

**Newborn Screening Advisory Committee
Meeting Minutes
July 30, 2020
9:00 a.m.**

Location: Microsoft Teams Live Event

Table 1: Newborn Screening Advisory Committee attendance Thursday, July 30, 2020.

MEMBER NAME	IN ATTENDANCE
Beryl (Pam) Andrews	Yes
Nancy Beck, M.D.	Yes
Khrystal Davis, J.D.	Yes
Titilope Fasipe, M.D., Ph.D.	Yes
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
Scott McLean, M.D.	Yes
Joseph Schneider, M.D.	Yes
Michael Speer, M.D.	Yes
Elizabeth (Kaili) Stehel, M.D.	Yes
VACANT	

Table 2: Newborn Screening Advisory Committee attendance Thursday, July 30, 2020.

GUEST NAME and ORGANIZATION	IN ATTENDANCE
Sanjiv Harpavat, MD, Asst. Professor, Pediatrics-Gastroenterology, Baylor College of Medicine	Yes

Agenda Item 1: Welcome and Introductions

Dr. Alice Gong, Chair of the Newborn Screening (NBS) Advisory Committee, convened the meeting at 10:00 a.m. and welcomed everyone in attendance.

Agenda Item 2: Committee Business Logistics

Dr. Gong introduced, Ms. Sallie Allen, HHSC, Policy & Rules, Advisory Committee Coordination Office and she reviewed logistics announcements, called roll, and determined a quorum was present.

Agenda Item 3: Review and Approve Meeting Minutes for January 31, 2020

Ms. Allen requested a motion to approve the January 31, 2020 meeting minutes.

MOTION: Dr. Charleta Guillory made a motion to approve the January 31, 2020 meeting minutes with the amendments recommended to Agenda Item #5 and #12. Dr. Michael Speer seconded. A roll call vote was taken. Ms. Allen conducted a roll call vote, and the motion carried with no objections or abstentions.

Agenda Item 4: Newborn Screening for Biliary Atresia

Dr. Gong introduced, Dr. Sanjiv Harpavat, M.D., Ph.D., Assistant Professor Pediatrics-Gastroenterology, Baylor College of Medicine. Dr. Harpavat referenced the PowerPoint/handout, *Newborn Screening for Biliary Atresia*.

Highlights of the presentation:

- Biliary atresia (BA) is a disease that occurs in 1:10-18,000 children, and it's relatively prevalent.
- BA is the #1 reason for all transplants in Pediatrics.
- Early intervention of BA of less than 30 days is major factor for treatment.
- Performance of the Kasai operation (less than 30 days of onset) may produce better outcome and less need of a liver transplant
- Level of conjugated (or direct) bilirubin is a marker for how well bile is flowing out of the liver.
- BA screening fits well with heel sticks done by the state; with a 2-week follow-up test for conjugated bilirubin. Results are captured in advance of the 30-day mark, thus advanced evaluations can be performed.
- BA qualifies as a disease for which newborns should be screened.
- A BA newborn screening test has been developed in Texas.
- State-wide implementation is an opportunity for Texas to guide the nation in newborn screening for BA.
- Important considerations: Knowledge issues/clear instructions, infrastructure issues, and acceptability, reliability and reasonable cost of the test
- Big challenge is how can it be integrated into the infrastructure already existing in the Department of State Health Services.

Members discussed:

- No other marker of bilirubin metabolism known besides the conjugated bilirubin, and no marker known that can be measured through the blood. Other markers may be found, but not without developing new tests with additional costs.
- Not every facility uses the total and direct bilirubin; there is a huge movement to just do transcutaneous and others just do total bilirubin, so this is a system issue.
- Based on the data represented, if it is worth measuring a total and direct on all children to potentially prevent need for liver transplant.
- Consider enlisting an economist to look at the cost and benefits and design a plan to convince others that it would be worthwhile to pursue.

- Feasibility of and opportunity for using software applications, mobile phones, etc. as a quicker solution with testing the children.
- Once it's able to be done at a state level, setting the standard in Texas and letting the nation benefit from what Texas can provide.
- Thinking about how it would look in a new system, either as a part of a formal newborn screening system administered by the state, or a point-of-care test. If it was a standard form of care, how would that exactly work with the cost and benefits, and clinical utility, in terms of who is interpreting results and taking actions and looking at the quality, and deciding if a good job is being done.

Dr. Gong took a moment to recognize Dr. Scott McLean and advised everyone it would be his last meeting with the Committee. She expressed the Committee's appreciation for his service and contributions, and his leadership of two of the subcommittees, Critical Congenital Heart Disease (CCHD) and Newborn Screening Consultant's Fees.

Agenda Item 5: DSHS Technology Interoperability

Dr. Gong introduced, Mr. Steve Eichner, Health Information Technology Lead, Center for Health Policy and Performance, DSHS. Mr. Eichner referenced the PowerPoint handout, *Update on Health Information Technology and Interoperability*.

Highlights of the presentation:

- Interoperability is the ability of two or more systems to exchange and use information from other systems without special effort on the part of the user.
- Benefits in reducing data entry and improve data quality, reduce unnecessary tests by sharing patient test result information more efficiently and effectively in a timely manner
- Enables improvements in computer decision support systems
- Health Information Exchange (HIE) helps facilitate and transfer data between different standards and service repositories for information collected from different providers.
- Application programming interfaces (APIs) support instantaneous access to information in real-time
- Additional tools and resources include Electronic Case Reporting (eCR), Patient Unified Lookup System for Emergencies (PULSE), and MedMorph.

Members discussed:

- Question on the roles the Health Insurance Portability and Accountability Act (HIPAA) plays and if anyone can get a patient's records through the recent Acts that have been passed.
- An automated interface between laboratory results and birth registry does not currently exist to allow matching of birth records with newborn screening tests.

- Need to link systems for the birth registry and the 1st and 2nd screening in the newborn screening program to know who is not getting screened and then working on quality improvement so every newborn gets their screens.
- eCR can support a variety of reporting conditions, and there is flexibility in setting the criterion framework. DSHS is working with national framework that supports it and working to implement it.
- Recommendation to allow for follow-up of a child with a positive case in the electronic system to highlight the progress of test results.
- Need for a presentation to the subcommittee to review the state's plan for the future and the intention of the plan to give members an idea of when the newborn screening system will integrate with the birth registry system.
- The intent of the interoperability presentation was more a global view of the framework. DSHS is still working on overall technology planning.
- Plans for technology projects are limited by constraints such as funding.
- Recommend information be taken to the Health Information Technology subcommittee for review and develop what steps the full Committee can present to the agency as to how vital this interoperability is for Texas and Newborn Screening Program.
- DSHS will contact subject matter experts within the agency to meet with the subcommittee and provide some input.

Agenda Item 6: Spinal Muscular Atrophy (SMA) screening implementation update

Dr. Gong introduced, Dr. Susan Tanksley, Laboratory Operations Unit Manager, DSHS Laboratory.

Dr. Tanksley stated:

- DSHS received approval from the Legislative Budget Board (LBB) for funding of the SMA newborn screening implementation.
- Implementation scheduled for June 2021 using the existing infrastructure for the Severe Combined Immunodeficiency (SCID) screening.
- The LBB disapproved the appropriations request for a space utilization study and to add bioinformatics infrastructure. Both items would have provided support in the implementation of Pompe Disease and Mucopolysaccharidosis Type 1 (MPS-1).
- Development of an educational brochure is in the works,
- Once funding is received and Full Time Employees (FTEs) are approved, DSHS will proceed with hiring staff, purchasing equipment and reagents, and making required changes to the newborn screening Laboratory Information Management System (LIMS).
- A newborn screening fee increase is planned to coincide with the Medicaid healthcare providers contract changes, but the amount is not yet determined.

Dr. Debra Freedenberg, Medical Director, DSHS Newborn Screening Unit, stated that with funding from Association of Public Health Laboratories (APHL), the program will sponsor a technical assistance group to bring in experts and the pediatric neurologists around the state to help in designing an algorithm and follow-up protocols and provide their expertise.

Members discussed:

- Lab only has funding for the first and second tier.
- Lab anticipating second tier will provide enough information to begin implementation.
- Plans include bringing on third tier on at a later date after acquiring, validating and adding to the LIMS.

Agenda Item 7: Future condition implementation update

Dr. Gong introduced, Dr. Susan Tanksley, DSHS, Laboratory Operations Unit Manager.

Dr. Tanksley stated:

- There are plans to create space within existing laboratory space to house instrumentation needed to screen for additional disorders.
 - Lab has already switched platforms for screening for Galactosemia and Congenital Adrenal Hyperplasia (CAH).
 - Additional platform changes in works for screening for Congenital Hypothyroidism, Cystic Fibrosis, and Biotinidase Deficiency.

Members discussed:

- Estimated timeline of about 2023 before the implementation process for Lysosomal Storage Disorders, including Pompe and MPS-1, would start.

Agenda Item 8: Screened condition status updates

Dr. Gong introduced, Dr. Tanksley, DSHS, Laboratory Operations Unit Manager.

Dr. Tanksley stated:

- Changing the platform for screening for Congenital Hypothyroidism will allow lab to get new, more functional instruments and an opportunity to look at how it is screened.
- There is a high prevalence of Congenital Hypothyroidism in babies, on average between 250 to 300 babies a year are diagnosed.
- Plans for evaluation of the new platform will include a six to nine-month pilot study screening for both Thyroxine ((T4) and Thyroid Stimulating Hormone (TSH) on every newborn screening specimen, which will provide data showing impact of a different algorithm on identifying and diagnosing babies earlier. Around 12% of babies are missed for hypothyroidism on the first screen.

- There is hope this will reduce false positive rates for hypothyroidism, which would have huge downstream effects for healthcare providers and babies and parents.
- Applied for grant from Centers for Disease Control and Prevention requesting funds to help pay for some of the additional re-agents that is needed for this study, which would greatly reduce the cost of the study and the plan. Dr. Nancy Beck wrote a letter of support of the grant application.
- Plan is to bring together a stakeholder group of experts to help evaluate the data and determine what that algorithm is.

Member discussed:

- If it is found that by going to Thyroxine that you could pick up Congenital Hypothyroidism on the first screen, if there is also a possibility that CAH can go to one screen, which would take Texas to a one-screen state as opposed to two screens.
- How the cost-benefit of two screens pays for itself from a systemwide perspective.
- Average time of collection in one-screen states.
- If Texas were to become a one-screen state, determining time of collection, 24-48 hours or at 2 weeks.
- If there is there a 7-day test that could catch more things.
- Federal recommendation for the first newborn screen is within the first 48 hours of life.
- Texas has timeliness recommendations with goals to record out time-critical disorders within 5 days of life.
- Screening target definitions vary by state, and the goals of each program vary across the nation and is ultimately a program-level decision.
- If screening for both T4 and TSH in Congenital Hypothyroidism screening will help decrease the number of repeat screens and eliminate false-positives for premature babies.

Agenda Item 9: X-linked Adrenoleukodystrophy (X-ALD) testing update

Dr. Gong introduced, Dr. Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit. Dr. Freedenberg referenced handout, *Texas NBS X-linked Adrenoleukodystrophy (X-ALD) Case update*.

Members discussed:

- How the neurologists are doing in their new role as responders.
- Besides neurology, there are multi specialist referrals for endocrinology and genetics.

Agenda Item 10: COVID-19 Newborn Screening Protocols

Dr. Gong introduced, Dr. Susan Tanksley, Ph.D., Laboratory Operations Unit Manager, DSHS Laboratory, and Dr. Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit. They referenced the PowerPoint handout, *COVID-19 Impact on Newborn Screening*.

Dr. Tanksley stated:

- In March agency staff notified to take a modified work approach in the laboratory and reduce number of staff onsite to implement social distancing and staggered shifts.
- Ceased work on many special projects to focus on critical work in March and resumed in late May, causing delays.
- Due to concerns with the second screen being collected and a decrease in the volume of second screens received, implemented a process to begin testing all the unsatisfactory specimens.
- Huge impact to maintain social distancing for those in the lab who punch the dry blood spot cards; this is busiest space in the entire newborn screening lab.
- Staff that are teleworking have been able to continue with some special projects and have successfully implemented HL7 2.5.1 connections with Texas Health Resources, University Health System and Memorial Hermann Health System.

Dr. Freedenberg stated:

- In early April, approximately 80% of the Clinical Care Coordination (CCC) staff transitioned to telework with some challenges in obtaining laptops and cell phones needed for staff to continue work.
- Challenges with couriers retrieving samples from hospital; nurses brought out.
- Affected responsibilities for babies at institutions since staff were being pulled to other duties. This affected the follow-up system because it took more time to find the responsible party.
- Obtaining the second screen made difficult since some hospitals refused to allow the well newborn back in. Alternative sites, laboratories or pediatric settings needed to be found for obtaining the second screen.
- Calls came from multiple stakeholders to CCC and the laboratory to identify where to send the baby for the second screening.
- Masks are now required in all workspace for DSHS staff, unless isolated in office.
- Funding opportunities available for institutions in the newborn screening system.
- Additional Frequently Asked Questions (FAQs) are available on the CCC website to provide guidance to Providers as well as the institutions.

Members discussed:

- The volume of the of screen being collected before 24 hours of life shows a 1-percent increase.

- An analysis has not been done to breakdown the actual timing or the effect on the increase of positives.

Agenda Item 11: Proposed Newborn Hearing Screening Rules

Dr. Gong introduced Mr. David R. Martinez, DSHS, Director, Newborn Screening Unit; however, based on time constraints she announced to the Committee that the rules for newborn hearing will not be released until August 7, 2020 and Mr. Martinez will be sure to advise the Committee when it is released so the members can provide their comments.

Agenda Item 12: Sickle Cell Subcommittee Reporting

Dr. Gong introduced Dr. Titilope Fasipe, Sickle Cell Subcommittee Co-Chair.

Dr. Fasipe stated:

The subcommittee is still working on tasks assigned from the last meeting and did not have any updates to report.

Agenda Item 13: Critical Congenital Heart Disease (CCHD) Subcommittee Reporting

Dr. Gong introduced Dr. Scott McLean, CCHD Subcommittee Chair. Dr. McLean referenced the PowerPoint and handouts, *Subcommittee Executive Summary*, *Subcommittee Conference Call meeting minutes* and *CCHD Recommendation Letter*.

Dr. McLean stated:

- Texas Health and Safety Code mandates the point of care screening procedure must be done but it only requires the reporting of confirmed cases.
- Without fundamental data, the quality of the CCHD screening procedure cannot be determined or improved.
- Over a 3-year period the rates of identification cases varied significantly across the regions; when compared with Texas Birth Defects Registry, less than 1 out of 5 newborns with CCHD are reported to the newborn screening system, although it is required by statute.
- Three draft recommendations were presented to the Committee for consideration related to CCHD newborn screen reporting.
- Suggested the subcommittee approach Texas Collaborative for Healthy Mothers and Babies (TCHMB) leadership to discuss with Regional Advisory Councils (RACs) and ask them to undertake a quality improvement project directed to hospitals to report their numbers of CCHD screening and results.

Dr. Gong stated the subcommittee drafted a letter to Dr. John Hellerstedt, DSHS Commissioner, to develop and support a network of community Champions to educate and motivate those responsible for CCHD screening and reporting of best practices.

MOTION: Dr. Joseph Schneider made a motion to approve the CCHD recommendation letter to Dr. Hellerstedt. Dr. Charleta Guillory seconded. Ms. Allen conducted a roll call vote, and the motion carried with no objections or abstentions.

Dr. Gong advised that Dr. McLean's term as the CCHD subcommittee chair has expired, and Dr. Michael Speer agreed to serve as the new chair for the subcommittee. Dr. McLean agreed to remain on the subcommittee as a subject matter expert.

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

Dr. Gong introduced, Dr. Tiffany McKee-Garrett, Subcommittee Chair.

Dr. Gong supplanted Dr. McKee-Garrett and advised that the subcommittee has not had the opportunity to meet, therefore they do not have an update to report.

Agenda Item 15: Newborn Screening Consultant (NSC) Fees Subcommittee Reporting

Dr. Gong turned the floor over to Dr. Scott McLean, Subcommittee Chair. Dr. McLean referenced the handout and PowerPoint, *NBS Consultant Fees Letter and DSHS Commissioner Response to the NBS Consultant Fees Letter*.

Dr. McLean stated:

- The recommendation letter sent to Dr. Hellerstedt, DSHS Commissioner, was well received, and he responded that he would ask the NBS program to develop ideas.

Member discussed:

- DSHS will look at existing programs to leverage funds to support the recommendations.
- DSHS will provide Committee a status update at the next meeting.
- Committee requested the program send thank you letters to providers who brought the issue before the Committee, advising their concerns are being addressed.
- Program will consult with management for confirmation to post the letters to the NBS Committee webpage outlining what the Committee has done.

Agenda Item 16: Review of Bylaws,

Dr. Alice Gong, M.D., Chair, and members reviewed the handout, *NBSAC Bylaws – Oct 19, 2018*.

Members discussed:

- Under Item #4, the number of members needs to change to agree with the number that is listed in the statute.
- Under Item #7, revising the terms and language for the presiding chair and vice chair. ACCO will work with Aimee Millangue, DSHS, Advisory Committee Support,

Newborn Screening Unit and Mr. Martinez on the wording and get it to the Committee for review at the next meeting.

- Dr. Guillory raised a question about serving on the CCHD Subcommittee, and Ms. Millangue confirmed that she would now be able to work on that subcommittee.

Agenda Item 17: Public Comment

Ms. Allen read the public comment logistical announcements and called on those registered for public comment.

Written public comment was received from:

- Ms. Emily Waugh, mother of Danni (10-month old) and a private citizen. Ms. Waugh supports SMA testing as part of regular newborn screening in the state of Texas.
- Ms. Jenna Martinez, mother of Gabriel (3-year old) and a private citizen. Ms. Martinez supports SMA testing as part of regular newborn screening in the state of Texas.
- Ms. Diane Murrell, clinical social worker in a pediatric neuromuscular clinic and a private citizen. Ms. Murrell advocates for the quick adoption and implementation of SMA screening for all newborns in Texas.
- Ms. Dorothy Mueth, supports newborn screening of SMA in Texas.
- Ms. Nicole Stickane, mother of Luke, (4-year old), supporter of Cure SMA. Ms. Stickane urges Texas leaders to speed up consideration and implementation of SMA in newborn screening.

Oral Comment was received from:

- Dr. Tim Lotze, Pediatric Neurologist and Director, Pediatric Muscular Dystrophy Association Care Center at Texas Children's Hospital and Associate Professor of Pediatrics and Neurology. Dr. Lotze fully supports SMA newborn screening in Texas.
- Dr. Diana Castro, Pediatric Neurologist, Children's Medical Center of Dallas, University of Texas Southwestern, urges state leadership to consider newborn screening of SMA for Texas.
- Dr. Dustin Paul joined the meeting during Dr. Harvapat's presentation; however, he was not able to connect into the meeting and provide his oral comment.

Oral and Written comment was received from:

- Dr. Mary Schroth, Chief Medical Officer, Cure SMA. Urges the Committee and state health officials in attendance to speed up implementation of SMA newborn screening in Texas, the most effective way for babies with SMA to access timely treatments and supports.

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

Dr. Gong stated the next meeting will be sometime in October 2020 and will most likely be conducted as a Microsoft Teams live event meeting.

Members discussed future agenda items:

- Take future action item follow-up list from the current minutes, plus the two action items talked about and move into the minutes of this meeting so that might be the most efficient way of not losing anything and carrying forward.
- Discuss impact of COVID-19 associated with obtaining a 2nd screen

Action item follow-up list:

- Dr. Freedenberg will follow up with details on the involvement of specialists on a borderline X-ALD case for which a primary care provider requested DNA.
- Discuss how Texas screening results can be included in ClinVar, a public archive that correlates the relationship among human variations and phenotypes, with supporting evidence, which is maintained by the National Center for Biotechnology Information.
- Medicaid funding from newborn screening reimbursements distributed outside of the program
- Vital Statistics data linking
- Even-year annual review of bylaws

Dr. Gong adjourned the meeting at 12:50 p.m.

To listen to the webcast recording of the July 30, 2020 meeting go to:

<https://texashhsc.swagit.com/play/07302020-1018>