

**Newborn Screening Advisory Committee
Meeting Minutes
October 8, 2021
11:30 a.m.**

Location: Microsoft Teams Live Event

Table 1: Newborn Screening Advisory Committee attendance Friday, October 8, 2021.

MEMBER NAME	IN ATTENDANCE
Kaashif Ahmad, M.D., M.Sc.	No
Beryl (Pam) Andrews	Yes
Khrystal Davis, J.D.	Yes
Titilope Fasipe, M.D., Ph.D.	No
Melissa Frei-Jones, M.D.	Yes
Alice Gong, M.D.	Yes
Charleta Guillory, M.D., M.P.H.	Yes
Tiffany McKee-Garrett, M.D.	Yes
Barbra Novak, Ph.D., C.C.C.-A.	Yes
Joseph Schneider, M.D.	Yes
Fernando Scaglia, M.D.	Yes
Michael Speer, M.D.	Yes
Elizabeth (Kaili) Stehel, M.D.	Yes

Agenda Item 1: Welcome, introductions, and logistical announcements

Dr. Alice Gong, Chair of the Newborn Screening (NBS) Advisory Committee, convened the meeting at 11:30 a.m. and welcomed everyone in attendance. Dr. Gong introduced Mr. Eric Owens, Health and Human Services Commission (HHSC), Policy & Rules, Advisory Committee Coordination Office. Mr. Owens reviewed logistical announcements, called roll, asked members to introduce themselves, and determined a quorum was present.

Agenda Item 2: Consideration meeting minutes for July 23, 2021

Mr. Owens requested a motion to approve the July 23, 2021 meeting minutes.

MOTION: Dr. Speer made a motion to approve the July 23, 2021 meeting minutes. Dr. Schneider seconded the motion. Mr. Owens conducted a roll call vote, and the motion carried with 10 approves, no objections or abstentions.

Agenda Item 3: Orientation

Ms. Shannon Brown, HHSC Legal Counsel, provided an overview of the Open Meetings Act (OMA) and referenced the PowerPoint, *Open Meetings Act and Public Information Act (PIA)*.

Highlights of the presentation included:

- Government code
- Quorum
- OMA
- Open and closed meetings
- Required training
- PIA
- Examples and questions and answers when conducting meetings under the OMA and PIA
- Guidance on requirements for open meetings, using video conference, and resources.

Members discussed:

- Retention of meeting notes

Mr. Owens turned the floor over to Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit and Susan Tanksley, Ph.D., Laboratory Operations Unit Manager, DSHS Laboratory. Dr. Freedenberg and Dr. Tanksley provided an overview of the administrative program area and support for committee and referenced the PowerPoint and handout, *Newborn Screening in Texas*.

Highlights of the presentation included:

- Newborn Screening (NBS) System
- Goals of Texas NBS Program
- Types of Kits
- Parent Decision Form
- Courier Services
- The Logistics of Newborn Screening in Texas
- Clinical Care Coordination (CCC) Organization Chart
- Finding the Medical Provider
- Finding the Family
- Sickle Cell Trait Notification
- Long Term Follow-Up
- NBS Support Group
- Advisory Committees
- System Stakeholders
- NBS/Genetics Educational efforts

Members discussed:

- Status of implementation of electronic ordering and reporting
- Including the Texas Pediatric Society among stakeholders
- Timing and receiving of specimens due to pick up by FedEx
- Long term follow up for hyperkalemia an anemia

Mr. Owens turned the floor over to Mr. John Chacón, HHSC, ACCO Facilitator, to review Advisory Committee Coordination Office support for the committee.

Highlights of the presentation included:

- Establishment of ACCO
- Support functions relating to how ACCO supports the committee
- Webcasting/virtual live streaming protocols
- Complying with the OMA while conducting virtual meetings during the COVID-19 pandemic
- Guidance for operations and decision making
- HHS enterprise policy establishes the guidelines that covers staff responsibilities, communication of activities and internal requirements for appointment of members to advisory committees.
- Public Comment
- Bylaws
- Guidance for subcommittees
- Best practices for communicating by email
- Definitions

Members did not have a discussion regarding this presentation.

Mr. Owens turned the floor over to Mr. David Reisman, Chief Ethics Officer. Mr. Reisman provided an overview of the HHS Ethics Policy as it relates to HHS Advisory Committees and referenced the PowerPoint and handout, *Ethics Advisory Committee Talking Points*.

Highlights of the presentation included:

- Representation
- Disclosure
- Honoraria
- Prohibition on lobbying
- Bribery
- Confidential information
- Misuse of government property
- Conflicts of interest
- Open Meetings Act/Public Information
- Public servants

Members did not have a discussion regarding this presentation.

Agenda Item 4: Presiding Officer Election

Mr. Owens read the Adoption of Procedure for Election of Officers and Officer Election Process in its entirety to members.

MOTION: Dr. Michael Speer made a motion to adopt the Procedure for Election of Officers. Dr. Joseph Schneider seconded. Mr. Owens conducted a roll call vote, and the motion carried with no objections and no abstentions.

After the adoption of the Procedure for Election of Officers, Mr. Owens opened the floor to nominations for Chair. Mr. Owens read for the record members who have been nominated and accepted their nomination through email prior to the meeting.

Nominees who have accepted their nomination for Chair:

- Dr. Michael Speer

No other nominations were made, and nominations were closed. Dr. Speer informed members of his qualifications for the presiding office. Mr. Owens then conducted a roll call vote to approve the election of Dr. Michael Speer for Chair. Members voted to approve the election of Dr. Michael Speer with 9 approves, no disapproves, and 1 abstention.

Mr. Owens read for the record members who have been nominated and accepted their nomination through email prior to the meeting.

Nominees who have accepted the nomination for Vice Chair:

- Dr. Melissa Frei-Jones

Mr. Owens opened the floor to nominations for Vice Chair. Dr. Charleta Guillory nominated Dr. Tiffany McKee-Garrett for Vice Chair, and Dr. McKee-Garrett accepted the nomination. No other nominations were made, and nominations were closed. Mr. Owens gave the nominees two minutes to each offer a qualifications speech. After nominees gave their qualifications speeches, Mr. Owens conducted a roll call vote for the election of Chair.

Vote for Vice Chair Tally:

- Dr. Melissa Frei-Jones was voted for by:
 - Dr. Alice Gong
 - Dr. Tiffany McKee-Garrett
 - Dr. Joseph Schneider
 - Dr. Elizabeth Stehel
 - Dr. Fernando Scaglia
- Dr. Tiffany McKee-Garrett was voted for by:
 - Ms. Khrystal Davis
 - Dr. Charleta Guillory
 - Dr. Barbra Novak
- Abstentions:
 - Dr. Melissa Frei-Jones
 - Dr. Michael Speer

Mr. Owens announced the new Vice Chair, Dr. Melissa Frei-Jones. Dr. Frei-Jones was congratulated and gave an acceptance speech. Dr. McKee-Garrett offered a concession speech. Mr. Owens advised that Ms. Aimee Millangue will contact the new Chair and Vice Chair to discuss the agenda for the next meeting. Dr. Gong announced that since this is her last meeting as Chair, she is available to members if they need it.

Agenda Item 5: Spinal Muscular Atrophy (SMA) screening implementation update

Dr. Gong introduced Susan Tanksley, Ph.D., Laboratory Operations Unit Manager, DSHS Laboratory and Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit. Dr. Tanksley and Dr. Freedenberg referenced the PowerPoint and handout, *Texas NBS Spinal Muscular Atrophy (SMA) Case Update, June 1st 2021- August 18th 2021.*

Highlights of the presentation included:

- 4 SMA cases identified
 - 1st screen abnormal (exon 7 deletion SMN1) with 2 copies of SMN 2
 - Older sibling Diagnosed with SMA
 - Confirmed Clinical and Molecular Diagnosis
 - 1st screen abnormal (exon7 deletion SMN1) with 1 copy SMN2
 - Confirmed clinical and molecular diagnosis
 - 1st screen abnormal (exon 7 deletion SMN1) with 2 copies of SMN 2
 - Confirmed clinical and molecular diagnosis
 - 1st screen abnormal (exon 7 deletion SMN1) with 3 copies of SMN 2
 - Confirmed clinical and molecular diagnosis

Members discussed:

- Not knowing long term outcomes of treatments such as gene therapy
- Long-term follow up of cases
- A case identified clinically with an SMA variant that is not picked up through the SMA newborn screen
- Cases identified clinically and not through a newborn screening test still need to be reported to the NBS program by law if condition is identifiable through NBS testing

Agenda Item 6: Screened conditions status updates

Dr. Gong introduced Susan Tanksley, Ph.D., Laboratory Operations Unit Manager, DSHS Laboratory, Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit and Karen Hess, Genetics Branch Manager, DSHS Newborn Screening Unit. They referenced the PowerPoint and handout, *Texas NBS X-Linked Adrenoleukodystrophy (X-ALD) Case Update, August 2019 – September 2021.*

Highlights of the presentation included:

- 25 Males Hemizygous Affected
 - 18 - both screens Abnormal
 - 4 - 1st screen Abnormal and 2nd screen normal
 - 1 - no first screen for X-ALD (due to starting of testing) 2nd screen abnormal
 - 1st screen normal 2nd and 3rd screen Borderline
 - 1st screen Abnormal 2nd screen Borderline
 - 1st and 2nd screen Borderline

- 15 Female Heterozygotes
 - 7 - both screens abnormal
 - 3 - 1st screen abnormal, 2nd screen normal
 - 1 - 2 normal screen, 3rd screen abnormal
 - 1st screen abnormal, 2nd screen normal, 3rd screen abnormal
 - Both screens borderline
 - 2-1st screen normal, 2nd and 3rd screens borderline
- CADD (Contiguous ABCD1 DXS1357E deletion syndrome) – 1 Case
 - 1 - Male 3 Abnormal screens
- Heterozygote Klinefelter– 1 Case
 - 1 – 1st screen normal, 2nd and 3rd Screens Borderline
- Zellweger Syndrome – 7 Cases, 1 Carrier
 - 4 - Male both screens Abnormal
 - Male Normal 1st screen, 2nd Abnormal
 - 2 - Female both screens Abnormal
 - 1 - Female Carrier, 1st screen Normal, 2nd screen Abnormal
- Peroxisome Disorders – 2 Cases
 - 1-Peroxisomal Biogenesis Disorder, Female with 2 Abnormal screens
 - 1-D-Bifunctional Protein Deficiency, Female with 2 Abnormal Screens

Members discussed:

- If Texas has identified other conditions from abnormal X-ALD screens

Agenda Item 7: Future condition implementation updates

Susan Tanksley, Ph.D., Laboratory Operations Unit Manager, DSHS Laboratory, and Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit provided an update on future condition implementation updates and referenced the PowerPoint and handout, *Future Disorders*.

Highlights of the presentation included:

- Status of conditions on Recommended Uniform Screening Panel (RUSP) not yet on Texas NBS Panel
 - Pompe
 - Approved for addition to the RUSP in March 2015
 - Mucopolysaccharidosis Type I (MPS-I)
 - Approved for addition to the RUSP in February 2016
 - No funding is currently available for implementation
 - Estimated cost to implement: ~\$10M
 - Estimated ongoing annual cost: > \$9M
- Conditions under consideration for addition to the RUSP
 - In evidence review:
 - Mucopolysaccharidosis Type II (Hunter’s Syndrome)
 - Guanidinoacetate Methyltransferase Deficiency (GAMT)
 - Nomination under review:
 - Krabbe disease
- Many conditions coming down the pike such as Cytomegalovirus (CMV) and Duchenne muscular dystrophy (DMD)

- A Public Health Impact Assessment is now part of the process for consideration of a condition to be added to the RUSP
- A public health impact assessment survey on MPS II is being conducted and will be shared with the committee and specialists who will be impacted
 - In order to determine impact, the following background information is given:
 - Screening methods
 - Rate of referrals
 - Data from other states already screening for MPS II
 - Some of the questions being asked:
 - Challenges of MPS II implementation in the state such as availability for treatment for MPS II
 - If testing was authorized and funding for testing and follow up was available:
 - Which following resource needs are available:
 - Access to appropriate diagnostic services after an abnormal or out of range screening result is reported (e.g., diagnostic testing, clinical evaluations)
 - Specialists to cover expected MPS II caseload
 - Treatment centers for expected MPS II caseload
 - The degree to which the following factors may impede or facilitate adoption of MPS II screening in the state:
 - Estimated cost of treatment for newborns diagnosed with MPS II
 - Expected clinical outcomes of newborns identified by screening
 - Expected cost-benefit of screening in your state
 - Advocacy for screening for MPS II
 - Most significant barrier(s) to screening for MPS II in the state
 - What would most facilitate screening for MPS II in the state?
 - Are there any special considerations regarding MPS II that need to be taken into account when assessing the impact on the public health system? (e.g., variants of unknown significance, pseudodeficiencies, age of onset, access to specialists, access to treatment, cost of treatment, etc.)?

Members discussed:

- If funding is available in the NBS Preservation account to implement conditions on the RUSP but not on the Texas NBS panel
- Estimate of when testing could be implemented once funding is available
- Feasibility of pursuing possible federal opportunities for funding
- Possibility of outsourcing testing
- Status of the Advisory Committee on Heritable Disorders, which has been reconstituted as a discretionary committee in the interim
- Availability of treatments and specialists for MPS II in Texas

- Possible barrier to MPS II testing due to known deletions in the gene and not being able to predict the severity of clinical phenotype and onset
- If same instruments can be used to diagnose MPS I and MPS II
- Program staff should not answer questions from members of the public during the meeting if those members are not registered for public comment or are not present in person. Staff can answer questions at a later date.

Agenda Item 8: Continuity of Operations Plans

Dr. Gong announced that this agenda item is tabled to the next meeting.

Agenda Item 9: Critical Congenital Heart Disease (CCHD) Subcommittee Reporting

Dr. Gong stated that the subcommittee has concluded their work unless Dr. Speer has something to add. The committee sent a recommendation letter to Dr. Hellerstedt for The Texas Collaborative for Healthy Mothers and Babies (TCHMB) and Regional Advisory Councils to take on CCHD as a quality improvement project, and the program was not able to put in rules to specify cardiologists are responsible for reporting.

Dr. Speer stated that he will keep an eye on its progress through TCHMB and will bring back information as it becomes available.

Dr. Gong stated that subcommittees are not doing their own minutes, and they are relying on Ms. Millangue to do them, which is not in the bylaws. Chairs of the subcommittees, or someone who is appointed, are responsible for doing their own minutes and subcommittee reports.

Agenda Item 10: Hearing Screening in Neonatal Intensive Care Unit (NICU) Subcommittee Reporting

Dr. Gong introduced Tiffany McKee-Garrett, M.D., Subcommittee Chair. Dr. Gong stated that the subcommittee's business has been closed out. They have developed the algorithm and sent the letter to Dr. Hellerstedt suggesting that the state help get that implemented as a quality improvement project.

Dr. McKee-Garrett asked if any of the subcommittee members on the call have anything to add, and if so, they will update the committee as needed.

Dr. Guillory stated that same algorithm went to Texas Pediatric Society as well.

Agenda Item 11: Sickle Cell Subcommittee Reporting

Dr. Gong introduced, and turned the floor over to, Titilope Fasipe, M.D., Ph.D., and Melissa Frei-Jones, M.D., Subcommittee Co-Chairs. Dr. Fasipe and Dr. Frei-Jones referenced the handout, *Sickle Cell Subcommittee Meeting Minutes*.

Highlights of the presentation included:

- The subcommittee met virtually on September 21st. Unfortunately, she was unable to attend.
- Dr. Fasipe led the meeting, and Dr. Stehel and Dr. Speer were present
- Subcommittee members discussed:
 - ACT and FACT sheets
 - Hemoglobinopathy specialist lists
 - Creation of a survey to send out to specialists to identify providers who care for adults with sickle cell disease
 - Update on the Sickle Cell Task Force
- A virtual Hemoglobinopathy meeting took place to for doctors in the state of Texas that see the infants that have positive newborn screening for Hemoglobinopathy disorders

Members did not have a discussion regarding this agenda item.

Agenda Item 12: Health Information Technology (HIT) Subcommittee Reporting

Dr. Gong introduced and turned the floor over to Joseph Schneider, M.D., Subcommittee Chair. Dr. Schneider referenced the handout, *Health Information Technology Subcommittee Meeting Minutes*.

Highlights of the presentation included:

- Met on September 17th
- Minutes were in packet for review that covered what happened in the subcommittee meeting
- The program has drafted a memorandum of understanding (MOU) to get access to retrospective vital statistics data for retrospective analysis but doesn't include that core use case.

MOTION: Dr. Schneider made a motion that the committee request the staff to add to the draft memorandum to get vital statistics data to identify missing newborn screens in a timely fashion.

Dr. Tanksley stated she would like to caution this motion because the laboratory is working on the MOU to get access to data so to take over the Medicaid matching for the purpose of reimbursement. The laboratory really needs the MOU to move forward.

Members discussed

- Retrospective analysis of retrospective vital statistics does not solve the problem of identifying missing newborn screens in a timely fashion
- Medicaid matching process
- Availability of zip code data
- Issue with matching birthday to a birth certificate due to the turnaround window for registration of a new birth event

Dr. Schneider withdrew his motion.

ACTION ITEM: Dr. Tanksley will attend the next HIT Subcommittee meeting to give an update on the MOU process.

Agenda Item 13: Rare Diseases Subcommittee Reporting

Dr. Gong introduced, Ms. Khrystal Davis, Subcommittee Chair. Ms. Davis referenced the handout, *Rare Diseases Subcommittee Meeting Minutes*.

Highlights of the presentation included:

- Subcommittee met for the first time on September 22nd
- Dr. Sanjiv Harpavat provided an update on the progress for developing a newborn screening test for Biliary Atresia
- Subcommittee developed a charter, as directed by the Committee at their July meeting
 - Charter was restricted to future conditions
 - Subcommittee will monitor clinical trials and pilot studies to better prepare before conditions are included on the RUSP
- Subcommittee discussed:
 - Ability to recommend screening for conditions before they are considered for RUSP inclusion
 - Being able to address conditions brought up in public comment
 - Innovative diagnostics research and work being done in Texas
 - Continuance of care for rare disease patients who are identified through newborn screening programs
 - Recommending the implementation of a pilot project to screen patients for biliary atresia using prospective data from the NBS program
 - Statutory authority of the committee and the constraints in recommending conditions that are not yet included on the RUSP
 - Possibility of a presentation at a future subcommittee meeting from Dr. Amy Brower with the Newborn Screening Translational Research Network

Members discussed:

- Rare Diseases Subcommittee membership and composition

Agenda Item 14: Consideration of Bylaws

Dr. Gong provided an update to members regarding the status of an update to the bylaws.

Dr. Gong stated:

- Updates to the bylaws are still undergoing agency review, and consideration of the bylaws will be tabled until the next meeting.
- Will be introduced to committee at the next NBSAC meeting in January 2022.

Agenda Item 15: Public Comment

Mr. Owens read public comment logistical announcements and called on Ms. Alice McConnell to address members.

Ms. McConnell addressed members regarding how her family, like many families with rare genetic disorders that are not screened for as a part of newborn screening, had to go through a long and unnecessary diagnostic odyssey. She asked for the initiation of a voluntary prospective pilot screening program for Succinic semialdehyde dehydrogenase deficiency (SSADHD) in Texas and that the development of a systematic pilot screening program in Texas be added to the agenda for the next meeting.

Ms. Khrystal Davis stated that someone from the newborn screening staff or the Rare Diseases Subcommittee will reach out to Ms. McConnell about adding the topic to the agenda for the next meeting.

Mr. Owens next called on Ms. Natalie Owen to address members.

Ms. Owen stated she was a pediatric nurse practitioner who works in the division of genetics at Vanderbilt in Nashville, TN. She addressed the committee regarding a patient diagnosed in her clinic with MPS I, which was missed by newborn screening because she was born in Texas. Ms. Owen urged that MPS I be added to the Texas NBS panel.

Dr. Gong thanked Ms. McConnell and Ms. Owen for their comments.

Ms. Khrystal Davis suggested that someone from the newborn screening staff or the Rare Diseases Subcommittee also reach out to Ms. Owen to discuss MPS I at a future meeting.

Dr. Schneider commented on the number children might be missed before the implementation of MPS I in Texas.

Agenda Item 16: Future Agenda Items/ Next Meeting Date/ Adjournment

Dr. Gong opened the floor for discussion of future agenda items and stated the next meeting was scheduled for January 2022.

Members discussed:

- Hearing screening consent form update
- NBS Preservation account
- Follow up on interoperability of the 3 systems that were going live and status of the other 3
- Effect of whole genomics sequencing on newborn screening in Texas
- Status of pilot project for new algorithm for Congenital hypothyroidism
- Action Item follow-up list:
 - Screened conditions updates
 - Future conditions implementations updates
 - Subcommittee reports from:
 - Health Information Technology Subcommittee
 - Sickle Cell Subcommittee
 - Rare Disease Subcommittee

- Continuity of operations
- Bylaws
- Updated funding request for meeting timeliness goals and the estimated cost of a 7-day working lab, to include follow up care costs if babies are not screened
- Distribution of Medicaid funding from reimbursements

Ms. Millangue reminded members about completing required training every 5 years and asked new members to email if they are interested in joining any of the subcommittees.

Dr. Guillory thanked Dr. Gong for her work as Chair.

Dr. Gong thanked members and adjourned the meeting at 3:54 p.m.

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Below is the link to the archived video of the October 08, 2021 Newborn Screening Advisory Committee (NBSAC) that will be available for viewing approximately two years from date meeting was posted on website and based on the DSHS records retention schedule.

<https://texashhsc.new.swagit.com/videos/151536>