

2009 Heartland NBS Workshop

Thursday, April 30th and Friday, May 1st, 2009

Hosted by the Nebraska Department of Health & Human Services
Sponsored by the Heartland Genetics and Newborn Screening Collaborative
HRSA Grant #U22MC03962

Meeting Summary

State Reports:

Arkansas

- July 2008 expanded to full panel of 28 recommend conditions
 - 6 panel cost \$14.83
 - 28 panel cost \$89.25
- Increase in rate allowed for Purchases of new equipment; adding staff in follow-up, lab and a nurse coordinator; a new data management system.
- Staff has attending training at Baylor, Mayo Clinic and Duke

Missouri

- Has been conducting Biotinidase screening since December 2008
- Dropped T4 screening, TSH only
- As of January 1st, MO screens for 67 disorders
- No results added to lab reports for 5 of the 9 disorder categories on early collection; collections without day/time are automatically defaulted to early collect status and get a “no result”. We practice “tough love” and do not amend these results unless there is a high risk positive detected. Instituting this policy has greatly reduced the non compliance of providing the collection date and time and has increased compliance to repeating the early collections.
- 16 scientists and 4 support staff
- 400 specimens per day
- MO will soon have a Lysosomal Storage Disorder law similar to Illinois requiring screening for Krabbe, Pompe, Gaucher, Fabry and Niemann Pick diseases.
- Now beta testing the Genetics Screening Processor (GSP) from Perkin Elmer which will test CH, CF, GALT, BIO and CAH all in one instrument.
- Web based integration of data records is used’ vital records to be link by 1/1/2010
- Currently receiving money from Heartland Collaborative for two pilot projects—public health profile and education seminar for providers and parents about NBS
- The Genetics Advisory Committee is currently in limbo
- Also supportive of Dr Bill Kimberling’s Usher Syndrome grant application and a grant for hemoglobinopathies

Kansas

- Lab and Follow-up staff have attended training at Baylor and Duke
- Participating in Region 4 MS/MS project
- Held regional trainings within Kansas for collection and lab procedures
- A has confirmed Biotinidase cases

- Reporting for CF and CAH
- No charge for NBS
- New software, forms and reports
- Linkage for vital records not yet in place
- Has Advisory Committee
- Has parent info online and also in Spanish

South Dakota

- Initial expand screening samples sent to Baylor
- As of June 2007, lab screening done in Iowa
- CF is mandated, but hearing is not
- Follow-up—short term done by IA, then taken over by South Dakota
- NBS is \$56, which may increase. The State doesn't collect the money it goes to IA
- Only one FTE—Lucy Fossen
- No food or formula program—referrals made to CSHN
- Lab reports and birth certificates linking; which helps to find missed babies
- No NBS Advisory Committee; unless it becomes mandated by a grant
- Working on building a LTFU program
- State Genetics Plan is currently “on hold”

North Dakota

- February 2008 – Wrote article for NDAAP Newsletter.
- April 2008 – Participated with Heartland NBS Exchange Program and visited Iowa.
- May 2008 – Statewide in-services conducted in collaboration with the Iowa Lab due to an increase of ‘poor quality’. We also provided each facility with a copy of the CLSI publication “Newborn Screening Collection.” Since this in-service their ‘poor quality’ rate decreased from 11.6% to 0% and another from 7% to 1%.
- June 2008 – Implemented private courier service.
- September 2008 – Dr. Sara Copeland presented at the NDAAP Meeting.
- Confirmed positives for North Dakota in 2008:
 - Identified first Sickle Cell Disease
 - Biotinidase – 1
 - CAH – 4
 - Galactosemia – 2
 - 3 MCC – 1
 - VLCAD – 2
 - Cystic Fibrosis – 3
 - Congenital Hypothyroidism – 3
 - Hemoglobinopathies – 57, this compared to 30 in 2003 (the first year screening began in North Dakota).
- January 2009 – Iowa short-term follow-up took over all cases for North Dakota. Barb Schweitzer assumed the duty of Regional Follow-up Coordinator.
- Petition to add Krabbe screening
- Advisory Committee meets by conference call
- Had a possible MCAD case

- Current annual birth rate is 11,000

Iowa

- Has good collaboration with North and South Dakota
- Staff has attended APHL CH training and also MS/MS training
- April 1, 2009 started pilot for Souace
- 2008 estimates of cases (birth rate of 40,000)
 - CF 10
 - CAH 0-3
 - Biotinidase 3
 - DG 3
 - PKU 0-3
 - MCAD 5-7
 - MMA 1
 - VLCAD 1-2
 - SCAD 1
 - Hypothyroid 25
- Turnaround time is critical—12 hours

Oklahoma

- Expanded MS/MS in three phases
- ACMG compliant
- Considering dropping T4 and using only TSH
- 9 staff, 2 data entry and QA nurse
- No current QA reporting
- Linking with vital records, immunization and EDHI and NBS is on the horizon, but needs money
- Genetics Advisory Committee meets quarterly
- A grant from Sanford in South Dakota will help Duncan, OK build a regional children's hospital.
- NBS cost \$115.93

Nebraska

- Screen for all 29 ACMG recommended conditions in the CORE panel
- Program administered out of DHHS
- Lab services contracted with PerkinElmer Genetics
 - Laboratory testing
 - Overnight courier
 - Access 24/7 to data system with all required:
 - Data elements
 - Follow-up reports
 - Daily tracking/monitoring reports
 - Quality assurance reports
- Short-term follow-up comments documentation

- Phone/Fax reporting 24/7- physicians/ submitters (hosp)/ program follow-up staff
- Lab charges \$38.50/infant screened to hospitals (no charge requested repeats)
 - \$28.50 stays with lab for their costs
 - \$10 of each comes back to State for metabolic foods formula
 - Metabolic foods/formula also paid with State General Funds & Title V
 - Program administration/follow-up operations costs paid by Title V MCHB
- Vital Records, Immunizations and EHDI all linked. Birth Defects coming on line soon.
- Capacity for lab export to also link Metabolic Data. Pending State IT prioritization.
- Key element: Newborn Screening Advisory Committee
 - Parent and technical expertise, stakeholder representation
 - Quarterly 1 / 2 day meetings
 - Advise on technical, procedural and policy issues, including regulations and statute
- Other key features that facilitate success for the program:
 - Longevity and expertise of program staff
 - Follow-up staff have developed great working relationships with providers & consultants
 - Active quality assurance element
 - Annual Report
 - Very refined screening algorithms that optimize testing (minimize false positives, maximize detection rates, minimize carrier detection in CF, and duarte heterozygotes in Galactosemia, relatively low false positive rate for CAH).
- In development:
 - Three .08 FTE public health nurses to be field liaisons for QA with hospitals
 - Preparation for data export to be able to more readily participate in long-term follow-up data system development
 - Evaluation of ways to integrate testing for congenital cytomegalovirus in the NBS DBS and EHDI programs
 - Need considerable revision & update to the contingency/emergency preparedness plan
 - Re-evaluate, revise fiscal sustainability plan, and re-energize political will around this issue

General Discussion

Data Collection Forms

- What do we want to accomplish?
 - Similar data elements
 - What is the minimal required information?
- Why is outcome data collected?
 - Leads to reliable screen results
 - Rapidly retrieve data for follow-up

- Linkages to birth record, data match (but not in all states), and reduce loss to follow-up
- How does system handle name changes? Mother or child?

Emergency Preparedness and LTFU

- Does your state have a computer system back-up for patient data?
- How would you make contact with patients, parents or families?
- Iowa has flash drives with protocols
- Oklahoma asked about intra-state back-up system? Who is the first line back up?
- Preparedness plans could and should depend on the type of disaster
 - Physical—fire, flood, tornado, computer
 - Illness—pandemic

Projects

Overall goals of the projects are to evaluate and harmonize the practices or strategies relative to quality assurance, including unsatisfactory specimens.

Laboratory

1. Create guidelines for project—Coordinated by Marcia Valbracht and involving 1 lab staff per state
2. Each lab test two samples from same card—one good, one unsat and compare results
3. Each state develops a “decision tree” to be distributed to all states

Follow-up

- Begin collecting data on transfusion practices in each State’s hospitals and blood banks
- Develop a list of questions for each state’s practice for transfusion
- Decision tree for tracking by FU for positive unsat
 - Nebraska has Lost to FU procedures for each disorder
- Urgency/Panic List for follow-up on positive unsat (Linda Williams, Annette Arnold, Julie Raburn and Kim Turner)