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ORIGINAL ARTICLE

Analysis of the Evaluation of a New Glucose Meter with Integrated Self-Management Software and USB Connectivity

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Abstract

Glucose meter technology has not kept up with the advances that have occurred in other sectors in mobile and health care technology. A new device that combines strip-based capillary blood glucose monitoring and USB flash drive technology is evaluated in an industry-funded study in a cohort of patients and health care professionals. The expanded memory capacity of flash drives allows the software program to be stored on the device for analyzing the blood glucose readings in memory. The study analyzes the device for precision and accuracy as well as for ease of adaptability and usage. This analysis focuses on shortcomings in the design of the study and methodology in addition to features of the hardware device itself. Although the device has distinct advantages over many devices on the market, a challenge is made to device manufacturers to encourage further innovation.

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Step into any diabetologist's office and ask the staff what is the greatest frustration that they encounter on a daily basis. The number one answer invariably would be the difficulty in downloading patient glucose data from their meters. Patients who remember to bring their meters present blood-stained kits to the staff, who then need to clean them, find correct connecting equipment, select the correct proprietary software, and then hold their breath while waiting to see if the entire array functions properly. Frequent calls to information technology support or to the manufacturer are necessary because of problems with connectivity [a Medusa's-head tangle of proprietary cords, infrared data transfer devices, or radio frequency or Bluetooth data transfer devices] or because of software malfunction/conflicts or data corruption (a clear example of where the free-market system has not led rapidly to a winning device/software combination). Patients are bombarded with advertisements for cheaper devices, and will come in without knowing that there is no way to download their new device that comes with more affordable test strips. In addition, some offices will check the accuracy of the meter periodically with a simultaneous sample analyzed on a reference laboratory or point-of-care device, adding another step to the already complex tasks that the diabetes office staff must repeat throughout the day.

The people at Bayer have attempted to overcome some of these challenges by developing a small device for self-monitoring of capillary blood glucose that incorporates the ease of plugging a flash memory device into a computer universal serial bus (USB) port with the extra

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Abbreviations: (BGM) blood glucose monitoring, (CGM) continuous glucose monitoring, (FDA) Food and Drug Administration, (HCP) health care professional, (IrDA) Infrared Data Association, (USB) universal serial bus

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memory capacity of flash memory storage to keep proprietary software on the meter device itself. This means no more searching for correct connecting device or cable and no more concerns about selecting correct software or worries about software conflicts or data corruption[1] on remote servers. In theory, this should be a winning combination.

The industry-funded study (Performance Evaluation and Labeling Comprehension of a New Blood Glucose Monitoring System with Integrated Information Management by List and colleagues[1]) in this issue of *Journal of Diabetes Science and Technology* took place at an internationally recognized center for diabetes care. The cohort was composed of patients and health care professionals (HCPs) who were compared regarding the:

- Precision of the device
- Accuracy of the device compared to a YSG analyzer
- Ease of use of brief written instructions and full documentation available on the USB device
- Ratings by users of ease of adoptability and performance

Patients continued to test using their own home meters to guide their self-management during the study duration. Controls were performed daily on the study device. The patient cohort was made up of 72% type 2 diabetes patients and were 91% Caucasian (thus not representative of the diabetes population at large). Ninety-two percent had no experience with diabetes management software, but 86% had received educational degrees beyond high school (a selection bias toward those who may be more likely to be familiar with thumb drives).

The Contour® USB device proved to be precise and accurate in the study subjects (n = 74), with 98.6% of subject results and 96.6% of HCP results exceeding the International Organization of Standardization 15197:2003 criteria. Of all study subjects and HCPs, 97.3% fell within Parke-Error Grid Zone A with benign errors in 2.7% falling into Zone B. Seventy-nine percent of subjects rated features of the blood glucose monitoring (BGM) system as "very good" or "excellent."

The study missed the opportunity to provide what is sorely missing in this field: comparative-effectiveness analysis. Had the design been to compare this device to one or more of the industry-leading devices, the impact of the innovation that this device provides would have been more meaningful. In addition, the study did not analyze what is critical in the office setting: do patients use the software and do they modify their behavior or contact their clinicians when confronted with blood glucose trends out of targeted goal ranges? As an example, Vigersky and colleagues[2] utilizing real-time continuous glucose monitoring (CGM) in type 2 diabetes patients for short intervals, resulted in clinically significant improvements in blood glucose control that were sustained for up to a year based on the self-observed effects of progressive improvements in diet and activity catalyzed by watching what happens to their glucose on the CGM devices.

Convergence has been a hot topic in diabetes as exemplified by discussions about smartphones becoming medical devices that can test blood glucose, receive CGM data transmissions, and control insulin pumps. The Contour USB is an example of convergence between a glucose monitor and a USB flash device. Of note, USB 2.0 devices capable of storing gigabytes of data and transmitting data at speeds of 480 Mbps have been on the market since 2000. What took the industry so long to develop a diabetes device based on this technology? In addition, USB devices are notorious for being sources of computer viruses and malware and are used regularly by hackers and thieves for accessing secure data on hard drives. Is this device a security threat?

As stated earlier, connectivity remains a huge stumbling block for blood glucose monitors. The simplicity of a USB flash drive that plugs right into the office or home computer and automatically allows software on the drive to display stored data in its memory is a step forward. Unfortunately, many of us have had the experience of losing a flash drive. The next version should include a slot for attaching to a key ring, etc.

Currently, no devices should be manufactured with IrDA (infrared) connectivity due to the need for line-of-sight point and shoot within a 30-degree cone to an infrared receiver connected to the computer. Bluetooth v4.0 will soon dominate the smartphone market, with 100% penetrance predicted by the end of 2012.[3] This low-energy technology will likely be adopted by blood glucose manufacturers, and holds major advantages over current Bluetooth and IrDA technology. A device for BGM that utilizes iPhones and iPods manufactured by sanofi-aventis is awaiting U.S. Food and Drug Administration (FDA) approval. A major stumbling block to convergence is the issue of

whether smartphone manufacturers want to have their devices labeled as medical devices and thus fall into the FDA regulatory quagmire. In addition, recently, a type 1 diabetes patient on an insulin pump and continuous glucose sensor was able to hack his own devices and demonstrate that someone could remotely manipulate an insulin pump or manipulate the data in a meter or sensor[4] (which begs the question, who would do such a thing?). Stay tuned...

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