



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 20 2014

ADMINISTRATIVE ORDER

No. 2014 - 0035

Subject: Implementing Guidelines on the Setting-up of Newborn Screening Continuity Clinics

I. Rationale

Pursuant to Section 13 of the Implementing Rules and Regulation of Republic Act 9288, otherwise known as the Newborn Screening Act of 2004, the DOH being the lead agency shall ensure that a network of facilities for referral and management of all positive cases is established. In addition, it shall develop referral centers and identify referral teams in strategic areas for referral and management of patients with any of the disorders.

Recognizing this need and of the mandate to develop referral centers, the Department of Health and the National Institutes of Health are setting-up Newborn Screening (NBS) Continuity Clinics in the country to strengthen the National Comprehensive Newborn Screening System Treatment Network and ensure the early treatment and appropriate management of identified positive cases.

Initially, one Newborn Screening Continuity Clinic and Birth Defects Continuity Clinic per region shall be set-up. Subsequently, provincial continuity clinics shall be established.

II. Objective

To provide policies and guidelines for the setting-up and implementation of NBS Continuity Clinics and Birth Defects Continuity Clinics for referral and management of all screened-positive newborns.

III. Scope and Coverage

This Order shall apply to all Newborn Screening Centers, DOH – Regional Offices (DOH-ROs), National Comprehensive Newborn Screening System Treatment Network and all other agencies and stakeholders concerned in the implementation of the newborn screening program.

IV. Definition of Terms

National Comprehensive Newborn Screening System Treatment Network refers to a network wherein total management of patient with confirmed diagnosis shall be referred to. It follows the DOH-approved clinical protocol in the management of patients diagnosed in any of the disorders included in the newborn screening panel.

National Institutes of Health – Institute of Human Genetics (NIH-IHG) refers to the unit at the National Institutes of Health that provides comprehensive clinical evaluation of

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families or individuals with or at risk for heritable conditions; it provides support for remote, real-time referral (the Telegenetics Referral System) and Birth Defects Surveillance System in the country. It also offers laboratory and diagnostic services pertinent to the management of heritable conditions.

Newborn Screening Panel of Disorders refers to the list of disorders tested under the Philippine Newborn Screening Program. The panel includes newborn screening for the following disorders: Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Phenylketonuria, Galactosemia, G6PD Deficiency and Maple Syrup Urine Disease. By mid-2014, an expanded newborn screening panel shall be offered as an option increasing the number of disorders from six (6) to twenty-eight (28) falling under various types of disorders namely: hemoglobinopathies, amino acid disorders, organic acid disorders, disorders of fatty acid oxidation, disorders of carbohydrate metabolism, disorders of biotin metabolism, cystic fibrosis and endocrine disorders.

Newborn Screening Reference Center (NSRC) refers to the central facility at the National Institutes of Health that defines testing and follow-up protocols, maintains an external laboratory proficiency testing program, oversees the national testing database and case registries, assists in training activities in all aspects of the program, oversees content of educational materials and acts as the Secretariat of the Advisory Committee on Newborn Screening.

Newborn Screening Center (NSC) refers to a facility equipped with a newborn screening laboratory that complies with the standards established by the National Institutes of Health, and provides required laboratory tests and recall/follow-up programs for newborns with heritable conditions.

Newborn Screening Continuity Clinic refers to an ambulatory clinic based in a tertiary hospital identified by the DOH to be part of the National Comprehensive Newborn Screening System Treatment Network. It is equipped to facilitate continuity of care of confirmed patients in its area of coverage.

Birth Defects Continuity Clinic refers to an ambulatory clinic based in regional and provincial referral centers identified by the DOH. It specifically caters to patients with birth defects for the purpose of diagnosis and management.

Telegenetics Referral System refers to provision of remote genetic clinical consults to physicians in the provinces for their patients over a computer network.

V. General Guidelines

- A. The NBS Continuity Clinics shall be established, initially in every region, equipped to facilitate continuity of care of confirmed patients in its area of coverage. Subsequently, the NBS Continuity Clinics shall be established in the provincial level.
- B. The Birth Defects Continuity Clinics shall be integrated in the National Comprehensive Newborn Screening System. The Birth Defects Continuity Clinics will share the same infrastructure and personnel of the Newborn Screening Continuity Clinics.
- C. The Telegenetics Referral System shall be utilized by the NBS Continuity Clinics and Birth Defects Continuity Clinics where subspecialists are not available in the hospital.
- D. Memoranda of Agreement shall be executed between NSRC, NSC, DOH-RO, Host Facility, and IHG for every regional/provincial Continuity Clinic.

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VI. Specific Guidelines

A. Patient Care

In terms of the different components of NBS patient care, the following shall be considered in the implementation of the NBS Continuity Clinics and Birth Defects Continuity Clinics:

1. Diagnosis and Initial Management

- a. In coordination with the DOH-ROs, the NSCs shall be responsible for the tracking of newborns with out-of-range screening results to ensure repeat specimen collection, repeat screening and/or confirmatory testing from the NBS laboratories or confirmatory centers.
- b. The NSCs shall facilitate the confirmatory testing for newborns with out-of-range screening results and initiate medical management for patients with confirmed diagnosis.

2. Long-term Management (including counseling, treatment, monitoring and follow-up).

- a. The NSCs shall refer all newborns who are confirmed positive with heritable disorders to NBS Continuity Clinic for long-term follow-up care.
- b. In coordination with the DOH-ROs, every effort shall be made by the personnel of the continuity clinics to contact and schedule patients referred from NSCs so that the necessary treatment and long-term follow-up care shall be given, as well as timely monitoring shall be undertaken.
- c. The continuity clinics shall facilitate referral of patients needing consults to available subspecialists in their facility or region. In cases wherein subspecialists are not available, the continuity clinics shall utilize the Telegenetics Referral System.

B. Operations of NBS Continuity Clinics

In terms of the different components of the newborn screening program, the following shall be considered in the implementation of the NBS Continuity Clinics and Birth Defects Continuity Clinics:

1. Selection, Recruitment and Hiring of Personnel

- a. The continuity clinics shall be manned by a part-time Medical Specialist and a full-time Nurse or Genetic Counselor.
- b. The Department of Pediatrics of every host facility shall be responsible for overseeing the recruitment and selection of personnel for the continuity clinic in their facility.
- c. The host facility shall make the necessary recommendations for the hiring of their personnel.

2. Funding

The operational expenses of these clinics, including, but not limited to communication and travel expenses, as well as financial support for indigent families, shall be shared responsibilities of NSRC, NSCs, DOH-ROs and host facilities.



C. Capacity Building

Long-term management of patients, require enhancement of skills and competencies and will be supported with a capacity building program organized by the DOH in partnership with NSRC.

D. Information Education and Communication

1. Information on the establishment of the continuity clinics and the Telegenetics Referral System, shall be disseminated to all agencies concerned;
2. Information on the long-term follow-up treatment and management of the disorders included in the NBS panel shall be made available to health professionals, parents, and the general public at all continuity clinics, NSCs and DOH-ROs.

E. Monitoring and Evaluation

A monitoring and evaluation plan shall be developed to provide the mechanism for monitoring and evaluation of the continuity clinics implementation and the key indicators for impact monitoring.

F. Roles and Responsibilities

1. Department of Health

The DOH shall be the lead agency in the implementation of expanded newborn screening. Its roles and responsibilities are stated in Section 13 of the Implementing Rules and Regulations of RA 9288.

a. Family Health Office shall:

1. Review and update guidelines on the operations of the NBS Continuity Clinics and Birth Defects Continuity Clinics.
2. Formulate and issue a monitoring and evaluation tool pursuant to the operations of these clinics.

b. Regional Offices shall:

1. Establish a mechanism for recall of confirmed patients for referral to experts for management and follow-up care;
2. On the basis of availability of funds, provide indigency support for confirmatory testing of patients with significantly elevated laboratory results and for treatment and long-term management of confirmed patients in the region.

2. Newborn Screening Reference Center shall:

- a. Oversee the implementation of activities of NBS Continuity Clinics and Birth Defects Continuity Clinics;
- b. Secure monthly, quarterly and yearly reports from participating units and ensures their timely dissemination to various program stakeholders;
- c. Participate in consultation and evaluation activities initiated by the DOH in relation to the NSRC and the NBS Continuity Clinics' and Birth Defects Continuity Clinics' performance and in improving of rules and regulations;
- d. Assist in the training activities of the program;
- e. Oversee and review content of educational materials as well as the production of the materials.

3. Newborn Screening Centers shall:

- a. Give diagnosis, make proper referral and initiate management for all confirmed NBS patients;
- b. Provide roster of confirmed patients, including their protocols for management and list of follow-up laboratory procedures, to the NBS Continuity Clinic.

4. Host Facilities of NBS Continuity Clinics shall:

- a. Set-up NBS Continuity Clinic and Birth Defects Continuity Clinic;
- b. Provide a clinic space for patient consultation and a work station for the follow-up nurse and/or genetic counselor.
- c. Oversee the selection and hiring of personnel for the NBS Continuity Clinic in their facility;
- d. Integrate NBS continuity clinic to the current services of the host facility;
- e. Ensure the sustained operation of NBS Continuity Clinic and Birth Defects Continuity Clinic according to the Operational Guidelines set by the Department of Health and the Newborn Screening Reference Center for these clinics.

5. Institute of Human Genetics shall:

- a. Strengthen the surveillance program for newborns with birth defects in the country;
- b. Establish systems for the referral of patients with birth defects from BDS health facility to Birth Defects Continuity Clinics;
- c. Provide support in the operations of Telegenetics Referral System;
- d. Establish an efficient system in the procurement and availability of medicines, medical food and other medical requisites needed in the management of patients with birth defects and confirmed patients detected through newborn screening.

VII. Repealing Clause

All orders and issuances, rules and regulations or parts thereof inconsistent with the provisions of this Order are hereby amended, modified or repealed accordingly.

VIII. Separability Clause

If any provision of this Order is declared invalid, the other provisions not affected thereby shall remain valid and subsisting.

IX. Effectivity

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



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