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QUALITY ASSURANCE PROGRAM FOR NEONATAL SCREENING OF G6PD 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. At present, the effective collection rate has reached 99.7% of all newborns and the overall incidence rate of G6PD deficiency is about 2%. The referral hospitals distributed all around Taiwan were organized for follow-up, confirmatory test, medical care and genetic counseling. To assess the reliability of the confirmatory and screening tests, an external quality assurance (QA) program for G6PD assay was developed.

Methodology: Workshops of G6PD assay were held for the referral hospitals to standardize procedures for quantitative assay and for spectrophotometer and micropipette calibration. For quantitative assay, lyophilized quality control (QC) materials were prepared from red blood cells. For screening test, the QC materials were prepared from whole blood and spotted on to Guthrie cards. Periodically (1-2 month), the QC materials were sent to each referral hospitals and screening centers by speed post delivery. The external QA results were evaluated and compared to the reference values determined by our laboratory. For participants with system errors detected by this QA program, troubleshooting were proceeded either by phoning or visiting.

Results & Discussions: Twenty-one referral laboratories and 8 screening centers (3 in Taiwan, 2 in Mainland China, and 1 each in Philippines, Thailand and Lebanon) are participating in the QA program at the present time. From January 1988 to June 2001, 104 QA surveys (3 to 5 QC specimens for each shipment) to referral laboratories were performed and 1,900 reports were received in reply to these QA surveys. Two hundred and thirty nine (12.5%, 239/1,900) abnormal QA results were found, which were attributed to clerk (29/239, 12%), experimental (43/239, 18%), and instrumental errors (112/239, 47%). Most of the experimental and instrumental errors were found in those laboratories, which did not execute internal QA restrictively. For the screening test, 10 blood spots were sent to each screening center for each QA survey. From March 1999 to June 2001, 12 surveys were performed and 112 reports were received. Four (3.5%, 4/112) abnormal QA reports were found. One false negative and 14 false positive results were reported from the 1,120 blood spots tested by all the screening centers.

Conclusions & Recommendations: The external quality assurance program had provided a good system for monitoring the performance of the referral hospitals and screening centers, and might be a guidance for the referral hospitals and screening centers to correct the analytical errors.

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