Screening for Critical Congenital Heart Disease in Newborns Using Pulse Oximetry – Role for a Birth Defect Registry

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Background

Who we are
What we do
How we do it
Mission: To assure that all children with special health needs have access to comprehensive, community based, culturally competent, and family centered care.
THE NJ WAY

- REGULATORY (LAWS)
- RULES
- REPORTING TO REGISTRY
- REFERRAL TO SERVICES
  - Resources
Several Mandates, 1 Registry

Laws Requiring Reporting:
- Birth Defects Registry (1983, 2005)
- Newborn Biochemical Screening (1964)
- Early Hearing Detection & Intervention (1977, 2001)
- Autism (2007; 2009)
- County Care and Treatment (1922)
Birth Defects Registry

- Regulation – N.J.S.A. 26:8-40 et seq
- Rules - N.J.A.C. 8:20-1
- Registry – ‘passive’ reporting to BDR
- Referral – link to services through SCHS Case Management units
- Resources $0 state
  - $ from MCH Block Grant
  - $ from CDC Cooperative Agreement
Birth Defects Reporting

• Rules require reporting from hospitals and all medical professionals who diagnose birth defects

• Rule out conditions often reported
• **ALL Cardiac defects are REQUIRED**

• Hospital reporting part of hospital licensing standards
Pulse Oximetry 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.”

- Unanimously passed by both the state Assembly and Senate
- Signed June 2, 2011
- Effective Date - August 31, 2011
  90 days after enactment
- Unfunded Mandate
C.26:2-111.4 Birthing facilities required to perform pulse oximetry screening; rules, regulations.

• 2. a. 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.

• b. As used in this section, “birthing facility” means an inpatient or ambulatory health care facility licensed by the Department of Health and Senior Services that provides birthing and newborn care services.

• c. The commissioner shall adopt rules and regulations, pursuant to the “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et seq.), necessary to carry out the purposes of this act.

• 3. This act shall take effect on the 90th day after enactment, but the commissioner may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.
Pulse Oximetry Screening

- Regulation – P.L. 2011, Chapter 74
- Rules – will be under hospital licensing
- Registry – law silent
- Referral – law silent
- Resources - $0 state
Implementation – 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)
• Survey hospitals on Echocardiogram availability
Does your facility have the ability to do an echocardiogram on site (by someone with expertise in conducting echocardiograms in newborns)?

- Yes Echo: 83%
- No Echo: 17%

N=52
Implementation - NJDHSS

• Hospitals
  – Mandated to screen, not how to screen
  – Hospitals responsible for ensuring follow up

• Department of Health
  – Division of Licensing (hospital compliance)
  – EBC not able to be modified
  – Division of Family Health
    • Newborn Screening Program
      – No active follow-up as with other disorders
      – Develop Best Practices Guidelines
      – Support/guide efforts to build an effective screening & surveillance program
    • Birth Defects Registry – how to leverage
Birth Defects Registry

• How to use existing process to require reporting of Failed Screens?

• So we needed a thinking cap…
Birth Defects Registry

- ALL Cardiac defects are REQUIRED
- Other conditions are reported as rule-out
- Consider failed pulse ox as rule-out cardiac defects with active follow-up
- ALL failed screens are to be reported
- Develop questions – use BDR ‘comment boxes’
- Add a Pulse Ox module to Birth Defects Registry
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 asymptomatic at time of pulse ox (if no, symptoms)
- Screen in response to symptoms or routine screen
Surveillance

• Short Term Plan:
  – Quarterly aggregate data
  – Birth Defects Registry – all failed screens – text field
    • Screen results, results of evaluation, prenatal history, history of symptoms…

• Long Term Plan
  – Electronic Birth Reporting System – all infants
  – Birth Defects Registry – Full module for reporting all newborns failing screening
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
Implementation: Data Sources

• Hospital Survey November 2011
  – 25/52 responded

• CDC interviews at birthing facilities
  – Epi-Aid: 11 birthing facilities
  – Econ-Aid: 7 birthing facilities

• Aggregate data quarterly report

• Birth Defects Registry
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 oximetrer, 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

(Surveyed hospitals in November 2011)
Cost to Screen – Econ-Aid

• Cost of Pulse Ox machines:
  – Range from $450 (handheld) to $2,500 (Standard)
  – Annual maintenance and parts: approximately $15-$400/yr

• Cost of Probes:
  – Reusable wrap + reusable sensor = $249
  – Disposable Wrap
    • Disposable wrap with disposable sensor = $8-$12
    • For use with reusable sensor = $0.30-$1.40
Method of Data Entry – Epi-Aid

- Electronic (EMR): 3 hospitals
- Manual (Paper): 5 hospitals
- Both Electronic & Paper: 3 hospitals

Number of Hospitals

State of New Jersey
Department of Health and Senior Services
# Screening Results - Preliminary Data

## August 31, 2011 – November 30, 2011

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of live births</td>
<td>25,955</td>
</tr>
<tr>
<td>Number of infants screened</td>
<td>25,504</td>
</tr>
<tr>
<td>Percentage of infants screened</td>
<td>98.3%</td>
</tr>
<tr>
<td>Number of Failed Screens</td>
<td>9</td>
</tr>
<tr>
<td>Number of asymptomatic infants diagnosed with CCHD</td>
<td>2</td>
</tr>
</tbody>
</table>

Data from BDR as reported to us by hospitals
Challenges

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

• Surveillance system/Data collection
  – Quality assurance/Accuracy of data
    • Correct information
    • #failed screens - not otherwise detected
    • #false positives
  – Aggregate data
  – Difficulty obtaining data from border hospitals
Challenges

• Hospitals
  – Protocol / screening device
  – Tracking mechanism
  – Missed babies

• What’s written in the law is the law…
  – Screen on or after 24 hours transfers/early discharge
  – No exemptions
  – Out of hospital births – not in law
Challenges

• BDR data collection is in text box

• Accuracy of reporters –
  – BDR told one baby was septic and asymptomatic, but upon follow-up with neonatologist, baby may have been symptomatic and would have otherwise been detected – Chart Review scheduled

• Classification
  – A baby with prenatal diagnosis of CCHD is not really a false positive - baby did fail the screen and had CCHD – BUT the baby was prenatally diagnosed...SO can not attribute the screen with success
Strengths

• BDR in place with ability to utilize text fields

• >95% of infants screened in first 90 days

• A little help from our friends…CDC Epi/Econ Aid, committed working group, dedicated state and hospital staff
Benefits

• Timely identification of children
• Unintended consequences – ID’d other potentially life threatening conditions

• Lives will be saved!
“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

“As Governor, you sign a lot of bills into law, but it’s a rare day when you know a piece of legislation you signed saved a life,” said Governor Christie.

The Bottom Line

- NJ has a system for the early identification of children; law and rules critical
- Linkage to service
- Flexible structure allows addition of disorders
The Bottom Line

★ THANKS!

- CDC – BDR Surveillance
- CDC – Epi Aid & Econ Aid
- HRSA - MCH Block Grant
- Working group
For More Information

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