

**Newborn Screening Advisory Committee
Meeting Minutes
July 12, 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 Friday, July 12, 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.	P		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.	P	
Charleta Guillory, M.D., M.P.H.	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 Friday, July 12, 2019 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Sam B. Cooper, III, Texas Medical Association	X		Kellie Dees, Texas Pediatric Society	X	
Terese Finitzo, OZ	X		Tina Findley, UTHealth	X	
Sriharsha Kambala, Baylor College of Medicine	X		Khrystal K. Davis, Texas Rare Alliance	X	
Sanjiv Harpavat, 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 10:31 a.m. Dr. Guillory greeted everyone, gave appreciation to state agency staff, 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 April 29, 2019

Ms. Gutierrez requested a motion to approve the April 29, 2019 meeting minutes. Dr. Joseph Schneider requested a sentence be stricken from the minutes.

MOTION: Dr. Michael Speer made a motion to approve the April 29, 2019 meeting minutes with the edit. 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 4: DSHS Commissioner Address

Dr. Guillory introduced and turned the floor over to Dr. John Hellerstedt, DSHS Commissioner. Dr. Hellerstedt reviewed statistics for Newborn Screening in Texas, gave praise to committee members, and informed members of legislative updates relevant to Newborn Screening.

Dr. Guillory reciprocated appreciation to Dr. Hellerstedt as well as gave appreciation to members of the committee. Dr. Gong echoed the sentiment. Dr. Schneider gave three positive recommendations:

- Configuring access to the Vital Statistics database to facilitate a better matching of first and second newborn screens.
- Move funding from the general funds of the state to payers to compensate providers for the care they provide to patients.
- Find funding to transition further from paper-based to electronic processes.

Dr. Hellerstedt stated he is interested in these recommendations and dedicated to doing the very best moving forward.

Dr. Gong added support for the importance of being able to properly reimburse providers as well as investing in electronic systems.

Agenda Item 5: Legislative Updates

Dr. Guillory introduced and turned the floor over to Ms. Mackenzie Spahn, DSHS Government Affairs, and Ms. Christy Havel, Deputy Chief Financial Officer. Ms. Spahn and Ms. Havel referenced the handout, *86th Legislative Session: DSHS Newborn Screening Program*.

Ms. Havel and Ms. Spahn stated:

- \$61.7 million was appropriated through House Bill (HB) 1 and Senate Bill (SB) 500 for all costs in the lab that will also support Newborn Screening.
 - The laboratory shortfall of \$17.5 million was fully funded.
 - \$7.9 million was provided for X-linked Adrenoleukodystrophy (X-ALD) startup.
 - Funding for a new laboratory emergency generator was obtained.
 - Funding for salary increases to help decrease staff turnover and retain qualified staff.
- SB747/SB748 creates a Newborn Screening Preservation Account.

- Funding approved to initiate startup implementation of adding new conditions to the Newborn Screening panel.
- Requires reporting to the legislature on the implementation of adding the new screening tests and how the funds are used.
- Not to be used for general operating expenditures.
- Electronic Parental consent for Newborn Screening was not funded.
- DSHS will recognize and promote Sickle Cell Disease Awareness every September for 10 years.

Members discussed:

- Newborn Screening Preservation Account funded by unspent funds from Medicaid reimbursements for newborn screening tests.
 - Payments from Medicaid for Newborn Screening funds DSHS State Hospitals.
- How Newborn Screening can keep 100% of the Medicaid money.
- While general revenue (GR) money needs to be spent within two years, the funds deposited in the preservation account will accrue.
 - The account accrues interest.
 - Preservation account can pay for new staff required for startup.
- Adding a system for storage of electronic parental consent records as a future agenda item.
- Outpatient hearing results with parental consent will be referred to the Texas School for the Deaf (TSD). Ultimately, the primary care provider will be responsible, and the audiologist will make the final diagnosis. HHSC Early Childhood Intervention (ECI) referrals are made for 'did not pass' screens.

Public Comment: Dr. Barbra Novak, Texas Children's Hospital, stated the outpatient screening is different with the Neonatal Intensive Care Unit (NICU) population. There are two different care paths for NICU babies versus well babies. Once a baby in the NICU fails an initial screening, they are immediately referred for a diagnostic evaluation. Dr. Novak stated as soon as a well-baby fails the outpatient screening, an ECI referral is made. Dr. Novak stated her concern is for the parents having stress over the automatic referral to TSD.

Agenda Item 6: Newborn Hearing Screening in Neonatal Intensive Care Unit (NICU)

Dr. Guillory introduced and turned the floor over to Dr. Tiffany McKee-Garrett, Subcommittee Chair, and Dr. Barbra Novak, Audiology Clinical Specialist and Newborn Hearing Program Manager, Texas Children's Hospital.

Dr. McKee-Garrett stated the subcommittee did not meet this last quarter but had requested Dr. Novak provide an update to the full committee on the ongoing pilot study at Texas Children's Hospital implementing the subcommittee's proposed recommendations for hearing screening in the NICU. 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.*

Members discussed:

- Dr. Novak will look at data on false positives occurring for babies on respiratory support/mechanical ventilation by reviewing follow-up diagnostic results for babies further tested for hearing loss.
- Critically ill babies are not being excluded from the study, only from the specific timeline criteria for the workflows.
- Working with organizations to include specifics on 0- to 3-month old babies in their recommendations and guidelines for screening for hearing loss.
- DSHS will consider collaborating/partnering with the Newborn Screening Advisory Committee regarding publication of the pilot study results.

Public Comment: Dr. Terese Finitzo from OZ Systems thanked Dr. Novak for providing a research-driven answer for NICU screening.

Agenda Item 7: X-ALD Implementation Update

Dr. Guillory introduced and turned the floor over to Dr. Rachel Lee, DSHS, Manager, Microbiological Sciences Branch.

Dr. Lee stated:

- The fee increase is estimated to be \$5 to \$6 per specimen effective January 2020. The announcement will be posted at least 90 days before the effective date.
- Grand Rounds will be held July 31, 2019.
- X-ALD Stakeholder meeting will take place July 26, 2019.
- Clinical Care Coordination
 - Updated laboratory information management system
 - Scheduled X-ALD training by a genetic counselor from Texas Children's Hospital
 - Finalized and published ACT and FACT sheets
 - Finalized provider letters
- Laboratory
 - Equipment has been converted for the first-tier of X-ALD screening
 - Validation plans were submitted and approved
 - Training is still in process
 - DSHS DNA Laboratory will provide third-tier DNA testing for X-ALD
- Main issue is purchasing process causing delays in obtaining instruments and the maintenance contracts that need to be in place
 - X-ALD implementation date is planned for August 5, 2019

Members discussed:

- Genetic testing for families as a fee-for-service.

Agenda Item 8: Break

Dr. Guillory announced a 10-minute break.

Agenda Item 9: WORKING LUNCH: Newborn Screening for Biliary Atresia

Dr. Guillory reconvened the meeting at 12:40 p.m. and introduced then turned the floor over to Dr. Sanjiv Harpavat, Assistant Professor, Pediatrics-Gastroenterology, Baylor College of Medicine. Dr. Harpavat referenced the PowerPoint and handout, *Newborn Screening for Biliary Atresia*.

Members discussed:

- Direct bilirubin versus conjugated bilirubin.
- Using artificial intelligence and web applications to identify biliary atresia.
- The DSHS laboratory's participation in Dr. Harvapat's study
- Not having enough long-term data that supports newborn screening for biliary atresia.

MOTION: Dr. Gong made a motion for the Newborn Screening Advisory Committee to fully support efforts to find a way for newborn screening of biliary atresia in Texas. Dr. Joseph Schneider seconded the motion. 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 10: Critical Congenital Heart Disease (CCHD) Subcommittee Reporting

Dr. Guillory turned the floor over to Dr. Tiffany McKee-Garrett, Subcommittee member presenting on behalf of Dr. Scott McLean, Subcommittee Chair. Dr. McKee-Garrett referenced the handout, *Newborn Screening Advisory Committee CCHD Subcommittee Meeting Minutes May 31, 2019*.

Members discussed:

- Dr. Donna Goff, Pediatric Cardiologist, Memorial Hermann-Texas Medical Center, to serve as a subject matter expert (SME) of the subcommittee.
- Exploring a simpler way to report CCHD versus the form on the DSHS website that is being used now.

MOTION: Dr. Michael Speer made a motion to table the motion for the full committee to support the two recommendations of the CCHD subcommittee. Dr. Joseph Schneider seconded the motion. 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 11: Newborn Screening Consultants Fees Subcommittee Reporting

Dr. Guillory turned the floor over to Dr. Schneider, Subcommittee member presenting on behalf of Dr. Scott McLean, Subcommittee Chair. Dr. Schneider

referenced the handout, *Newborn Screening Consultant Fees Subcommittee Meeting Minutes June 27, 2019*.

Agenda Item 12: Sickle Cell Subcommittee Reporting

Dr. Guillory introduced and turned the floor over to Dr. Titilope Fasipe, Subcommittee Co-Chair. Dr. Fasipe referenced the handout, *Newborn Screening Advisory Committee Sickle Cell Subcommittee Meeting Minutes May 30, 2019*.

Members discussed:

- Prepared implementation plans for the task force
 - HHSC expected to delegate DSHS as the agency responsible for formation of the task force.

Agenda Item 13: Texas Newborn Screening Panel Presentation-Current/Future Considerations

Dr. Guillory introduced and turned the floor over to Dr. Debra Freedenberg, Medical Director and Dr. Susan Tanksley, Laboratory Operations Unit Manager. Dr. Freedenberg and Dr. Tanksley referenced the PowerPoint and handout, *Texas Newborn Screening Panel Current and Future Considerations*.

Members discussed:

- Each state can decide which diseases they screen for. Newborn screening is a state-based program and not required to do what is on the federal Recommended Uniform Screening Panel (RUSP).
- Other states have added mandatory screening for some non-RUSP conditions.

Agenda Item 14: Abnormal Congenital Hypothyroid Screens Presentation

Dr. Alice Gong introduced and turned the floor over to Dr. Tina O. Findley, Assistant Professor, Pediatrics, The University of Texas McGovern Medical School. Dr. Findley referenced the PowerPoint and handout, *Newborn Screening of Congenital Hypothyroidism and Rates of True Cases in Premature Infants*.

Members discussed:

- ACT and FACT sheets include recommendations regarding abnormal thyroid levels.
- Normal screening results that later change and how diagnosis of true congenital hypothyroidism can still be made later in a baby's lifespan.
- Testing for premature babies is most effective in detecting congenital hypothyroidism.
- Ongoing project looking at birth weight versus age at the time of collection.
- Hypothyroidism being treated with medication for first three years of life, then thyroid levels checked to determine if patient needs further treatment.

ACTION ITEM: Dr. Findley will gather data for the Advisory Committee regarding how hypothyroidism cases may be missed.

Agenda Item 15: Future Conditions Status Updates

Dr. Guillory turned the floor over to Dr. Lee, DSHS, Manager, Microbiological Sciences Branch.

Dr. Lee stated:

- The laboratory has been looking at SMA screening that includes first-tier and second-tier testing.
 - Currently evaluating vendor kits
- Purchased reagents for testing
- Can request additional funding (up to \$12 million) from the legislative budget board and governor for new disorder implementation in the next biennium
- For SMA, the laboratory will purchase supplies and equipment, validate methods, hire new staff, and upgrade the laboratory information management system. In addition, if funds are used, there is a required report for the legislature.
- The goal is to implement screening for SMA in January 2021.
- Implementation tracker started for conditions on the Recommended Uniform Screening Panel but not yet on the Texas panel.
- The laboratory is updating equipment to create more space for adding new instruments to screen for lysosomal storage disorders.
- At this time, there is no definitive date for screening for future conditions Pompe and Mucopolysaccharidosis Type 1 (MPS-1)

Agenda Item 16: Public Comment

No public comment was made.

Agenda Item 17: Future Agenda Items/ Next Meeting Date

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

Members discussed:

- Reviewing most efficient methods available for CCHD Screening reporting
- False positive data in hearing screening in NICU pilot study
- Review of Medicaid funds distributed outside of the Newborn Screening program
- Letter supporting efforts of matching records with vital statistics data

The program will poll members for a date for the next meeting.

Agenda Item 18: Adjournment

Dr. Guillory adjourned the meeting at 4:16 p.m.

Webcast: <https://texashhsc.swagit.com/play/07122019-728>