Saving Lives…
One foot at a time

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Objectives

• Identify the Newborn Screening (NBS) program structure
• Recognize the history of NBS
• Distinguish between good and poor quality NBS specimens
• State the recommended age for an infant to have NBS drawn
• Identify the length of time the specimen needs to dry
• Identify contacts for NBS questions

Partnering for Healthy Babies

• North Dakota Department of Health
  • Newborn Screening Program Administration
• University of Iowa State Hygienic Laboratory
• University of Iowa Children’s Hospital
  • Short-term follow-up nurses
• North Dakota Hospitals and Clinics
  • Health Care Professionals
  • Midwives/Doulas
  • Parents/Families

Tri-state Collaborative

Partners include:
• ND, SD, and IA
• ND has approximately 13,000 births/year and 12 birthing hospitals
• SD has approximately 13,000 births/year and 26 birthing hospitals
• IA has approximately 40,000 births/year and 83 birthing hospitals

History of ND Newborn Screening

• 1964 – Phenylketonuria
• 1977 – Hypothyroidism
• 1991 – Galactosemia
• 1992 – Iowa began processing ND labs
• 1992 – Congenital Adrenal Hyperplasia & Maple Syrup Urine Disease
• 2002 – Pilot project with Iowa for tandem mass spectrometry (TMS)
• 2003 – Medium Chain Acyl-CoA Dehydrogenase, Biotinidase, Sickle Cell, and other Hemoglobinopathies
• 2004 – TMS officially part of newborn screening
• 2006 – Cystic Fibrosis
• 2007 – Iowa began coordinating short-term follow-up
• 2008 – Private Courier System
• 2016 – Severe Combined Immunodeficiency will be added

Why newborn screening?
Samantha’s Story

Severe Combined Immunodeficiency (SCID)

Newborn Screening Facts

- Public health initiative – population based screening
- NBS is mandated by law that every baby is screened in the US
- Nearly 4 million babies born in the US each year
- Estimated that 5,000 babies are identified with a NBS condition each year in the US
  - These babies often look normal and show no signs or symptoms of a disease at birth
  - Approximately 1 in 700 babies
- Early Identification & Treatment
  - Saves lives
  - Prevents health problems
  - Abnormal metabolism
  - Developmental delays = brain damage
  - Coma and even death

Conditions Identified through ND Newborn Screening

- 2011: 10,072 (80 conditions detected by NBS)
- 2012: 11,503 (87 conditions detected by NBS)
- 2013: 11,978 (96 conditions detected by NBS)
- 2014: 12,840 (126 conditions detected by NBS)
- 2015: 12,842 (estimated births) (estimated 142 conditions detected by NBS)

Statistics include traits identified through screening, not only disease
Newborn Screening Program List of Disorders

- Congenital Adrenal Hyperplasia
- Congenital Hypothyroidism
- Biotinidase Deficiency
- Galactosemia
- Hemoglobinopathies
- Cystic Fibrosis
- Amino acid, Organic acid, Fatty acid oxidation disorders (Tandem Mass Spectrometry)
- Severe Combined Immunodeficiency (SCID) – screening in July 2016

NBS Collection Guidelines

- Clinical and Laboratory Standards Institute (CLSI) guidelines
- NBS01-A6, Vol. 33 No. 9, 2013
  - Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition

Who collects the newborn screening specimen at your facility?

- Lab techs, nurses, clinic staff? Repeat screens?
- Each birthing facility varies
  - 7 Facilities in ND – Nurses draw initial NBS
  - 5 Facilities in ND – Lab techs draw initial NBS
- NBS can assist with staff education
  - Facility Reports – site visits from NBS program
  - Forthcoming:
    - Updated NBS website
    - NBS Videos
    - NBS Testimonials
    - Updated NBS brochure
    - Learning Modules for staff

Storage of Newborn Screening Dried Blood Spot Forms

- Clean and dry area
- Away from any direct sunlight
- Original wrapping
- Vertical position (avoids compression of the filter paper)
- Check the expiration date – shelf life 3 years

Completing the Dried Blood Spot Form

- Complete form at time of collection and not before
- Provide accurate information
- Be legible
- Ensure all fields are complete
- Verify form with a coworker

New Dried Blood Spot Form

Any missing information will delay test results
Newborn Screening Timeliness Recommendations:

- Presumptive positive results for time-critical conditions should immediately be reported to the child’s healthcare provider and no later than 5 days of life.
- All presumptive positive results for time-sensitive conditions should be reported to the healthcare provider as soon as possible but no later than 7 days of life.
- All NBS results should be reported within 7 days of life (the “normal” screening results).

In order to achieve these goals (and reduce delays in newborn screening):

- Initial NBS specimens should be collected in the appropriate time frame for the baby’s condition but no later than 48 hours after birth.
- NBS specimens should be received at the Laboratory as soon as possible ideally within 24 hours of collection.


Conducting the Heel stick

- Obtain the screen when the baby is 24-48 hours of age (as close to 24 hours as possible)
- Refer to the CLSI guidelines

Missing Information

- Early Collection (EC) or Unknown
  - Birth date or collection date or time 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

Early Collection Exceptions

- Early collection is < 24 hours of age
  - If baby is being transferred to another facility
  - If baby is going to be transfused

Specimen Quality

- Accuracy
- Timeliness
- Screening assesses the risk
  - Further testing is always required for abnormal results
- Poor Quality (PQ) MUST be recollected
  - Request to see your QA report for your facility from your birth center

Recollection

- Adds trauma to the infant
- Causes anxiety to parents
- Burdens the screening laboratory
- Burdens the collecting facility
- Delays testing
Blood Collection Techniques

- Heel Stick—Method of choice
- Avoid venous collections
- Avoid using syringes
  - clotting
  - settling
  - lysing of cells
- Avoid 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

Prepare for collection by...

- 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 by using:
  - Heel warming device
  - Soft cloth moistened with warm water (less than 42 °C) for 3-5 minutes
  - Do not use a microwave!

Positioning foot

- Infant's leg should be lower than the heart
- Increases venous pressure
- Wipe heel with 70% isopropyl alcohol
- Air dry
  - Important to let the area dry completely before applying blood to the filter paper

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 with sterile gauze
- Allow a large drop to form (50-75 µL)
- Touch paper to blood **ONCE** and let soak through
- 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

- Verify blood has soaked through both sides of the filter paper
- If blood is not soaking through try again on another circle
- Do not re-apply to same circle (will cause layered or clotted specimen)
- Blood can be applied outside of the circles if needed
- Blood still needs to be the same size of the circles

Good Quality Specimen

- After collection, determine whether or not the specimen is acceptable
- If unacceptable, recollect at that time on a new filter paper

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 are not consistent

Contamination or dilution

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

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
- 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.

Clotted Specimen
Serum separation

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

Air Drying the Specimens

- Do not touch other blood spots
- Keep away from direct heat and humidity
- No direct sunlight
- Horizontal
- Elevate off bench
- Dry at least 3 hours at room temperature
- To avoid contamination of the filter paper – wear gloves and make sure the flap is closed

Who coordinates courier services at your facility?

- Verify the form is complete and legible
- Check the quality of specimens prior to sending with the courier
- Send specimens within 24 hours of collection
- Communicate regularly with birth center and clinics about courier and newborn screening
- Avoid subjecting specimens to heat and humidity prior to transporting

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Courier Information

- Meadowlark Logistics LLC
  - Contact – David Lawson
    - Phone – 701.361.7666
    - Email - David.Lawson@MeadowlarkLogistics.net

State Hygienic Laboratory (SHL) Database

Advantages of Web Access - Newborn Screening

- Download and print patient results
- Patient look-up online
- NBS reports available as soon as released by lab
- Reports available for your facility
  - Quality control
  - Turnaround Statistics (i.e., birth to collection, birth to reported etc.)
  - Facility Summary
  - Facility QA
- Track unsatisfactory specimens back to collector
SHL Database Screen Shot

SHL Web Access
- Request permission for web access through NBS program
  - Email jbmeyer@nd.gov
- Request is sent to the laboratory
- Once approved, you will be given a unique user id and password
  - Training via phone from U Iowa IT on “How to use web access.”
- Login to access database:
  - www.shl.uiowa.edu

Quality Assurance
- Daily fax sent from Lab to collecting facility
- Need secure fax line
- Contact Person
- Fill out Info and fax back immediately

Abnormal Result Reporting
- All initial presumptive positive results are reported to:
  - Health Care Provider listed on the card
- With Recommendations for:
  - Re-screening, and/or
  - Diagnostic testing

Newborn Screening Website

Education Resources
- Newborn screening brochures available at no cost from our state office.
  - Contact ND Newborn Screening Program at 701.328.2493 or 1.800.472.2286 (Press 1)
- Link to ND Newborn Screening Panel:
- Link to ND Refusal form:
Refusals

- Newborn screening is mandated by law in ND but can be refused by families.
- Education must be provided to the family before they can refuse.
- Refusal form must be filled out, signed, and returned to the program within 6 days of refusing testing.

Contact Information

- Mike Ramirez, Lab Supervisor Iowa Laboratory
  - 515-725-1630
- Order supplies (DBS forms & drying racks)
  - 515-725-1630
- Computer issues (web access)
  - 319-335-4358
- University of Iowa Children’s Hospital (patient follow-up)
  - 866-890-5965
- Joyal Meyer, Director, Newborn Screening, ND Department of Health
  - 701.328.4534
- Katie Bentz, Nurse Consultant, ND Department of Health
  - 701.328.4538

Questions
Acknowledgments

- Mike Ramirez, Iowa State Hygienic Lab
- Carol Johnson, University of Iowa Children’s Hospital

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