Eur Thyroid J. 2014 Jun;3(2):109-16. doi: 10.1159/000358270. Epub 2014 M

# A Progress Report of the IFCC Committee for Standardization of Thyroid Function Tests.

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## Abstract

**BACKGROUND:** The IFCC Committee for Standardization of Thyroid Function Tests aims at equivalence of laboratory test results for free thyroxine (FT4) and thyrotropin (TSH).

**OBJECTIVES:** This report describes the phase III method comparison study with clinical samples representing a broad spectrum of thyroid disease. The objective was to expand the feasibility work and explore the impact of standardization/harmonization in the clinically relevant concentration range.

**METHODS:** Two sets of serum samples (74 for FT4, 94 for TSH) were obtained in a clinical setting. Eight manufacturers participated in the study (with 13 FT4 and 14 TSH assays). Targets for FT4 were set by the international conventional reference measurement procedure of the IFCC; those for TSH were based on the all-procedure trimmed mean. The manufacturers recalibrated their assays against these targets.

**RESULTS:** All FT4 assays were negatively biased in the mid- to high concentration range, with a maximum interassay discrepancy of approximately 30%. However, in the low range, the maximum deviation was approximately 90%. For TSH, interassay comparability was reasonable in the mid-concentration range, but worse in the pathophysiological ranges. Recalibration was able to eliminate the interassay differences, so that the remaining dispersion of the data was nearly entirely due to within-assay random error components. The impact of recalibration on the numerical results was particularly high for FT4.

**CONCLUSIONS:** Standardization and harmonization of FT4 and TSH measurements is feasible from a technical point of view. Because of the impact on the numerical values, the implementation needs careful preparation with the stakeholders.

**KEYWORDS:** Free thyroxine; Harmonization; Method comparison; Standardization; Thyrotropin; Traceability

PMID: 25114874 PMCID: PMC4109515 DOI: 10.1159/000358270