

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD  
Commissioner



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Governor  
Susan Bysiewicz  
Lt. Governor

### Universal cCMV Screening Working Group Planning for Implementation (DPH follow-up) Subgroup Minutes Thursday, January 18, 2024 12 - 1 PM

#### Subgroup Members

Present: Jafar H. Razeq, Ph.D., HCLD/PHLD (ABB), Adrienne Manning, Marie Burlette, RN, BSN, MPH, Debra Ellis, RN, BSN, and John Lamb

Other: Amaka Atuegbu

1. Call to Order
  - a. The meeting was held via Teams and Ms. Atuegbu called the meeting to order at 12:08 PM.
2. Public comment
  - a. No members of the public were in attendance.
3. New business
  - a. Subgroup questions
    - i. What are the follow-up plans after a cCMV diagnosis?
      - Should DPH be responsible for any follow-up? If yes, what should that be? Should DPH be the repository for all follow-ups?
        - o Ms. Manning and Dr. Razeq noted the importance of distinguishing between cCMV dried blood spot (DBS) positive screening result and confirmatory urine testing result. Ms. Manning stated that DPH Connecticut Newborn Screening Program (CT NBS) will be responsible for carrying out the follow-up on screen positive DBS samples, as is current practice, including locating infants and their PCPs, calling out results to PCPs, and connecting PCPs to treatment centers. Ms. Manning stated that CT NBS has more experience with DBS follow-up but noted that the addition of cCMV will present a bigger burden for the program.
        - o Ms. Burlette supported the previous point, noting the importance of consistency with reporting of positive screens for other disorders that CT NBS handles.

- o Ms. Manning noted that CT NBS will need information from EHDI on infants who fail the hearing screening, so that CT NBS can link infants who fail the hearing screening but not the cCMV DBS (potential false negative). Ms. Manning stated that in such cases, infants will need to receive a confirmatory urine test and their DBS may need to be sent out for molecular testing to determine why CT NBS missed infants in the initial DBS screening. The latter will help CT NBS determine the efficacy of its testing especially as DBS is not as sensitive as urine and saliva.
- o Ms. Burlette asked if CT NBS will also report positive DBS results to EHDI. Ms. Manning stated that CT NBS and EHDI will likely be able to share such information with a system/database, noting that both sections are in the CT DPH.
- o Ms. Burlette asked if EHDI will need an active notification of positive DBS results. Mr. Lamb responded that information sharing from Lab Info Management System (LIMS) to Maven data system will be sufficient. Mr. Lamb noted that, with funding, EHDI could develop a workflow for tracking. Mr. Lamb also noted that EHDI does not currently conduct cCMV outreach and if this continues post universal implementation, the DBS positive result will primarily be for tracking. Mr. Lamb noted that it could also be beneficial if EHDI could share the hearing results with CT NBS. Mr. Lamb stated that birth facilities enter hearing screening results into Maven and CT NBS should be able to easily access it from the new LIMS.
- o Dr. Razeq noted the need to educate families that a false negative result does not necessarily exclude a disease.
- o Ms. Burlette asked about the annual number of failed screenings and confirmed cCMV in the state. Mr. Lamb noted that the number of CMV positive cases average out to be less than or equal to 11.
- o Ms. Burlette stated that CT NBS may need to determine at what point to be notified of the failed hearing screening, noting that the notification of all failed hearing screenings would not be productive. Ms. Burlette suggested notifying CT NBS of confirmed positive CMV urine test.
- o Ms. Ellis asked if CT NBS will recommend confirmatory urine testing when calling out DBS positive results to PCPs and request PCPs to share the urine results. Additionally, for failed hearing screening, will EHDI call out to PCPs, or will CT NBS be able to give report both DBS and failed hearing at once, so EHDI does not call out? Ms. Burlette responded that after CT NBS' initial follow-up with the

PCP, it would be ideal to report the result to the treatment center and have the treatment center recommend diagnostic testing to the PCP. Ms. Burlette noted that CT NBS currently has a centralized system for doing this for the other disorders they screen for, but it would require additional funding to implement this type of system for CMV. Ms. Manning also noted the need to determine whether to work with treatment centers (as is current practice) or with ID docs (Yale and Connecticut Children's) on the follow-up from confirmatory urine testing.

- o Dr. Razeq noted that CT NBS can recommend actions, such as confirmatory urine testing, based on an ID doctors' algorithm recommendations. Ms. Burlette stated that currently, CT network gives specific recommendations based on consensus from health professionals, noting that such expert conversations need to be had if this is within CT NBS or contracted.
- o Ms. Burlette noted that CT NBS' short-term follow-up ends after the exclusion or confirmation of a disorder by diagnostic testing (which may include more than one type of confirmatory testing). The exclusion of a disorder or confirmation of a disorder is not done by the CT NBS program but by specialists.
- Is there any follow-up or long-term tracking that we should contract to a third party?
  - o Ms. Manning and Ms. Burlette noted that long-term tracking will be done through CT NBS. Ms. Burlette added that the third party conducting the clinical follow-up will need to report to CT NBS on cCMV specific metrics, similar to other disorders where CT NBS tracks disease specific outcomes up to 21 years.
  - o Ms. Ellis stated that ID doctors and the CT NBS will need to guide the third party on the metrics to follow.
- ii. Implementation of the education component
  - What education packets are needed?
    - o Education packets OB/GYNs give to pregnant families?
      - Ms. Ellis noted this is important, mostly in third trimester, and stated the benefit of combining these with general newborn screening education packet. The subgroup agreed on the need to educate parents pre-DBS screening (i.e. adding CMV information to current NBS pamphlets sent to birth hospitals and midwives and adding information for parents, and others, to CT NBS Program and EHDI web pages.

- Ms. Burlette noted that OB/GYNs have historically not been receptive, likely due to the amount of information they already provide to parents. Ms. Burlette noted that this trend may be changing. Ms. Manning stated that DPH can conduct outreach to OB/GYN partners. Dr. Razeq also noted that DPH can leverage annual OB/GYN meetings to inform the audience at once.
- Mr. Lamb asked if cCMV prevention will be included here. The subgroup stated that education on prevention should also be included. Ms. Burlette noted that the prevention piece is somewhat unique to cCMV as this is different from CT NBS work, so there is a need to consider that there may be other sections better situated for prevention education.
  - o Education packets at the time of cCMV diagnosis?
    - Ms. Ellis noted that this could be difficult if diagnosis is urine/DBS especially as families will be called to be given this information (not necessarily in the clinic), so unsure how this will be delivered and who will deliver it.
  - o General resources for pediatricians?
    - Ms. Ellis noted that peds will need this information and the state website should be updated to include cCMV information and resource links – DPH proposed algorithm, cCMV background info, info to share with parents, if a child is CMV positive – high potential for hearing loss, so diagnostic audiological follow-up.
- Do parents receive a comprehensive education packet if a newborn’s blood spot is positive or receive educational materials as needed?
  - o Dr. Razeq noted that parents are already overwhelmed with a lot of information at birth, so education materials should be targeted in addition to providing comprehensive materials – if a newborn tests positive in the DBS screening, the family should be educated on what that means and next steps.
- What is the list of cCMV information to include in education materials/packets for families and pediatricians?
  - o cCMV outcomes, what they mean, and follow-up: asymptomatic, symptomatic, false positive. Dr. Razeq noted the need to educate families that a false negative

result (failed hearing screening but not cCMV DBS) does not necessarily exclude a disease.

- o Algorithm
  - o cCMV background info
  - o cCMV prevention
  - o cCMV DBS screening — general information
  - o cCMV proposed algorithm
  - o cCMV fact sheet. Dr. Razeq noted that the state can utilize CDC cCMV templates to create one-page fact sheets for families and health providers. Dr. Razeq also stated the need to consult with ID docs, ENTs, other healthcare providers, and families, when creating these materials.
- iii. What length of follow-up do you recommend?
- What should be included in short vs. long-term follow-ups?
    - o Short-term
      - DBS and confirmatory urine results – Date of diagnosis needed and name of provider making diagnosis.
    - o Long-term
      - Ms. Ellis noted that the Network has identified two standard long-term follow-up metrics for up to 18 years (is the child still alive and is the child still seen yearly by a provider). Ms. Ellis stated that CT NBS and care teams will need to identify other required metrics for long-term database needs.
      - Ms. Burlette highlighted some metrics, including hearing diagnostics overtime, treatment(s) received, developmental milestones. Ms. Burlette noted that ID docs will be able to identify other metrics.
- iv. What kind of follow-up data should be collected? Who should be responsible for collecting the named data?
- Ms. Burlette noted that CT NBS will handle the long-term tracking, but the collection of data may be done outside of CT NBS unless the division is provided more resources. Ms. Burlette also stated the need for automated tracking using LIMS.
- v. What additional resources would be needed for a follow up program (within DPH or if contracted out) and for the education component – both creating and distributing the educational materials on an ongoing basis as well as any media campaigns to raise awareness?
- Ms. Burlette noted the need for more manpower and funding regardless of who handles follow-up. Ms. Burlette also noted the need for more education of follow-up staff from ID docs and families affected.

- Regarding media campaigns, the subgroup stated the need to hire media experts.
- Mr. Lamb noted that EHDI would need financial and technical support for its Maven database needs if EHDI were to substantially support follow-up. Mr. Lamb also stated the need for access to subject level experts, such as ID doc.

4. Next steps

- a. Ms. Atuegbu to begin preparing PowerPoints and share draft with subgroup for edits.

5. Adjournment

- a. Ms. Atuegbu adjourned the meeting at 1:15 PM.