Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NOTICE OF PUBLIC MEETING

Wednesday, March 26, 2025
10:00 a.m. – 3:00 p.m.

Note: This is a virtual meeting held via Zoom with in-person meeting space at the Department of Health Town Center 2, 111 Israel Rd. S.E. Tumwater, WA 98501. Room: 153. Meeting access and instructions are provided below. Language interpretation available.

Newborn Screening Technical Advisory Committee (TAC) Agenda

Review of the Condition Congenital Cytomegalovirus (cCMV)

Time	Agenda Item	Speaker
10:00 a.m.	1. Welcome and Agenda	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Nini Shridhar, TAC Co-Chair, Department of Health Kelly Kramer, State Board of Health Allegra Calder, BERK Consulting
10:15 a.m.	2. March Board Meeting Recap	Kelly Kramer, State Board of Health
10:30 a.m.	3. February cCMV TAC Review	Kelly Kramer, State Board of Health
10:50 a.m.	4. Update on cCMV Parent Education Materials	Julie Walker, Department of Health
11:00 a.m.	5. Cost-Benefit Analysis- cCMV	Megan McCrillis, Department of Health
12:00 p.m.	Break	

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Time	Agenda Item	Speaker
12:15 p.m.	6. Public Health Infrastructure Readiness	Megan McCrillis, Department of Health
12:35 p.m.	7. Washington Criteria Review for cCMV and Discussion	Kelly Kramer, State Board of Health Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Nini Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
1:35 p.m.	8. Vote	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Nini Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
1: 45 p.m.	Lunch	
2:15 p.m.	9. Discussion and Next Steps	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Nini Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
3:00 p.m.	Adjourn	

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Zoom Meeting Information:

Please click the link below to join the webinar:
https://us02web.zoom.us/j/81143045854?pwd=aoJ4LpxWixfxDra5awMDMs7VpA20rX.1
You can also dial-in using your phone for listen-only mode:
Call in: +1 (253) 215-8782 (not toll-free)
International numbers available:
Webinar ID: 811 4304 5854
Passcode: 281973

Important Meeting Information to Know:

- This meeting is open to the public. The public can observe the meeting online or in person at Town Center 2, 111 Israel Rd. S.E. Tumwater, WA 98501. Room: 153.
- The Technical Advisory Committee will not take formal action or receive public comment. If you have comments or materials you would like to share with the full Board, please send them to wsboh@sboh.wa.gov.
- Times are estimates only. We reserve the right to alter the order of the agenda.
- Every effort will be made to provide Spanish interpretation, and American Sign Language (ASL). Should you need confirmation of these services, please email wsboh@sboh.wa.gov in advance of the meeting date.
- If you would like meeting materials in an alternate format or a different language, or if you are a person living with a disability and need reasonable modification, please contact the State Board of Health at (360) 236-4110 or by email wsboh@sboh.wa.gov. Please make your request as soon as possible to help us meet your needs. Some requests may take longer than two weeks to fulfill.
  TTY users can dial 711.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

AVISO DE REUNIÓN PÚBLICA

Miércoles, 26 de marzo de 2025
de 10:00 a.m. a 3:00 p.m.

Nota: Esta es una reunión virtual mediante Zoom con sala de reunión presencial en en el Departamento de Salud del Estado de Washington Town Center 2, 111 Israel Rd. S.E. Tumwater, WA 98501. Salón: 153. A continuación, le proporcionamos el acceso a la reunión y las instrucciones. Hay servicios de interpretación a otros idiomas disponibles.

TAC (por su sigla en inglés, Comité de Asesoramiento Técnico) de la evaluación del recién nacido

Revisión de la infección por citomegalovirus congénito (CMVc)

Hora	Punto del orden del día	Orador
10:00 a.m.	1. Bienvenida y orden del día	Kelly Oshiro, copresidenta del TAC, Mesa Directiva de Salud del Estado Nirupama Nini Shridhar, copresidenta del TAC, Departamento de Salud Kelly Kramer, Mesa Directiva de Salud del Estado Allegra Calder, BERK Consulting
10:15 a.m.	2. Resumen de la reunión de la Mesa Directiva de marzo	Kelly Kramer, Mesa Directiva de Salud del Estado
10:30 a.m.	3. Revisión del CMVc realizada por el TAC en febrero	Kelly Kramer, Mesa Directiva de Salud del Estado
10:50 a.m.	4. Actualización de los materiales educativos para padres o madres sobre el CMVc	Julie Walker, Departamento de Salud
11:00 a.m.	5. Análisis del costo-beneficio: CMVc	Megan McCrillis, Departamento de Salud
12:00 p.m.	Receso	

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Hora	Punto del orden del día	Orador
12:15 p.m.	6. Preparación de la infraestructura de salud pública	Megan McCrillis, Departamento de Salud
12:35 p.m.	7. Revisión y debate de los criterios de Washington para el CMVc	Kelly Kramer, Mesa Directiva de Salud del Estado Kelly Oshiro, copresidenta del TAC, Mesa Directiva de Salud del Estado Nirupama Nini Shridhar, copresidenta del TAC, Departamento de Salud Allegra Calder, BERK Consulting
1:35 p.m.	8. Voto	Kelly Oshiro, copresidenta del TAC, Mesa Directiva de Salud del Estado Nirupama Nini Shridhar, copresidenta del TAC, Departamento de Salud Allegra Calder, BERK Consulting
1:45 p.m.	Almuerzo	
2:15 p.m.	9. Debate y próximos pasos	Kelly Oshiro, copresidenta del TAC, Mesa Directiva de Salud del Estado Nirupama Nini Shridhar, copresidenta del TAC, Departamento de Salud Allegra Calder, BERK Consulting
3:00 p.m.	Cierre de la sesión	

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Información sobre la reunión por Zoom:

Para unirse al seminario web, haga clic en el siguiente enlace:
https://us02web.zoom.us/j/81143045854?pwd=aoJ4LpxWixfxDra5awMDMs7VpA20rX.1
También puede participar por teléfono, mediante la modalidad de solo escucha:
Llamada: +1 (253) 215-8782 (no es un número gratuito)
Números internacionales disponibles:
Id. del seminario web: 811 4304 5854
Contraseña: 281973

Información importante de la reunión que debe saber:

- Esta reunión es pública. El público puede observar la reunión en línea o en persona en Town Center 2, 111 Israel Rd. S.E. Tumwater, WA 98501. Salón: 153.
- El Comité de Asesoramiento Técnico no tomará medidas formales ni recibirá comentarios del público. Si tiene algún comentario o material que desee compartir con toda la Mesa Directiva, envíelos a wsboh@sboh.wa.gov.
- Los horarios son estimativos. Nos reservamos el derecho de modificar el orden de los puntos que se tratarán en la reunión.
- Se hará todo lo posible para proporcionar interpretación en español y ASL (por su sigla en inglés, lenguaje de señas americano). Si necesita la confirmación de estos servicios, envíe un correo electrónico a wsboh@sboh.wa.gov antes de la fecha de la reunión.
- Si desea acceder a los materiales de la reunión en un formato alternativo o en otro idioma, o si tiene una discapacidad y necesita una modificación razonable, comuníquese con la Mesa Directiva de Salud llamando al (360) 236-4110 o enviando un correo electrónico a wsboh@sboh.wa.gov. Le pedimos que presente su solicitud lo antes posible para ayudarnos a satisfacer sus necesidades. Es posible que algunas solicitudes tarden más de dos semanas en atenderse.
  Los usuarios de TTY pueden marcar 711.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NBS TAC Membership

MEMBER	ALTERNATE	REPRESENTING
Kelly Oshiro, JD Board Co-Chair Assistant Attorney General		Washington State Board of Health (Board)
Nirupama (Nini) Shridhar, MPH, PhD Department Co-Chair State Genetics Coordinator		Department of Health (Department)
Joan Chappel, RN, MSN Nursing Consultant Advisor/Supervisor	**Sunpreet Bhangoo, RN** Occupational Nurse Consultant	Washington Health Care Authority (HCA)
Byron Raynz Parent Advocate		Parent/Child Advocacy
Emily Shelkowitz, MD Pediatrics, Medical Genetics	**Christina Lam, MD** Medical Director, Biochemical Genetics	Pediatric Specialty Care, Seattle Children's Hospital Biochemical Genetics
Eric Leung, MD Neonatologist		Neonatology and Washington Chapter of the American Academy of Pediatrics (WCAAP)
Heather Hinton, MS Certified Genetic Counselor		Genetic Counseling, MultiCare Yakima Memorial
Joon-Ho Yu, MPH, PhD Pediatrics/Public Health Bioethicist		Bioethics, Department of Epidemiology, University of Washington Bioethics, Treuman Katz Center for Pediatric Bioethics and Palliative Care
Kristine Alexander Senior Medical Policy Research Analyst		Private Insurers, Regence Health Plans
Krystal Plonski, ND, LAc, EAMP, FABNP Naturopathic Pediatrics and Acupuncturist		Naturopaths, Seattle Children's Hospital, and Washington Association of Naturopathic Physicians (WANP)

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NBS TAC Membership

MEMBER	ALTERNATE	REPRESENTING
Lisa McGill Vargas, MD Neonatologist	**Rucha Shukla, MD** Neonatologist	Pediatrics, Neonatal-Perinatal Medicine, Sacred Heart Medical Center Neonatology Intensive Care Unit (NICU)
Peggy Harris Public Health and Children's Health Advocate		Parent/Child Advocacy, Save Babies Through Screening Foundation
Priyanka Raut, DNP, MHS, RN Senior Director of Nursing		Pediatrics, Yakima Valley Farmworkers Clinic
Roberta (Bobbie) Salveson, ARNP, PhD Pediatric Nurse Practitioner, Medical Genetics		Pediatric Specialty Care, Mary Bridge Children's Hospital Biochemical Genetics
Taylor Kaminski, Community Doula		Perinatal and Postpartum Care, Global Perinatal Services
María Sigüenza Executive Director		State Commissions, Commission on Hispanic Affairs
Molly Parker, MD, MPH Family Medicine Physician		Provider, Population Health, Jefferson Healthcare
Cathleen Ackley Parent Advocate		Parent/Child Advocacy
Steve Kutz, BSN, MPH Chair, Washington State American Indian Health Commission		State Commissions, American Indian Health Commission
Tawny Hooley Parent Advocate		Parent/Child Advocacy

NBS TAC Staff Support

Kelly Kramer, Board Newborn Screening Policy Advisor
John Thompson, Department Director of Newborn Screening
Megan McCrillis, Department Newborn Screening Policy Advisor
Molly Dinardo, Board Policy Advisor

Crystal Ogle, Board Administrative Assistant
Michelle Larson, Board Communications Manager
Anna Burns, Board Communications Consultant

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Technical Advisory Committee (TAC) Charter

Start Date: October 28, 2024 **End Date:** June 30, 2025 (tentative)
Members: See TAC Membership Addendum A

OBJECTIVE

Serve as an expert advisory committee on newborn screening for the Washington State Board of Health (Board). Review and recommend possible updates to the Board's current newborn screening process and criteria. Additionally, evaluate several candidate conditions for potential inclusion in the Washington State mandatory newborn screening panel and provide recommendations to the Board.

BACKGROUND

The Board establishes the rules for newborn screening in Washington, including deciding which conditions all newborns must be tested for at birth. To make these decisions, the Board assembles a multidisciplinary Technical Advisory Committee (TAC) comprised of family representatives and representatives from healthcare, social services, advocacy organizations, public health, and more. Using available evidence, the TAC then assesses candidate conditions using guiding principles and five newborn screening criteria to determine which conditions should be added to the panel.

KEY ACTIVITIES

This TAC is being convened to complete the following key activities:

- Review the Board's current newborn screening candidate condition review process and criteria and identify opportunities for improvement.
- Determine whether branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency meets the Board's criteria for newborn screening panel inclusion and provide a recommendation to the Board. This is a requirement of Senate Bill 6234 (Chapter 105, Laws of 2024).
- Determine whether congenital cytomegalovirus (cCMV) meets the Board's criteria for newborn screening and provide a recommendation to the Board. This is a requirement of Senate Bill 5829 (Chapter 96, Laws of 2024).
- Review other possible candidate conditions recently brought in front of the Board between 2024 and 2025.

TAC TIMELINES (Tentative)

- Meeting 1, Process and Criteria Review – Monday, October 28, 2024
- Meeting 2, BCKDK Deficiency Review – January 2025
- Meeting 3, Criteria Intro to cCMV – February 2025
- Meeting 4, Cost-Benefit Analysis of cCMV – March 2025

COMMITTEE NORMS AND EXPECTATIONS

- Be here now and stay purpose-oriented
- Listen for understanding; seek clarification and resist assumptions
- Appreciate the strength of diverse cultures and perspectives
- Engage respectfully; see with new eyes and hear with new ears
- Move up into a speaking role; move into a listening role
- Stay on topic and mind the time
- Assume positive intent; acknowledge and repair harms
- Try to avoid speaking with someone else is speaking
- Commit to using inclusive language in committee discussions and if possible, try to avoid using idioms or slang terms
- State your name each time you begin talking, and speak at a moderate pace to ensure language interpreters can appropriately translate what is being said
- Use acronyms where possible after introducing technical terms or proper nouns and encourage other committee members to do the same.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Technical Advisory Committee (TAC) Charter

DECISION MAKING

- Proposed voting methods: This committee will use anonymous voting via Microsoft Forms and open discussion of results to inform committee decisions and recommendations.
- Proposed Primary or Alternative Member voting: Both primary and alternative TAC Members may attend these meetings, however, if both are in attendance the primary TAC member will be responsible for speaking and voting during the meeting. The alternative member only speaks and votes when the primary is not in attendance.

INFORMATION SHARING

The Newborn Screening TAC planning team will:

- Email and post meeting materials at least 48 hours before the scheduled meeting.
- Email updates and notices to TAC members and designated alternatives.
- Post information on the Newborn Screening Criteria Review Project webpage.

RESOURCES/REFERENCE MATERIALS

- Chapter 246-650 WAC – Newborn Screening.
- Washington State Board of Health Process to Evaluate Conditions for Inclusion in the Required Newborn Screening Panel.
- Washington Department of Health Newborn Screening Webpage

GUIDANCE FOR SPEAKING WITH LANGUAGE INTERPRETATION

The Washington State Board of Health (Board) offers American Sign Language and Spanish interpretation during our regular public meetings. We do this as a part of our work towards increasing language access.

We ask all speakers at Board meetings to follow this guidance to create an accessible meeting environment. If you have any questions or need guidance for presenting, please contact Board staff for support.

WHAT TO EXPECT DURING A BOARD MEETING

- You will receive a simplified version of this document at your seat on the day of the Board meeting.
- Board staff or interpreters may give you cues to slow down your pace. The cues may include:
  - Raising a paddle sign to signal you to slow down.
  - Making a brief verbal interruption asking you to slow down.

TIPS FOR SPEAKING AND PRESENTING DURING THE MEETING

We ask that you help us mitigate the need for interruptions by speaking at a comfortable pace. Our ASL and Spanish interpreters cannot deliver your message accurately if you speak too quickly.

- Take a breath after each sentence to give the interpreter time to deliver your message.
- If you are reading from a script, please be aware that you may read faster than you speak.
- To help the interpreters and audience identify you, state your name each time you begin talking.
- Wait until someone else finishes speaking before you speak. Interpreters can only choose one person to interpret at a time.
- Pause after introducing technical terms, proper nouns, dates, numbers, or figures to allow for interpretation.

TIPS FOR TECHNICAL TERMS

- We recommend including a pause after introducing technical terms, proper nouns, dates, numbers, or figures.
  - Example: *"This briefing will discuss rulemaking around newborn screening for Ornithine Transcarbamylase Deficiency (OTCD) [pause for interpretation, wait for cue from interpreter to continue], Chapter 246-650 WAC [pause for interpretation, wait for cue from interpreter to continue]."*
- After you introduce technical terms or proper nouns use their acronyms for the remainder of the introduction.
  - Example: *"For the remainder of this discussion, I will refer to this condition as OTCD."*
- If you are using visual materials (e.g., tables), incorporate descriptive language of the visual material.
  - Example: *"This is a table showing XXXX. And now, we'll look at this part of the table…"*

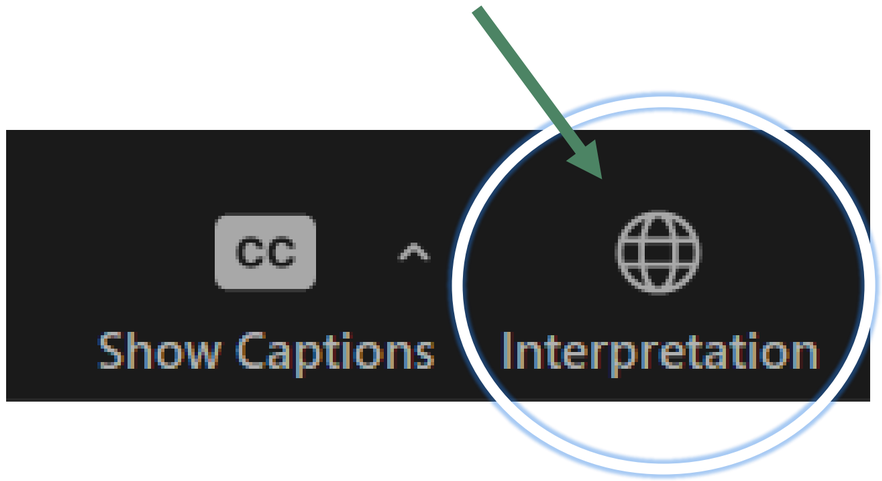
Newborn Screening Congenital Cytomegalovirus (cCMV) Review Continued

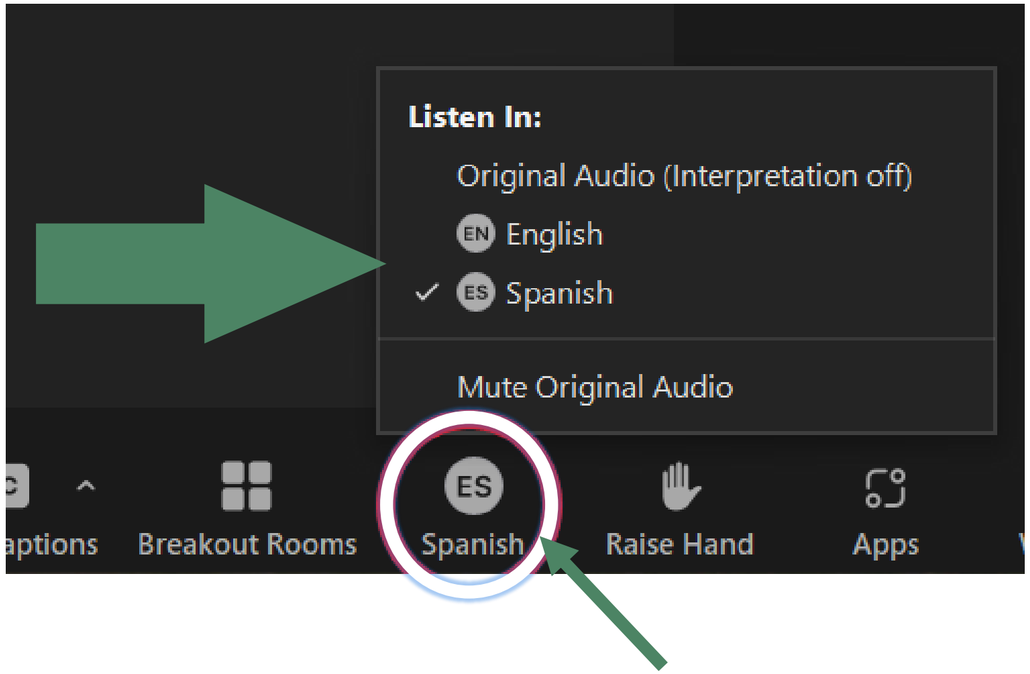
Newborn Screening Technical Advisory Committee (TAC)

WASHINGTON STATE BOARD OF HEALTH

Canales de Idioma de Zoom
Zoom Language Channels

Canales de idioma
Language channels





Elige un idioma
Choose a language

Zoom Webinar Functions

Mute/ unmute mic

View participants, change your name

Closed Captioning/Live Transcription

Turn webcam on/off

Raise hand feature

Leave meeting

Note: Depending on your role, you may not have access to all functions identified on this slide.

Agenda

- Meeting Introduction and Overview
- March Board Meeting Recap
- February cCMV TAC Review
- cCMV Parent Education Materials
- Cost Benefit Analysis
- New Criteria Review
- Discussion
- Vote
- Next Steps

Introductions

Virtual TAC Meeting Considerations

TAC Members

- Please rename yourself in Zoom: Firstname Lastname, TAC Member
- If possible, turn your camera on when speaking
  - Feel free to keep your camera on if you would like
- Raise hand option

Public Attendees

- Will not have option to raise hand, unmute, or turn cameras on

March 2025 Board Meeting

- BCKDK Deficiency
  - Board approved TAC recommendations
    - Will not add BCKDK deficiency to our mandatory newborn screening panel

- Criteria Updates
  - Board approved TAC recommendations
    - Amendment to Criterion 6
      - Public Health Infrastructure Readiness

- Other Updates:
  - HB 1697

February cCMV TAC Recap

- Parent perspectives
- Natural history, diagnostic testing, and treatment
- Available screening technology
- Early Hearing Detection, Diagnosis, Intervention Program
- Available resources - audiology

cCMV Parent Education Materials Update

Cost-Benefit Analysis

Break

6. Public Health Infrastructure Readiness

The Newborn Screening Program’s capacity to implement screening within a reasonable timeframe has been considered.

- The systems and staffing necessary to perform the test and report screening results have been identified.
- Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
- The accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.

Newborn Screening Criteria

1) Available Screening Technology

2) Diagnostic Testing and Treatment Available

3) Prevention Potential and Medical Rationale

4) Public Health Rationale

5) Cost-Benefit and Cost Effectiveness

6) Public Health Readiness

1. Available Screening Technology

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

- The sensitivity of the screening test is estimated to be ≥95%.
- The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on the healthcare system, newborn screening program, and families.
- A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting.
- There is adequate peer reviewed evidence to evaluate this criterion.

2. Diagnostic Testing and Available Treatment

Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

- A diagnostic test accurately identifies who needs treatment and is readily available to all newborns screened.
- The available treatment is effective in reducing morbidity or mortality and outweighs any risks or harms of the treatment.
- The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to all newborns screened.
- The availability and proximity to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.
- The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals.

3. Prevention Potential and Medical Rationale

The newborn identification of the condition allows early diagnosis and intervention. Important considerations include:

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life.
- The benefits of detecting and treating infantile-onset forms of the condition (within one year of life) balance the impact of detecting later onset forms of the condition.
- There is adequate evidence of acceptable quality to evaluate this criterion.

4. Public Health Rationale

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

- All available risk-based screening tools for the condition have been considered and are found to be inferior to universal newborn screening.
- There is adequate evidence of acceptable quality to evaluate this criterion.

5. Cost-benefit and Cost-effectiveness

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

- The prevalence of the condition among newborns.
- The positive and negative predictive values of the screening and diagnostic tests.
- Variability of clinical presentation by those who have the condition.
- Dollar values for costs and benefits of screening vs. no screening.

- The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as emotional or economic impacts on the family and medical system, must also be considered.
- The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening
- There is adequate evidence of acceptable quality to evaluate this criterion

6. Public Health Infrastructure Readiness

The Newborn Screening Program’s capacity to implement screening within a reasonable timeframe has been considered.

- The systems and staffing necessary to perform the test and report screening results have been identified.
- Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
- The accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.

Newborn Screening Technical Advisory Committee (TAC)

cCMV TAC Voting Ballot - Condition Evaluation with NBS Criteria - March 2025

Newborn Screening Technical Advisory Committee (TAC)

cCMV TAC Ballot - Overall Recommendation - March 2025

Lunch

Results and Discussion

Next Steps

- cCMV TAC Recommendations Reported at the April 9 Board of Health Meeting
- Wilson’s Disease Condition Review

WASHINGTON STATE BOARD OF HEALTH

THANK YOU

To request this document in an alternate format, please contact the Washington State Board of Health at 360-236-4110, or by email at **wsboh@sboh.wa.gov** | TTY users can dial 711

ACCESSIBILITY AND THE AMERICANS WITH DISABILITIES ACT (ADA)

- The Washington State Board of Health (Board) is committed to providing information and services that are accessible to people with disabilities. We provide reasonable accommodations, and strive to make all our meetings, programs, and activities accessible to all persons, regardless of ability, in accordance with all relevant state and federal laws.
- Our agency, website, and online services follow the Americans with Disabilities (ADA) standards, Section 508 of the Rehabilitation Act of 1973, Washington State Policy 188, and Web Content Accessibility Guidelines (WCAG) 2.0, level AA. We regularly monitor for compliance and invite our users to submit a request if they need additional assistance or would like to notify us of issues to improve accessibility.
- We are committed to providing access to all individuals visiting our agency website, including persons with disabilities. If you cannot access content on our website because of a disability, have questions about content accessibility or would like to report problems accessing information on our website, please call (360) 236-4110 or email wsboh@sboh.wa.gov and describe the following details in your message:
    - The nature of the accessibility needs
    - The URL (web address) of the content you would like to access
    - Your contact information

We will make every effort to provide you the information requested and correct any compliance issues on our website.

Washington State Board of Health

PROCESS TO EVALUATE CONDITIONS FOR INCLUSION IN THE REQUIRED NEWBORN SCREENING PANEL

Last updated March 14, 2025

Amended Section (Approved November 2024)
The Washington State Board of Health (Board) has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at Department of Health (Department), and/or Board members can request that the Board review a particular condition for possible inclusion in the newborn screening (NBS) panel.
To determine which conditions to include in the NBS panel the Board convenes a newborn screening technical advisory committee (TAC) to evaluate candidate conditions using guiding principles and an established set of criteria.

This document describes the Qualifying Assumption, Guiding Principles, and Criteria the Board has approved to evaluate conditions for possible inclusion in the newborn screening panel. The Board and Department apply the qualifying assumption. The Board-appointed Newborn Screening TAC applies the following three guiding principles and evaluates the five criteria to make recommendations to the Board on which condition(s) to include in the state's required NBS panel.

QUALIFYING ASSUMPTION

Amended Section (Approved November 2024)
Before the Board convenes a TAC to review a candidate condition against the five newborn screening criteria, staff should complete a preliminary review to determine whether sufficient scientific evidence is available to apply the criteria for inclusion, which is the qualifying assumption. If the candidate condition is on the Health Resources and Services Administration (HRSA) Recommended Uniform Screening Panel (RUSP), the Board and Department will consider the qualifying assumption met and convene a TAC.

New Section (Approved November 2024)
***A note on the RUSP*:** The RUSP is a list of conditions that the Secretary of the Department of Health and Human Services (HHS) recommends states screen for as part of their newborn screening programs. Once the HHS Secretary recommends a new condition, the Board and Department will review it for possible inclusion in the Washington NBS panel within two years of the recommendation.

New Section (Approved January 2025)

Conditions pending RUSP Review or Previously Denied for the RUSP: RCW 34.05.330 of the Administrative Procedures Act (APA) allows any person to petition a state agency to adopt, repeal, or amend any rule within its authority. Agencies must respond to the petitioner within 60 days. If the agency accepts the petition, it must initiate rulemaking. An agency can deny the request for rulemaking, and in doing so, it must explain its reasons and, if appropriate, describe alternative steps it is prepared to take.

If the Board receives a petition for rulemaking regarding a candidate condition currently under review for the RUSP, the Board will wait until the federal committee finishes its review and the HHS Secretary makes a final decision before convening a TAC. For petitions involving conditions that have already been reviewed and denied inclusion on the RUSP, the Board will instruct staff to work with the petitioner to determine if concerns raised during the federal review have been addressed before recommending the Board convene a TAC to review the condition.

THREE GUIDING PRINCIPLES

Three guiding principles govern all aspects of the evaluation of a candidate condition for possible inclusion in the NBS panel.

- Decision to add a screening test should be driven by evidence. For example, test reliability and available treatment have been scientifically evaluated, and those treatments can improve health outcomes for affected children.
- All children who screen positive should have reasonable access to diagnostic and treatment services.
- Benefits of screening for the disease/condition should outweigh harm to families, children and society.

CRITERIA

1. **Available Screening Technology:** Sensitive, specific and timely tests are available that can be adapted to mass screening.
    - The sensitivity of the screening test is estimated to be ≥95%.

- The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on the families, healthcare system, and newborn screening program.
- A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting.
- There is adequate peer reviewed evidence to evaluate this criterion.

2. **Diagnostic Testing and Treatment Available**: Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

- A diagnostic test accurately identifies who needs treatment and is readily available to all newborns screened.
- The available treatment is effective in reducing morbidity or mortality and outweighs any risks or harms of the treatment.
- The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to all newborns screened.
- The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals.

3. **Prevention Potential and Medical Rationale**: The newborn identification of the condition allows early diagnosis and intervention.

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life.
- The benefits of detecting and treating infantile-onset forms of the condition (within one year of life) balance the impact of detecting later onset forms of the condition.
- There is adequate evidence of acceptable quality to evaluate this criterion.

4. **Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk based screening or other approaches.

- All available risk-based screening tools for the condition have been considered and are found to be inferior to universal newborn screening.
- There is adequate evidence of acceptable quality to evaluate this criterion.

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.

- The economic analysis considers:
  - The prevalence of the condition among newborns.
  - The positive and negative predictive values of the screening and diagnostic tests.
  - Variability of clinical presentation by those who have the condition.
  - Dollar values for costs and benefits of screening vs. no screening.
- The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as psycho-social or economic impacts on the family and medical system, must also be considered.
- The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening.
- There is adequate evidence of acceptable quality to evaluate this criterion.

6. **Public Health Infrastructure Readiness:** The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered.

- The systems and staffing necessary to perform the test and report screening results have been identified.
- Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
- Accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.

Criterion	**Opinion**			**Comments**
	Meets	Does not meet	More info needed	
1. **Available Screening Technology** Sensitive, specific and timely tests are available that can be adapted to mass screening				
The sensitivity of the screening test is estimated to be ≥95%				

The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on families, the healthcare system, newborn screening program.				
A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting				
There is adequate evidence of acceptable quality to evaluate this criterion				
Overall impression of criterion 1:				
2. **Diagnostic Testing and Treatment Available** Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition				
A diagnostic test accurately identifies who needs treatment, and is readily available to all newborns screened.				
The available treatment is effective in reducing morbidity or mortality, and outweighs any risks or harms of the treatment.				
The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to everyone screened				

The availability and proximity to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed				
The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals				
There is adequate evidence of acceptable quality to evaluate this criterion				
Overall impression of criterion 2:				
3. **Prevention Potential and Medical Rationale** The newborn identification of the condition allows early diagnosis and intervention.				
There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention				
The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life.				
The benefits of detecting and treating infantile-onset forms of the condition balance the impact of detecting later onset forms of the condition				

There is adequate evidence of acceptable quality to evaluate this criterion				
Overall impression of criterion 3:				
4. **Public Health Rationale** Nature of the condition justifies population-based screening rather than risk based screening or other approaches				
Any available risk-based screening tools for the condition have been considered and are inferior to universal newborn screening				
There is adequate evidence of acceptable quality to evaluate this criterion				
Overall impression of criterion 4:				
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				
The economic analysis considers: • The prevalence of the condition among newborns. • The positive and negative predictive values of the screening and diagnostic tests. • Variability of clinical presentation by those who have the condition. • Dollar values for costs and benefits of screening vs. no screening				

The impact of ambiguous results, adverse effects, or unintended consequences of screening , such as emotional or economic impacts on the family and medical system, must also be considered.				
The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening				
There is adequate evidence of acceptable quality to evaluate this criterion.				
Overall impression of criterion 5:				
6. **Public Health Infrastructure Readiness** The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered				
The systems and staffing necessary to perform the test and report screening results have been identified				
Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified				

Accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed				
Overall impression of criterion 6:				
Overall impression of the condition:				
Recommendation:				

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Old Criteria	New Criteria
1. **Available Screening Technology**: Sensitive, specific and timely tests are available that can be adapted to mass screening.	**1. Available Screening Technology:** Sensitive, specific and timely tests are available that can be adapted to mass screening. • The sensitivity of the screening test is estimated to be ≥95%. • The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on the families, healthcare system, and newborn screening program. • A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting. • There is adequate peer reviewed evidence to evaluate this criterion.
2. **Diagnostic Testing and Treatment Available**: Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.	**2. Diagnostic Testing and Treatment Available**: Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition. • A diagnostic test accurately identifies who needs treatment and is readily available to all newborns screened. • The available treatment is effective in reducing morbidity or mortality and outweighs any risks or harms of the treatment. • The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to all newborns screened. • The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Old Criteria	New Criteria
3. **Prevention Potential and Medical Rationale**: The newborn identification of the condition allows early diagnosis and intervention. Important considerations: • There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention. • The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition. • Newborn screening is not appropriate for conditions that only present in adulthood.	3. **Prevention Potential and Medical Rationale**: The newborn identification of the condition allows early diagnosis and intervention. • There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention. • The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life. • The benefits of detecting and treating infantile-onset forms of the condition (within one year of life) balance the impact of detecting later onset forms of the condition. • There is adequate evidence of acceptable quality to evaluate this criterion.
4. **Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.	**4. Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk based screening or other approaches. • All available risk-based screening tools for the condition have been considered and are found to be inferior to universal newborn screening. • There is adequate evidence of acceptable quality to evaluate this criterion.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Old Criteria	New Criteria

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. Important considerations to be included in economic analyses include:
• The prevalence of the condition among newborns.
• The positive and negative predictive values of the screening and diagnostic tests.
• Variability of clinical presentation by those who have the condition.
• The impact of ambiguous results. For example, the emotional and economic impact on the family and medical system.
• Adverse effects or unintended consequences of screening.
	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.
	• The economic analysis considers:
	  ○ The prevalence of the condition among newborns.
	  ○ The positive and negative predictive values of the screening and diagnostic tests.
	  ○ Variability of clinical presentation by those who have the condition.
	  ○ Dollar values for costs and benefits of screening vs. no screening.
	• The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as psycho-social or economic impacts on the family and medical system, must also be considered.
	• The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening
	• There is adequate evidence of acceptable quality to evaluate this criterion

	6. Public Health Infrastructure Readiness: The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered. • The systems and staffing necessary to perform the test and report screening results have been identified. • Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified. • Accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.

To request this document in an alternate format or a different language, please contact the State Board of Health at (360) 236-4110 or by email at wsboh@sboh.wa.gov.

PO Box 47990, Olympia, WA 98504-7990
(360) 236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov

Minutes for the Newborn Screening Technical Advisory Committee (TAC)
February 11, 2025
Hybrid Meeting
ASL (or CART) and Spanish interpretation available
Washington State Department of Health, Town Center 1
101 Israel Rd S.E. Tumwater, WA 98501
Rooms 163 and 164
Virtual meeting: ZOOM Webinar

Technical Advisory Committee Members present:

In-Room Participants:

Kelly Oshiro, JD, Board Vice Chair and TAC Co-Chair
Eric Leung, Washington Chapter of the American Academy of Pediatrics (WCAAP)
Tawney Hooley, cCMV Parent Advocate

Online Participants:

Byron Raynz, Parent Advocate
Roberta (Bobbie) Salveson, Mary Bridge Children's Hospital Biochemical Genetics
Heather Hinton, MultiCare Yakima Memorial
Joon-Ho Yu, Department of Epidemiology, University of Washington Bioethics, Treuman Katz Center for Pediatric Bioethics and Palliative Care
Priyanka Raut, Yakima Valley Farmworkers Clinic
Krystal Plonski, Naturopaths, Seattle Children's Hospital, and Washington Association of Naturopathic Physicians (WANP)
Joan Chappel, Washington Healthcare Authority (HCA)
Sunpreet Bhangoo, Washington Healthcare Authority (HCA)
Kristine Alexander, Regence Health Plans
Lisa McGill Vargas, Sacred Heart Medical Center Neonatology Intensive Care Unit (NICU)
Rucha Shukla, Sacred Heart Medical Center Neonatology Intensive Care Unit (NICU)
Taylor Kaminski, Global Perinatal Services
Christina Lam, Seattle Children's Hospital Biochemical Genetics
Molly Parker, Provider and Chief Marketing Officer (CMO) of Population Health, Jefferson Healthcare
Cathleen Ackley, cCMV Parent Advocate

TAC Members Absent:

Emily Shelkowitz, Seattle Children's Hospital Biochemical Genetics
Steve Kutz, American Indian Health Association
Peggy Harris, Parent/Child Advocate, Save Babies Through Screening Foundation
Nirupama (Nini) Shridhar, MPH, PhD, TAC Co-Chair
María Sigüenza, Commission on Hispanic Affairs

State Board of Health (Board) staff present:

Michelle Davis, Executive Director
Kelly Kramer, Newborn Screening Project Policy Advisor
Molly Dinardo, Policy Advisor
Melanie Hisaw, Executive Assistant
Crystal Ogle, Administrative Assistant
Michelle Larson, Communications Manager
Anna Burns, Communications Consultant

Guests and Participants:

Allegra Calder, Facilitator
John Thompson, Department of Health
Dr. Ann Melvin, Seattle Children's Hospital, Infectious Disease
Samantha Fuller, Department of Health
Megan McCrillis, Department of Health
Julie Walker, Department of Health
Michele Greenwood, Providence Spokane Ear Nose and Throat

1. **WELCOME & INTRODUCTIONS**

   Kelly Kramer, Board staff, welcomed everyone to the meeting and provided an overview of the two topics that the Technical Advisory Committee (TAC) would cover during the meeting. The topics are reviewing the Board's newborn screening criteria and starting a review of the condition congenital cytomegalovirus (cCMV). Kelly K. added that voting on cCMV would occur at the next TAC meeting in March.

   Allegra Calder, Facilitator, invited TAC members to introduce themselves and reminded everyone to be mindful of their speaking pace to help support meeting interpretation.

2. **JANUARY TAC RECAP**

   Kelly K. summarized the January 14 TAC meeting, focusing on the TAC's discussion about adding branched chain ketoacid dehydrogenase kinase (BCKDK) deficiency to the newborn screening panel. The results of the TAC's vote were shared, with the recommendation not to add BCKDK deficiency to the panel at this time. Kelly K. also reviewed the split vote on proposed changes to the screening criteria. Kelly K. noted that the TAC would review and discuss suggested edits to the Board's criteria provided by the Department of Health's Newborn Screening Program during the meeting today.

3. **WA Criteria Review and Discussion**

   Kelly Oshiro, TAC Co-Chair, introduced the topic for discussion.

   Kelly K. reviewed the first newborn screening criteria, "Available Screening Technology," and the suggestions provided (presentation on file). Kelly K. then opened the floor for discussion.

   Eric Leung, Committee Member, expressed approval of the updates made to criterion one.

   Molly Parker, Committee Member, agreed with Member Leung's comment. Member Parker then suggested wordsmithing the second point and changing it to "potential impact on the families, healthcare systems, and newborn screening program" to emphasize families and patients first.

   Member Leung asked Member Parker to clarify if they just wanted to change the order of the items on point two.

Member Parker said that is correct.

Facilitator Calder asked if we could move forward with the change Member Parker suggested.

TAC Co-Chair Oshiro said that the change is a great suggestion, and we can adopt the change.

Member Leung asked moving forward if we need first or second motions.

Kelly K. answered no.

Kelly K. moved on to the second criterion, “Diagnostic Testing and Available Treatment,” and its suggested changes (presentation on file). Kelly K. opened it up for discussion.

Lisa McGill Vargas, Committee Member, commented liking how this is laid out. It defines a lot of points of discussion we had.

Member Leung said speaking to criterion two point four, understands the intent, but speaking to accessibility, not sure how we could influence that kind of structure.

Byron Raynz, Committee Member, agreed and wouldn’t want point four to say that we are not going to screen for a particular condition if folks are too far out to get treatment for this. This is what this point seems to allude to.

Member McGill Vargas said it is important to think about how we can influence access to care for some of the very rare diagnoses that do need specialized care. As we are considering our newborn screening, it's not so much for accepting or refusing the criteria, but what is the room for advocating for those families that have difficulties getting into our cities on the west side of the state.

Bobbie Salveson, Committee Member, suggested including something about telemedicine and that would increase the availability.

Heather Hinton Committee Member, said the part that stands out to them in point four is where it says, “considered acceptable.” That seems like it is subjective almost, especially coming from an area where there is difficulty accessing that kind of treatment.

Joan Chappel, Committee Member, agreed that “acceptable” and “proximity” is a vague term. Member Chappel suggested using the word availability.

Member Leung asked if the purpose of point four is to use it as leverage to increase or demand more accessibility from legislators. Does it help us go back to legislators and demand that we improve access?

Megan McCrillis, Department of Health, said the primary goal in spelling this point out specifically is to call attention to the fact that we know in this state there are geographic differences with vastly different resources. Trying to make sure that specific piece about

availability, proximity, and access was specifically addressed in each conversation with each specific condition. Megan discussed from their perspective it was trying to call attention to that issue that we know exists and create conversation around it without putting hard boundaries without it.

Member Leung appreciated that answer and suggested that this point might fit better under criterion number six “Public Health Readiness.”

Facilitator Calder recapped the discussion.

Kristine Alexander, Committee Member, agreed with TAC members that proximity is part of availability and doesn’t necessarily need to be separately stated. Unfortunately, you cannot always guarantee access to something, but the benefit of newborn screening is getting treatment. On the other hand, nothing is perfectly available to everybody.

Facilitator Calder asked TAC members for their thoughts on Member Leung’s suggestion to move this under “Public Health Readiness.”

Member Raynz expressed concerns about being diagnosed versus not being diagnosed. If there was no treatment available regardless of where it was, they would still want to know if their child still had that particular life-threatening condition.

Member Parker appreciates the discussion around this from a rural perspective and agreed to move this point under “Public Health Readiness.”

Cathleen Ackley, Committee Member, agreed with moving it to “Public Health Readiness.”

Facilitator Calder reminded folks that this is for all screening.

Member Leung suggested separating the idea of “available treatment to change the outcome” from the “accessibility for treatment” and redirecting the accessibility part as our state’s goal, moving that to criterion six, which might clarify some of the issues.

TAC Co-Chair Oshiro said to Member Leung’s point, that separating availability and tethering this criterion to four to proximity and frequency would better address Megan's intent in drafting the criterion.

Tawny Hooley, Committee Member, said from a parent perspective living in Spokane, they had to utilize several different doctors to be able to assist us who were not in proximity to our location. Agreed with moving the fourth point to the six criteria and removing the word “proximity.”

Facilitator Calder summarized that there seems to be support for removing proximity and moving this fourth point to the last criteria. Facilitator Calder asked Member Leung if they were separating availability, is that covered in the second point?

Member Leung said that Facilitator Calder was right. Point two speaks to the fact that there needs to be an intervention available to change the course of the disease so that officially separates that type of availability from accessibility.

Christina Lam, Committee Member, agreed.

Facilitator Calder asked Megan if availability and accessibility are somewhat interchangeably used in their thinking.

Megan said yes, but it is up to this committee how they best see it.

Facilitator Calder clarified for this criterion, the available treatment piece is staying, the issue around if it is accessible will move to criterion six, and the word proximity will be removed.

Kelly K. moved on to criteria three, “Prevention Potential and Medical Rationale,” and reviewed the suggested updates (presentation on file). Kelly K. opened it up for questions.

Member Leung posed a question for the genetic specialists on the committee. There are conditions that we screen that may only be unmasked by a precipitating illness and may not manifest in the first year of life or infancy. Does that create a contradiction?

Member Lam answered that point three can address that.

Member Leung thanked Member Lam and asked if they felt that the way this is written covers all situations adequately.

Member Lam answered that the way it’s written allows us to evaluate conditions appropriately and it’s based on our judgment on whether the goldy locks cases meet the criteria to be screened universally. Despite cases where there is not sufficient time between birth and onset of irreversible harm and cases that are late onset, which may or may not have true treatment or lead to substantial anxiety. That is a question for someone with more ethical expertise to weigh into.

Member Hooley spoke about their personal experience being an advocate for their son and the testing they had to go through.

John Thompson, Department of Health, noted that they would argue in the case of an infectious disease like cCMV, that the onset is the infection itself. So, that would fit within the proposed criteria.

Member Parker asked for clarification on point three. Is the intention to balance the negative impact of detecting later onset or just any impact?

Megan answered that point three is from the historical criteria. You can presume that might indicate a negative impact. It could be interpreted as whatever that might mean for the condition in question.

Member Parker clarified that the sense of bullet three is that the benefits of detecting and treating infantile forms balance the impact of detecting later forms. So, we would choose to select a condition for screening because the benefits of detecting early onset are more important than the negative impacts of detecting later.

John answered that this was a correct interpretation.

Joon-Ho Yu, Committee Member, noted always interpreting it as the benefits of early detection is worthwhile compared to waiting until it gets detected later. So, it's not exactly the negative impact of early detection, but that there is a greater benefit earlier.

Member Lam said there are later onset forms of conditions where there may not be treatment compared to early onset. Detecting these later onset forms of conditions may bring harm to patients and families.

Member Salveson agreed with what Member Lam said but also believes that knowing that there is an underlying condition can avoid much of the diagnostic odyssey that people go through. Knowing that they have this condition they could proceed with palliative treatments instead of being misdiagnosed.

Member Lam said that the impact of detecting later onset forms can be positive or negative. However, we are weighing the negative impacts against the benefits of detecting early onset.

Member Parker said this discussion clarified things for me and doesn't feel the need for changes now.

Kelly K. reviewed criteria four, "Public Health Rationale," and its edits (presentation on file). Kelly K. shared an email from Emily Shelkowitz, Committee Member with feedback for the committee to consider. In the email, Member Shelkowitz asked the committee to consider whether sufficient literature or guidelines inform clinicians on how to monitor asymptomatic individuals and when to consider treatment for our late onset conditions. Member Shelkowitz also noted in the email that this comment might belong under criteria four as there may be public harm that can come from those diagnosed with late onset forms.

Member Lam suggested that this comment applies to what we were just discussing for criterion three.

Member Leung vocalized agreement.

John asked the committee if we need to consider modifying the language in criterion three to reflect Member Shelkowitz's comments.

Member Lam said that in criterion three, under point three point three, the discussion should occur there. Not sure whether that should be laid out as something that should be discussed with every disorder.

Facilitator Calder responded that this reminded them of their discussion during their last meeting. We want enough direction and guidance but also have the flexibility to have discussions. The criteria are universal, but the conditions are all different.

Member Salveson said that point three in criterion three addresses this.

Facilitator Calder recapped the discussion. Based on the comments from Member Shelkowitz, we feel that will happen in criteria three.

BREAK

4. Washington Criteria Review and Discussion Continued

Criterion 5 Cost-benefit and Cost-effectiveness

Megan McCrillis, Department of Health, reviewed the cost-benefit analysis model and explained that short-term finite healthcare costs are included, along with other potential costs or benefits associated with screening for a condition. Megan explained that they are unable to include a dollar amount on hardships placed on families. Informed the group that the changes to this criterion likely won't change the cost-benefit analyses that they conduct but will now call out the complex considerations the TAC considers in their vote.

Christina Lam, Committee Member, liked seeing how we go through cost analysis, but didn't notice a formal way of the costs incurred for detecting late onset conditions or the emotional economic impact of false positives. Curious if there are additional calculations that haven't been displayed at the last meeting.

Megan said historically our cost-benefit modeling sticks to costs associated with diagnostic testing. The Department of Health typically doesn't put costs on the hardships or other costs.

John Thompson, Department of Health, confirmed Megan's answer and talked about the parts to costs. John said all the parts will come out when the analysis is done for any given condition.

Joon-Ho Yu, Committee Member, discussed recognizing the limits of cost benefits and analysis. Member Yu wondered if emotional could be substituted for psycho-social. Also, there's a lot of work on broadening and detaining our understanding of benefits, whether personal, psychological, social, and somewhere in-between.

Molly Parker, Committee Member, talked about the data on false positives and it is not condition specific, which is a negative outcome from false positives.

Eric Leung, Committee Member, appreciated the consideration of negative impacts on families that receive false positives. In more recent conditions, the testing techniques (e.g. Arginase), the screening test is the diagnostic test. That may fit more with the future on how we are testing. There are going to be some errors, and we always need to consider when trying to minimize negative impacts.

Allegra Calder, Facilitator, summarized Member Leung's comments.

Member Leung supports Member Yu's comment to replace emotional with psycho-social and doesn't suggest any additional change.

Heather Hinton, Committee Member, also supported this change.

Criterion 6 Public Health Readiness (new addition).

Byron Raynz, Committee Member, said the word identified is intentional. The spirit of why we are using is identified in both these cases. Megan confirmed yes.

Priyanka Raut, Committee Member, elaborated on the second point on the resources. Megan said in general this work has always happened, it just happened after the TAC made a recommendation and it was confirmed yes, to screen for a condition. The original intent was for the newborn screening program and sometimes we might need extra staff to address some conditions.

Member Raut would love to learn more from the group, maybe adding a dot point on the readiness point.

Member Leung talked about accessibility and suggested dot point two said "Resources, including accessibility, have been considered." It might not need its own dot point, but it's part of the resource consideration.

Member Lam likes "the accessibility" as a separate bullet.

John Thompson, Department of Health, appreciated the comment and thinks there is a value to having the separate dot point. John discussed XLD, from the Department of Health perspective, needed to purchase an expensive piece of equipment and form new protocols, and from a clinical standpoint, a need for the baby boys diagnosed, periodic adrenal function scans, brain MRIs, and more. It was a long-term plan that needed to be established. There are different spheres of influence to consider. Member Leung appreciates the new criteria and leading into Public Health.

Member Parker spoke to Member Raynz comment, asking for specifics around before or after conditions are discovered. Megan spoke to rough estimates and the work already happening, saying more details will be addressed once a condition is confirmed.

John said another benefit of the Public Health Readiness Criterion is it allows the Department, to work with the Board and government on timeframes scoped out in advance.

Kelly Kramer, Board staff, said we will vote on each piece.

Facilitator Calder talked about moving the accessibility piece, support for emotional to psycho-social. Staff will update this before voting.

Member Leung talked about other processes in the emails, such as the function of committee and asked if these are being considered separate from the sixth criteria.

Kelly K. clarified Member Leung's question about process and criterion. Kelly K. said the Board has already decided on the process, and now we are voting on the criterion changes.

Member Leung wanted to raise questions about the process adopted by the Board.

Member Leung talked about two legislative bills, House Bill (HB) 1697 and Senate Bill (SB) 5668. They challenge the process, and place demands on the committee that undermine the work we are doing. The proposed legislation stipulates we stick to the Recommended Uniform Screening Panel (RUSP), that currently exists as of January 2025. Last committee meeting we discussed aligning or considering our own condition to the RUSP. Member Leung finds this comes at a difficult time and asks staff how to respond.

Kelly K. said HB 1697 has a public hearing on Friday, February 14, at 8 a.m., and will testify and lay out those concerns. The Board appreciates the work of the legislators and the rare disease coalition that helped lay out the language on these bills and is currently working on this.

John said the Department has formally responded and made comments known to the committee.

Joan Chappel, Committee Member, said there is a fiscal note, and they have concerns that have passed along to the committee.

Bobbie Salveson, Committee Member, asked if this bill is in addition to the TAC work on the process and criteria. John said the bill as proposed would overturn some of the work this Committee has done, but ultimately the legislature can change the law.

Member Leung discussed the fees to fund screening and follow-up. It is $8.40 a birth for follow-up. For a state with 80,000 births, we are talking around more than $600,000 for programs that follow-up.

5. **Vote**

NBS Criteria Voting Results: Microsoft Forms

Criterion 1

Allegra Calder, Facilitator, said there is a large approval of 93.8%. One person would like to omit or suggest something else. An anonymous commenter said they appreciate the criterion.

Criterion 2

The proposed changes received a 100% approval from all TAC members.

Criterion 3
Facilitator Calder asked for comments.

Lisa McGill Vargas, Committee Member, discussed being confused about the wording of but chose to approve the changes.

Eric Leung, Committee Member, had comments but is ok overall with the changes.

Criterion 4
The proposed changes received a 100% approval from all TAC members.

Criterion 5
Most TAC members voted to approve the changes to the criterion. One to two TAC members voted against the second and third additional dot points but provided no additional comments.

Criterion 6
Most TAC members voted to approve the new criterion.

Member Leung asked about changing the wording from availability to accessibility in the third point in Criterion 6.

John Thompson, Department of Health, suggested when we moved it to Criterion 6, the proposal is to say remove the words availability and proximity to accessibility. John asked how we'd like to vote and decided on a hand raise.

TAC members voted unanimously for the change. No objections.

LUNCH

6. **Discussion and Next Steps**
   Kelly Kramer, Board staff, walked through the voting results and highlighted the incorporated changes from the previous discussion. Kelly K. then informed TAC members of the next steps. Kelly K. will present the recommendations to the Board at the March 12 meeting. The criteria updates will not be adopted and applied to conditions under consideration until the Board has approved of the proposed changes.

7. **Overview Congenital Cytomegalovirus (cCMV)**
   Kelly K. gave an overview of the legislative mandate to review cCMV for consideration for the state newborn screening panel and the results of the 2022 newborn screening technical advisory committee meeting. Kelly K. summarized the voting breakdown that resulted in the recommendation to reconsider cCMV at a future date. At that vote in 2022, most TAC members felt cCMV did not meet Criterion 2, were split as to whether it met Criterion 4, and voted with mixed results regarding the cost-benefit analysis.

   Kelly K. then introduced the two parent representatives that will share their experience with cCMV.

8. **Parent Perspective**

Tawny Hooley, Committee Member, thanked the group for discussing cCMV and shared a personal experience with cCMV as an occupational therapist at Sacred Heart in Spokane, WA. Member Hooley discussed treating a patient who had CMV while pregnant and later learned their son was diagnosed with cCMV. Member Hooley was one of the few patients diagnosed with cCMV during pregnancy and felt that providers were not prepared to provide appropriate care. Member Hooley received care at the University of Washington who performed amniocentesis and ultrasounds. Providers warned that the baby may need NICU care, antivirals, and additional treatment. Member Hooley was aware that most babies with CMV are ok, but it can be fatal. Member Hooley began to look for expert care elsewhere and found a doctor in Texas from the CMV Foundation website. This provider gave virtual guidance to Member Hooley's care team.

Once Member Hooley's child was born, their care team found hearing loss at six months and diagnosed them with sensorineural hearing loss (SNHL) at nine months, with rapid progression. Member Hooley discussed connecting with a clinical trial and received antivirals for six months with weekly blood work and growth checks. Member Hooley noted the lack of resources in Spokane. Member Hooley discussed that their child's hearing is now in the normal range, no longer needs hearing aids, and is meeting all developmental milestones with some speech therapy. Member Hooley emphasized that without early intervention, there could have been so much more medical care. Member Hooley said that if we can screen children at ages two and three before they start talking could significantly improve outcomes for both individuals and society. Member Hooley acknowledged the costs of screening but stressed the positive outcome from providers willing to try different treatments and noted educating pregnant friends and family about CMV prevention.

Cathleen Ackley, Committee Member, shared a different experience from Member Hooley. Member Ackley explained that their second child was born healthy but began to have rapid and deteriorating hearing loss due to cCMV. Member Ackley said they felt early prevention could have prevented the hearing loss and that providers could have done more to warn about cCMV.

Member Ackley then presented on costs and benefits related to early identification of cCMV. Member Ackley shared statistics, such as "1 in 200 babies are born with CMV" and 10% are symptomatic at birth. While the number may seem small, Member Ackley emphasized the significant costs, noting that vigilance is crucial for asymptomatic babies. While Washington would need to pay for the costs of education and screening for cCMV, the state is already paying the costs of late diagnoses. For example, special education costs can be $300-500k per child over 18 years and the cost of lifelong care can be $3-5 million. Member Ackley said that testing babies for cCMV could cost between $10 to $50 per baby and that for every $1 spent on screening, $10 would be saved. The annual cost of universal screening would be $809k - $4 million. Member Ackley said that the benefits of early detection would be to initiate antiviral treatment to reduce neurological damage and hearing loss. Parent education prevents emergency medical costs and unnecessary emotional impacts. Member Ackley concluded by stating that Washington needs to act now, and universal screening is cost-effective.

9. cCMV: Natural History, Diagnostic Testing, and Treatment

Dr. Ann J Melvin, MD, MPH, Emeritus Professor, Children's Hospital, reviewed the natural history, diagnostic testing, and treatment for cCMV (see presentation on file).

Allegra Calder, Facilitator, asked the committee for questions.

Eric Leung, Committee Member, thanked Dr. Melvin. Member Leung was struck by a couple of things; the proliferation of data in the last few years. Children that were considered asymptomatic and distinguishing between symptomatic and asymptomatic with deeper investigation. Member Leung asked about their stance on the universal screening program. Dr. Melvin personally feels universal blood spot testing is probably the most cost-efficient, but they are admittedly biased. There are so many steps that are outside of the screening program.

Member Leung asked further questions about Utah screening. Member Leung said Utah requires two failed newborn hearing screening tests. Member Leung said in Washington after two failed tests, then a referral to an audiologist. Some large areas only have one audiologist, so access is difficult.

Rucha Shukla, Committee Member, asked about pregnancy testing and consistent education. Dr. Melvin couldn't find any but wanted to dig deeper.

Tawny Hooley, Committee Member, spoke to their own perspective in Spokane. Member Hooley had been IGG tested and shared their results with their pregnant sister and friend. One of their providers said no need to test, another one said yes to test for CMV.

Julie Walker, Department of Health, said most hospitals in Washington technically do two hearing screenings, and then return in three weeks.

Bobbi Salveson, Committee Member, said this sounded like a concern and asked about other states' blood spot tests.

Dr. Melvin said Connecticut, Minnesota, and other states do targeted hearing screening.

Julie Walker said there is information online.

Molly Parker, Committee Member, talked about universal screening and false positives being so high that it didn't merit screening and cost benefit factors.

Kelly K. forwarded to TAC members the American College of Obstetricians and Gynecologists on cCMV that Member Parker shared.

Facilitator Calder thanked Dr. Melvin.

10. Available Screening Technology

Kelly Kramer, Board staff, introduced the criteria review (see presentation on file). Kelly K. reminded TAC members that recommendations will not be reviewed or approved until the March 12 Board meeting.

Megan McCrillis, Department of Health, reviewed the available screening technology criterion for Congenital Cytomegalovirus (cCMV) and the pros and cons of the biological specimen types used to screen newborns for cCMV. The options include a dried blood spot test, saliva swab, and dried urine paper filter (see presentation on file).

Dr. Ann Melvin, Seattle Children's Hospital, asked if the dried blood spots were mailed.

Eric Leung, Committee Member, said that is correct. The blood spots must dry first before we mail them. The same would be applied to the urine filter paper. Member Leung asked how these specimen types can be used in combination. It seems like even if you use dried blood spots and a saliva swab in combination, you're not going to get the sensitivity or specificity with urine.

Molly Parker, Committee Member, spoke from their observation working in a birth center. Any of these processes would be simple to implement, especially if the dried blood spot was combined in the same packaging as the urine filter paper. The biggest issues may be at the lab receiving end.

Joan Chappel, Committee Member, asked if we currently have the infrastructure at the lab to test dried urine filter papers. Member Chappell agreed with Member Parker's comments.

John Thompson, Department of Health, said we have the expertise on staff who are familiar with the techniques.

Member Leung clarified with Member Chappel if they were asking if hospital sites can test for cCMV and urine samples themselves.

Member Chappel responded that they were just concerned about the lab.

11. Overview: Early Hearing Detection, Diagnosis, and Intervention (EHDDI) Program

Julie Walker, Department of Health, introduced the Early Hearing Detection, Diagnosis, and Intervention (EHDDI) program and what they do for CMV. The program's goal is for all infants to receive a hearing screen by one month of age. Infants who do not pass two hearing screenings will have a diagnostic evaluation before reaching three months old. Infants identified as deaf or hard of hearing (D/HH) have a follow-up within six months. The EHDDI does a lot of work in a short time.

Julie noted that Washington is only one of three states that don't require universal screening, but all birth hospitals provide screenings. The program supports 63 midwives with equipment. One to three infants per 1,000 are identified as D/HH each year. Julie listed the risk factors for hearing differences or loss.

Julie explained that when a baby receives a hearing screen, the risk factors are reported to EHDDI on the hearing screening card. However, the risk factors are vague and don't specify if an in-uterine infection is CMV. It is hard to know how many moms with CMV are being reported. Julie went on to review the EHDDI program and how infants with cCMV are being followed (see presentation on file).

Julie discussed the cCMV bill that passed last legislative session, in which the EHDDI program is responsible for educational materials for cCMV. Julie explained that they are working on a short one-pager that focuses on how to prevent cCMV when pregnant. It will be translated into the top 11 languages in Washington and French. The EHDDI team will also launch a social media campaign. Kelly K. will help disseminate this information as well.

Dr. Ann Melvin, Seattle Children's Hospital, thanked Julie and noted that there may be even more cases of CMV. Instead of 30% of kids, it is likely to be 70%.

Tawny Hooley, Committee Member, asked about the flyer and suggested including Dr. Melvin's graph about the first trimester being the highest risk factor for cCMV. Member Hooley also suggested sending this information to primary care providers. It can take 8-12 weeks for a pregnant person to be seen for a check-up.

Julie responded that EHDDI began to work with SETNET that looks at cCMV data. They have created a flyer specifically for cCMV. The American Academy of Pediatrics should also distribute this information to pregnant people. Explained the other avenues EHDDI is exploring in terms of distributing the flyer to help prevent cCMV.

Rucha Shukla, Committee Member, thanked Julie and asked if there is literature regarding a child with CMV who has had normal hearing screenings for a long time. Member Shukla wondered if these kids will continue to be followed or if there is a way to determine if a child is at low risk for hearing loss. Member Shukla discussed concerns due to the lack of resources and the likely overwhelming number of kids needing follow-up. Member Shukla asked about older children on treatment and if other risk factors cause additional hearing loss.

Julie requested Dr. Melvin answer this question due to their expertise.

Dr. Melvin answered that in utero CMV infections get into the middle ear, which they aren't seen postnatally. CMV is still detected in patients with cochlear implants in the middle ear. This may be due to reactivation of the virus. There is limited study for risk stratification at this point.

Member Parker suggested that EHDDI looks at the Washington Academy of Family Physicians when they are distributing information as they work a lot with rural families and pediatrics. Member Parker also suggested the Washington State OB Community which includes any birth center or delivery provider.

BREAK

12. Available Audiological Resources and Access

Michele Greenwood, Audiologist, Providence Spokane Ear Nose & Throat, presented on the shared Pediatric Audiology Assessment, the challenges, clinic resources in eastern Washington and other considerations (see presentation on file). .

Heather Hinton, Committee Member, recently talked to a parent advocate about audiology and the lack of pediatric audiologists in the area and shared that there was a mobile audiology clinic, through Center for Deaf and Hard of Hearing in Washington State. Michele said this is a great solution for older kids and that pediatric audiology takes a lot of energy.

Julie Walker, Department of Health, said the Mobile unit was sitting at the Educational Service District 123, for two years and up. Believes that the mobile unit was being moved.

Rucha Shukla, Committee Member, talked about every child tested that requires follow-up, and the resources needed for pediatric support. Lack of resources on the east side falls to the resources on the west side of the state.

13. Discussion and Next Steps

Kelly Kramer, Board staff, reminded folks that the review of cCMV will continue to a virtual meeting on March 26. We will hear a presentation on the cost-benefit analysis for cCMV and will then move to a vote on the recommendation for inclusion to the newborn screening panel. Also, we will present the criteria recommendations to the Board on March 12. An update on the Board's decision will be shared at that meeting as well.

Kelly Oshiro, TAC Co-Chair, shared gratitude for all participants, the presentations, and the attention to detail from our TAC participants. Looking forward to the Board meeting and sharing recommendations from the TAC.

Eric Leung, Committee Member, asked John about someone within the lab who manages requests from dried bloodspots for cCMV testing. Might help in terms of collection and records estimates.

John Thompson, Department of Health, said we do have that information and can look into it and pull numbers for the next meeting.

ADJOURNMENT

Kelly Oshiro, TAC Co-Chair, adjourned the meeting at 3:20 p.m.

WASHINGTON STATE BOARD OF HEALTH

_____

Kelly Oshiro, TAC Co-Chair and Nini Shridhar, TAC Co-Chair

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Congenital Cytomegalovirus (cCMV) Overview
Newborn Screening Technical Advisory Committee
March 26, 2025

ABOUT THE CONDITION

- Congenital cytomegalovirus (cCMV) occurs when a pregnant person is infected with cytomegalovirus (CMV) and passes the infection to their unborn child.
- About 1 in 200 babies in the United States are born with cCMV.
- cCMV can result in decreases in hearing and is the leading cause of nonhereditary, sensorineural hearing change.
- About 1 in 5 babies with a cCMV infection will have long term health impacts, including decreases in hearing.
- cCMV can lead to other significant impacts, including developmental delay, changes in vision, seizures, or death.

SYMPTOMS

- Babies born with cCMV can have brain, liver, spleen, lung, and growth problems.
- The most common long-term health problem with cCMV infection is decreases in hearing.
- Decreases in hearing may be detected soon after birth or may develop later in childhood.

DIAGNOSIS

- Infants suspected of having cCMV can have a diagnostic DNA test for CMV infection.
    - Urine or saliva samples are the preferred samples for testing.
    - Blood samples may be used to test newborns with suspected CMV infection, however, compared with urine or saliva, it is not the most accurate option.
- Diagnostic testing must be completed within 21 days of life to confirm a congenital infection.

TREATMENT

- Antivirals can be used to treat babies born with symptoms of cCMV.
- Some antivirals, such as Valganciclovir, may cause serious side effects.
- Antivirals may reduce changes in hearing and improve development.
- All children born with cCMV should have regular hearing and vision checks.

- CDC. “About Cytomegalovirus.” *Cytomegalovirus (CMV) and Congenital CMV Infection*, 10 May 2024, www.cdc.gov/cytomegalovirus/about/index.html.
- Akpan US, Pillarisetty LS. Congenital Cytomegalovirus Infection. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK541003/

To request this document in an alternate format or a different language, please contact the State Board of Health at (360) 236-4110 or by email at wsboh@sboh.wa.gov.

PO Box 47990, Olympia, WA 98504-7990
(360) 236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov

NEWBORN SCREENING TAC – cCMV MATERIALS
MARCH 26, 2025

Washington State Department of HEALTH

EHDDI Program

CMV Flyer

- The English version is complete.
  - The translated versions should be finalized soon.
  - The flyer will be available in:
    - Spanish
    - Vietnamese
    - Russian
    - Marshallese
    - Ukrainian
    - Chinese – Mandarin
    - Chinese – Cantonese
    - Korean
    - Arabic
    - Somali
    - Tagalog
    - French

Protect your baby

If you are pregnant,
now is the time to learn about cCMV

What is cCMV?

Cytomegalovirus (CMV) is a common virus that you can get while pregnant and pass on to your baby. Most people with CMV won't have symptoms and may not know they have it. When you pass CMV to your baby, it's called congenital cytomegalovirus (cCMV). Congenital means "from birth."

Every year, **1 in 200** babies will be born with cCMV.

1 in 5 babies born with cCMV may have long-term health conditions, such as:

- Hearing differences (deaf or hard of hearing)
- Developmental delays
- Vision loss
- Lack of coordination or weakness
- Seizures
- In severe cases, death

How does CMV spread?

CMV can be spread though body fluids, such as saliva (spit), urine (pee), blood, tears, semen or vaginal fluids, and breast milk.

Contact with saliva or urine of young children is the major cause of CMV infection for pregnant people who are parents, daycare workers, preschool teachers, therapists, and health care workers.

What can I do for my baby?

Avoid getting CMV so you can't spread it to your baby.

- **Don't share food, drinks, utensils, or straws, especially with young children.**
- **Avoid contact with children's spit. No kisses on the mouth.**
- **Don't share toothbrushes.**
- **Wash hands with soap and water after wiping noses, changing diapers, feeding a child or handling toys.**

These healthy habits can help you avoid CMV, and stop you from spreading it to your baby.

Learn more about cCMV, testing for your baby and more:

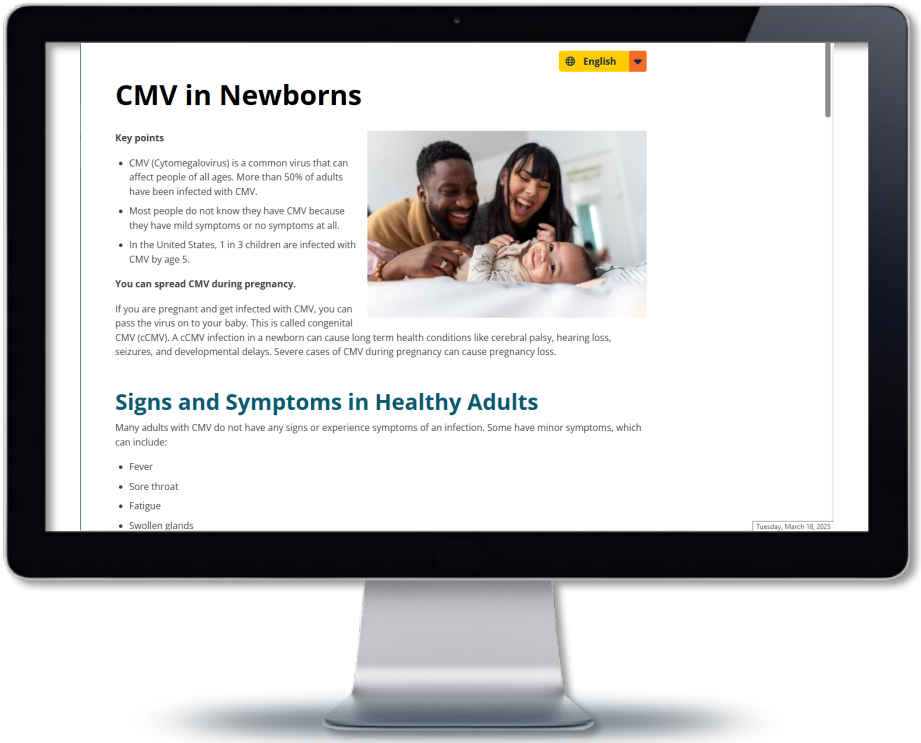
Washington State Department of HEALTH

DOH 820-308 CS February 2025

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

CMV Website

- DOH CMV website
  - It is currently live, but we are still working on getting a few design issues fixed.
  - The website is available in English and Spanish.



Other CMV Materials

- EHDDI Program Website
  - Currently, we have posted CMV flyers created in conjunction with DOH SET-NET, AAP & CDC.

Risk Factors for Late-Onset Hearing Loss

Extended Stay in Neonatal Intensive Care Unit (PDF)

Syndromes Associated with Hearing Loss (PDF)

Family History of Hearing Loss in Childhood (PDF)

Craniofacial Anomalies (PDF)

In-Utero Infections (PDF)

Congenital Cytomegalovirus

- English (PDF)
- Chinese Traditional (PDF)
- Russian (PDF)
- Somali (PDF)
- Spanish (PDF)

References for Risk Factor Fact Sheets (PDF)

Other CMV Materials

- DOH Surveillance for Diseases Affecting Pregnant People and Babies (SET-NET)

Congenital Cytomegalovirus (cCMV)

According to the CDC, "Cytomegalovirus (pronounced sy-toe-MEG-a-low-vy-rus), or CMV, is a common virus that infects people of all ages. ...When a baby is born with cytomegalovirus (CMV) infection, it is called congenital CMV. About one out of every 200 babies is born with congenital CMV infection. About 1 in 5 babies with congenital CMV infection will have long-term health problems."

The Washington CMV Project promotes testing and education about cCMV in WA state. In the future, SET-NET may review Washington's cCMV data.

Other states exploring how cCMV affects babies:

- Minnesota added cCMV to their Newborn Screening Program in 2023.
- New York temporarily added cCMV to their Newborn Screening Program for 2023 and 2024.
- Utah has a state program to promote awareness and testing of cCMV.

The following PDFs may be printed and shared with pregnant people, health care providers, and the community:

- cCMV Fact Sheet (for healthcare providers) - English (PDF)
- CMV Fact Sheet (for consumers/families) - English (PDF)
- cCMV Fact Sheet (for families) – Spanish (PDF)
- cCMV Fact Sheet (for families) – Chinese (traditional) (PDF)
- cCMV Fact Sheet (for families) – Russian (PDF)
- cCMV Fact Sheet (for families) – Somali (PDF)
- cCMV Fact Sheet (for families) – Vietnamese (PDF)
- Congenital Syphilis (CDC) (PDF)

Upcoming Projects

- Watch Me Grow Washington (WMG)
  - Watch Me Grow Washington sends health and safety information to all parents and caregivers of children birth to 6 in Washington.
  - The one-page flyer will be sent to parents when their child is 12 months and 24 months old.
- WMG – Prenatal Workgroup
  - WMG created a prenatal program that will create educational materials for people that are pregnant or planning on becoming pregnant.
  - cCMV materials will be incorporated into their educational materials.
- Social Media Campaign
  - We will complete a social media campaign in June.
    - June is CMV Awareness Month.

Upcoming Projects

- When all the materials are complete, we will send them out to our community partners.
  - We will also reach out to appropriate DOH programs and request they add a link to the CMV webpage on their program webpages.

Material Distribution

- DOH
  - WIC
  - Children and Youth with Special Healthcare Needs
  - SET-NET
  - WMG
  - NBS
  - Sexual and Reproductive Health
  - Washington State Perinatal Collaborative
- DCYF
  - Early learning and childcare programs
- OSPI/Local School Districts
  - Developmental Preschools
- County Health Departments
  - Nurse Family Partnership
- Associations
  - MAWS – Midwives
  - WCAAP – Pediatrics
  - WSOA – OBGYNs
  - WAFP – Family Physicians
  - AANP Region 10 – Nurse Practitioners
  - WA NAPNAP – Nurse Practitioners (Pediatrics)
  - WAPA – Physician Assistants
  - REACHE – Childbirth Educators
- Various non-profits

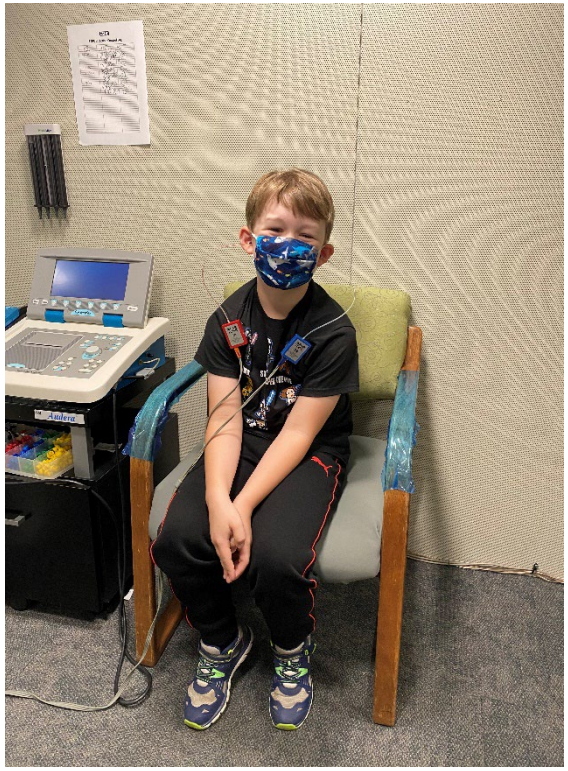
EHDDI Program

1610 NE 150th St
Shoreline, WA 98155
Toll-free: 1-888-WAEHDDI
Fax: 206-364-0074
Email: ehddi2@doh.wa.gov
Website: www.doh.wa.gov/earlyhearing

Julie Walker
Phone: 206-418-5556
Julie.Walker@doh.wa.gov

Kelsey Davis
Phone: 206-418-5613
Kelsey.Davis@doh.wa.gov

Anna Dodd
Phone: 206-418-5612
Anna.Dodd@doh.wa.gov



Protect your baby

If you are pregnant, now is the time to learn about cCMV

What is cCMV?

Cytomegalovirus (CMV) is a common virus that you can get while pregnant and pass on to your baby. Most people with CMV won't have symptoms and may not know they have it. When you pass CMV to your baby, it's called congenital cytomegalovirus (cCMV). Congenital means "from birth."

Every year, **1 in 200** babies will be born with cCMV.

1 in 5 babies born with cCMV may have long-term health conditions, such as:

- Hearing differences (deaf or hard of hearing)
- Developmental delays
- Vision loss
- Lack of coordination or weakness
- Seizures
- In severe cases, death

How does CMV spread?

CMV can be spread though body fluids, such as saliva (spit), urine (pee), blood, tears, semen or vaginal fluids, and breast milk.

Contact with saliva or urine of young children is the major cause of CMV infection for pregnant people who are parents, daycare workers, preschool teachers, therapists, and health care workers.

What can I do for my baby?

Avoid getting CMV so you can't spread it to your baby.

- **Don't share food, drinks, utensils, or straws, especially with young children.**
- **Avoid contact with children's spit. No kisses on the mouth.**
- **Don't share toothbrushes.**
- **Wash hands with soap and water after wiping noses, changing diapers, feeding a child or handling toys.**

These healthy habits can help you avoid CMV, and stop you from spreading it to your baby.

Learn more about cCMV, testing for your baby and more:

Washington State Department of HEALTH

DOH 820-308 CS February 2025

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Protect Yourself and Your Baby from CMV

CMV (cytomegalovirus) is a common virus that affects people of all ages. If you get CMV while you're pregnant and pass it on to your baby, it can cause serious health problems.

How does CMV affect babies?

When a baby is born with CMV, it's called **congenital CMV (cCMV)**. Some babies may show signs of cCMV at birth, such as a rash, jaundice (yellow skin or eyes), or low birth weight. Sometimes babies born with cCMV don't show any signs. cCMV can cause **serious health problems**, including:

- Hearing loss
- Vision loss
- Learning disabilities
- Delayed growth and development
- Small head size

How does CMV affect pregnant people?

If you get CMV, you might feel like you have a cold or the flu. CMV symptoms include fever, body aches, and feeling tired. Some people who get CMV don't have any symptoms.

If you notice these symptoms, **ask your doctor about CMV testing**. Your doctor can do a blood test to find out if you have CMV. If you do have the virus, your doctor may recommend additional testing for your baby.

How does CMV spread?

CMV **spreads from person to person through body fluids**, including urine (pee), saliva (spit), tears, breast milk, and semen or vaginal fluids.

Anyone can get CMV, but **you're more likely to get it if you're a parent of young children or work with young children**. That's because parents and people who work with kids are more likely to come into contact with urine or saliva from children who have the virus.

How can I lower my risk of CMV during pregnancy?

Take these simple steps to reduce your risk of getting CMV:

- Wash your hands after changing diapers, feeding a child, wiping a child's nose or mouth, or handling toys or pacifiers
- Avoid sharing food and drinks, utensils, or toothbrushes
- Clean toys and countertops often
- If you kiss a young child, kiss their cheek or forehead — that way, you'll be less likely to get saliva on your lip
- Don't put items that children have touched in your mouth

To learn more about CMV, visit **NationalCMV.org**.

This project is supported by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $350,000 with 100 percent funded by CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by American Academy of Pediatrics, CDC/HHS, or the U.S. Government.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Protéjase y proteja a su bebé del CMV

El CMV (citomegalovirus) es un virus común que afecta a personas de todas las edades. Si contrae CMV durante el embarazo y se lo transmite a su bebé, puede causarle problemas de salud graves.

¿Cómo afecta el CMV a los bebés?

Cuando un bebé nace con CMV, se denomina **CMV congénito (CMVc)**. Algunos bebés pueden mostrar señales de CMVc al nacer, como un sarpullido, ictericia (piel u ojos amarillos) o bajo peso al nacer. A veces, los bebés que nacen con CMVc no muestran ninguna señal. El CMVc puede causar **problemas de salud graves**, como:

- Pérdida de audición
- Pérdida de visión
- Problemas de aprendizaje
- Retraso en el crecimiento y el desarrollo
- Cabeza pequeña

¿Cómo afecta el CMV a las personas embarazadas?

Si contrae CMV, puede que sienta como si tuviera un resfriado o gripe. Los síntomas del CMV incluyen fiebre, dolor corporal y sensación de cansancio. Algunas personas que contraen CMV no presentan ningún síntoma.

Si nota estos síntomas, **pregunte a su médico sobre las pruebas de detección del CMV**. El médico puede hacerle un análisis de sangre para saber si tiene CMV. Si tiene el virus, su médico puede recomendarle pruebas adicionales para su bebé.

¿Cómo se transmite el CMV?

El CMV **se transmite de una persona a otra a través de los fluidos corporales**, como la orina (pis), la saliva (baba), las lágrimas, la leche materna y el semen o los fluidos vaginales.

Cualquiera puede contraer CMV, pero **es más probable que lo contraiga si es padre o madre de niños pequeños o trabaja con niños pequeños**. Esto se debe a que los padres y las personas que trabajan con niños tienen más probabilidades de entrar en contacto con orina o saliva de niños que tienen el virus.

¿Cómo puedo reducir el riesgo de contraer CMV durante el embarazo?

Tome estas medidas sencillas para reducir el riesgo de contraer CMV:

Lávese las manos después de cambiar pañales, dar de comer a un niño, limpiarle la nariz o la boca o manipular juguetes o chupetes.

Evite compartir alimentos y bebidas, utensilios o cepillos de dientes.

Limpie juguetes y encimeras con frecuencia.

Si besa a un niño pequeño, hágalo en la mejilla o en la frente para que sea menos probable que le quede saliva en el labio.

No se lleve a la boca objetos que hayan tocado los niños.

Para saber más sobre el CMV, visite **NationalCMV.org**.

Este proyecto cuenta con el apoyo de los Centers for Disease Control and Prevention (CDC, Centros para el Control y la Prevención de Enfermedades) del U.S. Department of Health and Human Services (HHS, Departamento de Salud y Servicios Humanos de los EE. UU.) en el marco de una ayuda financiera por un total de $350 000 financiada al 100 % por los CDC/el HHS. El contenido es responsabilidad de los autores y no representa necesariamente la opinión oficial ni el respaldo de la American Academy of Pediatrics, los CDC/el HHS o el U.S. Government (Gobierno de los EE. UU.).

Washington State Department of HEALTH

150-291 August 2024 To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Ka Difaac Naftaada iyo Ilmahaaga cudurka CMV

CMV (cytomegalovirus) waa fayras guud oo ku dhaca dadka dhammaan da'aha guud ahaan. Haddii uu kugu dhaco CMV inta aad uurka leedahay aadna u gudbiso ilmahaaga, wuxuu sababi karaa dhibaatooyin caafimaad oo daran.

Sidee ayuu CMV u sameeyaa ilmaha?

Marka ilmuhu ku dhasho CMV, waxaa la yiraahdaa **congenital CMV (cCMV)**. Ilmaha qaar ayaa muujin kara astaamaha cCMV markay dhashaan, sida finan, cagaarshow (maqaarka ama indhaha oo jaalle noqda) ama miisaanka hooseeya ee dhalashada. Mararka qaar ilmaha ku dhasha cCMV ayaan lahayn wax astaamo ah, cCMV ayaana sababi kara **dhibaatooyin daran oo caafimaadeed**, oo ay ku jiraan:

- Maqal beel
- Indho beel
- Naafonimada dhanka waxbarashada
- Kobaca iyo hormarka gaabiska ah
- Madax yari

Sidee ayuu CMV u sameeyaa dadka uurka leh?

Haddii uu kugu dhaco CMV, waxaad dareemaysaa astaamaha qaboowga ama hargabka. Astaamaha CMV waxaa ku jira qandho, jir xanuun, iyo daal. Dadka qaar oo uu ku dhaco CMV ayaan lahayn wax astaamo ah.

Haddii aad aragto astaamahaan, **ka codso dhakhtarkaaga inuu ku baaro**. Dhakhtarkaaga ayaa kugu samayn kara baaritaanka dhiiga si loo ogaado haddii aad qabto CMV. Haddii aad qabto fayraska, dhakhtarkaaga ayaa ku talin kara baaritaan dheeri ah oo lagu sameeyo cunugaaga.

Sidee ayuu CMV u faafaa?

CMV **wuxuu dadka iskaga dhex faafaa dheecaannada jirka**, ayna ku jiraan kaadida (kaadi) calyada (candhuufta), ilmada, caanaha naaska, iyo shahwada ama dheecaannada farjiga.

Qof kasta ayuu ku dhici karaa CMV, laakiin **waxay u badan tahay inaad qaado haddii aad tahay waalidka ilmo yaryar ama la shaqeyso ilmaha yaryar**. Taas waxaa sabab u ah in waalidiinta iyo dadka la shaqeeya ilmaha ay u badan yihiin inay taabtaan kaadida ama calyada ilmaha qaba fayraska.

Sidee ayaan ku yareyn karaa khatartayda CMV ee inta aan uurka leeyahay?

Qaad talaabooyinkaan fudud si aad u yareyso khatartaada qaadista CMV:

Farxalo kadib marka aad ilmaha ka badesho xafaayada, aad naaska nuujinayso, aad duufka ka tirto sanka ilmaha ama afka ilmaha, ama aad soo qaado boonbaleyaasha ama cinjirada ilmaha.

Iska ilaali wadaagista cuntada iyo cabitaannada, maacuunta, ama daawada cadayga

Si joogto ah u nadiifi boonbaleyaasha iyo dusha miisaska

Haddii aad shumiso ilmo yar, ka shumi dhabankiisa ama dhafoorka — qaabkaas, waxaa iska ilaalinaysaa in calyadu gaarto bishimahaaga

Afkaaga ha gelin waxyaabo ilmuhu taabteen

Si aad xog dheeri ah uga ogaato CMV, booqo **NationalCMV.org**.

Mashruucaan waxaa taageeraysa Centers for Disease Control and Prevention (CDC, Xarumaha Xakamaynta iyo Kahortaga Cudurka) ee U.S. Department of Health and Human Services (HHS, Waaxda Adeegyada Caafimaadka iyo Aadanaha ee Mareykanka) kaasoo qayb ka ah lacagta kaalmada dhaqaalaha oo wadarta guud dhan $350,000 taasoo ay 100 boqolkiiba ay maal gelinayso CDC/HHS. Xogta waxaa masuuliyadeeda leh qoraaga kama turjumayaan fikradaha rasmiga ah, mana taageerayso, American Academy of Pediatrics, CDC/HHS, ama U.S. Government (Dawlada Mareykanka).

Washington State Department of HEALTH

150-291 August 2024 To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Защитите себя и своего ребенка от ЦМВ

ЦМВ (цитомегаловирус) — распространенный вирус, который поражает людей всех возрастов. Если вы заразитесь ЦМВ в период беременности и вирус передастся плоду, это может привести к тяжелым нарушениям здоровья у будущего ребенка.

Как ЦМВ влияет на детей?

Когда ребенок рождается с ЦМВ, это называется **врожденной ЦМВ-инфекцией**. У некоторых новорожденных детей могут проявляться такие признаки этой инфекции, как сыпь, желтуха или низкий вес при рождении. Иногда признаки не проявляются. Тем не менее инфекция может вызывать **тяжелые нарушения здоровья**, в том числе такие:

- Потеря слуха
- Потеря зрения
- Трудности в обучении
- Задержки роста и развития
- Маленький размер головы

Как ЦМВ влияет на беременных женщин?

Симптомы ЦМВ очень похожи на грипп или простуду: жар, боли в теле и усталость. В отдельных случаях симптомы могут отсутствовать.

Если у вас возникли вышеперечисленные симптомы, **спросите своего врача о необходимости обследования на ЦМВ**. Врач может назначить анализ крови на ЦМВ. Если результат анализа окажется положительным, врач может назначить дополнительное обследования для плода.

Как передается ЦМВ?

ЦМВ **передается от человека к человеку через физиологические жидкости**, к которым относятся: моча, слюна, слезы, грудное молоко, сперма и вагинальный секрет.

Любой человек может заразиться ЦМВ, однако **вероятность заражения выше у родителей маленьких детей и тех, кто работает с такими детьми**. Это связано с тем, что родители и люди, работающие с детьми, чаще контактируют с мочой или слюной детей, которые могут быть инфицированными.

Как уменьшить вероятность заражения ЦМВ в период беременности?

Чтобы уменьшить риск заражения ЦМВ:

- Мойте руки после смены подгузника, кормления, протирания носа или рта ребенка, после контакта с игрушками или сосками-пустышками
- Не делитесь едой, напитками, посудой и зубными щетками
- Очищайте игрушки и столешницы
- Если хотите поцеловать маленького ребенка, целуйте его в щеку или лоб, чтобы уменьшить риск попадания слюны на губы
- Не кладите в рот предметы, к которым мог прикасаться ребенок

Чтобы узнать больше о ЦМВ, перейдите на сайт **NationalCMV.org**.

Этот проект поддерживается Centers for Disease Control and Prevention (CDC, Центры по контролю и профилактике заболеваний), регулируемыми U.S. Department of Health and Human Services (HHS, Министерство здравоохранения и социального обеспечения США), в рамках финансовой помощи в размере 350 000 долл. США. Денежные средства в полном объеме предоставляются CDC/HHS. Содержание документа выражает мнение авторов, не было одобрено и не обязательно отражает официальную позицию American Academy of Pediatrics, CDC/HHS или U.S. Government (правительство США).

Запросить этот документ в другом формате можно по номеру телефона 1-800-525-0127. Если вы страдаете нарушением слуха, обращайтесь по телефону 711 (Washington Relay) или по электронной почте doh.information@doh.wa.gov.

保護您自己和寶寶免受 CMV 感染

CMV（巨細胞病毒）是一種常見病毒，會影響各個年齡段的人群。如果您在懷孕期間感染了 CMV 並將其傳給了寶寶，那麼該病毒可能會導致嚴重的健康問題。

CMV 會對嬰兒造成怎樣的影響？

如果嬰兒出生時就患有 CMV，則稱為**先天性 CMV (cCMV)**。有些嬰兒在出生時可能會出現 cCMV 的症狀，如皮疹、黃疸（皮膚或眼睛發黃）、或出生體重過輕。有時，出生時就患有 cCMV 的嬰兒不會表現出任何症狀。cCMV 可能導致**嚴重的健康問題**，包括：

- 聽力損失
- 視力喪失
- 學習障礙
- 生長和發育遲緩
- 頭部較小

CMV 會對孕婦造成怎樣的影響？

如果感染了 CMV，您可能會感覺像是患上了感冒或流感。CMV 的症狀包括發燒、身體疼痛、以及疲倦。有些人在感染 CMV 後沒有任何症狀。

如果您發現此類症狀，**請向醫生諮詢有關 CMV 檢測的相關事宜**。醫生可以透過驗血來確定您是否感染了 CMV。如果您確實感染了該病毒，那麼醫生可能會建議您為寶寶進行額外的檢查。

CMV 是如何傳播的?

CMV **可以透過體液在人與人之間進行傳播**，包括尿液（小便）、唾液（口水）、眼淚、母乳、精液或陰道分泌物。

任何人都可能會感染 CMV，但**如果您是幼兒的父母或從事與幼兒有關的工作，則更有可能會感染 CMV**。這是因為父母和從事兒童有關工作的人更有可能會接觸到感染該病毒的兒童的尿液或唾液。

如何降低在懷孕期間感染 CMV 的風險?

可以採取以下簡單的步驟來降低感染 CMV 的風險：

- 在給孩子更換尿布、餵奶、擦拭口鼻或處理玩具或奶嘴後要洗手
- 避免共享食物和飲品，以及共用餐具或牙刷
- 經常清潔玩具和檯面
- 如果您親吻年幼的孩子，請親吻他們的臉頰或額頭 — 這樣，您的嘴唇便不容易沾到唾液
- 切勿將孩子接觸過的物品放入口中

要想瞭解更多有關 CMV 的相關資訊，請造訪 **NationalCMV.org**。

本專案獲得了 U.S. Department of Health and Human Services（HHS，美國衛生與公眾服務部）的 Centers for Disease Control and Prevention（CDC，疾病控制與預防中心）的支持，作為總金額為 350,000 美元的財政援助撥款的組成部分，100% 是由 CDC/HHS 予以資助。本內容僅代表作者個人觀點，並不代表 American Academy of Pediatrics、CDC/HHS 或 U.S. Government（美國政府）的官方觀點或認可。

Washington State Department of HEALTH

150-291 August 2024 To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Bảo Vệ Quý Vị và Con Nhỏ khỏi CMV

CMV (cytomegalovirus) là một loại vi-rút phổ biến gây ảnh hưởng đến mọi người ở mọi lứa tuổi. Nếu quý vị nhiễm CMV khi đang mang thai và truyền sang con nhỏ, điều này có thể gây ra các vấn đề sức khỏe nghiêm trọng.

CMV ảnh hưởng đến trẻ sơ sinh như thế nào?

Khi một đứa trẻ sinh ra đã nhiễm CMV, đây được gọi là **CMV bẩm sinh (cCMV)**. Một số trẻ có thể có dấu hiệu nhiễm cMV khi mới sinh ra, chẳng hạn như phát ban, vàng da (da hoặc mắt màu vàng) hoặc nhẹ cân. Đôi khi trẻ sinh ra nhiễm cMV lại không có bất kỳ dấu hiệu nào. cMV có thể gây ra **các vấn đề sức khỏe nghiêm trọng**, bao gồm:

- Mất thính lực
- Mất thị lực
- Khuyết tật học tập
- Tăng trưởng và phát triển chậm
- Kích thước đầu nhỏ

CMV ảnh hưởng đến người mang thai như thế nào?

Nếu nhiễm CMV, quý vị có thể cảm thấy như bị cảm lạnh hoặc cúm. Các triệu chứng của CMV bao gồm sốt, đau nhức cơ thể và cảm thấy mệt mỏi. Một số người nhiễm CMV không có bất kỳ triệu chứng nào.

Nếu quý vị nhận thấy những triệu chứng này, **hỏi bác sĩ của mình về việc xét nghiệm CMV**. Bác sĩ có thể làm xét nghiệm máu để phát hiện xem quý vị có nhiễm CMV hay không. Nếu quý vị nhiễm vi-rút, bác sĩ có thể đề nghị xét nghiệm thêm cho con quý vị.

CMV lây nhiễm như thế nào?

CMV **lây từ người sang người qua dịch cơ thể**, bao gồm nước tiểu, nước bọt, nước mắt, sữa mẹ và tinh dịch hoặc dịch âm đạo.

Ai cũng có thể nhiễm CMV, nhưng **quý vị có nhiều khả năng nhiễm vi-rút này hơn nếu đang là cha mẹ của trẻ nhỏ hoặc làm việc cùng trẻ nhỏ**. Đó là bởi vì cha mẹ và những người làm việc với trẻ nhỏ có nhiều khả năng tiếp xúc với nước tiểu hoặc nước bọt của trẻ nhiễm vi-rút.

Làm cách nào để giảm nguy cơ nhiễm CMV khi mang thai?

Thực hiện các bước đơn giản sau để giảm nguy cơ mắc CMV:

- Rửa tay sau khi thay tã, cho trẻ ăn, lau mũi hoặc miệng cho trẻ hoặc cầm đồ chơi hay ti giả
- Tránh dùng chung đồ ăn, đồ uống, dụng cụ ăn uống hoặc bàn chải đánh răng
- Thường xuyên lau chùi đồ chơi và mặt bàn
- Nếu quý vị hôn một đứa trẻ, hãy hôn vào má hoặc trán của các em - bằng cách đó, quý vị sẽ ít bị chảy nước bọt vào môi hơn
- Không cho đồ vật trẻ đã chạm tay vào miệng mình

Để tìm hiểu thêm về CMV, hãy truy cập **NationalCMV.org**.

Dự án này được Centers for Disease Control and Prevention (CDC, Trung Tâm Kiểm Soát và Phòng Ngừa Dịch Bệnh) của U.S. Department of Health and Human Services (HHS, Bộ Y Tế và Dịch Vụ Nhân Sinh Hoa Kỳ) hỗ trợ như một phần của trợ cấp hỗ trợ tài chính với tổng số tiền $350.000, trong đó 100% được tài trợ bởi CDC/HHS. Nội dung này là của (các) tác giả và không nhất thiết thể hiện quan điểm chính thức hay sự chứng thực của American Academy of Pediatrics, CDC/HHS hoặc U.S. Government (Chính Phủ Hoa Kỳ).

Washington State Department of HEALTH

150-291 August 2024 To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Congenital CMV: Tips for Pediatric Health Care Providers

Did you know congenital cytomegalovirus (cCMV) is the most common congenital virus in the United States? cCMV can cause serious health problems for newborn babies, including:

In the United States,
1 in 200 babies
are born with congenital CMV.

- Hearing loss
- Vision loss
- Learning disabilities
- Developmental delays
- Microcephaly (smaller head size)

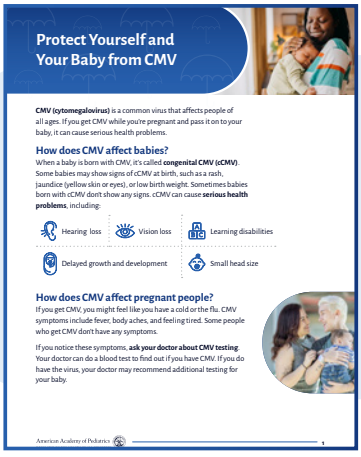
As a pediatric health care provider, you can help reduce rates of cCMV — and ensure infants with cCMV get the care they need.

Educate pregnant people about cCMV

Education is the key to prevention! You can educate pregnant people (like your patients' parents and caregivers) about cCMV by sharing these resources.

Fact sheet

This fact sheet includes basic facts about cCMV and simple ways that people can reduce their risk of getting CMV during pregnancy. Try using it to start the conversation about cCMV with pregnant parents and caregivers during patient appointments. You can also put a few copies in your waiting room or post it on your practice's webpage or social media accounts.


Protect Yourself and Your Baby from CMV

CMV (cytomegalovirus) is a common virus that affects people of all ages. If you get CMV while you're pregnant and pass it on to your baby, it can cause serious health problems.

How does CMV affect babies?

When a baby is born with CMV, it's called **congenital CMV (cCMV)**. Some babies may show signs of cCMV at birth, such as a rash, jaundice (yellow skin or eyes), or low birth weight. Sometimes babies born with cCMV don't show any signs. cCMV can cause **serious health problems**, including:

Hearing loss · Vision loss · Learning disabilities · Delayed growth and development · Small head size

How does CMV affect pregnant people?

If you get CMV, you might feel like you have a cold or the flu. CMV symptoms include fever, body aches, and feeling tired. Some people who get CMV don't have any symptoms.

If you notice these symptoms, **ask your doctor about CMV testing**. Your doctor can do a blood test to find out if you have CMV. If you do have the virus, your doctor may recommend additional testing for your baby.

American Academy of Pediatrics

Social media graphics

Share these graphics on your practice's social media accounts to spread the word about cCMV. To keep the momentum going, encourage other health care providers to share with their networks.

Because CMV is transmitted through body fluids, including saliva and urine, **pregnant people who have young kids or work with small children** are more likely to get CMV and pass it on to their babies. It's especially important to educate these pregnant people about cCMV.

Test for CMV

Know how to spot the signs and test your patients for CMV.

Newborn babies

Some babies may show signs of cCMV at birth, including rash, jaundice, or low birth weight. Sometimes there are no external signs of cCMV.

To determine whether a baby was infected with CMV while in utero, you'll need to administer a PCR (polymerase chain reaction) test on a urine sample. It's important to run this test within the baby's first 3 weeks of life.

Pregnant people

Many adults with CMV have no symptoms, while others have symptoms like fever, body aches, or fatigue. If pregnant people report cold or flu-like symptoms, encourage them to ask their OB or primary care provider about the possibility of CMV testing. IgM and IgG antibody testing can determine if patients have CMV antibodies.

Provide follow-up care or referrals

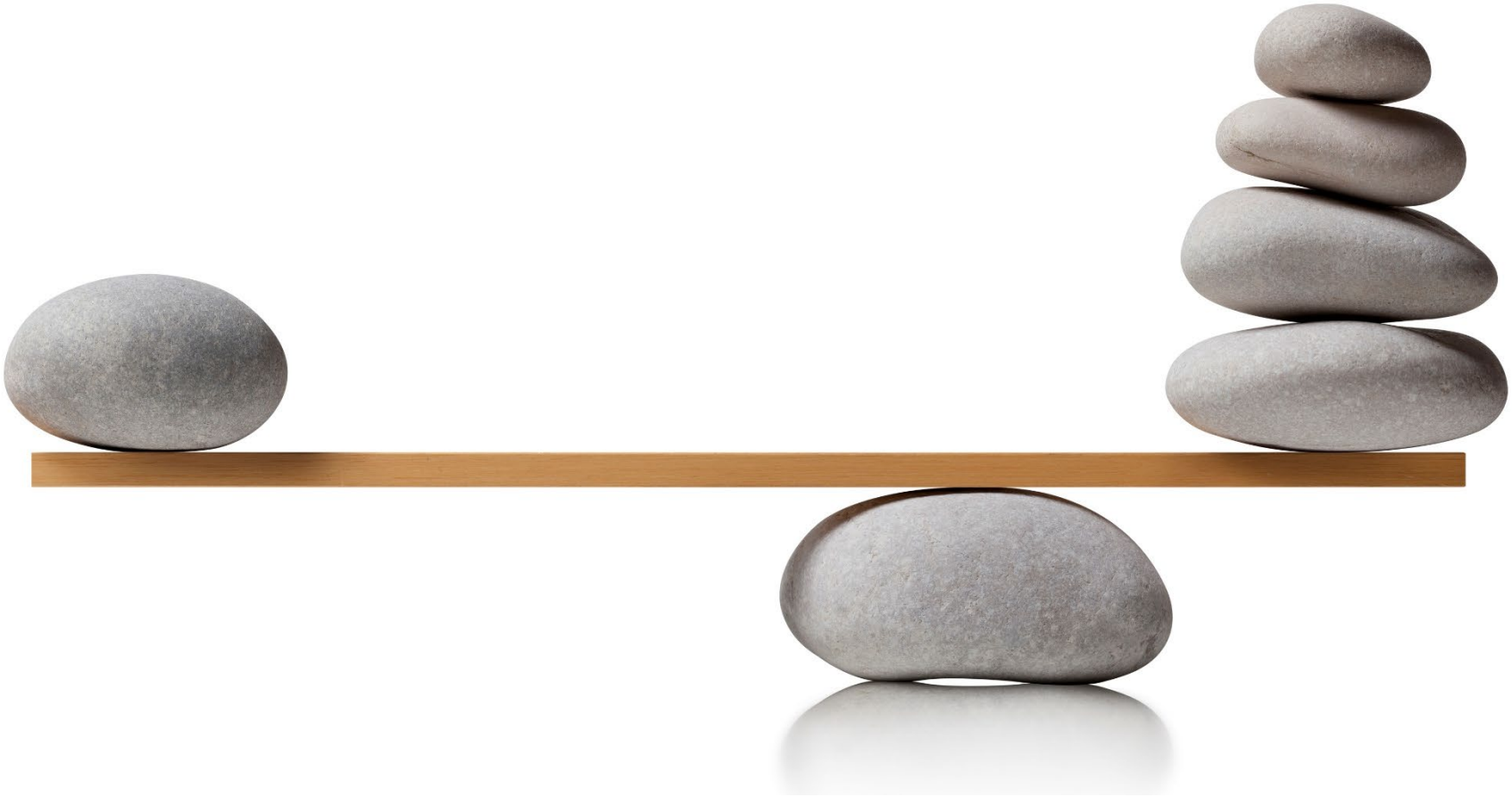
As of 2023, there's no standard treatment recommendation for cCMV. For babies with moderate to severe symptoms, antiviral medications can improve long-term hearing and developmental outcomes. However, these medications can have serious side effects and aren't recommend for babies with mild symptoms.

All babies diagnosed with cCMV should receive follow-up care, including:

- Monitoring for hearing loss, as recommended by the child's audiologist
- An eye exam during the first year of life
- Regular follow-up visits with a primary care doctor to monitor their developmental milestones and head size

For more information and clinical guidance on congenital CMV from the Centers for Disease Control and Prevention (CDC), visit **cdc.gov/cmv/clinical/index.html**.

This project is supported by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $350,000 with 100 percent funded by CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by American Academy of Pediatrics, CDC/HHS, or the U.S. Government.



COST-BENEFIT ANALYSIS OF NEWBORN SCREENING FOR CONGENITAL CYTOMEGALOVIRUS (cCMV)

Megan McCrillis, MPH
Policy Analyst, WA State Newborn Screening Program
John D. Thompson, PhD, MPA, MPH
Director, Newborn Screening Program

Washington State Department of HEALTH

Acknowledgement

- We would like to recognize Caitlin Maloney, who completed much of the cost-benefit work in 2022 during the original review of cCMV as a graduate student in the Institute for Public Health Genetics at the University of Washington.
- We will present an updated model using the framework of Caitlin's 2022 analysis.

Washington State NBS Criteria

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.

- The economic analysis considers:
  - The prevalence of the condition among newborns.
  - The positive and negative predictive values of the screening and diagnostic tests.
  - Variability of clinical presentation by those who have the condition.
  - Dollar values for costs and benefits of screening vs. no screening.
- The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as psycho-social or economic impacts on the family and medical system, must also be considered.
- The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening.
- There is adequate evidence of acceptable quality to evaluate this criterion.

Strategy

Decision Tree

- Compares status quo v. screening model

Data from:

- Primary literature
- States currently screening or pilot studies
- Expert opinion

Sensitivity analysis – vary assumptions

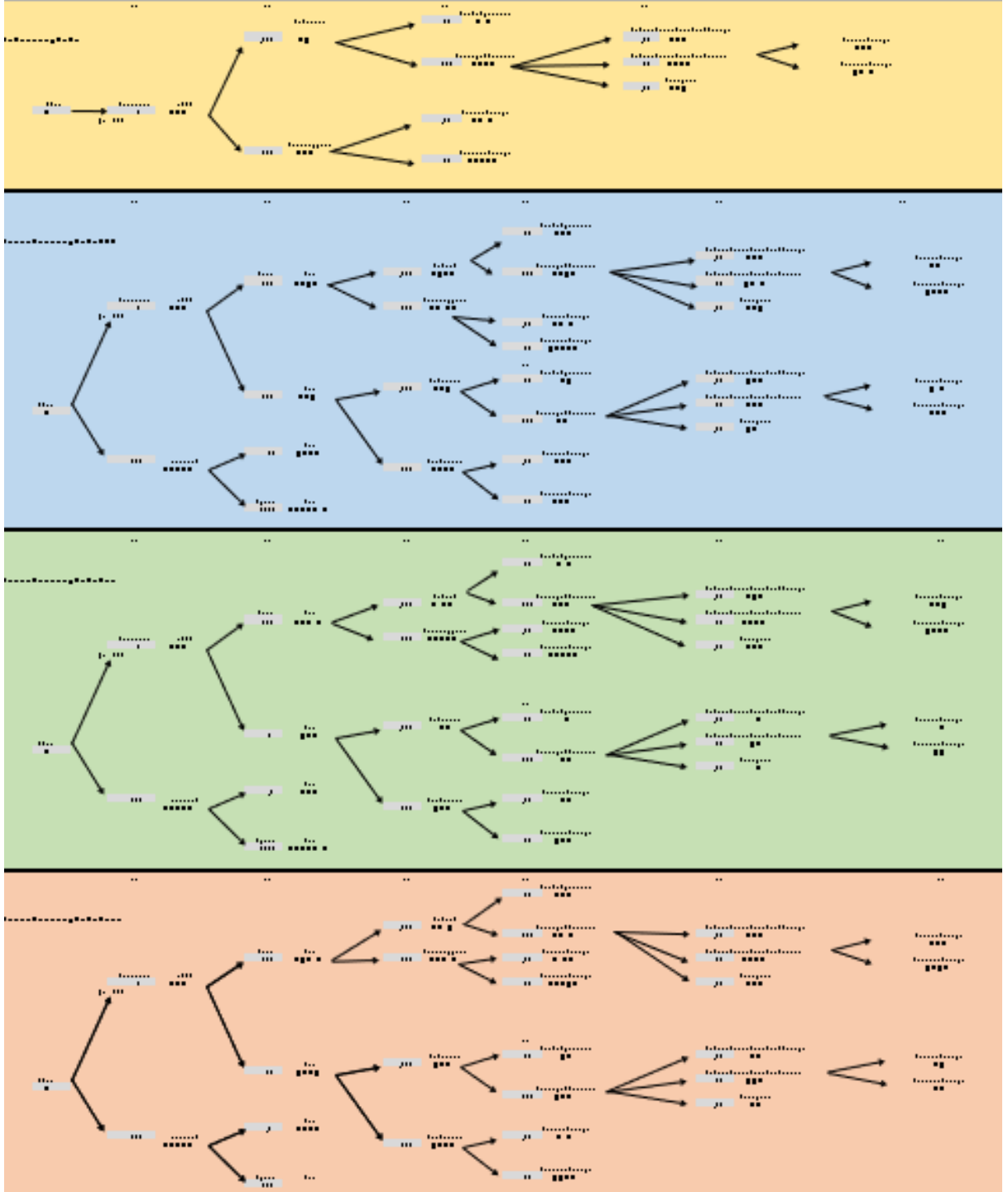
- High and low estimates for parameters

No Screening

Universal Screening: Dried blood spot

Universal Screening: Dried Urine Filter Paper

Universal Screening: Dried Saliva Swab



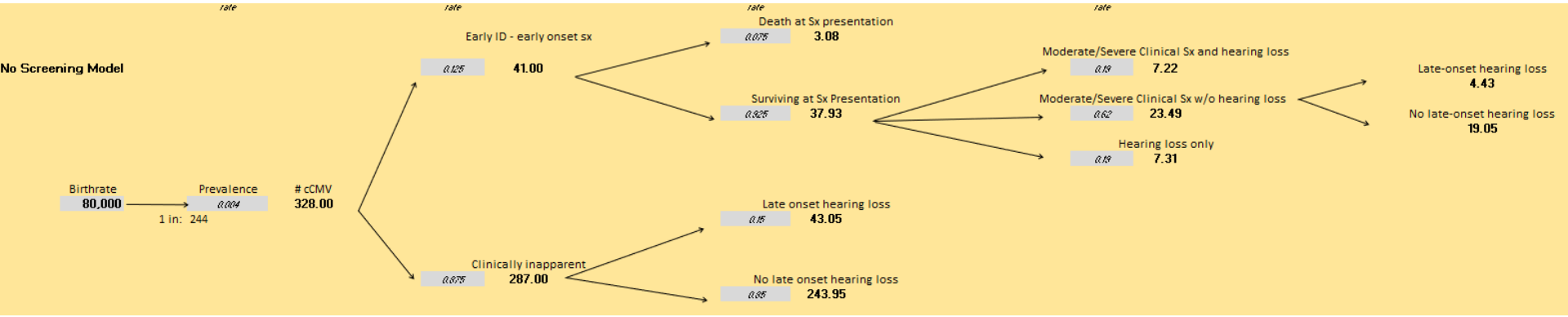
Decision Tree

cCMV does not fit typical newborn screening rationale

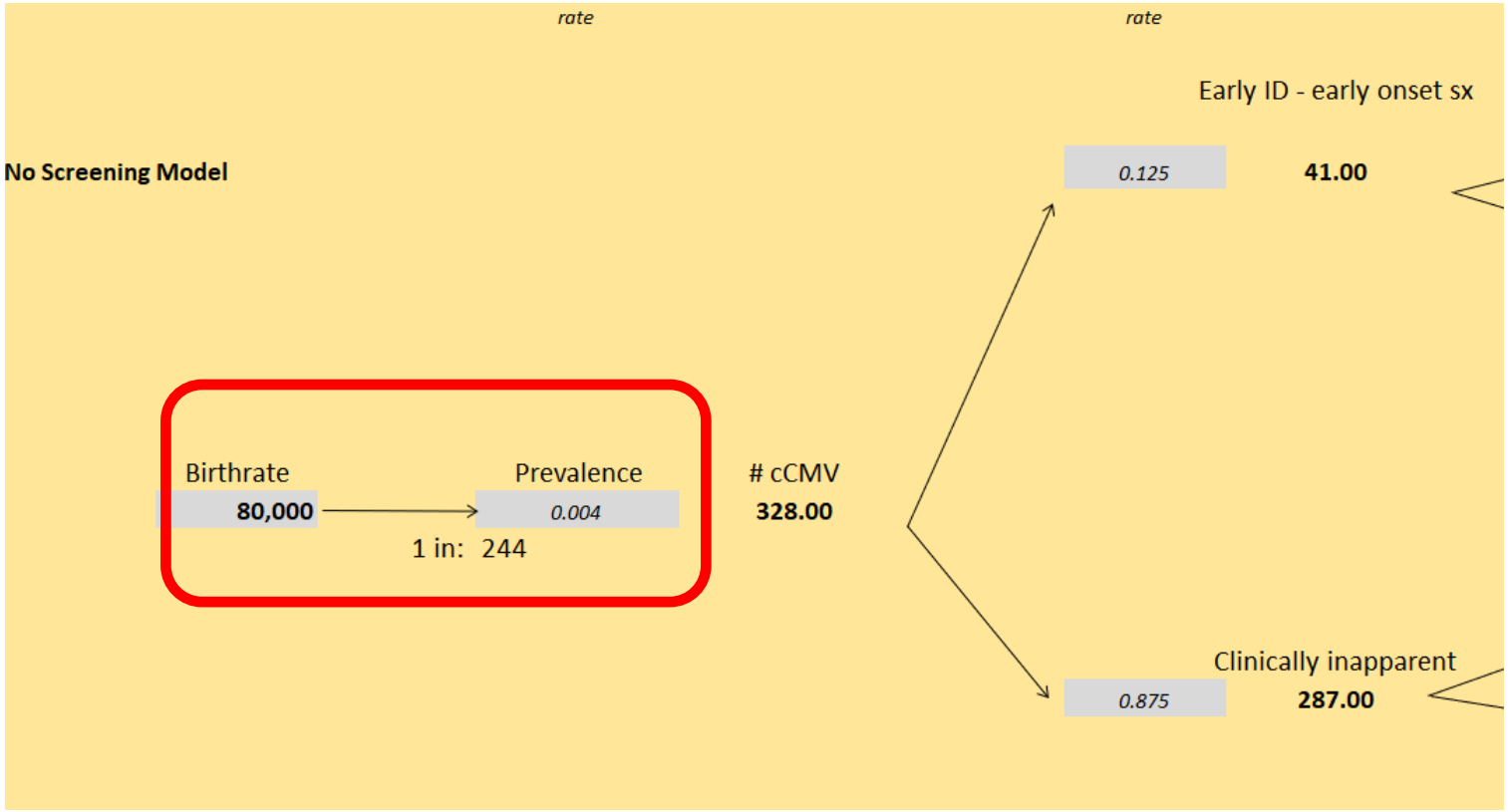
- No quantifiable difference in mortality or neurodevelopmental outcomes at this time

Potential benefit: early identification for infants with clinically inapparent cCMV infections for surveillance and early intervention for hearing loss

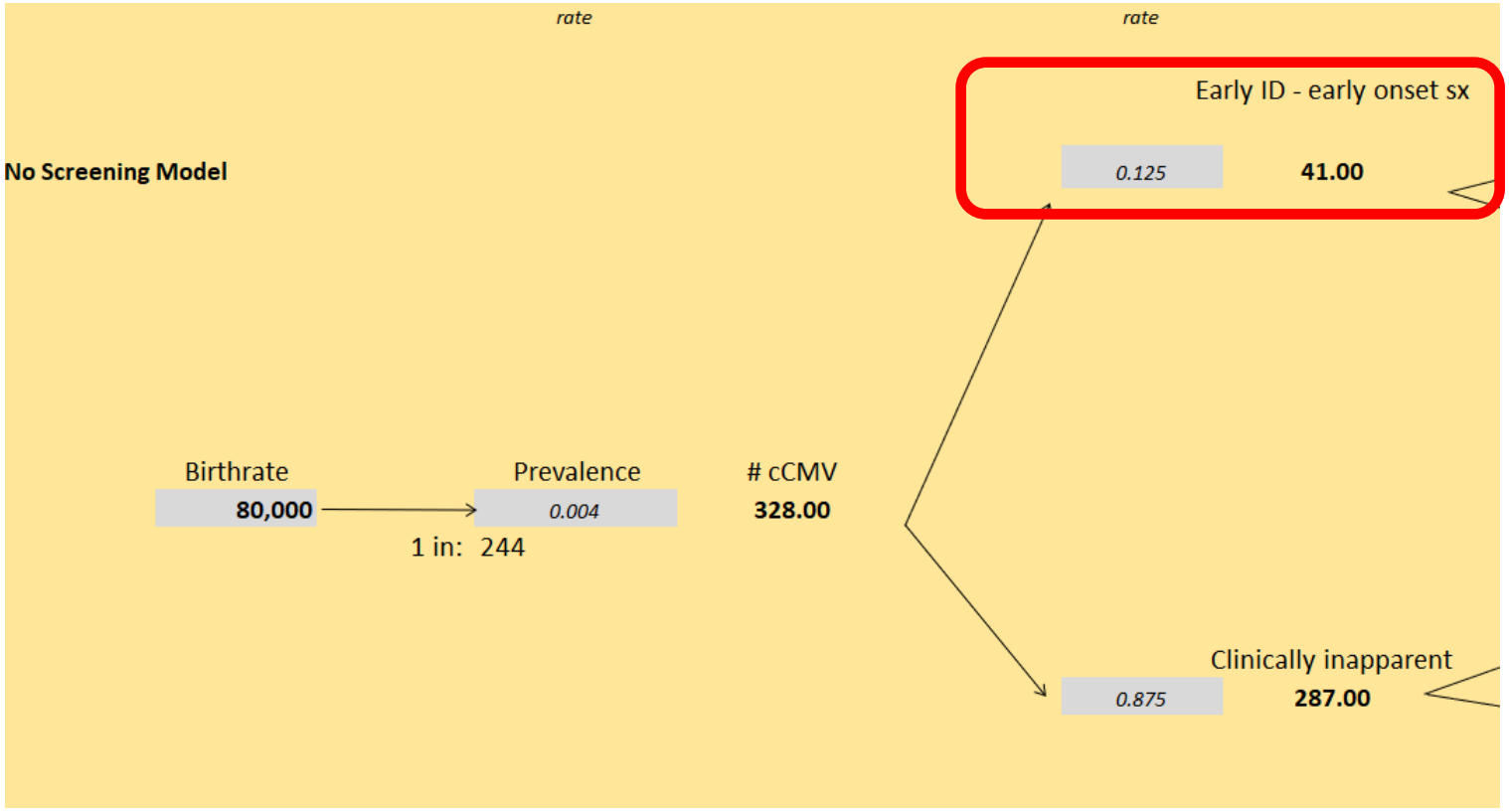
No Screening Model



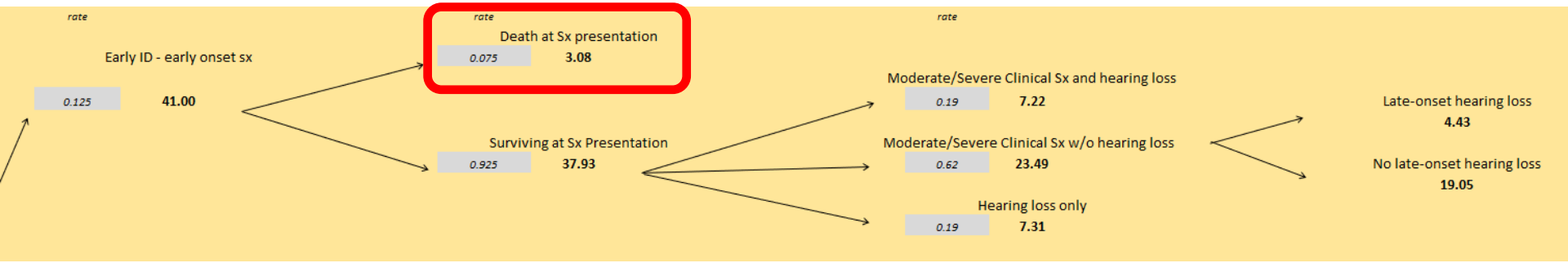
No Screening Model



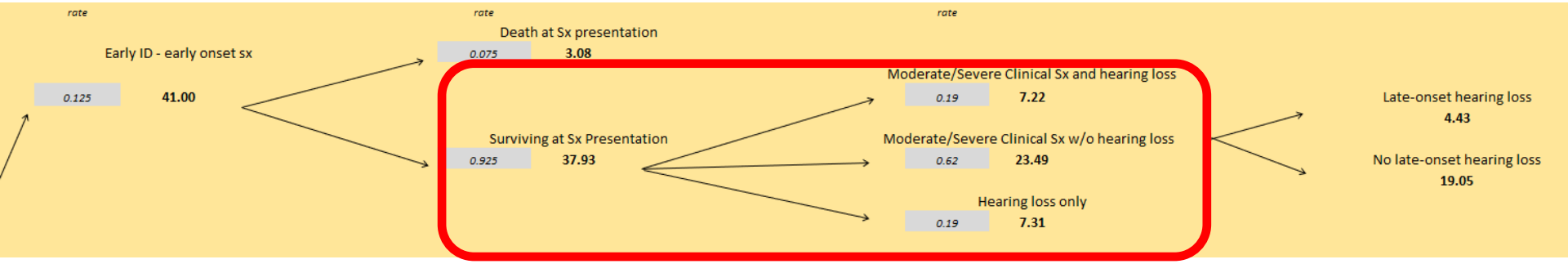
No Screening Model



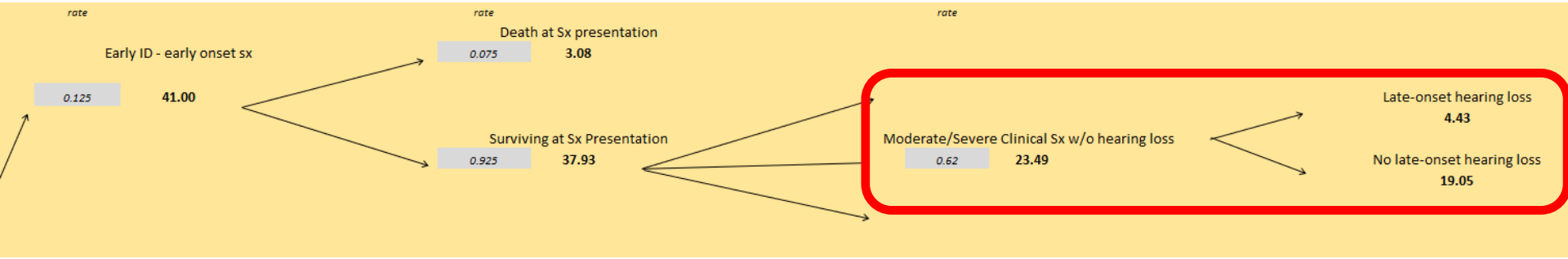
No Screening Model



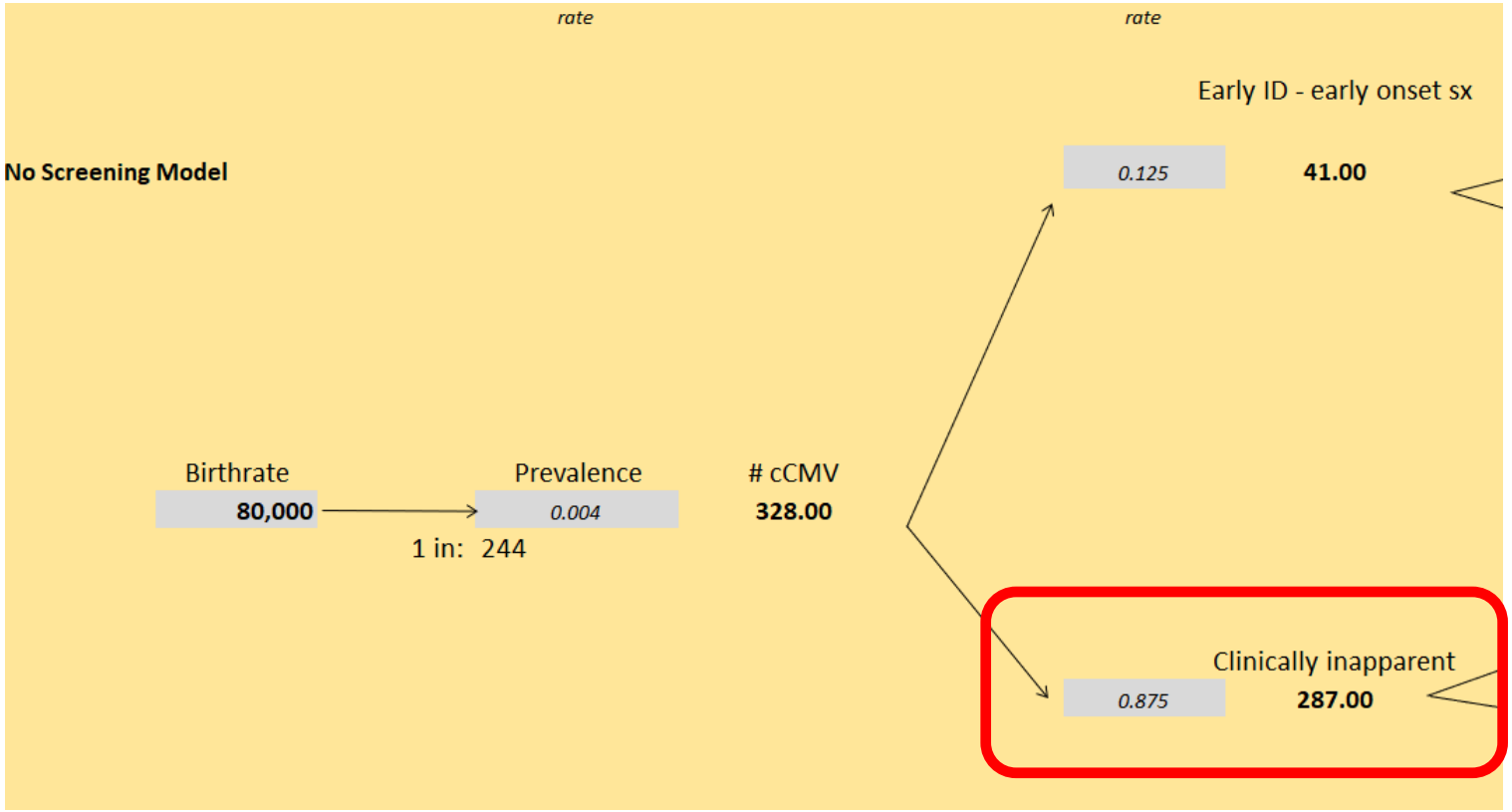
No Screening Model



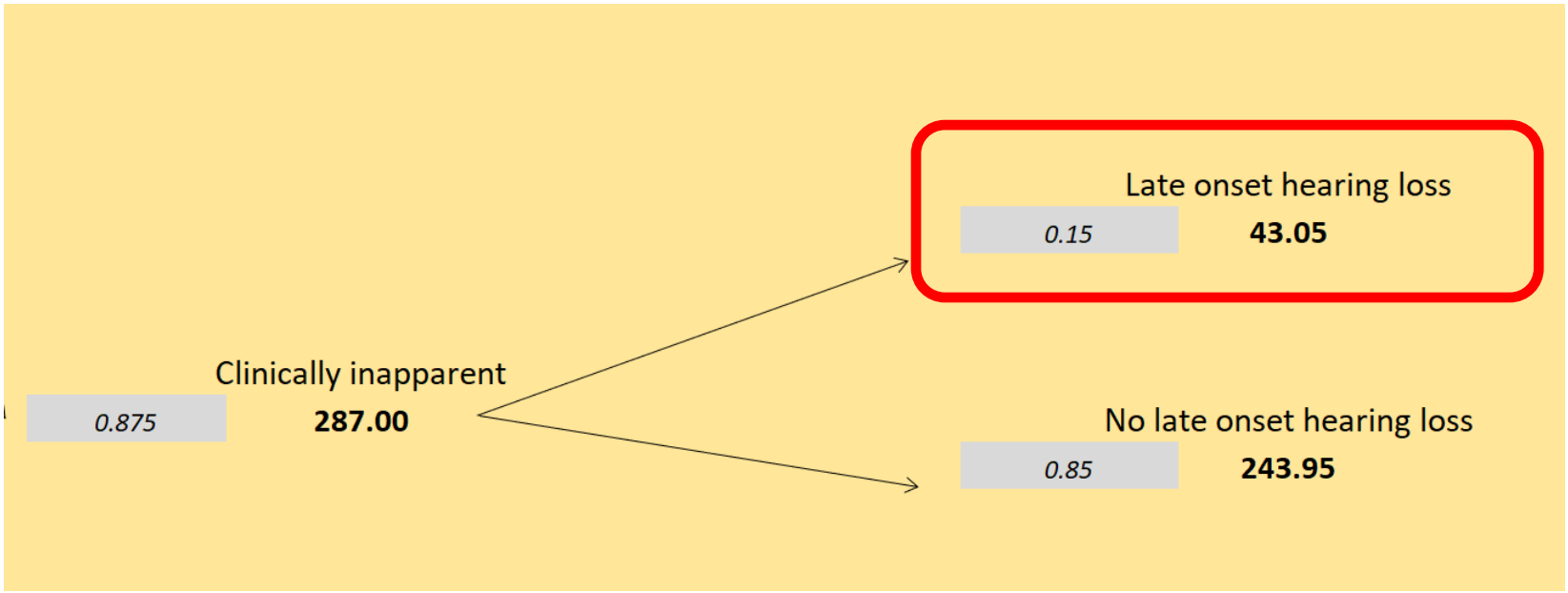
No Screening Model



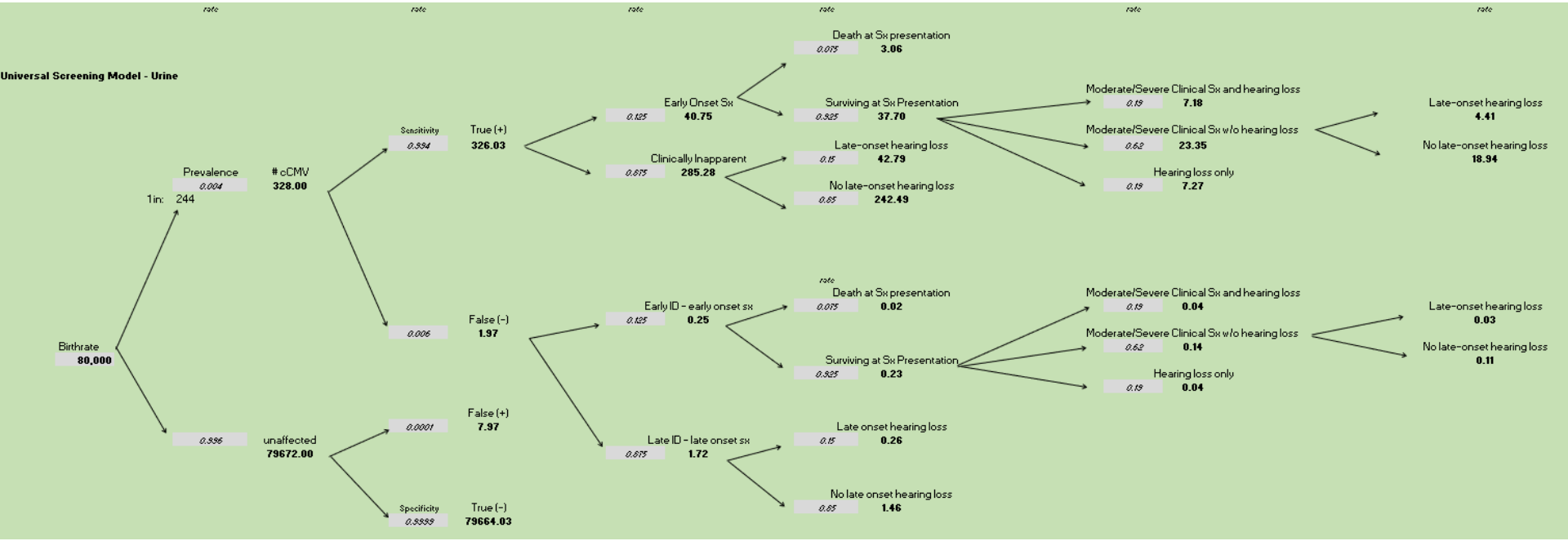
No Screening Model



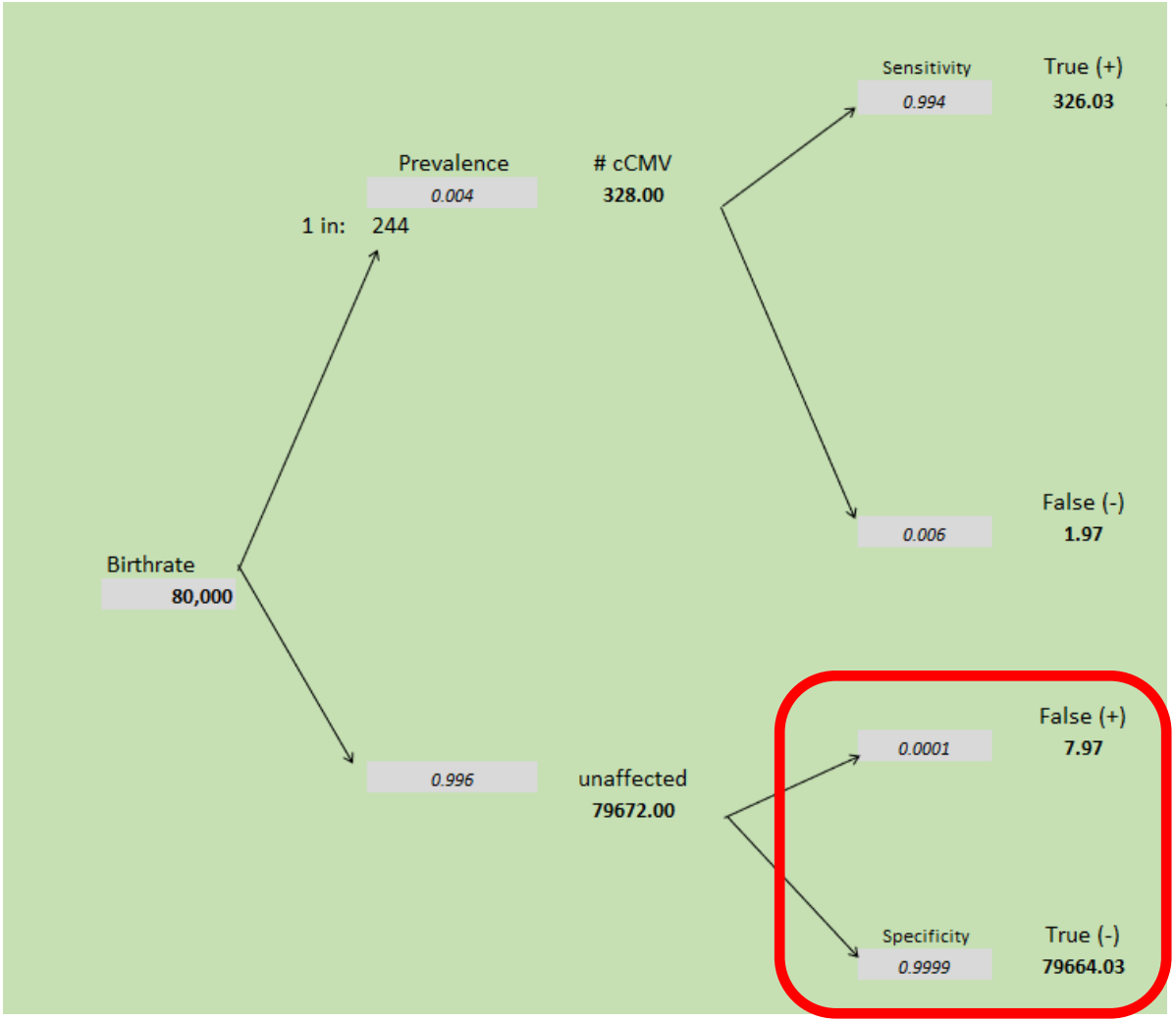
No Screening Model



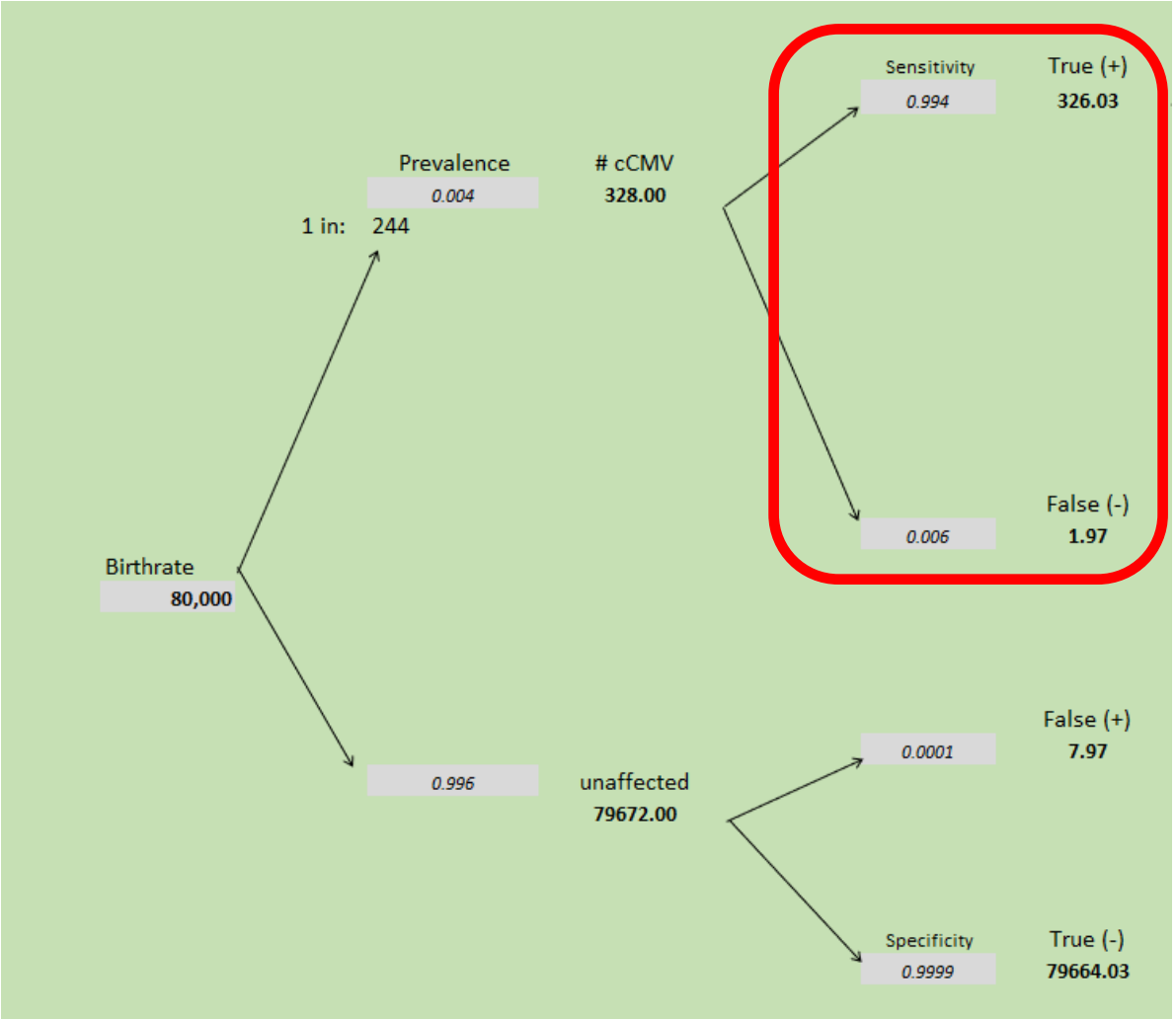
Universal Screening Model: Dried Urine Filter Paper



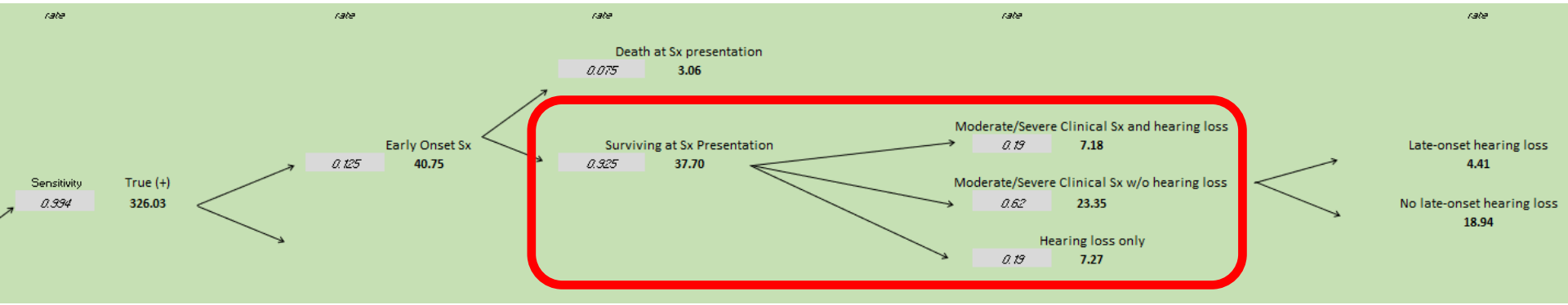
Universal Screening Model : Dried Urine Filter Paper



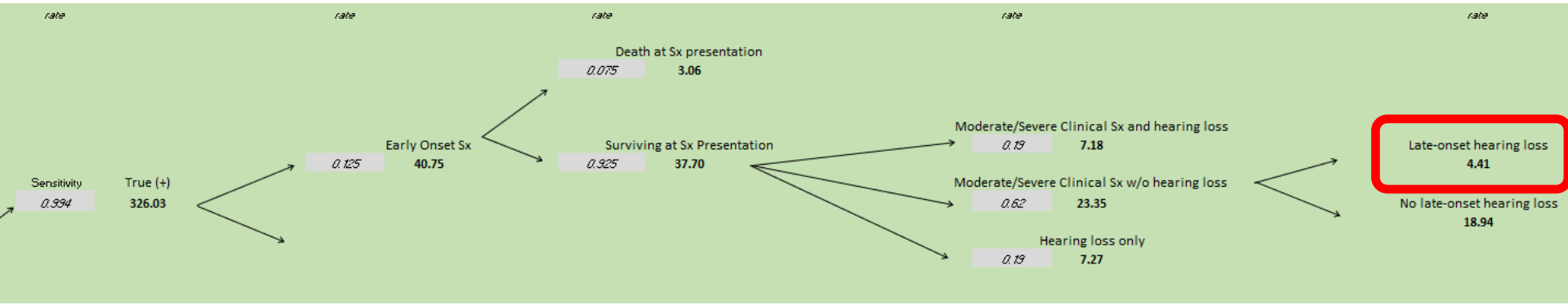
Universal Screening Model : Dried Urine Filter Paper



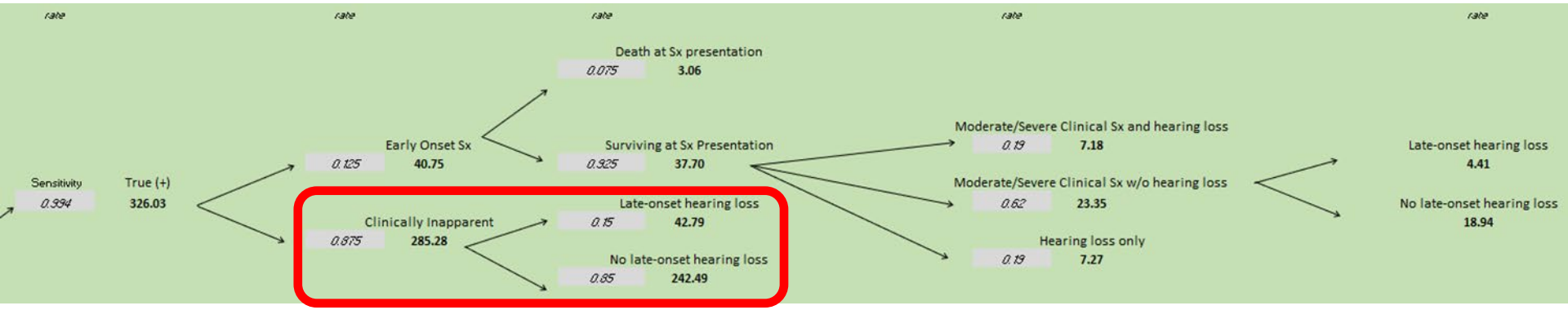
Universal Screening Model : Dried Urine Filter Paper



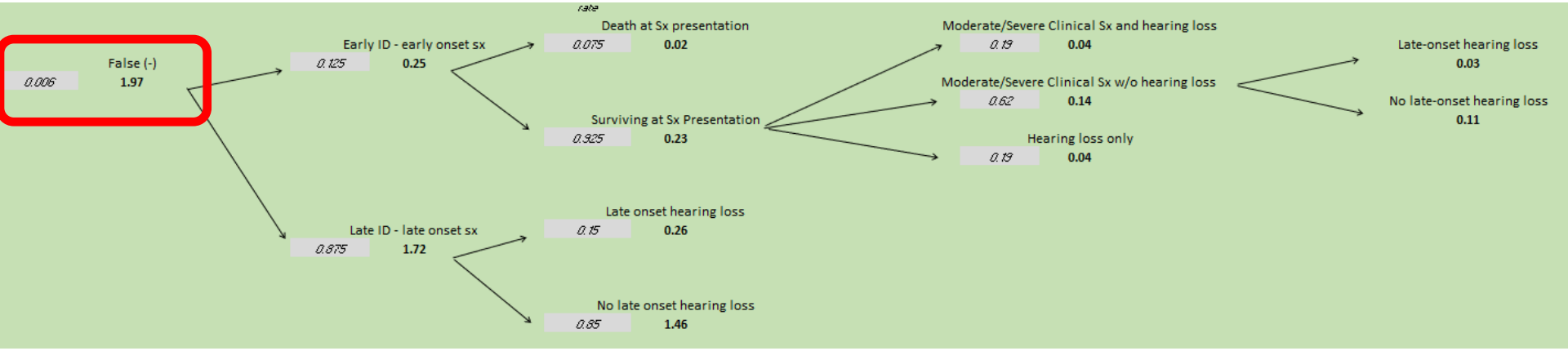
Universal Screening Model : Dried Urine Filter Paper



Universal Screening Model : Dried Urine Filter Paper



Universal Screening Model : Dried Urine Filter Paper



No Screening vs. Universal Urine Screening

	No Screening	Universal Screening (Urine)
Deaths	3.08	3.08
# of babies with diagnostic testing	41.00	334.25
# of babies w/ late onset hearing loss and early intervention	4.43	47.22
# of babies w/o hearing loss but 6 years surveillance	19.05	261.55

No Screening vs. Universal Urine Screening

	No Screening	Universal Screening (Urine)	Shift
Deaths	3.08	3.08	0.00
# of babies with diagnostic testing	41.00	334.25	+293.25
# of babies w/ late onset hearing loss and early intervention	4.43	47.22	+42.79
# of babies w/o hearing loss but 6 years surveillance	19.05	261.55	+242.50

Benefits vs. Costs: Universal Urine Screening

BENEFITS			
	TOTAL BENEFITS		**$2,424,044.97**
COSTS			
	TOTAL COSTS		**$3,383,327.01**
	ADDITIONAL ONE-TIME START-UP COSTS		**$203,442.94**

Benefit/Cost ratio = 0.72

Net benefit = -$959,282.04

Start-up costs (one-time only) = -$203,442.94

Benefits vs. Costs: Universal DBS Screening

BENEFITS			
	TOTAL BENEFITS		**$1,872,903.96**
COSTS			
	TOTAL COSTS		**$3,043,740.01**
	ADDITIONAL ONE-TIME START-UP COSTS		**$94,765.92**

Benefit/Cost ratio = 0.62

Net benefit = -$1,170,836.06
Start-up costs (one-time only) = -$94,765.92

Challenge: The screening methodology using dried blood spots does not meet the criteria of sensitivity estimated to be ≥95%

Benefits vs. Costs: Universal Saliva Screening

BENEFITS			
	TOTAL BENEFITS		**$1,872,903.96**
COSTS			
	TOTAL COSTS		**$3,043,740.01**
	ADDITIONAL ONE-TIME START-UP COSTS		**$94,765.92**

Benefit/Cost ratio = 0.66

Net benefit = -$1,219,756.97

Start-up costs (one-time only) = -$203,442.94

Challenge: The logistical requirements within the newborn screening lab to implement population-wide screening using swabs are substantial

Parameters

Parameter	Base
birthrate	80,000
birth prevalence	1:244
sensitivity	99.40%
specificity	99.99%
cost of universal NBS	$25.36
cost of diagnostic test	$505.50
cost antiviral treatment and initial evaluations	$7,868.98
cost surveillance for hearing loss	$3,042.10
% identified early based on symptoms	12.50%
% asymptomatic with late onset hearing loss	15.00%
value of early intervention for late onset hearing loss per baby	$56,647.55

Parameters

Parameter	Base	Break Even B/C = 1
birthrate	80,000	
birth prevalence	1:244	1:133
sensitivity	99.40%	
specificity	99.99%	
cost of universal NBS	$25.36	$13.00
cost of diagnostic test	$505.50	
cost antiviral treatment and initial evaluations	$7,868.98	
cost surveillance for hearing loss	$3,042.10	
% identified early based on symptoms	12.50%	
% asymptomatic with late onset hearing loss	15.00%	21.00%
value of early intervention for late onset hearing loss per baby	$56,647.55	$79,000.00

Intangible Benefits and Costs

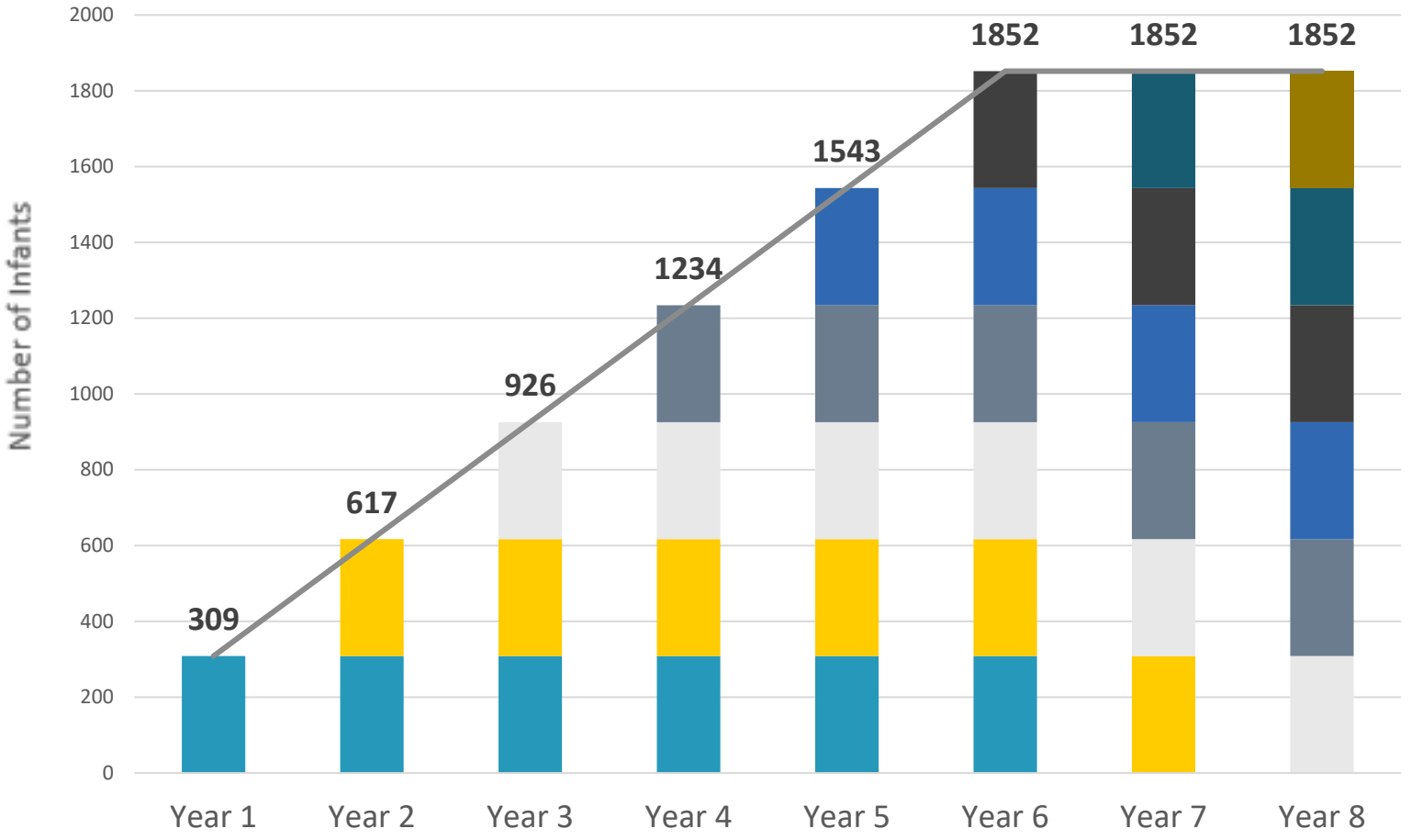
- Emotional impact on individuals and families

Surveillance for Hearing Loss

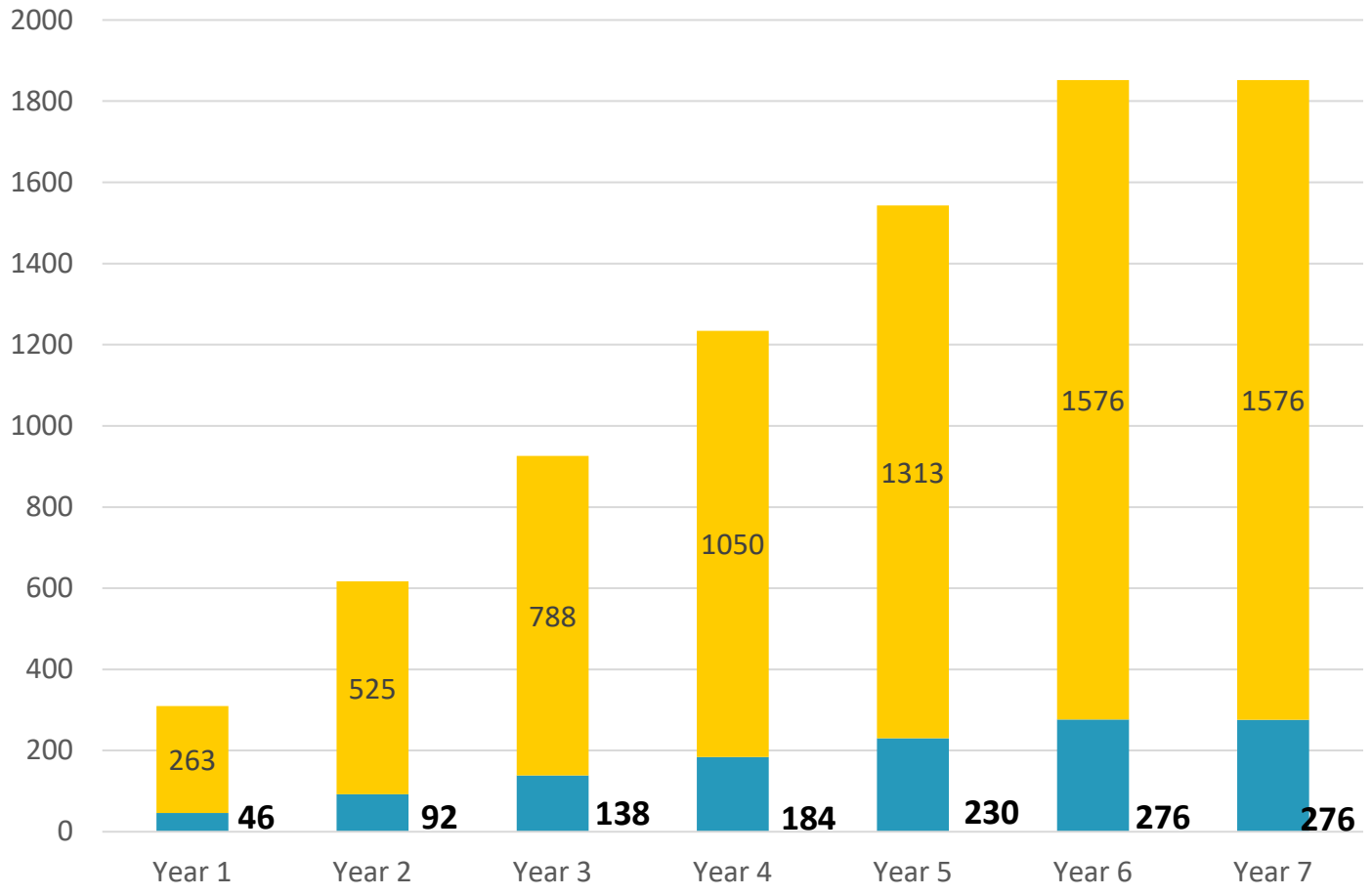
months of age	3	6	9	12	15	18	21	24	27	30	33	36	42	48	54	60	66	72
ABR	X																	
OAEs	X	X	X	X	X	X	X	X	X	X	X	X	X					
Tympanometry	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
VRA		X	X	X	X	X	X											
Condition play audiometry								X	X	X	X	X	X					
Select picture								X	X	X	X	X	X					
Standard audiometry														X	X	X	X	X
Pediatric speech testing														X	X	X	X	X

Based on Utah's EHDI hearing assessment schedule

Surveilling cCMV Positive Infants for Hearing Loss



cCMV Positive Infants Who Develop Late Onset Hearing Loss



Intangible Benefits and Costs

- Emotional impact on individuals and families
  - 43 additional infants benefit from surveillance and early identification
  - 242 additional infants will go through surveillance and not receive benefits from early identification

Intangible Benefits and Costs

- Emotional impact on individuals and families
  - 43 additional infants benefit from surveillance and early identification
  - 242 additional infants will go through surveillance and not receive benefits from early identification
- Wages lost for parents and families

Intangible Benefits and Costs

- Emotional impact on individuals and families
  - 43 additional infants benefit from surveillance and early identification
  - 242 additional infants will go through surveillance and not receive benefits from early identification
- Wages lost for parents and families
- CMV infections prevented from prenatal education and outreach
  - In 2024, Governor Inslee signed the State prenatal CMV education bill, SB 5829, which required DOH to develop educational materials for pregnant people to inform about CMV and strategies to reduce transmission

CMV and the RUSP

In 2022, the Advisory Committee on Heritable Disorders in Newborns and Children declined to move the CMV nomination forward to the evidence review step, due to the lack of a prospective population-based pilot study.

Minnesota CMV experience

- In 1 year (2023-2024), 60,115 newborns were screened for CMV using PCR on dried blood spots
- 184 (0.31%) screened positive
- Of 170 infants with confirmatory testing, CMV was confirmed in 169 (99%)
- 75% of confirmed infants had comprehensive evaluations and linkage to care
- 3 false negative cases were reported to the program
- Takeaways: Good specificity, observed prevalence lower than expected, further evaluation of sensitivity using dried blood spots is warranted

Ontario CMV experience

- In 4 years (2019-2023), 551,034 newborns were screened for CMV using PCR on dried blood spots
- 689 (0.13%, 1:800) screened positive
- 28 were false positive screens
- 100 symptomatic and 500 asymptomatic infants are being followed for ongoing hearing and neurodevelopmental surveillance
- 19 false negative cases were also reported to the program
- Takeaways: expected low sensitivity, more false positives than expected, the cost and utility of transitioning to saliva or urine should be evaluated, how to handle mild cranial ultrasound abnormalities, importance of utilizing primary care providers for follow-up assessments as much as possible

Questions?

PUBLIC HEALTH INFRASTRUCTURE READINESS FOR CONGENITAL CYTOMEGALOVIRUS (cCMV)

Megan McCrillis, MPH

Policy Analyst, WA State Newborn Screening Program

John D. Thompson, PhD, MPA, MPH

Director, Newborn Screening Program

Washington State Department of HEALTH

Washington State NBS Criteria

6. **Public Health Infrastructure Readiness:** The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered.

- The systems and staffing necessary to perform the test and report screening results have been identified.
- Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
- Accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.

Public Health Infrastructure Readiness

Systems and staffing needed to test and report test results:

Systems:

- Laboratory equipment:
  - (2) Punch indexers
  - (3) QuantStudio 7
  - (2) Zephyr liquid handlers
  - (2) Eppendorf thermomixers

Staffing:

- Ongoing
  - 1.2 FTE Chemist 2 to process and test urine filter papers
  - 0.5 FTE Chemist 3
- Start-up
  - Approximately 1000 hours of Chemist 3 work to develop workflow and validate equipment/methodology
  - Approximately 360 hours of operations staff work to distribute new kits, train birth facility staff, and create infrastructure for new specimen type

All of these needs were included in the cost-benefit analysis

Public Health Infrastructure Readiness

Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified:

Ongoing:

- 1 FTE Health Services Consultant 2 to follow up on abnormal results and make recommendations for diagnostic testing
- 1 FTE Health Services Consultant 2 for long term follow up of initial evaluations and ongoing hearing surveillance

Start-up:

- Establishment of a formal long-term follow up program for hearing surveillance
- Approximately 80 hours of Epidemiologist 2 work to develop follow-up procedures and infrastructure

All of these needs were included in the cost-benefit analysis

Questions?

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening (NBS) Technical Advisory Committee (TAC) Voting Instructions

Please use the Microsoft Forms ballot provided by staff during the meeting to vote.

All votes are anonymous. Your votes will be collected and presented by the TAC facilitator and Co-Chairs for further discussion by the group.

Instructions:

- Only TAC members may vote.
- Do not forward or share the form/ballot.
- If you are unsure of not comfortable voting on these options, please indicate so in the form.

If you encounter any technical issues or difficulties accessing the form, please let staff know as soon as possible.