State Hygienic Laboratory (SHL)
University of Iowa

Newborn Screening (NBS) Training

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Partnering for the Health of Babies—We all work together

- State Hygienic Laboratory-Newborn Screening Laboratory
- University of Iowa Children's Hospital
- South Dakota Department of Health
- South Dakota Hospitals
- South Dakota Clinics
- Health Care Practitioners
- Parents
Newborn Screening Disorders Detected from the Heelstick Blood Collection

- Congenital Adrenal Hyperplasia
- Congenital Hypothyroidism
- Biotinidase Deficiency
- Galactosemia
- Hemoglobinopathies
- Cystic Fibrosis
- Amino acid, Organic acid, Fatty acid oxidation disorders (Tandem Mass Spectrometry)
Why Screen?

- Inherited Disorders
  - Collectively about 1 in 700 babies affected
- Can’t Cure but Start Treatment Soon
- Health Problems
  - Abnormal Metabolism
  - Developmental Delays
  - Coma and even death

Newborn screening specimen
Components of this Training

- Application to the Blood Spot (BS) Collection Device (form)
- Techniques for Collection
- Filling Out the NBS collection form
- Transport of specimen
- Specimen Quality/Acceptability
Specimen Quality

- Based on Standards written by the Clinical and Laboratory Standards Institute (formerly NCCLS)
- NBS01-A6, Volume 33 No. 9, 2013
  - Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition
- Available from South Dakota Department of Health
Specimen Quality

- Need for a quality specimen
  - Accurate and timely results
  - Screen assesses risk
- Poor Quality (PQ) MUST be recollected
Recollection

- Adds trauma to the infant
- Causes anxiety to parents
- Burdens the screening laboratory
- Burdens the collecting facility
- Delays testing
Delays in Testing May:

- Delay diagnosis
- Delay treatment
- Lead to potentially irreversible mental retardation, coma or death
Blood Collection Techniques

- Heel Stick—Method of choice
- Avoid venous collections
- Avoid using syringes
  - clotting,
  - settling, and
  - lysing of cells
- Umbilical cord blood
  - maternal contamination
Unacceptable Collection Sites

- Arch of the foot
- Newborn’s fingers
- Earlobes
- Previously punctured sites
- Intravenous lines contaminated with interfering substances
Heel Stick Method Prep

- Check the expiration date on form
- Fill out the form (more on this later) properly and completely
Precautions

- Confirm infant’s identity
- Wash hands
- Wear powder free gloves and change between infants
- Follow safety precautions when handling and disposing of sharps
Site Preparation

- Warm the newborn’s heel
- Use heel warming device or
- Use soft cloth moistened with warm water (less than 42 °C) for 3-5 minutes
Positioning foot

- Infant’s leg should be lower than the heart
- Increases venous pressure
- Wipe heel with 70% isopropyl alcohol
- Air dry
Puncture Site

- Puncture made WITHIN shaded area
- Plantar surface of the heel
Puncture

- Use sterile lancet or heel incision device
- 1.0 mm deep by 2.5 mm long
- No scalpel blades or needles
Direct Application

- Wipe away first drop of blood
- Allow a large drop to form (50-75 µL)
- Touch paper to blood ONCE and let soak through
Apply Blood

- Apply ONE drop on a circle
- Apply to ONE SIDE only
- Continue and fill all circles
- Do not press filter paper against puncture site
Take care of puncture site

- Elevate foot above the body
- Press sterile gauze or cotton swab against puncture site until bleeding stops
- Do not apply bandages that may damage baby’s delicate skin
Examine blood collection

- Look at both sides of filter paper to assure blood has soaked through
- If blood is not soaking through try again on another circle
- Do not re-apply to same circle
Air Drying the Specimens

- Do not touch other blood spots
- Keep away from direct heat and humidity
- No direct sunlight
- Horizontally
- Elevate off bench
- Dry at least 3 hours at ambient temperature
Quality Assurance & You

- After collection of the specimen, take time to look at it and determine whether or not it is acceptable.
- If not, recollect it at that time.
Too much blood

- Over-saturated
Insufficient blood:

- Applying drops that are too small
- Removing filter paper before blood has soaked through to the other side
Uneven saturation

- Insufficient quantity so blood did not soak through
- Spreading the blood drop over the surface of the circle, contributing to uneven absorption.
- Improperly applying blood to the filter paper with a device.
Layering-

- Multiple drops added to each circle
- Non-uniform concentrations
- Analyte concentrations variable by amount of blood
Contamination or dilution

- Alcohol not dried on baby’s heel
  - Other fluid/substances
- Substances on bench top
- Not always this noticeable
- May affect analysis
Inadequate drying

- Putting in envelope before drying
- Folding the flap before dry – air dry for at least 3 hrs.
- Sending with the courier before dry
Capillary Tube Collection

- Avoid anticoagulants
  - EDTA causes false negatives for TSH & IRT, false positives for 17-OHP
  - Heparin may interfere with PCR analysis for Cystic Fibrosis testing
More on Capillary Tube Collection

- Apply the blood to the filter paper from each tube as it is collected
- Do not draw or swirl with the capillary onto the filter paper
- Avoid pressing capillary tube into the paper - causes dents or scratches.
Serum separation

- Serum rings
  - Squeezing or milking the heel causes hemolysis. Use gentle pressure.
  - RBCs have settled in capillary tube.
Clotting

- Apply blood from each tube as collected
- Don’t delay or hold
- Don’t “draw” blood on circles
Filling out the Collection Form

- All requested information must be provided
- Missing information may prevent or delay test results
Collection Information

- Age of baby at time of collection
  - Birth date and Time
  - Collection date and Time
- Early collection (<24 hrs. old) affects results
  - Amino acids
  - 17-OHP, TSH
Missing Information

- Early Collection Unknown
  - Date or time is missing
  - No results for tests affected by EC
- Unknown weight
  - CAH results not reported
- Transfusion status
  - Must be marked no
  - Not assumed as no if not marked
Transfusion Affects

- Biotinidase-plasma
- Cystic Fibrosis-plasma
- Galactosemia-RBC
- Hemoglobin Disorders-RBC
- Platelets carry RBC suspended in plasma
Submitter Information

- Submitter Receives Report
  - Hospital
  - Clinic
- Infant’s Physician & Telephone Number
  - Needed for follow-up for abnormal results
Quality Assurance

- Daily fax sent from Lab to collecting facility
- Need Secure Fax Line
- Contact Person
- Fill out Info and fax back immediately
How are Newborn Screening Forms Monitored?

- Are they stored in a clean dry place in a vertical position?
- Is the supply monitored to assure that the availability of forms are within the expiration date?
Filter Paper on Form:

- Should NEVER come into contact with anything other than the baby’s Blood
- Never let the filter paper touch the bench top
- When filling out the form wear gloves and make sure the flap is closed over the filter paper
- Do not crush the form; take care when storing in charts. The filter paper may not absorb blood if crushed.
Who completes the NBS form?

- Demonstrate that your staff completes ALL fields. Is the form checked before sending to screening lab?
  - Complete
  - Legible
  - Accurate
Who conducts parent education?

- Is newborn screening education started during the prenatal period?
- Does the nursery or obstetrician provide parents with the NBS pamphlet?
Who performs heel-sticks at your facility?

- Are they properly trained in the collection procedure on filter paper?
- Are they able to describe a satisfactory specimen?
- Are they able to describe an unsatisfactory specimen?
- Do you track unsatisfactory specimens back to the individual who collected it and retrain as needed?
Who sends the specimens?

- Are specimens checked for suitable quality prior to sending with the Courier?
- Are all specimens sent within 24 hours of collection using the Courier system?
- Are steps taken to avoid subjecting the specimens to heat and humidity prior to sending?
- Does someone review the demographic information prior to sending to make sure the form is complete and legible?
Courier Information

- ICS dispatch
  - 866/442-7247
  - www.icsair.com (website)
Abnormal Result Reporting

- All initial presumptive positive results are reported to:
  - Health Care Provider

- With Recommendations for:
  - Re-screening, and/or
  - Diagnostic testing
Reporting Test Results

- Reporting Options:
  - Paper Reports
    - Paper reports delivered by USPS.
  - Web Access And Paper Reporting
    - Paper report plus Web Access
  - Web Based – Paperless
    - Totally paperless, web based only
Advantages of Web Access - Newborn Screening

- Patient look-up online
- Downloading and printing patient results
- A variety of reports for your facility, i.e., status, turnaround, summary, quality control
- Results available as soon as released by lab
<table>
<thead>
<tr>
<th>Patient</th>
<th>Birth</th>
<th>Facility</th>
<th>Gender</th>
<th>Lab No.</th>
<th>Collection</th>
<th>Events</th>
</tr>
</thead>
</table>

**Patient Lookup**

- Patient
- Gender
- Birth From
- Birth To
- Id #
- Chart Number
- Lab Number
- Region

**Monitor Patient**

- Download Reports
- Samples Received
- Quality Control
- Turnaround Statistics
- Feeding Report
- Facility Summary

*Web Master | Site Map*

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Web Access

- To begin Web access for results:
  - Contact IT Web Access at:
  - 319-335-4358
    - Creation of a unique user id and password
    - Training via phone on “How to use web access.”
  - www.shl.uiowa.edu
Questions?

- Mike Ramirez, Lab Supervisor
  - 515-725-1630
  - michael-ramirez@uiowa.edu

- Order supplies
  - 515-725-1630

- Computer issues (web access)
  - 319-335-4358