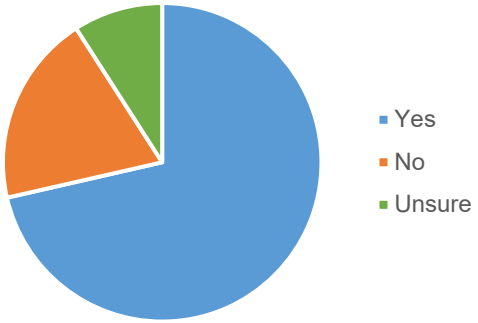
WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee: Congenital Cytomegalovirus (cCMV)
Summary of Comments

The following is a compilation of comments from technical advisory committee (TAC) members provided when voting on each individual criteria, and an overall recommendation. Comments have been summarized and are organized by each criterion and then overall comments provided.

Criteria Evaluation

Criteria	Major themes
1. Available Screening Technology 	• The sensitivity of 75% is insufficient for the blood spot assay. Higher sensitivity testing approaches (i.e., urine or saliva PCR testing) are not feasible, as we do not currently have the infrastructure for these approaches. • While the blood spot tests are not as sensitive, universal screening would still identify 27 additional babies with late onset hearing loss and early intervention. • Blood spot test sensitivity is acceptable. • Universal screening may not be feasible, but targeted screening could be feasible.
2. Diagnostic Testing and Treatment Available	• Lack of infrastructure and resources as it relates to increased hearing screening, monitoring, and follow-up; available audiology services in the state; training for

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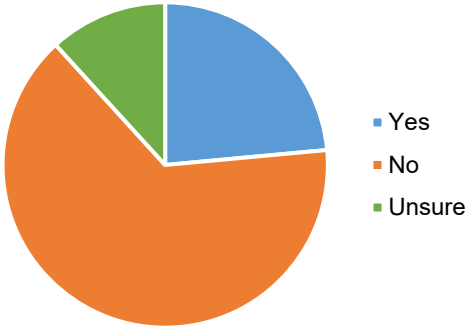
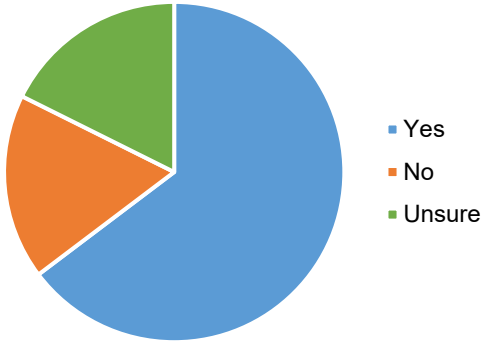
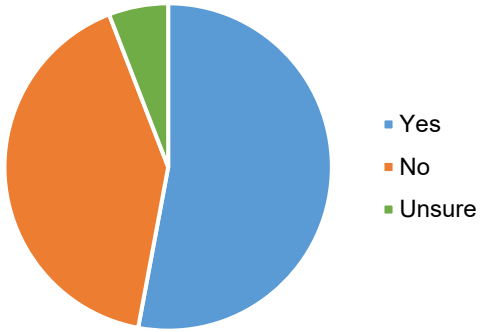
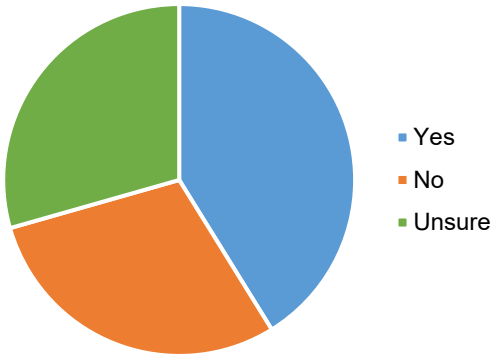
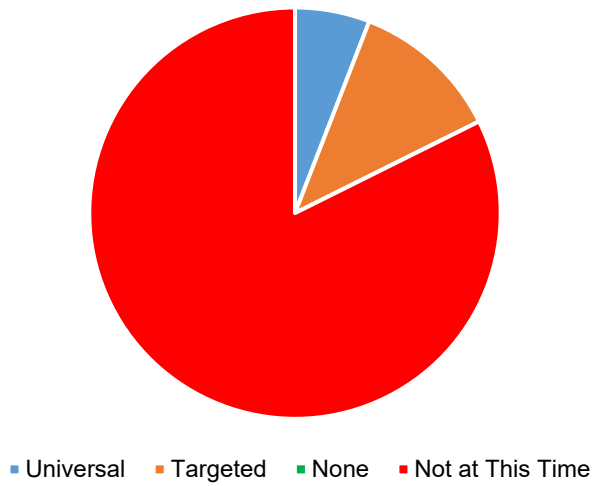
	audiologists and medical providers; availability of treatment; overall personnel for education and training; and alternative models for screening by primary care providers. • While it appears early intervention is effective for infants with late onset hearing loss, there is currently no established effective treatment for cCMV. • Why is cCMV not on the federal Recommended Uniform Screening Panel (RUSP)? • Unclear how much hearing interventions change outcomes. • One thought would be to educate pregnant women and possibly test for CMV during pregnancy.
3. Prevention Potential and Medical Rationale 	• There is no definitive treatment for cCMV; unsure that irreversible harm can be prevented. • Benefits of early antiviral treatment for cCMV are not well understood. As antiviral treatment (i.e., valganciclovir) is only used for patients with moderate to severe symptomatic cCMV, there is limited evidence on effectiveness of antivirals to treat asymptomatic babies. • Dried blood spot universal screening will not improve early diagnosis. Without screening most will be detected and receive care, albeit later. • Benefits of early intervention for late onset hearing loss are more clear. There may be benefits from earlier detection with regard to early childhood intervention and special education interventions on language development and education success. • Hearing is a contested medical goal by the deaf community, and the deaf community would argue for equity education for those with hearing impairment. • Early intervention is key to many problems, and this type of screening is a form of early intervention

4. Public Health Rationale  	• Risked-based or targeted screening would be more effective. • Population-based screening is justified, but not with the blood spot sample. • The public health rationale is present in theory, but the diagnostic and treatment technology doesn't exist at present to realize that benefit. • Hearing screens are done on a routine basis; we have school screenings that can further help with evaluation and detection. I think this would probably overwhelm an already overwhelmed system. • It is not clear that focusing on CMV will change the population of children with hearing loss. Parent-based assessments of hearing and language will allow detection of those with impairments. It may be better to focus on parent, school, and pediatrician education.
5. Cost Benefit / Cost Effectiveness  	• Based on the modeling and data presented, universal screening has a low cost-benefit ratio; does not seem to be very cost-effective. • The cost-benefit ratio is not comparable to other newborn screening conditions. • Even with an early diagnosis of cCMV, only a minority of babies with that diagnosis will develop late onset hearing loss. • Much of the cost effectiveness can't be quantified. There is a large emotional cost for families whose baby is diagnosed with cCMV who then are waiting years to find out whether their child will develop late onset hearing loss.

Overall Recommendation



Recommendation Options	Major themes
1. I recommend the Board add universal screening of cCMV to the list of conditions for which all Washington-born newborns must be screened.	*No comments received.*
2. I recommend the Board pursue steps to include targeted screening of cCMV to the list of conditions for which all Washington-born newborns must be screened. Note: this requires a change in the	If the cost-benefit analysis is not sufficient for universal screening at this time, the targeted screening should be a viable option to pursue, especially given that there are clear actions to take once a newborn fails the initial hearing test. Outside of screening, education and awareness for CMV should be considered as a low-cost 'win' in order to combat this important issue.

Board's statutory authority via legislation.	
3. I do not recommend the Board add cCMV to the list of conditions for which all Washington-born newborns must be screened.	*No votes or comments received.*
4. At this time, I do not recommend the Board add cCMV to the list of conditions for which all Washington-born newborns must be screened; I recommend the Board revisit cCMV screening at a future date.	• Once the technology allows for better sensitivity in blood spot testing, or urine screening becomes a viable option, the Board should revisit this topic. • The Board should continue to follow the data on the benefit of antiviral treatment for children identified with cCMV. • Recommend getting more data from states that have implemented the targeted program and take some of their learnings as well as more studies that are published. • Would support a universal screening option where positive results indicated more close monitoring of speech and language development in a primary care setting, and referral to audiologist would be reserved for those where concerns were present. • Recommend revisiting cCMV when it is included in the RUSP. • Highlighting the need for more awareness and resources on the early childhood detection of hearing loss, as well as the need for more research and advocacy for the prevention of cCMV. • Some concerns that were raised about impact on learning potential and education may be more reflective of other fractured systems; daycares and schools need to be involved for late onset hearing loss. • Need to discuss the availability of prenatal testing, OBGYN education, more training and availability for pediatric audiologists, and vaccination efforts.