

In Response to Gonzalez-Durio: “In Response to a Previous Letter to the Editor Titled, ‘Accuracy of a Blood Glucose Monitoring System’”

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Keywords

self-monitoring of blood glucose, blood glucose monitoring system, ISO 15197, system accuracy

In his letter to the editor,¹ Gonzalez-Durio initiates discussion regarding my letter to the editor on system accuracy of a blood glucose monitoring system (BGMS).² In the following, I would like to address the topics raised by Gonzalez-Durio.

Regarding omission of details about study date, test strip lot numbers, expiry dates, transport and storage, the main reason was that the “letter to the editor” format allows for 500 words. Therefore, the level of detail that can be provided in such publications is limited. I would like to point out that I made the following statement in my original letter to the editor: “The BGMS . . . were set up, adjusted and maintained according to the instructions for use.” Although not explained in detail, this does include that strips were used before the expiry date and that required storage, transport and operating conditions were met. The funder of the original study and the study site confirmed that storage and transport conditions were met after materials were purchased. The test strip lot numbers and expiry dates were not relevant enough in this specific context to warrant inclusion in the article. The same is true for the study date: BGMS should provide sufficiently accurate results independent from any specific dates and any specific test strip lots.

Working as a diabetes specialist across secondary and primary care, I value high-quality measurement performance of BGMS of great importance in order to ensure the patients’ good treatment. Knowledge about BGMS performance should be available both to the diabetes specialist, and for the patient. It is also my opinion, that BGM accuracy studies should be performed and overseen by independent bodies.^{3,4} The costs of such studies, however, are high and the studies require specific expertise. Without independent funding bodies, funding by other manufacturers and realization by independent bodies provides means to obtain study results that were not obtained by the specific BGMS’ manufacturer. Studies performed by the manufacturer itself bear the risk of potentially selecting “golden” lots.

Independent and impartial studies, however, cannot be performed if the manufacturer comments on the protocol or

supplies materials as suggested by Gonzalez-Durio. Because study procedures stipulated in ISO 15197:2013 are applicable to all BGMS for self-testing, there is no need for the manufacturer to comment on the protocol.

Authorship of the study site’s (Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm) personnel was not considered at all because the study site was commissioned only for the performance of the system accuracy study.

Omitting the letter to the editor by Salzsieder and Berg⁵ in my publication was unfortunate but not a deliberate decision. I submitted my letter to the editor a few days after Salzsieder and Berg’s letter was published online, and I did not realize its publication at the time of submission.

In conclusion, none of the points discussed are suited to question the fact that the BGMS did not fulfil the ISO 15197:2013 accuracy criteria in the study presented in my letter.

Abbreviations

BGMS, blood glucose monitoring system; ISO, International Organization for Standardization.

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