Texas Department of State Health Services
1100 W. 49th, Austin, Texas 78756
Laboratory Building, SMOC Room, 7th Floor
December 20, 2013
Minutes

Present
William Morris, LVN
Charleta Guillory, MD
Alice Gong, MD
Nancy Beck, MD
Kelly McDonald
Michael Speer, MD

Conference Call
V. Reid Sutton, MD
Mark Lawson, MD
Elizabeth Stehel, MD

Staff
David R. Martinez, Department of State Health Services (DSHS), Newborn Screening Unit
Debra Freedenberg, MD, PhD, DSHS Newborn Screening Unit
Susan Tanksley, PhD, DSHS, Laboratory Operations Unit Manager
Rachel Lee, PhD, DSHS Laboratory, Biochemistry & Genetics Branch
Sam Cooper, Director, DSHS, Specialized Health Services Section (SHSS)
Grace Kubin, DSHS Laboratory
Daisy Johnson, RN, DSHS, Newborn Screening Unit
Michael Chisum, DSHS Program Attorney
Karen Hess, DSHS, Newborn Screening Genetics Branch Manager
Lynette Borgfeld, DSHS Laboratory
Patty Hunt, DSHS Laboratory, Metabolic Screening
D'Andra Morin, DSHS Laboratory, DNA
Judy Cleek, DSHS, Newborn Screening Unit

Guests
Ada Drozd, Public Health Department, Texas Medical Association
Shannon Lucas, March of Dimes

Call to Order
Chairman Morris called to order the December 20, 2013 meeting of the Newborn Screening Advisory Committee at approximately 10:05 am.

Roll call of committee members, staff and guests
Chairman Morris asked that since there were some new people for everyone take the opportunity to introduce themselves. Members, staff and guests attending are listed at the beginning of these minutes.

Review and Approval of Minutes
Chairman Morris asked the committee if they had looked at the minutes from the October 25, 2013 meeting and whether any changes needed to be made. Dr. Lawson pointed out a typographical error on page 5, endocardiogram should be echocardiogram. Chairman Morris asked if there was a motion to approve the minutes. Dr. Stehel made a motion, Dr. Guillory seconded. Motion passed.

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Status of Newborn Screening in Texas Today-Debra Freedenberg, Rachel Lee

Debra Freedenberg and Rachel Lee spoke on the status of Newborn Screening in Texas today. Rachel stated that Newborn Screening is an essential, preventive public health program for early identification of disorders that can lead to catastrophic health problems. The cost of these disorders, if left untreated, is enormous, both in human suffering and in financial terms.

- Goals of newborn screening
  - Two screening tests for each baby born in Texas
    - First test 24-48 hours of age
    - Second test 1-2 weeks of age
  - Infants testing positive receive prompt and appropriate confirmatory testing
  - Diagnosed infants are maintained on appropriate medical therapy
- History of Texas Newborn Screening Program
  - 1963 – Phenylketonuria (PKU) pilot
  - 1965 – Mandated PKU screening
  - 1978 – Added Galactosemia and Homocystinuria screening
  - 1980 – Added Congenital Hypothyroidism screening, recommended second screening
  - 1983 – Discontinued Homocystinuria screening, added Hemoglobinopathy screening, required second screen
  - 1989 – Added Congenital Adrenal Hyperplasia screening
  - 1995 – Added second-tier DNA testing for hemoglobinopathies
  - 2002 – NBS task force recommended the program expand with MS/MS technology (add 4 disorders)
  - 2003 – Legislation to expand program did not pass
  - 2005 – HB 790 mandated expansion to American College of Medical Genetics (ACMG) recommended core panel of 29 disorders as funding allowed
    - No funding for Cystic Fibrosis provided
  - December, 2006 – First abnormal MS/MS results reported
    - 19 new disorders
  - January, 2007 – Added Biotinidase Deficiency screening
  - May, 2007 – Added second-tier DNA testing for Galactosemia
  - December, 2009 – Added Cystic Fibrosis screening
  - February, 2012 – Added second-tier DNA testing for MCAD
  - December, 2012 – Added Severe Combined Immunodeficiency (SCID) screening
- Currently screen for 29 disorders
  - Congenital Hypothyroidism
  - Congenital Adrenal Hyperplasia
  - 3 Hemoglobinopathies
  - Galactosemia
  - Biotinidase Deficiency
  - 6 Amino Acid Disorders
  - 5 Fatty Acid Oxidation Disorders
  - 9 Organic Acid Disorders

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  - Cystic Fibrosis
  - SCID
- Newborn Screening Workload
  - 2012 – received 740,000 specimens (380,000 newborns)
  - Specimens assayed and reported-734,500
    - Test specimens Monday through Saturday
    - Average 2,450 specimens per day
    - 6,200 unsatisfactory specimens (0.84%)
  - 16,145 (2%) specimens reported with presumptive positive results
  - 750 cases diagnosed annually
  - Since expansion, 5,280 babies with confirmed diagnosis identified (12/1/2006-8/31/2013)
- Types of Kits
  - Medicaid/CHIP/Charity
    - Newborn or mother is eligible for Medicaid
    - Newborn is eligible for CHIP Perinate
    - Parent cannot pay for the service and the newborn is not insured and the newborn is not covered or eligible to be covered by Medicaid or CHIP Perinate
  - Insurance/Self-Pay
    - Newborn is covered by private health insurance
    - The facility orders and pays for kits and receives direct payment for services
- Logistics of Texas Newborn Screening
  - Healthcare provider requests specimen collection forms
  - NBS Laboratory assigns form serial numbers to healthcare provider and ships the forms
  - Healthcare provider collects the specimen and sends it to DSHS
  - Specimen is assigned a laboratory ID number
  - Demographic sheet is separated from the blood spots and sent to Demo Entry Team where the information is entered into the database
  - Specimen is sent to NBS Laboratory for testing
  - Eight 3mm blood spots are punched from filter paper and distributed into eight 96-well plates
  - These 8 plates are distributed to 5 analytical areas for testing
    - Hemoglobinopathies (1)
    - Endocrine and Cystic Fibrosis (3)
    - Galactosemia & Biotinidase (2)
    - Tandem Mass Spectrometry (1)
    - SCID (1)
  - All specimens are analyzed and test results are reported
    - Out-of-range results are reported to Clinical Care Coordination for immediate reporting
    - All results are reported to the healthcare provider who submitted the specimen
- Quality Improvement Activities
  - Expedited submitter fax notification
    - All unsatisfactory specimens-February, 2012

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        - All unsatisfactory specimens not replaced within one month-February, 2013
    - Revised submitter quality report cards-available online July, 2013
    - Monthly submitter calls to consult providers with highest unsatisfactory rates
    - Weekly recruitment/promotion of NBS Web Application
    - NBS LEAN 6-Sigma projects
    - Transit Time Workgroup
- Routine Second Screen Study
    - Purpose-to evaluate evidence regarding the use of second screens for identification of hypothyroidism and congenital adrenal hyperplasia cases
    - Findings
        - In 2-screen states-12% of Primary CH and 38% of CAH cases (includes 9% of all Classical Salt-Wasting CAH cases) were detected on the abnormal 2nd screen
        - All of the Primary CH and more than half (48/89) of the CAH cases detected on the 2nd screen were clinically significant
        - Primary CH incidence-significantly higher in 1-screen states (1:1,926 vs 1:2,278)
        - Salt-Wasting CAH incidence-statistically equivalent
        - Simple Virilizing and Non-Classical CAH incidences-significantly higher in 2-screen states
- Second Tier Assay for CAH
    - Purpose-to dramatically cut false positive rate
    - Status
        - New LC/MS/MS installed
        - Method optimization is complete
        - Validation continues
        - 6 month pilot completed-analysis of results ongoing
    - Preliminary finding
        - Reduce false positive rate by 50%
- Electronic Data Transfer
    - Web-based demo entry and reporting
        - Available to any healthcare provider, username and password required
        - Users from 1,046 facilities submitting 75% of NBS specimens
        - 2% of all demographics
        - 12,000 result views per month
        - Monthly report cards available for all of 2013
    - HL7 file transfer functions for LIMS
        - Direct transfer of demographics and results between computer systems
        - 3 large hospital systems fully implements (10% of all specimens)
        - Several facilities waiting to start implementation
        - New facilities on hold pending system reevaluation
- Implementation of HB 411
    - Opt-in for long term storage and possible research uses-effective June 1, 2012
    - Parent decision form and parent education form developed and distributed

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        - 49% of NBS have a parental decision form returned
        - 74% of those returned and valid give permission for public health research uses (36% of all newborns)
        - Survey of all submitters to identify challenges in returning parental decision forms
            - Worst performers tend to be large hospitals
            - Most common practice is to include Decision form in discharge packet with little or no explanation
- Dr. Freedenberg spoke regarding Clinical Care Coordination (CCC).
- Clinical Care Coordination Team
    - Medical Director
    - Registered Nurses
    - Public Health and Prevention Specialists (PHPS)
        - Nurses and PHPS are assigned to specific disorders
        - Nurses and PHPS are cross-trained for full coverage Monday through Saturday
    - Educators
    - Ombudsman (currently vacant)
- Short Term Follow-Up
    - Overview
        - A case is opened for each screen positive result
        - Cases are monitored until an infant is cleared or diagnosis is determined
- NBS Clinical Care Coordination
    - In fiscal year 2012, the DSHS laboratory screened approximately 750,000 specimens for metabolic, endocrine and hematological disorders
    - Of those screens, approximately 16,000 were abnormal screens that required follow-up by CCC
    - There were approximately 750 diagnosed cases in fiscal year 2012
- Finding the Medical Provider
    - Find the medical provider responsible for the medical care of the baby
        - Determine if the baby is in the hospital
    - If a medical provider can be located
        - Provide results
        - Provide guidance for recommended actions
- Finding the family
    - If a medical provider cannot be located
        - Contact parents to obtain primary care provider (PCP) information
        - If a PCP is not identified
            - Provide results to family
                - Direct family to an emergency department if necessary
                - Clinical care nurse will coordinate with emergency department staff if family directed to emergency department
        - If baby cannot be located
            - Utilize DSHS regional social workers to assist with

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    - Locating the baby
    - Connecting baby with healthcare providers and services
    - Involve other agencies including law enforcement and/or Child Protective Services (CPS) if necessary
- Resources distributed
    - Screen positive NBS
        - Information mailed to parent
        - NBS letter
        - General NBS brochures
- Positive screen with very elevated levels
    - Medical Emergency
        - Reported immediately to nurses in NBS CCC
        - Nurse will notify PCP by phone and fax the same day the laboratory results reports are received from the DSHS lab
        - If no PCP is on record for the newborn or cannot be located, the nurse will notify the parents directly
- Resources distributed for a newborn requiring urgent follow-up
    - Faxed to medical provider
        - NBS letter with
            - NBS disorder-specific lab results
            - Contact information for the NBS nurse responsible for the NBS case
            - Disorder-specific ACT/FACT sheet
        - List of regional subspecialist consultants
- ACT (Action) sheets for providers
    - Adapted from the ACMG
    - Designed for the medical provider
    - Contain the following
        - Differential diagnosis
        - Condition description
        - For medical emergencies, follow the instructions in the black outlined box
    - Available on the NBS CCC website
- FACT sheets for parents
    - Each disorder has a FACT sheet that is modeled from the ACMG FACT Sheet
    - Designed for the PCP to share with the family
    - Information for the parents about symptoms, treatment and things to remember for the specific disorder
    - Available on the NBS CCC website
    - Available in English and Spanish
- NBS Benefits Program
    - Redesigned in 2007 to account for the expansion of NBS disorders screened
    - Targets families without Medicaid or private insurance
    - Eligibility

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        - Those with a presumed positive screen or a confirmed diagnosis of a disorder screened for in the Texas Newborn Screening Program
        - An income at or below 350% of the federal poverty income level (FPL)
        - Texas resident
    - Benefits
        - Confirmatory testing
        - Dietary supplements
        - Metabolic foods
        - Low-protein foods
        - Medications
        - Vitamins
        - Follow-up care
- Potential New Disorders
    - MS/MS Secondary Targets
        - Secondary conditions in the RUSP
    - Pompe
        - The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDBC) voted to add Pompe disease to the RUSP on May 17, 2013
        - Pending approval from the Secretary of Health and Human Services
- Texas Early Hearing Detection and Intervention (TEHDI)
    - Hearing screening by one of two tests
        - Otoacoustic Emissions (OAE)
        - Automated Auditory Brainstem Response (AABR)
    - Hearing grant activities
        - CDC 5 year $162,000/year
            - Tracking and date integration electronic health records
            - HL7 messaging
            - Enhanced interoperability of management information system
            - Education materials and training on enhancements
        - HRSA 3 year $300,000/year
            - Lost to follow-up
            - Multiple pilots on most effective follow-up procedures
                - National Initiative for Children's Healthcare Quality (NICHQ) Project for quality improvements
                - Early Childhood Hearing Outreach (ECHO) Project to better connect with Head Start
- NBS Education Efforts
    - NBS Grand Rounds 2013-2014
        - Dr. Elana O"Campo-CCHD
        - Dr. Priya Kishnani-Pompe Disease
        - Meg Comeau-Impact of changing health care system on Genetic Services in Texas
    - Tales from the Crib

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- NBS Journal Club
- Education outreach
  - Overview of NBS
  - CF
  - SCID-in development

- Genetics Activities
  - Sponsored through Title V funding MCH
  - Two Genetics centers funded for clinical care (other facilities requested nonrenewal)
    - Fee for Service
  - Teratogen Information Service contract awarded to UT Houston
  - Community based Genetics seminars-Baylor Evening with Genetics
  - Three medical provider educational conferences provided
    - Genetics to Genomics: The Future and Beyond
      - Conference sites
        - San Antonio 7/13/13
        - Dallas 6/22/13
        - Austin 6/29/13
    - Funding of 3 clinical genetics medical student summer internships during Summer 2013

House Bill 740 Health and Safety Code, §33.011, Test Requirement-David R. Martinez, William Morris

Mr. Martinez requested that the committee refer to a copy of HB 740 that was in their packet. This agenda item is a continuation of the discussion from the last meeting on secondary targets. We had toward the end of the discussion brought up the language that is in HB 740 relating to additional testing. Mr. Martinez wanted to put it on the agenda so that the committee could discuss it and think about some future plans when the committee is approached about additional tests and costs associated with those tests. He directed their attention to the highlighted section on page 5 that refers to additional screening tests. He stated that there are two areas where it is mentioned in HB 740. One is related to CCHD, and on page 5 under (f) this section that this resides is under 33.011 test requirements and the language that was added in HB 740 says *Before requiring any additional screening test for critical congenital heart disease, the department must review the necessity of the additional screening test, including an assessment of the test implementation costs to the department, birthing facilities, and other health care providers.* He then directed them to page 10, highlighted item 2 that falls under the Newborn Screening Advisory Committee section, it says *review the necessity of requiring additional screening tests, including an assessment of the test implementation costs to the department, birthing facilities, and other health care providers.* So these two areas when you first look at them sound like they are contradictory. David requested that Michael Chisum to take a look at the provisions to help clarify whether the secondary targets would even require that the committee would have to review those costs. Michael Chisum stated that his conclusion having read HB 740 provisions that are highlighted especially, that any mandatory conditions already stated in statute are not subject to the requirement that the committee review the costs.

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Newborn Screening Performance Measures-Susan Tanksley, Debra Freedenberg

Susan Tanksley stated that the Texas Newborn Screening Performance Measures Project (TNSPMP) was funded by a 3 year CDC cooperative agreement from September, 2007 to May, 2011.

- Overall project goal
  - Identify and develop evidence-based performance measures to improve patient care for newborns identified with disorders through the newborn screening program
  - Focus on pre and post-analytical aspects of NBS
- Universal measure
  - Time to initiate treatment
    - Series of steps that can be measured discretely or as a group
    - Help pinpoint where a breakdown has occurred

Susan presented pre-analytical universal performance measures and Dr. Freedenberg presented post-analytical disorder-specific performance measures information for the years 2010-2012 to the committee.

Secondary Panel-David R. Martinez

David R. Martinez reported to the committee that the same material presented to them at the last meeting was in their packet. Sam Cooper stated that the committee would be provided with more details regarding the proposed options, but he wanted to make sure that all options were covered and that executive management was aware of these as well. They will be working to schedule some time with Dr. Lakey to provide an overview of the options. Mr. Cooper wants to make sure that the committee is provided with all the information that they need in order to make their recommendation. Chairman Morris stated that he thinks it is very important that a recommendation come out of the advisory committee to Dr. Lakey about giving credit where credit is due. We are already picking up those 18 that we have. The Option 1 is basically something we are already doing, but make it official so that the children can have benefits and allow the Department to get a little credit. This is not something that is going to go away; we are going to be revisiting this. Chairman Morris stated that at the very least, he thinks the fact that they don't have all the information that they need right now, the least they can do is come out with an official recommendation from the advisory committee to Dr. Lakey saying that we need to count these 18 and take credit for them, get them on our report card and make the children that are being detected through our reporting eligible for the benefits package if they have no other resources to go to.

Newborn Screening Quality Improvement Initiatives-Susan Tanksley, Vanessa Telles

Susan Tanksley reported to the committee that this was a laboratory wide focus on continuous quality improvement.

- Outline
  - Lean Six Sigma
- NBS System Assessment
- Quality Improvement Initiatives
- Raised awareness
- New initiatives

Vanessa Telles gave an overview of the Newborn Screening Improvement Projects to the committee.

- Overview

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  - 5 individuals working on Lean Six Sigma Green Belt certification
    - Andrew Vinyard
    - Cathy Snider
    - Linda Cao
    - Shawn Tupy
    - Tiffunee Odoms
  - Team will examine processes from the arrival of specimens in the laboratory to the final reporting step in an effort to remove delays, duplications and bottlenecks
- Approach-DMAIC
  - Define-define the problem and the project goals
  - Measure-identify the baseline and key metrics
  - Analyze-the data and the processes
  - Improve-implement improvements
  - Control-maintain and sustain the improvements
- Establishing a baseline
  - Data collection
    - Forms were created for each area to capture major time points in the process
    - 3 bundles/day over a period of 2 weeks
    - Data collected was compared to the LIMS data
  - Data analysis
    - Overall TAT is meeting established expectations
    - The current process flow appears predictable and stable
- Objective
  - This project seeks to improve the average NBS turn-around-time by 10% from 5.26 days to 4.73 days, in a way that prioritizes the turn-around-time of abnormal results for the most crucial NBS tests.
  - The project will be completed by the end of March, 2014
- Five project areas selected
  - Check in and punching
  - Data entry and logistics
  - Congenital hypothyroidism
  - Galactosemia
  - Tandem mass spectrometry
- Check-in and Punching
  - Green belt-Tiffunee Odoms
  - Goal
    - To reduce the amount of time specimens spend in the check-in and punching areas
  - Reviewing processes and Standard Operating Procedures (SOPs) for the area
  - Will evaluate process flow using spaghetti diagram for the check in process and a value stream map for punching
  - Currently scheduling meetings with team members
- Data Entry and Logistics

- Green belt-Cathy Snider
- Goals
  - Bring the data entry process to completion no later than the end of testing processes
  - Reduce the time necessary for post-analytical reporting
  - Develop a method to expedite the transmission of abnormal result information
- Three processes will be mapped: data entry, results reporting, and specimen information logistics
- Measure TAT for normal and abnormal results with a focus on the specimens missing information

- Congenital Hypothyroidism (T4)
  - Green belt-Linda Cao
  - Goal
    - Reduce turn-around time with a focus on abnormal results
  - A current workflow diagram of the process has been created
  - Meeting with team members
  - Evaluating SOPs to evaluate best areas for improvement
- Galactosemia
  - Green belt-Shawn Tupy
  - Goal
    - Reduce the TAT notification for abnormal results
  - The current process only reports the abnormal results to the critical care team once the confirmation is completed
  - We want to measure the current process and theorize the impact if the process were changed to report a preliminary report for the abnormal results
  - In the process of pulling reporting data for abnormal test results
- Tandem Mass Spectrometry
  - Green belt-Andrew Vinyard
  - Goal
    - Reduce TAT for abnormal specimens with an impact on the process as a whole to ensure the overall goal is accomplished
  - Completed the visual stream and have a rough roadmap of goals and timeline
  - Held meetings with MS/MS staff for feedback on things they see that could be done more effectively
  - Collecting baseline metrics for the area by the end of January

Susan Tanksley gave an update on the following:

- TNSPMP
  - Overall project goal-identify and develop evidence-based performance measures to improve patient care for newborns identified with disorders through the newborn screening program
    - Phase 1-System evaluation
      - Gaps & Barriers Report (May, 2008)
    - Phase 2-Development of evidence-based performance measures

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- New report card
- Reporting of measures annually to advisory committee
- NewSTEPs

- Phase 3-Interventions

- Texas Newborn Screening System Assessment
  - Thorough review of issues ("gaps") identified in 2008 report
  - Current status as of December, 2013
  - Broken down in to 11 categories
    - Pre-analytical and post-analytical focus
    - Excludes analytical phase
  - Each section contains
    - Introduction to the topic
    - Achievements
    - Key outstanding gaps
    - Interventions
  - Tool for ongoing quality improvement
- Quality Improvement Initiatives
  - Courier pilot project-April, 2010
  - Expedited submitter fax notification on:
    - All unsatisfactory specimens-February, 2012
    - All unsatisfactory specimens not replaced within one month-February, 2013
    - Specimens with unsatisfactory testing results for SCID
  - Monthly submitter calls to consult providers with highest unsatisfactory rates
  - Weekly recruitment/promotion of NBS web application
  - Complete redesign of NBS lab website
  - NBS Lean 6-Sigma projects
    - Black Belt project-Improve the efficiency of the courier pilot project
  - Revised submitter quality report cards

Newborn Screening Rules Update-Karen Hess

Karen Hess gave an update on the Newborn Screening Rules.

- Newborn Screening Rules
  - Four year rule review pursuant to Gov Code Chapter 2001.039
    - Rules were proposed and approved by the DSHS Council at the April 3, 2013 meeting
    - Sent to the HHSC Executive Commissioner for approval to publish the rules as proposed
    - Proposed rules published in the *Texas Register* May 31, 2013 edition
  - The 30-day public comment period ended
  - Rules undergoing internal review
  - Final adoption December, 2013

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Update to Critical Congenital Heart Disease (CCHD)-Debra Freedenberg

Debra Freedenberg gave an update on CCHD.

- CCHD Activities
  - DSHS has distributed survey to all hospitals and birthing facilities to determine current readiness to implement CCHD screening survey
  - Funded Texas Pulse Oximetry Project (TxPOP), an educational initiative
  - Implementation planning has begun
- CCHD Project (TxPOP)
  - Funded with Children's Heart Outreach Program (CSHCN) funding
  - Education to medical professionals
  - PI-Dr. Alice Gong, University of Texas Health Science Center San Antonio
  - Joint project with Texas Children's Hospital (Baylor)-Dr.Guillory, Dr. O'Campo
- CCHD NBS Educational Tool Kits posted to DSHS web site
- TxPOP2-project anticipated

50th Anniversary Celebration Newborn Screening-Bill Morris

Chairman Morris is hoping that the committee can come up with some ideas on how to raise public awareness about the Newborn Screening Program through the celebration of the 50 years here in Texas. Dr. Stehel suggested getting 50 people to tell their stories. Chairman Morris suggested that he and Kelly McDonald get together and discuss further.

Public Comments

None

Adjournment

The next meeting will be held on Thursday, March 6, 2014 at 10:00 a.m. Location to be determined. Other potential meeting dates are for Friday, June 20, 2014 and Thursday, September 11, 2014. There being no further business, the meeting was adjourned at approximately 3:30 p.m.