STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD
Commissioner

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Universal cCMV Screening Working Group
Approved Meeting Minutes
Thursday, December 14, 2023
12 – 1 PM

**Working Group Members**
Present: Jody Terranova, DO, MPA (Chair), Nancy A. Louis, MD, FAAP, Carlos R. Oliveira, MD, PhD, Ashley C. Howard, DO, FAAP, Thomas Murray MD, PhD, FAAP, Jafar H. Razeq, Ph.D., HCLD/PHLD (ABB), Adrienne Manning, Marie Burlette, RN, BSN, MPH, John Lamb, and Amaka Atuegbu

Others present: Charbel Khalil

Absent: Scott Schoem, MD, MBA, FAAP and Debra Ellis, RN, BSN

I. Call to Order
   a. The meeting was held via Teams and Dr. Terranova called the meeting to order at 12:02 PM.
II. Approval of Minutes
   a. Dr. Murray moved to approve the minutes of November 14, 2023. Ms. Manning seconded the motion. The motion passed unanimously.
III. Public comment
   a. No members of the public were in attendance.
IV. New Business
   a. Lab methodology subgroup presentation
      i. Dr. Terranova called on Mr. Khalil to introduce himself. Mr. Khalil is a DPH lab consultant and PhD candidate.
      ii. Ms. Manning and Mr. Khalil presented on method development for cCMV detection by real-time polymerase chain reaction (RT-PCR)
      iii. Ms. Manning stated that the method development workflow will test two DNA extraction methods using dried blood spot (DBS) sample.
      iv. The workflow will also evaluate DNA amplification and cCMV detection methods. w
      v. Ms. Manning noted that the sample preparation will include newborn DBS sample. The preparation will include several controls to evaluate assay accuracy and validity.

vi. Ms. Manning provided an overview of the two DNA extraction methods, noting that the lab will evaluate which is more effective in extracting cCMV DNA.
vii. Mr. Khalil stated that the lab will use RT-PCR or qPCR for DNA amplification. RT-PCR is also a lab technique for rapidly amplifying a specific DNA segment in real-time. Mr. Khalil noted that RT-PCR is a gold standard method that labs use to quantify and qualify the presence of DNA.
viii. Mr. Khalil stated that RT-PCR requires a master mix for the DNA reaction to occur. The lab will be using a master mix that has the relevant chemistry to facilitate the reaction. This master mix will be used to identify two target genes to detect cCMV.
ix. Ms. Manning noted that the lab will use an existing lab instrument and software for cCMV detection and data analysis.
x. Ms. Manning stated that the lab will interpret the results after the data analysis. The interpretation will be based on expected cycle threshold values indicating whether the newborn's result is within normal limits, cCMV positive, or inconclusive. Ms. Manning also noted the follow up under each result: none for results with normal limits, refer to treatment center for cCMV positive, and request a repeat sample with 21 days of age for inconclusive results.
xi. Ms. Manning also shared the current lab setup with the working group, indicating that the lab has several isolated rooms for all the various method development workflow.
xii. Ms. Manning highlighted the lab's next steps, including, but not limited to, identifying the most effective cCMV DNA extraction method, determining the best target gene for cCMV detection, and developing a standard operating procedure and validation plan.

b. Working group discussion of lab methodology
    i. Dr. Murray suggested that the follow up for cCMV positive newborns should state 'refer for further evaluation' rather than 'refer to treatment center' because most of the newborns will not require treatment.
    ii. Dr. Murray asked about the quantity of viral particles that states with cCMV screening can pick up in the DBS sample. Ms. Manning noted that Minnesota uses a clean DNA extraction method with the incidence of about 1 in 350, but some published incidences are higher. Ms. Manning also added that the lab is considering multiplexing to amplify several different DNA sequences simultaneously, which can provide better sensitivity or specificity from DBS sample testing.
    iii. Dr. Terranova noted that the lab methodology subgroup will present is method development results and next steps in March 2024.
c. Key takeaways from Education Subgroup meeting with families affected by cCMV
    i. Ms. Atuegbu shared the key takeaways, including the need to educate families expecting a second child, convey cCMV information through multiple platforms, simplify educational materials for families, and leverage real family or lived experiences in cCMV education and marketing

ii. Dr. Howard asked if OB/GYNs are part of the working group given the role that families have identified they should play in cCMV education. Dr. Terranova noted that, though OB/GYNs are not in the working group, the Department can consult them when creating cCMV educational materials.
iii. Dr. Murray expressed the need for caution when creating cCMV educational materials because of some parents' misconception of what the cCMV screening can and cannot accomplish. Dr. Terranova agreed, noting that families are aware that there is no absolute prevention mechanism but want to be informed on what they can do, within their capacity, to prevent cCMV.

V. Announcements
   a. January meeting – Treatment of Asymptomatic Positives Subgroup presentation
      i. Dr. Terranova noted that the subgroup will present its recommendations on January 11.
   b. Upcoming February meeting poll
      i. Dr. Terranova stated that this will be a 90-minute meeting as the planning for implements has two subsets – algorithm and DPH-follow up – and members in each will present their recommendations.

VI. Adjournment
   a. Dr. Terranova adjourned the meeting at 12:38 PM.