Clinical Studies - Outcomes

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IMPACT OF MEASUREMENT ERROR OF PLASMA GLUCOSE ON CLINICAL CLASSIFICATION: A SIMULATION ANALYSIS

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BACKGROUND: According to EFLM Consensus Conference criteria on allocation of laboratory tests to the proper model to derive analytical performance specifications, the outcome-based model is well suited for fasting plasma glucose (PG), since the test is central to diagnose diabetes mellitus (DM) and to define glycaemic-related conditions. We previously described an indirect outcome model for the definition of allowable total error (TEa) of PG measurement. Here, we performed a simulation analysis to investigate the impact of derived TEa (±6.38%) on the clinical classification of the outpatient population served by our institution.

METHODS: We retrospectively retrieved PG results from outpatients for a 6-month period. PG was measured by a well-standardized and precise hexokinase assay on the Abbott Architect c16000 platform [average CV <1.3% and virtually unbiased (+0.2%) when compared with the CDC reference procedure]. The rate of subjects with impaired fasting PG (IFG), misclassified as frank DM or normoglycaemic if PG would be measured with a TEa of ±6.38%, was investigated.

RESULTS: The clinical classification of retrieved subjects [n=6537; median PG, 109 mg/dL; interquartile range (IQR): 99-128)] was 51.6% as healthy, 21.6% as IFG and 26.8% as DM. A +6.38% TE in PG measurement (median PG, 116 mg/dL; IQR: 105-136) resulted in +7.7% of subjects misdiagnosed as DM and +18.1% of healthy individuals classified as IFG. Conversely, a −6.38% TE (median PG, 102 mg/dL; IQR: 93-120) implied the shift of 6.2% DM to IFG category and of 12.6% IFG to the healthy group.

CONCLUSIONS: IFG represents a category at increased risk to develop DM. In this condition, the prevention of DM onset as well as of vascular hyperglycaemia-related complications is accomplished with interventions lowering PG over time. False negatives, i.e., IFG subjects misclassified as normoglycaemic, are therefore the most impacting results. In our served population, measuring PG with a TEa of ±6.38% theoretically implies that 12.6% of individuals would miss interventions necessary to stop the progression to DM and the worsening of related outcomes. Further clinical and economical evaluation is required to show if this misclassification rate is acceptable or a more stringent TEa should be applied.