

## Measurement Quality of Blood Glucose Meters: Is There a Need for an Institution with an Unbiased View?

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### Abstract

The quality of self-monitoring of blood glucose (SMBG) with modern blood glucose meters is considered by many as not being a relevant topic anymore. However, in reality, a number of open questions about the quality of the measurement exists. Even if the meters fulfill the established quality criteria when they receive approval, there is no independent institution that performs a regular, critical comparison of the quality of the measurement of all blood glucose meters after their approval. Such an institute could also evaluate the quality of the different batches of test strips. In addition, it can evaluate the impact of other factors that are known to have an impact on the quality of measurement, e.g., the ambient temperature and the hematocrit. Such an institution will be very helpful to counterbalance complaints by the patients, physicians and authorities about an industry that earns a lot of money but does not provide solutions for the topics raised.

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**S**elf-monitoring of blood glucose (SMBG) in people with diabetes is a cornerstone of modern diabetes therapy, and not only for patients on insulin therapy. We have come a long way from the first test strips to modern blood glucose meters. These new devices are easy to handle, the risk of preanalytical errors is reduced considerably, minimal amounts of blood are required, and the measurements are very rapid. Therefore, people with diabetes, as well as their physicians, believe that the quality of the results and the performance of SMBG meters are so high that this is a “no brainer.” This might be one of the reasons why the number of publications about this topic has decreased considerably in the last few years.

We should keep in mind that a glucose meter that systematically measures glucose values too low pleases the patient (and their treating physician) when looking at their glucose profiles; however, the elevated glycated hemoglobin values reflect the increased risk of diabetes-related late complications. Glucose meters that tend to measure glucose values too high induce an immediate risk for the patients by selecting inappropriately high insulin doses that might lead to hypoglycemic events. Thus, an inappropriate measurement quality is not of minor relevance, as the outcome of this is potentially severe or at least increases the morbidity of patients with diabetes.

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**Abbreviations:** (SMBG) self-monitoring of blood glucose, (FDA) Federal Drug Administration, (EU) European Union

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But what do we really know about the quality of the glucose measurement of the current generation of SMBG meters, especially in the hypoglycemic range, once they are approved? How do these meters perform under daily life conditions in the hands of people with diabetes? Do the initial performance conditions remain stable (constant)? Are the available quality control measures sufficient to detect (monitor) any deteriorations in meter performance? Concerning product placements in the advertising campaigns of the manufacturers, measurement quality does not seem to be of relevance anymore! In times of a “feature war,” aspects such as the size of the display, volume of blood required, rapidity of measurement, and the number of values that can be stored are apparently of higher relevance. This “lack of follow-up attention” is in sharp contrast to the economical relevance of SMBG devices, test strips, and so on with a total worldwide turnover of several billion dollars!

Once a given SMBG meter has market approval by the Food and Drug Administration or the European Union equivalent, no independent site checks the measurement quality ever again or compares the performance of different meters. Clinical experience shows that there are considerable differences in the performance of different batches of test strips for a given SMBG meter. To my knowledge there is no recent publication available that describes the magnitude of such differences between batches of test strips. Once the meter has approval, the quality of the batches is only evaluated by the manufacturers themselves. For an insider, it is quite clear that choosing a “good” batch of test strips is of high relevance so that a SMBG meter can pass any test (e.g., for approval). Therefore, the quality of batches should be checked by random samples by an independent institution as well.

For the users (and the prescribing physicians) it is virtually impossible to keep an overview of the plethora of glucose meters that are available. One of the reasons for this is the rapidity in which new systems are launched into the market. In addition to established companies with a long experience in developing devices, there are an increasing number of new blood glucose meters manufactured by companies with limited know-how. This does not necessarily mean that these meters (which are quite often less expensive) are worse in terms of measurement quality and other features, but we simply do not know.

What we need is an independent institution that performs a regular, standardized evaluation and comparison of the quality of the measurement of all blood glucose meters and test strips *after* they have received their initial approval. This institution would also take care of all the

practical aspects that have an impact on the measurement quality (e.g., patient handling). Such an institution should not be another bureaucratic monster that acts slowly, is cost intensive, and is influenced by political interests. It should be a private company or academic institution with a professional structure and professional management. Full transparency of data management and financial aspects should be absolutely mandatory. The quality of the work should be monitored by an independent board of scientists, manufacturers, and representatives of people from the health care system and of people with diabetes. In view of the degree of globalization that we have achieved, there is no need for having such an institute in every country or continent. Even if the treatment of diabetes differs considerably among countries, one can assume that SMBG as a diagnostic step has to be performed in a more or less identical manner everywhere on this earth.

The costs for such an institution will increase the costs of SMBG itself. However, in view of the potential risks, combined with an insufficient measurement quality, this cost appears to be vanishingly small. A cost/benefit analysis should also include the potential cost savings as a consequence of the risk reductions by detecting and removing insufficiently performing BG meters in time.

The next critical question is what criteria should the glucose meters fulfill? One can easily envisage endless discussions among manufacturers, scientists, and regulatory authorities regarding this topic. There are already a number of established standards in different countries and it should be possible to agree on a global standard. I suggest a pragmatic approach which focuses on the following topics.

- Standardized protocol for technical and clinical evaluation
- Analytical measurement quality
- Handling under controlled conditions
- Handling under daily life conditions

The exact procedures must be described in detail in standard operating procedures.

Until now, evaluation of analytical quality was performed most often by collecting capillary blood samples from patients with diabetes entering an outpatient clinic and by measuring the current glucose level with the meter and a reference system. Unfortunately, the number of glucose values in the hypo- or hyperglycemic range is most often low; we see uneven distribution across the measurement range. As long as we focus on analytical quality, an alternative would be to perform a glucose clamp in a relatively small number of patients. During this clamp technique, different blood glucose levels would be established for certain periods

of time. This would allow evaluating the measurement quality in the same subject over a range of glucose levels with repeated measurements. Thus, statements about the accuracy and precision at different glucose levels can be made with very high quality.

If the glucose meters are evaluated by highly trained technicians only, they could miss the complications that probably occur in the practical usability of the devices. Therefore, it appears to be mandatory that an adequate handling test is performed as well, and under controlled conditions. It is clearly predictable that such a test will also help the manufacturers optimize their devices, so there is a certain benefit for the manufacturers to conduct these tests as well. Due to the fact that daily life conditions differ from such conditions, the meters should also be used by patients for a couple of weeks routinely.

Such an institution would also be the ideal site to investigate all the other factors that have an impact on the quality of measurement, many of which are not fully understood. For example, what is the impact of the ambient temperature, ranging from below the freezing point (e.g., while skiing in the mountains) up to very high temperatures (e.g., at the beach)? What about the influence of drugs or other blood parameters such as bilirubin? Most modern blood glucose meters measure the ambient temperature and compensate for that. However, what exactly is measured? Is it the temperature inside the device or at the tip of the electrode (where the chemical processes take place)? Another aspect to consider is the hematocrit. Most modern glucose meters are declared not to be influenced by the hematocrit over a wide range. However, for evaluation of the dependence of the measurement result from the hematocrit, most often, blood is separated into plasma and blood cells and mixed again in different ratios. The question is, does this experimental procedure adequately reflect differences in the matrices observed in patients with a low or a high hematocrit?

One critical issue, although difficult to evaluate, is the long-term measurement quality of a given glucose meter. The performance of such a given system might be excellent immediately after it is manufactured, but how good is its measurement quality if the same system is used for several years? If the measurement quality deteriorates, how will this be detected? In this context it might be good to mention that certain other aspects have to be considered: When will the device start to show measurement deterioration? How large is the measurement error? What is the margin that we consider a measurement error to be relevant, and how long would

we consider this error to be negligibly small? Will this error become greater as more time passes? Finally, when will a new device be needed for everyday use? Without regular quality control by the patients (or their treating physician/diabetic nurse), a shift in measurement quality cannot be detected. The potential deleterious effects of such a change have already been discussed.

I envisage that it will be a time-consuming and difficult task to establish such an independent institution; however, I also see a pressing need to have such an institution in the near future to counterbalance complaints by the patients, physicians, and authorities about an industry that earns a lot of money but does not provide solutions for the topics raised. It is probable that the Diabetes Technology Meetings that already exist in the United States and most likely in Europe in the near future will provide a platform for an open and constructive discussion about this idea.

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**Disclosures:**

The author is CEO and shareholder of Profil Institute for Metabolic Research and has received funding from different companies for the performance of studies with blood glucose meters and systems for continuous glucose monitoring. He has received honoraria for talks about related topics. He is a member of scientific advisory boards for a number of companies active in this area.