UAMS Department of Pediatrics
Arkansas Newborn Screening
Long-term Follow-up Cohort Study
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Director
The following speaker has no financial relationships with commercial interests to disclose. There are no conflicts of interest or commercial support for this program.

Jo Ann Bolick, BSN, MA, APN
Purpose/Aim

• Purpose: Tracking and monitoring the clinical care and public health outcomes for children diagnosed with a NBS condition through the Arkansas NBS Program and to follow them until 21 years of age.

• Primary Aim: Record demographics, characteristics of disease and treatment, utilization patterns, QI measures, and clinical outcomes
Partnership/Funding

• University of Arkansas for Medical Sciences (UAMS), Pediatric Genetics Section with the Arkansas Children’s Hospital (ACH) and its Research Institute (ACHRI)

• Funding: Antenatal and Neonatal Guidelines, Education, and Learning System (ANGELS), a program at UAMS and in part by the UAMS, TRI, NCRR/NIH Grant 1 UL1 RR02988
NBS in Arkansas - Overview

• ~38,000 births per year
• Prior to July 1, 2008, Arkansas screened for 7 conditions
• Since July 1, 2008, screen for 29 conditions on primary core panel (SCID & CCHD have not been added to the Arkansas NBS panel yet)
• ~70 diagnosed with a metabolic condition and another 70 with hearing loss, every year
NBS in Arkansas (Continued)

• Legislative mandate – Regulated by the Arkansas Department of Health (ADH)
• NBS – by State Public Health Laboratory
• 2nd Tier CAH and CF – by ACH Laboratory
• UAMS/ACH Pediatric Genetics: Consultant to ADH; NBS Coordinator position at UAMS/ACH serves as liaison between ADH and UAMS/ACH for coordination of follow-up on + NBSs
Arkansas NBS LTFU Study

- IRB Approval: September 2011
- Database Implemented: January 2012
- Longitudinal, observational study
- Population: Four (4) Cohorts
  - ACH patients with NBS conditions meeting enrollment criteria
    - Study received waiver HIPAA and Consent forms for these subjects
  - Non-ACH patients with NBS conditions meeting enrollment criteria
    - Study will obtain consents for these subjects
  - Abstracting data from CF Registry on enrolled subjects
    - To date, this component has not been implemented
  - Obtaining health information from ADH
    - IRB approved the ADH component prior to implementation
    - Memorandum of Agreement established for the exchange of information between ADH and the Study; effective 1-2-12 through 12-31-13
    - Parental consent is required before health information can be shared with the Study
Arkansas NBS LTFU Database

• Acknowledgement to NBSTRN: Utilized common data elements developed by NBSTRN as our starting point
• Collaborated with ACH clinical experts to develop 8 disease-specific data sets
• Utilized REDCap (Research Electronic Data Capture) hosted by UAMS Translational Research Institute (NCRR/NIH 1 UL1 RR02988)
• REDCap secure, web-based application designed to capture research studies
• Database created by abstracting and compiling information from the medical record.
• Data abstraction from the medical record for each visit to ACH Specialty Clinics
Arkansas NBS LTFU Database – Organization

COMMON DATASET
(Leads to 8 sub-datasets)

MS-MS
CH
CAH
Biotinidase
Galactosemia
3 Hb Pathies
CF
Hearing
Common Dataset

COMMON DATASET
(Data entered at enrollment; Client seen in clinic or parent contacted every 12 months and data updated as needed)

- Demographics
- Vital Records (BC/DC)
- Co-Morbidities
- NBS/Second Tier
- Confirmatory/Diagnostic
- Medical Evaluation / Case DX
- Immunization Status
- Social HX

Key:
BC/DC - Birth Certificate/Death Certificate
DX - Diagnosis
HX - History
MS-MS Dataset

MS-MS DATASET
(Data entered at enrollment; and data updated when client seen in clinic or parent contacted every 12 months)

Key:
MS-MS - 20 Disorders (includes PKU) tested through Tandem Mass Spectrometry
TX – Treatment
HX - History
PMH - Past Medical History
EM - Emergency Management
CYSTIC FIBROSIS

Cystic Fibrosis (CF)
(Data entered at enrollment; and data updated when client seen in clinic or parent contacted every 12 months)

Key:
BMI/BSA - Basal Metabolic Index/Body surface area
VS - Vital Signs
Ht - Height
HX - History
PMH - Past Medical History
EM - Emergency Management
RESULTS
Calendar Year 2012

Descriptive Statistics for Unique Patients N=307

• Gender
  o Female 49% (151)
  o Male 51% (156)

• Race
  o African American 42% (128)
  o Caucasian 48% (146)
  o Hispanic 7% (23)
  o Other 3% (10)
Descriptive Statistics of NBS Conditions for Unique Cases (N=311*)

*Numbers above the bar represent the frequencies (percentages). Four children have 2 diseases; therefore we have 307 children in the database but 311 unique disease cases.
*Numbers above the bar represent the frequencies (percentages). There were a total of 871 clinic visits during Calendar Year 2012 consisting of 307 patients and 311 disease cases.
Average Number of Clinic Visits by Disease Set*

*Error bars represent one standard deviation.
Gender Distribution by Disease (N=311)
Race Distribution by Disease (N=311)
CONCLUSION/IMPLICATIONS /NEXT STEPS

• The Study will provide opportunity to monitor and track health outcomes over time; this could lead to improvements in health care.

• Study staff reviewing and refining data entry forms over the next 12 months and plan to do annually.

• Data analysis will be conducted yearly.
Acknowledgement/Thank You
Study Team

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THANK YOU!

QUESTIONS