

**Newborn Screening Advisory Committee
Meeting Minutes
April 29, 2019
10:30 a.m.**

**Moreton Building, Public Hearing Room M-100
1100 W. 49th Street, Austin, TX 78756**

Table 1: Newborn Screening Advisory Committee member attendance at the Wednesday, April 29, 2019 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Beryl (Pam) Andrews	X		Tiffany McKee-Garrett, M.D.	X	
Nancy Beck, M.D.	X		Scott McLean, M.D.	X	
Titilope Fasipe, M.D., Ph.D.	X		Joseph Schneider, M.D.	X	
Melissa Frei-Jones, M.D.	X		Michael Speer M.D.	P	
Alice Gong, M.D.	X		Elizabeth (Kaili) Stehel, M.D.	X	
Charleta Guillory, M.D.	X		Linda Zediana, R.N.	X	
Tiffany House, J.D.	P				

Yes: Indicates attended the meeting **No:** Indicates did not attend the meeting **P:** Indicates participated by phone

Table 2: Newborn Screening Advisory Committee guest attendance at the Wednesday, April 29, 2019 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Krystal K. Davis, Texas Rare Alliance, Rare Disease Parent	X		Jonathan Hyak, Medical Student at Baylor College of Medicine	X	

Agenda Item 1: Welcome and Introductions

Dr. Charleta Guillory, Chair of the Newborn Screening Advisory Committee, convened the meeting at 10:30 a.m. Dr. Guillory greeted everyone and requested Committee members and members of the public introduce themselves.

Agenda Item 2: Committee Business Logistics

Dr. Guillory turned the floor over to Ms. Stephanie Gutierrez, HHSC, Policy & Rules, Advisory Committee Coordination Office. Ms. Gutierrez reviewed logistics, called roll, and determined quorum.

Agenda Item 3: Review and Approve Meeting Minutes for January 23, 2019

Ms. Gutierrez requested a motion to approve the January 23, 2019 meeting minutes.

MOTION: Dr. Joseph Schneider made a motion to approve the January 23, 2019 meeting minutes. Dr. Alice Gong seconded. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried with no objections nor abstentions.

Agenda Item 4: Legislative Updates

Dr. Guillory introduced and turned the floor over to Mr. David Martinez, DSHS, Director of the Newborn Screening Unit. Mr. Martinez reviewed the handout, *NBS Bills Comparison – 86th Legislative Session*.

Mr. Martinez announced:

- The agency is neutral on bills
- March 8, 2019 was the last day to file bills
- May 18, 2019 is the last day for House Committee work
- May 22, 2019 is the last day for Senate Committee work
- The last day of the legislative session is May 27, 2019
- The veto period ends on June 16, 2019
- Government Affairs is tracking 502 bills and have assigned 326 for analysis
- Laboratory is tracking 53 bills
- Community Health Improvement division is tracking 119 bills

Members discussed:

- Consent forms being for both the dry blood spots and for the hearing screening to be provided to the department.
- A cost estimate to have a separate electronic portal for the blood spot and hearing screenings would be anticipated to cost in the millions.
- The current process is for parental consent as a manual process that requires manual data entry into the laboratory system.
- DSHS only has access to demographic data if the parent consents for hearing screening otherwise the department can only see if the test was passed or failed.
- The Sickle Cell Task Force is limited to a two-year period and will focus on four of the five recommendations of the Sickle Cell Advisory Committee.

Agenda Item 5: Estimated time and cost for full implementation of RUSP conditions

Dr. Guillory reviewed the PowerPoint and handout, *Implementation of Recommended Newborn Screening Panel (RUSP) Conditions* and shared the floor with Dr. Rachael Lee, DSHS, Manager, Biochemistry & Genetics Branch, Laboratory.

Members discussed:

- Cost analysis for Pompei disease.
- Highlighting the cost comparison of caring for a child with Spinal Muscular Atrophy (SMA) through their lifetime.
- Using various screening methods that could be more cost effective.
- X-ALD is scheduled to go live in September 2019.

Agenda Item 6: Rider 37

Dr. Guillory introduced and turned the floor over to Dr. Joseph Schneider, Chair of Rider 37 subcommittee.

Dr. Schneider reported to the full committee that the subcommittee reviewed the content of the letter to Dr. Hellerstedt.

MOTION: Dr. Alice Gong made a motion to approve the letter for Rider 37 to Dr. Hellerstedt. Dr. Tiffany McKee-Garrett seconded. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried with no objections nor abstentions.

Agenda Item 7: Sickle Cell Subcommittee Reporting

Dr. Guillory introduced and turned the floor over to Dr. Titilope Fasipe, Sickle Cell Subcommittee co-chair and Dr. Melissa Frei-Jones, Sickle Cell Subcommittee co-chair. Dr. Fasipe and Dr. Frei-Jones reviewed the PowerPoint and handout, *Sickle Cell Subcommittee Report*.

Members discussed:

- Measures of early prescription of Penicillin to children who have been diagnosed with Sickle Cell disease are being recorded at a national level.
- In the United States there is not a national database for Sickle Cell Disease.
 - The Center for Disease Control and Prevention (CDC) has a database.
- Sickle Cell life expectancy has improved, and children are living into adulthood.
- New therapies are being developed online that may change the course of Sickle Cell treatment.
- Dr. Elizabeth Stehel will be added to the Sickle Cell Subcommittee.

MOTION: Dr. Elizabeth Stehel made a motion that action items #1, #2, #3, and #5 from the Sickle Cell Subcommittee be handled by the Sickle Cell Subcommittee with support from the Newborn Screening Advisory Committee and action item #4 be managed and directed by the state program. Dr. Joseph Schneider seconded. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried with no objections nor abstentions.

Agenda Item 8: Break

Dr. Guillory announced an 11-minute break.

Agenda Item 9: DSHS Laboratory automated matching

Dr. Guillory reconvened the meeting at 12:31 p.m. and introduced then turned the floor over to Mr. Brendan Reilly, DSHS, Laboratory. Mr. Reilly referenced the PowerPoint and handout, *Newborn Screening Specimen Linking*.

Mr. Reilly stated:

- The Master Patient Index is through a Health Information Exchange (HIE) which Admission Discharge and Transfer (ADT) electronic messages are being input.
- The state has entered into a data use agreement with the Center for Health Statistics to receive newborn screening specimen data that does not include birth record information.
- The state is currently working on improving the second screen process.
- The state is trying to use vital statistics data to link both screens together.

Members discussed:

- The legal requirements of the creation of a birth certificate
- Linking the birth certificate with the newborn screening
- Texas does not have a law that says the department can access vital statistics data
- Having a QR code rather than a serial number or barcode
- Developing next steps for the next meeting regarding the second screen process
- The manual linkage taking place case by case by linking the percentage of babies that are not automatically linked
- The first screen being aggregate data with vital statistics to get an idea of the percentage of newborn screens taking place
- The state gets aggregate data from the Center of Vital Records on the number of babies born
- Dr. Schneider will draft a letter regarding access to the vital statistics database for laboratory staff

ACTION ITEM: The state will provide a follow up on second screening progress.

Agenda Item 10: Break

Dr. Guillory announced a 5-minute break.

Agenda Item 11: Newborn Hearing Screening in Neonatal Intensive Care Unit (NICU)

Dr. Guillory reconvened the meeting at 1:37 p.m. and turned the floor over to Dr.

Tiffany McKee-Garrett, Subcommittee Chair and Dr. Barbra Novak, Texas Children's Hospital. Dr. Novak referenced the PowerPoint and handout, *Development of Best Practices for the NICU Population: An update from the Newborn Hearing Screening in the NICU Subcommittee*.

Dr. McKee-Garrett stated the subcommittee met February 20, 2019 on a conference call. The subcommittee reviewed the pilot study at Texas Children Hospital as well as discussed, the proposed recommendations for hearing screenings in the NICU population.

Members discussed:

- Babies getting newborn screenings earlier also receiving treatment earlier
- The rate of the need of diagnostic testing at bed side has not changed nor has the false positive rate
- In the future, surveying parents on early screening for their babies
- Currently the Texas Administrative Code (TAC) for Level III and Level IV do not require a pediatric audiologist to be part of support staff
 - The full committee may make this recommendations in the future
- In the future, the state will streamline the parental consent process

Agenda Item 12: Critical Congenital Heart Disease

Dr. Guillory introduced and turned the floor over to Dr. Scott McLean, Subcommittee Chair. Dr. Scott McLean reviewed the PowerPoint and handout, *Report from the Critical Congenital Heart Disease (CCHD) Subcommittee*.

Dr. McLean introduced and turned the floor over to Mr. Jonathan Hyak, UT School of Public Health. Mr. Hyak reviewed the PowerPoint and handout, *Assessment of CCHD Screening Practices in Texas*.

Members discussed:

- How to capture if screening is taking place and being done correctly
- Having a newborn screening coordinator that follows up on screens
- Focusing on education of public health systems
- How can the screening process be improved
- The subcommittee put together a draft proposal
- The subcommittee recommends that DSHS develop a program to support champions that will educate those responsible for CCHD screening and reporting regarding best practices
- A cost analysis for a CCHD system

Agenda Item 13: NBS Consultants Fees

Dr. Guillory reviewed the discussion had by the committee at the last meeting and what steps have been taken as a result such as:

- Discussed the complexities of billing telephone consulting

- Metabolic data
- Broader spectrum of newborn screening
- Workforce shortage of geneticist
- Solutions for reimbursement payment for consultations
- Creation of the NBS Consultant Fee subcommittee

Agenda Item 14: Status of Parental Refusals/Consent Form

Dr. Guillory turned the floor over to Dr. Lee. Dr. Lee stated the QR code for the English video was removed from the Spanish version of the Refusal Form.

Agenda Item 15: Screened Conditions status updates- Clinical Care Coordination Follow Up Process

Dr. Guillory introduced and turned the floor over to Dr. Debra Freedenberg, DSHS, Medical Director, Newborn Screening and Genetics, Newborn Screening Unit. Dr. Freedenberg referenced the PowerPoint and handout, *Newborn Screening in Texas Clinical Care Coordination*.

Members discussed:

- Adding a cardiologist as a subspecialist
- Adding a pediatric cardiologist as a subspecialist
- Adding additional screening to the list of screened conditions
- Which secondary screens are not on the list

Agenda Item 16: Future conditions implementation updates

Dr. Guillory introduced and turned the floor over to Dr. Rachel Lee, DSHS, Manager, Biochemistry & Genetics Branch, Laboratory.

Dr. Lee gave an update on:

- X-ALD funding was approved by legislators
- CDC grant money of \$300,000 per year for new disorders
 - Purchase instruments
 - Provide trainings
 - Grand Rounds
 - Travel for X-ALD meetings
- Newborn screening fee increase to include X-ALD
 - Will be posted at a minimum of 90 days before it takes effect
- Medicaid reimbursement for X-ALD screening
- The current laboratory instruments will need to be converted for use of the new X-ALD kit
 - Five of the ten instruments have been converted
 - All instruments will be converted by July 2019 for validation
- Three tier methodologies
 - Write up and plan is in progress
- Standard Operating Procedures are being developed for second tier testing

- Hired new staff:
 - Research specialist working on SMA
 - Two additional new staff working on DNA sequencing
- A new mailer has been validated
- Working on a press release for the go live
- In May an announcement for the new report format
- Grand Rounds on 07/31/2019
- A X-ALD stakeholder meeting in July 2019 will be held at DSHS
- Texas Health Stem Cell Educational model is under development
- Received a small amount of funding for SMA to update educational materials, fund a Grand Rounds, purchase reagents, and develop laboratory algorithm.

Members discussed:

- Secondary screenings picked up during the screening process
- Additional conditions that were removed from the RUSP
- SMA could move up by a year, the implementation funding is \$3.7 million

Agenda Item 17: Public Comment

Dr. Guillory turned the floor over to Ms. Gutierrez. Ms. Gutierrez read public comment logistical announcements and called Ms. Krystal K. Davis, Texas Rare Alliance, Rare Disease Parent. Ms. Davis gave an update to members regarding efforts at the Capital for Newborn Screening.

Agenda Item 18: Future Agenda Items/ Next Meeting Date/Adjournment

Dr. Guillory opened the floor for discussion of future agenda items.

Members discussed:

1. Secondary disorders presentation
2. Presentation on additional conditions that are not recommended on the RUSP
3. Presentation on process for what is screened on a state and national level
4. Presentation on congenital hypothyroid abnormal values
5. Review of letter to Dr. Hellerstedt
6. Officer Election review and member terms

The next meeting is July 12, 2019.

Dr. Guillory adjourned the meeting at 4:51 p.m.

Webcast: <https://texashhsc.swagit.com/play/04292019-732>