

Newborn Screening in the Philippines and India: Its Implementation and Problems Encountered in the Program

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ABSTRACT

This study dealt with the status and implementation of Newborn Screening (NBS) program in the Philippines and India. It determined the profile of and the problems encountered in the NBS program in both countries. A comparison was done on the status of the Newborn Screening along legal mandate, cost of testing, specimen used, diseases screened, consent required, funding agencies and the availability of screening centers. The descriptive-comparative research design was utilized. The data from the Philippines were gathered from the Provincial Health Office while in India, the data came from health providers of Gujarat. Ethical clearance was secured. Frequency and percentages were used. Results showed that in the Philippines, the screening includes five metabolic and genetic diseases. There are more screening services in India than the Philippines. Out of the seven (7) diseases screened, Glucose-6-phosphate dehydrogenase (G6PD) is the most common metabolic disorder in the Philippines; while in India, the incidence of B -Thalassemia takes the lead in Gujarat and G6PD followed. As to the profile of the NBS Program in both countries, Philippines has the National Policy on Newborn Screening. NBS is mandatory in the Philippines, therefore highly implemented while in India, the NBS program has no standards or any national guidelines followed. In India, the cost of testing is more expensive and there are more metabolic and genetic disorders screened. The Philippine Health Insurance covers the program. In India, there is no federal support, mostly private hospitals perform the NBS. Problems encountered include resistance of some mothers to the NBS and confirmatory testing.

Keywords: *comparison, live births, metabolic disorders, status*

INTRODUCTION

Newborn screening (NBS) is a public health strategy that enables early detection and intervention of the identified genetic/metabolic disorders. Early identification and timely treatment can assure the newborn's safety and live to the fullest without threats of the disabilities brought about by genetic diseases.

This Newborn Screening (NBS) in the Philippines started in June 1996 and was integrated into the public health delivery system with the enactment of the Newborn Screening Act of 2004 which is Republic Act 9288 (DOH Manual of Operation, 2004).

Potts (2003) as cited by Tadena, stated that the health screening provides the opportunity to assess and detect any problems the infants may have. Health screening actually begins immediately after birth with the first Apgar scoring and physical examination.

Neonatal Screening is one of the most essential preventive community health programs of the 21st century. It is already well established in many of the developed countries. Most of the developing countries are starting to become aware and to implement it. In India, this program is still in its neonatal stage and yet to evolve into childhood. Currently, there is no government funded neonatal screening program for the masses (Kumar, 2014).

Still from Kumar, he mentioned that according to the World Health Organization (WHO), out of the 140 million children born every year in developing countries, a significant 5 million of them die in their first month of life. It was also disclosed that there are four percent of the population in India that are diagnosed to be mentally retarded, and 5-15 percent of the newborns are thought to have metabolic problems. It is then advocated that screening may be done to most if not all children to prevent disability and death by timely detection, treatment, follow-up and counseling.

Kamath, (2015) explained that India is going through a progressive transitional transformation in their efforts to reduce infant mortality and morbidity due to diseases, and the emergence of inherited metabolic disorders. The World Health Organization (WHO) has recommended to many countries for the implementation of programs geared towards the reduction of infant mortality rate. India having an infant mortality rate of 40 should be introducing newborn screening and genetic services. The Indian Academy of Pediatrics strongly campaigns that NBS to become a public health policy, and assured of its support in terms of the technical and logistic assistance to the Government of India for initiating this program.

Patel et al. (2011) emphasized that newborn screening test is a simple procedure to find out if the baby has a rare metabolic disorder. Although the baby may look healthy at birth, one cannot be sure if it will not manifest negative effects caused by these metabolic disorders. These birth defects have no immediate visible signs on the baby but, unless discovered and given intervention on time, can create many health problems physical or mental retardation or even death.

The study was conducted in the Philippines and in India, the first research of its kind as basis of knowing differences in the health policies. The University of Northern Philippines offers the Medical and Allied Health Courses where students from the India are enrolled in. thus, a partnership and collaborative activities were forged between both countries.

This study aimed to determine the status and implementation of the Newborn Screening Test in the Province of Ilocos Sur, Philippines and in the State of Gujarat, India from CY 2015-2017. Specifically, it tried to compare the status of the Newborn Screening Program in the Philippines and in India along the following: Legal Mandate , Cost of the testing, Test Specimen, Diseases screened, Consent required, Funding Agencies, and Availability of screening facilities for the procedure. The study also described the profile of the Newborn Screening Program in both countries in terms of the following: population, number of live births, and the number of screened babies for the past 3 years, and compared the problems encountered in the newborn screening program in both countries.

The results of the study may serve as a baseline data on cases of congenital abnormalities detected through Newborn Screening Test in the Philippines, in India and other countries. It is hoped that the results may help health administrators and political leaders to facilitate the decentralization of facilities, technical and professional resources and to make it available for rural people. In the areas of medicine, nursing and other allied disciplines, this investigation will contribute to the pool of knowledge in health education as it provides a local blueprint of the status of congenital abnormalities in the locality.

To the mothers, this would provide them knowledge on what the newborn screening is all about and the benefits derived, therefore giving them the ability to decide whenever a situation comes that they need to decide whether or not to let their child undergo screening test.

To the health facilities, this research is seen to contribute in the assessment of cases of congenital abnormalities in their area of responsibility. This would assist the health providers in mapping up projects and programs to help families deal with cases associated with congenital abnormalities. To medical and nursing students, this study would serve as a reference material in their pursuit for other related researchers and more knowledge and understanding on the newborn screening procedures, which they can apply during their duties when giving health teachings.

To the researchers from the Philippines and India, this endeavor is seen as a doorstep towards a borderless exposure into health-related investigatory ventures which undeniably would help them appreciate more the significance of their chosen field of career for the advancement of the welfare of humanity.

The Philippine Constitution states that the child is the hope of every nation. Every struggle should be enacted to promote children's welfare and enhance their happy life. It further provides that the health care provider and the academe are expected to assist the family in attaining the desired healthy condition of the child.

As cited by Tadena (2015) there are four newborns out of one thousand live births in the Philippines die before reaching the age of one year old, and that almost 8,000 newborn deaths are recorded to comprise the 30 percent or even more of the infant mortality every year which are mostly due to conditions commencing in pregnancy or during childbirth. They are a result of inadequate or inappropriate care during pregnancy, childbirth, or the first critical hour after birth.

It is expected that all health institutions or health facilities where babies are delivered like hospitals, lying-in clinics, Rural Health Units and District hospitals in cooperation with the Department of Health will implement this policy. If babies are born at home, babies may be brought to the nearest institution offering NBS. A negative screening means that the result of the test is normal and the baby is not affected by any of the disorders screened (Quilana, 2011).

Sulaiman et al. (2015) stated that with the advances in Deoxyribonucleic Acid (DNA) technologies, genetic testing has quickly changed from home to hospital in coming out with an accurate finding of the presence of inherited disorders, carrier testing, prenatal diagnosis thru the newborn screening (NBS). With this advanced procedure in child health is an essential tool in reducing infant morbidity and mortality.

Still by Patel (2011), blood specimen should be taken from every newborn prior to hospital release. NBS is ideally done on the 48th hour or 24th hour from birth. The baby must be screened again after two (2) weeks for more accurate results.

Statistical considerations on infant mortality rate were also given importance, wherein world current infant mortality recorded (United Nation World Population prospect report, as of 2005-2010), 49.4 deaths/1000 live births. The 73 percent of these deaths are children under five years of age. In the Philippines, April 2009 estimation, it recorded 20.56/1000 live births and ranked number 121 on infant mortality.

As stated by Batong (2011), the U.S. National Newborn Screening and Genetics Resource Center in some states only mandate tests such as: CH- Congenital hypothyroidism, H-HPE- Benign hyperphenylalaninemia, PKU- Phenylketonuria, HEAR- Hearing, and GALT-Transferase deficient galactosemia.

As mentioned by Tubadeza (2014), in order to make the NBS more accessible and affordable to the general public, the Department of Health (DOH)

issued Administrative Order 2005-0005 standardizing the NBS Fee at Php 550 and setting the maximum allowable service fee at Php 50.25. One year later, in 2006, as stipulated in the law, NBS became a mandatory DOH hospital Licensing requirement. Likewise, it is included as part of the Philippine Health Insurance Corporation (PHIC) accreditation of all health facilities and 90 percent of the screening cost is paid by the national social health insurance as part of the PHIC package.

On financial, legal, and social issues, these pose many concerns on the use of the technology. There are also issues along financial as to the increased cost of the procedure and the payment of the follow-up testing that would confirm the initial result. The ethical issues identified are testing for untreatable disorders and storage and disposal of testing samples. Socially, there is an issue of the “informed consent.” NBS is mandated in some countries like the Philippines, so that the parents may not be required to go through the informed consent process like the signing of a document or consent form (Quilana, 2011).

In India, consent for the test has become a major concern for discussion. Currently, most hospitals are doing the test after obtaining the verbal consent from the parents. So far in most countries, verbal consent has been obtained for the Guthrie test (Kumar, 2014).

It was found out that in India, which is a country known for its diversified cultures and genetic make-ups, the studies and pertinent data from one of its state may not be necessarily relate to another region. Thus, the knowledge, attitude, and compliance towards newborn screening and the prevalence of diseases may also vary. An example would be the incidence of Congenital Adrenal Hypoplasia which is noted to be higher in Southern India; whereas the occurrence of G6PD is highest in Punjab and Gujarat, while Thalassemia takes the lead in Gujarat (Kumar, 2014).

There are no national policies for this genetic assessment in the United States as autonomy varies in every state’s public health department. However, almost all states now perform tests for more than 30 disorders and many of them made it mandatory for newborns to undergo the procedure. However, parents’ decision still prevail if they opt that their children should not be subjected to this test.

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of the infant mortality every year which are mostly due to conditions commencing in pregnancy or during childbirth. They are a result of inadequate or inappropriate care during pregnancy, childbirth, or the first critical hour after birth.

It is expected that all health institutions or health facilities where babies are delivered like hospitals, lying-in clinics, Rural Health Units and District hospitals in cooperation with the Department of Health will implement this policy. If babies are born at home, babies may be brought to the nearest institution offering NBS. A negative screening means that the result of the test is normal and the baby is not affected by any of the disorders screened (Quilana, 2011).

METHODOLOGY

This study employed the descriptive –comparative research design to gather data on the status of the newborn screening in the Philippines as represented by the Province of Ilocos Sur and India as represented by the State of Gujarat. Records review and previous researches were also utilized. Ethical clearance was secured after the review of the protocol.

The Province of Ilocos Sur, Philippines was represented by the government Hospitals namely; Ilocos Sur District Hospital- Sinit, Ilocos Sur District Hospital- Magsingal, Ilocos Sur District Hospital - Sta Lucia, and the Ilocos Sur Provincial Hospital- Gabriela Silang, after getting permission from the Chief of the Provincial Health Office. The records filed where data on the number of mothers who delivered and who subjected or did not subject their children for the newborn screening for the last three years were taken, analyzed and interpreted. In India, the data taken were supplied by the Indian medical practitioners and other researchers who conducted research studies on Newborn Screening. Further, the records, journal reports and previous research studies were reviewed and analyzed as sources of data.

The following ethical principles were considered:

Conflict of Interest. The researchers declared that there was no conflict of interest as they are public health providers concerned with the well-being of babies, mothers and the community as a whole. There are no personal gains derived except for the information which they can use for their health education activities.

Privacy and Confidentiality. This is not much of a problem considering that the data gathered were of public in nature as they had been published in journals and the Health reports. However, to maintain the privacy of the hospitals, Code numbers were assigned to each hospital.

Informed Consent. The informed consent was taken from the Provincial Health Office Administrators after which the permission was granted to utilize the

data from the reports submitted by the health workers from the government hospitals three (3) of which are District Hospitals and one which is the Ilocos Sur Provincial Hospital-Gabriela Silang.

Benefits. The benefits derived from the study were discussed to the Chief Provincial Health Officer and the other administrators in- charge of the Newborn Screening Program. And with this, pertinent reports from the different health facilities covered by the provincial health office were given for the ready reference of the researchers. This process was also done with the Health Administrators of the locale under study in Gujarat, India.

Risks. The study is of minimal or even no risk considering that the data gathered did not violate the ethical guidelines particularly on confidentiality of data and the privacy to the identity of the mothers and their babies. The data gathered are of public health information on the newborn screening program.

Output Dissemination. The results of the study may be disseminated to both the health authorities representing the stakeholders of the Philippines and India of the need to increase the awareness of mothers on the benefits of the screening program; and likewise for the health authorities for policy formulation. It shall also be published in a journal, so that the program on NBS may be publicly known and the community people will realize the importance of it.

The statistical tools that were used to analyze the data gathered are the following: frequency and percentage in determining the total births and number of Screened babies. Comparative analysis was done on the status of the Newborn Screening in the Philippines and in India for the past three years.

RESULTS AND DISCUSSION

A. Comparison on the status of the newborn screening program in the Philippines and India.

Table 1 shows the status as revealed in the assessment points: On Policy and Guidelines of the NBS. In the Philippines, the legal mandate is the Republic Act No. 9288 or the Newborn Screening Act of 2004. Newborn Screening in the Philippines is mandatory, therefore it is highly implemented. While in India, there is no policy or Guidelines pertaining to this program. There are more diseases screened in India than in the Philippines where there are five diseases tested (Maple Urine Syrup Disease and Biotinase) in addition to the five initial tests. It can be noted also that there are more Screening Centers established in the Philippines and some more additional centers created to do the screening; while in India, only a few private hospitals as Screening Centers and the cost is much higher in this country.

Table 1
Comparative analysis on the status of the newborn screening program in the Philippines and India

Assessment Points	Philippines	India
a. Legal Mandate.	Rep. Act 9288- 2004	No National Policy
b. Cost or Fee	Php 550.00	Rs 2,500 -6,000 Php equi.
c. Test Specimen	Blood specimen	Blood Specimen
d. Diseases Screened	Congenital Hyperthyroidism (CH), Congenital Adrenal Hyperplasia (CAH) Galactosemia, Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD) Phenylketonuria (PKU) Maple Urine Syrup disease, Biotinase	Congenital Hyperthyroidism (CH), Congenital Adrenal Hyperplasia (CAH) Galactosemia, Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD) Phenylketonuria (PKU) Maple Urine Syrup disease, Biotinase alcaptonuria <i>B</i> -Thalassemia Syndrome, Cystic Fibrosis, Sickle Cell Disease. Dehydrogenase deficiency Tyrosinemia and fatty acid Oxidation defects.
Consent Form Required	Written Consent	Verbal Consent/ Written Consent
Funding Agencies	Coverage- Phil. Health Insurance Inc.	Not funded by the federal government
Availability of Screening Centers	4 NBS centers and 3000 health facilities initial, and additional centers established	Very few Centers, most are private hospitals

In 2010, there were four Newborn Screening Centers (NSCs) established in the Philippines to perform the testing all over the country: NSDC- National Institutes of Health in Manila; NSC- Visayas in Iloilo City; NSC- Mindanao in Davao City; and NSC- Central Luzon in Angeles City. The four provide laboratory and follow up services for more than 3000 health facilities (Department of Health Report, 2010).

B. Profile of the Newborn Screening Program in the Philippines and in India for the past three years in terms of the population \number of births, and Birth rate per 1,000 population

Table 2
Distribution of population and live births for the past 3 years in Ilocos Sur Philippines and in Gujarat, India

Ilocos Sur Year	Population	Total Number of Births	Birthrate per 1000 Population
2017	703,174	3,101	0.44
2016	696,421	2,992	0.43
2015	689,668	3,124	0.45
Gujarat , India Year	Population	Total Number of Births	Birthrate per 1000 Population
2017	67,141,736	13,898,339	20.7
2016	66,032,362	13,272,504	20.1
2015	64,919,427	13,243,563	20.4

Table 2 shows the number of live births in the four (4) government hospitals in Ilocos Sur and the number of babies who underwent the newborn Screening. It further shows that in all the hospitals, almost all babies were subjected to this screening procedure. This is in compliance to the Newborn Screening Act of the Department of Health. Further, it also shows the population, number of births and the birth rate for the past three years in Gujarat India.

Diseases Screened in Gujarat India

It can be gleaned from the table that there were cases screened for Sickle Cell Disease and the number of those affected newborns in 2014 was 73.6 percent, followed by G6PD with 16.3 cases affected.

A periodic quarterly review was carried out for each facility in coordination. The screening panel included CH, G6PD, IRT, Amino acids and tests for Galactosemia. A total of 18573 selected newborns had been screened for congenital hypothyroidism with 143 (0.8%) testing positive. The expanded panel (except CH) had been done in 3456 selected newborns with a positive yield of 16.3 percent (total 562 in year the 2014-15) (Shah, 2018).

It was found out in this study that in India, which is a country known for its diversified cultures and genetic make-ups, the studies and pertinent data from one of its state may not be necessarily relate to another region. An example would be the incidence of Congenital Adrenal Hypoplasia which is noted to be higher in Southern India; whereas the occurrence of G6PD is highest in Punjab and Gujarat, while B Thalassemia takes the lead in Gujarat (Kumar, 2014).

Table 3
Diseases screened for the newborn screening test in Gujarat, India

Diseases Screened Among Newborns Ilocos Sur	Total Number Screened	Total number of diseased babies	Percent
G6PD	9174	733	7.99
CAH	9174	4	0.04
Congenital Hypothyroidism	9174	5	0.05
PKU	9174	1	0.010
Diseases Screened Among Newborns In Gujarat *	Total Number Screened	Total number of diseased babies	Percent
Sickle cell	2827	2083	73.6%
G6PD,IRT	3456	562	16.3%
Congenital Hypothyroidism	18573	143	0.8%

According to the DOH Philippines (2012), the coverage of NBS in December 2010 was at 35 percent, which a decrease was noted in 2012. The six disorders included in the National Comprehensive Newborn Screening System with the ratios noted are Congenital Hypothyroidism (CH) – (1:3,004), Congenital Adrenal Hyperplasia (CAH) – (1: 10,046), Phenylketonuria (PKU) – (1: 388,367), Galactosemia (Gal) – (1: 310,694), Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD) – (1: 50), and Maple Syrup Urine Disease (MSUD). Maple Syrup Urine Disease was combined to the screening panel in the last quarter of 2012.

While in India, Devi and Naushad (2004) stated, there is scarcity of printed studies on normal newborn assessment. In a pilot project which involved 125,000 newborns, it was found out that homocysteinemia, hyperglycinemia, MSUD, Phenylketonuria, hypothyroidism and G6PD are the common errors of metabolism (Rao and Bittles , 1988).

In Hyderabad, City of India, there was another study in 2000 on the “Expanded Newborn Screening” which tested 18,300 babies for amino acid disorders such as CH, (CAH), G6PD deficiency, biotinidase deficiency, galactosemia and cystic fibrosis. The testing resulted to a high prevalence of CH with one case in 1700 babies, followed by CAH and G6PD deficiency. Further, aminoacidopathies came out as the next most common disorder. It was also worthy to note that there was a very high prevalence of inborn errors of metabolism having one (1) in every thousand newborns (Devi and Naushad, 2004).

Dr. Shah of Gujarat also presented 12 programme modes in a conference entitled, “Implementing NBS Programme: The Gujarat Experience.” This would lead to the creation of epidemiological data for IEMS and select gene disorders and would be first in India (Shah, 2018).

Problems encountered in the NBS program in the Philippines and India

In the Philippines, the problems encountered in the NBS Program include the following: a. There are still mothers who do not understand the importance of NBS; there are still those who resist the procedure especially in remote areas; b. There are mothers who do not submit their children for the confirmatory test because of the fees they may pay and the cost of treatment, and may not understand the nature of the disease; and c. There are only few designated centers to do the screening; and that the results may be delayed.

In India, the problems encountered in the program include the following: a. Many neonatologists performed genetic screening for the babies born under their care without any national guidelines to follow; b. With the large number of children born with the disorders and paucity of centers carrying out newborn screening; c. The procedure is expensive and accessible only in few centers; and only a few qualified geneticists are available. d. The screening program in India is currently not funded by the Federal Government and e. There is limited awareness among the medical fraternity and research teams in some government hospitals and there is resistance from the in-house staff (Kumar, 2014).

Table 4
On problems encountered in the NBS program in the Philippines and India

AREAS	PHILIPPINES	INDIA
NBS Guidelines	a. Not a Problem. With RA. 9288 004 in 2004	Many neonatologists performed genetic screening for the babies born under their care without any national guidelines to follow.
Knowledge on NBS	b. There are still mothers who do not understand the importance of NBS; there are still those who resist the procedure especially in remote areas;	There is limited awareness among the medical fraternity and research teams in some government hospitals and there is resistance from the in-house staff.
Confirmatory Test	c. There are mothers who do not submit their children for the confirmatory test because of the fees they may pay and the cost of treatment, and may not understand the nature of the disease;	Only few babies are subjected for the confirmatory Testing because of the cost and low knowledge on the benefit
Designated Centers	Nationwide, there are still few testing Centers that delay the result	Most testing is done in private hospitals. With the large number of children born with the disorders and paucity of centers carrying out newborn screening;
Government Support	Not a problem	Not state funded

CONCLUSIONS

In the Philippines, for the past three years, there are only few babies born in government hospitals who were not subjected to the newborn screening; while in India, there were only few newborn babies screened in government hospitals. Out of the seven (7) diseases screened, G6PD is the most common metabolic disorder topping the number of cases in the Philippines; while in India, with the big population, where there is diversified cultures and genetic make-ups, the incidence of B -Thalassemia takes the lead in Gujarat and G6PD followed. As to the profile of the NBS Program in the Philippines and India lies on the following: the National Policy on Newborn Screening in the Philippines (NBS is mandatory) while in India, the NBS program has no standards or any national guidelines followed. The cost of the testing is more expensive in India; there are more metabolic and genetic disorders screened in India; the Philippine Health Insurance covering the program, while in India, there is no federal support, mostly Private Hospitals in India perform the NBS. The problems encountered in the NBS Program include the following: resistance of some mothers to the NBS testing which may be due to their low awareness level; the resistance of mothers for the confirmatory testing because of the high cost of treatment; and there are few Testing Centers and that the release of results may be delayed.

RECOMMENDATIONS

Based on the findings of the study, the Philippines having different problems from that of India, the following are recommended:

A. Philippines.

Doctors and staff nurses, especially those assigned at the Obstetrical/ Delivery ward must continue to fully discuss RA 9288 known as “Newborn Screening Act” as part of their discharge plan to the mothers. This may increase the level of knowledge of mothers on the said law and will improve their compliance to the highest level. Community Health Workers should form part of their functions to conduct health education classes to discuss the newborn screening especially on the importance, the disorders screened, the process of the screening, the benefits of screening and the consequences of not subjecting to newborn screening procedure. The cost of the procedure should be subsidized by the Government, especially for those families who cannot afford it.

B. In India.

In as much as there is no national guidelines, the Indian government should create a standard Newborn Screening policy to regulate the program. The Government should establish more regional centers which can offer conclusive diagnosis to high-risk neonates and strengthen them with procedural capability to undertake this responsibility. Such regional centers identified as reference centers

for confirmatory diagnosis and therapy should be funded by the government. A public-private partnership should be established in order to offer a low-cost package of newborn screening. Screening Centers should be made available strategically in many hospitals. Mass education and media propagation should be conducted by the medical communities to increase the knowledge of all parents and would-be parents. Lastly, more research activities need to be conducted on the compliance of mothers to this program, the status of implementation by health facilities, as well as the benefits and impact to the community.

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