



9 December 2003

ADMINISTRATIVE ORDER
No. 121 s. 2003

**SUBJECT: STRENGTHENING IMPLEMENTATION OF THE NATIONAL
NEWBORN SCREENING SYSTEM**

I. RATIONALE:

Newborn screening was introduced more than 40 years ago in the United States. It is now considered a standard of routine newborn care among developed countries. Newborn screening enables early detection and management of certain metabolic disorders, which if left untreated may lead to mental retardation and death. The early diagnosis and treatment of these disorders assures the child's right to live and safeguards him/her to reach his/her full potential.

In the Philippines, newborn screening was initiated in 1996 by the Newborn Screening Study Group consisting of pediatricians and obstetricians from 24 hospitals accredited by the Philippine Pediatric Society, Inc (PPS) and the Philippines Obstetrics and Gynecological Society, Inc (POGS).

Pilot studies on 272,547 newborns (NIH, June 2003) have shown the following incidences of disorders:

Congenital hypothyroidism	1:3 284
Congenital adrenal hyperplasia	1: 5 925
Phenylketonuria	1: 68 137
Galactosemia	1: 90 849
Glucose-6-phosphate dehydrogenase deficiency	1: 61

From these statistics, it is predicted that newborn screening for these disorders can save at least 33,000 newborns from mental retardation and death if all 1.5 million newborns born annually are screened. Cost benefit analysis has demonstrated that a national newborn



screening program vs a do-nothing alternative yield benefits of P600 million pesos annually (NIH, July 2003).

In line with the Vision of the Child 21 Framework that by the year 2025 it is crucial that newborn screening be integrated in the current health care delivery system. DOH recognizes that newborn screening will contribute in the objective of ensuring that all Filipino children have access to, and avail themselves of total quality care for their optimal growth and development to their full potential.

The Department has made efforts in implementing newborn screening in a limited scale. On January 2001, the Department of Health (DOH) issued Administrative Order No. 1-A known as "Policies on the Nationwide Implementation of Newborn Screening". This Order envisioned that by the year 2004, newborn screening shall be a part of standard newborn care and a formal national program would be in place. Since then, newborn screening has been pilot-tested and implemented in more than 250 hospitals and communities all over the country through the collaboration of DOH and the National Institutes of Health (NIH).

Considering that newborn screening is now an internationally accepted and was declared as medically necessary, full nationwide implementation is the next challenge for the program. With the end-view of strengthening the newborn screening program and making this more accessible among the general population, this Administrative Order aims provides the general guidelines for the national implementation of the NBS. This order also prescribes procedures for integrating newborn screening into various health efforts and activities at the national and local levels, including emphasis on community newborn screening implementation.

II. COVERAGE AND SCOPE

This Administrative Order shall apply to all government and private hospitals, clinics, and other health facilities.

III. GOALS AND OBJECTIVES

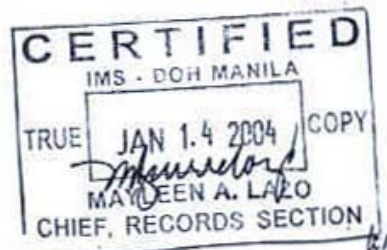
A. GOAL

All Filipino newborns are screened for the more common and life-threatening heritable disorders.

B. OBJECTIVES

The objectives of the National Newborn Screening System are:

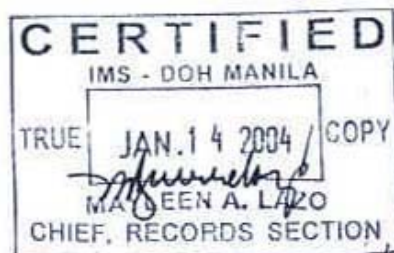
1. To ensure that every newborn has access to newborn screening for certain heritable conditions that can result in mental retardation, serious health complications, or death if left undetected and untreated;



2. To establish and integrate a sustainable newborn screening system within the public health and hospital delivery system;
3. To ensure that all health practitioners are aware of the availability and advantages of newborn screening and of their respective responsibilities in offering parents of newborns the opportunity to take advantage of newborn screening;
4. To ensure that parents recognize their responsibility in promoting their child's right to health and full development, within the context of responsible parenthood, by protecting their child from preventable causes of disability and death through newborn screening.

V. DEFINITION OF TERMS

- 1) Newborn Screening System means a system or an institutionalized process that includes, but is not limited to, education of relevant stakeholders; collection and biochemical screening of blood samples taken from newborns; tracking and confirmatory testing to ensure the accuracy of screening results; clinical evaluation and biomedical/medical confirmation of test results; drugs and medical/surgical management and dietary supplementation to address the heritable conditions; and evaluation activities to assess long term outcome, treatment compliance and quality assurance.
- 2) Follow up means the monitoring of a newborn with a heritable condition for the purpose of ensuring that the medical or dietary prescriptions are fully complied with.
- 3) Health facilities/institutions means hospitals, health infirmaries, health centers, lying-in centers or birthing homes or puericulture centers and other medical outpatient clinics with obstetrical and pediatric services, whether public or private.
- 4) Healthcare practitioner means physicians, nurses, midwives, nursing aides, traditional birth attendants and allied health professionals.
- 5) Heritable condition means any condition that can result in mental retardation, physical deformity or death if left undetected and untreated and which is usually inherited from the genes of either or both biological parents of the newborn.
- 6) Newborn Screening (NBS) means the process of collecting a few drops of blood from the newborn onto an appropriate collection card and performing biochemical testing for the purpose of determining if the newborn has a heritable condition.

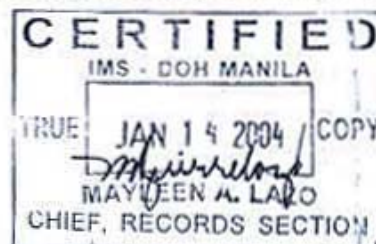


- 7) Newborn Screening Center (NSC) means a facility equipped with a newborn screening laboratory that complies with the standards established by the NIH and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.
- 8) Newborn Screening Reference Center (NSRC) means the central facility at the National Institutes of Health (NIH) 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.
- 9) Parent education means the various means of providing parents or caregivers with information about newborn screening.
- 10) Recall means a procedure for locating a newborn with possible heritable condition for purposes of providing the newborn with access to appropriate laboratory testing to confirm the diagnosis and, as appropriate, provide treatment.
- 11) Treatment means the provision of prompt, appropriate, and adequate medicine, medical and surgical management, or dietary prescription to a newborn for purposes of treating or mitigating the adverse health consequences of the heritable condition.

VI. GENERAL POLICY STATEMENTS

The DOH, together with the National Institutes of Health (NIH) which is the technical arm in the implementation of newborn screening and other concerned partners, adopts the following policies and principles in the nationwide implementation of newborn screening:

1. Newborn screening shall be an integral part of the child, adolescent, and maternal health programs and services.
2. It shall be a standard and routine procedure for newborns in public and private health and hospital facilities. Health practitioners shall fully inform their parents, legal guardians or other caregivers about the availability, nature, and benefits of newborn screening.
3. Newborn screening services available in all health facilities nationwide shall be supplemented with efforts necessary to increase the demand for these services.
4. Expenses for the newborn screening tests shall be borne by parents, and therefore financing mechanisms shall be explored to make newborn screening free or affordable. Hospital and local government or non-government organization are therefore highly encourage to develop a scheme providing partial or full subsidy



depending on the financial capability of the parents. Newborn screening fees however, shall be regulated by the Newborn Screening Advisory Committee to prevent exorbitant overhead costs.

5. The DOH shall establish mechanisms to ensure that newborn screening is available in all Philippine Health Insurance Corporation (PHIC) accredited health facilities and accessible to all its members.
6. DOH shall ensure that a network of facilities for referral and management of all positive cases is established.
8. The DOH shall ensure inter-agency collaboration through inclusion of newborn screening in the agenda of existing committees on children's health and welfare. In such venues, the following agencies shall be represented: DOH, NIH, and DILG.
9. The DOH, the NCDPC, in partnership with NIH shall ensure quality and sustainability of newborn screening system through the establishment of NSRC as well as its attendant requisites:

VII. IMPLEMENTING MECHANISMS

A. NEWBORN SCREENING PROCEDURE

The following Standard Operating Procedures for Newborn Screening shall be observed by health facilities and/or NSC's.

1. It shall be the responsibility of the healthcare practitioner providing prenatal services or delivering the newborn to ensure that parents of the newborn are informed of the availability and advantages of newborn screening services.

A parent or legal guardian may refuse testing on the grounds of religious belief, but shall acknowledge in writing their understanding that refusal for testing places their newborns at risks for undiagnosed heritable conditions. A copy of this refusal documentation shall be made out of the newborn's medical record and refusal shall be indicated in the national newborn screening database.

2. Collection of a screening specimen shall occur after twenty four (24) hours of life but not later than three (3) days from complete delivery of the newborn. A newborn placed in intensive care may be exempted from the 3-day requirement but must be tested by seven (7) days of age.
3. Collected blood samples are transported to the accredited Newborn Screening Centers by courier or any available speedy mode of transport.



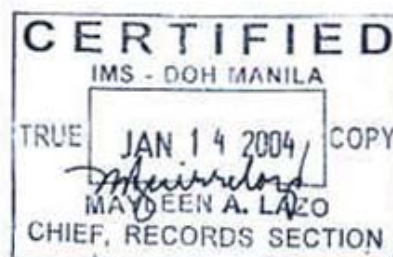
4. Testing of samples will be performed at accredited Newborn Screening Centers of the DOH-NIH network. Results, particularly those that are found positive of any of the disorder, are immediately released so that appropriate management can be instituted right away. Release of negative screens shall be released 7 working days after receipt in the NBS laboratory.
5. A newborn with positive screen is recalled or located as soon as possible to confirm the diagnosis and appropriate treatment provided if necessary. This is primarily the responsibility of the newborn screening team of the health facility where sample was collected.
6. The newborn with positive heritable condition is referred to for treatment and management to a medical specialist or the attending physician in close coordination with a medical specialists.
7. Prompt management of newborns with positive screen is essential to prevent the debilitating consequences or death of the newborn.
8. All of the congenital metabolic disorders require lifetime management. Monitoring should be done regularly through the attending physicians or by direct inquiry from the parents.

B. ESTABLISHMENT OF NEWBORN SCREENING CENTERS (NSCs)

1. The DOH shall ensure access to the newborn screening procedure by establishing Newborn Screening Centers (NSC) that are strategically located to be accessible to the relevant public.
2. The establishment of NSC shall be phased depending on the overall demand in the country. At the initial phase, two (2) NSC shall be established in Luzon, 2 in the Visayas and 1 in Mindanao.
3. The need to put up an additional NSC shall likewise be planned depending in the country's and the newborn screening system's evaluation by the National Technical Committee on Newborn Screening.

C. ESTABLISHMENT OF NEWBORN SCREENING REFERENCE CENTERS (NSRCS)

- a. The NSRC shall be responsible for ensuring good laboratory practice standards for NSC, including the establishment of an external laboratory proficiency testing and certification program. It shall also act as the principal



repository of technical information relating to standards and practices and shall provide technical assistance to NSC as needed.

- b. The NSRC shall be located at the National Institutes of Health, University of the Philippines Manila.
- c. It shall provide the BHFS the technical assistance in accrediting NSC's which shall include, but not limited to, a minimum of 50,000 samples a year.
- d. It shall strictly observe the compliance of standard newborn screening procedures by health facilities and assurance of prompt submission of samples only to accredited NSC.
- e. For the purpose of program evaluation and monitoring, the NSRC shall maintain a database of all patient tested and registry for each condition which will be submitted to DOH annually.

VIII. IMPLEMENTING STRUCTURES

1. National Center for Disease Prevention and Control, DOH
 - a. National Center for Disease Prevention and Control (NCDPC) shall serve as the lead office for newborn screening and shall coordinate activities and programs in pursuit of the objectives of this order as shown in Annex A. It shall likewise spearhead the continuous organization of the National Technical Working Group on Newborn Screening (D.O # 29-C s 2000) until the said TWG has fully implemented and institutionalized all the necessary components of the Newborn Screening System.
 - b. It shall provide technical assistance to CHD's relative to newborn screening and shall establish coordination with other stakeholders in planning, materials development, monitoring and evaluation for newborn screening.
 - c. It shall provide avenues in developing innovative approaches and models of implementation in partnership with other cooperating agencies.
 - d. It shall advocate for the adoption of newborn screening among public and private institutions and practitioners
 - e. Monitor and evaluate the field implementation of newborn screening.



2. Role of the National Institutes of Health

1. Provide technical advice to the National Newborn Screening System.
2. Provide assistance to DOH in setting up the criteria in the Newborn Screening Centers
3. Formulate good laboratory practice standards for newborn screening facilities including the establishment of an external laboratory proficiency testing and certification program.
4. Act as the principal repository of the technical information relating to newborn screening standards.
5. Establish the Newborn Screening Reference Center which will be responsible for the program review, laboratory proficiency, training and continuing education and research.

3. Technical Working Group on NBS

- a. The Technical Working Committee on NBS shall be composed of the following:
 - i. representatives from the DOH offices namely: NCPDC, National Epidemiology Center (NEC), National Center for Health Facility Development (NCHFD), Bureau of Health Facilities and Services (BHFS), The National Center for Health Promotion (NCHP) involved in the implementation
 - ii. representatives from the Center for Health and Development
 - iii. representative from Philippine Society of Endocrinology
 - iv. representative from NIH
 - v. representatives from Department of Interior and Local Government
 - vi. representative from any of the national organizations of pediatricians, obstetricians, family physicians, nurses and midwives
- b. It shall have the following responsibilities and functions:
 - i. Develop/review policies, standards and guidelines on newborn screening for recommendations and approval of the management
 - ii. Recommend the conditions to be included in the newborn screening panel
 - iii. Review and recommend the newborn screening fee to be charged by the newborn screening centers



- iv. Develop/review strategies and tools that will ensure effective and efficient implementation of the program at various levels
- v. Formulate national program/project plan, proposals and collaborative studies on newborn screening
- vi. Review the report of the Newborn Screening Reference Center on the performance of the Newborn Screening Centers and recommend corrective measures as deemed necessary

4. Bureau of Health Facilities and Services (BHFS)

The BHFS, in collaboration with NIH shall be responsible for regulating health facilities performing newborn screening procedures through:

1. Accreditation procedures and monitoring for compliance and quality assurance.
2. Development of needed rules and regulations pertaining to the regulation of the same.
3. Monitoring and evaluation of the newborn screening centers.

5. National Epidemiology Center (NEC)

The NEC in collaboration with the regional/ provincial epidemiology units shall be responsible for developing a surveillance system for heritable conditions. It shall establish registry of cases linked with the NIH as the central registry center, and the rural health units as the base registry units

6. National Center for Health Facility Development (NCHFD)

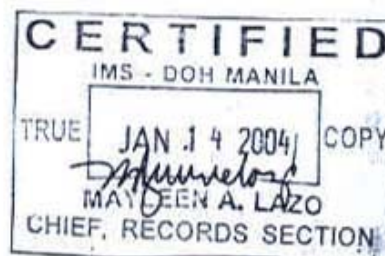
The NCHFD shall participate in providing technical assistance and leadership for the continuous effective and efficient implementation of the Newborn Screening in hospitals in coordination with the Center for Health and Development. It shall also encourage hospitals to participate in the monitoring and participation in the research and development efforts that will be pursued and initiated by concerned stakeholders and the NIH.

7. National Center for Health Promotion (NCHP)

The NCHP shall act as the lead office in the promotion of newborn screening and shall develop advocacy materials for dissemination to all partner agencies (LGUs, Academe, NGO's) and stakeholders. All IEC materials and collaterals shall be screened and reviewed by NCHP.

8. Center for Health Development (CHD)

The CHD's shall be responsible for the following:



- a. Translate and implement newborn screening national policies and framework at the local and regional levels.
- b. Provide technical and logistics assistance to LGUs, NGOs, Academic Institutions, and other stakeholders.
- c. Advocate for the implementation of newborn screening at the regional level.
- d. Reproduce newborn screening prototype materials for general distribution.
- f. Conduct orientation and training on newborn screening.
- g. Develop innovative approaches and models of implementation on newborn screening with local partners.
- h. Establish a public and private sector collaborative partnerships to plan and manage the newborn screening implementation in the region.
- i. Monitor and evaluate the implementation of newborn screening in the region..

9. DOH Retained Hospitals, Other government and private hospitals and lying-ins

All DOH Retained Hospitals other government and private hospitals clinics and lying-ins shall be responsible for the following:

- 1. Create an NBS team to ensure implementation of NBS and coordinate activities with DOH.
- 2. Ensure that adequate and sustained newborn screening services such as information, education, communication, screening, recall and management of identified cases are being provided in the hospital.
- 3. Establish an appropriate financial system that will ensure effective and efficient collection of fees and payment of laboratory services to the Newborn Screening Center
- 4. Conduct orientation and/or training of hospital staff on newborn screening or clinic.
- 5. Monitor and evaluate the implementation of newborn screening within in the institution.
- 6. Define creative financial packages to make newborn screening accessible particularly among the economically deprived populace.



7. Establish a functional referral system with local as well as national agencies
10. Local Government Units (LGUs)

The LGUs through the Chief of Hospital and Municipal Health Officers shall be responsible for the following:

1. Ensure that adequate and sustained newborn screening services such as information, education, communication, screening, recall and follow-up are being provided in all LGU Health facilities (Rural Health Unit/ City Health Unit, Lying-ins, City/Municipal/ District/ Provincial Hospitals)
2. Establish a functional case management referral system with strategically accessible tertiary hospitals
3. Establish coordination and networking among concerned agencies in Newborn screening implementation
4. Monitor and evaluate the newborn implementation in their localities
5. Define creative financial packages to make newborn screening accessible particularly among the economically deprived populace.

VIII. RECORDS AND REPORTS

Proper recording of newborn screening data shall be instituted in all participating health facilities. Reports using the required format must be submitted to NSRC quarterly for documentation and analysis.

IX. MONITORING AND EVALUATION

Monitoring of newborn screening activities shall be incorporated in the routine monitoring activities.

Annual program reviews and periodic evaluation of the program shall be done every three years. Special studies may be conducted to address issues and problems that may surface.

X. FINANCING

All offices concerned shall allocate resources in support of the newborn screening system. External agencies are encouraged to provide funds for the implementation of newborn screening.



Funds for the program shall be derived from the funds allocated for Child Health and Development. Supplemental funds and other resources shall be sourced out from extension services and other key stakeholders. LGU's shall be encouraged to provide funds for the implementation of newborn screening.

XI. REPEALING CLAUSE

Any existing issuance or provision thereof that is inconsistent with this Order is hereby repealed.

XII. EFFECTIVITY

This Order shall take effect immediately.


MANUEL M. DAYRIT, MD, MSc
Secretary of Health

