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

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Objective: 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. In order 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.

Results: Twenty-nine screening laboratories (3 in Taiwan, 10 in Mainland China, 4 in Philippines, 2 in German, 2 in India, 2 in Mexico and 1 each in Australia, Greece, Lebanon, Thailand, Turkey, and Vietnam) and 20 referral laboratories in Taiwan are participating in the QA program at the present time. From 1999.3 to 2011.12, 80 surveys for screening test were performed and 1051 reports were received. One hundred and forty (13.3%, 140/1051) abnormal QA reports were found. One hundred and thirty false negative and 274 false positive results were reported from the 10,510 blood spots tested. From 1988.1 to 2011.12, 172 QA surveys were sent to referral laboratories and 3,120 reports were received in reply to these QA surveys. Three hundred and one (9.6%, 301/3,120) abnormal QA results were found. Interlaboratory C.V. for the quantitative test has reached below 10% in recent years. Between 2007.1 and 2011.12, 3 QC materials with different G6PD activities (5.1, 8.1, and 12.7 U/gHb) have been used 8 times in different surveys during this 4 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 4.1% and 17.3%. Since July 2009, 15 surveys (2009.7~2011.12) have been carried out for the newly established network of confirmatory testing laboratories (n=10) in Philippines. Thirty-three (24.4%, 33/135) abnormal QA results were found from 135 reports. Interlaboratory C.V. were between 9.9% and 22.7% (1.9 ~ 20.5 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.

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