Screening for Critical Congenital Heart Disease in Newborns Using Pulse Oximetry – New Jersey’s Experience

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Pulse Oximetry Screening Legislation

P.L. 2011, Chapter 74

“The Commissioner of Health and Senior Services shall require each birthing facility licensed by the Department of Health and Senior Services to perform a pulse oximetry screening, a minimum of 24 hours after birth, on every newborn in its care.”

-Signed June 2, 2011
-Effective Date -August 31, 2011
90 days after enactment
-Unfunded Mandate
Implementation - Define Role of NJDHSS

- Mandated to screen, not how to screen
- Point of care test
  - Hospitals responsible for ensuring follow up, not NJDHSS
  - No active follow up as with biochemical NBS
- Divisional Responsibilities
  - Division of Licensing
    - Oversight of hospital compliance with legislation
  - Newborn Screening Program
    - Initial charge to develop Best Practices Guidelines
    - Expanded to support and guide implementation efforts to build an effective screening & surveillance program
Implementation – Establish Partners

- Identified pulse ox contacts at each birthing facility

- Convened Critical Congenital Heart Disease Screening Working Group
  - Initial focus to develop recommended screening protocol
    - Two in-person meetings
    - Extensive correspondence (email and conference calls)
Screening Algorithm for Critical Congenital Heart Disease
Recommendations from the New Jersey Department of Health and Senior Services

All babies 24-48 hours of age or shortly before discharge if < 24 hours*

Perform and document pulse oximetry in both RIGHT HAND and either FOOT.

Is Pulse Oximetry reading < 90% in either the HAND or FOOT?

Are both HAND and FOOT 95-100%?

YES

FAIL
Do not rescreen.

FAIL
Repeat the above pulse oximetry screening algorithm in one hour by obtaining new measurements from both right hand and either foot. If baby does not pass after a total of three screenings (initial screen and 2 repeat screens), notify responsible medical practitioner and follow recommendations in box below.

- Notify responsible medical practitioner of the failed screen and of need for further evaluation.
- Evaluate for other causes of low oxygen saturation (e.g., persistent pulmonary hypertension, pneumonia, infection, etc.).
- In the absence of a clear cause of hypoxemia, obtain a diagnostic echocardiogram by an expert in the interpretation of infant echocardiograms and review the report prior to discharge home. This may require transfer to another institution or use of telemedicine.
- If saturation is < 90% in either the hand or foot, the baby should have immediate clinical assessment and immediate referral to pediatric cardiology. In this case, do not wait and rescreen.

NO

YES

Is the difference between the two measurements 3 or less?

YES

PASS

NO

- A pass on the screen does not exclude the existence of a cardiac disorder.
- If cardiac evaluation is otherwise indicated (e.g., clinical signs, prenatal diagnosis of critical congenital heart disease, dysmorphic features, etc.), proceed with cardiac evaluation even if baby receives a pass on the pulse oximetry screen.

- Optimal results are obtained by using a motion-tolerant pulse oximeter that reports functional oxygen saturation, which has been validated in low perfusion conditions, has been cleared by the FDA for use in newborns, and has a 2% not-mean-square accuracy.
- Document results in medical record.
- Screen in the right hand and one foot, either in parallel or direct sequence.
- Apply probe to lateral aspect of right hand and foot in areas that are clean and dry. The two sensors (light emitter and detector) should be placed directly opposite of each other.

- Administration of supplemental oxygen may alter the interpretation of the screening result. For infants requiring supplemental oxygen, delay this screening algorithm until infant is stable in room air. For infants being discharged home on supplemental oxygen, perform screen prior to discharge and review results with responsible medical practitioner.
- Symptomatic babies require clinical evaluation.
- This screening algorithm should not take the place of clinical judgement or customary clinical practice.

* Children in Special Care Nurseries (including Intermediate Care Nurseries, Neonatal Intensive Care Nurseries, etc.) should be screened at 24-48 hours of age or when medically appropriate after 24 hours of age. In all cases, screening should occur prior to discharge from the hospital.

Education/Training

- Distributed Protocols
- Conducted 2 webinars
- Frequent communication with hospitals
- More intensive efforts planned (pending resources)
  - Best Practices Guidelines
  - Development of parent education handout
  - Train the trainer model for nursing education
  - Standardized slide deck for physicians conferences at each hospital
Surveillance

Short Term Plan:

- Quarterly aggregate data
  - # births
  - # screened
- Birth Defects Registry – all failed screens
  - Screen results, results of evaluation, prenatal history, history of symptoms…

Long Term Plan

- Electronic Birth Reporting System
- Birth Defects Registry
Aggregate Data Questions

- Number of Live Births
- Number Screened
- Explain discrepancies – expired, transferred in/out, not medically appropriate, not 24 hours, born in prior reporting period,
- Number of Failed Screens
CURRENT REPORTING PERIOD:

HOSPITAL NAME:  

| 1. Number of live-births born at birthing facility during current reporting period* | TOTAL |
| 2. Number of live-births screened with pulse oximetry during current reporting period* | |
| 3. Number of failed screens | |

EXPLANATION OF LIVE-BIRTHS SCREENED AND NOT SCREENED IN CURRENT REPORTING PERIOD

**Live-births who were SCREENED at your birthing facility in current reporting period**

- a. Number born and screened at your birthing facility in current reporting period
- b. Number born at your birthing facility in previous reporting period, but screened in current reporting period
- c. Number not born at your birthing facility, but transferred into your birthing facility and screened in current reporting period
  - Name(s) of hospital(s) transferred from and number of infants transferred
- d. Other explanation(s), provide number of infants for each explanation:

**Live-births BORN at your birthing facility during current reporting period, who were NOT SCREENED in current reporting period**

- e. Number of expirations
- f. Number not medically appropriate to screen
- g. Number born at birthing facility, but <24 hours of age at end of current reporting period
- h. Number transferred out of your birthing facility at <24 hours
  - Name(s) of hospital(s) transferred to and number of infants transferred
- i. Number transferred out of your birthing facility at ≥24 hours
  - Name(s) of hospital(s) transferred to and number of infants transferred
- j. Other explanation(s), provide number of infants for each explanation:

DEFINITIONS FOR DATA ITEMS ABOVE
BDR Follow-up Questions

- Location at time of screen
- Date and time of screen
- Readings (UE and LE) x 3
- Postnatal echo (date and result)
- Transfer (where and when)
- Final diagnosis explaining failed screen
- Cardiac consult prior to screen
- Prenatal ultrasound (date and result)
- Baby asx at time of pulse ox (if no, list sxs)
- Screen in response to sxs or routine screen
## Sample Log

<table>
<thead>
<tr>
<th>Name and MRN</th>
<th>DOB</th>
<th>Time of Birth</th>
<th>Test Date</th>
<th>Test Time</th>
<th>RH O2</th>
<th>FOOT O2</th>
<th>Test Date</th>
<th>Test Time</th>
<th>RH O2</th>
<th>FOOT O2</th>
<th>Test Date</th>
<th>Test Time</th>
<th>RH O2</th>
<th>FOOT O2</th>
<th>Pass or Fail</th>
</tr>
</thead>
</table>

### Documentation for Failed Screenings:

<table>
<thead>
<tr>
<th>Name and Medical Record #</th>
<th>Cardiac consult prior to screen</th>
<th>Prenatal CHD diagnosis</th>
<th>Date of Echo</th>
<th>Echo result</th>
<th>Transferred</th>
<th>Date transferred</th>
<th>Final diagnosis(es)</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe, 123456</td>
<td>No</td>
<td>None</td>
<td>10/10/2011</td>
<td>HLHS</td>
<td>CHOP</td>
<td>10/10/2011</td>
<td>HLHS</td>
</tr>
</tbody>
</table>
PRELIMINARY DATA
Data Sources

- Initial Survey re: Infrastructure August 4, 2011
- Hospital Survey November 2011
  - 25/52 responded
- Informal feedback from hospitals
- CDC interviews at birthing facilities
  - Epi-Aid: 11 birthing facilities
  - Econ-Aid: 7 birthing facilities
- Quarterly Aggregate Data Reports
- Birth Defects Registry
Does your facility have the ability to do an echocardiogram on site (by someone with expertise in conducting echocardiograms in newborns)?
Hospital Feedback on the Process

- **Documentation**
  
  “Very difficult to keep accurate log as our EMR cannot provide report…”

- **Short implementation time**
  
  “Issues were with turnaround time from receiving the screening protocol from NJDHSS and implementation of the program.”

- **Cost**
  
  “Costly - had to purchase additional pulse oximeter, as well as reusable probes, that require a "disposable" wrap that was not budgeted for.”

- **Most stated no significant issues**
  
  “The implementation has gone smoothly. No particular challenges.”

- **Majority utilizing NJDHSS protocol**
Challenges

- Overall
  - 90 day implementation period
  - Unfunded mandate/limited staffing resources
  - Inclusion of all infants (NICU too)

- Education
  - Need for more intensive training
  - Need for educational materials

- Surveillance system
  - Accuracy of data—steep learning curve
  - Aggregate data
  - Quality assurance
Strengths

- >95% of infants screened in first 90 days
- Mechanism to collect data for program evaluation
- Covered a lot of ground with very limited resources—both financial and staff
- Committed working group, dedicated staff and established connections with birthing facilities
“It is because of your law that our son’s life was saved, and my husband and I are very grateful to you…”

Letter to Governor Christie from the family of Dylan Gordon
Acknowledgements

- Pulse Ox Core Team at the NJDHSS
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