Navigating the NICU: Implementing CLSI guidelines in Hawai`i

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Presenter Disclosure

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

No relationships to disclose
Background

CLSI recommended collection times:

1.) at time of admission in NICU
2.) at 48-72 hours following admission
3.) at day of life 28 or time of discharge; whichever comes first
Hawaiʻi NICU’s

- Kapiʻolani Medical Center
  - 30 bed – level II nursery
  - 20 bed – level III NICU

- Tripler Army Medical Center
  - 16 bed – level III NICU

- Kaiser Permanente - Moanalua
  - Level III NICU

- Queen’s Medical Center
  - 6 bed – level II NICU

~ 18,000 births / year
Implementation process

- NICU leaders across Hawai‘i were brought together
  - Began April 2010
  - Agreed that Kapi‘olani Medical Center should pilot project

- NBS lab receives 3-part form
  - Nov 2010

- Formal meeting w/NICU
  - Jan 2011

- Education of NICU staff
  - May 2011

- Pilot project started
  - July 2011

- Pilot project completion
  - Dec 2011
Three Part Newborn Screening for Preterm, Low Birth Weight and Sick Newborns: Pilot Project

What?
Three-part dried blood spot NICU newborn screening pilot project at KMCW.

Why?
National call to examine the effectiveness of utilizing the three part newborn screening system in Neonatal Intensive Care Units. Given its expertise, Kapiolani Medical Center for Women and Children has been chosen as the pilot site for Hawaii.

- The physiological states associated with preterm, low birth weight (LBW), and sick newborns, and the treatments that they receive, directly affect the reliability of results for many conditions screened in dried blood spot and hearing screening programs.

- Difficulty already exists in determining the best collection time for samples with multiple conditions being tested for, some requiring collection in the first 24-48 hours and some requiring days or weeks for analytes to elevate.

- Of all abnormal NBS specimens, 10% to 40% belong to infants in the special care baby units (SCBUs).

*Study data (not specific to Hawaii)*

When?
The pilot project is aimed to launch mid - May 2011

How?

1. Birth of preterm or sick newborn
2. Transfer/Admission to NICU
3. Draw 1: On admission collect first NBS specimen regardless of age before any other treatments are begun (except respiratory)
5. Draw 3: Discharge or Day 28, whichever comes first.

Goals of the new procedures:
1. Ensure rapid, consistent, and complete blood spot screening, including appropriate follow-up to ensure early diagnosis and treatment for preterm, LBW, or sick newborns affected with a screened condition.
2. Minimize the risk of a missed or delayed diagnosis and treatment for all screened conditions.
3. Optimize the timing and minimize the number of blood spot specimen collections.
4. Define essential elements of quality assurance relevant to this guideline.
5. Provide education on the effects of SCBU treatments on newborn blood spot screening.
6. Identify areas needing further research.
Figure 1: NBS Algorithm for NICU / SCN Infants
(adapted from NWRNBS Flowchart)

- Infant admitted to the NICU
  - Infant screened before admission to NICU?
    - Yes → Collect SECOND NBS between 10 - 14 days of age
    - No → Infant transfused* before NBS collections?
      - Yes → Infant will need an additional NBS 90 - 120 days after the LAST transfusion. (NBS Follow-Up)
      - No → Collect 1st NBS upon NICU admission. Document time of collection
        - 48 - 72 Hrs of Age
        - Collect 2nd NBS**
          - Discharged before 9 days old
            - Collect 3rd NBS*** 10-14 days (send 3rd NBS kit/envelope with family)
          - Discharged 10 - 28 days old
            - Collect 3rd NBS*** at time of discharge
          - Still in NICU at 28 days ok!
            - Collect 3rd NBS*** at 28 days of age

*Galactosemia, hemoglobinopathies and biotinidase is masked by transfused RBC

**Infants with amino acid, organic acid & urea cycle disorders will be found with this NBS. TSH, 17-OHP & IRT will be resolved from the 1st NBS

***3rd NBS helps testing for CH & CAH, which is increased in the NICU population

Adapted from the NW Regional NBS Program
Obstacles

- Convincing NICU staff of value
  - Although apprehensive at first, possible benefits outweighed the inconvenience

- NICU Education
  - Creation of materials
  - Scheduling
    - Scheduling set education sessions were ineffective
    - Instead held 9 floating information sessions over 3 weeks
    - Arranged both day and night sessions to cover all NICU shifts
Obstacles

- Practicality of sample collection times
  - Each NICU operates within their own protocols
  - Hawaiʻi uses:
    1.) at admission to NICU
    2.) at day of life 2 (33-57 hrs)
    3.) if baby discharge after day of life 11 (sample drawn in NICU), or;
       if baby discharged between day of life 3-10 (sample kit sent home with family to be drawn on day 28)

- Communication with families (3rd sample)
## Preliminary Data

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<tr>
<th>MONTH</th>
<th>NBS cases</th>
<th>SCREEN POSITIVE cases</th>
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<tbody>
<tr>
<td>JULY</td>
<td>51</td>
<td>8</td>
</tr>
<tr>
<td>AUGUST</td>
<td>75</td>
<td>18</td>
</tr>
<tr>
<td>SEPTEMBER</td>
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<td>13</td>
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</tbody>
</table>
Preliminary Data

- True positive cases: 3
  - 1 – Hemoglobin E disease
  - 1 – Hemoglobin E trait
  - 1 – Hemoglobin S trait (sickle cell)

“Didn’t necessarily cut down the number of screen positives. However, the cases are getting resolved more quickly.”
Conclusions

- The data collection and analysis are still pending
  - Uncertain if we’re actually reducing false positive or negative rates
- As expected, the workload has increased
  - However, the cost-benefit hasn’t been established
- NICUs are very self-sustained
  - Implementing guidelines may require individual modifications
  - Lessons learned can be used as broad model for other NICUs
- Modification of NICU treatments may also help
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