



Republic of the Philippines
Department of Health *DMHEPS: 11-20-1*
OFFICE OF THE SECRETARY

November 16, 2009

ADMINISTRATIVE ORDER

No. 2009 - 0020

SUBJECT: Designation of the Newborn Screening Reference Center (NSRC), National Institutes of Health-University of the Philippines Manila to Oversee the Quality Assurance Program for G6PD Confirmatory Test.

I. RATIONALE/BACKGROUND

Under Section 4 of the Republic Act (RA) 9288 or the Newborn Screening Act of 2004, one of the components of the National Comprehensive Newborn Screening System (NCNBSS) is the tracking and confirmatory testing thereof to ensure the accuracy of screening results.

In accordance with this, Art. 4 Sec. 10-4 of RA 9288 mandates the Department of Health to *"coordinate with the NIH Newborn Screening Reference Center for the accreditation of Newborn Screening Centers and preparation of defined testing protocols and quality assurance programs."*

Subsequently, the NCNBSS has initiated steps to ensure accessibility of confirmatory testing centers to the relevant public and to guarantee quality of confirmatory results. The move has started with the Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency, one of the disorders included in the newborn screening panel. It is a condition where the body lacks the enzyme called G6PD. Babies with this deficiency may have hemolytic anemia resulting from exposure to oxidative substances found in drugs, foods and chemicals. Among the five congenital metabolic disorders being screened in the Philippines, G6PD Deficiency has the highest prevalence rate of one out of fifty-five (1:55).

Since the start of the newborn screening program, almost 60,000 babies were initially found deficient in G6PD, about 50% of which have not undergone confirmatory test due to financial reasons and accessibility of the test. With the release of Department Memo No. 2008-0123 *"Newborn Screening Coverage"*, the number of patients that need confirmatory test for G6PD is expected to increase.

Some of the steps undertaken by the NCNBSS were the appointment of an Expert Committee on G6PD Deficiency which participates in the review of datasets and cutoffs of the disorder, treatment and management protocols among others; and the identification of tertiary hospitals in the different regions of the country equipped and willing to integrate G6PD enzyme assay as one of their services.

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The next step in the efforts to ensure the quality of the confirmatory results of the disorders included in the newborn screening panel, is the establishment of the quality assurance program, initially for G6PD confirmatory test in the country. NSRC being the central facility at the NIH that defines testing and follow-up protocols, maintains an external laboratory proficiency testing program is the ideal agency to manage the quality assurance program for the G6PD Deficiency Confirmatory Testing.

II. OBJECTIVE

To designate the Newborn Screening Reference Center (NSRC) of the National Institutes of Health (NIH), University of the Philippines, Manila to oversee the quality assurance program for G6PD Confirmatory test in the country.

III. SCOPE AND COVERAGE

This Order shall apply to the Newborn Screening Reference Center and other health facilities that shall run G6PD Confirmatory Test.

IV. GUIDELINES

The NSRC is designated to oversee the quality assurance program for G6PD confirmatory test. Facilities that shall provide G6PD Confirmatory testing in their laboratories in country shall comply with the standards set by NSRC.

Roles and Responsibilities:

NSRC:

1. Provide technical assistance to laboratories offering G6PD confirmatory test;
2. Ensure good laboratory practice in laboratories doing G6PD confirmatory test by establishing external laboratory proficiency testing and certification program in partnership with the International QA Program in Taiwan for G6PD. NSRC shall send Proficiency Testing Samples to G6PD testing Laboratories every two months and submit the results to the International QA Program in Taiwan; and
3. Report and make recommendations, if necessary, to the National Center for Disease Prevention and Control (NCDPC) semi-annually.

G6PD Testing Laboratories:

1. Provide skilled medical technologists to extract blood from neonates and perform the G6PD confirmatory testing services on a regular basis, at least once a week;
2. Provide immediate relay of G6PD confirmatory results (whether confirmed positive or negative) to the patient's family, attending physician and Newborn Screening Center's for their records;
3. Comply with the standard confirmatory testing fee set by the Department of Health;
4. Comply with the standards set by NSRC to ensure good laboratory practice; and

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5. Participate in the International QA program set by NSRC by running quality assurance samples and submit the result to NSRC.

Funding

Incidental costs for sending of quality assurance samples to G6PD Confirmatory Testing Laboratories shall be shouldered by the NSRC.

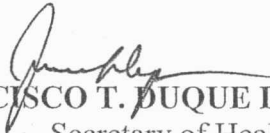
V. REPEALING CLAUSE

This shall repeal and supersede all administrative issuances inconsistent thereof.

VI. EFFECTIVITY

This shall take effect fifteen (15) days after completion of its publication in the official gazette or in a newspaper of general circulation.

This Order takes effect immediately


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

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