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An Analysis: To Code or Not to Code—That Is the Question

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Abstract

Most blood glucose monitoring systems need coding to correct for variation in lots of enzyme, which leads to differences in lots of strips. About 16% of patients miscode the meters, although the magnitude of the miscoding is unstudied. This miscoding has the potential to cause errors as high as 30% and to cause errors in adjusting insulin therapy that could lead to hypoglycemia at least 10% of the time. Studies of these systems suggest that they have accuracy similar to other current meters and have similar physical characteristics. Because they do not require coding, they are often easier to use. No-coding systems have the potential to avoid some errors in blood glucose.

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The earliest blood glucose meter, the Eyetone, required a two-point calibration before each test, making it too difficult for most patients to use at home.[1] When newer meters did away with this cumbersome procedure by just inserting a code (number) into the meter, the era of modern blood glucose (BG) monitoring began.

The enzymes used in blood glucose strips are purified from microorganisms and often have significant lot-to-lot variation. Used in the BG strips, this enzymatic variation can lead to alterations in the amount of electrical current produced per unit of glucose in the meter. To overcome this, the strips are given a code that calibrates the meter for that batch of strips. Recently, better enzyme purification methods and better quality control have decreased the variation in the strips. Many manufacturers need to use only a few different codes, and most of their strips are only one code. Coding does not eliminate the error due to strip-to-strip variation.

If the patient forgets to code the meter it may be less accurate (see later), so strip manufacturers have sought to develop strips that do not need coding. The earliest "no code" systems use cartridges of strips in which the meter reads the code from the package (auto code. This article uses the term "no code" for both auto-code and no-code monitoring systems). The patient does not need to code the meter since the cartridge provides the code. The next systems selected the most common code and set up a "no-code" meter to use this code. Other lots of strips with different codes are labeled for use in their meters that required coding. Finally, some manufacturers have managed to overcome the variation in enzyme and truly have a no-code system. It is also possible to utilize

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Abbreviations: (BG) blood glucose, (BGM) blood glucose monitoring, (ISO) International Standards Organization

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enzyme made by DNA recombinant techniques and therefore is uniform.

How Great an Error Can Miscoding Cause?

Manufacturers generally do not provide this information but I am sure it varies. My own laboratory experience with one brand suggested an error of about 2% per unit of miscoding. For example, with the proper code of 21, the error was 6%; miscoding with a 22, the error was 8%; and with a 23, it was 10%. The error may not always be linear. Proud[2] demonstrated a 45% increase in error when one brand of meter was maximally miscoded. For an actual glucose of 60 mg/dl, an error of that magnitude would lead to an average reading as high as 85 and to a 95% upper confidence limit of 120. Raine and colleagues[3] performed a study in which 116 patients underwent an oral glucose tolerance test. At 0, 60, and 120 minutes, finger stick blood samples were tested in five different blood glucose monitoring (BGM) systems and compared to a YSI 2300 STAT PLUS Glucose Analyzer. Two of the systems were no-code meters and three were miscoded intentionally (using two random codes). Median errors of the miscoded meters were very high, with errors of about 30% in either direction. The no-coded meters had errors of less than 10%.[3] Clearly, miscoding can be a potential problem.

Is Miscoding a Problem in Clinical Practice?

There is only a small amount of literature on the frequency with which meters are miscoded. Four independent studies evaluated miscoding.[4–8] With a total of about 500 patients, two found about 3% of patients miscoded and two found about 16%. My conclusion is that most patients code correctly, but a few and perhaps a significant minority miscode. Unfortunately, none of the studies looked at the magnitude of the miscoding.

The July 2008 issue of *Journal of Diabetes Science and Technology* published a symposium on miscoding.[9–12] Linda Schrock provided data on patients seen in her practice and who were told to bring their meters and strips to their clinical visit.[12] A full 25% had miscoded meters. In addition, 50% either didn't bring their meters or strips or had dead batteries. Given the inability or unwillingness of these latter patients to follow directions, it is likely that miscoding would be even higher in this group.

Blood glucose monitoring serves four purposes: a guide for alteration of therapy, detection of glucose extremes, providing personal responsibility, and motivation.[13]

In the same issue, Raine and colleagues[11] studied the effect of miscoding on insulin dose. They found that the theoretical probability of causing hypoglycemia of less than 70 or 50 mg/dl was 10 and 5%, respectively, for a miscoded meter, but only 2.5 and 0% for a correctly coded meter. Clearly there is a clinical risk from miscoding.

Are There Reasons Not to Use a No-Code Meter?

There are at least four possible negative consequences of using no-code meters: they might be less accurate, harder to use, more expensive, or lack features some patients want. In this and the July issue, several papers described the accuracy of the no-code meters. Consensus error grids[14] showed values in the A zone 98.8% of the time for the FreeStyle Lite, 98.4% of the time for the OneTouch Vita, and 99% for the Ascensia Contour. In other studies, the AgaMatrix Jazz showed A zone 99.4% of the time.[9,15–17] All of these systems have passed the International Standards Organization (ISO) 15197 standard used by the European Union to evaluate meters.[18] Thus, all of the no-code systems used to present data are acceptably accurate. In my opinion, the best method of evaluating clinical accuracy is the extended ISO 15197 system, in which the percentages of values with less than 5, 10, and 15% inaccuracy (and their appropriate absolute values below 75 mg/dl) are reported. Only the Jazz reports these values now and has an amazing 68% of the values with a less than 5% error.

Roche has presented data that alteration in coding makes little difference to the accuracy of the Aviva BGM monitoring system. As a result, this meter system may be similar to a no-code system.[10]

The systems are generally not harder to use. Most systems are of average size and weight and are actually easier to use because of the no-code feature.

Price and features are individual items. For the most part, the no-code meters are priced comparably with the brand name meters requiring coding and have similar features.

In summary, the need to code is bothersome for most patients and causes accuracy problems for some. This inaccuracy has the potential to cause poorer blood glucose control and to increase hypoglycemia. Data suggest that no-code meters generally have advantages over meters that require coding. They have similar accuracy, design, features, and price. Each new no-code meter, however, will need to prove its accuracy in independent trials.

Disclosure:
Dr. Ginsberg is a consultant for Bayer Diabetes Healthcare, Roche Diagnostics, and AgaMatrix.

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