Avoiding Deadly Delays in Newborn Screening

Richard Parad, MD MPH
Problem Statement

• Newborn Bloodspot Screen (NBS) tests for over 50 serious congenital disorders for which early treatment is critical.
• The MA DPH mandates a NBS on all newborns between 24 and 72 hours of life.
• In-hospital steps for obtaining NBS include sample ordering, collection and transportation to the State Lab (NENSP) for testing.
• Delayed diagnosis and treatment in a newborn with a time-sensitive disorder tested in the mandated Massachusetts (NBS) may lead to significant lifelong morbidity or death.
• In response to deaths from such delays, Congress passed the “Newborn Screening Saves Lives” legislation that requires timeliness in obtaining, testing and reporting samples.
• Key stakeholders: newborns, parents, nurses, physicians, laboratory personnel, NENSP and the MA DPH, all of whom desire optimization of this system towards the goal of protecting our newborns from avoidable devastating outcomes.
Process Map

NEWBORN SCREENING: Pre-analytic

Baby is born

Is baby 24 hours + 1 min old?

Does baby have any factors that should delay sample (hypothermia, transfusion, etc.)?

Night nurse pulls EPIC list of babies who need samples drawn and their Guthrie cards for phlebotomists

Is baby ready to have sample drawn?

Is baby 24 hours + 1 min old?

Sample picks up by courier; pickup slip is signed and scanned

Sample arrives at NENSP

Samples are picked up by courier; pickup slip is signed and scanned

Sample pickup is manually logged/resulted along with card # by lab control

Is sample dry?

Phlebotomists come between 4-5 AM to draw daily samples.

Nurse releases list to handheld scanner on Phleb arrival

Phlebotomists draw samples and print and place labels. Note time of sample in paper log and on card.

Nurse puts card out to dry

Nurse puts card in front desk basket

Nurse puts card in front desk basket

Night nurse pulls EPIC list of babies who need samples drawn and their Guthrie cards for phlebotomists

Nurse pulls Guthrie card from chart, fills out medical info, and places on desktop at baby’s bed

Sample is properly labeled?

Sample is left to air dry

Sample is dry?

Sample is placed on drying rack to air dry

Sample is pulled from drying rack to air dry

Sample is sorted

Sample is placed on drying rack

Sample is placed on drying rack and places in baby’s paper chart

Unit Coord. fills out demo info on Guthrie card upon admission and places in baby’s paper chart

Unit Coord. logs NBS screening has taken place

Phlebs deliver [non-dried] Guthrie cards to Lab Control

Sample arrives in lab via chute (NICU) or drop off (phleb)

Physician

Phlebotomist

Nurse

Lab Control

Unit Coordinator

Courier
Cause & Effect Diagram

ORDERING
- RN doesn’t take off
- MD doesn’t order

BLOOD DRAW
- Phlebotomy doesn’t get order
  - Mixup samples
  - Wrong time/date
- Sample drawn from wrong patient

EARLY DISCHARGE
- Baby to leaves before valid sample can be drawn

TRANSPORT
- Sample drawn but not sent to lab
- Sample lost in transport

DATA ENTRY
- Entered in EPIC but not drawn

UNSAT SAMPLE
- RN/phlebotomist doesn’t collect properly
  - Delay in Lab Control login
- Sample drawn too early
  - Time or MD info inaccurate on card

Delayed or missed NBS

Appropriate Day window overlooked
Diagnostic Data

- REDCap database output
  - Number of samples
  - Number of Unsatisfactory samples (rejected by NENSP)
  - Number of too early (drawn at <24 hours)
  - Time of birth
  - Time sample drawn
  - Time sample received in lab control
  - Time courier picks up sample
AIM Statement

• We propose to minimize delays in sending NBS samples to the State Lab.

• All samples should be shipped to the testing laboratory on the “Appropriate Day” (AD) in order for fastest transit time.

• AD = NBS sample is drawn between 24 and 48 hours of life and reaches lab control for the next possible 11 AM courier pickup.

• Our first SMART goal will be to reduce the % NBS samples NOT sent on the AD by 50% from 6% to 3% by June 16, 2016.
# Measures

<table>
<thead>
<tr>
<th>What is your measure?</th>
<th>Process Measure</th>
<th>Outcome Measure</th>
<th>Balance Measure</th>
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</thead>
<tbody>
<tr>
<td>% samples that left lab control on time</td>
<td>% of samples not sent on the “Appropriate Day” (AD)</td>
<td>Increase in % of missed samples that could lead to delay in critical diagnoses</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient population (exclusions if any)</th>
<th>Newborns</th>
<th>Newborns</th>
<th>Newborns</th>
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<thead>
<tr>
<th>Calculation methodology</th>
<th>(# samples that didn’t reach lab control by 11 AM)/ (total # daily samples)</th>
<th>(# samples not sent on AD)/ (total # daily samples)</th>
<th>(# missed samples)/(total # of daily samples)</th>
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<thead>
<tr>
<th>Data source</th>
<th>Birth Certificate Registry (EPIC) + SunQuest</th>
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</table>

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<thead>
<tr>
<th>Data collection frequency</th>
<th>Daily (compiled weekly)</th>
<th>Daily (compiled weekly)</th>
<th>Daily (compiled weekly)</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Data Quality</th>
<th>Excellent quality</th>
<th>Excellent quality</th>
<th>Unknown</th>
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**Prioritized List of Changes (Priority/Pay-Off Matrix)**

<table>
<thead>
<tr>
<th>Ease of Implementation</th>
<th>High Impact</th>
<th>Low Impact</th>
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<tbody>
<tr>
<td><strong>Easy</strong></td>
<td>Nursing + phlebotomy Education re: 24h+1 min</td>
<td>Rapid login in of samples at Lab Control</td>
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<tr>
<td></td>
<td>Restructure EPIC orders from timed to list for nursing with hour of age</td>
<td>Increase number of courier runs</td>
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<td></td>
<td>Time stamp on Sunquest labels to confirm draw time with written information</td>
<td>More frequent phlebotomy draws</td>
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<tr>
<td></td>
<td>Confirm and advertise shortest filter paper drying time</td>
<td>Nurses draw their own samples in Well Baby Nursery</td>
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<tr>
<td><strong>Difficult</strong></td>
<td></td>
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# PDSA Plan (Tests of Change)

<table>
<thead>
<tr>
<th>Date</th>
<th>Description of Intervention</th>
<th>Results</th>
<th>Action Steps</th>
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<tbody>
<tr>
<td>2/8/2015</td>
<td>• Change nursing policy from drawing sample by 72h to draw sample at 24h+1 min and no later than 48h.</td>
<td>• Improvement from 45% – 12% (% not AD)</td>
<td>• Continuing education</td>
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<tr>
<td>3/1/2016</td>
<td>• Change EPIC order by MD from admission template to EPIC list for nursing with baby age (to maintain parameters 24 – 48h) for those without sample in lab</td>
<td>• Improvement from 6 - 3% (% not AD)</td>
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<td>Planned</td>
<td>• Create EPIC list which crosses Birth Certificate and Lab Control lists to check for missing samples</td>
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Conclusions

• With thorough process evaluation, in-hospital NBS sample collection can be optimized to lower the number of samples transported outside of the Appropriate Day window, thus minimizing time to results, diagnosis and initiation of therapy.
## Next Steps/Plan for Sustainability

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<tr>
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<th>Things to consider</th>
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| **Additional tests of change** | ▪ Missed sample safety net – EPIC list  
▪ Decrease “too early” through education |
| **System based changes**      | ▪ Getting newborn screening results into the lab system  
▪ Disseminate evaluation to other hospitals through NeoQIC  
▪ Change EPIC pop-ups to remind repeat samples in NICU |
| **Measurement & reporting**  | ▪ Missed samples, unsatisfactory sample rate                                       |
| **People**                | ▪ Parad/Murphy                                                                    |