



**Department
of Health**


**Wadsworth
Center**

Newborn Screening Regulations

Process Improvement

October 4, 2019

New Regulation: Webinar Series

- Specimen collection, shipping, tracking and resulting
- Babies in the NICU
- Requests for repeats
- **Process improvement** 
- Referrals to specialty care centers
- Midwives



NBS Outcomes in NYS

- In terms of age collection,
 - 74.7% of specimens were collected within 36 hours*
 - 94.7% of specimens were collected within 48 hours*
- If the benchmark is set to 100%,
 - 12 out of 124 hospitals can meet it for 36 hours*
 - 37 out of 124 hospitals can meet it for 48 hours*



*NBS Outcomes from November 2018



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Changes within the State NBS Program

To avoid outcomes associated with deadly delays by NBS systems, the state NBS program utilized the **LEAN initiative** beginning in 2016 to improve timeliness in screening results.



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What is the LEAN?

“Lean provides a way to provide value, line up value creating actions in the best sequence, conduct these activities without interruption and whenever someone requests them, and perform them more and more effectively.” Lean Thinking-James Womack and Daniel Jones, 1996

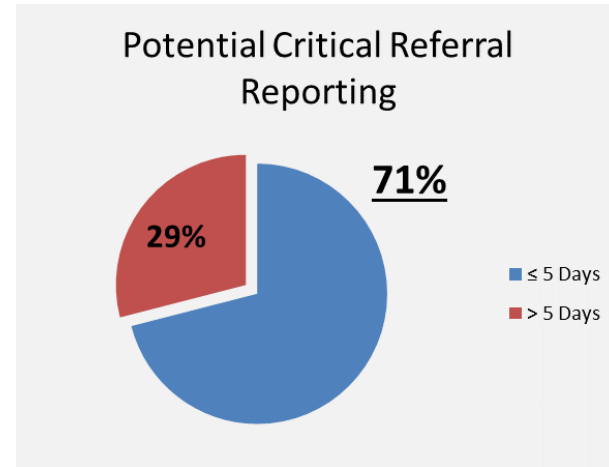
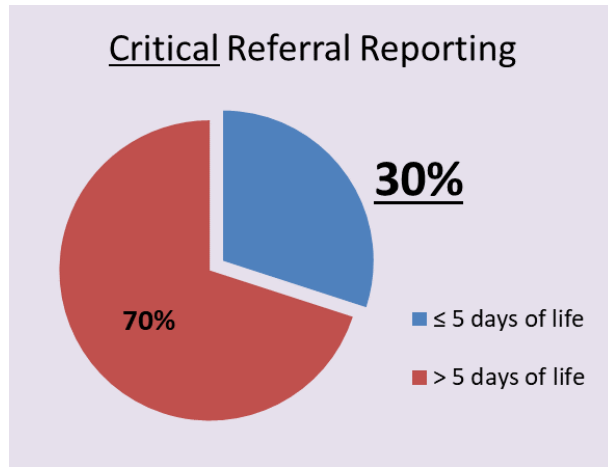
Key Lean Principles

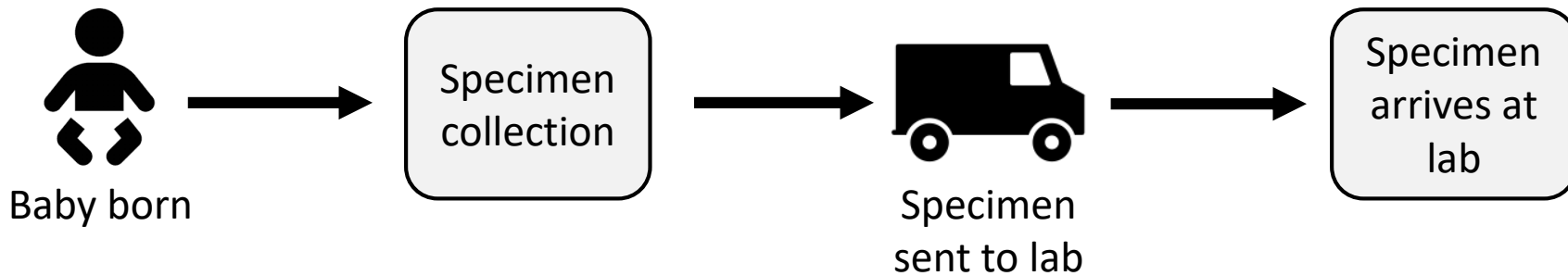
- Value - what customers are paying for
- Flow - continuous movement
- Perfection - never stop improving



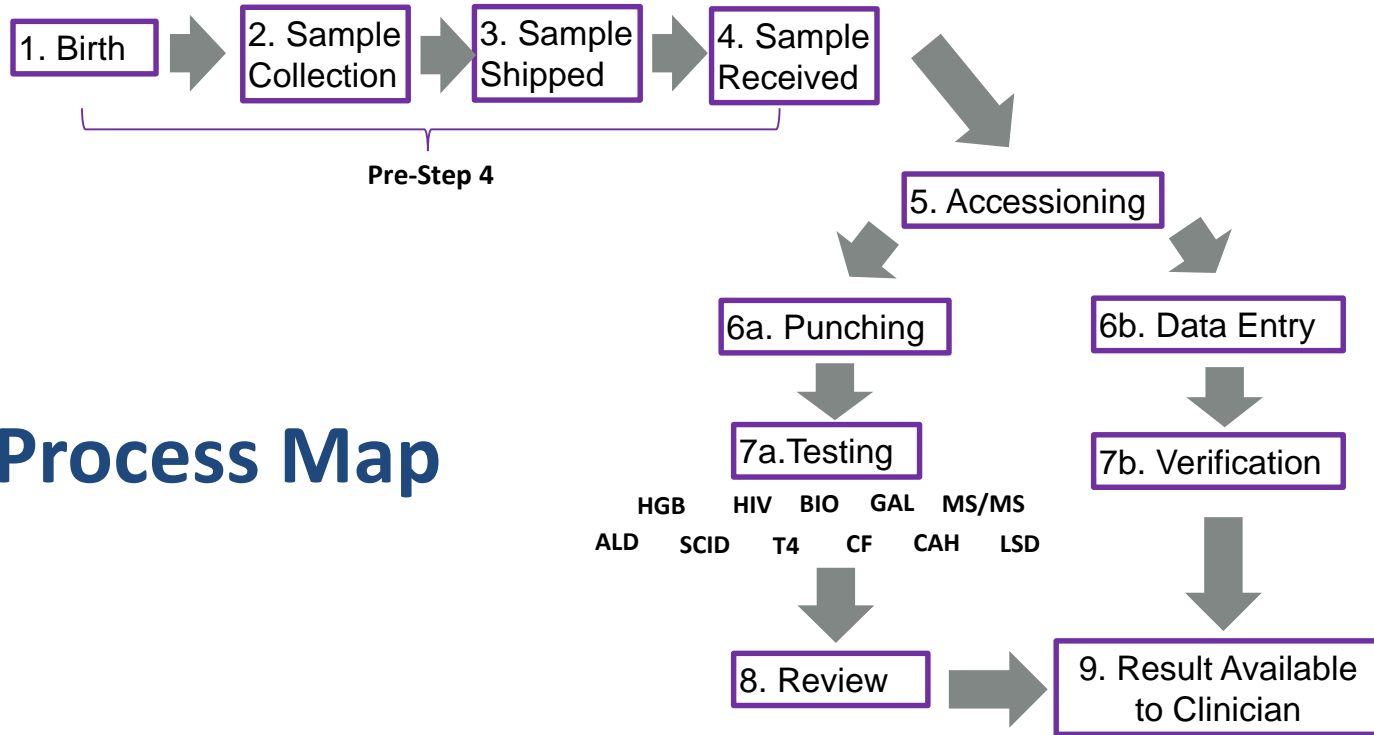
LEAN Initiative

Goal: To meet turnaround time from recipient of sample to reporting of 2 days for critical conditions, and 4 days for all other conditions.





NBS Process Map



LEAN Initiative

Improvements with Transport:

- Monthly reports now issued by the NBS Program to hospitals as a tool for internal quality improvement measures; looking at removing UPS delays from report
- Assigned a staff member to work daily with UPS
- UPS placards distributed to all hospitals so all drivers know where they should pick up specimens
- A very dedicated UPS employee works with our staff to find lost/delayed packages



LEAN Initiative

Internal Program Improvements:

- All hands on deck mail opening / punching
- Testing on instrumentation earlier; preliminary critical results called out the day received for many tests
- Data entry changed; help solicited across the program to allow for results to be analyzed earlier
- Improvements in result analyses



Recommendations in New Regulation



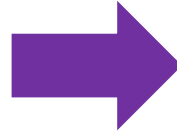
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Title Change

Previously regarded as:

*“Testing for
Phenylketonuria and Other
Diseases and Conditions”*



Now regarded as:

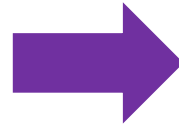
*“Newborn Screening for
Phenylketonuria and
Other Diseases”*



Title Change: Please Note

Previously regarded as:

“Testing for Phenylketonuria and Other Diseases and Conditions”



Now regarded as:

“Newborn *Screening* for Phenylketonuria and Other Diseases”

Please do not call it “the PKU”- the newborn screen tests for 50 different conditions of which PKU is one. Referring to it as “the PKU” causes confusion and has led to unnecessary and incorrect lab work for babies.



What has changed from the old regulation?

1. Revised timeframes

- Specimen should be collected from the infant 24-36 hours after birth
- Specimen should be submitted to testing laboratory within 24 hours of collection



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What has changed from the old regulation?

2. Reporting of infant mortality to the NBS Program
 - Reporting must happen within 5 days of death
 - Actions will be cancelled for the infant to avoid the testing laboratory from contacting families after the infant's death



What has changed from the old regulation?

3. Training for specimen collection
 - Prior to performing any specimen collection any employee involved must be trained
 - An annual training should also occur after the initial training
 - Hospital should retain documentation of completion of all such training



What has changed from the old regulation?

4. Repeat testing
 - Providers must notify parents of need for a repeat within (1) business day



What has changed from the old regulation?

5. Appointment of a NBS Coordinator to act as a program liaison between the hospital and testing laboratory
 - The CEO of the hospital must task an employee to: receive and act on newborn screening results
 - The CEO of the hospital should also ensure the testing laboratory receives the current contact information for the designated program liaison



What has changed from the old regulation?

6. Written policies and procedures for the hospital's NBS processes for:
 - The collection, storage, tracking and shipping of specimens; and,
 - The tracking and disposition of test results (there are additional requirements for HIV testing)



Potential Changes to NBS Processes



Revised Timeframes

- Process:
 - Ensure smooth UPS pick-up by clearly identifying pick-up location
 - Make sure 'Saturday' box is checked on labels prepared for Friday pickup
 - Utilize Newborn Screening Transport Form to track specimen transport and delivery
 - Track UPS envelopes; if they get diverted or do not progress to lab, notify UPS and NBS Program staff
 - Consider creating a process map of your institution's newborn screen collection and shipping process to identify steps that could be improved



Reporting of Infant Mortality

- Process:
 - Report infant mortality **within (5) days** of death
 - Notification must be written and sent to the NBS Program in the form of faxes, formal letters, and/or notebooks entered in the internet Case Management System (iCMS)



Training for Specimen Collection

- Process:
 - Include specimen collection training in orientation for RNs and other nursery staff
 - Establish a yearly refresher on specimen collection for staff
 - Formalize and emphasize the critical process of specimen collection
 - Improve competency of newborn screening processes and regularly educate staff on changes made to testing



Repeat Testing

- Process:
 - Obtain a repeat by contacting the primary care provider and parent(s)
 - If unable to obtain a repeat, the hospital must document the steps taken to notify parents and the primary care provider
 - Electronic notification of follow-up efforts is preferred
 - If repeat screen is not done, submit documentation of follow-up efforts to NBS **within (90) days** of notification



Appointment of a Program Liaison

- Process:
 - Report any program liaison changes to NBS **within (30) days** of the change

Health Electronic Response Data System (HERDS)

Level Selector	Home	Data Entry	Reports
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Data Entry

Activity:*



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Written Policies and Procedures

- Process:
 - Create individual written policies and procedures for collection, storage and shipping of specimens and the tracking and disposition of test results
 - Guidance document from NBS Program is in development



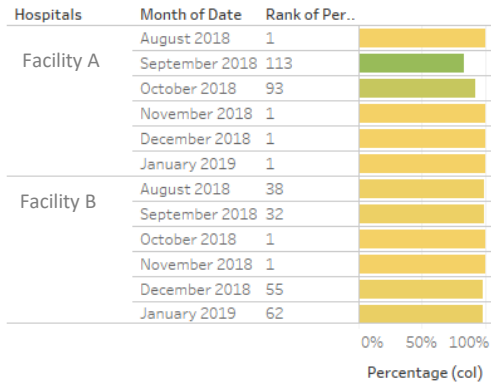
Suggestions from Peer NBS Programs

- Implement a chain of custody guide that staff can use to map out their processes for future evaluation.
- Utilize the NewSTEPs Timeliness Toolkit located [here](#).
- Create educational tools (“buddy badges”, posters, videos, indoor billboard advertisements, etc.) that highlight timeliness standards in specimen collection.

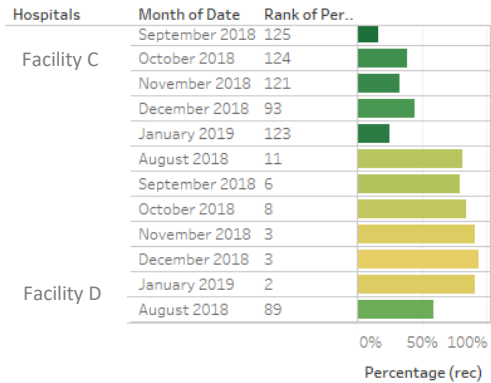


Coming Soon: New Monthly Report Cards

Specimen Collection within 48 Hours of Age



Specimens Received at Lab within 48 Hours



Hospitals
(All)

Month Year
(All)

% of Specimens Collected..



% of Specimens Collected..



% of Specimens Received ..



% of Specimens Received ..



% of Unsuitable Specimens

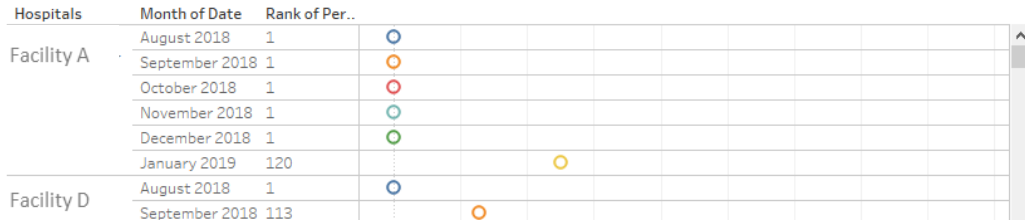


Month Year

- August 2018
- September 2018
- October 2018
- November 2018
- December 2018
- January 2019

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Unsuitable Specimens



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Upcoming Webinars



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New Regulation: Webinar Series

- Referrals to specialty care centers: October 10, 2019 @ noon
- Birth attendants: October 17, 2019 @ noon



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.



The NBS Regulation can be found on the NBS website [here](#).

