Newborn Screening Webinar Series:
Specimen Collection, Shipping, Tracking & Resulting

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September 11, 2019
New Regulation: Webinar Series

- Specimen collection, shipping, tracking and resulting
- Babies in the NICU
- Requests for repeats
- Referrals to specialty care centers
- Birth attendants

- Process improvement
New Regulation: Webinar Series

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All webinars will be recorded and then posted on the NBS Program’s website:
https://www.wadsworth.org/programs/newborn/screening
New Regulation: An Impetus for Change

“Deadly Delays” article in Milwaukee Journal Sentinel in November, 2013

New Regulation: Deadly Delays

Findings:

- Labs closed on weekends & holidays
- Delays in specimen shipping
- Little standardization between newborn screening systems
- Hospital data not made available
New Regulation: Federal Guidance

Recommendations from the Department of Health and Human Services’ (DHHS) Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Discretionary Advisory Committee on
Heritable Disorders in Newborns and Children
5600 Fishers Lane, Room 18W68
Rockville, Maryland 20857
www.hrsa.gov/heritabledisorderscommittee

April 16, 2015

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

During the past eighteen months, the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee) has been reviewing current policies and practices relating to timelines for diagnosis and treatment of serious or life-threatening health conditions in the United States. Prompted by a public comment during the Committee’s April 2015 meeting, the Committee determined that it

New Regulation: SACHDNC Recommendations

“To achieve the goals of timely diagnosis and treatment of screened conditions and to avoid associated disability, morbidity and mortality, the following timelines should be achieved by NBS systems for the initial newborn screening specimen:

- Presumptive positive results for time-critical conditions should be communicated immediately to the newborns healthcare provider but no later than five days of life.
- Presumptive positive results for all other conditions should be communicated to the newborn’s healthcare provider as soon as possible but no later than seven days of life.
- All NBS tests should be completed within seven days of life with results reported to the healthcare provider as soon as possible.”
New Regulation: SACHDNC Recommendations

- “In order to achieve the above goals:
  - Initial NBS specimens should be collected in the appropriate time frame for the newborn’s condition but no later than 48 hours after birth, and
  - NBS specimens should be received at the laboratory as soon as possible; ideally within 24 hours of collection.”

- New York State Department of Health (NYSDOH) endorses these recommendations, although the new regulation is actually more stringent (collection at < 36 hours).
New Regulation: Changes Needed

• In 2015 in New York State:
  • 83.7% of initial NBS specimens were collected within 48 hours of birth
  • New York ranked 32 out of 37 states that reported data to NewSTEPs (Newborn Screening Technical assistance and Evaluation Program)
  • 28.3% of NBS specimens arrived at the NYSDOH within 24 hours of collection
  • New York ranked 29 out of 36 states according to NewSTEPs data
New Regulation: Revision

- In New York State, newborn screening is mandated by Public Health Law, sections 2500-a and 2500-f.
- Due in part to the DHHS recommendations, the NYSDOH embarked on a multi-year process of revising the regulation that details how this public health law should be enacted.
New Regulation: It’s Here!

• “Newborn Screening for Phenylketonuria and Other Diseases,” Subpart 69-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations went into effect on February 13, 2019
New Regulation: Where to Find It

Title: SubPart 69-1 - Newborn Screening for Phenylketonuria and Other Diseases

Effective Date
02/13/2019

SubPart 69-1 - Newborn Screening for Phenylketonuria and Other Diseases

- Section 69-1-1 - Definitions
- Section 69-1-2 - Diseases screened
- Section 69-1-3 - Responsibilities of the CEO of a Hospital
- Section 69-1-4 - Responsibilities of the birthing attendant
- Section 69-1-5 - Duties of the responsible provider
- Section 69-1-6 - Responsibilities of the public health officer
- Section 69-1-7 - Responsibilities of the specialty care center director
- Section 69-1-8 - Follow-up review, tracking and educational activities
- Section 69-1-9 - Applicability of this Subpart

New Regulation: Topics Covered

- Specimen collection, shipping, tracking and resulting
- Babies in the NICU
- Requests for repeats
- Referrals to specialty care centers
- Birth attendants
Baby born → Specimen collection → Specimen sent to lab → Specimen arrives at lab
Recommended Timing Under New Regulation

- Baby born
  - Hour 0
- Specimen collection @ 24-36 Hours
- Specimen sent to lab within 24 hours of collection
- Specimen arrives at lab within 48 hours of collection
Specimen Collection
Recommended Timing Under New Regulation

- Baby born Hour 0
- Specimen collection @ 24-36 Hours
- Specimen sent to lab within 24 hours of collection
- Specimen arrives at lab within 48 hours of collection
Specimen Collection: Early Discharge

• If a newborn is less than 24 hours old at the time of discharge, the hospital should collect a specimen prior to discharge

• Hospital should schedule and collect a second screen from the newborn between 48-72 hours of age
Specimen Collection: Late Admission

• If a newborn is admitted to the hospital within the first 28 days of life and no specimen was previously collected, the hospital should collect one.
Specimen Collection: Drying Time

Specimens should be air dried on a flat, nonabsorbent surface for at least 3 hours prior to shipment.
Specimen Collection: NBS Documentation

- Specimen collection forms shall be submitted as directed by the testing laboratory:
  - Fill out ALL fields as clearly as possible
  - ‘Infant’s Last Name’ should be filled out with the newborn’s new, legal name if known at time of sample collection
Specimen Collection: NBS Documentation

• Missing, incomplete, or incorrect demographic information on the specimen collection form can delay screen results and reporting.
• Please make every effort to ensure this information is on the filter paper and correct before submitting to NBS lab.
Specimen Collection: Staff Training

- Hospital staff should complete comprehensive specimen collection training prior to collecting any samples
- Training annually
- Hospital should retain records of training completion
- Resources available on NBS website:
  - Video
  - Specimen collection guide

https://www.wadsworth.org/programs/newborn/screening/providers/specimen-collection
Specimen Collection: Hospital Procedures

- Hospitals should establish written policies and procedures for:
  - Specimen collection, storage, tracking and shipping
  - Tracking and disposition of results
Hospital Contacts

- Hospitals should provide the NBS Program with the names and contact information for its hospital administrative designee(s) and medical designee(s) annually
  - The NBS Program should be notified within 30 days of a change of designee
Specimen Shipping
Recommended Timing Under New Regulation

- Baby born Hour 0
- Specimen collection @ 24-36 Hours
- Specimen sent to lab within 24 hours of collection
- Specimen arrives at lab within 48 hours of collection
Specimen Shipping

• All specimens should be submitted to the NBS lab within 24 hours of collection

• Specimens should arrive at the NBS lab within 48 hours of sample collection
Specimen Tracking
Specimen Tracking: Hospital Documentation

- The Lab ID should be documented in the baby’s discharge summary and medical record, including the date & time of collection.

Lab IDs are unique identifiers for each baby/specimen.
Specimen Resulting: Hospital Documentation

- Each newborn’s NBS results should be documented in the baby’s medical record at the hospital.

- Discharge summary containing Lab ID or copy of NBS result should be transmitted to the responsible provider.
Questions?

• Please email questions to nbsinfo@health.ny.gov

• We will do our best to respond individually, and will also compile all the questions in a ‘Frequently Asked Questions’ document which will be posted on the NBS website.
New Regulation: Webinar Series

- Babies in the NICU: September 12, 2019 @ noon
- Requests for repeats: September 19, 2019 @ noon
- Process improvement: October 3, 2019 @ noon
- Referrals to specialty care centers: October 10, 2019 @ noon
- Birth attendants: October 17, 2019 @ noon