

TECHNICAL ADVISORY COMMITTEE SPECIAL MEETING SUMMARY NOTES

What: Newborn Screening Technical Advisory Committee: Congenital Cytomegalovirus

When: September 21, 2022

Participating via Zoom:

- Technical Advisory Committee (TAC) Members: Kelly Oshiro (Co-Chair), Dr. Tao Sheng Kwan-Gett (Co-Chair), Joan Chappell, Phyllis Smith, Mary Kay Asuenhus, Dr. Eric Leung, Dr. Krystal Plonski, Dr. Lydia Groseclose, Erin Boespflug, Dr. Karen Fukui-Miner, Nancy Aguilar, Dr. Usha Sankrithi, Melissa Moxley, Kara Hamilton-McGraw, Dr. Ben Wilfond, Dr. Betty Gilchrist, Peggy Harris.
- State Board and Department of Health Staff: Kaitlyn Donahoe, Michelle Davis, Melanie Hisaw, Jo-Ann Huynh, Nathaniel Thai, John Thompson, Karin Neidt, Marcie Rider, Samantha Fuller, Sarah Keefe, and Caitlin Maloney.
- Other Guests: Allegra Calder (Facilitator), Dr. Joseph Bocchini, and approximately 30 members of the public.

Summary Notes:

Welcome and Introductions

- Kaitlyn Donahoe provided introductory remarks; Allegra Calder asked TAC members to introduce themselves, their role, and represented industry.

TAC Expectations & Meeting Norms

- Dr. Tao Sheng Kwan-Gett and Kelly Oshiro discussed the scope and purpose of the TAC and the plan for the day. Dr. Kwan-Gett said that as a pediatrician for many years, he had a responsibility for testing newborns for hearing loss and metabolic conditions and highlighted the importance of newborn screening. Ms. Calder provided an overview of Zoom functions and meeting norms.

Overview: Newborn Screening Program & Early Hearing Detection, Diagnosis, and Intervention (EHDDI) Program

- Dr. John Thompson provided an overview of the state's newborn screening program, noting that 32 disorders are screened through dried blood spot specimens. He said nearly 12 million tests are conducted each year, of which 200 infants benefit from early diagnosis and treatment.
- Marcie Rider provided an overview of the state's early hearing detection, diagnosis, and intervention (EHDDI) program. She noted that every state has an

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EHDDI program to ensure infants meet national hearing screening goals. Ms. Rider said the first few months are critical for language development and that a lack of diagnosis or misdiagnosis can cause developmental delays in children.

- Dr. Lydia Groseclose, Joan Chappell, Ms. Oshiro, and Ms. Rider discussed financial assistance for early hearing interventions and hearing aids, as well as the cadence for regular hearing monitoring.

Criteria Review

- Ms. Donahoe provided an overview of the Board's guiding principles and criteria for evaluating candidate conditions for the state's newborn screening program.
- Dr. Ben Wilfond noted that not all states use this process or criteria, and that Washington does a great job in establishing these principles.

Natural History of cCMV; Diagnostic Testing & Available Treatment

- Dr. Joseph Bocchini shared a presentation on the natural history of cCMV. He noted that cCMV is the most common congenital infection and leading cause of sensorineural hearing loss and neurodevelopmental delay. Dr. Bocchini discussed the diagnosis and treatment of cCMV, the current recommendations for antiviral therapy of infants with cCMV, and prevention tools that include increasing awareness and education, such as hygiene prevention measures.
- Dr. Wilfond and Dr. Bocchini discussed the selection process of asymptomatic infants enrolled in clinical trials for antiviral therapy.

Family Perspective

- Melissa Moxley provided a presentation on the impact of cCMV on her child and family. She explained that she contracted cytomegalovirus during pregnancy and her daughter was symptomatic of cCMV at birth. Ms. Moxley said that her daughter underwent antiviral therapy and improved, and eventually received a cochlear implant. She explained that she became an advocate for families who experience cCMV, which is the number one cause of non-genetic hearing loss.
- TAC members and staff thanked and commended Ms. Moxley for sharing her family's story.

Available Screening Technology

- Dr. Thompson and Ms. Rider provided an overview of available screening technology for cCMV using blood specimens and hearing screening, including targeted and universal screening methods.
- Dr. Wilfond asked about the proportion of babies screened that have hearing loss. Dr. Thompson said that about 170 babies are detected with hearing loss, and that about 31 of those babies experience late onset hearing loss acquired between birth and school age.
- Peggy Harris asked about fees for the newborn screening program and the availability of long-term follow up.

Cost-Benefit Analysis

- Caitlin Maloney provided a presentation on the economic model and results of the cost-benefit analysis. She said the hallmark of the newborn screening program is to prevent death and disability, and the team identified through their research that there is currently not strong evidence that screening for cCMV prevents death and disability.
- Dr. Wilfond, Dr. Eric Leung, and Ms. Rider discussed interventions to identify or prevent late onset hearing loss in children outside of the newborn screening program.
- Dr. Kwan-Gett, Ms. Maloney, and Dr. Bocchini discussed antiviral therapies, and the benefit of screening asymptomatic babies for cCMV to qualify for antiviral treatment options.
- Dr. Groseclose, Ms. Chappell, and Dr. Betty Gilchrist discussed the availability of audiology services in pediatric clinics and access to hearing monitoring for the Medicaid population.
- Ms. Moxley discussed elements that cannot be quantified in the cost-benefit analysis, such as the emotional impact to families.

Application of Criteria & Discussion

- Dr. Leung, Ms. Chappell, Dr. Kwan-Gett, Dr. Thompson, and Ms. Rider discussed the availability of screening technology and the audiology workforce, particularly in Eastern Washington, as well as concerns timely screening, and the ability to obtain urine samples in lieu of blood spot samples.
- Dr. Wilfond, Ms. Oshiro, Ms. Maloney, Dr. Thompson, Dr. Leung, and Dr. Groseclose discussed the health care system's infrastructure and ability to perform timely targeted cCMV testing, medical training and continuing education for cCMV, as well as strategies for outreach, education, and testing for pregnant persons.
- Dr. Kwan-Gett, Ms. Chappell, and Dr. Leung discussed equitable access to audiology services for communities of color and rural populations, the sensitivity of dried blood spot testing for cCMV, as well as the emotional burden on families experiencing late onset hearing loss.
- Dr. Wilfond and Dr. Gilchrist discussed targeted cCMV screening and the impacts of late onset hearing loss in children, including disparities in school punishments without the consideration of disability.

Vote #1 – Criteria

- TAC members participated in an anonymous, online vote to assess whether cCMV meets or does not meet criteria established by the Board. *See addendum for vote summary.*

Vote #1 Results & Discussion

- Dr. Kwan-Gett and Ms. Oshiro reviewed the results of the TAC's vote and associated comments for each of the criteria established by the Board.

Vote #2 – TAC Recommendation

- TAC members participated in an anonymous, online vote on an overall recommendation to the Board regarding the addition of cCMV in the state's newborn screening panel. *See addendum for vote summary.*

Vote #2 Results & Next Steps

- Dr. Kwan-Gett and Ms. Oshiro reviewed the results of the TAC's vote and associated comments. Dr. Kwan-Gett thanked the TAC for their votes and conversation on this complex topic.
- Dr. Usha Sankrithi, Dr. Wilfond, Dr. Leung, Dr. Krystal Plonski, Dr. Groseclose, and Ms. Harris participated in a discussion regarding their motivation for the recommendation to the Board, including the challenges of implementation, availability of data, desire to hear from the deaf or hard of hearing community, and alternative methods to screen for late onset hearing loss.
- Ms. Donahoe described next steps for the TAC and invited TAC members to attend the Board's upcoming meeting.
- Dr. Kwan-Gett and Ms. Oshiro thanked TAC members, presenters, and staff for their hard work today.

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