

Newborn Screening Advisory Committee

**Texas Department of State Health Services
1100 West 49th Street, Austin, Texas
Moreton Building, M-739
December 19, 2011
Minutes**

Members Present

William Morris, LVN
Charleta Guillory, MD
Elizabeth Stehl, MD
Mark Lawson, MD
V. Reid Sutton, MD
Susan Spencer, MSN, RNC, IBCLC

Staff

John Waara, Department of State Health Services (DSHS), Newborn Screening Unit
David R. Martinez, DSHS, Newborn Screening Unit
Brendan Reilly, DSHS, NBS Specimen Logistics Manager
Susan Tanksley, PhD, DSHS, Biochemistry and Genetics Branch Manager
Debra Freedenberg, MD, Department of State Health Services (DSHS), Newborn Screening Unit
Jann Melton-Kissel, RN, MBA, DSHS, Specialized Health Services Section
Rachel Lee, PhD, DSHS, DNA Analysis Group
Patricia Hunt, DSHS, Newborn Screening Laboratory

Guests

Sofia Poonawala, Cook Children's Cystic Fibrosis Center
Jennifer Garcia

Call to Order

Mr. Morris called to order the December 19, 2011, meeting of the Newborn Screening Advisory Committee at approximately 1:00 p.m.

Roll call of committee members, staff and guests

Mr. Morris welcomed everyone to the meeting and asked that everyone introduce themselves particularly for the benefit of the new members. He thanked everyone for taking the time out of their busy schedules to attend the meeting. Members, staff and guests attending are listed at the beginning of these minutes.

Review and Approval of Minutes

Mr. Morris asked if there was a motion to accept the minutes from the May 20, 2011 meeting and enter them into the record. Dr. Sutton made a motion to approve the minutes and Dr. Guillory seconded. Motion passed.

Severe Combined Immunodeficiency (SCID) Pilot Update-Rachel Lee

Rachel Lee gave updates to the SCID pilot study.

SCID Pilot Study Updates:

- ◆ SCID pilot study was sponsored by CDC and collaborated with University of Massachusetts which is New England Screening Program
- ◆ Program began September, 2008; however the Texas pilot did not begin until October, 2010
- ◆ 9 participating facilities
 - St. David's Medical Center, Austin, TX
 - St. David's North Austin Medical Center
 - Ben Taub at Houston (just joined)
 - St. Joseph Hospital, College Station
 - College Station Medical Center, College Station
 - 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
 - Receive 300/400 consents each month
 - Currently have received 3,229 consents as of today
 - Tested more than 5,500 specimens
- ◆ All are normal – sent all specimens to University of Massachusetts where they are testing normal also
- ◆ Other states implemented SCID newborn screening
 - Wisconsin
 - Louisiana
 - Massachusetts
 - New York
 - California
 - Michigan
 - Puerto Rico (Territory)
 - Minnesota and Colorado are in the process of implementing SCID testing
- ◆ Incidence rate
 - Variable trend of 1 in 30,000 to 1 in 60,000 depending on state
 - California – similar ethnicity distribution to Texas
 - ◆ SCID Only – 1 in 34,000 (1 in 22,000 for Hispanic population)
- ◆ SCID Grant
 - Officially over in September, 2011; no longer have funding
 - Did receive a no cost extension which means University of Massachusetts is going to test samples for us until February, 2012
 - Continue to look for funding and continue the pilot study

Secondary Targets “How many diseases on the panel are being counted?”-William Morris, Susan Tanksley

Chairman Morris and Susan Tanksley discussed with the committee the core conditions and the secondary target conditions that are on the Texas NBS Panel. He discussed how other states counted disorders that were being tested with Texas being tied for last place with the number of diseases we are testing for. He indicated that we need to make sure that we are doing the best job counting the targets and determining what is being tested for.

HB411 Update and Newborn Screening Program Changes-Susan Tanksley, Brendan Reilly

Susan Tanksley gave the committee a brief summary on HB411. Susan stated that the biggest impact of HB411 that we are working to implement is that it essentially changes residual specimen uses from opt out to opt in. Currently, physicians and anyone drawing a screen are required to give the parents what is called a

newborn screening disclosure, which is information on newborn screening, and it says that the specimens will be kept and can be used for research and other purposes, but it gives them the option if they don't want the specimen to be retained and used for those purposes, to ask that the specimen be destroyed. At that point, after we have received the specimen, we have 60 days to destroy the specimen. That's per HB1672 in the 81st Legislative Session.

During the 82nd Legislative Session, HB411 was passed. What HB411 says is that when the specimen is collected, that parents be given a disclosure (more newborn screening information) that says specimens can be used for these things; however, the parents have to actually sign the consent in order for the specimens to be retained and used past the 2 year window. Any external research requires parental consent. We have been working for several months obtaining stakeholder feedback, redeveloped the newborn screening consent form and reviewed almost everything we own that has newborn screening on it, as far as information, website, resources, educational material, training and on line modules to determine what will need to be revised prior to the implementation date of 6/1/12 for the opt in. We have begun developing notification materials for providers to begin the training process. The information the committee has received is one of the things that has been developed where we are going to try to begin training health care professionals in their responsibilities in regards to implementing HB411.

Brendan Reilly discussed the document the committee received. It was developed because of the 2 very different laws that are almost exactly opposite. It shows the responsibilities of the healthcare providers under the current law and what their responsibilities will be under HB411 beginning 6/1/12.

New Recommendations by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) for Critical Congenital Health Disease (CCHD) Screening-William Morris

Chairman Morris discussed a letter that was released from the Secretary of Health and Human Services to Dr. Rodney Howell on the committee saying that they were going to accept the recommendations of the committee to add CCHD to the testing process.

- ◆ CCHD causes up to 3% of all infant deaths in the first year of life
- ◆ Heart defects affect about 7 to 9 of every 1000 live births, one quarter of which could be detected and potentially treated by measuring blood oxygen saturation.

Chairman Morris wanted to open up for everyone to discuss or mention anything that they thought was pertinent about CCHD screening. It has been adopted to core panel by the SACHDNC.

Dr. Freedenberg stated that at the time that this was first reviewed by the SACHDNC, there was thought to be some issues with implementation, and with those issues, there was some direction given to both the CDC and HRSA in terms of follow-up and terms of how to implement. HRSA has now come out with a \$300,000 3 year grant that is due 1/17/12. They are planning on funding 6 or 7 grants to essentially states but it is open. We have been exploring whether this was something that we wanted to undertake as a state. One of the big issues for us right now is where do the stakeholders stand. Is it ready for implementation or are there still too many issues? HRSA projects are considered demonstration projects. There have been discussions; however, there has been no clear direction from some of the groups in terms of whether this was something that was ready for prime time in this state or whether we should hang back a little bit and see how this all plays out. Dr. Freedenberg asked for input from the committee on two questions. First, should we try to apply for the demonstration project and second, should we plan for implementation with or without the grant at some point; to start working towards that a date in the future? The committee discussed the topic and Dr. Freedenberg thought that the best course at this point is to follow Dr. Guillory's suggestion and speak with the people that have been looking at things statewide and then try to make some decisions about whether or

not to do it. Will be happy to send an e-mail to the advisory committee to let them know where we stand with everything.

The Baby's First Test Website and Other Discussion Items from the SACHDNC Meeting in Washington, DC in September-William Morris

Chairman Morris reported to the committee that another item that was put forth at the SACHDNC meeting in Washington, DC in September, was a report from the committee to put together a website. This would be kind of a one stop shop for parents to get their questions answered. They came up with a website called baby's first test and the link is <http://www.babysfirsttest.org>. He would like to encourage everyone to take a look at it and consider incorporating it into things that they do.

Public Comments

None.

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 3:30 p.m.