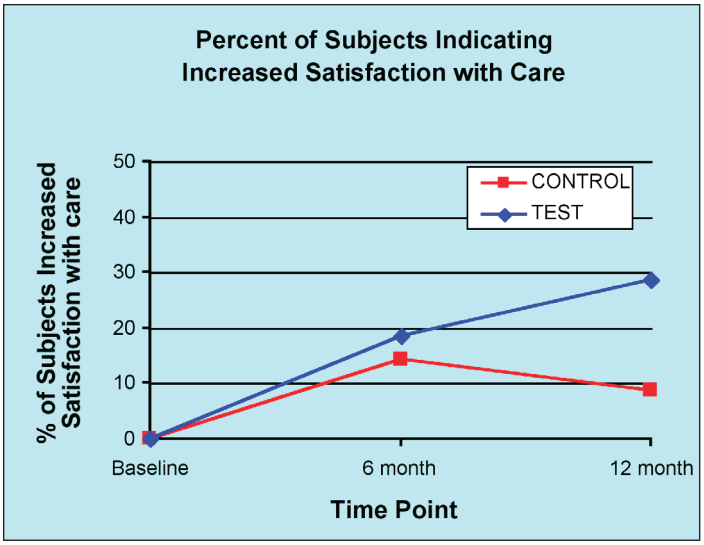

Figure 3: Percent of subjects in each group who indicated an increase in satisfaction with care as determined by surveys given at baseline, 6 months and 12 months. Subjects rated satisfaction with their diabetes care as *Very Satisfied*, *Satisfied* or *Unhappy*. Percent of subjects with increased satisfaction (y-axis) is plotted versus time (x-axis).

Diabetes related parameters

There was a positive effect of WinGLUCOFACTS on the subjects' frequency of SMBG (**Figure 2**) and on their self-reported satisfaction with their diabetes care (**Figure 3**).

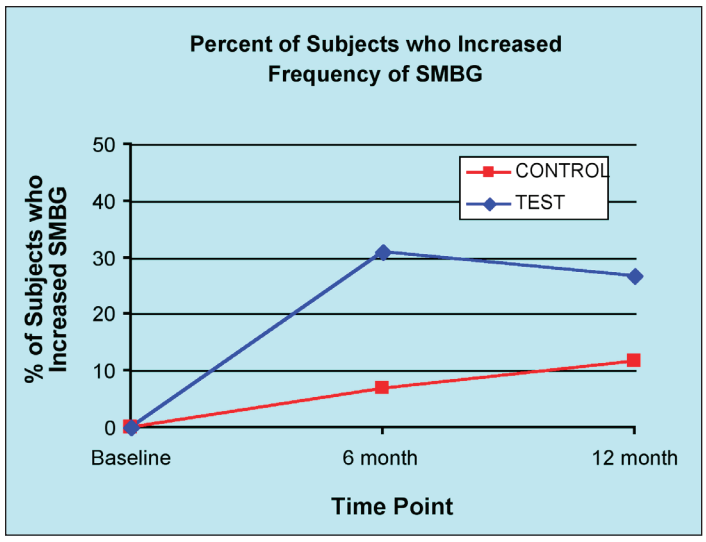

Figure 2: Percent of subjects in each group who increased their frequency of SMBG. Surveys that asked how frequently they tested their blood sugar were given to the subjects at their clinic visits at baseline, 6 months and 12 months. The percentage of subjects who reported increased test frequency is plotted (y-axis) versus time (x-axis).

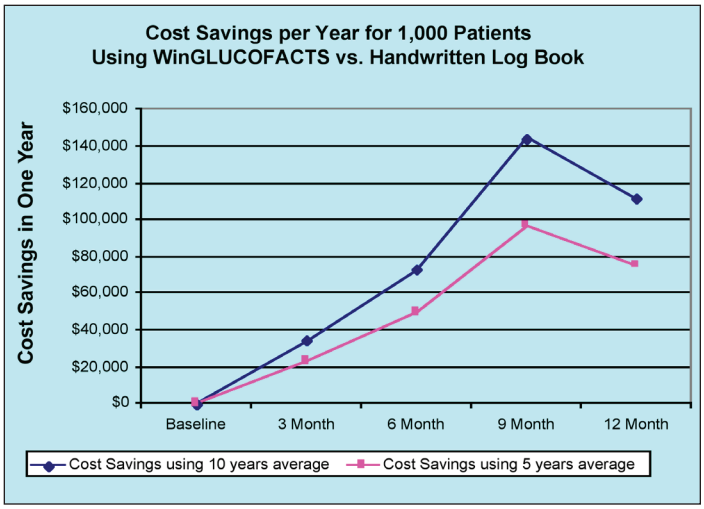

Figure 4: Cost benefit of using WinGLUCOFACTS projected per year for 1,000 patients, based on observed reduction in A1C. The projected cost savings in dollars (y-axis) is plotted versus time (x-axis).

Other behavioral measurements, including compliance with the prescribed medication regimen, meal program, and exercise plan, all improved for both the Control Group and Test Group, probably as a result of participating in a study. A number of other parameters appeared not to be affected by the use of WinGLUCOFACTS including blood pressure, which improved for both groups, and weight which remained unchanged for both groups.

Satisfaction with WinGLUCOFACTS

Both physicians and Test Group subjects responded favorably in the surveys about their experience with WinGLUCOFACTS. All Test Group subjects reviewed the WinGLUCOFACTS printouts in the office while waiting to see the doctor. Most Test Group subjects reported that the printouts they received at their medical appointments were *useful or very useful*. Ninety-five percent (95%) of Test subjects responded that WinGLUCOFACTS helped them better understand their blood glucose numbers, while 96% of Test Group subjects indicated that WinGLUCOFACTS helped them to *better understand what their doctor tells them*. Eighty-nine percent (89%) of Test Group subjects reported that they also reviewed their printouts at home, and many (60%) routinely showed them to their families. A majority (70%) of Test Group subjects responded that they would like their physician to continue to provide them with such printouts in the future. However, many subjects, most of whom were elderly, were not interested in being able to download their meter memory contents into a computer at home.

Cost Benefits of Using WinGLUCOFACTS

To estimate the impact of WinGLUCOFACTS on costs, we assume that the observed A1C changes can be sustained for one year. At the conclusion of the study (i.e., after 12 months), the average drop in A1C of the Control Group was 0.08%, while the average drop in A1C of the WinGLUCOFACTS Group was 0.41% (**Figure 4**). According to Eq. (1), the cost savings for those subjects in the WinGLUCOFACTS Group compared to the Control Group would be $75.04 to $111.54/subject/year.

For a group of 1,000 patients, the annual cost savings would be $75,040 to $111,540. If one assumes that the A1C reduction can be sustained for 5 years, the cost saving for 1000 patients would be $375,200 to $557,700.

Discussion

BG meters capable of storing data that they generate have been available for two decades, and have spawned the development of a substantial quantity of computer software programs dedicated to tabulating and analyzing stored information. While the various programs differ in detail, all function as electronic logbooks and most are able to display parameters such as the frequency of BG testing, time averaged BG levels, success at meeting target ranges, and standard deviations (reviewed in reference 8). It seems reasonable to suppose that the widespread availability of such tools would make a positive contribution to the management of diabetes, but scant evidence to support this contention has emerged. Anecdotally, it has been reported that conscientious use of SMBG software in conjunction with written logbooks led to improved outcomes for particular patients, but we are unaware of any controlled clinical studies of this technology. Moreover, it has been suggested that the extant software is insufficiently user-friendly to work effectively in the real-world, and that, in any case, the copious amount of data generated by memory meters and their associated software sometimes has the perverse effect of discouraging careful clinical analysis by time-pressed HCPs.[8]

The goal of this outcome study was to determine whether a modern diabetes management software program, Ascensia® WinGLUCOFACTS® Professional Software, would have a positive effect on measurable clinical parameters in a population of diabetes patients in a primary care practice. The results show clearly that it did. Most importantly, A1C levels were lowered in the group using the program. The drop was both clinically and statistically significant. Moreover, in the WinGLUCOFACTS Group, the decrease in A1C was sustained throughout the one year course of the study. The A1C values of the Control Group also showed an initial drop at 3 months, however, the Control Group's A1C values increased at each succeeding visit, so that at 9 and 12 months it was statistically indistinguishable from baseline. The initial drop in A1C may be attributed to the fact that participating in a study is sufficient motivation for many people to increase the diligence that they apply to managing their diabetes care. Without additional tools such as WinGLUCOFACTS, this *participation* effect (also called the Hawthorne effect) waned over time.

Evidently, these Test Group subjects improved their glycemic control based on the better information afforded to them and their physicians by use of WinGLUCOFACTS. Even after a year, more subjects in the Test Group increased their frequency of SMBG than did those in the Control Group. Additionally, more subjects in the WinGLUCOFACTS Group reported increased satisfaction with the overall state of their diabetes care than did those in the Control Group. Several other parameters that were measured, including blood pressure and body weight, showed no improvement associated with the use of WinGLUCOFACTS, but none showed any deterioration.

Both physicians in the study responded favorably in the follow-up survey about their experience with WinGLUCOFACTS. By midway in the study, the doctors reported that they had better access to patient information in the Test Group than in the Control Group. Also, when asked about common problems in delivering good diabetes care (i.e., difficulty interpreting SMBG logs, insufficient time

to evaluate patients' SMBG data, lack of clarity with regard to BG trends, and incomplete or illegible handwritten BG logs), they reported that the incidence of such problems decreased significantly for the Test Group, while they increased somewhat for the Control Group.

One of the physicians wrote, *"I wonder if the information I see from home records is cooked, whereas with WinGLUCOFACTS, you can trust the record."* The other physician wrote with reference to handwritten logbooks, that *"…patterns as to time of day are difficult to see…the power of the computer program to organize the data clearly helps in multiple ways."* Other quotes from the physicians included: *"WinGLUCOFACTS was helpful in interpreting patient's BG data"*; *"It adds an added dimension to care; manual records are erratic and sometimes misleading"*; *"WinGLUCOFACTS organizes and interprets the statistical information"*; *"Fifty percent of my patients' records are erratic"*; *"…fewer problems in delivering good diabetes care for patients managed with WinGLUCOFACTS like faulty logbooks, insufficient time to evaluate logbooks, ambiguity in BG trends."*

The doctors were unanimous in their contention that a computerized analysis would not only be helpful to them in interpreting their patients' BG levels and in motivating their patients to comply with their advice, but would also save them time.

Conclusions

In summary, Bayer's Ascensia® WinGLUCOFACTS® Professional Software was shown to have a positive effect on the health of people with diabetes. The fact that BG control and diabetes related behaviors improved for the Test Group patients is not surprising since they clearly benefited from one-on-one discussions with their physician about their WinGLUCOFACTS printouts. The physicians were able to use the critical BG information shown in the printouts, and effectively communicate the BG trends to their patients. This useful information, presented in an organized manner, enabled the physician to identify BG changes related to timing of meals and medications, and provided them with an effective tool to motivate their patients to change their diabetes-related behaviors. The printouts continued to provide useful information to the subjects, many of whom took their printouts home and discussed their glucose trends with their family. To download this software free of charge, go to http://software.ascensia.com

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Disclosures:

Joan Parkes, Jane Wallace, and Weiping Zhong are Bayer employees. Drs. Janssen and Portalatin do not have a financial interest.

References:

1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329:977-86.
2. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352:837-53.
3. Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ 2000;321:405-12.
4. Palmer AJ, Dinneen S, Gavin JR 3rd, Gary A, Herman WH, Karter AJ. Cost-utility analysis in a UK setting of self-monitoring of blood glucose in patients with type 2 diabetes. Curr Med Res Opin 2006;22:861-72.
5. Martin S, Schneider B, Heinemann L, Lodwig V, Kurth HJ, Kolb H, Scherbaum WA. Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study. Diabetologia. 2006;49:271-8.
6. Gonder-Frederick LA, Julian DM, Cox DJ, Clarke WL, Carter WR. Self-measurement of blood glucose: accuracy of self-reported data and adherence to recommended regimen. Diabetes Care. 1988;11:579-85.
7. Ziegler O, Kolopp M, Got I, Genton P, Debry G, Drouin P. Reliability of self-monitoring of blood glucose by CSII-treated patients with type 1 diabetes. Diabetes Care. 1989;12:184-8.
8. Hirsch IB Blood glucose monitoring technology: translating data into practice. Endocr Prac. 2004;10:67-76.
9. Deutsch T, Gergely T, Trunov V. A computer system for interpreting blood glucose data. Comput Methods Programs Biomed. 2004;76:41-51.
10. Minshall ME, Roze S, Palmer AJ, Valentine WJ, Foos V, Ray J, Graham C. Treating diabetes to accepted standards of care: a 10-year projection of the estimated economic and health impact in patients with type 1 and type 2 diabetes mellitus in the United States. Clin Ther. 2005;27:940-50.
11. Menzin J, Boulanger L, Langley-Hawthorn C, Cavanugh R, Friedman M. Potential short-term economic benefits of improved glycemic control: a managed care perspective. Diabetes Care. 2001;24:51-5.
12. Gilmer TP, O'Connor PJ, Rush WA, Crain AL, Whitebird RR, Hanson AM, Solberg LI. Predictors of health care cost in adults with diabetes. Diabetes Care. 2005;28:59-64.
13. American Diabetes Association. Economic costs of diabetes in the U.S. in 2002. Diabetes Care. 2003;26(3):917-32.
14. Ng YC, Jacobs P, Johnson JA. Productivity losses associated with diabetes in the US. Diabetes Care. 2001;24:257-61.