EQALM

European Organisation For External Quality Assurance Providers in Laboratory Medicine

EQALM symposium 2014

October 23rd – 24th

Hotel Palladia, Toulouse, France

ABSTRACT BOOK

External Quality Assurance Program for Neonatal Screening of Glucose-6-Phosphate Dehydrogenase Deficiency

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Background

The nationwide neonatal screening of Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency in Taiwan was started on July 1, 1987. The effective collection rate has reached >99% of all newborns since 1996 and the overall incidence rate of G6PD deficiency is about 2%. A network of referral hospitals distributed all around Taiwan was organized for follow-up, confirmatory test, medical care and genetic counseling of G6PD screening positive cases.

Objective

To assess the reliability and assure the quality of the confirmatory and screening tests, an external quality assurance (EQA) program for G6PD assay was developed.

Methods

For screening test, the QC materials were prepared from whole blood by spotting on to Guthrie cards. For confirmatory quantitative test, lyophilized quality control (QC) materials were prepared from human red blood cells. Periodically (1-2 month), 3 ~ 5 lyophilized QC samples and 10 QC blood spots were sent to referral and screening laboratories, respectively. The external QA results were evaluated and compared to the reference value (and medium/mean for quantitative test).The test results were submitted through internet and the summary reports were published on the webpage within two weeks after each survey started <http://g6pd.qap.tw>.

Results

Forty-three screening laboratories (3 in Taiwan, 14 in Mainland China, 5 in Philippines, 5 in India, 4 in Vietnam, 3 in German, 2 in Mexico, 2 in Greece, and 1 each in Australia, Lebanon, Switzerland, Thailand, and Turkey) and 22 referral laboratories in Taiwan are participating in the EQA program at the present time. From 1999.3 to 2013.12, 92 EQA surveys for screening test were performed and 1469 reports were received. One hundred and sixty-one (11.0%, 161/1469) unsatisfactory EQA reports were found. One hundred and thirty-two false negative and 288 false positive results were reported from the 14,690 blood spots tested by all the screening laboratories. The unsatisfactory results were mainly caused by inappropiate cut-offs. From 1988.1 to 2013.12, 184 EQA surveys were sent to referral laboratories and 3,371 reports were received in reply to these QA surveys. Three hundred and three (9.0%, 303/3,371) unsatisfactory reports were found. Interlaboratory C.V. for the quantitative test has reached less than 10% in recent years. Between 2008.1 and 2013.12, 3 QC materials with different G6PD activities (5.2, 8.3, and 13.1 U/gHb) have been used 6 times in different EQA surveys during this 5 years period of time. The long term intra-laboratory between run CV of the G6PD confirmatory test in those referral laboratories were found to be between 1.9% and 15.2%. Since July 2009, 15 EQA surveys (from 2009.7 to 2013.12) have been carried out for the newly established network of confirmatory testing laboratories (n = 15) in

Philippines. Thirty-three (22.9%, 65/284) unsatisfactory EQA results were found from 284 reports. Interlaboratory C.V. were between 6.6% and 22.8% (1.7 ~ 20.5 U/gHb), which is lower than those found in other EQA programs (*e.g.* CAP, RCPA) for G6PD quantitative test.

Conclusions

These G6PD external quality assurance programs have been useful for monitoring the performance and to improve the laboratory test quality of the referral and screening laboratories, and might be a reference for the participating laboratories to adjust the cut-offs for the screening test.

PNAEQ – Parasite Morphology Performance evaluation of participants between 1995-2013

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Introduction

PNAEQ (Programa Nacional de Avaliação Externa da Qualidade), has implemented the Parasite morphology (blood and feaces) since 1995.

The collaboration of experts has been an asset in sample selection and result analysis aimed at continuous improvement of the performance of the participants.

In this retrospective study, we intend to evaluate the participant performance since the beginning of the program until 2013, with regard to the correct identification of fecal and blood parasites. The quantification and differentiation of the stages will be the subject of future analysis.

The program includes three annual distributions being sent at least one stool and one blood sample per distribution.

114 samples containing protozoa and helminths with a total of 29 species were sent. The qualitative statistical analysis of the identification of faecal and blood parasites was analysed taking into account the parasite present in the sample. A evaluation and feedback from PNAEQ experts, had always a formative character.

The analysis of the participant's results was accomplished considering the biological product and the number of parasites sent per sample.

Faeces:

Considering the results of the identification of samples sent with only a parasite, there was a variation of correct identification between 38,3 to 95,0%. The parasites identified with percentage greater than 90% were *Cryptosporidium*, *Giardia*, *Ascaris lumbricoides* and *Strongyloides stercoralis*. Up to 75%, and in descending order, *Ancylostomideo*, *Diphyllobothrium latum*, *Clonorchis sinensis, Fasciola hepatica*, *Enterobius vermicularis* and *Isospora belli*. In multiinfested samples, were observed less performance of laboratories [7,3 -84,1]%. The 7,3% was observed in