

TNSPMP MEETING AGENDA AND NOTES



TNSPMP QUARTERLY TEAM MEETING

TEXAS CHILDREN’S HOSPITAL CLINICAL CARE CENTER, HOUSTON, TEXAS

6701 FANNIN STREET, 3RD FLOOR ROOM D.0360.04 LARGE CONFERENCE ROOM

THURSDAY – JANUARY 6, 2011

TNSPMP FACILITATOR: ROBIN SCOTT, OPEN CIRCLE CONSULTING

MEETING NOTES

ATTENDEES:

<i>Sue Berry</i>	✓
<i>Sandra Billings</i>	✓
<i>George R. Buchanan</i>	✓
<i>Colleen Buechner</i>	✓
<i>Kari Casas</i>	✓
<i>Donna Claeyes</i>	✓
<i>Liza Creel</i>	✓
<i>Margaret Drummond-Borg</i>	
<i>R. Michael Dulaney</i>	✓
<i>Alice Gong</i>	✓
<i>Jose L. Gonzalez</i>	
<i>Charleta Guillory</i>	✓
<i>Cheryl Hermerath</i>	
<i>Eldridge Hutcheson</i>	
<i>Lisa Kalman</i>	
<i>Scott D. McLean</i>	✓
<i>Javier Ramirez</i>	
<i>John Saito</i>	
<i>Morgan Sanders</i>	
<i>Stuart K. Shapira</i>	✓
<i>Susan Snyder</i>	✓
<i>Michael E. Speer</i>	
<i>Reid Sutton</i>	✓
<i>Larry Sweetman</i>	✓

<i>Lois Taylor</i>	✓
<i>Brad Therrell</i>	✓
<i>Simran Tiwana</i>	
<i>Sister Mary Nicholas Vincelli</i>	✓
<i>Don P. Wilson</i>	✓
<i>Erica Wright</i>	✓
<i>Jerald L. Zarin</i>	
<i>Dawni Allen</i>	✓
<i>Wendy Beathard</i>	✓
<i>Cheryl Burcham</i>	✓
<i>Shery Clay</i>	
<i>Patrick Clynh</i>	✓
<i>Debra Freedenberg</i>	✓
<i>Paula Geurin</i>	✓
<i>Daisy Johnson</i>	✓
<i>Grace Kubin</i>	
<i>David R. Martinez</i>	
<i>Diane McCoy-Edwards</i>	✓
<i>Jimi Ripley-Black</i>	
<i>Robin Scott</i>	✓
<i>Susan Tanksley</i>	✓
<i>Jill Wallace</i>	✓
<i>Donna Williams</i>	✓

WELCOME

Susan Tanksley welcomed the group and announced that Susan A. Berry, Eldridge Hutcheson and Simran Tiwana are new stakeholders. Dr. Hutcheson recently retired from DSHS and was unable to attend due to health issues. Dr. Tiwana was unexpectedly delayed in her return from a trip to India.

Dr. Stephen E. Welty, Neonatology Service Chief, welcomed the meeting attendees to the Texas Children's Hospital facility.

Robin Scott facilitated introductions and the agenda review.

TNSPMP SUMMARY OVERVIEW

Cheryl Burcham provided a summary overview of the TNSPMP project.

Project Goal 3 – Pilot key performance measures for effectiveness in improving time to treatment for infants with newborn screening disorders

- Pre- and post-analytical report cards have been developed.
 - Data is being validated
 - Produced through automated process
 - Provide a gold standard and state average for comparison
- Retrospective data analysis has been completed for July to December 2009.
- Pilot are in progress
 - July to December 2010 data being collected and analyzed for comparison to retrospective data.
 - New report card process in final phases of implementation.

Project Goal 4 – Identify, recommend, and document evidence-based interventions

- Exploring evidence-based interventions through an assessment of available literature and linking to the gaps & barriers when possible.
- Distributed online survey to other US NBS Programs asking for ideas on intervention strategies.
- Proposed interventions to address gaps and barriers identified through the project will be documented and made available for national distribution.

Key Deliverables and Accomplishments

- Texas NBS Program Gaps and Barriers Summary Report (May 2008)
- Summary Evidence Report (May 2009)
- Performance Measures Selection Process and Development of Pilot Plans (January 2010)
- Awarded 8 month no cost extension (September 2010)

Issues, Risks, and Mitigations

- Issue: Funding for FY11 not yet allocated.
 - Mitigation Plan: Weekly contact with budget staff on status of TNSPMP budget. Escalate to laboratory director if necessary.
 - Issue: Short timeframe to complete post-analytical pilots.
 - Mitigation Plan: Collaboration with follow-up staff for internal only distribution of post-analytical report cards.
 - Issue: Distribution of Pre-Analytical Universal Report cards has been delayed.
 - Mitigation Plan: Pre-Analytical Universal Report cards will be mailed as soon as data validation is completed. Pilot period can be extended if necessary.
 - Issue: Pre-Analytical Universal Report cards will move to web-based reporting system; however, only ~25% of submitters have access to the web-based system.
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- Mitigation Plan: Plans to contact submitters using variety of methods to encourage enrollment in web-based system.

Regional and National Significance of TNSPMP

- Association of Public Health Laboratories (APHL) grant awarded November 2010.
- “Innovations in Quality Public Health Laboratory Practice”
- Project team will use strategies and lessons learned from TNSPMP to improve the Blood Lead Screening Program.
- Focus is on pre-analytical performance measures and improving the report card process.
- Information sharing with other states
- Western States webinar – January 18
- SERGG presentation – July 2011
- NYMAC
- Potential Multi-State Performance Measure Pilot
- Potential inclusion of TNSPMP performance measures in national NBS certification program.

INTRODUCTION OF PANEL

TOPIC: THE NEWBORN SCREENING SYSTEM

Dr. Freedenberg introduced the four panel guests: Charleta Guillory, MD, FAAP, Lori A. Sielski, MD, R. Michael Dulaney, MD, and Tiffany McKee-Garrett, MD.

Dr. Guillory gave a comprehensive review of Texas Children’s Hospital (TCH) Newborn Screening System. While putting her presentation together, she considered:

- Medical doctors
- Laboratory
- Administrative follow up
- Specialty care
- Source of payment
- Family
- Politicians (and other concerned personnel)

Dr. Guillory and Dr. Sielski with the help of others evaluated their processes at TCH and found it to be very instructive. They reviewed the overall NBS system, TCH’s system, and TCH’s challenges discovering gaps and barriers that need to be addressed.

After Dr. Guillory’s presentation, Dr. Dulaney spoke about conversations he had with colleagues and others referencing the effectiveness of the NBS system. He stated that in general they were happy with the process.

The panel then addressed questions from the stakeholders ranging from specimen collection to newborn follow-up in an effort to gain insight into the different processes doctors/hospitals use. Some of the discussion points are noted below.

Increasingly difficult to get a 2nd Screen:

- Get a list of hospitals willing to do a 2nd screen and pay the cost → find out what resources are available
 - There is no way of tracking babies that don’t get a 2nd screen
 - Babies and their families need a “Medical Home” to identify:
 - Who sees the baby at birth
 - Who sees the baby at 2 weeks
 - Who takes ownership of 2nd screen
 - Legal vs. ethical (ownership) responsibility for 2nd screen
 - Need a 2-tier approach of follow up for 2nd screen
 - Texas should follow California’s follow up system of regional Clinical Care Coordination
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- Send a postcard with foot or ear printed on it as soon as the infant is diagnosed to a person at the hospital or PCP office
- Have hospitals set up a link so that *any* nurse can go into the web system and look at results

All on the panel agree on 3 issues that continually affect Newborn Screening:

- 1) Education
- 2) Communication
- 3) Economics

TNSPMP REPORT CARD UPDATE

Donna Williams provided an update of the status of the performance measure report cards.

The new process to date:

- Design and automation of the report cards is complete
- Jill Wallace is validating the formulas and calculations
- The data validation needs to be completed before the Newborn Screening Report Cards can be distributed
- The goal is to mail *only one set* of three months before the web based reporting becomes available
- Online accessibility for NBS submitters to view reports is near completion
 - Post with secure login and password
- The web page is currently available on the Natus test server only

GUEST SPEAKER

William T. Shearer, MD, is director of the BCM Pediatric HIV Research Center, funded by several National Institutes of Health and private organization grants and contracts. He is a member of the Network Executive Committee of the International Maternal Pediatric Adolescent AIDS Clinical Trials Group, which consists of 14 centers in the United States and 24 international sites, all performing clinical trials of antiretroviral agents, such as protease inhibitors, and immune reagents. He pioneered the treatment of SCID patients and was David's (The Boy in the Bubble) primary physician.

Topic: Severe Combined Immunodeficiency Disease (SCID)

Dr. Shearer's presentation encompassed the following objectives:

- Define immunodeficiency
- Understand the genetic basis
- Describe types of immunodeficiencies
- Learn how to diagnose immunodeficiency
- Consider treatment options for patients

After his presentation, he and Dr. Celine Hanson fielded questions/comments from the audience.

The importance of diagnosis of SCID cases and transplants before 3 months of age was emphasized. After that the baby will likely have developed one or more infections which decrease the success of bone marrow or stem cell transplant.

An infant has 80% or better chance of normal life if diagnosed within 3 months, a match is found and transplant is successful.

NEWBORN SCREENING LEGISLATIVE AND PROGRAM UPDATE

Susan Tanksley provided updates related to the Newborn Screening Program.

NBS Specimen Retention & Use

- New collection kits – began distribution in June 2010
 - Disclosure/Request to Destroy form is part of kit
 - Next order of NBS collection kits will include revised form
- Valid requests received through 1/3/11 → 39,551 (~7% of newborns)
- New policy approved 8/6/10
 - Posted on NBS Laboratory website:
 - <http://www.dshs.state.tx.us/lab/nbsBloodSpotDataPolicy.pdf>
 - Defines acceptable uses and authorization/approval process
 - Notice of studies approved by commissioner must be posted on the website
- 82nd Legislative Session
 - HB 411 introduced to codify new policy and limit use to public health uses
 - Session begins January 11, 2011
- HB 1795 – Requires screening for secondary targets, as funding allows
- No funding provided when HB 1795 passed in 2009 session
- Removed from the DSHS exceptional item request for 2011 session

Newborn Screening Advisory Committee

- 9 member committee formed in May 2010
- 4 Meetings held
 - June 7, 2010 (in-person)
 - Business meeting
 - Adopted by-laws
 - June 29, 2010 (conference call)
 - Election of officers:
 - Chair: William Morris
 - Vice-chair: Charleta Guillory
 - October 18, 2010 (conference call)
 - Disclosure form language review
 - Committee proposed simplified language
 - Secondary panel discussion
 - SCID update
 - Status of lost to follow-up
 - SCID focused meeting – December 6, 2010
 - Next Meeting: *March 2011*

Courier Pilot Project

- Funding received through Frew initiative
 - Focus – improving services for Medicaid-enrolled providers
 - Full-service courier
 - Routes include Dallas, Fort Worth, Houston, Beaumont, Tyler, Texarkana, Wichita Falls, Brenham, San Antonio, Brownsville, McAllen, Laredo, Del Rio, Corpus Christi, Austin, Temple, Waco, San Angelo, Midland, Odessa, El Paso, Lubbock, Amarillo
 - Daily pick-ups started April 12, 2010
 - Will-call pick-ups started July 12, 2010
 - Total Sites: 309
 - Total Submitters: 631
 - Sites selected based upon volume of submissions & rejection rates
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Average Weekly Volume of Specimens Received via Courier

	Received via Courier (4/13/10 thru 07/4/10)	Received via Courier (7/5/10 thru 8/24/10)	% of Total Received (7/5/10 thru 8/24/10)
THSteps	4,336	5,209	44.7%
NBS	5,354	7,274	49.4%
Total Specimens	9,690	12,483	47.3%

Routine Second Testing in Newborn Screening

- Multi-state study
- Coordinated through APHL and CDC
- Involves collection of de-identified data for newborns diagnosed with CH or CAH
- 5 year retrospective study
 - Texas data to encompass 4½ years
 - July 2004 through Dec. 2008
- Purpose of multi-state study
 - Evaluate evidence regarding the use of second screens for identification of cases

Diagnosed Cases in Second Screen Study (July 2004 – Dec. 2008)

	1 st Screen Abnormals	2 nd Screen Abnormals
Congenital Adrenal Hyperplasia	110	109 (49.8%)
Congenital Hypothyroidism	905	128 (12.4%)

Second Screen Study: Current Status

- Data Collection
 - Texas data collection is complete
 - Data has been sent to APHL
 - Data collection for other states is winding down
- Next Steps:
 - Data analysis
 - National data set
 - Texas data to be analyzed separately as well (by DSHS)
 - Summarized data from national data set to be presented to Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children who may/may not make a recommendation regarding routine second screening
 - Goal – complete analysis by June 2011

Development of Second Tier Assay for CAH

- History: Significant increase in CAH presumptive positive rate over the last few years
- Two year CDC grant awarded
 - October 2009 through September 2011
 - “Performance Evaluation Study of a Second-Tier CAH Screening Method Utilizing Steroid Profiling by LC-MS/MS”
 - 6 month pilot to begin in early 2011

- Goals
 1. Dramatically cut false positive rate
 2. Knowledge transfer that leads to development of additional 2nd tier tests by LC/MS/MS
 3. Acquisition of NBS-specific LC/MS/MS

MSGRCC Pilot of Second Tier Testing for MS/MS Disorders and CAH

- ARUP Laboratories – Salt Lake City, UT
- CDC grant funded – open to all Mountain States
- Included in study:
 - Steroid profile (Congenital Adrenal Hyperplasia): samples with elevated 17-OHP
 - Succinylacetone (tyrosinemia type I): samples with elevated tyrosine
 - Methylmalonic and methylcitric acid (methylmalonic and propionic acidemia): samples with elevated C3, C3/C2
 - Homocysteine (classic and remethylation defect homocystinuria): samples with elevated methionine
 - Alloisoleucine (maple syrup urine disease): samples with elevated leucine/isoleucine and valine
- Study approved by DSHS IRB and DSHS Commissioner
- Staff trained at ARUP
- Have started sending specimens to ARUP for analysis

SCID Pilot Project

- Severe combined immunodeficiency disorder (SCID)
- May 21, 2010: Sec. of HHS approved the addition of SCID to the uniform core panel
- Pilot project with New England NBS Program
- Requires informed consent to enroll baby
- Study approved by DSHS/Seton/UTHSCSA IRB
- Study approved by DSHS Commissioner
- Initial sites: St. David's Hospital systems, Austin
 - Trainings held at two St. David's facilities in Austin
 - Received first consent forms in October
- Two hospitals have determined informed consent too burdensome
- Houston & Dallas immunologists working on implementation plans/IRB submission
- Attended 50 state SCID meeting in October
- Are receiving consents from other hospitals (web information)

Educational Activities

- Staff education
 - NBS Journal Club
 - NBS Tales from the Crib - NBS M&M Conference
 - NBS Grand Rounds
 - Provider education
 - Outreach Educator to present Grand Rounds type presentations
 - NBS 360 Review
 - Review of all algorithms, protocols, and educational materials related to screened conditions – brochures, web sites, etc.
 - All algorithms, protocols & letters have been aligned
 - Finalizing educational components
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**Health Information Exchange**

- National Efforts to standardize NBS data collection and reporting
- HL7 Standards for electronic reporting of NBS results in development by National Library of Medicine
- Defining LOINC and SNOMED codes for all NBS tests/results
- Potential changes in DSHS NBS reports
 - Includes reporting quantitative values for analytes
- Data integration efforts
 - NBS Web-based system
 - HL7 data exchange with hospitals
 - Links to Vital Statistics and other DSHS systems

Other Issues

- Changes in laboratory management
 - Laboratory Director resigned – position still open
 - Laboratory Operations Manager resigned – position filled by Dr. Grace Kubin
 - State Auditors' Office Report
 - Redoing cost allocation for all testing including NBS
 - Studies being conducted to incorporate all costs associated with testing
 - Fees will be adjusted to cover costs
-