

Newborn Screening Advisory Committee

Texas Department of State Health Services
1100 W. 49th, Austin, Texas 78756
Moreton Building, M2-204
February 27, 2015 via conference call
Minutes

Members via Conference Call:

William Morris, LVN
Kelly McDonald
Nancy L. Beck, MD
Charleta Guillory, MD
Michael E. Speer, MD
Mark E. Lawson, MD
Scott D. McLean, MD
Felicia M. Adams, MSN

Staff

David R. Martinez, Department of State Health Services (DSHS), Newborn Screening Unit Manager
Debra Freedenberg, MD, PhD, DSHS Newborn Screening Unit
Beth Rider, DSHS, Newborn Screening Unit, Ombudsman, Committee Support
Brendan Reilly, Program Specialist, DSHS Laboratory, Biochemistry & Genetics Branch
Rachel Lee, PhD, Branch Manager, DSHS Laboratory, Biochemistry & Genetics Branch
Patricia Hunt, DSHS Laboratory, Metabolic Screening Group
Karen Hess, DSHS, Newborn Screening Genetics Branch Manager
Sam Cooper, DSHS, Director, Specialized Health Services Section

Guests

Jennifer Needham via conference call with Dr. Guillory
Sarah Kingsberry, Hays County

Call to Order and Roll Call of Committee Members, Staff and Guests

Chairman Morris called to order the February 27, 2015 meeting of the Newborn Screening Advisory Committee at 10:07 am. Introductions were made and Chairman Morris welcomed everyone. Members, staff and guests attending are listed at the beginning of these minutes. A GoToMeeting link was provided for the benefit of Committee members to allow them to visually follow along with each agenda topic and PowerPoint presentation.

Review and Approval of Minutes

Chairman Morris asked if everyone had a chance to review and approve the minutes from the October 2, 2014 meeting. He stated that he took a quick look and did not see anything that needed to be changed. Dr. Guillory seconded the motion to approve the minutes. Motion passed.

Newborn Screening Program Updates-Debra Freedenberg, Rachel Lee

Debra Freedenberg and Rachel Lee gave updates on the newborn screening programs. The PowerPoint presentation included the Newborn Screening System; information on courier services; and electronic data transfer. Information was provided on the efforts to increase web-based demo

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entry and expand HL7 electronic data transfer. Updates to the technology/instrumentation upgrades and developments were given. Potential new screening conditions are Pompe; Mucopolysaccharidosis Type I (MPS1); and X-linked Adrenoleukodystrophy (X-ALD). Potential issues include the proposed Senate Bill (SB) 475; and the “Newborn Screening Saves Lives” reauthorization. The Updates included NBS educational efforts, including DSHS Grand Rounds, webinars, and THSteps modules. There are also NBS Hearing Grant activities which were provided in the presentation.

Secondary Panel Updates-David R. Martinez

David R Martinez gave an update on the secondary panel. Mr. Martinez informed the Committee that a metabolic workgroup meeting was held where metabolic specialists were invited to a working meeting to review information being prepared to get ready to roll out the secondary panel. Mr. Martinez informed the Committee that the needed hardware and software upgrades mentioned at the last meeting had been done. At the metabolic meeting, the metabolic specialists helped review the data collected for metabolic conditions and looked at the ACT and FACT sheets that were prepared for the secondary conditions. Mr. Martinez stated that the edits received from Committee members on the brochure that the Committee had reviewed at the previous meeting in October, 2014, were incorporated and shared with the metabolic specialists. Mr. Martinez stated input was received from the metabolic specialists on many ACT and FACT sheets, including lab cutoffs, and algorithms. There is educational information on our website which was shared with the specialists. We have other brochures that mention the number of conditions that we are screening for. In anticipation that we may add more conditions, we are going to a more generic terminology. Mr. Martinez stated that we were fortunate to get the metabolic specialists’ input and the workgroup meeting was very productive. Mr. Martinez stated that we are still preparing some of the software changes that need to be made. He stated that we still do not have a firm implementation date, but the Committee would be notified.

Critical Congenital Heart Defect (CCHD) Updates-Karen Hess

Karen Hess gave the Committee a PowerPoint presentation update on CCHD.

- CCHD reporting began September 1, 2014
- Only cases that have been diagnosed are reported
- To date we have received 64 reports from 18 different sites
- The data is fairly new so the statistics may not be reflective across the state
- Of the facilities reporting, 33% of babies get ECHO within 24-48 hours

Dr. Guillory and Dr. Gong are both involved in the TxPOP project and work with the facilities diagnosing and reporting CCHD. The Newborn Screening Algorithm includes screening for CCHD based on pulse oximetry of the right hand and foot after 24 hours.

Timeliness of Newborn Screening-Rachel Lee, Brendan Reilly

Rachel Lee and Brendan Reilly discussed timeliness of newborn screening. A PowerPoint presentation was presented to the Committee.

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- Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) recommendations related to timeframe for first newborn screen, including the presumptive positive results for time-critical conditions should be communicated to the newborn's healthcare provider within five days of life; all other presumptive positive results should be communicated to the newborn's healthcare provider within seven days of life; all NBS tests should be completed within seven days of life; and encouraging states to have 95% or more of newborns meeting the timeliness goals by 2017.
- Pre-analytical measures in Texas – 96.2% of first screens collected within 48 hours after birth and 23.8% first screens received within 24 hours of collection. Many ongoing activities to improve transit time have been conducted and are effective (~90% of specimens are received within 72 hours of collection). Additional considerations and requirements are needed to achieve further improvement.
- Analytical and post-analytical measures in Texas – 30.7% of presumptive positive results for time-critical conditions were reported within five days of life, 79% of all other presumptive positive results were reported within seven days of life, and 67% of all NBS tests were reported within seven days of life.
- Potential requirements and considerations to improve analytical and post-analytical measures, including Check-in / Punching (Ch-IP) Workflow redesign and update testing platform.
- Discussion during and following the presentation included Committee members' and DSHS staff commenting on any potential impact to timeliness after the secondary conditions are required. The rules currently only require the initial screen to be collected between 24 and 48 hours, but have no requirement on transit time. However, the national goal is to receive the initial specimen within 24 hours of collection. Certain other states, such as Iowa and North Dakota have couriers seven days a week; courier cost is included in their newborn screening fee. Iowa appears to be a model state as they receive 94% of their specimens within 24 hours. The question was asked whether Iowa regulates the costs through legislation, and whether that would be feasible for Texas (cost-effective). Texas DSHS currently publishes the top performers on the website, and discussion included whether the poor performers should also be posted online. It was recommended that the timeliness issue specific to poor performing facilities be brought to the applicable facility CEO's attention. Reportedly, a comparison between Texas and other states shows Texas to rank in the lowest quartile based on percentage of specimens meeting recommended timeframes. The discussion concluded with a suggestion that we gather high-level benchmark data to provide a fiscal impact statement with regards to taking measures for improvement of transit time to 24 hours.

NBS Follow-up Activities-Specialist Perspective-Debra Freedenberg

Dr. Freedenberg informed the Committee that Newborn Screening is a system, and we are collaborative partners with clinical care providers (the specialists as well as the primary care providers)

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and the families. Questions and some concerns related to both short-term and long-term follow-up activities have been received. Dr. Freedenberg stated that what was wanted was an open discussion with the Committee about what concerns or issues specialists have related to short-term and long-term follow-up. Short-term follow-up is defined as immediate follow-up of an abnormal screen until the case is cleared or diagnosed, and long term follow-up is periodic contact with specialists after a child is diagnosed with a condition. Follow-up for the long-term is challenging because the data is not captured easily and consistently. It would be helpful to find a way to share the data electronically or web-based. Dr. Guillory mentioned providers may also explore collaborating with the March of Dimes. Dr. Lawson mentioned that for geographically large and/or more rural areas, such as west Texas, follow-up is particularly difficult because there are fewer specialists available. It is also difficult to know who the newborn's primary care provider may be, and whether the family is enrolled with a Medicaid Managed Care Organization (MCO). The ACT and FACT sheets should be available to MCOs and providers. Sam Cooper informed the Committee that someone from the Health and Human Services Commission could talk about the case management responsibilities of the MCOs with the Committee if that would be of interest to them at the June meeting. David Martinez advised the NBS Unit webpage includes a list of the Texas Newborn Screening Specialists and the link to that webpage will be provided via email following the meeting. The map of the Regional Public Health Coverage across the state of Texas will be included in that email and as an additional resource.

Legislative Session/Sunset Review-David R. Martinez

David R. Martinez gave the Committee an update on the 84th Legislative Session and the Sunset Review. Mr. Martinez stated that on January 13, 2015, the Regular Legislative Session began. The Legislature is working on the state budget and the bills that will affect the Texas Department of State Health Services (DSHS). Last week, the Senate and the House had a Finance Hearing where DSHS presented the budget in Senate Bill 1 and House Bill 1 in hearings that have already begun. More bills will be forthcoming. As the Committee is aware, the Legislators will review the recommendations that were submitted by the Sunset Advisory Commission regarding DSHS and Health and Human Services (HHS) agencies, and the recommendation to consolidate the five agencies under the Health and Human Services Commission. The deadline for filing a bill is March 13, 2015. Mr. Martinez stated that as we get closer to the deadline, we will see bills being filed. Some of the major milestones are:

- March 13, 2015 – Deadline for filing bills
- May 26, 2015 – Last day for House and Senate to adopt conference committee reports
- May 27, 2015 – Last day of session; only corrections permitted
- June 21, 2015 – Date by which the Governor must approve or veto bills
- August 31, 2015 – September 1, 2015 – Dates on which most bills are effective

Mr. Martinez stated that throughout this time frame, we are responding to inquiries from Legislators as they seek the information they need to make informed decisions. Department staff will serve as resource witnesses and provide bill analysis and fiscal notes throughout the session. The Newborn

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Screening Program monitors any filed bills that relate to blood spot screening and point of service screening that includes Hearing and Critical Congenital Heart disease. Mr. Martinez advised that the information on the proposed bills that are of importance to our Committee: Senate bill (SB) 219, Senate Bill (SB) 475, Senate bill (SB) 791, and Senate Bill (SB) 628, will be provided via email.

Public Comments

None

Agenda Items

- 1) Secondary Panel Updates
- 2) Follow-up activities
- 3) Follow-up on biliary atresia
- 4) Bench mark data related to the timeliness piece maybe with high level fiscal impact kind of estimate
- 5) Have someone from HHS to discuss the case management responsibilities of MCOs

Adjournment

The next meeting will be held on Thursday, June 18, 2015 at 10:00 am via conference call. There being no further business, the meeting was adjourned at approximately 1:00 p.m.