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Analysis of the Performance of the OneTouch SelectSimple Blood Glucose Monitoring System: Why Ease of Use Studies Need to Be Part of Accuracy Studies

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Abstract

The article entitled "Precision, Accuracy, and User Acceptance of the OneTouch SelectSimple Blood Glucose Monitoring System" by Philis-Tsimikas and colleagues in this issue of *Journal of Diabetes Science and Technology* demonstrates that the OneTouch® SelectSimple™ glucose meter meets current regulatory expectations for glucose meter performance. These authors describe three studies: precision, accuracy, and ease of use. Accuracy study analysis includes the effects of accuracy and precision. The ease-of-use study was analyzed separately, as recommended by the International Organization for Standardization 15197 glucose standard. The ultimate goal of an evaluation is to estimate the distribution of errors (from any source) that will be experienced in routine use. To accomplish this, ease-of-use results need to be part of the accuracy dataset.

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The OneTouch® evaluation reported by Philis-Tsimikas and colleagues[1] closely follows recommendations of the International Organization for Standardization (ISO) 15197 glucose standard.[2] I have commented on the inadequacy of this standard[3,4] and wish to elaborate based on the OneTouch evaluation. These authors have gone beyond most glucose meter accuracy evaluations by providing an ease-of-use study with details. The problem is that most ease-of-use studies, as is the case here, are evaluated independently from accuracy studies, just as recommended by the ISO standard. But from a clinician perspective—and self-monitoring of blood glucose (SMBG) patients are often acting as clinicians—an error in the reported result can cause harm *regardless* of the origin of the error. Studies suggest that most laboratory error, including SMBG error, is due to preanalytical and postanalytical error and not analytical error.[5–7] The ISO 15197 standard mentions that accuracy follows the Clinical Laboratory Standards Institute EP21 standard[8] for total error. EP21 is currently being revised to state that preanalytical and postanalytical error should not be excluded from experiments designed to estimate total error. It was surprising how much resistance there was to this change.

Returning to the OneTouch evaluation, in two cases, a subject misread the numerical value on the display (a postanalytical error), and in one case, the difference was 35.1% (171 misread as 111). While this value is still in the B zone of a Parkes error grid, it is pretty close to the C zone.

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Abbreviations: (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose

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The ultimate goal of an evaluation is to estimate the distribution of errors (from any source) that will be experienced in routine use. Said another way, "The observations must be a fair (representative, random) sample of the population about which inferences are desired."[9] This is needed to assess the risk of patient harm. So if nothing else, this question of risk must be answered. This means that the misreading error mentioned earlier must be included in the accuracy dataset as must all preanalytical and postanalytical error. The resistance to including preanalytical and postanalytical error with analytical error usually goes something like this: "But preanalytical and postanalytical error is generic, and I am interested in the specific analytical performance of meter ABC." There are several responses to this concern:

1. Preanalytical and postanalytical errors fall into different categories. Some are independent of meters (and generic), such as failing to wash and dry hands, and with others, there may be an interaction between the error and the meter such as an insufficient sample or a misreading of the display.

2. There is nothing wrong in performing studies to answer individual questions, such as, what is the analytical performance of meter ABC, and what is its ease of use? However, authors of these studies often make a statement about the suitability of a meter to be used clinically without any attempt to combine results from different studies—which would be difficult—and answer the question about the distribution of errors *from any source* that will be experienced in routine use.

3. The easiest way to inform about the risk of patient harm is to conduct a method comparison study where potential errors from all sources (preanalytical, analytical, and postanalytical) are allowed to occur and are included in the analysis.

4. Finally, of course, the data can be presented with and without suspected preanalytical and postanalytical error.

Accuracy studies provide a valuable snapshot of glucose meter performance, although, since the study sample size is a tiny fraction of the population of glucose results that will be determined, one should not overinterpret the results. It is worth noting that the 1987 American Diabetes Association recommendation for glucose meters was for "total error (user plus analytical)."[10] It is time to return to that goal.

References:

1. Philis-Tsimikas A, Chang A, Miller L. Precision, Accuracy, and User Acceptance of the OneTouch SelectSimple Blood Glucose Monitoring System. J Diabetes Sci Technol. 2011;5(6):1602–9.
2. International Organization for Standardization. *In vitro* diagnostic test systems -- requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva: International Organization for Standardization; 2003.
3. Krouwer JS. Wrong thinking about glucose standards. Clin Chem. 2010;56(5):874–5.
4. Krouwer JS, Cembrowski GS. A review of standards and statistics used to describe blood glucose monitor performance. J Diabetes Sci Technol. 2010;4(1):75–83.
5. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. Clin Chem. 2002;48(5):691–8.
6. Bergenstal R, Pearson J, Cembrowski GS, Bina D, Davidson J, List S. Identifying variables associated with inaccurate self-monitoring of blood glucose: proposed guidelines to improve accuracy. Diabetes Educ. 2000;26(6):981–9.
7. Skeie S, Thue G, Nerhus K, Sandberg S. Instruments for self-monitoring of blood glucose: comparisons of testing quality achieved by patients and a technician. Clin Chem. 2002;48(7):994–1003.
8. Clinical and Laboratory Standards Institute. Estimation of total analytical error for clinical laboratory methods; approved guideline. CLSI document EP21-A. Wayne: CLSI; 2003.
9. Daniel C. Application of statistics to industrial experimentation. New York: Wiley; 1976.
10. Consensus statement on self-monitoring of blood glucose. Diabetes Care. 1987;10(1):95–9.