EXTERNAL QUALITY ASSESSMENT FOR THE RIA OF THYROID RELATED HORMONES: SECOND PHASE

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ABSTRACT

An external quality assessment was conducted to assess the performance of various laboratories for RIA of thyroid related hormones in two phases. In the first phase thirty five laboratories participated. At the end of first phase a meeting cum workshop was organised to discuss the results of first phase, difficulties faced by the participants and pinpoint the short coming. A second phase was then initiated with an objective of improvement in the performance, if any, where twelve samples from four pools were distributed to twenty four laboratories who participated for the second phase. The overall return of the results increased significantly from 71.8% (1586/2208) for the first phase to 92.4% (732/792) for the second phase. The inter laboratory %CV for $T_s$, $T_4$ and TSH were lower during the second phase (30.6%, 19.0% and 31.6% respectively) as compared to those observed during first phase (36.3%, 22.7% and 52.8% respectively). Similarly, there was an improvement in reproducibility of ALTM as %CV for $T_s$, $T_4$ and TSH decreased from 6.0%, 9.8% and 13.4% respectively to 4.5%, 4.6% and 8.5% respectively. The individual performances of the participating laboratories viz. bias, variability of bias and imprecision also showed a trend towards improvement as percent laboratories having desirable or acceptable results for $T_s$, $T_4$ and TSH increased from 10.7%, 60.7% and 0.0% respectively to 20.8%, 66.7% and 22.2% respectively. External quality assessment thus appears to be beneficial in assessing the performance of a laboratory in comparison with other laboratories and indeed helps in improving the performance.

INTRODUCTION

We have earlier reported an external quality assessment (EQA) scheme for thyroid related hormones which was undertaken to assess the performance of various laboratories in the country under a joint auspices of International Atomic Energy Agency (IAEA) and Bhabha Atomic Research Centre (BARC) India (1).

The programme was conducted in two phases. At the end of the initial phase, the data gathered was analysed and a copy of analysis was sent to each participating laboratory. To gather feedback, a meeting cum workshop of participating laboratories was held and the shortcomings, the difficulties faced, etc. were discussed. A second phase, with an aim of improving the performance of the participating laboratories was then initiated.
In this report, we present the results of the second phase along with a comparison with the outcome of initial phase.

**MATERIAL AND METHODS**

**Participating laboratories:** Twenty four laboratories, who showed their willingness to pursue the programme and/or attended the meeting held at the end of the first phase participated in the second phase.

**Construction and distribution of pools:** Four manipulated pools, by adding known quantities of T₃, T₄ and TSH to euthyroid pools, were constructed (Table 1) and distributed to participating laboratories as described earlier (1).

**Data analysis:** All laboratory trimmed mean (ALTM), unbiased standard deviation, between laboratories coefficient of variation (CV), histogram showing frequency distribution and outliers were estimated for each sample in the same way as was done for first phase (1). Estimation of recovery, inter- and intra-assay CV was done for each laboratory from samples designed for obtaining these parameters. The bias and variability of bias (VB) for each laboratory and reproducibility of ALTM and overall recovery for each pool were also estimated as described earlier (1).

**RESULTS**

Of the 24 laboratories who participated in the second phase 18 performed RIA for all the hormones (T₃, T₄ and TSH) while the remaining six estimated only T₃ and T₄. There was a significant improvement (p<0.001) in the response during second phase as percent return for T₃, T₄ and TSH were more 92.7% (267/288), 92.7% (267/288) and 91.7% (198/216) respectively as compared to 75.0% (612/816), 73.1% (614/840) and 65.2% (360/552) respectively during the first phase. The overall percent return for all the three hormones was 92.4% (732/792) for the second phase as compared to 71.8% (1586/2208) for the first phase.

**ALTM and CV:** The ALTM and unbiased CV are shown in Table 1. The weighted mean CV were lower during second phase as compared to that observed in initial phase (30.6% vs 36.3% for T₃, 19.0% vs 22.7% for T₄ and 31.8% vs 52.4% for TSH). The trend observed during first phase of lowest overall mean CV with T₄ and highest with TSH reaminned unchanged.

**Precision:** There was an improvement in reproducibility of ALTM. The percent CV obtained around the mean during the second phase for T₃, T₄ and TSH were 4.5%, 4.6% and 8.5% respectively as compared to 6.0% 9.8% and 13.4% respectively during the first phase (Table 2).

**Recovery:** The mean recovery of added hormones for T₃, T₄ and TSH were 76.6%, 73.8% and 117.4% respectively during second phase as compared to 117%, 86.9% and 100.5% respectively during first phase (Table 3).

**Bias, Variability of bias (VB) and Imprecision (IP):** Based on the guidelines followed by