A Performance Evaluation and Assessment Scheme (PEAS) for Improving the Philippine Newborn Screening Program

Carmencita David-Padilla[1,2], Juanita A.Basilio[3], Bradford L. Therrell[4,5]

[1]*Deparment of Pediatrics, College of Medicine and Philippine General Hospital, University of the Philippines Manila*
[2]*Newborn Screening Reference Center, National Institutes of Health, University of the Philippines Manila*
[3]*Department of Health, Manila, Philippines*
[4]*U.S. National Newborn Screening and Genetics Resource Center, Austin, Texas, USA*
[5]*Depatment of Pediatrics, University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA*

ABSTRACT

Newborn Screening in the Philippines began as a small pilot project in Manila in 1996 and has expanded to a nationwide program screening for 5 conditions today. Along the way, professional, political and public support has increased. As a result, a national law requiring the offering of screening to all newborns was put into place. The Department of Health (DOH) is actively providing follow-up support, and the National Institutes of Health – University of the Philippines Manila (NIH) provides laboratory and technical expertise. Expansion has evolved to the point that there are now two DOH accredited screening laboratories with further expansion anticipated. The Newborn Screening Reference Center at the NIH has partnered with the DOH to develop a performance evaluation and assessment scheme (PEAS). The Philippine PEAS is designed to monitor quality and improvements made in the regional DOH screening program. The Philippine PEAS was developed building on a PEAS previously developed by the US National Newborn Screening and Genetics Resource Center, and we report here the development, implementation and results of the Philippine PEAS.

Key Words – newborn screening, performance evaluation, quality assurance

Introduction

Newborn screening (NBS) is a SYSTEM composed of six component parts: education, screening, follow-up, diagnosis, management, and evaluation.[1] It is a system that functions within local geographic, economic and political constraints, and seeks to smoothly and seamlessly integrate sample collection, laboratory analysis, follow-up, diagnosis and treatment. Because the Philippine Performance Evaluation and Assessment Scheme (PEAS) draws from a PEAS already available in the U.S., it is appropriate to first review the development of that PEAS.[2]

The U.S. national health improvement plan, Healthy People 2010 (U.S. Department of Health and Human Services, 2000) emphasized the importance of newborn screening.[3] The need was identified in the following statement, "Therefore, it is vital that screening be universally available, that screening be of the highest quality, that diagnostic testing provided for those newborn who screen positive, and that follow-up treatment be offered to children with diagnosed disorders." As a result, the U.S. Health Resources and Services Administration (HRSA), Genetic Services Branch (GSB) provided cooperative agreement funding for development of a comprehensive PEAS for the U.S. Responding to the Request for Proposal (RFP), the US National Newborn Screening and Genetics Resource Center (NNSGRC) was subsequently awarded a 2-year cooperative agreement to develop U.S. PEAS. In cooperation with GSB/MCHB/HRSA, the NNSGRC convened the appropriate national stakeholders to accomplish the task, and a comprehensive PEAS was developed.[2] The U.S. PEAS indicators were proposed by working groups of stakeholders who were national representative of U.S. newborn screening programs, consumer advocacy groups, birthing facilities, community organizations, and federal support agencies.[4]

While the U.S. newborn screening system is larger, older, and more complex, there are many similarities between the U.S. system and the Philippine system, particularly in the overall goals and objectives. Basic assumptions in the U.S. system are also similar and have been previously listed, including: "(1) infants should benefit from and be protected by NBS systems; (2) not all conditions are good candidates for NBS based on previous World Health Organization criteria: (3) NBS is a system and every newborn should receive appropriate and timely services; (4) NBS is an essential public health prevention activity requiring service integration for affected newborns; (5) state public health agencies have responsibility for assessment, assurance and policy development; (6) the NBS system must be clinically, socially, and ethically acceptable to the public and health professionals: (7) every newborn should have a medical home; (8) all newborns should have access to screening according to nationally accepted criteria regardless of their location; (9) parents have a right to information about NBS, the right to refuse testing, and the right to privacy protection; (10) increased newborn screening program coordination and uniformity will benefit families, health-care professionals and public health agencies; and (11) parents and consumers must be involved in policymaking and program implementation."[5] The fact that many of

Corresponding author: Carmencita David-Padilla, MD, MAHPS
Institute of Human Genetics, National Institutes of Health - Philippines
625 Pedro Gil St., Ermita, Manila 1000, Philippines
Tel/ Fax Number: 02 – 525 7459
Email: cpadilla@upm.edu.ph

the items listed could not be validated, led to many of the indicators eventually defined in the U.S. PEAS.

The U.S. PEAS emphasized improved operation of screening and follow-up through a system of self evaluation and quality assurance. The development project included an oversight committee of knowledgeable individuals experienced in working with NBS systems (including consumers) to: (a) better define the goals of the project; (b) outline the activities necessary to complete the goals and the project; (c) review and develop working group charges and challenges; (d) develop a timeline for project completion; (e) review and develop a project evaluation plan; and (f) provide ongoing project oversight. To accomplish the project, two working groups, one for laboratory and one for non-laboratory system issues, were assembled. These groups were tasked with: (1) accumulating any previously published guidelines and operational models that related to quality assurance in the birthing facility, the screening laboratory, and the follow-up system; (2) surveying national and international NBS programs to obtain current practices relative to ongoing evaluation and assessment of pre-analytic, analytic, and post-analytic activities in NBS systems; (3) suggest ideas on how a model PEAS could best be utilized and disseminated, with emphasis on interactivity; (4) utilize NBS system stakeholders to assess strengths and weaknesses of the ideas, models, evaluation and dissemination strategies.

In contrast to the state and territorial jurisdictions in the U.S., the Philippines is politically divided into 17 regions, including the National Capital Region (NCR). Each region is subdivided into provinces and there is further subdivision into municipalities. Provinces and municipalities are locally administered by local government units (LGUs) headed by provincial governors and municipal mayors. The Department of Health (DOH) is represented in each region by a Center for Health Development (CHD). The CHD monitors implementation of newborn screening at the regional level.

In the Philippine health system, regional commitment to program implementation is a key factor for success. If a national NBS system is to function properly, there should be clarity in the expectations for those involved in the system, and quality indicators should provide a basis for evaluation. Therefore, the Philippine NBS leadership concluded that development and utilization of a Philippine PEAS would be a useful tool for improving system quality.

Collaboration between the DOH and the NSRC was initiated to develop a usable Philippine PEAS, based on the PEAS indicators and experiences in the U.S. The Philippine PEAS aims to help ensure and improve NBS quality at regional and local NBS health facilities (NSFs), as mandated by Republic Act 9288 (also known as the Newborn Screening Act of 2004).[6] Two evaluation tools were envisioned: (1) an evaluation tool for CHDs, as regional implementers of NBS; and (2) an evaluation tool for NSFs, as participants in the screening processes.

The objectives of the Philippine PEAS – CHD included: (1) identification of gaps, solutions, and areas for improvement in the implementation of the newborn screening at the level of DOH Region or CHD; (2) determination of the status of communication and reporting between the CHD and key agencies (DOH's National Center for Disease Prevention and Control, NSRC, Newborn Screening Centers (NSCs; the screening laboratories), NSFs, LGUs and other organizations); and (3) assessment of overall performance of the CHDs.

The objectives of the Philippine PEAS – NSF included: (1) identification of the status of NBS program implementation based on the existence of (a) adequate personnel and manpower, predefined coverage targets, feedback, and systematic NBS implementation, and (b) information, education and advocacy campaign programs within the hospital for its personnel and clients; (2) determination of the problems encountered, solutions provided and other concerns including (a) information, education and advocacy campaigns within the hospital for personnel and clients, and (b) NSC issues regarding sample collection materials, relaying of results, recall/follow-up compliance, billing and fee collection, and case monitoring; (3) verification of the status of NBS program performance based on percentages and averages of newborns screened compared to the number of deliveries and walk-in patients, and; (4) determination of perceptions from clients regarding the adequacy and efficiency of NBS service provision.

Methods

To take maximum advantage of experiences in the U.S. and to minimize the time taken in debating and creating measurable indicators for inclusion in the Philippine PEAS, the director of the U.S. PEAS project was contacted and agreed to serve as a project consultant. A working retreat of key DOH and NSRC stakeholders allowed collaborators and the consultant to exchange information and begin the PEAS development process. The U.S. process was reviewed along with the indicators developed. Each indicator was explained and, where appropriate, included in the draft Philippine PEAS evaluation tools. Because of the complexities of the U.S. NBS system and its evaluation indicators, many of the chosen indicators were modified to meet the more modest demands of the local system. The draft PEAS developed at this collaborative session was subsequently vetted to other stakeholders within the DOH and the NSRC. The final PEAS evaluation tools were developed through an iterative process of discussion and review to achieve consensus, including a scoring system for quality comparison between facilities. Final PEAS review documents were then created as tools for quality comparison.

The PEAS – CHD and PEAS – NSF were circulated to the appropriate entities for their use in self-evaluation preliminary to an on-site inspection by a DOH/NSRC quality evaluation team. At a pre-arranged time, review team members visited the facilities involved to review and

Table 1. Performance Evaluation and Assessment Scheme Indicators for the Center for Health Development (CHD)

I. **Operational Structure (17 points)**
- A. Staffing
  - 1. Sufficient staff are available to administer the program composed of:
    - i. CHD Program Coordinator
    - ii. Medical/Nurse Coordinator/s
    - iii. Alternate staff from the CHD for contingencies
  - 2. Written defined roles and responsibilities
- B. Personnel Training
  - 1. A personnel training plan/program exists
  - 2. The training plan for new personnel includes (in writing) instruction in:
    - i. Administrative policies and procedures
    - ii. Program operation (including all systems components)
    - iii. Technical procedures (as appropriate – Heel Prick Method, Specimen checking, Recall and Follow-up Protocols, Safety Measures)
    - iv. Available resources (local, regional, national, international)
    - v. Continuing education (attendance at conferences at least annually)
- C. Personnel Competency
  - 1. Competency assessment includes:
    - i. Documentation of sufficient educational background (doctor or nurse)
    - ii. Documentation of appropriate experience (heel prick method)
    - iii. Documentation of continuing education/certification
    - iv. Performance competency evaluation for each employee at least annually

II. **Plan of Action (Work and Financial Plan) (2 points)**
- 1. Action plan (WFP) for year containing objectives, targets, activities (advocacy, training and monitoring, budget and fund source)
- 2. Accomplishment report for previous year

III. **Systems in Place (26 points)**
- 1. Financing schemes for NBS activities (advocacy, training, monitoring, recall, follow-up and confirmatory testing)
  - i. Provision of confirmatory fees for indigent patients (for CH and CAH)
  - ii. Community-based financing
  - iii. Inter-local health zone
  - iv. Inclusion of supplemental budget for LGUs
- 2. Information system
  - i. Updated directory of all health facilities indicating the name of the health facility, NBS coordinator and contact details
  - ii. Statistics (Number of deliveries, newborns screened, positive screens, confirmed positive, lost to follow-up, unsatisfactory samples, dissents, and list of health facilities indicating status of implementation [active/inactive])
  - iii. Reporting system/Tracking and frequency of reports given to NSRC (documented reporting)
  - iv. Directory of specialists for referral and case management
- 3. Network and linkages
  - i. Established network with the inter-local health zones for advocacy, recall of patients and financing)
  - ii. Referral system (written protocol)
- 4. Monitoring scheme
  - i. Monitoring plan containing Health Facilities to be visited and frequency of visit
  - ii. Monitoring checklist (from NSRC)
  - iii. Documentation of monitoring conducted reflecting issues and concerns, agreements and action points
- 5. Documentation of planning and consultative meetings reflecting issues and concerns, agreements and action points
- 6. Annual program implementation review with documentation
- 7. Recall, follow-up, referral and management protocols (written)

IV. **Health promotion plan (15 points)**
- A. Communication Plan
  - 1. A comprehensive, written communication plan prepared with input from representative stakeholders exists
  - 2. IEC/reference materials available (Manual of Operations, Posters, Brochures, CDs and Books on Guide for Primary Physicians and NBS Coordinators, Flipcharts, IEC materials and DOH Issuances)
  - 3. A method for periodic review and update of the plan
  - 4. Members to assess its usefulness, its impact, and its relevance to current program activities, with updates as appropriate.
- B. Training program
  - 1. Training plan (indicating target participants, content, objectives, schedule, cost of training and funding source)
  - 2. Training for trainers
  - 3. Training materials
  - 4. Follow-up after training

V. **Contingency Plan (2 points)**
- 1. Addressing manpower turnover
- 2. Other issues

Score Responses: Yes – 1 point; No/Maybe – 0 point; Maximum Total Points – 62

Table 2. Performance Evaluation and Assessment Scheme Indicators for the Newborn Screening Facilities

A. **Existence of an Effective Newborn Screening Team**
1. The health facility has a working NBS Team
2. The composition of the NBS Team is appropriate
3. All NBS Team members underwent NBS orientation/training
4. All NBS Team members are well-informed about newborn screening
5. The role of each NBS Team member is clearly defined
6. Every NBS Team member effectively performs his/her tasks

B. **Existence of a newborn screening program in the health facility**
1. The health facility has a 'newborn screening plan of action'
2. The newborn screening action plan for the year is being implemented
3. Clear targets indicated in the action plan
4. The NBS action plan targets are being met
5. The health facility has an advocacy program
6. A newborn screening advocacy program is being implemented

C. **Implementation of NBS program**
1. Motivating parents to have their newborns screened is never a problem
2. Most patients were motivated to have NBS service once they know about it
3. Collecting the NBS blood sample is done routinely and skillfully
4. A logbook of patients is maintained
5. A quality check of samples is being made prior to submission to NSC
6. Samples are promptly sent to the NSC
7. Samples sent to the NSC have never been rejected due to contamination or insufficiency
8. The courier service is prompt and efficient for pick-up of samples
9. There have been no problems in the service of the courier
10. Normal results received from the NSC are relayed to the parents immediately
11. Abnormal results received from the NSC are relayed to the parents immediately
12. The health facility has a well-defined system in recalling patients
13. The health facility can easily recall patients
14. The health facility can easily refer, manage and recall positive cases
15. NIH assisted in recall of any patients in the past
16. The DOH-CHD assisted in recall of any patients in the past
17. The LGU assisted in recall of any patients in the past

D. **Awareness on availability of NBS service in the health facility**
1. All personnel in the health facility are aware that we offer NBS services

E. **Adequacy of NBS IE materials**
1. NBS posters posted in strategic places in the health facility
2. NBS brochures are available for target patients

F. **Administrative support for NBS implementation**
1. Administrative support is given to the NBS Team
2. Administration provides financial support to ensure smooth implementation of NBS
3. The Local Government Unit provides support in financing the health facility's NBS program

G. **Existence of a Monitoring and Evaluating mechanism on the Implementation of NBS**
1. The health facility administration has a quarterly assessment of the implementation of the NBS program
2. The NBS team conducts a quarterly assessment to review implementation and problems encountered
3. The health facility administration conducts an annual assessment of the implementation of the NBS program
4. The NBS team conducts an annual assessment to review implementation and problems encountered

H. **Transactions with the NSC**
1. The health facility is using the Purchase Order system
2. Purchase orders are processed and received from the NSC within 7 working days
3. Supplies received from the NSC are always complete and in good condition
4. Rejected samples are immediately conveyed by the NSC for immediate recall of patients
5. Billing statements received from the NSC are always accurate
6. Health facility id able to pay the purchase request within the 45-day payment period
7. Normal results are relayed within 7 working days by the NSC through email, phone or fax
8. Abnormal results are relayed promptly by the NSC for recall
9. Monthly summary of results is received from the NSC regularly
10. Inquiries are immediately entertained and handled by the NSC
11. Concerns are given prompt action by NSC

validate their responses to the PEAS, review records and other relevant information, discuss problems and possible solutions, and assess progress in achieving successful NBS implementation. Results of PEAS scoring were summarized; overall performance assessed; and plans for improvement developed.

The PEAS scoring system for CHDs included quantitative evaluation of 5 groups of indicators covering the primary areas of interest (Table 1). For each area of interest, there were several indicators. Each could be assessed as yes (in place and monitored), no (not in place), or 'in progress.' Points were given for yes = 1 and no = 0. Items in progress were not given points. For NSFs, the scoring was more qualitative with 8 qualitative areas of interest assessing overall performance (Table 2). Each of these was characterized with one or more indicators for which the response could be 'yes,' 'no,' or 'maybe.'

The CHD's performance was assessed based on the points earned during the program review using the PEAS – CHD Evaluation Tool. Scoring was based on review scores combined with scores for regional coverage. Empirical iterations were done to arrive at the ideal percentages for the formula based on current perceived performance level. Final scoring included the following scale: (1) very good = 81-100; (2) good = 61-80; (3) fair = 41-60; (4) poor = 21-40; (5) very poor = 0-20.

Results

Results of the CHD assessment and program reviews performed in 2005, 2006 and 2007 for CHD – NCR, CHD – 3 and CHD – 6 are shown in Table. The 2005 review reflected the beginnings of a national program recently implemented as a result of the Newborn Screening Act of 2004. The DOH had just assumed a major management role following on the heels of successful piloting and CHDs were just learning the intricacies of their responsibilities. The scores are shown here to illustrate what can be expected early in a national program implementation. The two subsequent reviews showed marked improvements.

The data in Table 3 illustrate the consistent improvements in CHD – NCR, CHD – 3 and CHD – 6 across the years in both compliance in implementing the components of the newborn screening programs, as reflected in the PEAS assessments, and improved screening coverage of the newborn populations in the regions. It is particularly noteworthy that CHD – NCR and CHD – 6 progressively improved their ratings and consistently had the highest rankings. CHD – 3, which ranked tenth in 2005, made the most remarkable improvements. In 2007, it ranked third among the 17 regions.

Discussion

The point of having PEAS is to provide standardized indicators against which various components of the newborn screening system can be compared. Review visits included interactions with CHD and NSF staff members who were focused on program evaluation and improvement. The experiences gained from these reviews and interactions with NBS personnel provided information essential to improving the quality of the national NBS program. While bits and pieces of PEAS may exist in progressive parts of the screening community, a comprehensive model for this type of program evaluation in the Philippine setting did not exist prior to this project. The thought process in developing the indicators and the process of using them for quality improvement has been an eye-opening process. CHDs and NSFs now understand better their roles in the system and the accompanying expectations. With this evaluation tool in hand, it will be much easier to provide the leadership required at the community level to ensure quality NBS.

While there are national DOH hospital standards designed to ensure optimal patient care, these standards might not necessarily be applied to the intricacies of newborn screening activities. Other routine newborn screening system activities (education, follow-up, diagnosis) are generally only governed by loosely defined best practices. National models for newborn screening are only now being developed and assessed. Responsibility for assuring and improving the quality of newborn screening services lies with every individual working within the screening system. In order to benefit from Philippine PEAS, a clear understanding of individual and collective newborn

Table 3. Notable performances in terms of implementation and coverage using the PEAS assessment tool.

REGION	EVALUATED YEAR								
	2005			2006			2007		
	PEAS Score[a]	Percent Coverage[b]	Overall Performance[c]	PEAS Score[a]	Percent Coverage[b]	Overall Performance[c]	PEAS Score[a]	Percent Coverage[b]	Overall Performance[c]
CHD – 3	20.97	6.30	Very Poor	69.36	10.66	Poor	85.48	18	Fair
CHD – 6	62.9	10.30	Poor	98.38	15.78	Fair	98.38	23	Good
CHD – NCR	62.9	18.90	Fair	90.32	25.68	Fair	100	33	Good

[a] PEAS Tool Points / Total Points x 100
[b] Newborn screening coverage for the region
[c] PEAS Evaluation Tool (50%) + Regional Coverage (50%)

screening system responsibilities is necessary. Both CHDs and NSFs have responsibilities within the system that need to be clearly understood and continuously assessed for quality. PEAS provides a mechanism for this to occur. Indeed, our initial experiences with using PEAS as a quality improvement tool have been extremely successful.

Conclusion

The Philippine PEAS has been useful in regional and hospital evaluation and in making recommendations for program improvement. The Philippine PEAS will continue to be validated through periodic scoring comparisons and impact on program improvement. Experiences to date have been positive with a better understanding of responsibilities within the screening system by both CHDs and NSFs. Additionally, the exercise of developing meaningful indicators provided a useful exercise for DOH and NSRC personnel to realistically consider quality indicators and how best to share their importance. The future of the Philippine NBS program is bright and tools such as PEAS provide a unique opportunity to ensure a healthy life for all Filipinos.

Acknowledgments

The authors thank the staff of the Newborn Screening Reference Center for their assistance in the preparation of the manuscript and the review/validation of the PEAS scores.

References

1. Therrell BL. U.S. newborn screening policy dilemmas for the twenty-first century. Molec Genet Metab. 2001;74:64-74.
2. Performance Evaluation and Assessment Schemes. Available at http://genes-r-us.uthscsa.edu/NBS_PEAS.htm. Accessed February 15, 2009.
3. U.S. Department of Health and Human Services. Healthy People 2010. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000. Available at http://www.healthypeople.gov/Document/tableofcontents.htm#volume1. Accessed February 15, 2009.
4. Therrell BL, Hannon WH. National evaluation of U.S. newborn screening system components. Ment Retard and Develop Disabil Res Rev. 2006;12:236-45.
5. American College of Medical Genetics, Newborn Screening Expert Group. Newborn screening: toward a uniform screening panel and system. Genetics in Medicine. 2006;8 (suppl 1):1S-252S.
6. Republic Act No 9288 or Newborn Screening Act of 2004. Available at http://www.newbornscreening.ph. Accessed February 17, 2009.