The Consensus Statement on the Standardization and Evaluation of Growth Hormone and Insulin-like Growth Factor Assays Lacks a Recommendation to Attempt Efficacious Harmonization

To the Editor:

Similar to the 2006 consensus statement on the standardization of growth hormone (GH) assays (1), the guidelines regarding improvement of assay comparability in a recent consensus statement in Clinical Chemistry (2) are limited to the recommendation of common use of the Second International Standard for Somatropin (IS 98/574), although it is recognized that discrepancies between different assays may remain. As a comment on this consensus statement, we pointed out that the recombinant IS 98/574 standard intrinsically lacks commutability, and therefore one can expect only a partial reduction in the variation between assay methods (3). The recent consensus report (2) states that a demonstration of commutability has not yet been published. The Endocrinology section of SKML (Dutch Foundation for Quality Assessment in Clinical Laboratories) performed such a study with the predecessor of IS 98/574 (numbered 88/624 and produced by an identical procedure) as part of a harmonization study that used a natural, commutable serum obtained from healthy individuals during exercise to stimulate GH secretion. In brief, the results (3) were as follows: the imprecision among the results of 6 different assay methods was reduced from 25% when all assays were performed with their own calibrators to 15% when IS 88/624 was used as a common standard. A further reduction to 6.7% was obtained by using the harmonization serum, to which was assigned a value equal to the mean of the results obtained by these 6 assay methods with IS 88/624 used as a standard. The harmonization procedure has since been adopted by the Dutch Growth Foundation as the best approach for excluding GH deficiency after proper stimulation of GH secretion. Consequently, we assert that a harmonization procedure as implemented in the Netherlands may improve clinical decision making, especially with respect to the selection of patients who are eligible for treatment with GH. We wonder why this approach has not yet been adopted elsewhere.

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