PROGRAM BRIEFER FOR THE
NATIONAL NEWBORN SCREENING PROGRAM

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Sources
Newborn screening (NBS) is a public health program aimed at the early identification of infants who are affected by certain genetic/metabolic/infectious conditions. Early identification and timely intervention can lead to significant reduction of morbidity, mortality, and associated disabilities in affected infants.

NBS in the Philippines started in June 1996 and was integrated into the public health delivery system with the enactment of the Republic Act 9288 also known as the Newborn Screening Act of 2004.

The National Comprehensive Newborn Screening System (NCNBSS) was established under RA 9288 to ensure that every baby born in the country is offered the opportunity to undergo newborn screening and thus be spared from heritable conditions that can lead to mental retardation and death if left undetected and untreated.

At the end of 2012, the national newborn screening coverage is at 49.6% using a 1.8M live birth as denominator.

Six disorders are currently being screened. As of December 2011, the incidences of the following disorders are: Congenital Hypothyroidism or CH (1: 3,004); Congenital Adrenal Hyperplasia or CAH (1: 10,604); Phenylketonuria or PKU (1: 388,367); Galactosemia or Gal (1: 310,694); Glucose-6-Phosphate Dehydrogenase Deficiency or G6PD deficiency (1: 50) and Maple Syrup Urine Disorder or MSUD.

There are four Newborn Screening Centers (NSCs) – NSC-National Institutes of Health in Manila; NSC- Visayas in Iloilo City; NSC-Mindanao in Davao City; and NSC-Central Luzon in Angeles City – that provide laboratory and follow up services for more than 4200+ health facilities.

In addition to the existing laboratories, four (4) more laboratories in strategic areas of the country will be opened in the succeeding years for the following areas: Region 4A, Northern Luzon, Region 7 and Region 10.

DOH and program implementers remain aggressive in identifying strategies to intensify awareness in the communities and increase coverage among home deliveries which account for 55.4% of the newborn population [FHSIS, 2008].

To save more babies, the program is now geared towards expansion from screening 6 to >20 disorders by mid of 2013. A technical working group (TWG) on expanded screening was created to prepare the necessary guidelines for the implementation of expanded newborn screening in the country.

Upgrading of Newborn Screening National Laboratory Information Systems is underway to ensure that national data base system is established and maintained in all the laboratories. Parallel testing and exposure training are ongoing in the different Newborn Screening Centers.
• DOH and Department of Interior and Local Government (DILG) continue to monitor the strict implementation of the Law and the Implementing Rules and Regulations (IRR) to strengthen the capacity of the Newborn Screening Reference Center (NSRC), Centers for Health Development (CHDs) and Local Government Units (LGUs) in regulatory and monitoring aspects.
PROGRAM BRIEFER FOR
NATIONAL NEWBORN SCREENING PROGRAM

I. **Rationale:**

In a country where almost one-third of the population lives below the poverty threshold, where only 3.5% of its GNP is expended for health, taking care of the health of its population as mandated by the Constitution, particularly of newborns, is a challenging task.

The Philippines is currently working to achieve Millennium Development Goal No 4 (Reduction of Child Mortality) decreasing its under-5 child mortality rate of 33.5 per 1,000 live births and infant mortality rate of 24.9 per 1,000 to 26.7 and 19, respectively, for 2015.

Newborn screening (NBS) is a well recognized public health program that can contribute to the attainment of MDG Goal 4 through the early identification of infants who are affected by certain genetic, metabolic or infectious conditions for early intervention that may lead to significant reduction of morbidity, mortality and associated disabilities.

It is estimated that 33,000 of the 1.7 million babies born a year in the country may be saved from mental retardation and death through newborn screening (NBS). [Padilla, 2002; Padilla, 2009]

An estimated net benefit of 600 million pesos annually accrues to the society if newborn screening is done on all newborns. [Padilla, 2009]

II. **Scenario**

**Global Situation**

NBS represents the first population-based genetic screening program, and signaled the integration of genetic testing into public health programs. [AAP Taskforce, 2000] NBS has been universally accepted for almost about five decades. Historically, it was first used for the detection of phenylketonuria (PKU) with the filter paper screening method developed by Dr Robert Guthrie. [Guthrie, 1963] PKU is an inborn error of metabolism, which leads to mental retardation if not treated with a low phenylalanine diet early in life. [Bickel, 1953] Since its inception in the 1960’s, at least 20,000 affected patients all over the world are now leading normal lives.

Today, NBS is being used for a number of other conditions, including metabolic and infectious diseases. [AAP Taskforce, 2000; Therrell, 2001; Therrell, 1992]

In the Asia Pacific Region, there are different levels of newborn screening involvement. The developed countries (Japan, Korea, Australia, New Zealand, Singapore, Taiwan) have almost 100% coverage for newborn screening of more than 20 disorders However, particularly those with depressed and developing economies, many countries are just initiating newborn screening programs for selected metabolic and other congenital disorders. The cultural, geographic, language and economic
differences that exist throughout the region add to the challenges of developing sustainable newborn screening systems. Among the Low to Middle Income Countries (LMIC), China is currently screening 65% of their 17M newborns and Thailand is screening 95% of their 1M newborn population. [Padilla, 2012; Padilla, 2010]

Local Situation

In the Philippines, NBS was introduced by a group of obstetricians and pediatricians from 24 Metro Manila hospitals in June, 1996 as a research study and was adopted by the Department of Health (DOH) as one of its programs in 1999. [Padilla, 2002]

NBS was institutionalized as a national program with the passing of Republic Act 9288 in 2004. RA 9288 established the National Comprehensive Newborn Screening System (NCNBSS) which was to ensure that a) that every baby born in the Philippines is offered NBS; b) the establishment and integration of a sustainable NBS System within the public health delivery system; c) that all health practitioners are aware of the benefits of NBS and of their responsibility in protecting their child from any of the disorders. [RA 9288 at www.newbornscreening.ph]

The program currently includes six disorders in the screening panel: Congenital Hypothyroidism (CH), Congenital Adrenal Hyperplasia (CAH), Phenylketonuria (PKU), Galactosemia (GAL), Glucose Phosphate Dehydrogenase Deficiency (G6PD) and Maple Syrup Urine Disorder (MSUD). [www.newbornscreening.ph]

Statistics/Local Data

61,699 have been saved through screening since 1996. For 2012, 49.6% of babies born were screened out of the 1.8M deliveries in the country.

Currently, four (4) Newborn Screening Centers (i.e., in Visayas, Mindanao, Central Luzon and Metro Manila), strategically located in various parts of the country have been established to provide access to the service.
The national program is currently working towards its implementation at the community level.

III. **Interventions/ Strategies**

To address the problem on low coverage, DOH and program implementers have worked together to improve the program targeting the high percentage (55.4%) of babies being born at home and addressing the barriers including those posed by geographically disaggregate areas of the country and the large population [FHSIS, 2008]. Among the major strategies were:

- Develop national policies on newborn screening (i.e. DOH Memo No. 2008-0123 imposing the following targets: 2008 (30%); 2009 (50%); 2010 (85%) and AO No 2008-0026 and 2008-0026A imposing penalties for non-implementation and/or overpricing of NBS)
- Develop health financing schemes for newborn screening
  - Issuance of PHIC Circular No. 11, s-2011 on the subject: PHIC Newborn Care Package
  - Increase of package from Php1000 to PhP 1750
- Integrate newborn screening with existing child health programs –
  - Aquino Health Agenda (AHA) - Universal Health Care (UHC) – Kalusugan Pangkalahatan (KP)
  - Community Health Teams (CHT) mobilization (barangay midwives, barangay nutrition scholars, BHWs, TBAs, community volunteers, RN HEALS, BSPOs, etc.) for CCT areas under the NHTS
- Issuance of DILG Memorandum Circular 2011-57 to ensure adherence to MC 2009-160 on the subject: Implementation of RA 9288
- Promote advocacy on newborn screening at all levels-
  - New video with community setting
  - Primers and Facilitator’s Guide for Midwives, Chief of Hospitals, and Physicians
- Offer MS Genetics Counseling in SY 2011. Target: One counselor per province
- Regular monitoring and review of the newborn screening program
- Creation of the Committee on Use, Retention and Storage of Residual Dried Blood Spots for policy recommendations
- Motivate existing regional professional societies and NGOs to promote newborn screening
- NSC Assembly was conducted to improve further on coordination, networking and collaborative operation of all four NSCs.
- External Audits in all the NSCs were also made in the first half of the year to ensure good laboratory practices.
- Program Review at the Center for Health and Development Level has been conducted in the first half of 2012 to ensure compliance and targets are met.
### IV. Status of implementation/ Accomplishment

Milestones in the history of newborn screening in the Philippines:

<table>
<thead>
<tr>
<th>Year</th>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>22 February</td>
<td>First organizational meeting attended by representatives from Philippine Pediatric Society (PPS) accredited and Philippine Obstetrical and Gynecological Society (POGS) accredited hospitals in Metro Manila</td>
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<tr>
<td></td>
<td>02 April</td>
<td>Creation of the NBS Study group composed of pediatricians and obstetricians from pilot hospitals. Project name: Philippine NBS Project</td>
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<tr>
<td></td>
<td>27 June</td>
<td>Commencement of the PNSP - NBS. Samples were sent daily to the New South Wales NBS Program in Australia for test performance and analysis.</td>
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<td>1997</td>
<td>18 September</td>
<td>Start of operation of the NBS Laboratory at the NIH</td>
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<td>1999</td>
<td>March</td>
<td>Inclusion of NBS in Children’s Health 2025</td>
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<tr>
<td></td>
<td>30 July</td>
<td>Creation of the DOH Task Force on NBS composed of representatives from DOH, Institute of Human Genetics-NIH, DILG and other health groups.</td>
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<tr>
<td>2000</td>
<td>3 January</td>
<td>Issuance of Administrative Order No 1A s 2000 by the DOH stating the Policies for the Nationwide Implementation of NBS</td>
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<tr>
<td>2001</td>
<td>07 February</td>
<td>Issuance of Department Order No. 29-C s, 2001 by DOH Subject: Creation of the National Technical Working Group on NBS Program, tasked to provide direction and guidance for the nationwide implementation of the NBS program.</td>
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<tr>
<td>2003</td>
<td>April</td>
<td>NBS bills filed at Congress</td>
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<td></td>
<td>May</td>
<td>NBS bills filed at Senate</td>
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<td></td>
<td>9 December</td>
<td>Issuance of DOH Administrative Order No 121, s2003, Subject: “Strengthening Implementation of the National NBS System”</td>
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<tr>
<td>Year</td>
<td>Date</td>
<td>Event Description</td>
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<td>2004</td>
<td>20 January</td>
<td>Issuance of the Presidential Proclamation No 540 entitled “Declaring the First Week of October of each year as “National NBS Awareness Week”</td>
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<td></td>
<td>07 April</td>
<td>Enactment of Republic Act No 9288 known as the Newborn Screening Act of 2004</td>
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<td>05 October</td>
<td>Signing of the Implementing Rules and Regulations of the Newborn Screening Act</td>
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<td>Signing of the Memorandum of Agreement for the creation of the Newborn Screening Reference Center (NSRC) by the DOH and UP Manila</td>
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<td>2005</td>
<td>02 December</td>
<td>Opening of the 2nd NBS Center at West Visayas State University Medical Center</td>
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<td>2006</td>
<td>22 January</td>
<td>NBS included in licensing requirement of Philippine hospitals; 90% of NBS fee covered by national health insurance</td>
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<tr>
<td>2007</td>
<td>January 2</td>
<td>Offering of Scholarships for Genetics and Endocrinology for Regions without specialists</td>
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<td>2008</td>
<td>12 June</td>
<td>Issuance of DOH Memo No. 2008-0123 imposing the following targets: 30%-2008, 50%-2009 and 85% by 2010</td>
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<td></td>
<td>08 August</td>
<td>Issuance of AO No. 2008—0026 and 2008-0026A by DOH imposing penalties for non-implementation and/or overpricing of NBS</td>
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<td>2009</td>
<td>January</td>
<td>Creation of Expert Panel Committees</td>
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<td>July</td>
<td>Creation of National Follow-up Committee</td>
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<td>September</td>
<td>Opening of Newborn Screening Center in Mindanao</td>
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<td>2010</td>
<td>October</td>
<td>Opening of the 4th Newborn Screening Center in Central Luzon</td>
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<td>2011</td>
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### Future Plans/Actions

#### A. Operations/Systems/Network
- Expansion to >20 disorders (endocrinologic, hemoglobinopathies, metabolic) by mid of 2013
- Development of a reference laboratory for confirmation of metabolic disorders
- Establishment of a treatment/referral network and other components necessary for the efficient implementation of the program.
- Increase the number of G6PD confirmatory centers, preferably 1 per province
- Establishment of additional Newborn Screening Centers (NSCs) in strategic areas in the country (Region 7, Northern Luzon, Southern Luzon, Southern Mindanao) in the next 5 years. The timing of the opening of the NSCs is dependent on the volume of samples from the catchment area of the proposed sites.
- Upgrading of Newborn Screening National Laboratory Information Systems

#### B. Treatment and Management
- Identification of regional NBS follow-up clinics to handle the long term follow up of confirmed patients.
- Undertake collaborations with medical subspecialty organizations (e.g. pediatric hematology, neonatology and pediatric endocrinology) critical in the proper and standardized referral and management of positive cases, in line with the planned expansion of screening.
- Conduct of Monthly Case Audits among NSCs to ensure that babies with positive screens are provided with prompt and appropriate management essential for saving them from debilitating consequences of the disorders being screened. The Case Audits are attended by the NSC Follow-up Teams
and the adviser of the Newborn Screening National Follow-up Committee (NNSFC) chair, and presided by the National Follow-up Coordinator.

- Provision of scholarships to new MS Genetics Counseling students currently enrolled for SY 2012. These prospective graduates are expected to respond to the counseling need of the patients and their families who will be identified positive by the program.
- Support fellowships in Pediatric Endocrinology and Genetics at the Philippine General Hospital

C. Financing

- Currently, PHILHEALTH is funding 5 diseases for P550. The proposed panel of >20 disorders will cost P1500.

D. Advocacy/Promotion/Linkages

- Promote awareness on NBS among home deliveries which account for 55.4% of the newborn population
- Inclusion of NBS in the assessment criteria of performance-based grants (e.g. those in score cards) to serve as leverage for the LGUs to make sure all their MCP accredited facilities are performing NBS package.
- Incorporation of NBS in pre-natal education
- Inclusion of NBS in curricula for public health, medical, nursing, midwifery and law schools
- Development NBS IECs for various audiences

E. Program Monitoring/Evaluation

- DOH and DILG to continue program monitoring of strict implementation of the Law and the IRR and strengthen the capacity of the NSRC, CHDs and LGUs in regulatory and monitoring aspects.
- The DOH and program implementers to remain aggressive in identifying strategies to intensify awareness in the communities and increase coverage among home deliveries which account for 55.4% of the newborn population.

F. Capability Building

- The CHDs will continuously provide capability building activities to increase the knowledge of the health professionals included in the Women’s Health Teams or Barangay Health Teams on the importance of NBS and help empower parents to plan and prepare for the cost of having their baby undergo newborn screening.
VI. Objectives of the National Comprehensive Newborn Screening System

In pursuit of protecting and promoting the right to health of the people, including the rights of children to survival and full and healthy development as normal individuals, the National Newborn Screening System was institutionalized with the following objectives:

- 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;
- Establish and integrate a sustainable newborn screening system within the public health delivery system;
- Ensure that all health practitioners are aware of the advantages of newborn screening and of their respective responsibilities in offering newborns the opportunity to undergo newborn screening; and
- 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. [IRR of the RA 9288 at www.newbornscreening.ph]
SOURCES:


23. DOH Administrative Order No. 2008-0026. Addendum to the Rules and Regulations Implementing Republic Act No. 9288, otherwise known as the “Newborn Screening Act of 2004”.

24. DOH Administrative Order No. 2008-0026A. Amendment to the Administrative Order No. 2008-0026 on Addendum to the Rules and Regulations Implementing Republic Act No. 9288, otherwise known as the “Newborn Screening Act of 2004”.

