P-235 - EXTERNAL QUALITY ASSURANCE PROGRAM FOR NEONATAL SCREENING IN LATIN AMERICA: PITFALLS AND ERRORS IN THE MEASUREMENTS AND REPORTING RESULTS.

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INTRODUCTION: External Quality Assurance (EQA) is an essential component of the Laboratory Quality System. The EQA Program for Neonatal Screening (PEEC-PN) of the Fundación Bioquímica Argentina was implemented in 2000. It distributes bimonthly control materials for Phenylalanine, TSH, IRT and Galactose to more than 190 Laboratories from 13 countries from Latin America. OBJECTIVE: To describe the main pitfalls and errors made by the participants in the measurement and reporting results of Phenylalanine and TSH in the period Jun/17-May/18.

MATERIALS AND METHODS: Surveys 103 to 108 for Phenylalanine and TSH were included in the analysis. Parameters evaluated: number of registered Laboratories; number of results received after the deadline; shipping time of controls; time of analysis; time of reporting results; outliers; percentages of: units expression (UE), transposition results (TE), and results interpretation (IE) errors; and false negatives (FN) and false positive (FP) rates. RESULTS: 194 laboratories participated in the 6 surveys, 92/194 (47.4%) had perfect attendance, but 13/194 (6.7%) did not send any result. 23 new laboratories applied for registration and 17 were deregistered. 898 results (84.4%) were received. 177/898 (19.7%) were received after the deadline, but they equally were included in the specific survey evaluation. Mean shipping time was 8.2 and 28.2 days for Argentina and the rest of the countries, respectively. Mean times of analysis and reporting results were 7.2 and 9.4 days, respectively. Outliers_{Phe}=2.3%; Outliers_{TSH}=4.2%; UE_{Phe}=0.0%; UE_{TSH}=1.9%; TE_{Phe}=0.5%; TE_{TSH}=0.7%; IE_{Phe}=0.5%; IE_{TSH}=1.0%; FN_{Phe}=3.3%; FN_{TSH}=1.9%; FP_{Phe}=5.6%; FP_{TSH}=3.7%. Percentages of Laboratories without FN results for Phe and TSH were 95.1% in both cases, while they were 94.4 and 93.3% in the case of FP, respectively. CONCLUSIONS: The scenario of the EQA in Latin America pose different aspects that require to be improved: the continuous replacement of Laboratories (registration/deregistration), the lack of compromise of some participants who do not report any result, the logistic of shipments to countries out of Argentina, the constant presence of non-analytical errors caused by inattention in the reporting results (TE and IE), and the poor knowledge about the units used by the reagent manufacturers to assign values to the calibrators (UE), are the main topics to work.