Control Solutions for Blood Glucose Meters: A Neglected Opportunity for Reliable Measurements?

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Blood glucose meter systems (BGMs) are used by millions of patients with diabetes worldwide each and every day under the assumption that the meters (in combination with the test strips) provide reliable glucose measurements. However, the only option that patients have in their daily life to check that this assumption is correct is to measure the glucose level of control solutions (CSs) with their BGM. It is of interest to note that in the respective ISO norm 15197, usage of CS is clearly stated. It is also of interest to note that a PubMed literature search with the terms "SMBG AND control solution" resulted in only 3 hits![1-3]

Bottles with CS are provided by many, but not all manufacturers for their BGMs; nowadays it is difficult to buy or get CSs from several BGM manufacturers.[1] It might very well be that the size of this market segment is surprisingly small (personal communication with different manufacturer indicates this); however, it would be great if somebody (most probably only the manufacturer can do this) would publish data about this.

It appears as if most patients don't use CS at all, probably driven by the additional costs of CS and usage of test strips.[1] However, I'm not familiar with any data about which patients use CS how often in daily practice. This might also differ between patient groups/countries considerably. Probably patients "trust" their BGM always provides reliable measurement results.

The aim of this editorial is to consider the pros and cons of CS usage.

1. What shall patients do when the measurement result with a CS is outside the (broad) range of acceptance? They might be concerned and contact their treating physician or pharmacist and discuss the "wrong" measurement result, blaming this on the BGM; however, this can also be the result of a user error (see below). If during a physician visit an insufficient measurement quality of the given BGM is confirmed by a laboratory measurement with a laboratory measurement, the BGM should be replaced. Thereby a potential source of clinically relevant measurement error can be abolished. However, if the control measurement does not confirm the CS results, will they ever use a CS again?
2. In case the CS measurement result is outside the acceptance range, this can be due to an issue with the meter itself or with the test strips (more plausible). The only measure for patients to clarify this is to open another vial of test strips. If a test strip from the new vial shows a measurement result inside the acceptance range, the patients should discard the old vial of test strips (even if this is associated with costs).
3. Will the manufacturer ever be informed about such a replacement by a customer complaint? If this is the case (which will be rare), will they report this as a "malfunction" of their meter?
4. A measurement outside the measurement range can also be due a decrease in the glucose concentration in the CS. In principle a CS is nothing but water mixed with a certain amount of glucose and addition of buffer and preservatives to avoid too much bacterial/fungi growth after the CS is opened. The CS should be stored adequately (in a refrigerator) to avoid decline of the glucose content due to such contamination; but the solution should be at room temperature before using it for the measurement! However, in practice it is difficult for a patient to judge whether a given CS is still "good" or not. Patients should be trained to note the date of opening a given CS bottle and replace this at least in regular intervals (some months?).
5. It is well known that there can be considerable batch-to-batch variability in test strips (that are manufactured in batches); however, not much has been published

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about such differences, and patients most probably are not aware of this fact. In addition, even less is known about differences between vials with test strips from a given batch. Anecdotal reports by experienced colleagues confirm that this can be an issue. Therefore, 1 measurement with a CS once a new vial is opened appears to be advisable to get a hint if significant differences between vials exist or not.

6. One reason for a limited usage of CS in practice is that their usage is most probably not trained adequately in diabetes teaching programs.
7. How often should a CS measurement be performed: once per week, each and every time a new dose with test stripes is opened (or emptied), or after each 10th/100th measurement? No clear instructions are usually provided in patient teaching/leaflets of the different manufacturers.
8. One advantage of CS is that a regular usage can help the patient to detect a deterioration of meter performance over time. A given BGM might fulfill all quality requirements successfully immediately after manufacturing; however, does this remain so over prolonged periods of time (several years) of daily usage of this meter? Carrying around a meter all the time provides a certain "stress" to this system.
9. Does measurement of CS truly provide an additional safety information, that is, can a measurement result in the range provided with each CS be regarded as a sufficient reflection of a precise/reliable glucose measurement? One wonders why such broad acceptance ranges are usually given for CS. In principle one would assume that the acceptance range would be much smaller to be clinically meaningful.
10. When looking at the development of BGM systems over the past 20 to 30 years, the analytical and handling performance of these devices has massively improved over this period. The implementation of built-in safety features in the meters (eg, checking if a given test strip is valid) has also increased significantly the safety of these devices. It is not clear to me if these improvements make CS obsolete or not. It appears as if some BGMs accept "defective" test strips, whereas others do not. Usage of CS can help to detect if the test strips are functioning appropriately.
11. Is the relevance for CS usage the same for all BGMs? Probably this is lower with "good" meters, no higher with more "simple" meters? No respective studies are available.
12. One might wonder why no universal control solution exists, but each manufacturer offers their own CS for their BGM. The viscosity of the watery CS differs from that of capillary blood, which has an impact on the measurement result. Therefore CSs from different manufacturers are not interchangeable but are system-specific; that is, they also differ between BGMs of the same manufacturer. This also means that each time a new test strip is developed, also a new CS has to be developed that fits the measurement properties of this. This is associated with additional costs.
13. Looking into the future, it might be an idea to offer CSs with well-defined glucose content (3 different concentrations?) in small quantities (like eye drops) for single usage. This should enable a better evaluation of the meter performance.

In summary, I believe that CS represents a way to improve the quality of self-monitoring of blood glucose (SMBG) that is undervalued. I also acknowledge that CS represents a more complex topic than one might think at the first glance. In view of the recent attempts of, for example, the Diabetes Technology Society to establish systems that regularly check the measurement quality of BGM after market introduction, usage of CS can be an additional way to make a costly and cumbersome diagnostic procedure more reliable and should therefore gain more attention. Unfortunately, to my knowledge we have no data from clinical studies (or real-world observations) available that show that usage of CS really improves safety and efficacy of SMBG by patients with diabetes.

Abbreviations

BGM, blood glucose meter system; CS, control solution; SMBG, self-monitoring of blood glucose.

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