Updating the National Newborn Screening Contingency Plan to Facilitate Preparedness

APHL Newborn Screening and Genetic Testing Symposium
New Orleans, LA – 9/11/2017

Scott Shone, PhD
**Background**

- **2004**
  - APHL Subcommittee
    - Developed framework for PH Labs to prepare and respond to emergencies

- **2005**
  - Hurricanes Katrina and Rita

- **2008**
  - Newborn Screening Saves Lives Act
    - Directs CDC, HRSA, and State Agencies to develop a national NBS contingency plan for use by a state, region, or consortia of states in the event of a public health emergency

- **2010**
  - Current CONPLAN published

- **2014**
  - Newborn Screening Saves Live Reauthorization Act
    - The national CONPLAN shall be updated as needed and at least every five years

- **2015**
  - AMCHP partnered with CDC, HRSA, APHL, and expert stakeholders to update the national CONPLAN
Advisory Committee

- Newborn Screening Programs
- Public Health Labs
- Regional Collaboratives
- Family Voices
- HIT
- Metabolic Specialists
- Title V

- AAP
- AMCHP
- APHL
- ASTHO
- CDC
- HRSA
- March of Dimes
- NACCHO
Advisory Committee

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Background

2005
Hurricanes Katrina & Rita

2004
APHL PHL Emergency Plan

2008
NBS Saves Lives Act

2010
CONPLAN Published

2012
Superstorm Sandy

2014
NBS Saves Lives Reauthorization Act

2015 - 2016
AMCHP/APHL Revise CONPLAN

Dec-15
Advisory Committee Kick-off Call

Feb-16
Advisory Committee In-Person Meeting
APHL NBSGTS Symposium

Jan-16 - Feb-16
Advisory Committee Call
Public Comment Survey

Mar-16 - Jun-16
Advisory Committee Calls
Iterative Revisions to CONPLAN

Jul-16
Final Draft
Revised CONPLAN Submitted to CDC
Contingency Planning ≠ Preparedness

- Plan must be USABLE
- Focus on gaps in laboratory and clinical follow-up
  - Vulnerability Assessment
  - Planning Assumptions
  - Essential Functions
  - Preparation Documents
  - Training and Exercise
  - Funding guidelines
  - MOUs
  - How to connecting with other states / supports
  - Case Examples
When we last met...

Dec 2015 – Advisory Committee Orientation & Kick-off Call ✓
Jan. 2016 - Advisory Committee Call ✓
Jan. – Feb. 2016 – Public Comment Survey Open ✓
Feb. 27, 2016 – In-person Advisory Committee Meeting
  o Recommendations for updates to the plan and resources
  o Dissemination plan for updated CONPLAN and resources

March – June 2016:
  o Incorporate recommended updates
  o Circulate updated draft to Advisory Committee for final review/comment
  o Finalize updates

June 2016 – Submit final product

June and beyond – Disseminate and promote updated plan and resources
“It’s not about what it is, it’s about what it can become.” —
Original CONPLAN
1. A framework for specimen collection is established.
2. Specimens are shipped to the designated newborn screening laboratory site.
3. Specimens are processed.
4. Screening results are reported to the newborn screening follow-up program and physicians and families.
5. Positive diagnostic screening results are confirmed.
6. Availability of treatment and management resources is ensured.
7. Families are educated about newborn screening.
8. Carry out other activities determined appropriate by the HHS Secretary.

Revised CONPLAN
1. Ensure ongoing communication to families, providers, birth facilities, and agency staff is ensured.
2. Educate families about newborn screening.
3. Conduct screenings; collect and transport specimens.
4. Ship specimens to the designated newborn screening laboratory site.
5. Process specimens.
6. Report screening results to physicians and families.
7. Perform diagnostic testing for infants with urgent positive screening results.
8. Ensure availability of treatment and management resources.
9. Carry out other activities determined appropriate by the HHS Secretary.
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New Resources – Making the CONPLAN Usable

- Strategic Objectives
  - Added Communication
  - Reworded remaining to make more active
- Included Point-of-Care Testing
- Updated Responsibility Matrix
- New Appendices
  - NBS CONPLAN Flowchart
  - NBS Contingency Planning Checklists and Tips
  - Resource Lists
    - State examples
    - Templates
## Updated Responsibility Matrix

**Strategic Objective #4 - Specimens are shipped to the designated newborn screening laboratory site.**

<table>
<thead>
<tr>
<th>Operational Objective</th>
<th>Activity</th>
<th>Responsible Entity (State)</th>
<th>Responsible Entity (Local)</th>
</tr>
</thead>
</table>
| 1. Specimens are shipped to the appropriate laboratory within 24 hours of collection. | 1. Assess situation and operational status of laboratories and transport system  
2. Ship to primary laboratory, if available; ship to secondary or tertiary laboratories when necessary.  
3. Operationalize tracking system to document chain of custody of specimens.  
4. Notify courier of any special pick-up or delivery issues (e.g., timing, location). | • State Health Official  
• State Preparedness Director  
• Newborn Screening Program Director | 1. Newborn screening programs; hospital preparedness coordinator.  
2. Jurisdictional health official or designee; newborn screening programs.  
3. Hospital and other potential collection facilities.  
4. Newborn screening program |
| 2. Specimens en route to potential impacted laboratories are redirected to alternate laboratories. | 1. Notify courier of any special pick-up or delivery issues.  
2. Contact transport system provider in times of emergency and execute change of address. | • State Health Official  
• Newborn Screening Program Director | 1. Newborn screening programs.  
2. Newborn screening programs; potentially impacted laboratory. |
| 3. Track and identify missing specimens (including those not shipped), and obtain a new specimen, as needed. | 1. Identify missing specimens.  
2. Locate the newborn and his/her family.  
3. Collect a second specimen.  
4. Use Public Service Announcements (PSAs) to aid in advising parents of newborns affected by an emergency incident when necessary. | • State Health Official  
• Newborn Screening Program Director  
• Hospital Preparedness Director | 1. Hospitals and other potential collection facilities, newborn screening programs, health care provider, parents.  
2. Hospitals and other potential collection facilities, newborn screening programs, health care provider, parents. |
### Strategic Objective 3 – Screens are conducted; and dried blood spot specimens are collected and transported.

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Are the following activities/plans in place?</th>
<th>Resources / Tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 - NSQAP-certified blood spot collection cards with the ability to capture appropriate demographics that also allow follow-up are available for use by any U.S. NBS program.</td>
<td>☐ Identify a repository of blood spot collection cards for use by any U.S. newborn screening program.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Ensure cards are not expired.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Facilitate redistribution of locally available cards until supplies are exhausted.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Notify and activate national repository to deliver cards in anticipation of local supplies being depleted.</td>
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<tr>
<td></td>
<td>☐ Facilitate distribution of cards to jurisdiction.</td>
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</tr>
<tr>
<td></td>
<td>☐ Facilitate distribution of cards to collection points.</td>
<td></td>
</tr>
<tr>
<td>3.2 - Other materials required for</td>
<td>☐ Ensure availability of materials required for blood spot collection, including lancets, alcohol pads, and packaging at hospitals and other potential collection sites.</td>
<td></td>
</tr>
</tbody>
</table>
NBS Contingency Planning Flowchart

Ongoing communication to families, providers, birth facilities, and agency staff is ensured.
- An effective newborn screening communication network is established.
- A plan for communications to all stakeholders during an emergency event is established.
- Multiple communication modalities are in place and utilized.

Families are educated about newborn screening.
- Families know about the need for newborn screening.
- Families with newborns who are screened know how to obtain newborn screening results.
- Families know what to do in response to newborn screening results.

Screens conducted; Specimens are collected and transported.

Specimens shipped to designated newborn screening laboratory site within 24 hours.

Specimens are processed.

Screening results reported to physicians and families.

Diagnostic testing is performed.

Availability of treatment and management resources is ensured.

What should be available?
- NSQAP-certified blood spot collection cards.
- Other materials required for blood spot collection, hearing screening and pulse oximetry (ODI).
- Training on how to conduct blood spot and point-of-care screenings.
- Training and processes on how to collect and ship dried blood spot specimens.

How do you manage en route or missing dried blood spot (DBS) specimens?
- Ensure DBS specimens to inspected labs should be redirected to appropriate labs.
- Missing / not shipped DBS specimens should be recognized, and new specimen obtained.

What should be secured?
- Integrity of specimens and records of all DBS specimens sent to and received by back-up labs.
- All DBS specimens are processed.
- Address emergency situation to preserve or restore capacity.

What decisions should be made?
- The need for additional / alternative capacity.
- Appropriate internal and external stakeholders to notify.
- Whether to activate back-up lab system for managing external specimens.

What communication lines should be established?
- Screening/receiving laboratories, hospitals and NBS follow-up coordinator.
- NBS program and physician or health care provider.
- If health care provider is not available, communication between NBS program and families should occur.

What should be identified and tracked?
- All screening specimens and results.
- Infants who are not screened.

What actions should be taken?
- Diagnostics testing and tracking is ensured.
- Diagnosis is established.
- Results are communicated to the health care provider, family, and NBS screening program.

Carry out other activities determined appropriate by the HHS Secretary.

Preparedness issues are identified and addressed for NBS systems.

Implementation, maintenance, and validation of the NBS Contingency Plan are performed by HHS.
Next Steps

- CDC/HRSA Clearance Process
- Get the Band Back Together
  - Advisory Committee Dissemination Plan
  - Publish
  - Review/Revise
- Work with Programs to Develop, Implement, and Maintain
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