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SYMPOSIUM

A Review of Standards and Statistics Used to Describe Blood Glucose Monitor Performance

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Abstract

Glucose performance is reviewed in the context of total error, which includes error from all sources, not just analytical. Many standards require less than 100% of results to be within specific tolerance limits. Analytical error represents the difference between tested glucose and reference method glucose. Medical errors include analytical errors whose magnitude is great enough to likely result in patient harm. The 95% requirements of International Organization for Standardization 15197 and others make little sense, as up to 5% of results can be medically unacceptable. The current American Diabetes Association standard lacks a specification for user error. Error grids can meaningfully specify allowable glucose error. Infrequently, glucose meters do not provide a glucose result; such an occurrence can be devastating when associated with a life-threatening event. Nonreporting failures are ignored by standards. Estimates of analytical error can be classified into the four following categories: imprecision, random patient interferences, protocol-independent bias, and protocol-dependent bias. Methods to estimate total error are parametric, nonparametric, modeling, or direct. The Westgard method underestimates total error by failing to account for random patient interferences. Lawton's method is a more complete model. Bland–Altman, mountain plots, and error grids are direct methods and are easier to use as they do not require modeling. Three types of protocols can be used to estimate glucose errors: method comparison, special studies and risk management, and monitoring performance of meters in the field. Current standards for glucose meter performance are inadequate. The level of performance required in regulatory standards should be based on clinical needs *but can only deal with currently achievable performance*. Clinical standards state what is needed, whether it can be achieved or not. Rational regulatory decisions about glucose monitors should be based on robust statistical analyses of performance.

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Abbreviations: (ADA) American Diabetes Association, (ATE) allowable total error, (CLIA 88) Clinical Laboratory Improvement Amendments of 1988, (CLSI) Clinical and Laboratory Standards Institute, (CV) coefficient of variation, (FDA) Food and Drug Administration, (FMEA) failure mode effects analysis, (ISO) International Organization for Standardization, (LDL) low-density lipoprotein, (LER) limits for erroneous results, (LS MAD) locally smoothed median absolute differences, (POC) point of care, (SMBG) self-monitoring of blood glucose, (TE) total error

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