Texas Department of State Health Services
1100 W. 49th, Austin, Texas 78756
Moreton Building, Conference Room M618
February 18, 2016 via Conference Call
9:00 a.m. – 1:00 p.m.
Minutes

Members via conference call
William Morris, LVN
Thomas M. Zellers, MD
Nancy Beck, MD
Michael Speer, MD
Charleta Guillory, MD
Felicia M. Adams, MSN
Benna Timperlake, BSN
Scott D. McLean, MD
Aida Gonzalez

Staff Present
Susan Tanksley, PhD, Department of State Health Services (DSHS), Manager, Laboratory Operations Unit
Karen Hess, DSHS, Branch Manager, Newborn Screening Unit
Patti Lanfranco, DSHS, Unit Coordinator, Newborn Screening Unit
Rachel Lee, PhD, DSHS, Branch Manager, Laboratory, Biochemistry & Genetics Branch
Debra Freedenberg, MD, PhD, DSHS, Medical Director, Newborn Screening Unit
Beth Rider, DSHS, Ombudsman, Committee Support, Newborn Screening Unit
David R. Martinez, DSHS, Manager, Newborn Screening Unit
Doug Dittfurth, DSHS, Newborn Hearing Screening Coordinator, Newborn Screening Unit
Eugenia Dunham, DSHS, Manager, Newborn Screening Support Group
Elizabeth Fitzgerald, DSHS, Attorney, Office of General Council
Lynette Borgfeld, DSHS, Newborn Screening Laboratory
D'Andra Luna, DSHS, Newborn Screening Laboratory
Brendan Reilly, DSHS, Laboratory, Program Specialist
Patricia Hunt, DSHS Laboratory, Metabolic Screening Group
Sam Cooper, DSHS, Director, Specialized Health Services Section

Guests
Ada Drozd, Texas Medical Association (TMA)
Rachel Jew, Texas Pediatric Society (TPS)
Elizabeth Sjoberg, Texas Hospital Association (THA)
Shannon Lucas, March of Dimes (MOD)
Eve Lapin, Stop ALD
Brian Chandler, ALD Connect

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Call to Order

Chairman Morris called to order the February 18, 2016 meeting of the Newborn Screening Advisory Committee at 9:00 a.m.

Review and Approval of Minutes

Chairman Morris requested a motion be made to approve the October 9, 2015 minutes. Dr. Michael Speer made the motion, and Dr. Charleta Guillory seconded. Motion passed and minutes were approved.

Timeliness of Newborn Screening-Rachel Lee, Brendan Reilly

Rachel Lee and Brendan Reilly gave updates on the timeliness of newborn screening.

- Have been speaking with the Committee about timeliness for a couple of years
- Working on improving the time from collection of specimen to the time of receipt in the DSHS laboratory
- Initially focusing on receiving the specimen within 3 days of the date of collection
    - Utilized assessment and educational tools
    - Improved from about 70% to about 95% compliance
- In February, 2015, the Secretary's Advisory Committee for Heritable Disorders in Newborns and Children (SACHDNC) came up with final recommendations for timeless in newborn screens
    - Presumptive positive results for critical conditions should be reported to child care providers no later than 5 days of life
    - For all other presumptive positive results for time sensitive conditions should be reported to the health care provider as soon as possible but no later than 7 days of life
    - For all newborn screening results should be reported within 7 days of life
    - In order to achieve these goals, they also recommended that initial newborn screenings should be collected in the appropriate time frame, but no later than 48 hours after birth
    - In addition, newborn screens should be received in the laboratory as soon as possible, ideally within 24 hours of collection
- DSHS Laboratory did some analysis on how Texas is doing right now
    - Only have about 24% of time critical conditions were reported with 5 days of life
    - Non-critical but time sensitive conditions were reported within 7 days of life, about 56%
    - About 60% of all results reported within 7 days of life
    - Have about 96% of specimens collected within 48 hours of life; however, in terms of how soon it gets to the laboratory it is only about 24% of first screens specimens received within 24 hours of collection

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    - Have a long way to go and the SACHDNC recommends that we reach about 95% for each of the above recommendations
- Because of the recommendations, a new goal is being set
    - Trying to encourage the providers to submit their specimens as soon as possible hoping to receive in the laboratory within 24 hours of collection
    - Currently only 24% of first specimens received within 24 hours of collection; initial goal is to increase this number to 60%
- Rachel Lee went over a proposed report that will be available to providers online
Brendan Reilly discussed with the Committee two of the laboratory projects.
- We are finishing up the LEAN 6-Sigma project to assess the internal laboratory work flow and identify some ways we can reduce the turn-around time within the laboratory (referred to as the Check-In/Punching Work Flow). Finalized recommendations and approved to move forward with piloting the recommendations which they hope to do within the next few months. They expect this work flow redesign to significantly improve the 3 primary measures of reporting presumptive positive results and all results. They are looking at anywhere from 1 to 2 day reduction in our laboratory turn-around time. Would be translating to at least for the second 2 measures moving that number up above 80%. With some additional changes, they are expecting the first measure, the time critical conditions to move closer to 60%.
- The other project is a HRSA funded grant called NewSteps 360. We are one of twenty states awarded to work on this grant. We essentially have 4 primary goals or focus points that we are addressing through this grant. Two of them are related and have to do with increasing the amount of demographic information that we are getting electronically as opposed to requiring our internal data entry staff to complete that data entry. Our goal through this is to help further reduce that burden of meeting those internal laboratory turn-around times. Two aspects that we are doing, we currently have a web application that allows for remote demographic entry specimen orders and as part of this project we are using some of the funding to help us promote the use of that application and assist providers in getting setup, implementing it within their work flow and using it. Another related aspect is that the NewSteps 360 is contracted with a company that has developed a solution where they can leverage existing connections that they have with hospitals to generate a label for the demographic forms and the concept is this will help hospitals in reducing the amount of time that it takes to fill out the demographic forms for newborn screening. At the same time, we will get the benefit of being able to receive the electronic order. We are also going to be using this funding to revise our educational materials. The third aspect that we are focusing on using this funding is to increase to our ability to work with the facilities onsite. We can travel to these facilities and provide training on both the web application and work flows, going through this self-assessment document. Our goal for this project is to improve multiple aspects of the timeliness issues. We are trying to take this whole thing as a holistic view looking at improving our internal laboratory turn-

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around times, improving pre-analytical measures that we are looking at within the facilities, but then also working with hospitals to improve some of these post-analytical issues that we run into from the follow-up side.

Informed Consent on Blood Spot Cards (Common Rule)-Update-Susan Tanksley, Rachel Lee

Susan Tanksley and Rachel Lee gave an update to the Committee on the informed consent on blood spot cards (Common Rule). A notice of Proposed Rulemaking was released on 9/8/15. It is the Office of Human Research Protections' (OHRP) goal of releasing the revised Common Rule by September 2016. The plan is to change the current decision form to a new broad consent form and improve informed consent. There will be a three-year implementation to work through the process. A PowerPoint presentation, which focused on potential Common Rule changes, the impact to newborn screening and review and discuss consent form revisions, was presented to the Committee.

Critical Congenital Heart Disease (CCHD) Reporting-Karen Hess

Karen Hess gave the Committee an update on the CCHD reporting. A PowerPoint presentation was presented to the Committee.

- Information presented was from 9/1/14 to 2/1/16
- To date approximately 258 reports have been received from 32facilities
- One birthing center is now reporting
- Facilities are just reporting on diagnosed cases
- About 50% identified as CCHD are having surgery
- Receive hand written reports by fax

Pompe and Recommended Uniform Screening Panel (RUSP)-Susan Tanksley

Susan Tanksley informed the Committee that DSHS is looking at including a higher resolution sensitivity instrument to do second-tier screening. She reminded the committee that Pompe disease was added to the RUSP in June, 2013. The Secretary of Health and Human Services submitted the letter dated February 16, 2016 accepting the recommendations from the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) to add Mucopolysaccharidosis Type 1 (MPS 1) and X-linked Adrenoleukodystropy (X-ALD) to the Recommended Uniform Screening Panel (RUSP). Perkin-Elmer is identifying sites to conduct studies to submit to the Federal Drug Administration (FDA), and if approved the kits will be available in 2018. Regarding the logistics of adding new disorders to the panel: there are changes needed to the laboratory management system, educate providers, develop follow-up for the conditions. These disorders are systemic so we need to consult with more specialists, such as neurologists, more cardiologists, ophthalmologists. Currently about 60% of births are Medicaid covered. The concern regarding the costs of caring/treating for the children with the disorders screened was also discussed during this topic. Briefly, providers (e.g., geneticists, hematologists,

endocrinologists) are not compensated for the telephone consultation, which results in the inability to charge for patient follow-up because they are not actual patients. Dr. Tanksley mentioned that Dr. Freedenberg has talked with other states to determine other models to review regarding uncompensated follow-up care. DSHS staff mentioned we will look at all of the costs to the Health and Human Services system, including looking into additional funding requests, and developing the cost projections.

Newborn Hearing / ECI Referrals-Doug Dittfurth

Doug Dittfurth shared with the Committee a new brochure providing information on the collaboration between the Texas Early Hearing Detection and Intervention (TEHDI) and Early Childhood Intervention (ECI) to provide a better understanding on how ECI can benefit both healthcare providers and families once there is confirmation that the infant is deaf or hard of hearing. The collaboration includes providing case coordination. The brochures are available through the Texas Health Steps (THSteps) Resource online catalog. Mr. Dittfurth presented a PowerPoint presentation to the Committee discussing appropriate referrals to ECI, the work flow in the Management Information System (MIS), ECI services in coordination with TEHDI, TEA, and requirements for deaf education services. Early intervention and education is crucial in assisting infants and toddlers to develop communication, social and cognitive skills, as well as support families. TEHDI staff are collaborating with Jean Origer with ECI, to provide the Committee with the numbers of infants who have been confirmed deaf or hard of hearing and referred to ECI. Presently, time has not allowed the final de-identified data to be obtained. The goal is to obtain the information by the next advisory committee meeting. TEHDI staff have updated the website with the current audiology providers in each region across the state.

Discussion and Possible Action-Newborn Screening Fee Increase-Susan Tanksley, Rachel Lee

Susan Tanksley and Rachel Lee discussed with the Committee the potential fee increase for Newborn Screening. The laboratory must charge a fee for services, and the fee is calculated to recover the department's direct cost of providing the service. The fee estimation procedure includes lab overhead costs, to include labor to test the specimens, equipment costs, quality assurance, and management costs; agency wide overhead; and contingency cost. Also included in the fee estimation procedure are clinical care coordination costs for care coordination at DSHS Central Office; case management in Health Service Regions and client benefits. In order, to recover costs for the current testing and follow-up, a proposed increase of the newborn screening fee from $33.60 to $55.24 per screen is needed. This does not include additional funding for specialists, although we recognize that need and will investigate further, involving Texas Department of Insurance (TDI) and Texas Medical Association (TMA). The members were provided a hand-out showing the fee calculation and factors contributing to the fee increase for additional information. Ideally, the new fee would go into effect September 1, 2016. The laboratory's fees must be listed in the Texas Administrative Code (TAC), so DSHS will go

through the rules process in order to increase the fee. Currently, that process takes nine to twelve months. An additional discussion included the inclusion of the Texas Association of Health Plans at the recommendation of TDI.

Public Comments

Eve Lapin with Stop ALD is a parent who lost a child that was diagnosed with Adrenoleukodystrophy (ALD), which is a genetic neuro-degenerative disease, and has another child with the defective ALD gene. The critical point is the need to treat ALD before the disease process begins and manifests in clinical symptoms, basically halting the disease progression. . Approximately 24 babies are born with ALD in Texas. As of yesterday, the U.S. Secretary of Health and Human Services, Sylvia Burwell, approved the addition of ALD to the Recommended Uniform Screening Panel (RUSP). Ms. Lapin urges DSHS and the advisory committee to prepare the newborn screening lab in Texas to test for ALD. She thanked the committee and also indicated her willingness to assist.

Brian Chandler represents ALD Connect, a non-profit organization that acts as a consortium for seven different research institutions, and mentioned the organization's willingness to assist the committee by acting as a resource.

Future Agenda Items

1) Fee increase
2) Biliary Atresia – Sanjiv Harpavat
3) ALD advocate
4) Election of New Chairman
5) Possible change in By-Laws
6) Pompe, X-Linked ALD, MPS
7) Referral data from Doug Dittfurth with TEHDI and Jean Origer from ECI
8) NewSteps Site Visit Reporting (if applicable)

Adjournment

The next meetings will be held on June 17, 2016 via conference call and October 14, 2016 will be a face to face meeting. There being no further business, a motion to adjourn the meeting was made and seconded. The meeting was adjourned.