

## **Newborn Screening (General Messaging), November 2013**

### **Primary Message:**

**It's about the babies. Accurate and early testing is a critical part of the system to save babies' lives.**

#### **1. The newborn screening system is essential. It is much more than isolated laboratory tests.**

- The system involves sampling, screening, notification, confirmation, treatment, counseling, education, training and follow-up.
- Public health laboratories are part of a team that includes:
  - Public health staff responsible for performing screening and follow-up analysis of abnormal results;
  - Birthing facility staff;
  - Primary care physicians;
  - Metabolic specialists;
  - Educators;
  - And families.
- Coordination between all of the following entities is key:
  - Public health laboratory and Maternal and Child Health (MCH) staff;
  - Primary care physicians and medical specialists;
  - And public health staff, medical community and families.
- **Program improvements require the involvement of and advocacy from the entire team.**

#### **2. State laboratories are critical.**

- Public health laboratories conduct 97% of testing for the four million babies born in the US each year.
- Public health laboratories assure high quality, accurate screening results in collaboration with the Centers for Disease Control and Prevention (CDC).
- Public health laboratories are ready to do more when authorized by state legislatures.

#### **3. The newborn screening process is dynamic.**

- Advancing technology has led to expanded screening (e.g., tandem mass spectrometry (MS/MS), microarray, chip).
- An expanded process detects more newborns with treatable disorders.
- More conditions are under consideration to be included in the core panel of disorders (e.g., Lysosomal Storage Disorders (LSDs)).
- Public health laboratories do not determine the screening panel. They follow recommendations of state advisory groups which include parents.

#### 4. Funding is needed.

- Funding must cover a comprehensive, coordinated program of testing, treatment and follow up.
- Emerging testing technologies require expensive analytical equipment and specially trained personnel.
- Funding for the following agencies is critical to ensure quality screening, technical assistance, data repository, new methods and screening tools, training, pilot testing, capacity building, and continuous quality improvement:
  - Newborn Screening Quality Assurance Program (NSQAP)
  - Centers for Disease Control and Prevention (CDC)
  - Maternal and Child Health Bureau (MCHB) at the Health Resources and Services Administration (HRSA)

#### **Transport of Newborn Screening Specimens**

- In collaboration with local hospitals and other health partners, each state health department establishes the policies and procedures governing transport of newborn screening specimens to their state's public health laboratory or laboratories.
- In 1982, the Clinical Laboratory Standards Institute (CLSI) promulgated a national [standard](#), *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard – Sixth Edition, 2013, NBS01-A6*, Section 5.5, “Specimen Handling and Transport”, that requires hospitals to transport newborn screening specimens to testing facilities within 24 hours after collection. This standard was established to assure prompt turnaround of newborn screening test results and to protect the viability of specimens. A second related CLSI standard is [Newborn Screening Follow-up; Approved Guideline: NBS02-A2](#).

##### *5.5.3 Timing and Transport*

*Unless otherwise directed by the screening laboratory, the dried blood specimen should be transported or mailed to the laboratory within 24 hours after specimen collection. The appropriate tracking documentation for all stages in specimen transit, from collection to laboratory delivery, should be maintained. The tracking process should undergo periodic reviews for timely handling at each stage along with QA audits (see CLSI document NBS02). Daily courier transport is recommended whenever possible to control the environmental conditions, sustain tracking, and minimize delays in shipment. Delays at collection sites should be avoided, and the shipping environment relative to possible delays should be structured to maximize transport efficiency. Specimens shipped in a timely*

*manner decrease the time to diagnose affected newborns and preserve the integrity of the blood spot and the biochemical analytes to be measured.*

- APHL has been tasked by the U.S. Department of Health and Human Services Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children and HRSA to review current policies and practices around transport of newborn screening specimens. While the Milwaukee Journal Sentinel's reporters did a fine job of surveying many state laboratories on this topic, APHL will further survey member laboratories for additional information.
- Currently the Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs) does have a quality indicator (QI) measuring "Time elapsed from birth to screening, follow-up testing, confirmed diagnosis" with one component focusing specifically on time from specimen collection to receipt by lab. This QI is stratified into the following categories: same day as collection, calendar day after collection, 2 calendar days after collection, 3 days, 4 days, 5-6 days and more than 7-10 days. Additionally, NewSTEPs is collecting data on state newborn screening policies for various activities that include:
  - Specimen transport, testing, etc.;
  - Hours of operation of the newborn screening laboratory and follow-up program (where appropriate);
  - And newborn screening programs' daily responsibilities.

These data will all be used in conjunction with the QI data to identify best practices and provide opportunity for quality improvement.

- Within the NewSTEPs site evaluation visits, a component is dedicated to visiting several birthing facilities, and includes recommendations offered when evaluating their activities within the newborn screening program.

### **50<sup>th</sup> Anniversary of Newborn Screening Campaign Messages**

- More than 12,000 lives are saved or improved by newborn screening each year in the US.
- Newborn screening is perhaps the fastest, safest way to protect your baby against certain medical conditions.
- Parents should follow up with the hospital and health care provider for their baby's newborn screening results.
- If parents receive a call that their baby's results are positive, they should take it seriously and follow-up immediately.

**Resources:**

[\*What's the Best Thing You Can Do to Protect Your Newborns Health\*](#)

[\*Four Facts that Policy Makers Should Know About Newborn Screening\*](#)

[\*The Story of Newborn Screening: How One Simple Test Changed Lives Science and Health in America\*](#)