

**Newborn Screening Advisory Committee
Meeting Minutes
January 23, 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, January 23, 2019 meeting.

| MEMBER NAME | YES | NO | MEMBER NAME | YES | NO |
|------------------------------|-----|----|--------------------------------|-----|----|
| Beryl (Pam) Andrews | X | | Tiffany McKee-Garrett, M.D. | X | |
| Nancy Beck, M.D. | P | | 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. | X | |
| Alice Gong, M.D. | X | | Elizabeth (Kaili) Stehel, M.D. | P | |
| 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, January 23, 2019 meeting.

| GUEST NAME/ORG. | YES | NO | GUEST NAME/ORG. | YES | NO |
|--------------------------------------|-----|----|---|-----|----|
| Jeremy Crabb, Sentido Health | x | | Benna Timperlake, Deaf & Hard of Hearing Center | x | |
| William Atallah, Sentido Health | x | | Xingwang Fang, Thermo Fisher Scientific | x | |
| Tiffany Britton, Caddo Associates | x | | Marsha Zimmerman, AMDA | x | |
| Kellie Dees, Texas Pediatric Society | 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.

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.

Dr. Guillory requested Committee members and members of the public introduce themselves.

Agenda Item 3: Review and Approve Meeting Minutes for October 19, 2018

Ms. Gutierrez requested a motion to approve the October 19, 2018 meeting minutes.

MOTION: Dr. Michael Speer made a motion to approve the October 19, 2018 meeting minutes. 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 or abstentions.

Agenda Item 4: Sickle Cell Advisory Committee 2018 Annual Report Recommendations

Dr. Guillory introduced and turned the floor over to Dr. Melissa Frei-Jones and Dr. Titilope Fasipe.

Dr. Frei-Jones gave background information of the Sickle Cell Advisory Committee and discussed the five recommendations made from the Sickle Cell Advisory Committee. Dr. Frei-Jones referenced the handout, *2018 Sickle Cell Advisory Committee Final Report*.

Mr. David Martinez, DSHS, Newborn Screening Unit Manager, stated the 2018 Sickle Cell Advisory Committee report will be reviewed by Executive Council on February 21, 2019 at 10:00 a.m.

Members discussed:

- National efforts for Sickle Cell
- Gaps in registries after the newborn screen
- The process of what the Executive Council will do with the recommendations
- Medical therapy funding for Sickle Cell
- Sickle Cell patients going to primary care doctors to obtain referrals
- Continuing the work the Sickle Cell Advisory Committee has started

MOTION:

Dr. Guillory made a motion to create a Sickle Cell Subcommittee. Dr. Alice Gong 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 or abstentions.

Dr. Frei-Jones and Dr. Fasipe will co-chair the Sickle Cell Subcommittee.

ACTION ITEM: Ms. Aimee Millangue will provide the 2018 Sickle Cell Advisory Committee Final Report to members.

Agenda Item 5: Legislative Updates

Dr. Guillory introduced and turned the floor over to Ms. Rachael Hendrickson, DSHS, Manager, Government Affairs Unit.

Ms. Hendrickson introduced Ms. Christy Havel, DSHS, Deputy Chief Financial Officer.

Ms. Hendrickson, Ms. Havel, and members discussed:

- Future funding for Newborn Screening
 - \$8 million yearly shortfall
 - Additional \$1 million shortfall for lab
 - New federal guidelines restricts previous source of funding from covering shortfall
 - Requesting \$17.6 million for Newborn Screening and lab operations
 - Instability of budget limits addressing implementation of future conditions and issues with test kit billing system
 - Appropriating Medicaid reimbursement revenue from new conditions into revolving fund instead of relying on appropriations from general revenue funding may help toward self-sustainability
- House Bill 1 and Senate Bill 1
 - Both bills were filed
 - Both bills have the base amount of funding as in previous years
 - The house bill has funds to include implementation of X-ALD but does not account for the revenue
 - The house and senate bills are requesting 1.6 billion over the biennium

Mr. Martinez reminded members their recommendations go to Dr. John Hellerstedt, DSHS Commissioner, rather than the legislature.

MOTION: Dr. Joseph Schneider made a motion that the committee request from the state an amount it would take to implement fully all existing diseases, which are not on the Texas panel, within a two-and-a-half year time frame to be used in the current legislative period effectively. Dr. Gong 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 or abstentions.

ACTION ITEM:

- Ms. Hendrickson will provide the estimated amount necessary to get the laboratory up to date to include all four diseases and what it costs to implement screening.
- Ms. Hendrickson will provide a timeline of when diseases could be added to the screening panel.

Agenda Item 6: NBS Medicaid Funding

Ms. Hendrickson continued discussion and blended both her presentations on Legislative Updates and NBS Medicaid Funding. Please see Agenda Item 5.

Agenda Item 7: Status of Parental Refusal/Consent Form

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

Ms. Lee reviewed the form with members and referenced the PowerPoint and handout, *Parental Refusal-Consent Form*.

Members discussed:

- Making a Spanish video
- Creating QR code linking to a Spanish video
- Removing the QR code for the English video off of the Spanish form

Agenda Item 8: Break

Dr. Guillory announced a 15-minute break.

Agenda Item 9: NBS 2016 Consultants Survey-Telephone Consultations

Dr. Guillory reconvened the meeting at 12:36 p.m. and turned the floor over to Dr. Debra Freedenberg, DSHS, Medical Director Newborn Screening Unit and Dr. Joseph Ray, Director, Division of Medical Genetics at University of Texas Medical Branch Galveston.

Dr. Freedenberg referenced the PowerPoint and handout, *NBS 2016 Consultants Survey*.

Dr. Freedenberg gave background information regarding the Consultants Survey and turned the floor over to Dr. Ray.

Dr. Ray introduced Dr. Erin Cooney, Assistant Professor of Pediatrics at University of Texas Medical Branch Galveston and Ms. Danielle Vice, Dietitian, Newborn Screen Coordinator at University of Texas Medical Branch Galveston. Dr. Ray, Dr. Cooney and Ms. Vice referenced the PowerPoint and handout, *Assessment of the Need for Funding Support of Newborn Screening Follow-Up Services for Metabolic Disorders in Texas*.

Members discussed:

- Complexities of telephone consultation billing
- Metabolic data from Metabolic Consultation Centers
- Recognizing the broader spectrum of newborn screening
- Workforce shortage of geneticists being a nationwide issue
- Solutions for reimbursement/payment for consultation

MOTION: Dr. Guillory made a motion to create a subcommittee to look at the issue regarding how to handle presumptive positive results by consultants and identify processes as well as researching possible funding. Dr. 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 or abstentions.

Members of the subcommittee:

- Dr. Scott McLean - Chair
- Ms. Beryl (Pam) Andrews
- Dr. Nancy Louise Beck
- Dr. Melissa Frei-Jones
- Dr. Joseph Schneider

Agenda Item 10: Break

Dr. Guillory announced a 5-minute break.

Agenda Item 11: X-ALD Screening Implementation

Dr. Guillory reconvened the meeting at 2:21 p.m. and turned the floor over to Dr. Lee. Dr. Lee referenced the PowerPoint and handout, *X-ALD Screening Implementation*.

Members discussed:

- The timeframes for testing and reporting
- Second screen testing particularly for abnormal results
- DNA testing

Agenda Item 12: Algorithm for linking 1st and 2nd screens

Dr. Guillory introduced and turned the floor over to Mr. Brendan Reilly, DSHS Laboratory Staff.

Mr. Reilly referenced the PowerPoint and handout, *1st and 2nd Screens*.

Members discussed:

- Process and cost for linking the two screens
- How normal results are provided to physicians
- How are missing specimens determined
- Linking birth records to newborn screening

ACTION ITEM: Mr. Reilly will provide an update on the effort of getting aggregate data on linking birth records to determine missing specimens when it is available.

Agenda Item 13: Rider 37 Subcommittee Reporting

Dr. Guillory turned the floor over to Dr. Schneider. Dr. Schneider stated the subcommittee will meet to review and approve the Rider 37 letter.

Agenda Item 14: Newborn Hearing Screening in Neonatal Intensive Care Unit (NICU) Subcommittee Reporting

Dr. Guillory turned the floor over to Dr. McKee-Garrett. Dr. McKee-Garret stated the subcommittee did not meet. However, Texas Children's Hospital conducted a pilot of the proposed algorithm of screening babies in the NICU. 149 patients were screened in the NICU, 50 of those patients were in NICU for one month, and 18 of the patients were referred.

At the next subcommittee meeting, members will discuss the results of the pilot and how to implement this algorithm for Texas.

Agenda Item 15: Critical Congenital Heart Disease (CCHD) Subcommittee Reporting

Dr. Guillory stated the subcommittee is looking at all birthing hospitals in the state to determine how many are conducting screenings, what algorithm is being used, and what method is being used for reporting positive screens to the state.

Agenda Item 16: Screened conditions status updates

Dr. Guillory turned the floor over to Dr. Lee. Dr. Lee referenced the PowerPoint and handout, *Screened Conditions Status Updates*.

Members did not have a discussion.

Agenda Item 17: Future conditions implementation updates

Dr. Guillory announced the agenda item for the record and turned the floor back over to Dr. Lee. Dr. Lee referenced the PowerPoint and handout, *Future Conditions Implementation Updates*.

Members did not have a discussion.

Agenda Item 18: Public Comment

No public comment was made.

Agenda Item 19: Future Agenda Items/ Next Meeting Date/Adjournment

Dr. Guillory noted an email sent to members regarding the next meeting date and the importance of members responding. Dr. Guillory also stated the subcommittee chairs need to coordinate with the state for meeting dates. Dr. Guillory opened the floor for discussion.

Members discussed:

1. Dr. Freedenberg will provide a report on the clinical care coordination follow up process
2. Dr. Barbra Novak, Texas Children's Hospital to present on hearing screening in the NICU

3. Discuss the cost and time estimated to fully implement all four newborn screens not yet added to the Texas NBS panel
4. The DSHS Laboratory will identify the top five items needed to reach 100% automated matching of 1st and 2nd screens
5. Update of the Parental Refusal Consent form
6. Standing items

Dr. Guillory adjourned the meeting at 3:59 p.m.

Webcast: <https://texashhsc.swagit.com/play/01232019-1736>