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Harmonization of Serum Thyroid-Stimulating Hormone Measurements Paves the Way for the Adoption of a More Uniform Reference Interval.

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Abstract

BACKGROUND: The IFCC Committee for Standardization of Thyroid Function Tests developed a global harmonization approach for thyroid-stimulating hormone measurements. It is based on a multiassay method comparison study with clinical serum samples and target setting with a robust factor analysis method. Here we describe the Phase IV method comparison and reference interval (RI) studies conducted with the objective to recalibrate the participating assays and demonstrate the proof-of-concept.

METHODS: Fourteen manufacturers measured the harmonization and RI panel; 4 of them quantified the harmonization and first follow-up panel in parallel. All recalibrated their assays to the statistically inferred targets. For validation, we used desirable specifications from the biological variation for the bias and total error (TE). The RI measurements were done with the assays' current calibrators, but data were also reported after transformation to the new calibration status. We estimated the pre- and postrecalibration RIs with a nonparametric bootstrap procedure.

RESULTS: After recalibration, 14 of 15 assays met the bias specification with 95% confidence; 8 assays complied with the TE specification. The CV of the assay means for the harmonization panel was reduced from 9.5% to 4.2%. The RI study showed improved uniformity after recalibration: the ranges (i.e., maximum differences) exhibited by the assay-specific 2.5th, 50th, and 97.5th percentile estimates were reduced from 0.27, 0.89, and 2.13 mIU/L to 0.12 , 0.29, and 0.77 mIU/L.

CONCLUSIONS: We showed that harmonization increased the agreement of results from the participating immunoassays, and may allow them to adopt a more uniform RI in the future.

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