

## **Genetics and Newborn Screening Advisory Council Minutes**

The Genetics and Newborn Screening Advisory Council (GNSAC) meeting was held Friday, February 28, 2020, 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 9:35 am, by Paul Pitel, Council Chairperson. Roll was taken and Introductions were made.

### **Members Present**

Robert Fifer

Roberto Zori

Paul Pitel

Dorothy Shulman

Gary Kleiner

Lindsay Kahn (Conference call)

Heather Smith (Conference Call)

### **Guest**

### **DOH Personnel Present**

Bonnie

Lori

Sajani

Elliot bailey

Larry

Amy van meeting

Ely

Jeanne Patti

### **Attended via Conference Call**

Lori kohler

Lindsey Kahn

Kristin Spense

Jessie Botcher

Heather smith

### **Children's Medical Services (CMS) Division Director Update**

Marcy gives a Division update we still have 2 weeks left of session, eye examination bill. Require that all newborns receive an eye exam before the child is discharged. Dr. Pitel is concerned with the effectiveness of the bill. Dr. Pitel expresses his frustrations with SMA coming about and now the eye screening being put into session before hearing before our council. The council would like too to move in objection in the process of adding things to the newborn screening process. Dr. Pitel would like to motion to the legislatures on how these new additions go against process. Dr. Zori brings up the point that adding screens to the panel takes an in-depth discussion and due process of discussion to the council. Marcy will get the legislature person responsible for putting the bill in and notify the council of the party so education can be done and conversations of how to improve the process. House bill for 1 million for Genetics, house and Senate bill to require telemedicine coverage by insurance. Dr. Pitel and Zori State the gaps in commercial insurance which would lead a big portion of the still neglected. Telehealth services for genetics are generally not covered, this bill does not mention requiring all insurances to cover telehealth in addition to Medicaid. Robert Karsh is announced as our Deputy Secretary will start in March. Dr. Zori would like clarification on the Medicaid case workers in CMS as UF is having issues with getting patients care. Dr. fifer informs the council representatives Jacobs introduced the bill.

### **Newborn Screening Hearing Follow- Up Update**

Jessica Meyer provides a hearing update, 9:59 am. Introduces Peggy Waterman and Teryl Camus as new additions to the NBS Hearing staff. Over 100 Pediatric audiologists have been trained on the new electronic recording system since May 2019. The new Grant is actively moving as they are about to hire 5 parents of deaf or blind children to be advocates to new parents with kids who are diagnosed as deaf and blind. Dr. Fifer brings up a barrier of Early steps funding and information that limits how much information hearing gets on patients. The results represent a small number of our states population for this reason. Dr. Zori says they have a hard time to provide genetic services to children at the school for the deaf and blind. Infant hearing loss can be caused by some genetic issues and the need to get them genetic help is important the council would like to work with new grant program that connects us with children from 0-6 years of age we could better connect to the families and break the barrier that has been establish between the deaf community and genetics. Jessica suggest going to the regional learning communities Jessica and Dusty suggest adding the EDI advisory council to our council

### **Newborn Screening Follow-Up Update**

Dusty provides an NBS updated for the program 10:18 am

We have added 3 nurses to the team, added 2 supervisors Emily and Bryan. We are adding a Genetic counselor and additional contract manager. We just need to fill the positions. Dusty shows the newsteps info to the members to show Florida's progress and standing compared to other states. Dr. Kleiner is on the US team for SCID and they are trying to compare the US to the nation and Florida seems to be reporting way more the other states. Update on the progress Linda has made on PKU since she started with NBS in March. We are currently fighting for Formula for PKU patients, but we still need to change the process for low protein foods. Presents other barriers with insurances and payments for formula and low protein food. Dr. Pitel suggest reaching out to the legislature to see if we can have a sit down with them to voice the problems. Patients are aging out of coverage and we have no way to get them the food and formula they need unless they are pregnant. Private insurances are covering formula but then not low protein foods because the money they used to cover low proteins food is now being used to pay for formula. We hit barriers with patient's assistance companies on insurance. CCHD data is presented and explained to what we provide ACHA quarterly. The Federal Advisory committee expired on September 30, they were supposed to meet on February 13<sup>th</sup> and 14<sup>th</sup> but it was canceled and has not been rescheduled at this time. We are at a standstill on adding new disorders due to this committee not being authorized at this time.

### **Newborn Screening New Disorders Update**

Emily Reeves provides an update on New Disorders at 10:57 am, LSDs went live on February 3<sup>rd</sup> in addition to MPS1. New data bases were implemented, amendments to contracts were made, now are we going to follow babies' long term for the disorders that need long term follow-up. 2-year mark of X-ALD, the lab is working on a new validation process, which led to new referral process. SMA is anticipated to start on April 27, 2020. We are still working on where these children will go and how they will get treatment. Discussion on implementing SMA between Dr. Pitel and dr. Zori and Dr. Sanchez. Dr. Pitel would like to have a call with the council and other interested parties offline.

### **Newborn Screening Laboratory Update**

Bonnie provides a lab update 11:22 am, the lab successfully implemented the new disorders successfully. Due to the time constraints of launching SMA PerkinElmer with be handling SMA screening until the lab can get the proper staff and testing measures. Dr. Kleiner ask about coop plans for hurricanes. Dr. Taft states we have an agreement with Perkin Elmer and Texas if the lab would be impacted by a disaster. Dr. Pitel ask about the Coronavirus and how it could affect the labs stability. The lab is ready, and all staff is cross trained, it could put a strain on our turnaround times for NBS test but hopefully it would be a short limit. The lab is working on how to improve our turn around time now that we are counting all 7 days of the week instead of business days. Bonnie announces the tour of the lab will be offered today now that the renovations are done.

### **Newborn Screening Program Study**

Dusty provides and update on the study presented to the legislature on November 1 at 11:32 am. We have had no comment from the legislature to this day. RTI is going to do a follow-up study, contacts are being established so they can start the process. Dr. Pitel wants a meeting with RTI and the council before the report is finalized. Dr. Zori seconds, Dr. Kleiner wants to know if they will compare us to other states in this study. How long before we get the RTI data

**Dr. Pitel announces lunch break 11:51 am**

**Pitel calls the meeting back to order at 12:20pm**

### **Critical Congenital Heart Disease Presentation**

Dr Hudak presents at 12:21 pm, gives a formal presentation on CCHD in other states compared to Florida's testing methods. There is a gap in Florida's reporting as we the newborn screening program are limited on what information we get. Not all collection facilities know how to report the information correctly. 1:03 Dr Pitel motions to have a meeting to determine how effective the reporting is. We must get permission from IRB before pulling a meeting with Kristin Dr. Hudak, Vital Stats, birth defects, etc. to determine if we are getting the best care for our babies. 1:10 pm Dr. Pitel moves to make a working group on how we are going to consider the optimal ensure collection and quality improvement on CCHD data. Dr. Fifer seconds motion 1:11pm. there was a voted and it passed at 1:13

Approving min 1:13 they vote them in at 1:14 pm

### **New Discussions**

**1:15 dusty ask about next meeting date, New dates for August meeting August 28<sup>th</sup>**

**Lindsey will send out a doodle poll on Monday to ensure August 28<sup>th</sup> works for everyone**

#### **Public comment**

Dr. Schiebler wants to know where we are in getting funding for formula

Stephanie Hacker responds dr. Pitel motions for a working group on formula needs 1:19 pm

How can we fix the problem, Dr, Sanchez ask that all metabolic formula be discussed? Dr. Zori and Dr. Kleiner second 1:20pm the council votes the workgroup in at 1:21pm.

Dr. Sanchez wants to know how to handle babies without insurance that have abnormal results. Dusty lets them know we discovered the problem and are working on a solution so the NBS can approve and authorize the funds.

Dr. Kleiner brings up a possible issue with therapy treatments and Medicaid and public insurances not covering them or not being able to get them in a timely fashion.

There is a gap of coverage between our ability to diagnose and screen but then treat or confirm diagnosis is blocked by insurance or lack thereof.

Dr Pitel