

Microformats: Three Proposed Standards for Solving the Need for Standard Data Presentation

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Abstract

The continuous glucose monitor market is just starting to develop. Current trends in the availability of diabetes information tools highlight the need for standard data presentation for continuous glucose monitors. These trends and their implications are discussed. This article proposes a set of standards for blood glucose data presentation. If device manufacturers adopt these standards, they will ensure that their continuous glucose monitors meet both the short-term and the long-term needs of users. This should increase the demand for these monitors and enable future device developments that appeal to a wider range of users.

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The medical device news from 2006 might be reason to celebrate for those of us with diabetes. Two different continuous glucose monitoring (CGM) devices were approved by the Food and Drug Administration (FDA), and a third appears close to approval.

We want to use a CGM device to help us deal with the short-term issues of hypoglycemia and hyperglycemia, but we also need to use the data these devices make available to address long-term diabetes challenges. This is where 2007 has the potential for even more good news. I believe by implementing reasonable standards manufacturers can enable us to do that. This article reviews current trends in diabetes information tools and presents three proposed standards to improve data presentation for continuous glucose monitors.

Current Trends in Availability of Diabetes Information Tools

Four current trends in the availability of diabetes information tools underscore the need for standard data presentation for continuous glucose monitors. These trends include (1) the increasing amount of available glucose data, (2) the increasing scarcity of diabetes health-care professionals, (3) the lack of standards for glucose data presentation, and (4) the scarcity of software for manipulating glucose data.

We Are Moving from a Data Shortage to a Data Surplus

The FDA-approved CGM devices allow users to track 288 blood glucose (BG) readings every day. One device yet to be approved would allow a user to track 1440 BG readings every day.

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Abbreviations: (API) application programming interface, (BG) blood glucose, (CGM) continuous glucose monitoring, (URL) Uniform Resource Locator, (USB) Universal Serial Bus

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Compared to the four to eight test strips per day that most type 1 patients with diabetes use, this seems like a 50-fold increase in the ability to see what is happening with BG levels. The resulting information should help in better controlling future levels and reducing the risk of complications.

However, this is just raw data. Until there is software that can help people with diabetes and their health-care teams interpret it in useful ways, it is far too much data for a normal person to use. Without software we cannot do any long-term interpretation. For example, 90 days of values from a DexCom™ STS device provide almost 26,000 readings. People with diabetes and their health-care teams need tools that enable extraction of usable information from this torrent of data.

There Is a Current and Increasing Shortage of Diabetes Health-Care Professionals

Based on data from 1999,¹ there were approximately 2390 endocrinologists in office-based practices. Using a similar analysis to that of David Mendosa,² if one assumes that 14.6 million people in the United States have diabetes, then there is an average of 6106 patients for each endocrinologist. With generally accepted predictions of the increase in the number of people diagnosed with diabetes each year, this ratio will not improve in the near future.

For me, this means that people with diabetes will continue to be in charge of their disease and they will need access to tools to help them interpret the data they receive from CGM devices in useful ways.

We can divide the population of those with diabetes in any number of ways. One division that I find interesting is between those who are motivated to improve their diabetes control and those who are not. Members of the former group tend to do their own online research, attend diabetes conferences, write blogs (see <http://diabetesoc.blogspot.com/>), and generally work hard to best reduce their risks of complications and increase their quality of life.

I believe it is safe to assume that members of this group would be very interested in obtaining and using CGM devices. I do not think that most of these people have the necessary mathematical and statistical skills to interpret all the data without assistance from others or by means of software.³

There Are No Existing Standards for Blood Glucose Data Representation

There are already a number of CGM devices from different manufacturers. It is reasonable to expect more CGM

devices in the future. Currently there are no accepted standards for representing the data collected by these devices. The nascent CGM marketplace is mimicking the approach already laid down by the mature blood glucose meter marketplace.

If a patient uses a CGM device from one manufacturer for 6 months and then needs to change devices, the more than 52,000 readings they have collected might not be transferable to the software provided with the new system.

As a software professional, with over 30 years experience in software design and development, I believe this inability to readily move data from one system to the other will have a depressive effect on the CGM marketplace. The early adopters of CGM devices will include many who understand the importance of being able to interact with the data to provide long-term benefits beyond reducing hypoglycemic and hyperglycemic excursions.

There Is Little Software Available to Store and Manipulate User Data That Can Be Easily Shared with Health-Care Providers

There is a huge market in blood glucose meters (\$5.9 billion in 2004⁴) and a potentially large market in CGM devices. Despite this there is little software available that can readily upload data from most blood glucose meters and allow both patients with diabetes and their health-care team to use it in a way to improve their control.

Even with the small number of CGM devices currently available (there are more than 30 different makes and models of blood glucose monitors), software to effectively capture and analyze CGM data from any device will probably not be available in the immediate future.

To be of most benefit to the individual with diabetes, or their caregiver, this software must be able to combine data from the collection device(s) with information about insulin dosage, other medications, food taken, exercise, weight, and health. The results should be available to both the health-care team and the person with diabetes. This indicates the need for a web-based or client-server solution. (I started using <https://www.dhealth.net/dhealth/LoginPage.do?Mode=>, which seems like a step in the right direction, although it is slow and the user interface is not very polished at present.)

The lack of software is surprising given the size of the potential market for this type of software: 14.6 million people diagnosed in the United States (2005, Centers for Disease Control National Diabetes Fact Sheet) and more than 3300 endocrinologists, as well as nurse educators and others.

So why is there not that much software available right now? Here are some of the contributing factors that I see.

- There is no standard control interface that enables software to download data from a variety of meters.
- Meter manufacturers do not readily provide information on the control interfaces that do exist. Most of them treat this as proprietary or patented information, causing people to waste time trying to reverse engineer the formats.
- Data formats for the same information from different meters are not uniform.

Given these constraints it is hard for potential software manufacturers to develop the software. The only option for most meter users is the software provided by the manufacturer of their meter.

For users of more than one meter type (perhaps one at home and a different one in the office), there are almost no usable alternatives.

Proposals for the Future

From a quick analysis, it might appear that CGM device manufacturers can enjoy a large untapped market with relatively few existing devices in the hands of users. (For example, there are currently estimated to be about 200,000 insulin pump users in the United States⁵ and it is easy to believe that many of these would benefit from a CGM device. If a manufacturer can sell their devices to 1% of the current population with diabetes, then that is a multibillion dollar market.)

Without tools in the hands of users that can help them to effectively use the data from CGM devices the adoption rate will be extremely slow. It may not even match that of insulin pumps.

I have worked in software design and development for over 30 years. I believe that there are some key features that CGM device manufacturers need to agree upon *and implement* if they want to enable the development of a robust software tool market.

Without that market there will be limits to how patients can translate CGM data into usable and useful information. Without this information the market for CGM devices may not be much greater than the current insulin pump market.

So what are these key enabling features that should be implemented in a standard CGM device?

These features all revolve around the use of a small set of standards. In talking about these standards, I will compare what CGM devices might do against what the current set of blood glucose meters already do. I will try and highlight why these proposed standards make sense.

Proposed Standard 1: Cooperate to Develop a Standard Data Format

Data downloaded from blood glucose-measuring devices are not very complex. This data consist of a series of readings, each with a date and time of measurement and a blood glucose level.

There is no reason to use proprietary data formats for something this simple. Instead manufacturers should cooperate to develop a standard format for storing this data.

One way of doing this, which is gaining wide acceptance in the marketplace, is to define and use a microformat.

Microformats use Extensible Markup Language to represent data in a way that is both human readable and easily transferable between different systems.

Microsoft is now looking at a way to use some microformats to “Wire the Web”⁶ by connecting different systems using the web-based interfaces they already support. Also, Microsoft has provided some extensions to data-sharing approaches in a way that allows others to adopt the same approach. Work is already underway to support microformats directly in the Firefox web browser.

One widely used microformat is the hCalendar. This microformat specification defines how to represent an event on a calendar. The following piece of data in hCalendar format (based on the web page <http://microformats.org/wiki/hcalendar-example1-steps>) is the microformat way to represent the Diabetes Technology Meeting at the Westin Peachtree Plaza Hotel, Atlanta, Georgia, November 4–6, 2006, with a Uniform Resource Locator (URL) at <http://www.diabetestechology.org/>.

```
<span class="vcalendar">
  <span class="vevent">
    <a class="url" href="http://www.diabetestechology.org/">
      <span class="summary">Diabetes Technology Meeting</span>:
      <span class="dtstart">20061102</span>-
      <span class="dtend">20061104</span>,
      at the <span class="location">Westin Peachtree Plaza
      Hotel, Atlanta, GA</span>
    </a>
  </span>
</span>
```

Currently there is no defined microformat to represent a blood glucose reading. An example of how a blood glucose value might be encoded as a microformat is given next. This represents a blood glucose reading of 128 mg/dl taken on January 5th, 2007 at 8:06:25 AM. At the time this reading was taken, the person had some illness.

```
<span class="vcalendar">
  <span class="bgvalue">
    <span class="dttaken">20070105T080625</span>
    <span class="bgvalue">128</span>
    <span class="bgunits">mgdl</span>
    <span class="health">illness</span>
  </span>
</span>
```

Microformats can be extended to add manufacturer-specific data or to provide further features in the future.

Clearly this approach increases the amount of data transferred between the CGM system and a computer. However, a Universal Serial Bus (USB) connection is capable of transferring significant amounts of data at high speed.

Adopting this approach enables the development of tools to consume the raw data and to transfer it between systems. Thus getting the data from a patient's computer to a doctor's office, or from one software package to another, becomes a small amount of work.

Proposed Standard 2: Cooperate to Develop a Standard Control API for CGM Devices

An application programming interface (API) is a defined way to control hardware or software using a program. The API defines the commands that are understood by a CGM device and the data returned by running each command.

This standard API would need to be licensed such that anyone is free to use it. It must control all the basic functions needed by software to interact with the CGM device.

Suggested software commands include the following.

1. Obtain device information (make; model; serial number; CGM software version; date of manufacture; CGM API version; etc.). This is useful for gathering statistics for different devices and perhaps advising consumers of new hardware and software versions. There need to be ways to support changes to an interface over time. This is why there must be a way to determine which version of the application programming interface a specific device supports.

2. Obtain date and time on the device. We need to synchronize results from the CGM device with results from other devices to ensure that events can be correlated.
3. Set date and time on the device. This is in case the user or software wants to synchronize time with a central clock.
4. Download all results. Provide a bulk download of all blood glucose readings. An approximate estimate for a month's worth of data is slightly larger than one compressed digital picture:

$$30 \text{ days} \times 288 \text{ readings} \times 240 \text{ bytes per reading} = 1.98 \text{ Mbytes}$$

With a proprietary connection this is an enormous download. With a USB connection this much data can be downloaded in less than 1 minute.

5. Download a range of results. Allow the software to request results between a range of dates and times.

Manufacturers may see some benefit in implementing additional commands for their own meters. Without broad industry support, I would strongly warn against adding commands and building incompatible APIs.

By standardizing on a single API, manufacturers will encourage a strong software market that provides solutions to problems that people with diabetes currently face every day. As consumers see the benefit in these solutions, they will be more likely to look at using a CGM device.

Proposed Standard 3: Use a Standard Hardware Interface to Connect CGM Devices to Computers

Currently, each blood glucose meter has its own hardware interface and cable type. At this time, some connect to printer ports, whereas some connect to parallel ports on computers, usually found at the back of a personal computer. A cable from one manufacturer cannot be used on another meter, and sometimes cables need to be changed just to go from one meter to another meter made *by the same manufacturer*.

I propose that CGM device manufacturers standardize on a USB connection. These are used in millions of digital cameras (according to estimates, about 30 million in the United States in 2006). Circuitry to embed the USB port in the meter itself is both small and inexpensive. In some cases the included circuitry provides data collection facilities for the device itself. Also, all computers produced today have

multiple USB ports. Many PCs have a USB port at the front of the computer, making it even easier to connect a meter.

Because the associated cables are inexpensive to purchase, they should be included with the CGM meters. This removes a barrier for those who want to start collecting data.

Net Benefits

Developing and getting CGM devices to market is a competitive business. What would it benefit device manufacturers to adopt the standards that I am proposing?

First, without the right tools it will be hard to convince people with diabetes that using a CGM device will provide substantial benefits beyond the short-term hypoglycemic and hyperglycemic ones mentioned earlier.

I have had type 1 diabetes since 1972. Initially I used multiple daily injections to achieve a good level of control. For the last 9 years I have used an insulin pump. Because I typically test my blood sugar seven or more times each day I am used to tracking numbers associated with my diabetes.

With my extensive background in the software industry I could easily develop software that allows me to manipulate large sets of numbers. With this I might derive some basic information from all the data that a CGM device could provide.

However, I do not have the time it takes to write software that might provide the answers to the following questions.

- A. On which day of the week do I have the worst variability in my blood glucose levels?
- B. What happens to my levels after I have been working out for 30 minutes?
- C. Are my blood glucose levels stable? Rising? Falling? What is the trend?
- D. What is the comparison between my breakfast postprandial readings for the weekend and for weekdays?
- E. How do hormone levels affect my readings?

Without answers like these, I know I would just get frustrated by collecting all this data and then not having a way to use it effectively.

I feel that those with diabetes who are not comfortable with numbers will just be scared by these devices—until they

can get easy-to-use software that can provide them with useful answers and even guidance about improving their control. If there are tools to help them with long-term issues, this might encourage them to get a CGM device.

Second, enabling a software industry around these devices will allow CGM device makers to learn from the problems people are solving. This feedback can enable manufacturers to build more capabilities directly into the next-generation devices and systems.⁷ Software makers, device makers, and consumers can learn from and teach each other.

Finally, I firmly believe that adopting these open standards will cause a network effect (http://en.wikipedia.org/wiki/Network_effect) in the CGM industry. Here the value to the individual is increased as more people use CGM devices and more software is available to transform the data into answers that increase the quality of life for people with diabetes.

Possible Challenges

What are the challenges in adopting this set of proposals?

1. Time. Based on past standards approaches, interested parties will need to meet several times to agree on the details and develop the standard. This will take some time—I would not be surprised if it was 6 months to 1 year of elapsed time.
2. Cost. Some manufacturers may have already invested a great deal in developing their current approach for data transmission.
3. Loss of consumer lock-in. With these standards, it is going to be easier for people to switch between devices. Device makers can use ergonomics, support offerings, and other features to build and keep customer loyalty.

Summary

With the availability of alternatives in CGM devices, we are at the edge of a new era in diabetes care. To develop a vibrant market for these devices, manufacturers need to consider the long-term value to consumers. Manufacturers can maximize the consumer value if they make it incredibly easy to retrieve and manipulate the data collected by CGM devices.

The standards I propose mimic those that have long been in place for devices such as telephones, fax machines, and personal computers. They would enable interoperability between the collection devices and the interpretation

software. This software is a crucial component for user success with CGM devices.

Unless effective standards are adopted, the potential market for these devices will be needlessly limited. With software that can interpret the data and provide answers to everyday diabetes challenges, a CGM device will be attractive to more people with diabetes.

By enabling development of software to interpret the data, the CGM device becomes an effective tool for managing both short- *and* long-term challenges of diabetes. Manufacturers who do this demonstrate to their customers their commitment to empower their users. These visionary companies can expect a strong network effect that will grow the marketplace for CGM devices.

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