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QUALITY ASSURANCE PROGRAM FOR NEONATAL SCREENING OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY

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Abstract

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 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 for each survey <http://g6pd.tw>.

Results: Twenty-three screening laboratories (3 in Taiwan, 9 in Mainland China, 3 in Philippines, 2 in German, and 1 each in Australia, India, Lebanon, Thailand, Turkey, and Vietnam) and 21 referral laboratories in Taiwan are participating in the QA program at the present time. From 1999.3 to 2010.5, 71 surveys for screening test were performed and 813 reports were received. One hundred and twenty-eight (15.7%, 128/831) abnormal QA reports were found. One hundred and fourteen false negative and 268 false positive results were reported from the 8,130 blood spots tested by all the screening laboratories. From 1988.1 to 2010.5, 163 QA surveys were sent to referral laboratories and 2,935 reports were received in reply to these QA surveys. Two hundred and ninety-eight (10.2%, 298/2,935) abnormal QA results were found. Interlaboratory C.V. for the quantitative test has reached below 10% in recent years. Between 2007.1 and 2010.5, 3 QC materials with different G6PD activities (5.1, 8.1, and 12.7 U/gHb) have been used 6 to 7 times in different surveys during this 3 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 2.9% and 19.8% . Since last year, 7 surveys (from 2009.7 to 2010.7) have been carried out for the newly established network of confirmatory testing laboratories in Philippines. Eleven (18.0%, 11/61) abnormal QA results were found from 61 reports. Interlaboratory C.V. were between 11.0% and 24.6% (2.1 ~ 20.4 U/gHb), which is lower than those found in CAP surveys.

Conclusions: The external quality assurance program has been useful for monitoring the performance of the referral hospitals and screening laboratories, and might be a guidance for the participating laboratories to correct the analytical errors. (These works were partially supported by grants from the Dept. of Health, Executive Yuan, Taiwan, R.O.C.)