TNSPMP QUARTERLY TEAM MEETING

HYATT REGENCY HILL COUNTRY RESORT AND SPA, SAN ANTONIO, TEXAS

FREDERICKSBURG E-G CONFERENCE ROOM

FRIDAY – MAY 21ST, 2010

TNSPMP FACILITATOR: ROBIN SCOTT, OPEN CIRCLE CONSULTING

## MEETING NOTES

### ATTENDEES:

| | | | |
|---|---|---|---|
| *Sandra Billings* | ✓ | *Brad Therrell* | |
| *George R. Buchanan* | | *Sister Mary Nicholas Vincelli* | ✓ |
| *Colleen Buechner* | ✓ | *Don P. Wilson* | ✓ |
| *Kari Casas* | ✓ | *Erica Wright* | ✓ |
| *Donna Claeys* | ✓ | *Jerald L. Zarin* | ✓ |
| *Liza Creel* | ✓ | *Barbara Zehnbauer* | ✓ |
| *Margaret Drummond-Borg* | | *Wendy Beathard* | ✓ |
| *Alice Gong* | ✓ | *Brigitte Bright* | ✓ |
| *Jose L. Gonzalez* | ✓ | *Cheryl Burcham* | ✓ |
| *Charleta Guillory* | ✓ | *Sherry Clay* | |
| *Cheryl Hermerath* | | *Debra Freedenberg* | ✓ |
| *Lisa Kalman* | | *Paula Guerin* | ✓ |
| *Scott D. McLean* | ✓ | *Eldridge Hutcheson* | ✓ |
| *Javier Ramirez* | ✓ | *Daisy Johnson* | ✓ |
| *John Saito* | ✓ | *Marcie Kirtz* | ✓ |
| *Morgan Sanders* | ✓ | *David R. Martinez* | |
| *Stuart K. Shapira* | ✓ | *Sara Copeland* | ✓ |
| *Eileen Sheridan-Shayeb* | | *Susan Neill* | |
| *Susan Snyder* | | *Sharon Newcomb-Kase* | ✓ |
| *Michael E. Speer* | ✓ | *Jimi Ripley-Black* | |
| *Reid Sutton* | ✓ | *Susan Tanksley* | ✓ |
| *Larry Sweetman* | ✓ | *Jill Wallace* | ✓ |
| *Lois Taylor* | ✓ | *Donna Williams* | ✓ |

### CLINICAL COORDINATION REVIEW

*Debra Freedenberg, Daisy Johnson and Paula Geurin presented on specific follow up case studies. The case studies included twins with cystic fibrosis, a female infant with MCAD, a female infant diagnosed with Duarte Galactosemia and a difficult to reach case of an infant with Congenital Hypothroidism.*

### RULEMAKING PROCESS

*Marcie Kirtz presented the process, phases and development of DSHS rulemaking. The presentation included the process flow, publication and adoption phases.*

### GAPS AND BARRIERS SUMMARY REVISITED PART II

*Susan Tanksley and Marcie Kirtz presented an update on the last six of the eleven topics from the Gaps and Barriers Summary. The first five topics were covered in Part I at the February meeting.*

- **Provide updated status on NBS System**
  - Additional deficiencies identified by focus group input.
  - Improvements or changes implemented.
- **Categories Included in the Update**
  - Medical Management – five additional gaps were identified based on Focus Group feedback, highlighted updates include: HB 1795, 81st Legislature, created the Newborn Screening Advisory Committee; 11% of NBS fee is allocated to CM activities; 2 full time educators have been added.
  - Program Evaluation – Highlighted updates include: NBS protocols require CM staff to request confirmatory results in order to identify a diagnoses so that a case can be cleared or closed; CM Nurse Team Lead and Team Manager positions are in place; CM is working internally to create long-term database tracking.
  - Program Administration and Finance – Highlighted updates include: the NBS fee was increased January 2010 from $29.50 to $34.50; NBS Benefits Program was enhanced as a proactive approach to increased case load anticipated by expansion in 2006.
  - Personnel – Highlighted updates include: 13 positions have been added due to recent changes; trainer position in lab now focuses on employee training; CM protocols are reviewed on an annual basis by the Medical Director and program consultants.
  - Information Systems – Highlighted updates include: web-based system allows remote entry of demographic data by providers; HL7 file transfer system in place for 2 hospital systems; ~87% of 2nd specimens are linked to 1st specimens.
  - Contingency Planning – Highlighted updates include: COOP agreement with Florida; CQI exercise for a 5 day outage completed; web-based system (MYCOOP) allows documents to be posted online for fast recovery.
- **Overarching Barriers**
  - Additional funding is difficult to obtain.
  - Size and demographics of Texas pose many challenges for the NBS program.
  - 2,000 to 3,000 healthcare providers in Texas collect newborn screens and/or follow children diagnosed with disorders.
  - Texas has a high percentage of children (per capita) relative to other states.

- There are many undocumented children.

- **Next Steps**
  - Discussion regarding potential interventions.

**BRAINSTORMING ON INTERVENTIONS PART II**

*Cheryl Burcham asked the stakeholders to divide into workgroups and assigned six topics for discussion and brainstorming for potential interventions from the Gaps and Barriers Summary. The topics and results of the work groups are listed below.*

- **Information Systems** (Sandra Billings, Jill Wallace, Don Wilson, Jose Gonzalez)

| Intervention | Who to Implement |
|---|---|
| Develop business plan to assess the needs of DSHS for exchanging information – requirements<br>Link to vital statistics | DSHS & Other Agencies<br><br>State Advocates |
| Identify Vendors needed to meet these requirements | |
| Overhaul in communication flows | |
| Create a central agency to collect information and reduce redundancy | THSA |
| Automate process to reduce data entry and increase quality | |
| Health Information Exchange → RICO<br>Statewide<br>NBS lab, MCOs, Vital Statistics, Birth Certificate | THSA<br>↓<br>Medicaid |
| | |

- **Personnel**

| Intervention | Who to Implement |
|---|---|
| Train the Trainer<br>• Manuals (Electronic, downloadable- how to do test, ACT/FACT, specialist listings, imp of confirmatory testing and sending results to CM) | Public Health Reg |
| Continue Grand Rounds NBS continue State ACOG<br><br>$50, 00 grant for education opportunities | March of Dimes<br><br>HRSA |
| Office Management/Train Trainer | TPS -Professional Org that represent medical office personnel |
| Insufficient number of specialists-<br>• Travel- getting patients to specialists<br>• Assist local hospital in recruiting – not sure for underserved areas<br>• DSHS counterparts in other states- get young ones and pay off loans<br>• DSHS act as middle man work with rural hospitals. Start 1st year of fellowship | |

| | |
|---|---|
| • Traveling Specialists with Medicaid payment/reimbursement | |
| Keep staff we have –<br>• What one childe costs – ROI<br>• Costs studies on a lifetime – 1 million or cost of 2 yr – 4 yr | |
| Determine ROI and get these people: Senator Jane Nelson, Zaffirini, Colkorst, Ellen Cohen – March of Dimes, March for Babies | |
| Out of box: Make into law that Medicaid and insurance companies reimburse for 1st screening, 2nd screening and diagnostic testing | |

- **Medical Management** (Erica Wright, Wendy Beathard, Scott McLean, Reed Sutton, Colleen Buechner, Jerald Zarin, Debbie Freedenberg)

| Intervention | Who to Implement |
|---|---|
| Current funding for NBS does not incorporate NBS Cost<br>• Telemedicine for areas specialist<br>• Personnel (regional) to case manage and ensure f/u and coordinate appointments<br>• Regional Resources | |
| Counseling Services are not provided<br>• Funding from insurance to pay for counselors<br>• Use Houston Children's Hospital Sickle Cell Trait/CF counseling sheets<br>• Get info on carriers from Genetic Alliance<br>• Make Nurse certification for genetic counseling more available<br>• Web-based training<br>• Add Genetic counseling to f/u database<br>• Add info page on genetics/confirmed cases or carrier cases to packets going to parents and PCPs<br>• Checkout "Informed DNA"- telemedicine genetic counseling decision making algorithm for family and MD.<br>• Counseling check off sheet for PCP to go over simple genetic issues. | |
| Lack of Specialist<br>• Funding for phone consultation<br>• Telemedicine – add list of specialist to letter that goes out to parents. | |
| Providers do not consistently provide case info to NBS program<br>• Subspecialty report<br>• Pay for data<br>• Give PCP and subspecialty feedback on how info helps | |
| Parent Support Activities | |

| | |
|---|---|
| • Web Link to support groups (disease specific) on website<br>• Blogs for parents<br>• Facebook<br>• Social Networking | |
| ACT/FACT Sheet<br>• Need outcome data ACT/FACT Sheets<br>  o Ask HRSA/ACMG about survey<br>  o Student/ Intern Project<br>  o Survey Monkey<br>• Add info about lawsuits where PCP ignored recommendations to newsletter | |
| Transition to Adult care (tabled) | |
| Longterm F/U activities<br>• Awaiting recommendations of Nat'l Advisory Comm | |
| Timely receipt of results on hospital charts<br>• IT solution<br>• Increase use of HL7 | |
| Lack of ECI<br>• Website improvement<br>• TEHDI is working on this issue<br>  o New 1-3-6 plan and goal of ECI & med intervention by 6 mo | |
| Missed appointments<br>• More active intervention (CPS/Police) in critical cases | |

- **Program Administration and Finance** (Morgan Sanders, Susan Tanksley, Liza Creel, Eldridge Hutcheson, Donna Claeys)

| | |
|---|---|
| Combine NBS lab with Clinical Care in one building and have them report to same Unit director | DSHS |
| Allow NBS to carry funds over to next biennium | Legislature |
| Allow NBS to increase fees to implement new screenings and improve clinical care | Legislature |
| Require hospitals and others doing NBS to report opt-out of NBS | DSHS/Legislature |
| Contract with specialty centers to do confirmatory testing and report to DSHS | DSHS |
| Cost benefit analysis of NBS (possible grant) | Graduate Student<br>Texas Comptroller |
| Money Trees | Texas A&M Horticulture |

- **Program Evaluation** (Larry Sweetman, Javier Ramirez, Kari Casas, Sharon Newcomb-Kase, Daisy Johnson)

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|---|---|
| Program evaluation<br>• In order to get a documented uniform system, suggestion- | Legislature rules-<br>DSHS |

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|---|---|
| Lab and CCC should be one eval system linked. Need rule change. | |
| Post link on website to NNSGRC date from Lab & CCC | DSHS |
| Anne Phillips our new Program Specialist<br>• Implement a ITC data base, respond to adhoc requests for data, she is creating new database for diagnosed cases. | DSHS |
| Develop web-based form<br>• Physicians complete and return<br>• Send form to parents ahead of time for physicians to complete<br>• Request to present annually at TPS<br>• Give discount to specialists for filling out form | DSHS, Stakeholders, Legislature |
| Out of Box<br>• Another State (Peer Review) evaluate both Lab & CCC<br>• Rep from House Public Health Committee shadow the program for one week with KXAN TV coverage<br>• UBS be required to provide date to NBS program | DSHS, Other State, NNSGRCC<br><br>HHSC Commission |

- **Contingency Planning** (Lois Taylor, Paula Geurin, Barbara Zehnbauer, Stuart Shapira, Donna Williams)

| | |
|---|---|
| Pre-analytical – CDC generic NBS card send out for emergency<br>• Contract with Goodwill for temp agency fill<br>• Coop plan for displaced families<br>• Direct phone lines for nurses in flap<br>• If courier services breakdown – backup system<br>• Postal service for delivery of NBS cared – if no Saturday delivery, what put in place?<br>• If DSHS down in central office – how do you notify hospitals to send samples? – PSA's, alert emails , emergency contact list for start and stop date | CDC<br><br>DSHS/Courier Services |
| If TX down and formula down due to pharmacy available, what system set up to deliver formula?<br>Keep formula on hand | DSHS<br>Laye Institutions- medical<br><br>Local/? Health depts |
| Run out of medications, repeat local Rx, unable to reach the local doctor, local metabolic providers. Who to contact? | Drug companies<br><br>DSHS COOP<br>Plan for endo, metab centers |
| PC anywhere to release results | |
| Out of Box<br>• Alternate lab site, and f/u program, increase funding and stock of formulas and medications. Additional funding | |

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|---|---|
| **Pre**<br>• Lack of specimens<br>• CDC reserve of generic | CDC |
| **Post Analytical**<br>• If specimens are lost in transit (Region disaster)<br>• Telephone bank to call missing specimens | DSHS |
| **Loss of contact with persons displaced**<br>• Notified by hospital where baby was transferred | |
| **Saturday contact**<br>• Direct lines | |
| **Saturday mail**<br>• Courier service expanded | |
| **Lack of telephone contact to regional social worker**<br>• Back up cell phone | |
| **Submission of specimens to alternate lab**<br>• PSA's<br>• DL emergency list to start/stop | |
| **Personnel notification to hot case**<br>• Call tree<br>• 1-800 | |
| **FL – ↑ eq ↓ staff**<br>**TX - ↓ eq ↑ staff** | |
| **Alternate worksite for follow-ups**<br>• Working at home, no access, PC anywhere | |
| **Distribution of formula during disaster**<br>• Local provider stores extra formula<br>• CMD, hospital storage<br>• Drug companies overnight (National Guard) | |
| **Out of Box**<br>• 2nd Lab/F/U & Formula storage | |

## NBS AND LEGISLATIVE UPDATES

*Susan Tanksley provided updates related to the Newborn Screening Program and Legislature.*

**Cystic Fibrosis NBS**

Authorizes an NBS Advisory Committee and the addition of additional disorders to the screening panel

- Using IRT/IRT/DNA methodology with 3 fail safes.
  - Ultra-high IRT w/no mutations
  - If 1st screen is elevated, but no 2nd screen is received by 30 days of age, 1st screen goes to DNA
  - 1st normal IRT, 2nd elevated IRT goes to DNA
- Expect 82-94 diagnosed cases annually
- Round Table discussions at NBS Symposium comparing IRT/IRT/DNA in CO, UT & TX
- Implemented statewide December 1, 2009.

**Implementation of HB 1795**
Authorizes an NBS Advisory Committee and the addition of additional disorders to the screening panel

- Change to Health and Safety Code, Chapter 33.
- Adds screening for secondary targets in ACMG panel, as funding allows.
- Adds a Newborn Screening Advisory Committee.
- Effective September 1, 2009.

**Implementation of HB 1672**
Requires parents be notified of retention of bloodspot cards after testing and given process to request destruction

- Change to Health and Safety Code, Chapter 33.
- Adds provisions:
    - Disclosures that NBS specimens can be stored and used by DSHS for other purposes.
    - Allows parents or adults to request destruction of their child's/own specimen(s).
    - Confidentiality of NBS data and specimens and defines acceptable uses.
    - Interim Legislative study of NBS focusing on disclosure/destruction/notification processes.
    - Screening for sickle cell trait.
- Effective Date: May 27, 2009.
- Interim Plan – began August 1, 2009.
    - Separate sheet for disclosure/destruction request form in English & Spanish.
    - Labels on existing NBS collection kits w/checkbox for physician verification.
- Long-Term Plan- ~late May/early June 2010.
    - Disclosure/Destruction request form to be included as separate sheet of NBS collection kit.
    - Physician verification checkbox preprinted in same location as label currently in use.
- Valid requests received through 5/12/2010 → 21, 120.
- Form has been revised to increase readability.
- Now available in Vietnamese.
- Legislative Hearing held May 17.
    - Probable changes to law in 82nd session (January 2011).
- More education needed regarding disclosure /parent options.

**Newborn Screening Advisory Committee**

- Members have been selected and notified.
    - First meeting – June 7, 2010.
- Purpose to develop plan to implement screening for secondary targets in ACMG panel.
- 9 member committee.
    - Health care providers.
        - Charleta Guillory – neonatologist, Baylor College of Medicine.
        - Alice Gong – neonatologist, UT Health Science Center- San Antonio.
        - Javier Ramirez – social worker – South Texas.
    - Hospital representative.

        - Elizabeth Stehel – pediatrician – UT Southwestern, Parkland Hospital.
- Individual with family members affected by a condition for which newborn screening is or may be required under this subchapter.
    - William Morris – son has PKU diagnosed through NBS and another son who had Krabbe disease.
    - Sandra Billings – two sons with CAH
- Individuals who are involved with the delivery of newborn screening services, follow-up. Or treatment in this state.
    - Reid Sutton – metabolic specialist/genetic – Baylor College of Medicine
    - John Saito – pulmonologist – Cook Children's Hospital
    - Alan Rice – endocrinologist – Texas Tech Health Science Center

**New Public Health Service Fee**

- As of December 1, 2009, the fee increased to $34.50.
    - Increase was required to cover the additional tests and follow-up and the infrastructure for the destruction requests.
    - 28 disorders screened (blood spot).
        - Cystic Fibrosis which was added Dec. 1st.
    - HB 1672 additional infrastructure
        - Changes to NBS kit
        - 2 new FTE's to administer destruction requests.
    - Letter sent to 2094 providers and to TMA, TPS & THA for distribution to members.

**NBS Program Projects**

- Courier Pilot Project
    - Frew initiative funding approved at $2.6M per year for 4 years.
    - LoneStar Delivery & Process
        - Full-service.
        - Routes include Dallas, Fort Worth, Tyler, Houston, Beaumont, Texarkana, Wichita Falls, Brenham, San Antonio, Brownsville, McAllen, Laredo, Del Rio, Corpus Christi, Austin, Temple, Waco, San Angelo, Midland, Odessa, El Paso, Lubbock, and Amarillo.
        - Daily pick-ups started date is April 12, 2010.
        - Will-call to be implemented in a few months.
- Second Screen Study
    - Background
        - 9 states require 2nd routine screen
        - 3 additional states recommend routine 2nd screen & have >85% compliance
        - In total, ~25% of babies born in US get 2 screens
    - Purpose of national study
        - Evaluate evidence regarding use of second screens for identification of case of CH and CAH.
        - All states with 2 screens to participate except Colorado.
        - Few states with single screen to participate as control group.
- Second Screen Study – Texas Status.
    - July 2004 to 2008.

- 2nd Screen abnormals for CAH in TX.
  - 96/205 cases = 46.8%.
- 2nd Screen abnormals for CH in TX.
  - 117/1012 cases = 11.6%.
- Data collection
  - Data gathered for all 2nd Screen abnormals.
  - Data for 1st screen abnormals being collected.
  - Goal – complete data collection in June/July.
- Next steps
  - Data analysis.
  - Summarize data presented, published and discussed.
  - Present to Secretary Advisory Committee.

- Grant Activities: 2nd tier CAH Assay
  - Goal: dramatically cut false positive rate.
  - Objective: Develop and refine 2nd tier assay and pilot
  - 2 year grant, ~$150,000 per year.
  - Hired 1 chemist.
  - Investigated protocols in use in other states.
  - Now testing and tweaking the protocol.
  - 2° goal- prove cost effectiveness of second tier testing in order to validate need for NBS – specific instrument.
    - Potential for other 2nd tier LC/MS/MS assays.
    - Update – plans to order LC/MS/MS for NBS laboratory in summer 2010.
- MSGRCC Pilot of 2nd tier testing for MS/MS disorders and CAH
  - ARUP Laboratories – Salt Lake City, UT.
  - CDC grant funded – open to all Mountain States.
  - Approved by DSHS IRB.
  - Awaiting DSHS commissioner approval.
  - ARUP will provide training to participating states.
- Grant Activities: SCID pilot project
  - Secretary Advisory Committee on Heritable Disorders in Newborns and Children voted in January to recommend addition of SCID to core panel.
  - Collaborative project with New England NBS program
    - Goal: screen 20, 000 Texas babies (both screens) per year.
    - Use informed consent to enroll.
    - Initial sites: Seton & St. David's Hospital systems- Austin.
    - Working with local immunologist, Dr. Howard Rosenblatt.
    - Study approved through DSHS & Seton IRBs.
    - Contract signed with UMass.
    - Training to begin soon at St. David's.
    - Other sites (Houston, Dallas, San Antonio) working on implementation plans prior to IRB submission.

**SPECIAL RECOGNITIONS**

*Sharon Newcomb-Kase thanked Texas Health Steps for providing the pens and USB drives.*

*Paula, Daisy, Marcie, Cheryl and Jill were recognized for enduring the "painful process" of evaluating the performance measures and all their hard work.*

*Brigitte Bright was recognized for her efforts and support of TNSPMP.*

Susan Tanksley was recognized for perseverance and dedication to the Newborn Screening program.

**NEXT STEPS**

- Send out notes and new interventions for further comment.
- Final version of report cards
- Data on specific disorders
- Webinar for subspecialties – report cards
- Report on first Advisory Committee

**TNSPMP Quarterly Meeting Dates**

August 19 & 20, 2010 Austin, Texas

**MEETING PLUS/DELTA (FEEDBACK)**

*Participants shared thoughts about what they liked and didn't like about the meeting.*

| Positive Feedback | Delta |
|---|---|
| Case Presentations. | Better A/V. |
| Meeting Organization. | Too cold. |
| Nice hotel. | More discussion on case studies. |
| Brainstorming times. | More time to present and discuss intervention. |
| Food. | Better HH deals. |
| The meeting. | Primary Care Physician. |
| Congrats to staff. | Present out intervention ideas. |