In Response to Teodorczyk and Coauthors: System Accuracy of Blood Glucose Monitoring Devices According to the Current and Proposed ISO 15197 Standards

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In a letter to the editor, Teodorczyk and coauthors[1] comment on our data[2] published in *Journal of Diabetes Science and Technology*. In studies[2] conducted at the Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Germany, the OneTouch Verio Pro system showed a positive bias compared with reference measurements with the YSI 2300 STAT Plus™ glucose analyzer. Not all evaluated test strip lots met system accuracy requirements of DIN EN ISO 15197:2003[3] and the draft revision of this standard.[4] In contrast, Teodorczyk and coauthors[1] refer to two LifeScan-sponsored studies in which the OneTouch Verio systems met the requirements of the current and the draft revision of the International Organization for Standardization standard.[5,6]

However, a positive bias of the OneTouch Verio system compared with the reference measurement method has been reported in several studies. Dimeski and coauthors[7] showed a deviation of 9.2% between the system and the glucose oxidase (GOx) reference measurement method (Beckmann DxC800). In an evaluation of the Scandinavian organization Skandinavisk Utprøving av Laboratorieutstyr for PrimæRhelsetjenesten, a positive bias of 4.5% at blood glucose (BG) concentrations <7 mmol/liter and a positive bias of 2.9% at BG concentrations between 7 and 10 mmol/liter compared with a hexokinase (HK) reference measurement method (Architect *ci*8200) was observed (www.skup.nu). In a clamp study, the OneTouch Verio IQ system also showed a positive bias of approximately 10% compared with YSI 2300 STAT Plus glucose analyzer (personal communication with Dr. L. Heinemann).

In the LifeScan-sponsored studies mentioned earlier, measurements were performed by trained clinical staff on capillary blood samples. In our studies, measurements were also performed on capillary blood samples by well-trained clinical personnel. In the LifeScan-sponsored studies, blood samples were centrifuged immediately after collection to avoid glycolysis, and plasma glucose was measured directly on the YSI 2300 STAT Plus glucose analyzer. In our studies, reference measurements on the YSI 2300 STAT Plus glucose analyzer were performed from whole blood samples, and results were converted to plasma equivalent values. Teodorczyk and coauthors[1] suppose that glycolysis in the whole blood sample before the reference measurement could have affected the accuracy results. In our studies, the reference measurement procedure was performed immediately after the sample collection; therefore, an impact of glycolysis on system accuracy results is excluded.

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Teodorczyk and coauthors[1] have questioned the use of two different reference measurement methods in our studies. The standard DIN EN ISO 15197:2003 specifies that, for system accuracy evaluation, individual measurements from the BG monitoring system shall be compared with reference BG concentration values determined by the manufacturer's measurement procedure. According to this standard, we used a GOx reference measurement method (YSI 2300 STAT Plus glucose analyzer) for GOx/YSI-calibrated systems, and we used a HK reference measurement method (cobas® 6000 c501) for HK-calibrated systems. In our laboratory, maintenance, control, and use of the YSI 2300 STAT Plus glucose analyzer complied with the manufacturer's instructions. In addition, the trueness of YSI 2300 STAT Plus glucose analyzer and cobas 6000 c501 was verified against control standards traceable to National Institute of Standards and Technology reference material (as described in our publications[2]).

However, only a few studies have investigated possible variations between the GOx and HK reference measurement methods. In these studies, a bias of up to approximately 8% between the GOx reference measurement method and HK reference measurement method was reported.[8,9]

Today, the YSI 2300 STAT Plus glucose analyzer is widely accepted as a method for reference measurements and used for system calibration by most of the manufacturers of BG monitoring systems. We assume that not only variations between different reference measurement methods (GOx versus HK) but also measurement differences between one brand of reference measurement system used in different laboratories over the world (e.g., YSI 2300 STAT Plus glucose analyzer) may affect certain variations in system accuracy results.

In order to improve the comparability of measurement quality of BG monitoring systems, the traceability of the reference measurement system used should be verified and reported. Additionally, harmonization of the reference measurement method used for calibration of the systems by the manufacturer is desirable.

Disclosures:

Guido Freckmann is general manager of the Institute for Diabetes Technology Research and Development GmbH at Ulm University (IDT), which carries out studies evaluating BG meters and medical devices for diabetes therapy on behalf of various companies. Guido Freckmann/IDT received speakers' honoraria or consulting fees from Abbott, Bayer, Menarini Diagnostics, Roche Diagnostics, Ypsomed and Sanofi.

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