

Washington State Board of Health

Newborn Screening Technical Advisory Committee Recommendation on
Congenital Cytomegalovirus(cCMV)

October 12, 2022

Background

- The Board has authority under RCW 70.83.050 to adopt rules for screening Washington-born infants for hereditary conditions using blood samples
- WAC 246-650 defines and lists conditions for which all newborns must be screened
- The Board convenes a technical advisory committee (TAC) to inform its decision on candidate conditions
- The TAC uses available information and data to evaluate candidate conditions using a set of criteria established by the Board

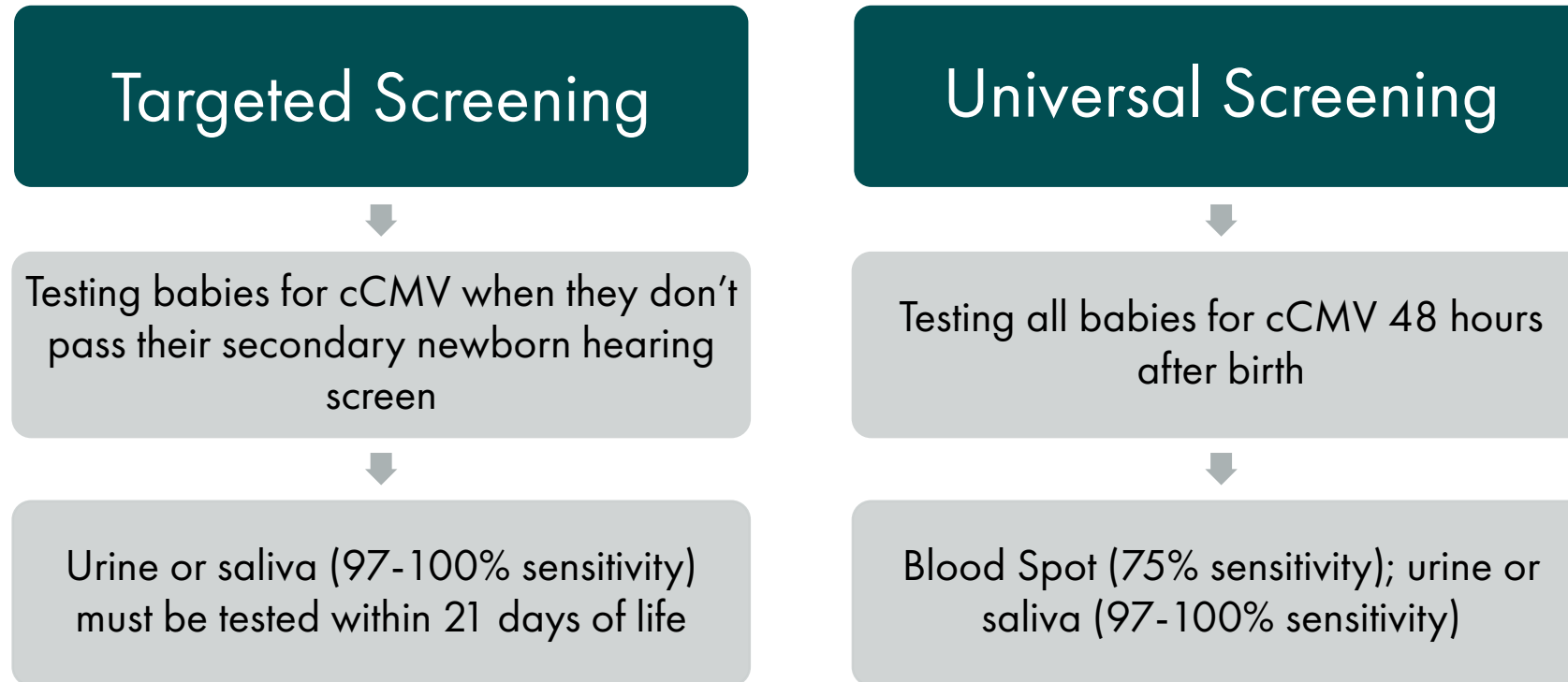


Congenital Cytomegalovirus (cCMV)

- Cytomegalovirus (CMV)
 - Part of the herpes family; easily contracted through exchange of bodily fluids
 - Can result in mild to severe flu-like symptoms; 50-80% of adults have contracted CMV by the age of 40
- Congenital Cytomegalovirus (cCMV)
 - A pregnant person can experience CMV infection and pass to the fetus in utero; their history of infection and fetal gestational age can influence severity of disease
 - cCMV can have severe and life-threatening impacts on infants (e.g., hearing loss, vision loss, cerebral palsy, seizures, developmental delays, microcephaly)
 - ~10% are symptomatic at birth → 50% will develop disabilities
 - ~90% asymptomatic → 10% will develop disabilities

**1 in 200
babies are
born with
cCMV
each year**

cCMV Screening Methods



Consideration of cCMV – Timeline



cCMV Technical Advisory Committee

Public Health

Department of Health
(Dr. Kwan-Gett, Co-chair)

State Board of Health
(Kelly Oshiro, Co-chair)

Advocates

Family Impacted by cCMV

Save Babies Through Screening

March of Dimes

State Ethnic Commissions

Commission on Asian Pacific American Affairs

Commission on Hispanic Affairs

Insurance

Health Care Authority

Association of WA Health Care Plans

Regence

Kaiser Permanente

Health Care Providers / Facilities

WA State Nurses Association

WA State Hospital Association

American Academy of Pediatrics, WA Chapter

WA Association of Naturopathic Physicians

Other

Audiologist

Bioethicist

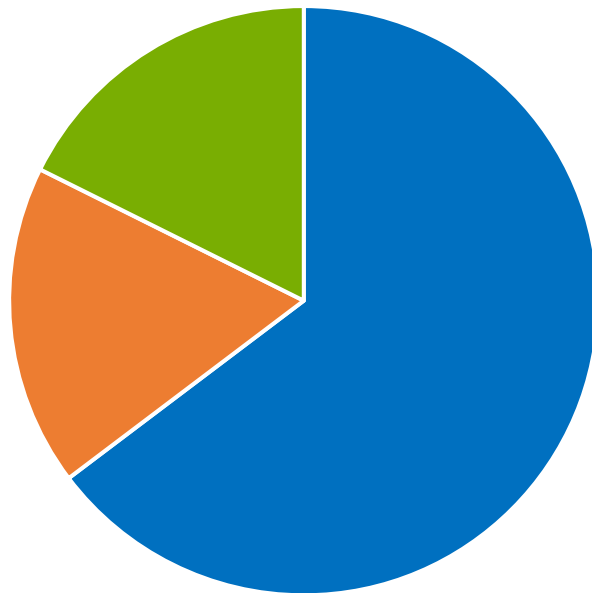
Guiding Principles & Criteria



- 1 Available Screening Technology
- 2 Diagnostic Testing and Treatment Available
- 3 Prevention Potential and Medical Rationale
- 4 Public Health Rationale
- 5 Cost-Benefit / Cost-Effectiveness

1 Available Screening Technology

Sensitive, specific and timely tests are available that can be adapted to mass screening.



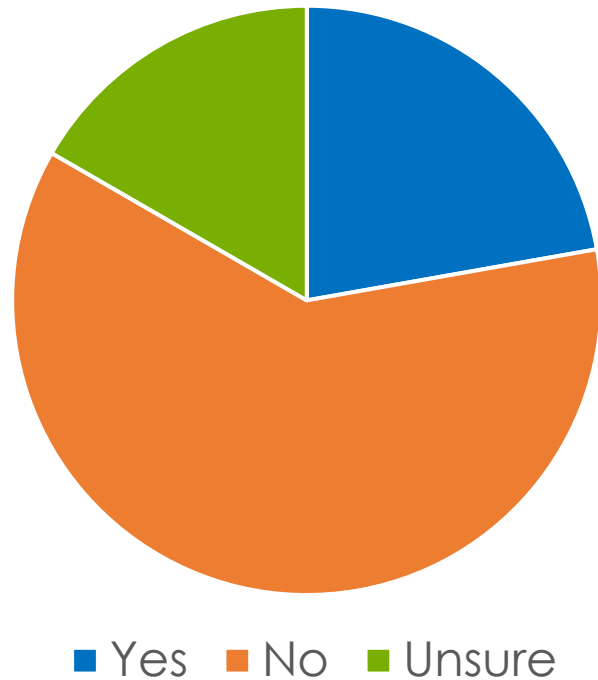
■ Yes ■ No ■ Unsure

Major themes

- Differing opinions on the sufficiency of the blood spot sensitivity
- Universal screening may not be feasible, but targeted screening could be
- Feasibility/infrastructure to support testing approaches with higher sensitivity (urine or saliva)

2 Diagnostic Testing and Treatment Available

All children who screen positive should have reasonable access to diagnostic and treatment services.

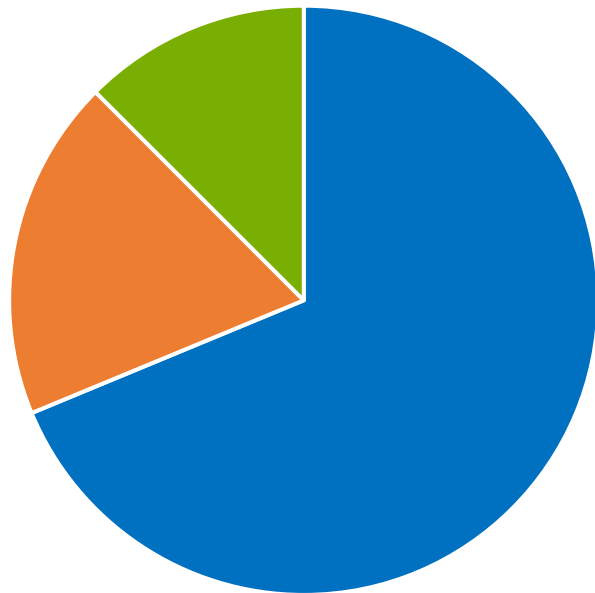


Major themes

- Lack of resources and infrastructure
- Currently no established effective treatment for cCMV
- Unclear how much hearing interventions change outcomes
- Educating/testing for cCMV during pregnancy

3 Prevention Potential and Medical Rationale

The newborn identification of the condition allows early diagnosis and intervention.



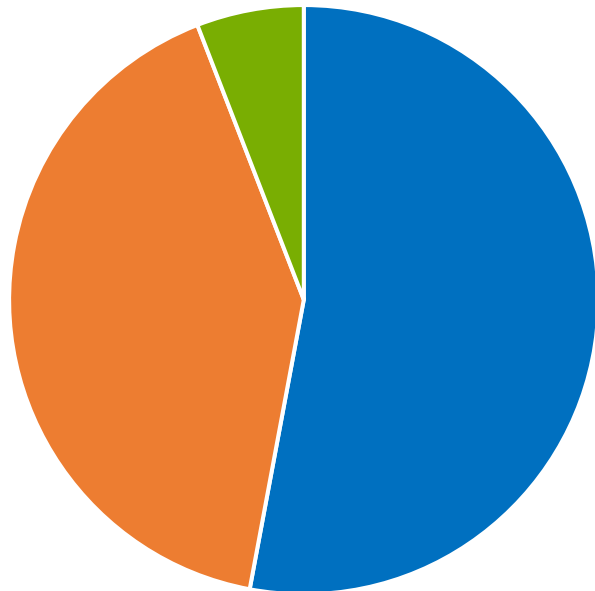
■ Yes ■ No ■ Unsure

Major themes

- No definitive treatment for cCMV; benefits of early antiviral treatment not well understood
- Blood spot universal screening will not improve early diagnosis
- Benefits of early intervention for late onset hearing loss are clearer
- Early intervention is key

4 Public Health Rationale

Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.



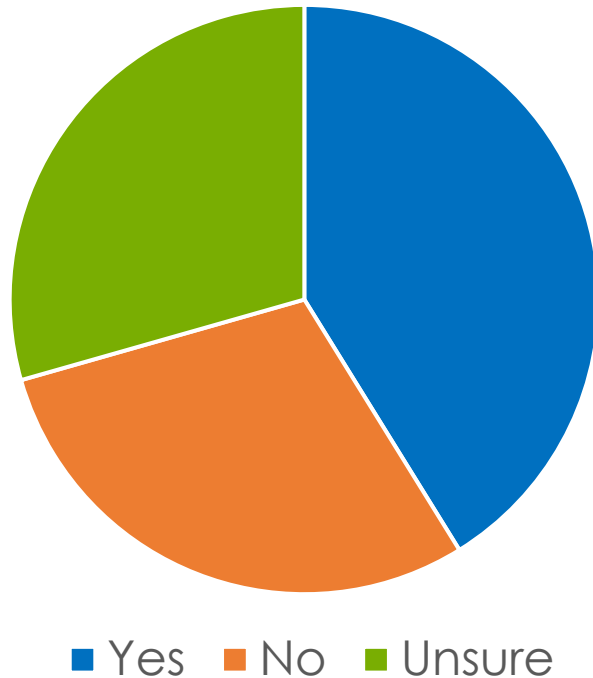
■ Yes ■ No ■ Unsure

Major themes

- Risk-based or targeted screening would be more effective
- Population-based screening is justified, but not with blood spot
- Diagnostic and treatment technology doesn't exist to realize public health benefit
- Involvement of parents, daycares, schools, pediatricians, etc. in assessments

5 Cost-benefit / Cost-effectiveness

The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis.



Major themes

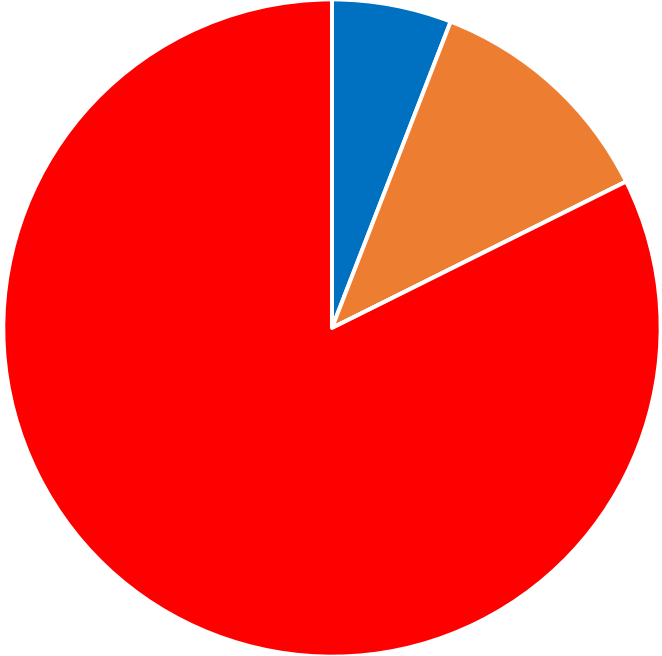
- Based on modeling and data presented, universal screening is not cost-effective
- Cost-benefit ratio is not comparable to other NBS conditions
- Much of the cost effectiveness cannot be quantified (i.e., large emotional cost for families)

cCMV TAC Voting Summary – Criteria

Criteria	Yes	No	Unsure
Available Screening Technology	11	3	3
Diagnostic Testing and Treatment	4	11	2
Prevention Potential and Medical Rationale	11	3	3
Public Health Rationale	9	7	1
Cost-benefit / Cost-effectiveness	7	5	5

cCMV TAC Voting Summary – Recommendation

Option	Vote
<p>● I recommend the Board add universal screening of cCMV to the list of conditions for which all Washington-born newborns must be screened.</p>	1
<p>● 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 Board's statutory authority via legislation.</p>	2
<p>● I do not recommend the Board add cCMV to the list of conditions for which all Washington-born newborns must be screened.</p>	0
<p>● 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.</p>	14



Next Steps

The Board may consider the following action:

- Direct staff to initiate rulemaking to include universal cCMV screening in the NBS panel
- Direct staff to explore the feasibility of including conditions screened using non-blood specimens
- Determine cCMV should not be considered at this time and revisit the condition in 3 years



| QUESTIONS?

| THANK YOU