

Newborn Screening Advisory Committee

Texas Department of State Health Services
1100 West 49th Street, Austin, Texas
Moreton Building, M-739
May 20, 2011
Minutes

Members Present

William Morris, LVN
Charleta Guillory, MD
Alice Gong, MD
Elizabeth Stehl, MD

Present By Conference Call

V. Reid Sutton
Sandra Billings

Staff

Debra Freedenberg, MD, Department of State Health Services (DSHS), Newborn Screening Unit
David R. Martinez, DSHS, Newborn Screening Unit
Susan Tanksley, PhD, DSHS, Biochemistry and Genetics Branch
Rachel Lee, PhD, DSHS, DNA Analysis Group
Jeanne Lain, DSHS, Specialized Health Services Section (SHSS)
Patrick Clynch, DSHS, Newborn Screening Unit
Nick Dauster, DSHS, Director, Government Affairs

Guests

Alicia King, IDF SCID Initiative
Jane MacDougall, SAMMC
Jennifer Garcia
Jean Ricciardello

Call to Order

Mr. Morris called to order the May 20, 2011, meeting of the Newborn Screening Advisory Committee at approximately 10:35 a.m.

Roll call of committee members, staff and guests

Mr. Morris welcomed everyone to the meeting; asked everyone to take the opportunity to introduce themselves and why they are there. Members, staff and guests attending are listed at the beginning of these minutes.

Review and Approval of Minutes

Mr. Morris made a motion to accept the minutes from the March 25, 2011 meeting and enter them into the record. Dr. Gong seconded. Motion passed.

Updates from Hematology Ad Hoc Committee Meeting-Debra Freedenberg, Susan Tanksley

Dr. Freedenberg stated that the Hemoglobinopathy Consultants Meeting was held on April 1, 2011 from 9:30 a.m. – 3:00 p.m. She gave an overview of what was discussed at the meeting.

- ◆ Hemoglobinopathy data presented – this is done at all ad hoc committee meetings
 - Review number of children that have been diagnosed with a condition
 - Look at statistics
 - Look to see if we need any changes in laboratory or clinical follow-up

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- Procedure in Hemoglobinopathy since our protocols include both isoelectric focusing, HPLC and reflect to DNA, go over DNA as well to help give us feedback in terms of improving program
- ◆ Susan Tanksley spoke about the post-analytical report card for hematology which was from the Texas Newborn Screen Performance Measures Project (TNSPMP). Essentially looking at kinds of treatment for children with Sickle Cell Disease
- ◆ Guest speaker Kathy Hassell, Director, Colorado Sickle Cell Treatment & Research Center has worked on an on-line primary care education module for Sickle Cell Trait. She subsequently sent it to us and it is now in data testing. She would like it distributed as widely as possible
- ◆ Dr. Buchanan shared with us “Development of Evidence Based Management Guidelines for Sickle Cell Disease and Recommendations Regarding Quality of Care”. Essentially, this was a pre-print of an article which is now out. There is now a new recommendation for hydroxyurea for treatment of Sickle Cell Disease in that some of the age ranges do not apply anymore
- ◆ Discussions about some of the results that have been reported out
 - F, A, Other, F,A, Barts
 - ◆ What this represents clinically; long discussion with lots of involvement from all the hematologists. As a result of that, we have reassessed some of our reporting for BARTS and it probably will change for F,A, Other
 - ◆ Dr. Buchanan and Dr. Rogers are composing an educational letter for parents, and it probably will be on our website
- ◆ Amanda Broden gave legislative updates
- ◆ Discussion about ACT and FACT sheets and our Sickle Cell Trait letter to parents
 - ACT sheets are what tell the primary care physician (PCP) what to do with a positive screen
 - FACT sheets are informational sheets with more about the disease; designed for the parent and to help the PCP speak to the parents about a condition that they may not have seen a lot of children with
 - Sickle Cell Trait letters – mailed to all parents of children that have been found to have Sickle Cell Trait through the screening program

Susan Tanksley stated that one assignment they received at the meeting was to look at F,A, Barts and how it is recorded and the frequency of that reporting. The lab uses two different codes to report, but it all comes out the same on the lab report. It comes out as F,A, Barts as an abnormal result. The lab actually records it in the system as a light Barts versus a regular Barts. They have found a much higher frequency of reporting light Barts than just Barts. They have made a proposal that has been forwarded to the hematologists for consideration. The proposal is to eliminate reporting the light Barts as an abnormal result. They are waiting on feedback from the hematologists before they proceed with it.

Newborn Screening Lawsuit Update-William Morris

Mr. Morris reminded the DSHS employees that they could stay and listen, but could not participate in the discussion because of the fact that they are directly involved in the lawsuit as employees. Discussion would be held between committee members only. Mr. Morris gave a brief summary on the history of the lawsuit.

- ◆ 2008-2009 lawsuit filed by a group called Civil Rights Project centered around the idea that there should have been no use of residual NBS bloodspots without consent

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- ◆ DSHS settled this suit by agreeing to, among other things, destroy all residual NBS bloodspots in the possession of DSHS as of a certain date for which consent was not obtained
- ◆ Current lawsuit filed December, 2010 in a San Antonio federal court and is the 2nd federal lawsuit filed by the Texas Civil Rights Project
- ◆ Focuses on residual NBS bloodspots which were not destroyed as part of the settlement of the 1st lawsuit because they were not in the agency's possession
- ◆ Agency has filed several motions with the court
- ◆ As of May 16, there have been no rulings on motions

Mr. Morris opened the discussion to the committee.

- ◆ Mr. Morris concerned as a parent about the loss of research and the gains that can be made from the bloodspots. He would recommend to the commissioner and the department that they fight the lawsuit this time. He understands that the logistics last time were overwhelming, but we need to protect the whole program at this point
- ◆ Dr. Stehl was curious as to how many plaintiffs make up the Texas Civil Rights Project and if any of them have children that have been affected with any disorder. Mr. Morris stated that the 1st lawsuit was made up of 5 and none of them had any affected children
- ◆ Dr. Stehl asked what the motivation is and was there a particular issue. Mr. Morris said that their concern is that the state is building a DNA database. Dr. Gong stated that it wasn't just Texas, but other states also. Dr. Gong also stated that the SCID parents have been trying to get a pilot study to verify the tests. One of the proposals was to go back and find the kids who had SCIDs, who died, and use their bloodspots. But they got destroyed before we were able to do that. That is another example of lost research
- ◆ Dr. Stehl wondered if any of these groups of parents that make up this project, if they have been approached by any groups of parents they are directly affecting with the lawsuit. Mr. Morris stated that he was at an interim hearing on HB 1672. Several plaintiffs, including the main plaintiff Andrea Beleno, were there testifying, and the press was there also. He attempted to approach Ms. Beleno and speak with her as a parent with an affected child about his concerns. He also tried to speak with the press. They were not interested.
- ◆ Dr. Gong asked if there were any formal groups of parents of children who have diagnosed by newborn screenings. Mr. Morris stated that there are several formal groups, he has worked with one recently.
- ◆ Dr. Guillory stated that she totally agreed with Mr. Morris and Dr. Gong in what they previously said. She wanted to mention 3 things
 - She agrees in the value of research; it is reasonable that parental consent occur, but she knows if it is made an opt-in position, one thing that gets confusing is that do you opt-in to just doing newborn screenings. There is some confusion there, so not only does it decrease the number of newborn screens for research, it may also decrease the number of parents refusing to do newborn screening and making it even more difficult
 - Have DSHS go back for years and spend a lot of manpower trying to get a lot of data for this lawsuit. She knows how difficult that can be in just a plain lawsuit. Then it takes away excellent work DSHS is doing; not only in research and new/innovative programs (looking at SCID

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programs right now). She thinks it takes away from the fact that they are a nationally renowned newborn screening program statewide, and they are trying to use their manpower to really do the best for all babies.

Texas Newborn Screening Performance Measures Project (TNSPMP) Update-Susan Tanksley, Debra Freedenberg

Susan Tanksley stated that the TNSPMP was a CDC grant essentially 3 years of funding. She reported to the committee on the grant goals, history of the project, retrospective data and lessons learned. The project started September, 2007 and is in the last stages at this point. Project funding ends May, 28th; however, still have several deliverables that have to be turned into CDC by the end of August.

- ◆ Overall project goal
 - Develop and identify 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 newborn screening
- ◆ TNSPMP Goals
 - Goal 1 – formalize a steering committee to guide project (external project team)
 - ◆ Developed external stakeholder team representative of the NBS system. Initially planned on about 17 members, ended up with about 24
 - ◆ Created DSHS project team from laboratory and follow-up
 - ◆ Held 14 meetings with external stakeholder team
 - Goal 2 – develop and define performance measures that may reveal gaps
 - ◆ Assessed NBS system in Texas using:
 - 2005 National Newborn Screening and Genetics Resource Center (NNSGRC) review
 - NNSGRC Performance Evaluation and Assessment Scheme (PEAS)
 - Stakeholder input
 - ◆ Investigated existing measures in the NBS community
 - ◆ Reviewed literature to identify evidence-based performance measures
 - Time to treatment and its affect on patient outcome
 - Potential performance and measures suggested by experts
 - Disorders focused on:
 - CAH
 - Galactosemia (GALT)
 - MCADD
 - Congenital Hypothyroidism (CH)
 - MSUD
 - PKU
 - Sickle Cell Disease
 - Difficult to find solid evidence
 - ◆ Identified approximately 50 performance measures
 - ◆ Hosted 9 focus groups with healthcare professionals and consumers to assist with defining the measures and developing standards

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- Goal 3 – pilot key performance measures for effectiveness in improving time to treatment for infants with newborn screening disorders
 - ◆ Each of the final performance measures has been defined, evaluated and data summary reports developed
 - ◆ Pre- and post-analytical report cards have been developed
 - Refined pre-analytical NBS report card format
 - Provide a gold standard and state average for comparison
 - Produced through automated process/to be available online
 - ◆ Retrospective data analysis has been completed for July to December, 2009
 - ◆ July to December, 2010 data being collected and analyzed for comparison to retrospective data
 - ◆ New report card process in final phases of validation
- Goal 4 – identify, recommend and document evidence-based interventions
 - ◆ Brainstorming sessions held with stakeholders to gather intervention ideas and score feasibility of those ideas
 - ◆ Literature review completed on evidence-based interventions
 - ◆ Interventions to be included in updated gaps/barriers document
 - ◆ Publications regarding outcomes of project being drafted
- Key Deliverables
 - ◆ 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 – May, 2011)
 - ◆ Final report due to CDC
 - August 28, 2011
- Lessons Learned
 - ◆ Get to know the NBS system in your state
 - Work to develop and nurture strong relationships with system stakeholders
 - ◆ Program evaluation is essential for improvement
 - NNSGRC review
 - Program Evaluation and Assessment Scheme
 - Listen to stakeholders
 - Ask why?
 - ◆ Strong evidence is hard to find in NBS
 - Pay for performance and other evidence-based initiatives will require development and use of evidence-based measures
 - Few evidence-based measures exist for NBS
 - Future data collection and analysis will help build stronger evidence-base
 - Actively searching for funding to pilot measures in other states
 - ◆ Performance measures must be carefully defined, understood and consistently reported

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- Comparison is meaningless otherwise
- Potential for inclusion of performance measures as part of program evaluation/certification program
 - Continuous Quality Enhancement Program
 - Outgrowth of program evaluations at NNSGRC
 - HRSA/CDC initiative introduced by Sara Copeland
- What Next?
 - ◆ Applicable to other areas of public health
 - 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
 - ◆ Potential inclusion of TNSPMP performance measures in national performance metrics project

Dr. Gong made a motion to accept the performance measures as a quality improvement project for NBS and the committee get results annually. Sandra Billings and Dr. Guillory seconded. Motion passed.

Legislature Updates-Nick Dauster

Nick Dauster discussed with the committee the 82nd regular session dates of interest and gave updates on the Newborn Screening bills. Dr. Guillory asked once a bill has been passed in the House and Senate and it has an added unexpected amendment and it goes to a conference committee, if the conference committee does not remove the amendment what happens to it. Mr. Dauster said that the amendment stays attached and the Governor has the option of signing the bill, allowing it to become law or vetoing it.

- ◆ HB 411- relating to the confidentiality of newborn screening information
 - Status – Reported from Senate Health and Human Services Committee 5/19/11
- ◆ SB 229 – relating to birthing facilities required to offer newborn hearing screenings
 - Status – Voted favorably from House Public Health 5/18/11. Must now be considered in the Calendars Committee and has until early next week. See if it goes through the Dates of Interest calendar to get on a calendar and be considered by House as a whole
- ◆ SB 270 – relating to newborn hearing screenings
 - Status – Heard in House Public Health 5/19/11. Committee report has been published and forwarded to the Calendars Committee. Eligible to be considered by the House
- ◆ HB 2312 – relating to the creation of a sickle cell disease program
 - Status – passed the Senate 5/19/11. On the way to the Governor
- ◆ HB 3336 – relating to information regarding pertussis for parents of newborn children
 - Status – reported favorably from Senate Health and Human Services Committee 5/13/11

There are two sets of fiscal related bills. These change the law, so that the budget will be consistent with the statute. The concern here is there are some provisions that allow the department to modify their fees. This is being done for the fees being charged by the lab and also in the regulatory area. Some have expressed

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concerns about the increasing of fees as a way of funding programs and the one that is moving forward is SB 1811. It should reach the House floor today (5/20). It has some language that is intended to allow the department and other agencies to increase fees to make up for lost revenue or reduced appropriations. SB 1580 appears to not be moving forward.

Potential Addition of New Committee Members-Committee

Mr. Morris informed the committee that Dr. Saito and Dr. Rice had resigned their positions on the committee effective at the end of the month. There will be 2 positions that will need to be filled, endocrinologist and pulmonologist.

Dr. Freedenberg went over SB 1795 which is the bill that authorizes the establishment of a NBS Advisory Committee. She conveyed to the committee what the agency policy is for making appointment recommendations.

Discussion followed by the committee.

Severe Combined Immunodeficiency (SCID) Pilot Update – Rachel Lee

Rachel Lee gave updates to the SCID pilot study.

SCID Pilot Study Updates:

- ◆ Program began September, 2008; however pilot did not begin until October, 2010
- ◆ 6 participating facilities
 - St. David's Medical Center, Austin, TX
 - St. David's North Austin Medical Center
 - Pediatric Associates of Austin
 - Felici Pediatric Clinic, McAllen, TX
 - Betta Pediatric Clinic, San Benito, TX
 - Maternidad La Luz, El Paso, TX
- ◆ Number of consents and specimens
 - In 2010, received 189 consent forms; 343 specimens tested
 - In 2011, received 647 consent forms; 1,103 specimens tested
- ◆ All specimens have normal TREC levels
- ◆ States implemented SCID newborn screening
 - Wisconsin (Louisiana)
 - Massachusetts (Puerto Rico)
 - New York
 - California
- ◆ Incidence rate
 - Wisconsin
 - ◆ SCID Only – 1 in 60,927
 - ◆ SCID, SCID variant & other T-cell lymphopenia – 1 in 20,308
 - Massachusetts

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- ◆ SCID Only – 1 in 161,707
- ◆ SCID, SCID variant & other T-cell lymphopenia – 1 in 10,780
- California
 - ◆ SCID Only – 1 in 34,000 (1 in 26,000 for Hispanic population)
 - ◆ SCID, SCID variant & other T-cell lymphopenia – 1 in 26,000 (1 in 20,000 for Hispanic population)
- New York
 - ◆ SCID Only – 1 in 47,093
 - ◆ SCID, SCID variant & other T-cell lymphopenia – 1 in 9,418
- ◆ Grant opportunity
 - Application due 5/31/2011, project period September, 2011 – August, 2013, funding \$450,000/yr
 - Expansion and extension of the current pilot study
 - Aim to enroll 45,000 newborns per year, 90,000 specimens per year
 - Proposed budget includes funding to facilitate the consent process
 - Target medical facilities
 - ◆ Parkland Memorial Hospital
 - ◆ Woman's Hospital of Texas
 - ◆ Ben Taub
 - ◆ Memorial Hermann Hospital
 - ◆ Texas State University Medical Center
 - ◆ Christus Santa Rosa in San Antonio
 - ◆ St. David's system in Austin
 - Received more than 30 letters of support

Public Comments

Alicia King and Jennifer Garcia spoke with the committee about the deaths of their children by SCID. They wanted the committee to know that they would support the committee in any way possible to help get SCID on the panel.

Dr. Stehl made a motion that SCID formerly be added to the NBS panel in Texas. Dr. Guillory seconded. Motion passed.

Dr. Guillory made a motion that the committee officially recommend that we establish an ad hoc committee or committee of immunologists in the state that are interested in expanding SCID to NBS at the next legislative session. Dr. Stehl seconded. Motion passed.

Motions Passed

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Next Meeting Agenda Items

Agenda items to be determined at a later date.

Adjournment

The next meeting will be determined at a later date. There being no further business, the meeting was adjourned at approximately 3:25 p.m.