

GENETICS AND NEWBORN SCREENING ADVISORY COUNCIL MEETING

The Genetics and Newborn Screening Advisory Council meeting was held on Friday, February 3rd, 2017 at the Florida Department of Health Bureau of Public Laboratories, 1217 North Pearl Street, Jacksonville, Florida.

Call to Order:

The meeting was called to order at 10:10 am EST by Paul Pitel, MD, Council Chairperson. Roll was taken and introductions were made.

Members Present:

Paul Pitel, MD, Chairman, Hematologist
David Auerbach, MD, Florida Hospital Association Representative
Robert Fifer, PhD, Audiologist
Dorothy Shulman, MD, University of South Florida (USF)
Daniel Driscoll, MD, University of Florida (UF); representing Dr. Zori
John Curran, MD, CMS Deputy Secretary (via teleconference)
Gary Kleiner, MD, PhD, Practicing Pediatrician
Carina Blackmore, MS Vet Med, PhD, Department of Health, Delegate for the Surgeon General
Cyril Blavo, DO, MPH & TM, Nova Southeastern University (via teleconference)
Lori Gephart, RN, Agency for Persons with Disabilities
Heather Smith, Parent Consumer
Melissa Perez, Parent Consumer (via teleconference)

Guests:

Amarillis Sanchez-Valle, MD, Genetics, USF
Cheryl Garganta, PhD, UF Genetics
Dan Kilbride, parent consumer (via teleconference)
Donna O'Steen, Genetics, USF
George Fox, parent of child with Pompe
Gerold Schiebler, MD, CMS Consultant
Jeanne Brunger, PerkinElmer, Inc.
Larry Vroegindewey, PerkinElmer, Inc.
Lindsay Raub, UF Genetics
Mike Strenges, parent of child with ALD
Thais Asper, EveryLife Foundation
Sharon Bowden, Pediatrix Medical Group
Susan Weinger, Pediatrix Medical Group

DOH Personnel Present:

Cassandra Pasley, JD, BSN, Tallahassee
Marcy Hajdukiewicz, MS, Tallahassee
Dusty Edwards, BSN, RN, Tallahassee
Jessica Meyer, Tallahassee
Bonnie Taffe, PhD, MPH, Bureau of Public Health Laboratories, Jacksonville
Patti Ryland, MT, BS, Bureau of Public Health Laboratories, Jacksonville
Patty Parrish, Bureau of Public Health Laboratories, Jacksonville
Sherry Ray, Bureau of Public Health Laboratories, Jacksonville
Gary Fields, Bureau of Public Health Laboratories, Jacksonville
Ming Chan, PhD, Bureau of Public Health Laboratories, Jacksonville
Rachel Eastman, Tallahassee

Emily Reeves, BSN, RN, Tallahassee

Attended Via Conference Call:

Jennifer Moore, BSN, RN, Tallahassee

Su Meter, BSN, RN, Tallahassee

Kristin Barnette, RN, Tallahassee

Request for a pediatrician to be added to the group was made for possible recommendations by the Council.

2017 Legislative Update

Cassandra Pasley provided the Council an update on legislation related to Child Protection Program and Newborn Screening. Child Protection Team has one proposal and Newborn Screening has a proposal clarifying language to include the “word” detection in the services provided by the program, clarifying the language including medical schools, and aligning state law with federal law when releasing test results.

Additional information was provided on the release of the Governor’s budget and the impact on the Division of Children’s Medical Services (CMS). The budget included 7 full-time equivalent (FTE) positions for the Early Steps Program, 3 FTEs for the Newborn Screening Hearing Program, and 1 FTE for the Newborn Screening Follow-up Program. Funding was included for the NBS Program to implement screening of x-linked Adrenoleukodystrophy and for the Child Protection Team to expand to include an ARNP and coordinators.

Several council members shared concerns on medical inflation increasing with no additional funding since 2005 for the current services provided through the NBS Program and the Long-Term Genetics (LTG) Program. Cassandra Pasley clarified that additional funding to support the NBS and LTG Programs was supported in the Department of Health’s (DOH) Budget, and though it was not included in the Governor’s Budget, it still could be added by the Senate or the House. Drs. Driscoll and Auerbach expressed concern with regard to adding new disorders without the budget to treat. Dr. Driscoll suggested reaching outside of DOH and include advocacy groups. Members discussed ways to reach out for support. Cassandra Pasley informed that the members that the Council could not petition against the Governor’s ruling. Dr. Pitel posed a question to Dr. Carina Blackmore on the funding of the NBS Program and revenues collected, specifically is the program collecting sufficient funding to support the needs of the program. Dr. Blackmore informed the Council that the program had a significant shortfall and has recently made up for that and is now in the black.

Zika Update

Cassandra Pasley provided and update on Zika, including the approval of a federal grant to increase the capacity for Zika services in the state. The Division of CMS received a three-year federal grant in the amount of 2.3 million as a result of local transmission in the Miami-Dade area. The primary goal of the grant is to establish two centers in the state to act as resource and referral centers. The CDC is working on a Zika website, Zika CareConnect, and has asked DOH to partner with them to create a database of healthcare practitioners able to treat for Zika infection. Any woman in Florida can receive free zika testing at the local CHDs.

EveryLife Foundation

The EveryLife Foundation gave a presentation via teleconference. Discussion by the Council regarding lobbying for this group and it is not a possibility but can be done outside the purview of the Council.

Newborn Screening Laboratory Update

Dr. Bonnie Taffe informed that the NBS Laboratory staffing is current with no vacant positions. Gary Fields was the most recent addition who comes from Jacksonville Mayo to work with the MSMS instruments. A Quality Assurance update was given and the laboratory has passed proficiency testing for the last two quarters.

Dr. Taffe provided an update on the data system, Screening Center, and the laboratory system, Disorder Utilities. These updates will provide the data entry team more efficient linking and the laboratory upgrade will allow the program to comply with Windows updates.

The cutoff values for Congenital Hypothyroidism have been evaluated by Dr. Dorothy Shulman and will be addressed after the software implementation is complete. The modification will reduce the number of screens abnormal for newborns less than 24 hours of age. Dr. Cheryl Garganta and Penny Edwards are also looking at the cutoffs for MSMS with the goal to rule out false positives.

Testing for CF has begun with Luminex, after the recall from Hologic last year. The lab has also spent considerable time testing specimens from Texas and Michigan.

The PerkinElmer x-linked ALD testing kit has not been approved by the FDA as of this time. The earliest estimation is currently in 2018.

Dr. Pitel requested there be a discussion on the meeting minutes from the February meeting. Dr. Shulman made a motion to accept the draft minutes and was seconded by Dr. Auerbach and all were in favor.

Newborn Hearing Screening Follow-Up Program Update

Dusty Edwards introduced Jessica Meyer as the new Director for the Newborn Hearing Screening Unit.

Jessica Meyer provided information on program staff and the related duties. There was also an update provided on changes to the grants that support the hearing program. There were changes to the HRSA and the CDC grant deliverables, some being significant programmatic changes. The program will modify goals and objectives according to the grant deliverables. Jessica Meyer reviewed the hearing data.

Newborn Screening Follow-Up Program Update

Dusty Edwards provided update on the status of the Electronic Laboratory Order/Electronic Laboratory Results (ELO/ELR) objective. ELO/ELR went live and are doing well for the two hospitals that went live in December 2016 and January 2017. The program is continuing to move forward with the Baycare hospitals for future roll-out to the state.

The new Web Portal is an ELO with the same goal to increase productivity and decrease data entry errors. Tallahassee Memorial Hospital is the beta site and will begin testing.

Dusty Edwards provided an update on the Hologic recall affecting the cystic fibrosis screening. All specimens retested from the Hologic recall returned the same results as the original. Dr. Weatherly provided an update on the Florida experience testing for cystic fibrosis in the state.

The NBS data was reviewed with the council members. The program updated the language related to the partial unsatisfactory specimens as discussed at the last meeting. The TSH borderlines, MSMS borderlines, and unsatisfactory rates were reviewed with an emphasis placed on meeting the goal of a having a hospital unsatisfactory rate at one percent or lower.

There was an update provided on the Ad Hoc Committee to address the addition of x-linked ALD and the disorders that have already been recommended on the national panel. Dusty Edwards reached out to APHL and NewSteps regarding available tools for reviewing the current state of the program.

An update on Rule 64C-7 was provided and to include collection language and minimum requirements for referral centers, and the program will wait on the formula language. Many concerns were expressed from parent consumer Jodi Hatin, whose daughter has PKU, Melissa Perez, and Lindsay Raub. Dusty Edwards and Cassandra Pasley assured that the program will have future discussions with stakeholders prior to additional modifications to the Rule.

The meeting adjourned at 2:20 pm EST.