Meeting Minutes: Advisory Committee for Heritable and Congenital Disorders

DATE: JANUARY 11, 2022
MINUTES PREPARED BY: JESSIE CAVAZOS, HEALTH EDUCATOR
LOCATION: VIRTUAL (MICROSOFT TEAMS)

Advisor Present

- Jennifer Arveson
- Sue Berry
- Rae Blaylark
- Bob Jacobson
- Courtney Jarboe
- Steve Johnson
- Peter Karachunski
- Amy Karger
- Jan Larson
- Dieter Matern
- Brooke Moore
- Eva Morava-Kozicz
- Katie Pfister
- Teresa Rink
- Annamarie Saarinen
- Kathy Stagni
- Renee Temme
- Marcelo Vargas
- Joseph Williams

Advisors Absent

- Becca Williams

Summary of Decisions Made

- Decision: congenital cytomegalovirus was recommended for addition to Minnesota's newborn screening panel

Meeting Agenda and Notes

Welcome and Roll Call: Mark McCann, Jan Larson

- Mark McCann welcomed everyone to meeting and thanked the public and professional testimonials that were sent to us and shared with the committee members. He also alerted the advisors about the receipt of nominations for two additional conditions: Duchenne muscular dystrophy and Krabbe disease.
- Chair, Jan Larson, opened the meeting and performed the advisor roll call.

EHDI Advisory Committee Comments: Abby Meyer, chair

- The Newborn Hearing Screening Advisory Committee (aka EHDI Advisory Committee) wanted to provide some comments for this committee to consider.

- Diagnosis of cCMV:
  - 21-day window for detection of CMV fits well within and supports EHDI's 1-3-6 goals
  - Monitoring for audiologic change is critical for infants with cCMV. Families will need ongoing access to audiology. Follow-up on risk factors is part of our existing EHDI System.
  - Early identification of cCMV may help provide families with answers, important information regarding potential and/or identified hearing differences, and time to explore language opportunities.
- Primary and Specialty Care:
  - Education to primary care, ENT, and other providers who support families is critical.
    - Positive cCMV result is an opportunity for MDH to reach out to infant's PCP and talk about protocols, best practice recommendations.
    - Standardizing follow-up protocols statewide would be helpful
- Infants who are Asymptomatic:
  - Messaging
    - We don't want parents to be overly concerned yet monitoring is vital.
    - We need to advise parents about the way symptoms/concerns can be discovered.
    - Accurate information presented in clear ways
    - Access to parent-to-parent support will be very important
  - Recognize that frequent hearing or other necessary screening or tests can be a burden and costly to families. Support for families will be important.
- Early Intervention:
  - cCMV (symptomatic or asymptomatic) is an established condition eligible for Part C Services. Early Intervention services would connect the child and family to information and supportive services.
  - Early identification and intervention for children with hearing differences improves language outcomes

MDH Readiness: Unit Supervisors

- Sondra Rosendahl: Regardless of the outcome of today's vote, a package outlining the Advisory Committee's decision and the rationale behind it will be developed and sent to the Commissioner of Health.
  - The Commissioner will review that package and make a final determination.
    - Not ready at this time
      - Decision will be documented and shared with relevant stakeholders
    - Ready/add

        - Decision will be documented and shared with relevant stakeholders
        - MDH will begin the implementation process – there are many tasks that need to happen in order to be ready to begin screening, which we will outline in the next slides
- NBS Operational Needs—Jill Simonetti
    - Hire and training more staff – CRITICAL NEED and there are HR delays in hiring across the entire department impacting all units of the program
    - Communicating to providers and public (e.g., prepping providers for implementation, submitters, website, fee increase, etc)
    - Changes to laboratory information management systems (LIMS) for both lab and follow-up work efforts – timing will depend on vendor availability (~6m-1y)
    - Fee will increase by $43 per specimen per the Vivian Act
    - Purchase of supplies and equipment
- NBS Lab Needs—Carrie Wolf
    - Hire and training more staff
    - Space accommodations for new testing and instrumentation
    - No CDC Quality Control material available, so control material will need to be found and made using blood spiked with CMV.
    - Assay development and validation
    - No CDC Proficiency Testing program, so we would need to find another CLIA certified lab who is testing cCMV on dried blood spots and trade samples with them to prove to CLIA our assay works
    - Changes to NBS card – depending on method selection, may need an extra spot on the filter paper
- NBS Follow-up Needs—Sondra Rosendahl and Jenna Laine
    - Hire and train more staff
        - cCMV case load (~217/yr) compared to current case load (showed chart including 30+ metabolic conditions accounting for the same N) for blood spot results
    - Draft notification packets as well as diagnostic and follow-up forms
    - Develop follow-up processes/protocols
    - Host implementation work group meetings with a group of providers and parents to finalize follow-up algorithms
    - After diagnostic confirmation, what other evaluations are needed? (Ontario's below)
        - Physical exam
        - Other laboratory investigations?
        - Diagnostic audiology

        - Head ultrasound - does it matter who reads this?
        - Ophthalmologic assessment
    - When? How often? For how long? Covered by insurance?
    - At what point do we transfer case to long-term follow-up?
- Long-Term Follow-up Needs—Jennifer Hauser
    - Hire and train more staff
        - This is in addition to the nurse that will be hired for education and outreach efforts as per Vivian Act legislation
        - Staff from our program have frequently been reassigned for COVID activities, which could impact timing
    - Determine what supports are needed for confirmed cases
    - Determine developmental monitoring and longitudinal follow-up for confirmed cases (both asymptomatic and symptomatic cases)
    - Changes to LIMS system – timing will depend on vendor availability
- Question:
    - Sue Berry: You mentioned needing to add an additional blood spot. How many do you currently have now and what does that look like?
        - Carrie Wolf: Right now, we have 5 blood spots on our newborn screening card. We would add an additional circle, so a total of 6 spots on the card. This would make the screening card longer. Depending on sample collection and testing procedure (if we go with dried blood spots), sometimes there's plenty of blood on the card, but frequently there isn't enough. The additional circle would need to accommodate 3 punches just to run the sample once, and then we'd also take more punches if retesting is necessary.

Condition Readiness Work Group – Final Report Out: Sondra Rosendahl

- Sondra thanked the workgroup members and invited them to provide additional comments.
- The list of work group members was shared again, please refer to the October 2021 minutes for details.
- Objective: complete the Condition Readiness Criteria defined and approved by Advisory Committee on April 23, 2019.
    - This work group does NOT provide recommendation of whether a condition should be added or not, rather, it is a scientific/technical work group
- The work group met: 10/7/2021, 11/17/2021, and 12/1/2021 and the completed document was sent to all advisors on Tuesday, Jan. 4th.
- Readiness Criteria and Matrix
    - Criteria Breakdown:

    - Number of Required Criteria Met (6 max): 6 – Investigative/Ready
    - Number of Supporting Factors Met:
        - Clinical Characteristics of the Condition (6 max): 2 – Not Ready
        - The Screening Test (8 max): 5 - Investigative
        - Diagnosis, Follow-up, Treatment and Management (10 max): 8 - Ready
- Sondra requested that committee members re-review the completed Condition Readiness Document over the break and be prepared to discuss it.

Break

Discussion: All Advisors

- Some advisors asked how long it would take to implement cCMV screening if it was recommended. Mark McCann shared that there are a lot of moving parts and that MDH doesn't have a calibrated answer to that question today.
- They also discussed the fee increase of $43 per specimen (if cCMV was included in the screening panel) and how that money would be utilized and if it will support and sustain screening, not just implementation. MDH affirmed that that dollar amount does include our best estimate of not only the implementation but for sustaining as well.
- Some advisors expressed concern over the 75% sensitivity rate as well as the high number of cases that are asymptomatic and will require ongoing surveillance. Other advisors felt that 75% is a lot better than 0% and that the testing would improve a pediatrician's ability to monitor patients.
- The pros and cons of targeted cCMV screening (screening for cCMV after an infant doesn't pass their newborn hearing screening) were discussed and that children would be missed if targeted screening was implemented.
- Advisors discussed what monitoring for asymptomatic infants would look like (what would be considered part of a normal follow-up routine, who would handle this (primary care provider/medical home, specialists, etc.), for how long and how often would follow-up be recommended, what marks would need to be met for a child to be considered "clear" and no longer require follow-up, etc.). Sondra shared some information learned from Ontario's experience screening for cCMV and the evaluations recommended and the timelines for those assessments.
- Advisors wondered if this would be covered by insurance companies (without parents/guardians/providers jumping through hoops) and if the increase in appointments, co-payments, etc. would create an unnecessary burden for the families of asymptomatic children. Dr. Mark Schleiss could only respond with his personal experience with not having any 3rd party payers or insurance companies balk at any of the costs.
- It was asked if MDH could contract with outside laboratories for cheaper. MDH responded that it would be preferable to keep testing in-house but that outsourcing could be a path forward if there were commercial laboratories that could do testing with less blood.

- Communication and education to primary care and pediatric physicians about cCMV and the need to educate providers on how to provide uniform follow-up using the best standards of care. MDH shared that past practice has been to convene an implementation workgroup once a disorder is added to the panel and one of the tasks of this group is to establish follow-up protocols of children identified through newborn screening.
- There was a request for an update on the availability of vaccines and how that would impact their decision and screening. A representative from the National CMV Foundation shared that Moderna is the furthest along, but that she doesn't expect mass vaccination to be available within the next few years.
- Concerns regarding the antiviral therapy were brought up; how successful is antiviral therapy, how often would follow-up be required to monitor the toxicity of the antivirals. It was shared that there is only modest benefit with antivirals for symptomatic newborns. Instead, the discussion focused on the advantages of the interventions for hearing loss.
- Jan Larson called for any additional comments/discussion and said he would entertain a motion to close comments. Bob Jacobson moved to close the discussion; Courtney Jarboe seconded.

Vote: All Advisors

- It was confirmed that the committee had a quorum, and a vote could be held. Members who had a real or apparent conflict of interest were welcomed to abstain from voting.
- Advisors casted their votes electronically via MS Forms.
  - Do you recommend that the Commissioner of Health add congenital cytomegalovirus (cCMV) to the Minnesota Newborn Screening panel?
    - No, it is not ready for addition at this time = 3
    - Yes, I recommend its addition = 16
- The Minnesota Advisory Committee for Heritable and Congenital Disorders has voted to recommend the addition of cCMV to the Commissioner of Health.

Closure: Jan Larson

- Meeting adjourned.

Next meeting

Date: April 12, 2022
Time: 1-3 PM
Location: Microsoft Teams