Meeting Minutes
Virginia Early Hearing Detection and Intervention Advisory Committee Workgroup:
Promulgating Regulations for Congenital CMV(cCMV) Screening in Virginia's Infants

Date:	March 25, 2019
Location:	VHHA – Jefferson Room 4200 Innslake Dr. Glen Allen, VA 23060
Schedule:	10:00 AM Workgroup convenes session 3:00 PM Workgroup concludes session
Objective:	To promulgate regulations for Virginia's Administrative Code regarding congenital Cytomegalovirus (CMV) screening for those infants who fail their newborn hearing screening.
Present:	Karen Durst (DBHDS), Valerie Abbott (EHDI-AC, parent), Dr. Rebecca Levorson (INOVA), Mary Lynn Jones (Parent), Ashleigh Greenwood (EHDI-AC, INOVA-Pediatrix), Dr. Tim Lukenbill (VCU), Dr. Stephanie Moody (EVMS), Dr. Tiffany Kimbrough (VCU), Dr. Ryan Murray (INOVA), Rebecca Napier (Parent), Joan Williamson (VHHA), Dr. Mark Astoria (VCU), Willie Andrews (DCLS), Daniel Shearer (VSDB), Dr. Scott Vergano (CHKD), Dr. Cornelia Deagle (VDH), Daphne Miller (EHDI, VDH), Deepali Sanghani (VDH), Antoinette Vaughan (VDH), Kathleen Watts (VDH), Jennifer Macdonald (VDH)

Meeting Minutes

Please refer to Power Point for more information.

Notes in bold are relevant comments made in meeting

Agenda

10 AM – 12 Noon

1. Introductions — All
2. Background & Charge of Review — J. Macdonald
3. Description of Process — J. Macdonald
4. Defining cCMV — VDH EHDI Team
    - *a. Pathophysiology*
    - *b. Incidence*
    - *c. Screening Methods*
    - *d. Diagnostics*

    Hearing loss should be considered a symptom of cCMV

    - *d. Treatment*

    No treatment to mitigate maternal infection. No standard of care for asymptomatic infants. Vaccination studies are in progress.

    - *e. Long term outcomes*
5. Review of Current Research and Scientific Literature — A. Greenwood

& 2019 EHDI Meeting Highlights

-A list of scientific articles and studies were sent to workgroup prior to meeting and workgroup discussed these.
-VCU currently targeting cCMV screening on those infants who fail a newborn hearing screening (2,600 birth rate/year; 3+ cases failed hearing screening).
-**CHKD currently conducting ValEAR clinical trial (targeted screening).**

12N BREAK

12:30 PM – 3:00 PM Working Lunch

6. Available screening methodologies and costs W. Andrews

-Testing can be done by urine or saliva. Limitations of methodologies: Dried blood spot (DBS) sensitivity low. Urine difficult to obtain. Saliva must be done one hour after breastfeeding.
-Discussion on storage of DBS and possibility of expanding storage time for future cCMV testing if needed. Could not be done in short-term. A workgroup would need to convene from both DBS and hearing screening advisory committees on best possible way to approach that and discuss privacy, parental opt-in, storage costs, etc.
-Meridian introduced first FDA approved testing kit for saliva swabs.
-To implement cCMV testing at DCLS, the current NBS fee would need to increase by approximately $1.28 per baby. This figure is based on 1600 tests and the Meridian kit fees. This figure is tentative and could change based on differing methodology and number of tests. DCLS would need to increase the fee 9 months ahead of implementation.

7. Other State NBS Program perspectives VA EHDI Team

a. Review of States Currently Screening and Respective Language in Code/Regulations

-Workgroup Members received copies of Illinois, New York, Iowa, Utah, Texas, Tennessee and Maine's regulatory language.
-Workgroup agreed that Virginia's regulatory should include high level language and current protocols should be updated with more detailed language on how cCMV screening and referral should be implemented, including well baby, NICU and border babies.
-Utah's state EHDI program coordinator to speak to workgroup when protocols are being developed.

Workgroup was able to start promulgating regulatory language.
Definitions to add to 12VAC5-80-10 (underlined words are current definitions in regs):

1. **"Failed Newborn Hearing Screening" Final newborn hearing screen that resulted in a *refer and/or fail* in one or both ears prior to discharge from hospital or other**

birthing place or center. **(refer to Virginia Early Hearing Detection and Intervention Program Protocols for Hospital Newborn Hearing Screening, 2018)**

2. **"Congenital Cytomegalovirus (cCMV)" - need to define**

Potential Regulatory Language

1. **If a newborn has a failed newborn hearing screening, the discharging facility shall collect and submit a sample for cCMV testing prior to discharge.**

   a. **To ensure full implementation of cCMV testing, the Virginia Department of Health (VDH) may establish contract(s) with a designated testing laboratory to ensure testing, and the established contracts shall comply with all federal assurances.**

8. Next steps J. Macdonald, All

Next meeting preferred in 6 weeks. Two hour meeting will be a combo of in-person at VHHA and webinar for others who cannot travel. Google poll to go out to workgroup for best date by Friday, 3/29.

To do list for next meeting:

- **More Information on methodologies. Dr. Rebecca Levorson will research Meridian testing and bring information back to group.**
  - **Willie Andrews will research sensitivity on dried blood spot, and may need to contact ARUP.**
- **Need definition of cCMV for regs**
- **Propose regulatory language on providing Information and education to:**
  - **parent and/or guardian: birth defects caused by congenital CMV, incidence, transmission, method of diagnosing cCMV, prevention, etc.**
  - **Pregnant Women: prevention**
  - **Public: prevention**
- **Propose regulatory language on reporting to VDH**
- **Need to decide where in regulations to insert new language**