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APEX

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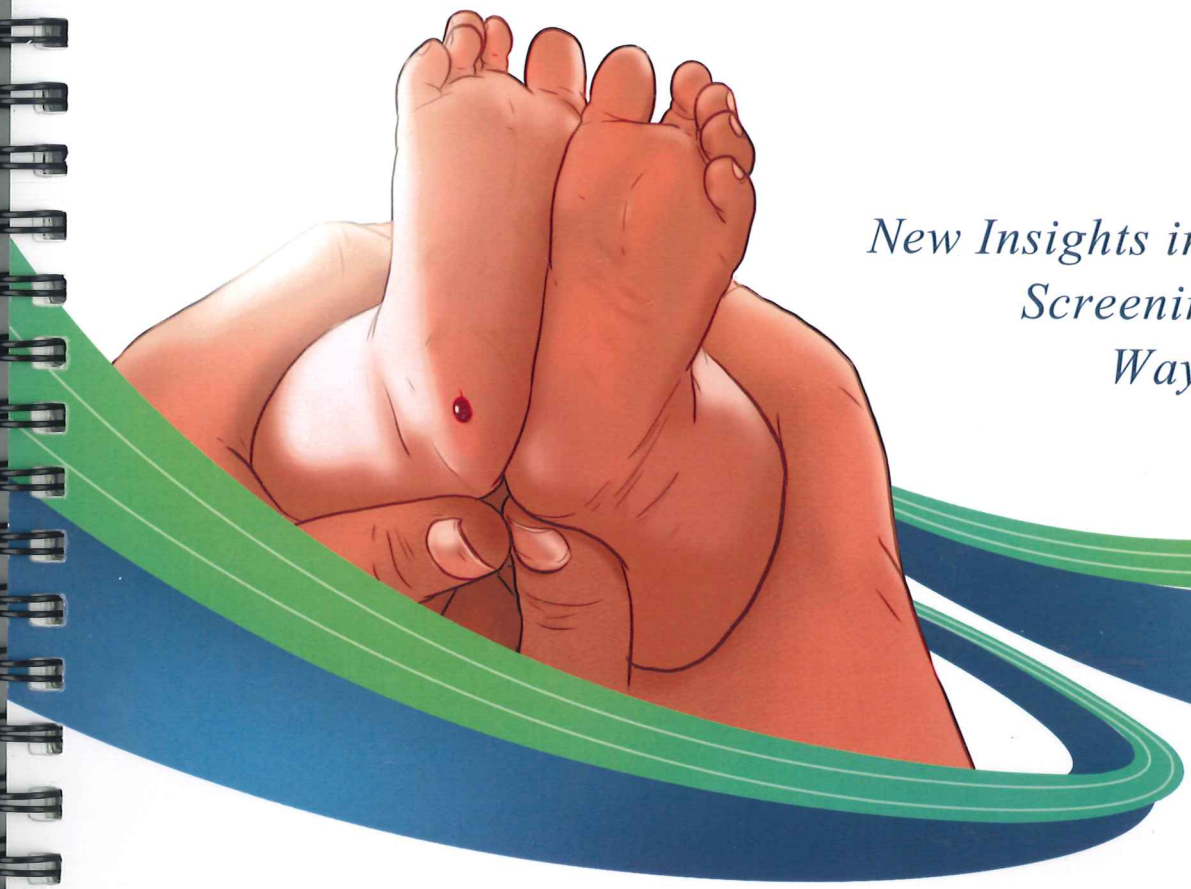
ParkRoyal Hotel, Penang



New Insights in Neonatal Screening and the Way Forward

Results: Of 6,387 live births in these twelve birthing facilities during this period of time, 98.9% (n = 6,296) underwent pulse oximetry. Sixteen (0.25%) newborns had a final failed result. Five neonates were confirmed as CCHDs, two of them had diagnoses solely attributable to the CCHD screening. All the CCHD cases were referred and confirmed before 3 days after birth. Through repeated measurements for those with first measurement <90% saturation, only eleven of seventeen cases had a final failed result. False-positive rate was 0.17%.

Conclusion: The result indicates this is an efficient screening system with high screening rate. The community-based newborn CCHD screening program in Taipei successfully integrated screening, referral and public health systems which provided a scheme for nation-wide implementation.

09 INTERNAL QUALITY CONTROL (IQC) PROGRAM FOR NEONATAL SCREENING OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY

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Introduction: Glucose-6-phosphate dehydrogenase (G6PD) deficiency is the most common human enzymopathic disease. Many Southeast Asia countries have included G6PD as a routine newborn screening item.

Objective: IQC program has been developed to monitor the quality of screening and quantitative G6PD tests between the EQA surveys.

Methods: For screening test, the QC materials were prepared from human whole blood by spotting on to Guthrie cards. For quantitative test, lyophilized QC materials were prepared from human red blood cells. The homogeneity and stability of the QC materials were checked according to ISO 13528. Two levels of QC materials were provided. The results were reported via an online system. The real time statistics and control chart were available as soon as the results had been input. The summary statistic reports of all the participants were published online monthly for comparison. <http://iqc.g6pd>< http://nsiqc.qap.tw>.

Results: Fifteen screening laboratories (Taiwan, Mainland China, Philippines, and Turkey) and 26 referral laboratories (Taiwan and Philippines) participated in the IQC program in 2014. Total 16,515 pair screening test results were reported. In high level, the range of CV, TE, and σ were 5.8%~27.0%, 11.8%~681%, and 0.5~3.4, respectively. In low level, the CV, TE, and σ were 4.6%~17.0%, 9.3%~766%, and 0.7~4.6, respectively. Total 2,095 pair quantitative test results were reported. In high level, the CV, TE, and σ were 0.7%~17.8%, 2.0%~52.8%, and -0.8~>6, respectively. In low level, the CV, TE, and σ were 2.4%~65.2%, 8.5%~172.6%, and -1.3~>6, respectively.

Conclusions: The data indicated that the quality of daily routine G6PD tests was varied widely in different laboratories. These G6PD IQC programs are useful for monitoring the intra-laboratory daily performance of the laboratories and provide good third party QC samples for the laboratory to compile the requirements for the quality and competence required by international standards (ISO 15189:2012, CLSI C24-A3:2006).