

**Newborn Screening Advisory Committee  
Meeting Minutes  
February 24, 2017  
12:30 p.m.**

**Moreton Building, Conference Room M-653  
1100 W. 49<sup>th</sup> Street, Austin, TX 78756**

Table 1: Newborn Screening Advisory Committee member attendance at the Friday, February 24, 2017 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Dr. Nancy Beck	P		Dr. Scott McLean		X
Dr. Alice Gong	P		Dr. Michael Speer	P	
Ms. Aida Gonzalez	P		Dr. Elizabeth "Kaili" Stehel	P	
Dr. Charleta Guillory	X		Ms. Benna Timperlake	P	
Ms. Tiffany House	P		Dr. Thomas Zellers		X

**Yes:** Indicates attended the meeting **No:** Indicates did not attend the meeting **P:** Indicates participated by phone

Table 2: Newborn Screening Advisory Committee staff attendance at the Friday, February 24, 2017 meeting.

HHS STAFF NAME	YES	NO	HHS STAFF NAME	YES	NO
David Martinez	X		Dr. Susan Tanksley	X	
Dr. Debra Freedenberg	X		Dr. Rachel Lee	X	
Felipe Rocha	X		Karen Hess	X	
Sara Gutierrez	X		Lynette Borgfeld	X	
Katlyn Le	X		Brendan Reilly	X	
Patricia Hunt	X		D'Andra Luna	X	
Yan Chen	X		Monica Molina	X	
Beth Rider	X		Stephanie Gutierrez	X	

Table 3: Newborn Screening Advisory Committee guest attendance at the Friday, February 24, 2017 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Shannon Lucas, March of Dimes	X		Carriston Hendricks, Indy's Law	X	
Brandy Lee, OZ Systems	X		Amanda Deason, Indy's Law	X	
Anthony Valdez, Gardere Law Firm	X		Gwendolyn Quintana, Texas Medical Association	X	
Shelbye Almeida, Indy's Law	X		John Sepehri, Gardere Law	X	
Donna Porter, Indy's Law	X		Francis Gutierrez, Yeled Shalom Pediatric Clinic	X	

### **Agenda Item 1: Welcome and Introductions**

Dr. Charleta Guillory greeted everyone and turned the floor over to Ms. Stephanie Gutierrez. Ms. Gutierrez called roll and reviewed logistics with the Committee. Dr. Guillory requested participants in the room introduce themselves for the sake of members on the phone.

### **Agenda Item 2: Review and Approval of Minutes for October 14, 2016**

**MOTION:** Dr. Alice Gong

**SECOND:** Ms. Benna Timperlake

Dr. Guillory requested a motion to approve the minutes. Dr. Gong motioned with Ms. Timperlake seconding. The motion carries to accept the October 14, 2016 minutes as approved by unanimous vote.

### **Agenda Item 3: Committee Discussion: Second Screen Impact to Small Practices**

Dr. Guillory informed the Committee of the concern regarding the payment of the second screen, especially regarding private pay insurance companies. Dr. Guillory stated this was particular to physicians with small practices. Physicians felt they were not getting reimbursed and if they were it was at the lower screening kit fee rather than the newly implemented kit fee. The concern is that more physicians will not conduct the second screen at their clinics and offices due to financial burden. Another concern is the second screen will then be requested at the hospitals but the financial burden would continue as well as a potential of losing second screen results. A proposal is made of insurance companies to refund the physicians at full cost.

Dr. Guillory requested this item remain on the Agenda for next meeting.

### **Agenda Item 4: Update: Newborn Hearing Screening "TKIDS" and Family Educational Rights and Privacy Act (FERPA) Consent**

Dr. Guillory introduced Mr. Doug Dittfurth. Mr. Dittfurth informed the Committee of a new collaboration between the Early Childhood Intervention (ECI) and the Texas Early Hearing Detection and Intervention (TEHDI) programs. ECI staff work with parents to obtain a FERPA consent and outcome data, which has not been consistently available to the TEHDI staff through the TEHDI Management Information System (MIS) system. A new "TEHDI referral" button is being added to the ECI referral database known as TKIDS. It is necessary for Early Childhood Intervention (ECI) specialists to access TKIDS daily in order to receive reimbursement. Once the TEHDI MIS referral button is approved and available online in TKIDS, a report can be run to produce aggregate data on the number of infants who are TEHDI

referred. Information can, therefore, be made available on infants who are deaf or hard of hearing and identified as receiving services.

Mr. Dittfurth will be attending the National EHDI Conference. The Committee requested Mr. Dittfurth research how other states conduct early screening on NICU babies, and provide a follow-up to the Committee

### **Agenda Item 5: Update: Newborn Screening Fee Increase**

Dr. Guillory introduced Dr. Rachel Lee. Dr. Lee informed the Committee of the increase in the Newborn Screening kit fee. The increase was needed to cover costs and to perform follow up activities. Dr. Lee referred to the PowerPoint and handout titled, *Newborn Screening Fee*.

Dr. Lee introduced Mr. Brendan Reilly. Mr. Reilly explained to the Committee the Impact of Newborn Screening Fee Increase as displayed on slide five of the PowerPoint and handout. Mr. Reilly summarized that there was an increase in the follow up specimens from smaller volume facilities whereas in larger volume facilities there was a decrease in follow up specimens. However, overall there was no significant change in the percentage of second screen specimens received.

The Committee discussed who received the results of the screenings and it was determined that the provider who submits the second screen specimen gets the results back, e.g., if Texas Children's submits the specimen they will receive the results. The Committee also discussed that the physicians are responsible for the second screening.

### **Agenda Item 6: Pompe: A Clinical and Patient Perspective**

Dr. Guillory introduced Dr. Debra Freedenberg. Dr. Freedenberg informed the Committee about the etiology of Pompe Disease. Dr. Freedenberg also discussed the symptoms of Pompe. Dr. Freedenberg reviewed the PowerPoint and handout titled, *Pompe and MPS 1 Clinical Overview*.

Dr. Freedenberg turned the floor over to Ms. Tiffany House. Ms. House shared her personal experience with the Committee, as she is an individual living with the disease after her diagnosis in 1994. Ms. House shared other patient stories as well.

The Committee had questions on how Pompe is diagnosed, and clinical DNA testing. The Committee also discussed the plan and cost for the Pompe study. This includes the FDA approved screening kit.

Dr. Guillory requested that this item be kept on the agenda for next time.

### **Agenda Item 7: Clinical Perspective on MPS-1 Action: Cost Estimate for Pompe and MPS-1**

Dr. Guillory introduced Dr. Freedenberg. Dr. Freedenberg informed the Committee of what Mucopolysaccharidosis Type 1 (MPS1) is and discussed clinical outcomes and rate of progression for this condition.

Dr. Freedenberg turned the floor over to Dr. Lee and Ms. Patricia Hunt. Dr. Lee and Ms. Hunt informed the Committee that both Pompe and MPS1 can be screened using the same assay. Dr. Susan Tanksley mentioned there will be additional staff needed.

### **Agenda Item 8: Update: Laboratory Continuous Quality Improvement Plan**

Dr. Guillory introduced Dr. Lee. Dr. Lee referred to the PowerPoint and handout titled, *Laboratory Continuous Quality Improvement Project(s)*. Dr. Lee informed the Committee about the NewSTEPS 360 grant award to aid in the timeliness project. Dr. Lee also mentioned the project to reduce turnaround time by automation, this includes electronic ordering and reporting. Dr. Lee turned the floor over to Mr. Reilly. Mr. Reilly explained the pilot program with Oz systems to implement a new electronic order, this is an unfunded portion of the grant; however, the goal is to go live with this new system on March 2017.

Mr. Reilly also explained a national effort to develop an implementation guide for HL7 ordering and reporting. Mr. Reilly provided information regarding an upgrade and complete replacement to the Laboratory Information Management System (LIMS). There is a two year timeframe for this project. After this upgrade there is an anticipated increase in expansion of electronic reporting by about 20%.

Dr. Lee provided information about a new two year grant funded by the Association of Public Health Laboratories (APHL). Department of State Health Services (DSHS) staff will attend training in sequencing for X-linked Adrenoleukodystrophy (X-ALD). Clinical care coordination will establish a clinical care network to gather specialists that will help with implementing X-ALD screening, scheduling conferences, and developing or updating educational materials.

Dr. Guillory asked about cost analysis for X-ALD. Dr. Lee explained the need for the lab building retrofit and equipment purchasing for second tier sequencing. Dr. Lee also explained that startup costs include upgrade of the LIMS and to hire three staff to do sequencing and assay development. The startup cost analysis is 1.5 million dollars, and 3.6 million dollars each year which includes the reagent costs.

**ACTION ITEM:** Dr. Lee will research the Pompe Cost analysis both in Texas and other states' analyses.

Dr. Lee informed the Committee on documenting newborn screening refusals best practices. A copy of the refusal form is kept in the baby's medical record.

Dr. Guillory requested a motion. Dr. Elizabeth "Kaili" Stehel made a motion to form a sub-committee that will work with the Department of State Health Services, including the legal department, to develop recommendations regarding better documentation on the newborn screening refusal form.

**MOTION:** Dr. Elizabeth "Kaili" Stehel

**SECOND:** Dr. Alice Gong

The motion carried by unanimous vote.

Dr. Guillory nominated Dr. Stehel as Chair of the sub-committee. Dr. Michael Speer and Dr. Alice Gong volunteered.

#### **Agenda Item 9: Public Comment**

Ms. Carriston Hendricks addressed the Committee regarding Indy's Law.

Ms. Shannon Lucas from March of Dimes informed the Committee of X-ALD newborn screening issues and questions taken up at the Capitol.

#### **Agenda Item 10: Future Agenda Items/Confirm Next Meeting Date**

Dr. Guillory turned the floor over to Ms. Beth Rider. Ms. Rider announced to the Committee that the next Newborn Screening Advisory Committee meeting is on June 16, 2017, Friday at 12:30 p.m. through 4:30 p.m. by teleconference.

The agenda items for the next Newborn Screening meeting are:

1. Follow-up on hearing screens for NICU babies
2. Impact of 2<sup>nd</sup> screen on pediatricians
3. Pompe and MPS-1 cost estimate
4. X-ALD cost estimate
5. Parental refusal forms
  - a. Sub-committee report
6. Follow up with CCHD education
7. An Update regarding the Texas Medical Association (TMA) and the Texas Pediatric Society (TPS) letter to the Texas Department of Insurance (TDI).

**Agenda Item 11: Adjourn**

Dr. Guillory adjourned the meeting at 3:30 p.m.