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Clinical Studies - Outcomes

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MODELS 1B AND 2 ACCORDING TO EFLM CONSENSUS CONFERENCE GIVE THE SAME SPECIFICATION FOR ALLOWABLE TOTAL ERROR (TEA) OF PLASMA GLUCOSE MEASUREMENT

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BACKGROUND: The 2014 EFLM Consensus Conference (CC) identified outcome- and biological variation (BV)-based as the highest hierarchical models for defining analytical performance specifications (APS) of a measurand. Fasting plasma glucose (PG) plays a central role in diagnosis of diabetes mellitus (DM) and decision limits for the definition of glycaemic-related conditions have been established. As direct studies investigating the impact of performance of PG measurement on clinical outcome are not available, we aimed to apply an indirect outcome model (1b according to CC) to derive APS for TEa, by investigating the impact of performance of PG measurement on clinical classifications of fasting subjects. The 1b-TEa was validated by comparison with TEa obtained using PG BV data (CC model 2). Since PG is under strict homeostatic control, robust BV data can be derived. In particular, we employed data from the study by Carlsen et al. (CCLM 2011;49:1501) (CVI, 5.4% and CVG, 5.6%), which totally fulfilled the EFLM checklist for BV study appraisal.
METHODS: The decision limits defining impaired fasting PG (IFG) concentrations (110 to 125 mg/dL) were considered and 1b-TEa was derived by assuming that a subject with a fasting PG of 117.5 mg/dL should be differentiate from healthy condition from one side (<110 mg/dL) and a frank DM from the other side (>125 mg/dL). Model 2-TEa was estimated according to the equation: TEa = [1.65 x 0.5CVI + 0.25(CVI2 + CVG2)0.5].
RESULTS: A subject with fasting PG of 117.5 mg/dL will not be misclassified as diabetic or healthy if TE of PG measurement is <7.5/117.5 = <6.38%. The corresponding TEa derived from PG biological variability was ±6.4%.
CONCLUSIONS: The described model 1b, based on assumptions drawn from what evidence there is about the definition of glycaemic-related conditions and thereby on the probability of subject outcome, is applicable for the definition of TEa of PG measurement. The similarity with TEa derived from model 2 confirms the equivalence of the two models advocated in the EFLM CC in case of measurands with well-defined biological and clinical characteristics, as PG. Additional studies are necessary to determine the clinical impact of the TEa.