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Report to the General Assembly
Public Health Committee
Report on the Findings of the Universal cCMV Working Group
Public Act 23-204

Manisha Juthani, MD, Commissioner
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State of Connecticut Department of Public Health
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Executive Summary

On June 12, 2023, Connecticut passed Public Act 23-204, which requires the Department of Public Health (DPH) to begin universal screening for congenital cytomegalovirus (cCMV) on July 1, 2025. This legislation also created a working group tasked with studying issues concerning CMV, including, but not limited to, CMV screening in other states, treatment for asymptomatic newborns with positive screening results, best practices for universal screening, planning for implementation of universal screening, and education for health care providers and vulnerable populations. This act mandates that the Commissioner of Public Health report the findings of the working group no later than January 1, 2025.

The universal cCMV working group met beginning in October 2023 and through April 2024. The group included physicians from specialties including infectious diseases, neonatology, primary care pediatrics, and otolaryngology; laboratory staff from the Connecticut Newborn Screening Program; the director of the State Public Health Laboratory; an epidemiologist from the Connecticut DPH Early Hearing Detection and Intervention (EHDI) Program; and a nurse from the Connecticut Newborn Screening Network. The working group created four subgroups to leverage the expertise of members to address the legislative mandates. Each subgroup presented its findings to the larger group, which then discussed, amended, and adopted the subgroup's recommendations. Overall, the focus of the working group was to develop guidelines for an efficient implementation framework for the universal cCMV screening program and not to prescribe how healthcare providers should practice medicine.

The working group first reviewed the universal cCMV screening in Minnesota and two Canadian provinces, Ontario and Saskatchewan, which were the only jurisdictions conducting universal cCMV screenings during the timeframe the working group met. The practices and lessons learned from these jurisdictions helped inform the working group's recommendations.

The Treatment for Asymptomatic Newborns Subgroup developed a cCMV algorithm including recommendations for infants with CMV detected in their dried blood spot (DBS) and/or infants who fail the hearing screening. This subgroup also defined asymptomatic and symptomatic infants and included an algorithm for symptomatic newborns and false positive outcomes. They further identified systemic considerations, emphasizing the importance of consulting relevant stakeholders and addressing potential capacity concerns.

The Lab Methodology Subgroup identified the most efficient and effective methods for performing cCMV DBS screening using quantitative real-time polymerase chain reaction (qPCR) and established a workflow for DBS punching (sample preparation), DNA extraction, DNA amplification, and cCMV detection. They determined that two DBS punches and the QuantaBio Extracta DBS method were most effective for CMV DNA extraction. For DNA amplification, the subgroup found that multiplexing UL83 and UL122 target genes and the Centers for Disease Control and Prevention (CDC) thermocycling method produced the best sensitivity for cCMV detection.

The Planning for Implementation Subgroup recommended that the Connecticut Newborn Screening (CT NBS) Program should be responsible for cCMV follow-up and tracking short- and long-term follow-up data in collaboration with the EHDI Program and with outside entities that provide care coordination for diagnostic and treatment services and long-term follow-up. Additionally, this subgroup suggested that educational materials should be disseminated through birth hospitals, obstetricians and gynecologists (OB/GYNs), and midwives, and targeted to the relevant audience, specifically, individuals who are or want to become pregnant, individuals in high-risk occupations who interact frequently with young children, and early interventionists such as Birth to Three providers. While the NBS was allocated $440,000 and one full-time staff position to begin this work, the subgroup identified the need to monitor for additional resource needs to implement the proposed follow-up protocols, including funding for personnel, IT systems, and educational materials.

The Education Subgroup recommended updating existing CT NBS and EHDI Program educational materials to align with the new legislation, creating new resources to guide follow-up processes for families and providers, ensuring adequate staffing for educational initiatives, developing prevention guidelines, and implementing a comprehensive distribution plan for educational materials. Moreover, the Education Subgroup met with families affected by cCMV. The families identified relevant stakeholders to educate and highlighted the importance of prenatal cCMV education, simplified materials, and increasing cCMV awareness. They emphasized the need for diverse dissemination channels, follow-up education, and effective monitoring and care coordination upon cCMV diagnosis. Additionally, the families recommended leveraging real family experiences in cCMV marketing and education.

With the anticipated rise in the number of infants identified with cCMV through universal newborn screening, the working group emphasized the need to evaluate the need for increased resources for the CT NBS and EHDI programs to effectively implement the proposed screening and follow-up protocols. Using estimates of prevalence from the CDC, it is anticipated that between 150 and 200 cases of cCMV may be identified in Connecticut each year, an increase from less than 12 cases per year. To address this increase in identified patients, the CT NBS Program required additional personnel for laboratory and follow-up staffing as well as funding for short- and long-term follow-up, including care coordination, and enhanced LIMS/Maven integration to link CT EHDI hearing and all cCMV-related data, including confirmatory urine results. In the FY 2024 and 2025 budget, the legislature allocated one staff position and $440,000 in FY 25, to validate testing and screening for cCMV. The CT EHDI Program may also need financial and technical support for Maven database needs. Furthermore, resources for the development and distribution of educational materials, as well as funding to hire media consultants to create cCMV media campaigns should be made available. Early detection and intervention for newborns infected with cCMV is crucial to improve outcomes, underscoring the need for continued statewide resources to provide timely evaluation and initiation of treatment for infants with cCMV.

Background

On June 12, 2023, Connecticut passed Public Act 23-204 which requires the Department of Public Health to begin universal screening for congenital Cytomegalovirus (cCMV) on July 1, 2025.[1] This legislation also created a working group tasked with studying issues concerning CMV, including, but not limited to, CMV screening in other states, treatment for asymptomatic newborns with positive screening results, best practices for universal screening, planning for implementation of universal screening, and education for health care providers and vulnerable populations. This act mandates the Commissioner of Public Health to report the findings of the working group no later than January 1, 2025. The text of the bill is contained in Appendix A of this report.

What is CMV?

CMV is a common virus that can infect people of all ages and is generally passed from infected people to others through direct contact with body fluids like urine, saliva, and breast milk.[2] Nearly one in three children will have been infected with CMV by age five while over half of adults are infected by age 40.[3] The majority of people infected with CMV have no symptoms and are unaware that they have been infected; however, CMV remains in the body for life and can reactivate.

People infected with CMV who are otherwise healthy can experience mild illness, including fever, sore throat, fatigue, and swollen glands.[4] Individuals infected with CMV who have weakened immune systems may experience more serious symptoms that affect the eyes, lungs, liver, esophagus, stomach, and intestines.

Blood tests are used to diagnose CMV infection in adults who have symptoms.[5] Generally, healthy people infected with CMV do not require medical treatment, but medications are available to treat CMV infection in people with weakened immune systems.

What is Congenital CMV (cCMV)?

Pregnant people infected with CMV can transmit the virus to their baby during pregnancy, resulting in congenital CMV in the baby. CMV is the leading infectious cause of birth defects in the United States. To confirm a cCMV diagnosis, a saliva or urine sample must be collected in the first 2 to 3 weeks of life.[6] If delayed beyond this timeframe, the testing cannot differentiate

[1] An Act Concerning the State Budget for the Biennium Ending June 30, 2025, and Making Appropriations Therefor, and Provisions Related to Revenue and Other Items Implementing the State Budget, Public Act No. 23-204, §191 (2023).
[2] "Early Hearing Detection and Intervention Program," CT.gov, 2024a, https://portal.ct.gov/DPH/Family-Health/EHDI/CMV
[3] "About Cytomegalovirus (CMV)," Centers for Disease Control and Prevention, May 10, 2024, https://www.cdc.gov/cytomegalovirus/about/index.html
[4] "About Cytomegalovirus (CMV)," CDC, 2024.
[5] "About Cytomegalovirus (CMV)," CDC, 2024.
[6] "CMV in Newborns," Centers for Disease Control and Prevention, May 10, 2024, https://www.cdc.gov/cytomegalovirus/congenital-infection/index.html

between congenital and postnatally acquired CMV. Approximately 1 in 200 infants are born with cCMV, and while most babies born with cCMV do not have signs of the virus and are considered asymptomatic, some have health problems at birth or that develop later. Signs of symptomatic cCMV at birth may include hearing loss, rash, jaundice (yellowing of the skin or whites of the eyes), microcephaly (small head), low birth weight, hepatosplenomegaly (enlarged liver and spleen), seizures, and retinitis (damaged eye retina).[7] Of those infected with cCMV, one in five will have long-term health issues such as hearing loss, developmental and motor delay, vision loss, microcephaly, and seizures.

Furthermore, hearing loss is common in babies with cCMV. Hearing loss may not be detected at birth but can develop later, so infants with cCMV should be monitored beyond the neonatal period. Hearing loss may advance from mild to severe within the first two years of life and can impede a child's communication, language, and social skill development over time. Therefore, the CDC encourages early intervention services like speech or occupational therapy for children with hearing loss.[8]

Antiviral medications such as valganciclovir may improve hearing and developmental outcomes for symptomatic newborns.[9] However, valganciclovir may pose serious side effects and has been primarily studied in symptomatic newborns. Clinical trials of symptomatic newborns have indicated that the medication is most effective if administered within the first month of life.[10] There is currently insufficient evidence on the benefit of antiviral medications for asymptomatic newborns. Clinical trials are ongoing to investigate the potential benefits of valganciclovir for newborns with cCMV who have only hearing loss at birth.[11]

<u>Targeted cCMV Screening in Connecticut</u>

In Connecticut, all birthing facilities are required to provide universal newborn hearing screening.[12] Per Connecticut General Statute (CGS) 19a-55, every Connecticut-born infant who fails their newborn hearing screening is to be screened for cCMV as soon after birth as is medically appropriate.[13] This targeted cCMV screening continues until July 1, 2025. The law also requires healthcare providers to report any cases of cCMV to the Department of Public Health.

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[7] "CMV in Newborns," CDC, 2024.

[8] "Congenital CMV and Hearing Loss," Centers for Disease Control and Prevention, Mayl 10, 2024, https://www.cdc.gov/cytomegalovirus/congenital-infection/hearing-loss.html

[9] "CMV in Newborns," CDC, 2024.

[10] William D Rawlinson et al., "Congenital Cytomegalovirus Infection in Pregnancy and the Neonate: Consensus Recommendations for Prevention, Diagnosis, and Therapy," *The Lancet Infectious Diseases* 17, no. 6 (June 2017), https://doi.org/10.1016/s1473-3099(17)30143-3.; David W. Kimberlin et al., "Valganciclovir for Symptomatic Congenital Cytomegalovirus Disease," *The New England Journal of Medicine* 372, no. 10 (March 5, 2015): 933–43, https://doi.org/10.1056/nejmoa1404599.

[11] "Randomized Controlled Trial of Valganciclovir for Cytomegalovirus Infected Hearing Impaired Infants (ValEAR)," Clinicaltrials.gov, February 24, 2022, https://clinicaltrials.gov/study/NCT03107871.; "Valganciclovir Therapy in Infants and Children With Congenital CMV Infection and Hearing Loss," Clinicaltrials.gov, June 2, 2021, https://clinicaltrials.gov/study/NCT01649869.

[12] "Early Hearing Detection and Intervention Program," CT.gov, 2024b, https://portal.ct.gov/dph/Family-Health/EHDI/Home-page--Early-Hearing-Detection-and-Intervention-Program-Home-Page.

[13] An Act Concerning Cytomegalovirus, Public Act No. 15-10 (2015).

The Connecticut Department of Public Health's CT EHDI Program is responsible for tracking newborn hearing and cCMV screenings.

If an infant fails a second hearing screening, either in one or both ears, a saliva or urine sample is collected before 21 days of age to test for cCMV. If the test confirms that the newborn is CMV positive, the primary healthcare provider is responsible for reporting the result to the parent or guardian, and a diagnostic hearing test is conducted on the newborn to determine if hearing loss is present. This diagnostic test is more comprehensive than the hearing screening done at birth. The CT EHDI Program also advises that children be monitored regularly since cCMV can cause hearing and vision loss over time. The Program generally recommends hearing follow-up no later than three months after cCMV diagnosis and every twelve months until age three but notes that audiological surveillance should be considered on an individual basis.

Beyond the audiology follow-up, the further management of babies who are CMV positive is not well-defined.[14] The CT EHDI Program advises that an infectious disease specialist should evaluate a newborn with suspected cCMV infection, but there are no official recommendations regarding the treatment of newborns with signs of cCMV. According to the CT EHDI Program, approximately 35,000 babies are born in Connecticut annually, and about 500 of them per year fail their newborn hearing screening and require CMV and audiological testing.[15] Among those tested for CMV after failing their hearing screening, fewer than twelve babies per year test positive for the virus.

Connecticut Universal cCMV Screening Working Group

The universal cCMV working group established pursuant to Public Act No. 23-204 convened in October 2023 and continued through April 2024. The group included physicians from specialties including infectious diseases, neonatology, primary care pediatrics, and otolaryngology; laboratory staff from the CT NBS Program; the director of the State Public Health Laboratory; an epidemiologist from the CT EHDI Program; and a nurse from the Connecticut Newborn Screening Network. The working group created four subgroups to leverage the expertise of members in addressing the legislative mandates. Each subgroup presented its findings to the larger group, which then discussed, amended, and adopted the subgroup's recommendations. Overall, the focus of the working group was to develop guidelines for an efficient implementation framework for the universal cCMV screening program and not to prescribe how healthcare providers should practice medicine.

The working group was asked to study issues concerning CMV, including, but not limited to:

- CMV screening in other states
- treatment for asymptomatic newborns with positive screening results

[14] "About Cytomegalovirus (CMV) for Pediatric Care Providers," CT.gov, 2024, https://portal.ct.gov/-/media/DPH/EHDI/About-CMV-for-Pediatric-Care-Providers-082923.pdf.
[15] "Newborn Hearing and CMV in Connecticut: Identifying, Tracking, and Supporting," CT.gov, 2023, https://portal.ct.gov/-/media/dph/ehdi/2023-fact-sheet-080523.pdf.

- best practices for universal screening
- planning for implementation of universal screening
- education for health care providers and vulnerable populations

Universal cCMV Screening in other States and Jurisdictions

The working group's first activity was to review universal cCMV screening in other states. cCMV screening in Minnesota and two Canadian provinces, Ontario and Saskatchewan, were investigated as they were the only jurisdictions conducting universal screening during the timeframe the working group met. The following sections summarize the cCMV screening procedures used across these three jurisdictions.

Minnesota

In 2021, the Minnesota legislature passed the Vivian Act directing the Minnesota Commissioner of Health to provide evidence-based cCMV information, including recommendations for CMV testing, the incidence and transmission of CMV, associated birth defects, preventive measures, and available resources for affected families, to expectant parents, parents of infants, and women who may become pregnant.[16] The Vivian Act also required the Commissioner to adhere to current departmental procedures, such as community engagement, to ensure that educational information is culturally and linguistically appropriate for all recipients and to establish an outreach program to raise CMV awareness among the community and healthcare providers. Additionally, the act required the Advisory Committee on Heritable and Congenital Disorders to review cCMV for inclusion in the state's newborn screening panel. After a comprehensive review process, the Advisory Committee recommended the addition of cCMV to the newborn screening panel in January 2022 and the Commissioner approved the recommendation in February 2022.[17] On February 6, 2023, Minnesota became the first state to conduct universal cCMV screening for newborns.

Minnesota uses the qPCR screening method to identify CMV DNA in DBS.[18] Some cCMV cases will be missed because some infected newborns will have insufficient virus in their blood to be detected during screening. Therefore, the Minnesota Department of Health (MDH) advises clinicians to maintain a high level of suspicion for newborns with clinical signs of cCMV even if CMV is not detected during the blood spot screening. If CMV is not detected in the DBS screening, no additional follow-up is required, but parents and guardians are advised to consult with a pediatric infectious disease specialist if the newborn presents signs of cCMV.

If CMV is detected in the DBS screening, a Newborn Screening Program staff contacts the infant's doctor or clinic to notify them of the result and recommend confirmatory urine testing.

[16] The Vivian Act, Minnesota Statutes § 144.064 (2021).
[17] "The Vivian Act," Minnesota Department of Health, June 29, 2023, https://www.health.state.mn.us/diseases/cytomegalovirus/vivianact.html.
[18] "CMV Screening and Results," Minnesota Department of Health, March 6, 2023, https://www.health.state.mn.us/people/newbornscreening/program/cmv/results.html.

The infant's doctor then contacts the family to discuss the next steps. MDH recommends a confirmatory urine test using polymerase chain reaction (PCR) analysis on urine specimens collected before 21 days of age for accuracy.[19] A positive result may reflect an acquired and not a congenital CMV infection if the urine is collected after 21 days of age. If the urine PCR analysis detects CMV, the newborn undergoes evaluations, including physical examination, head ultrasound, blood and liver function tests, hearing tests, and eye exams. The MDH-recommended cCMV algorithm is contained in Appendix B. Newborns with no clinical signs (asymptomatic) are monitored for signs and those with clinical signs of infection (symptomatic) are referred to a pediatric infectious disease specialist who may treat them with antiviral medication.[20] MDH emphasizes the need for families to discuss the benefits and risks of the medication with the specialist.

Ontario

Newborn Screening Ontario and the Infant Hearing Program partnered to begin genetic risk factor screening for permanent hearing loss (PHL) for babies born on or after July 29, 2019.[21] This risk factor screening for PHL looks for the presence of CMV and genetic mutations in the GJB2 and SLC26A4 genes using the DBS sample collected for newborn screening.[22] The follow-up when newborns have a positive DBS screen for genetic risk factors for PHL or CMV involves the coordinated efforts of various health care providers.[23] Newborn Screening Ontario or the primary care provider (PCP) contact families with infants who screen positive to discuss the results and recommend follow-up. If there is a positive CMV screening result from the DBS sample, a pediatrician or infectious disease specialist conducts an initial evaluation, including a confirmatory urine test, blood tests, physical exam, and head ultrasound.[24] See Appendix C for Newborn Screening Ontario's proposed initial evaluation for infants with CMV detected in DBS.

[19] "CMV Screening Follow-up," Minnesota Department of Health, August 27, 2023, https://www.health.state.mn.us/people/newbornscreening/program/cmv/followup.html

[20] "About Cytomegalovirus and Congenital Cytomegalovirus," Minnesota Department of Health, June 29, 2023, https://www.health.state.mn.us/diseases/cytomegalovirus/aboutcmv.html.

[21] "Congenital Cytomegalovirus," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/en/screening/types-of-screening/permanent-hearing-loss/congenital-cytomegalovirus/; "Risk Factor Screening for Permanent Hearing Loss in Ontario," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/media/vl4bwe0h/community-peds-infographic-jan-8-2024-1.pdf.

[22] "Risk Factor Screening Process," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/en/screening/types-of-screening/permanent-hearing-loss/risk-factor-screening-process/; GJB2 and SLC26A4 genes provide instructions for producing proteins crucial to inner ear development. The mutations can disable the genes or alter their functionality. "Genetic Risk Factors," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/en/screening/types-of-screening/permanent-hearing-loss/genetic-risk-factors/.

[23] "Risk Factor Screening for Permanent Hearing Loss (PHL)," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/en/screening/types-of-screening/permanent-hearing-loss/risk-factor-screening-for-health-care-providers/.

[24] "Information for Parents/Guardians: My baby has a positive Cytomegalovirus (CMV) screening result," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/media/yyfc12wd/cytomegalovirus-and-your-baby-v3-final-2023.pdf.

The Infant Hearing Program also arranges for diagnostic audiology to be conducted. There are four possible outcomes from the assessment.

1. The newborn has cCMV but no clinical signs (asymptomatic): A pediatrician monitors general development throughout childhood, and the IHP arranges hearing monitoring.
2. The newborn has cCMV with clinical signs (symptomatic): The newborn is referred to an infectious disease specialist for further assessment, and the physician may begin to treat with antiviral medication within the first month of life. The pediatrician or infectious disease specialist also continues developmental surveillance, and the Infant Hearing Program arranges hearing monitoring.
3. The newborn does not have cCMV (false positive): This does not require further testing.
4. The results are unclear: The pediatrician or infectious disease specialist assesses the need for other tests and follow-up.

Saskatchewan

On February 23, 2022, Saskatchewan announced the inclusion of cCMV screening in the province's universal newborn screening program, which the Saskatchewan Health Authority administers.[25] Saskatchewan screens for cCMV infection using the newborn's DBS sample.[26] If there is a positive cCMV screening result from the DBS sample, the newborn screening team will follow up to arrange confirmatory urine and hearing tests. Newborns with positive urine confirmations are referred to an infectious disease specialist for further evaluations, including a physical exam, head imaging, and blood tests.

The Saskatchewan Health Authority lists three possible outcomes from the assessment:[27]

1. The newborn has cCMV but no clinical signs (asymptomatic): A pediatrician or infectious disease specialist monitors general development throughout childhood, and the Newborn Hearing Program arranges for hearing monitoring.
2. The newborn has cCMV with clinical signs (symptomatic): The newborn is referred to an infectious disease specialist who may treat with medication upon further assessment. The pediatrician or infectious disease specialist also continues developmental surveillance, and the Newborn Hearing Program arranges for hearing monitoring.
3. The newborn does not have cCMV (false positive): A result is ruled as a false positive if there is a negative urine confirmation. In this case, no further testing is required.

[25] "Saskatchewan Expanding Newborn Screening Program," Government of Saskatchewan, February 23, 2022, https://www.saskatchewan.ca/government/news-and-media/2022/february/23/saskatchewan-expanding-newborn-screening-program.
[26] "cCMV Positive Result Newborn Screening," Saskatchewan Health Authority, November 2023, https://rrpl-testviewer.ehealthsask.ca/SCI/Requisitions/Screening%20Programs%20-%20Newborn%20Screening/CS-PIER-0012-cCMV-Positive-Newborn-Screening-Info-Parents%20Nov%202023.pdf.
[27] "cCMV Positive Result Newborn Screening."

Subgroup Activities and Recommendations

Treatment for Asymptomatic Newborns with Positive Screening Results

The Treatment for Asymptomatic Newborns Subgroup included Ashley C. Howard, DO, FAAP, Carlos R. Oliveira, MD, PhD, Nancy A. Louis, MD, FAAP, Thomas Murray, MD, PhD, FAAP, and Scott Schoem, MD, MBA, FAAP.

Prior to presenting its recommendations, the subgroup convened to discuss any current cCMV clinical practice guidelines from the Infectious Diseases Society of America, Pediatric Infectious Diseases Society, and other professional organizations. The subgroup determined that there are no comprehensive and consistent cCMV clinical practice guidelines.[28] The literature review showed that definitions of asymptomatic and categorization of mild, moderate, and severe symptomatic vary and, generally, antiviral treatment is not routinely recommended for asymptomatic or mildly symptomatic patients.[29] The subgroup also reviewed the cCMV algorithms in Minnesota and Ontario and discussed best clinical practices to adopt or amend for Connecticut. After extensive research and discussion, the subgroup created a draft of a proposed Connecticut algorithm, which the larger group discussed, amended, and subsequently adopted (Figure 1). As members worked through the algorithm, the need to include processes for symptomatic and false positive outcomes became apparent and was addressed concurrently by the subgroup.

Furthermore, the subgroup identified healthcare provider and state-level systemic considerations. They highlighted the need for providers to consult with the relevant stakeholders like neonatologists on special cCMV circumstances, such as twin gestation and newborns in neonatal intensive care units (NICU), and for pediatric infectious disease specialists to develop a standard treatment algorithm for their institutions.[30] They also cited potential capacity concerns, emphasizing the need for providers to consider the order and timing of

[28] Stephanie Kalb et al., "A Qualitative Assessment of Clinical Practice Guidelines and Patterns for Congenital Cytomegalovirus in the United States," *International Journal of Neonatal Screening* 9, no. 3 (June 30, 2023): 37, https://doi.org/10.3390/ijns9030037.

[29] Concetta Marsico ans David W. Kimberlin, "Congenital Cytomegalovirus Infection: Advances and Challenges in Diagnosis, Prevention and Treatment," *Italian Journal of Pediatrics* 43, no. 1 (April 17, 2017), https://doi.org/10.1186/s13052-017-0358-8; Suzanne E. Luck et al., "Congenital Cytomegalovirus: A European Expert Consensus Statement on Diagnosis and Management," *Pediatric Infectious Disease Journal* 36, no. 12 (December 2017): 1205–13, https://doi.org/10.1097/inf.0000000000001763; William D Rawlinson et al., "Congenital Cytomegalovirus Infection in Pregnancy and the Neonate: Consensus Recommendations for Prevention, Diagnosis, and Therapy," *The Lancet Infectious Diseases* 17, no. 6 (June 2017), https://doi.org/10.1016/s1473-3099(17)30143-3.

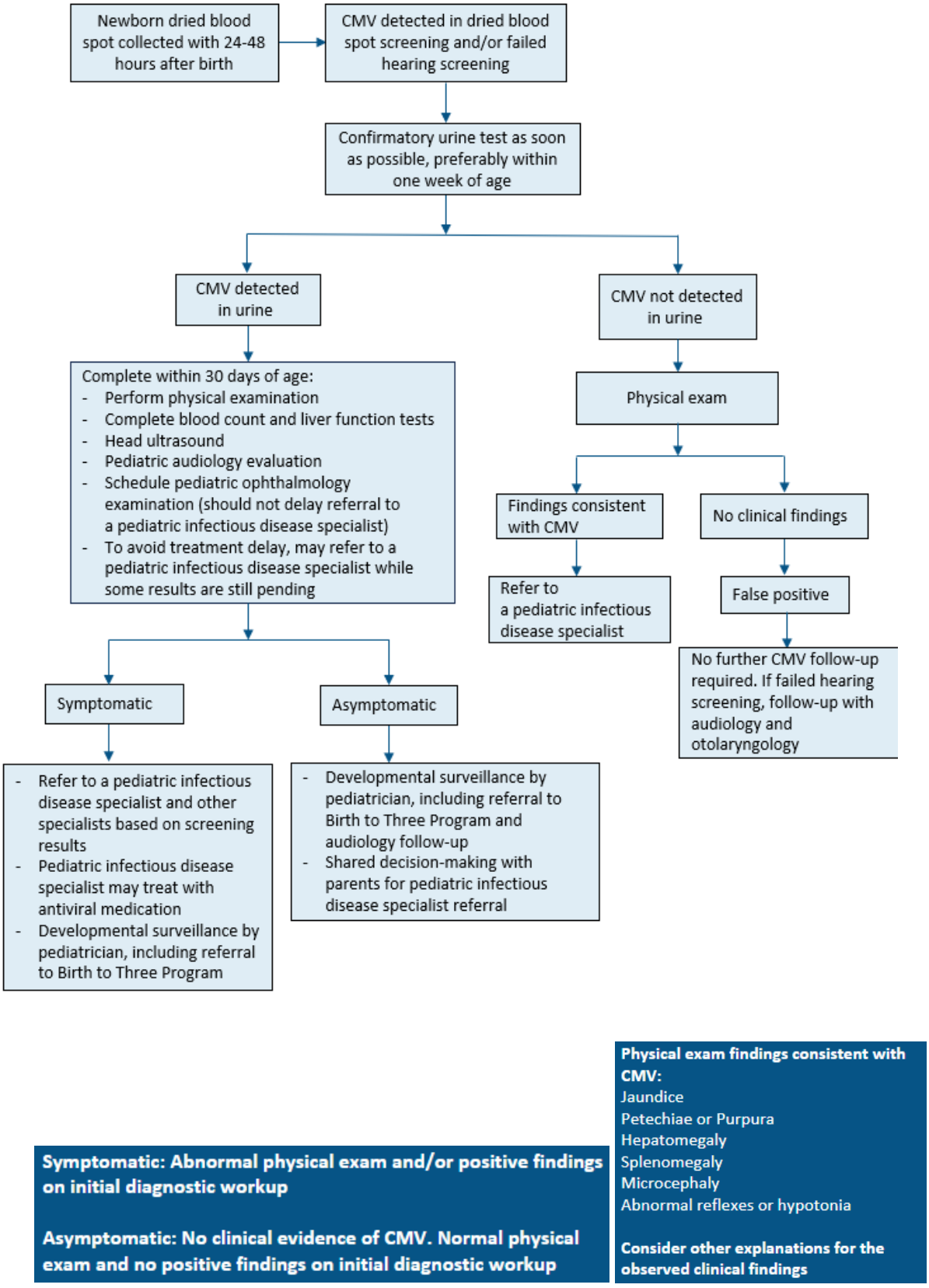
[30] Twins may or may not both be infected with cCMV; Ana Araújo Carvalho et al., "Congenital Cytomegalovirus Infection in Twin Pregnancy," *BMJ Case Reports* 14, no. 7 (July 2021), https://doi.org/10.1136/bcr-2021-242712; Gabriela Egaña-Ugrinovic et al., "Congenital Cytomegalovirus Infection among Twin Pairs," *The Journal of Maternal-Fetal & Neonatal Medicine*, December 21, 2015, 1–21, https://doi.org/10.3109/14767058.2015.1130818; Tiziana Lazzarotto et al., "Congenital Cytomegalovirus Infection in Twin Pregnancies: Viral Load in the Amniotic Fluid and Pregnancy Outcome," *Pediatrics* 112, no. 2 (August 1, 2003), https://doi.org/10.1542/peds.112.2.e153.

medical evaluations so that treatment is not delayed. Additionally, the subgroup proposed that the state consider a repository for initial diagnostic workup data, short- and long-term outcomes, and timing of assessments for future research.

As shown in Figure 1, newborns can enter the pathway through two mechanisms: (1) CMV detected on NBS DBS or (2) newborn fails hearing screening. Either scenario will trigger collection of urine sample for confirmatory testing.

Guiding principles identified by the working group: Due to the importance of starting treatment within the 30-day window, referral to ID should not be delayed if cCMV is suspected and initial work up is not yet completed. Additionally, the working group encouraged shared decision making between parents and providers for referral of asymptomatic infants.

Figure 1. Proposed Connecticut cCMV Algorithm



Best Practices for Universal Screening

The Lab Methodology Subgroup included Adrienne Manning, Division Director of Newborn Screening at Connecticut's State Public Health Laboratory, and Charbel Khalil, a DrPH student at University of South Florida.

The Lab Methodology Subgroup provided an overview of lab methodology development for CMV detection by qPCR and subsequently presented results of the development of laboratory processes and proposed methodology to the working group. The subgroup's lab method development workflow included DBS punching, DNA extraction, DNA amplification, and CMV detection. The goals of the subgroup were to establish the most efficient and effective methods for performing CMV screening. Their results were as follows:

a. DBS Punching (Sample Preparation)

The subgroup determined that two DBS punches were sufficient for CMV DNA extraction. A sample punching instrument was used to punch two 3.2-millimeter-wide DBS samples into a 96-well microtiter plate with 0.2-milliliter wells.[31]

b. DNA Extraction Method

The subgroup evaluated two DNA extraction methods, namely QuantaBio Extracta DBS and Qiagen DNA Purification Solution 1 and DNA Elution Solution 2, which utilized DNA extraction reagents for rapid and efficient recovery of PCR-ready DNA from DBS. The subgroup determined that QuantaBio Extracta DBS was the more effective method for extracting CMV DNA in DBS.[32]

c. DNA Amplification

The subgroup used qPCR to rapidly produce millions to billions of copies of CMV DNA in real-time.[33] This method was used to evaluate the presence of two target genes – UL83 and UL122 – to identify which target gene could reliably detect CMV from the DBS.[34] Additionally, the subgroup evaluated two thermocycling programs, one from the University of Minnesota School of Medicine and the other from the CDC, to identify which detected CMV more effectively.[35] The subgroup's experiment revealed that multiplexing UL83 and UL122 target genes produced

[31] Sheila C. Dollard et al., "Sensitivity of Dried Blood Spot Testing for Detection of Congenital Cytomegalovirus Infection," *JAMA Pediatrics* 175, no. 3 (March 1, 2021), https://doi.org/10.1001/jamapediatrics.2020.5441.
[32] Sheila C. Dollard et al. 2021; "ExtractaTM DBS," Quanta BioSciences, Inc., 2017, https://www.quantabio.com/media/wysiwyg/pdfs/IFU/IFU-113.1_REV_A_Extracta_DBS_Instructions_for_Use_EFF_14FEB2017.pdf.
[33] Lela Buckingham, *Molecular Diagnostics: Fundamentals, Methods and Clinical Applications*, 2nd ed. (F. A. Davis, 2012).
[34] Sheila C. Dollard et al. 2021; "P06725 · PP65_HCMVA," UniProt, 2024, https://www.uniprot.org/uniprotkb/P06725/entry; "Q6SW29 · VIE2_HCMVM A," UniProt, 2024, https://www.uniprot.org/uniprotkb/Q6SW29/entry.
[35] Sheila C. Dollard et al. 2021.

better sensitivity for detecting CMV than either alone, and that the CDC method was the better thermocycling program for CMV detection.[36]

d. CMV Detection

The subgroup utilized the QuantStudio DX RT-PCR instrument and software to detect CMV and analyze the data, respectively. The subgroup interpreted the results based on expected cycle threshold values.[37]

e. Next Steps

The subgroup's next steps include identifying and purchasing validation and testing supplies, methodology training for lab staff, developing a Clinical Laboratory Improvement Amendments (CLIA) approved validation plan for quality assurance and lab director approval, and validating other parameters before routine screenings begin in 2025.

Planning for Implementation of Universal Screening

The Planning for Implementation Subgroup included Jafar H. Razeq, Ph.D., HCLD/PHLD (ABB), Adrienne Manning, Marie Burlette, RN, BSN, MPH, John Lamb, and Debra Ellis, RN, BSN.

Following a series of meetings, the Planning for Implementation Subgroup outlined the summary recommendations below.

- The CT NBS Program should be responsible for CMV NBS DBS laboratory testing and follow-up/tracking, and the CT EHDI Program should be responsible for ensuring that all Connecticut-born infants receive the hearing screenings (Figures 2 and 3).
- DPH should track short-and long-term follow-up data.
- DPH may contract with outside entities to provide care coordination for diagnostic and treatment services and long-term follow-up.
- Pediatric infectious disease and audiology specialists should determine the long-term metrics to follow. Some metrics include hearing diagnostics over time, treatment(s) received, and developmental milestones.
- Educational materials should be provided for expectant families and those who want to become pregnant through birth hospitals, OB/GYNs, and midwives. Furthermore, educational materials at the time of cCMV diagnosis should be targeted at the relevant audience.
- For each disorder added to the panel, the CT NBS Program requires personnel for laboratory and follow-up staffing, funding for short- and long-term follow-up, and additional LIMS/Maven integration to link CT EHDI hearing and all CMV-related data,

[36] Multiplexing means amplifying multiple targets simultaneously in a single test; Richard S. Olney et al., "2023 APHL/ISNS Newborn Screening Symposium," *International Journal of Neonatal Screening* 9, no. 4 (October 9, 2023): 54, https://doi.org/10.3390/ijns9040054.

[37] Sheila C. Dollard et al. 2021.

including urine confirmation results. This funding was provided by the legislature in FY 24 and 25.

- Additional resources for development and distribution of educational materials, as well as funding to hire media consultants to create cCMV media campaigns should be made available.

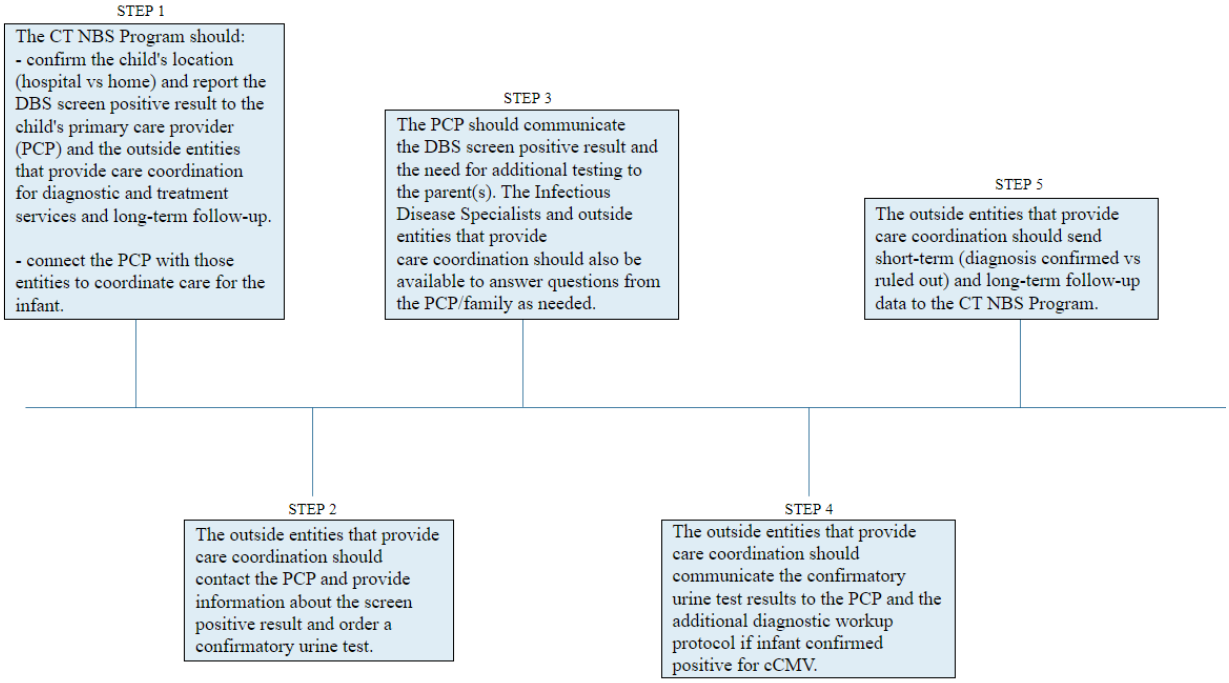
To inform its recommendations, the Subgroup examined a variety of questions, including:

- What are the follow-up plans after a positive newborn screening DBS for cCMV?
- What are the cCMV follow-up plans for infants who fail their hearing screenings?
- What is the recommended length of follow-up? What kind of follow-up data should be collected? Who should be responsible for collecting the named data?
- What cCMV information should be included in education materials/packets for families and pediatricians?
- How should the education component be implemented?
- What additional resources would be needed for a follow-up program and the education component?

What are the follow-up plans for a positive DBS screening for cCMV?

The Planning for Implementation Subgroup recommended that the follow-up on positive cCMV DBS results should be in-line with CT NBS protocols for follow-up on all other positive NBS DBS results (Fig 2).

Figure 2. Proposed Follow-Up Plan for Infants with Positive DBS

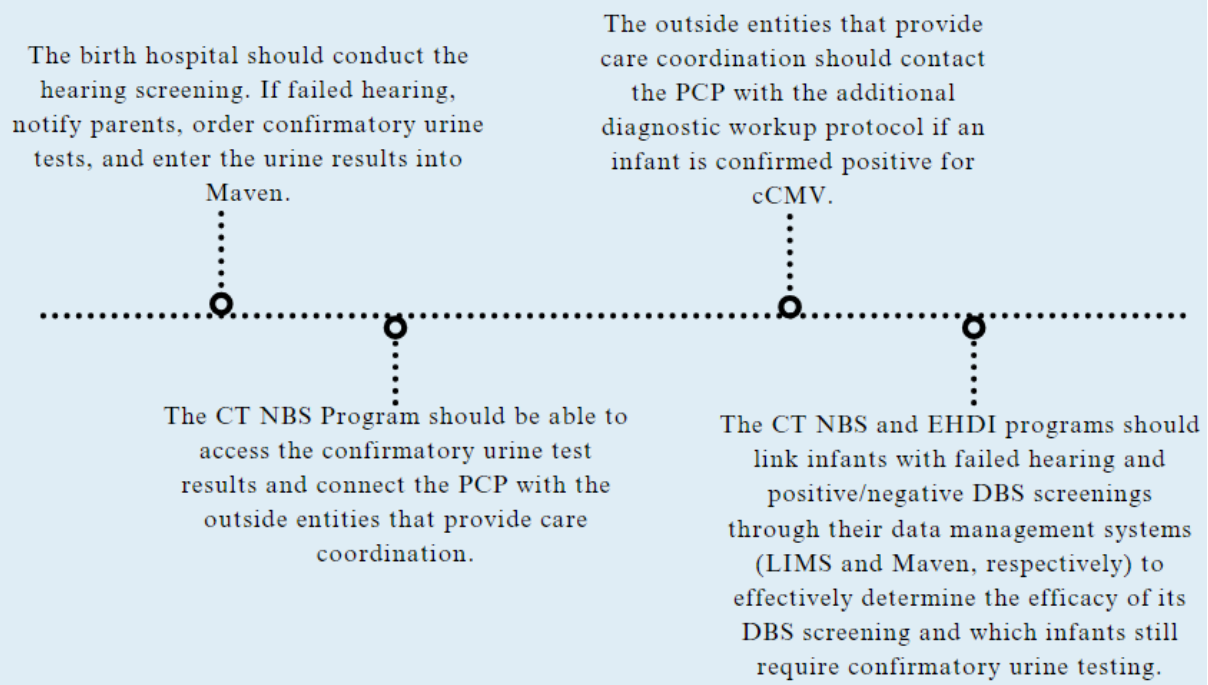


Note: The outside entities should work with pediatric infectious disease specialists before universal cCMV screening begins to establish an appropriate standard follow-up protocol.

What are the cCMV follow-up plans for infants who fail their hearing screenings?

The subgroup recommended that the follow-up plan for infants who fail their hearing screening should be similar to the pathway for infants with positive DBS (Fig 3).

Figure 3. Proposed Follow-Up Plan for Infants with Failed Hearing Screenings



Note: Infants with failed hearing screening and positive DBS screening for cCMV may not need to undergo confirmatory urine testing, as this would have already been ordered at the time of the failed hearing screening.

What is the recommended length of follow-up? What kind of follow-up data should be collected? Who should be responsible for collecting the named data?

The subgroup recommended that the CT NBS Program should track short- and long-term follow-up data, and CT DPH may contract with outside entities to provide care coordination for diagnostic and treatment services and long-term follow-up. In such cases, for short-term follow-up, upon receiving the diagnostic result, the outside entities would report the confirmation or exclusion of cCMV infection to the CT NBS Program and notify the Program if a child is lost to follow-up before the confirmation or exclusion of cCMV infection. For long-term follow-up, the outside entities would enter children who confirm positive for cCMV into a confirmed case database for care management and long-term follow-up through the age of 21.

What cCMV information should be included in educational materials/packets for families and pediatricians?

The subgroup proposed that cCMV educational materials for families should include information about CMV and cCMV, cCMV prevention, and general information on universal cCMV and hearing screening, including outcomes and follow-up. For pediatricians, the subgroup recommended a resource page on the DPH website containing the cCMV algorithm and relevant cCMV literature. The subgroup further recommended that pediatric infectious disease and audiology specialists should determine the long-term metrics to follow, but

identified some long-term metrics, including hearing diagnostics over time, treatment(s) received, and developmental milestones.

How should the education component be implemented?

The subgroup proposed three categories of implementation, each with their relevant recommendations:

1. Educational materials for expectant families and those who want to become pregnant should be distributed through birth hospitals, OB/GYNs, and midwives. Such education should include physical materials like a cCMV fact sheet and CT NBS pamphlets updated with cCMV screening information and online materials like CT NBS and EHDI program web pages updated with cCMV information for families. The subgroup also noted that DPH may refer to the CDC fact sheets for pregnant women, parents, and healthcare providers when developing its documents.[38] Please refer to the Education Subgroup section for additional details on education.

2. Educational materials at the time of cCMV diagnosis should be targeted at the relevant audience. This may be through a fact sheet outlining what it means and the next steps if an infant has a positive DBS screening result, fails their hearing screening, or has CMV detected in urine.

3. General education for pediatricians through the DPH website containing cCMV information and other resources to share with providers and families.

What additional resources would be needed for a follow-up program and the education component?

The subgroup further identified potential resource needs for the CT NBS and EHDI Programs and cCMV education. The CT NBS Program required personnel for laboratory and follow-up staffing, which was provided in the FY 24 25 budget, but the subgroup recommended additional funding for short- and long-term follow-up, and additional LIMS/Maven integration to link EHDI hearing and all cCMV-related data, including urine confirmation results. Currently, the Newborn Screening Program has spent down all of the $440,000 allocated by the legislature to purchase screening equipment. In addition to testing and validating results, resource needs will continue to be evaluated for educational components, such as funding for development and distribution of educational materials, as well as funding to hire media consultants for cCMV media campaigns.

[38] **"Clinical Overview of CMV and Congenital CMV"**

Centers for Disease Control and Prevention, April 5, 2024, https://www.cdc.gov/cytomegalovirus/hcp/clinical-overview/index.html.; "CMV in Newborns," Centers for Disease Control and Prevention, May 10, 2024, https://www.cdc.gov/cytomegalovirus/congenital-infection/index.html.

Education for Health Care Providers and Vulnerable Populations

The Education Subgroup included Marie Burlette, RN, BSN, MPH, John Lamb, and Debra Ellis, RN, BSN.

The Education Subgroup met with families of children affected by cCMV to discuss cCMV education needs. The families identified relevant stakeholders to educate, including PCPs, OB/GYNs, pediatricians, families planning to be pregnant, expectant mothers, families expecting a second child, and early childcare providers. The families emphasized the need for prenatal cCMV education, high-level cCMV awareness, and simplification of educational materials for families. Regarding the dissemination of educational materials, the families highlighted the importance of conveying information on multiple platforms, including, but not limited to, posters with bullet points on cCMV prevention and cCMV pamphlets or brochures in healthcare provider offices. Notably, the families proposed that cCMV details should be included in the information packets that OB/GYNs distribute to families, and OB/GYNs should verbally convey cCMV information during families' first prenatal visit before handing out the information packets. The families also proposed public service announcements on television and newspapers and cCMV social media campaigns, possibly including videos of physicians speaking on the issue. The families further recommended leveraging real family experiences in cCMV marketing and education. Additionally, the families underscored the need for follow-up education on potential outcomes upon cCMV diagnosis, an effective follow-up monitoring and tracking process, and assistance in care coordination.

Following a series of meetings, the Education Subgroup outlined the summary recommendations below.

- Educate relevant stakeholders by three education methods:
    - Universal cCMV legislation: families, PCPs, OB/GYNs, birth hospitals, NICU providers. Midwives, and advocacy groups (e.g. Connecticut Family Support Network, American School for the Deaf)
    - Prevention: individuals and families who are or who want to become pregnant, individuals in high-risk occupations who interact frequently with young children like early childhood education providers (e.g. Early Head Start, daycares, preschools), early interventionists (e.g. Birth to Three providers), and healthcare workers
    - Follow-up after screening: families, birth hospitals, PCPs, NICU providers, and audiologists
- Update existing CT NBS and EHDI Program educational materials to match new universal cCMV legislation.
- Create new materials and guidelines to outline the follow-up process and recommended timelines for families and providers.
- Ensure adequate staffing for education and outreach.
- Create prevention guidelines for those who are pregnant or at risk and for relevant providers.

- Create a comprehensive plan to distribute educational materials to relevant stakeholders.

To inform its recommendations, the Education Subgroup examined a variety of questions, including:

- What are the current available resources?
- What is missing or needed?
- Who are the relevant stakeholders to educate?
- Who will create the materials and how will they be distributed?
- What type of educational materials and media campaigns will be employed?

What are the current available resources?

The CT EHDI Program maintains a website that provides information on cCMV prevention, signs, and diagnosis for parents and resources for healthcare providers, including obstetric healthcare providers and pediatric care providers.[39] The CT EHDI Program also provides newborn hearing screening and CMV testing brochures in English and Spanish for parents and caregivers.[40] Appendix D contains the brochure titled "*Can Your Baby Hear?*" given to all families at birth. The brochure details information on newborn hearing screening, risk factors for hearing loss, newborn hearing development checklist, CMV definition and prevention, and audiology facilities.

Appendix E contains the brochure titled "*Your Baby Needs A CMV test and a Hearing Test*" given to families whose babies have failed their newborn hearing screening. The brochure details information on cCMV testing and assessment, CMV definition and prevention, risk factors for hearing loss, audiology facilities, CMV specialists, and frequently asked questions on cCMV and hearing testing.

Appendix F contains a Shared Plan of Care document that the CT EHDI Program also provides to help families track and share their infant's hearing information with their PCP, audiologist, and CMV specialist. The document also enables parents to maintain an updated record of hearing testing and next steps according to the CT EHDI Program's 1-3-6 timeline. This timeline includes newborn hearing screenings for all Connecticut newborns and subsequent cCMV screening for those who fail their hearing screening before 1 month of age, a pediatric diagnostic audiology evaluation for infants who fail their hearing screening before 3 months of age, and enrollment in early intervention services, such as Connecticut Office of Early Childhood's Birth to Three program, before 6 months of age for infants diagnosed with a hearing loss.[41]

[39] "Early Hearing Detection and Intervention Program," 2024b.
[40] "Resources & Forms," CT.gov, 2024, https://portal.ct.gov/DPH/Family-Health/EHDI/Links-Resources-and-Forms.
[41] "Early Hearing Detection and Intervention Program," 2024a.

What is missing or needed?

The Education Subgroup identified six educational aspects that are missing and needed, including:

1. Ownership: There needs to be a determination of what DPH section(s) or program(s) will take responsibility for creating, printing, and disseminating print and digital educational materials and providing technical assistance. DPH will also need to determine if this will be a stand-alone program or merged with an existing program in the agency.
2. Funding: Funding is necessary to maintain educational costs, including printing, postage, translation, and marketing, among others.
3. Prevention: There is a need for an active prevention education component. There needs to be a determination of who will be responsible for outreach to midwives, daycares, camps, and preschool staff, such as the Connecticut Department of Public Health Facility Licensing & Investigations Section, Connecticut Occupational Safety and Health, and Connecticut Office of Early Childhood.
4. Stakeholder Education: Educating relevant stakeholders about the implementation of universal cCMV screening.
5. Messaging: The Education Subgroup emphasized the need for consistent cCMV messaging across programs and agencies.
6. Staff:
    - Social media, marketing, and website staff to assist in developing a public awareness campaign and updating content as needed.
    - Staff to conduct outreach and education to families and providers.
    - Staff or subject matter experts to develop educational materials.

Who are the relevant stakeholders to educate?

The Education Subgroup identified relevant stakeholders by three education types, including education on the new universal cCMV legislation, prevention, and follow-up after screening (to ensure stakeholders are aware of and understand cCMV results and next steps). The relevant stakeholders to educate on the new universal cCMV legislation are families, PCPs, OB/GYNs, birth hospitals, NICU providers, midwives, and advocacy groups like the Connecticut Family Support Network and American School for the Deaf. The relevant stakeholders to educate on prevention are individuals and families who are or who want to become pregnant, with a particular emphasis on educating those in high-risk careers who interact frequently with young children. This would include early childhood education providers, such as Early Head Start, daycare and preschool staff, early interventionists like Birth to Three providers, and healthcare workers. Lastly, the relevant stakeholders to educate on follow-up after screening are families, birth hospitals, neonatal intensive care unit providers, PCPs, and audiology practices.

Who will create the materials and how will they be distributed?

The CT NBS and EHDI Programs should update all their existing print and digital materials to match the new universal cCMV legislation. The CT NBS Program provides *"Make Sure Your Baby is Healthy"* pamphlets to birth hospitals for families. The pamphlet, in Appendix G, includes

frequently asked questions on newborn screening, a newborn screening checklist, and a description of the types of disorders that the CT NBS Program screens for. The CT NBS Program should add cCMV to the list of disorders described in the pamphlet and follow past practice by sending a letter to birth hospitals, NICUs, and the Genetics Advisory Committee notifying them of the addition of cCMV to the newborn screening panel. Additionally, the CT NBS Program should add cCMV to the A-Z disorder listing and cCMV analyte and cut-off to its recommended uniform screening panel.[42] The subgroup further recommended that DPH be responsible for determining what DPH division or outside entity may create additional cCMV educational materials.

The Education Subgroup recommended that the educational materials be distributed through mail and brochures by birth facilities, OB/GYNs, midwives, birth educators, and audiologists. Importantly, the subgroup noted that websites should not be the primary source of dissemination as families will not know to refer to a website for a condition they have never heard of. Hence, the subgroup emphasized the need for a public awareness campaign, including press releases and social media – Facebook, Twitter, Instagram, among others – campaign. The subgroup also recommended outreach to local chapters of professional organizations, such as the American Academy of Pediatrics, American Congress of Obstetricians and Gynecologists, American Academy of Family Physicians, and Connecticut Infectious Disease Society.

Conclusion

This report is the culmination of the working group's research, collaboration, and deliberation to develop recommendations to inform the implementation of universal cCMV screening in Connecticut. It covers a range of findings and recommendations per the legislative mandate for the working group to study issues concerning CMV, including, but not limited to, CMV screening in other states, treatment for asymptomatic newborns with positive screening results, best practices for universal screening, planning for implementation of universal screening, and education for health care providers and vulnerable populations.

With the anticipated rise in the number of infants identified with cCMV through universal newborn screening, the working group emphasized the need for increased resources for the CT NBS and EHDI programs to effectively implement the proposed screening and follow-up protocols. Using estimates of prevalence from the CDC, it is anticipated between 150 and 200 cases of cCMV may be identified in Connecticut each year, an increase from less than 12 cases per year. To address this increase in identified patients, the CT NBS Program required additional personnel for laboratory and follow-up staffing, funding for short- and long-term follow-up, including care coordination, and enhanced LIMS/Maven integration to link CT EHDI hearing and all CMV-related data, including confirmatory urine results. As of the spring of 2025, the NBS has spent all of the allocated money from the legislature to purchase equipment and

[42] "Newborn Screening Disorders A-Z Listing," CT.gov, 2024, https://portal.ct.gov/Newborn-Screening-Program/Disorders; "CT NBS Recommended Uniform Screening Panel," CT.gov, September 23, 2022, https://portal.ct.gov/-/media/Newborn-Screening-Program/CTNBS_Expanded-RUSP_09232022.pdf.

hire staff to determine the best screening method and ensure that the assays are reliable and effective prior to the July 1, 2025 start. The NBS is in the process of coordinating with the EHDI Program to coordinate screening in children who fail their hearing test. Early detection of and intervention for newborns infected with cCMV is crucial to improve outcomes, underscoring the need for state-wide resources to provide timely evaluation and initiation of treatment for infants with cCMV. While there has been financial commitment to promote a smooth launch of cCMV's addition to the newborn screening panel, the group recommends resources for the development and distribution of educational materials, as well as funding to hire media consultants to create cCMV media campaigns.

Appendix A: Public Act No. 23-204[43]

AN ACT CONCERNING THE STATE BUDGET FOR THE BIENNIUM ENDING JUNE 30, 2025, AND MAKING APPROPRIATIONS THEREFOR, AND PROVISIONS RELATED TO REVENUE AND OTHER ITEMS IMPLEMENTING THE STATE BUDGET.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Sec. 191. Section 19a-55 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) There is established a newborn screening program. The Commissioner of Public Health shall (1) administer the newborn screening program, (2) direct persons identified through the screening program to appropriate specialty centers for treatments, consistent with any applicable confidentiality requirements, and (3) set the fees to be charged to institutions to cover all expenses of the comprehensive screening program including testing, tracking and treatment, subject to the approval of the Secretary of the Office of Policy and Management. The fees to be charged pursuant to subdivision (3) of this subsection shall be set at a minimum of ninety-eight dollars.

(b) The administrative officer or other person in charge of each institution caring for newborn infants, a nurse-midwife licensed pursuant to chapter 377 or a midwife shall cause to have administered to every such newborn infant in his or her care a blood spot specimen and an HIV-related test, as defined in section 19a-581, except that the person responsible for testing may omit such test if the mother has had an HIV-related test pursuant to section 19a-90 or 19a-593. The blood spot specimen shall be collected not earlier than twenty-four hours after the birth of the newborn infant and not later than forty-eight hours after the birth of such infant, unless the institution caring for newborn infants, nurse-midwife licensed pursuant to chapter 377 or midwife determines that a situation exists to warrant an early collection of the specimen or if collection of the specimen is medically contraindicated. Situations that warrant early collection of the specimen shall include, but not be limited to, the imminent transfusion of blood products, dialysis, early discharge of the newborn infant from the institution, transfer of the newborn infant to another institution or imminent death. If the newborn infant dies before a blood spot specimen can be obtained, the specimen shall be collected as soon as practicable after death. The institution licensed to care for newborn infants, nurse-midwife or midwife shall notify the Department of Public Health when a specimen is not collected within forty-eight hours after the birth of such infant due to: (1) The infant's medical fragility, (2) refusal by the parents when newborn infant screening is in conflict with their religious tenets and practice, (3) the newborn infant receiving comfort measures only, or (4) any other reason. Such notification

[43] An Act Concerning the State Budget for the Biennium Ending June 30, 2025, and Making Appropriations Therefor, and Provisions Related to Revenue and Other Items Implementing the State Budget, Public Act No. 23-204, §191 (2023).

shall be documented in the department's newborn screening system pursuant to section 19a-53 by the institution caring for newborn infants, nurse-midwife or midwife or sent in writing to the department not later than seventy-two hours after the birth of the newborn infant. The institution caring for newborn infants, nurse-midwife or midwife shall send the blood spot specimen to the state public health laboratory not later than twenty-four hours after the time of collection. The department may request an additional blood spot specimen if: (A) There was an early collection of the specimen, (B) the specimen was collected following a transfusion of blood products, (C) the specimen is unsatisfactory for testing, or (D) the department determines that there is an abnormal result. The state public health laboratory shall make and maintain a record of the date and time of its receipt of each blood spot specimen and make such record available for inspection by the institution caring for newborn infants, nurse-midwife or midwife that sent the blood spot specimen not later than forty-eight hours after such institution, nurse-midwife or midwife submits a request to inspect such record.

(c) The Commissioner of Public Health shall publish a list of all the abnormal conditions for which the department screens newborns under the newborn screening program, which shall include, but need not be limited to, testing for (1) amino acid disorders, including phenylketonuria, organic acid disorders, fatty acid oxidation disorders, including, but not limited to, long-chain 3-hydroxyacyl CoA dehydrogenase (L-CHAD) and medium-chain acyl-CoA dehydrogenase (MCAD), hypothyroidism, galactosemia, sickle cell disease, maple syrup urine disease, homocystinuria, biotinidase deficiency, congenital adrenal hyperplasia, severe combined immunodeficiency disease, adrenoleukodystrophy, spinal muscular atrophy and any other disorder included on the recommended uniform screening panel pursuant to 42 USC 300b-10, as amended from time to time, and as prescribed by the Commissioner of Public Health, and (2) on and after July 1, 2025, cytomegalovirus.

(d) In addition to the testing requirements prescribed in subsection (b) of this section, the administrative officer or other person in charge of each institution caring for newborn infants shall cause to have administered to **[**(1)**]** every such infant in its care a screening test for **[**(A)**]** (1) cystic fibrosis, and **[**(B)**]** (2) critical congenital heart disease. **[**, (2) any newborn infant who fails a newborn hearing screening, as described in section 19a-59, a screening test for cytomegalovirus.**]** Such screening tests shall be administered as soon after birth as is medically appropriate.

(e) **[**(1)**]** The clinical laboratory that completes the testing for cystic fibrosis **[**,**]** shall report the number of newborn infants screened and the results of such testing, not less than annually, to the Department of Public Health into the newborn screening system pursuant to section 19a-53. The administrative officer or other person in charge of each institution caring for newborn infants who performs the testing for critical congenital heart disease shall enter the results of such test into the newborn screening system pursuant to section 19a-53.

[(2) The administrative officer or other person in charge of each institution caring for newborn infants shall enter any case of cytomegalovirus that is confirmed as a result of a screening test administered pursuant to subdivision (2) of subsection (d) of this section to the Department of Public Health into the newborn screening system pursuant to section 19a-53. The provisions of

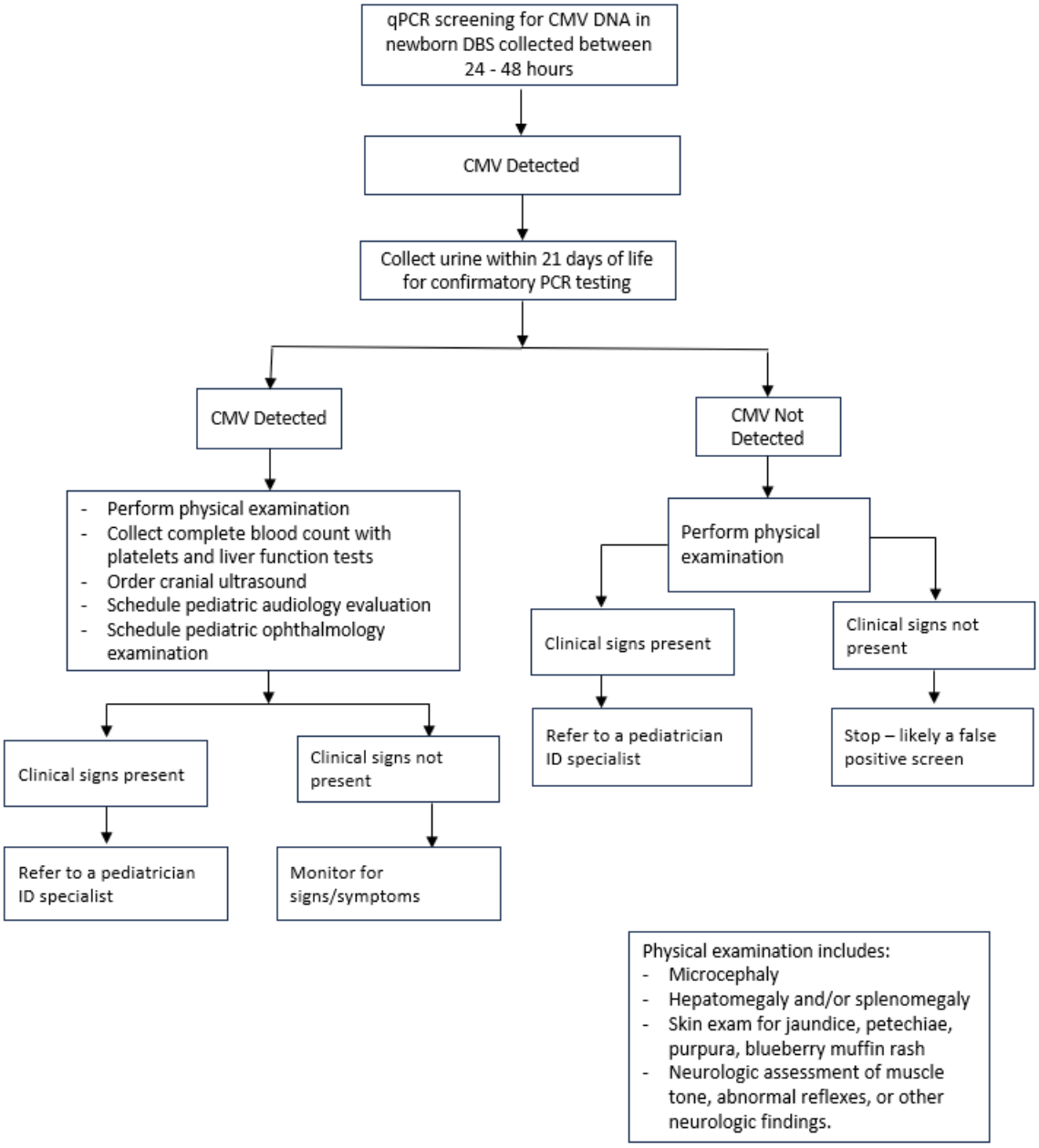
this subsection shall apply regardless of the patient's insurance status or source of payment, including self-pay status.**]**

(f) The provisions of this section shall not apply to any infant whose parents object to the test or treatment as being in conflict with their religious tenets and practice. The commissioner shall adopt regulations, in accordance with the provisions of chapter 54, to implement the provisions of this section.

Sec. 192. (*Effective from passage*) (a) The Commissioner of Public Health shall convene a working group to study issues concerning cytomegalovirus, including, but not limited to, screening for cytomegalovirus by other states, treatment for newborns with positive asymptomatic screening results, best practices for universal screening, planning for implementation of universal screening and education for health care providers and vulnerable populations. The commissioner, or the commissioner's designee, shall serve as chairperson of the working group.

(b) Not later than January 1, 2025, the Commissioner of Public Health shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health regarding the findings of the working group.

Appendix B: Minnesota Department of Health Recommended cCMV Algorithm[44]



[44] "CMV Screening Follow-up," Minnesota Department of Health, August 27, 2023, https://www.health.state.mn.us/people/newbornscreening/program/cmv/followup.html.

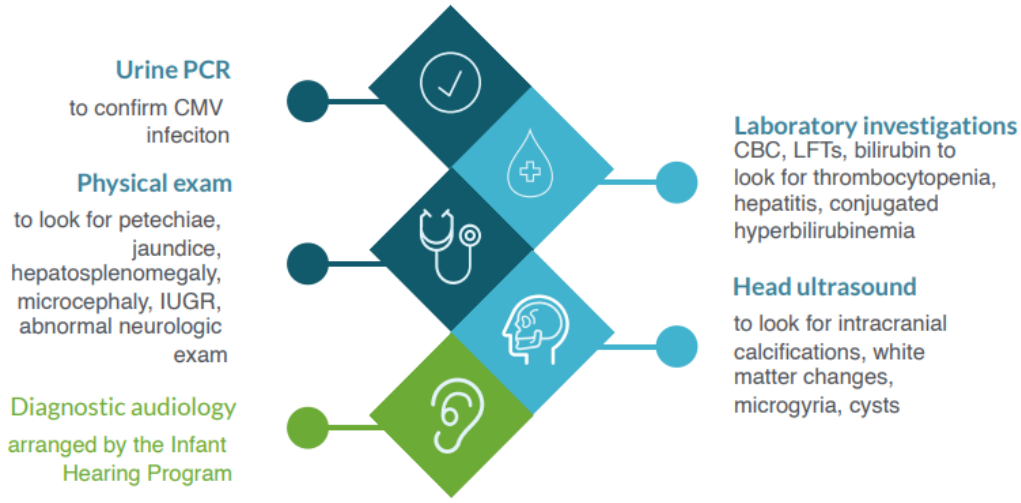
Appendix C: Newborn Screening Ontario Proposed Initial Evaluation[45]

cCMV signs and symptoms:

- petechiae
- jaundice
- hepatosplenomegaly
- microcephaly
- IUGR
- chorioretinitis/optic atrophy
- seizures
- intracranial calcifications
- permanent sequelae can include hearing loss, intellectual and motor disabilities, seizures, and/or vision loss

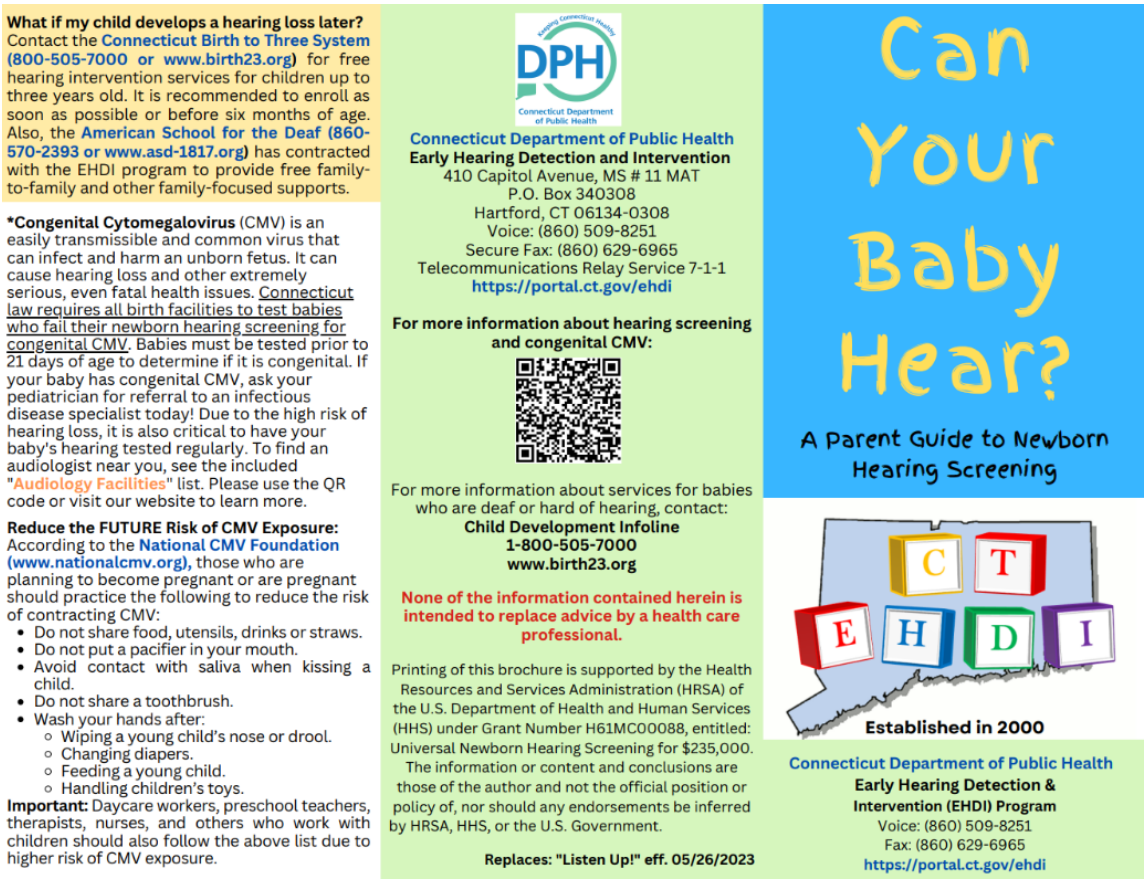
Note: the majority of infants with cCMV (~85%) will be asymptomatic.

Proposed initial evaluation of CMV screen positive infants by pediatrician:



[45] "Risk Factor Screening for Permanent Hearing Loss in Ontario," Newborn Screening Ontario, 2024, https://www.newbornscreening.on.ca/media/vl4bwe0h/community-peds-infographic-jan-8-2024-1.pdf.

Appendix D: Connecticut Early Hearing Detection and Intervention Brochure I[46]



What if my child develops a hearing loss later? Contact the **Connecticut Birth to Three System (800-505-7000 or www.birth23.org)** for free hearing intervention services for children up to three years old. It is recommended to enroll as soon as possible or before six months of age. Also, the **American School for the Deaf (860-570-2393 or www.asd-1817.org)** has contracted with the EHDI program to provide free family-to-family and other family-focused supports.

***Congenital Cytomegalovirus** (CMV) is an easily transmissible and common virus that can infect and harm an unborn fetus. It can cause hearing loss and other extremely serious, even fatal health issues. Connecticut law requires all birth facilities to test babies who fail their newborn hearing screening for congenital CMV. Babies must be tested prior to 21 days of age to determine if it is congenital. If your baby has congenital CMV, ask your pediatrician for referral to an infectious disease specialist today! Due to the high risk of hearing loss, it is also critical to have your baby's hearing tested regularly. To find an audiologist near you, see the included "Audiology Facilities" list. Please use the QR code or visit our website to learn more.

Reduce the FUTURE Risk of CMV Exposure: According to the **National CMV Foundation (www.nationalcmv.org),** those who are planning to become pregnant or are pregnant should practice the following to reduce the risk of contracting CMV:

- Do not share food, utensils, drinks or straws.
- Do not put a pacifier in your mouth.
- Avoid contact with saliva when kissing a child.
- Do not share a toothbrush.
- Wash your hands after:
  - Wiping a young child's nose or drool.
  - Changing diapers.
  - Feeding a young child.
  - Handling children's toys.

Important: Daycare workers, preschool teachers, therapists, nurses, and others who work with children should also follow the above list due to higher risk of CMV exposure.

Connecticut Department of Public Health
Early Hearing Detection and Intervention
410 Capitol Avenue, MS # 11 MAT
P.O. Box 340308
Hartford, CT 06134-0308
Voice: (860) 509-8251
Secure Fax: (860) 629-6965
Telecommunications Relay Service 7-1-1
https://portal.ct.gov/ehdi

For more information about hearing screening and congenital CMV:

For more information about services for babies who are deaf or hard of hearing, contact:
Child Development Infoline
1-800-505-7000
www.birth23.org

None of the information contained herein is intended to replace advice by a health care professional.

Printing of this brochure is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under Grant Number H61MC00088, entitled: Universal Newborn Hearing Screening for $235,000. The information or content and conclusions are those of the author and not the official position or policy of, nor should any endorsements be inferred by HRSA, HHS, or the U.S. Government.

Replaces: "Listen Up!" eff. 05/26/2023

Can Your Baby Hear?

A Parent Guide to Newborn Hearing Screening

Established in 2000

Connecticut Department of Public Health
Early Hearing Detection & Intervention (EHDI) Program
Voice: (860) 509-8251
Fax: (860) 629-6965
https://portal.ct.gov/ehdi

[46] "Resources & Forms," CT.gov, 2024, https://portal.ct.gov/DPH/Family-Health/EHDI/Links-Resources-and-Forms.

Why are newborns screened for hearing loss?
Two reasons: First, birth facilities are required to screen all newborns for hearing loss under Connecticut law (C.G.S. §19a-59). Second, hearing loss is one of the most commonly occurring disabilities found in newborns. The newborn hearing screening identifies babies who need additional testing to determine their ability to hear. Most babies with hearing loss don't show any symptoms, which is why it's critical to have your baby's hearing screened by one month of age.

How are babies screened for hearing loss?
A quick and painless method is used to measure your baby's responses to sound.

What if my baby PASSES their screening?
It is recommended to have your baby's hearing checked again, at least once before 36 months old, even if they passed their newborn hearing screening. The first three years of life are the most important for developing language and communication skills, and an undetected hearing loss could cause a preventable delay in speech and language development.

What if my baby FAILS their hearing screening?

- **Step 1:** Before leaving the birth facility, be sure your baby was tested for congenital Cytomegalovirus (CMV)*, which is a virus that may cause harm to your baby. Your baby must be tested before 21 days of age to determine if it is congenital or not.
- **Step 2:** Schedule a diagnostic hearing test with an audiologist that specializes in pediatric cases today! This comprehensive test is the only way to know if a hearing loss is present. Your baby should complete their hearing testing before three months of age. To find an audiologist near you, see the included "Audiology Facilities" list.

Is my baby at risk of a hearing loss?
Ask your healthcare provider if your child has any of the risk factors in the enclosed "**Risk Factors for Hearing Loss**" list. Even if your baby passed their newborn hearing screening, these risk factors could still cause a hearing loss later on. If your baby has risk factors for hearing loss, it is extremely important to discuss a follow-up hearing test schedule with your child's healthcare provider or a pediatric audiologist.

Audiology Facilities

The following audiology centers have the specialized equipment and experience to conduct hearing testing in infants and children:

Connecticut Children's Medical Center
Hartford, Farmington, and Glastonbury, CT.
(860) 545-9642 or (860) 837-6300

Lawrence & Memorial Hospital
Waterford, CT. (860) 271-4900

UConn Speech & Hearing Clinic
Storrs, CT. (860) 486-2629

Yale New Haven Children's Hospital
New Haven and Trumbull, CT. (877) 925-3637

Or, visit **www.ehdi-pals.org** for a list of pediatric audiologists by location.

Risk Factors for Hearing Loss

If any of the below conditions are present, have your child's hearing monitored regularly due to the increased risk of a hearing loss developing later on.

- Caregiver concern regarding hearing, speech, language, developmental delay or developmental regression.
- Family history of childhood hearing loss.
- **Congenital Cytomegalovirus (CMV)*.**
- Syndromes: There are many syndromes associated with hearing loss, please visit: **www.hereditaryhearingloss.org.**
- Antibiotics in the Aminoglycosides family (gentamicin or others) for more than 5 days.
- In utero infections, such as herpes, rubella, syphilis, toxoplasmosis, Zika, etc.
- NICU stay > 5 days.
- Craniofacial malformations, temporal bone abnormalities, congenital microcephaly, microtia, atresia, or head trauma.
- Hyperbilirubinemia exchange transfusion.
- Asphyxia\Hypoxic Ischemic Encephalopathy.
- Extracorporeal membrane oxygenation
- (ECMO).
- Chemotherapy.

Your Baby's Hearing and Communicative Development Checklist

The checklist below presents the average age by which most babies accomplish a variety of early speech and language skills. If your child has not accomplished all the items by end of the age range, contact your pediatrician and an audiologist.

Birth to 3 Months

- Reacts to loud sounds.
- Calms down or smiles when spoken to.
- Recognizes your voice and calms down if crying.
- When feeding, starts or stops sucking in response to sound.
- Coos and makes pleasure sounds.
- Has a special way of crying for different needs.
- Smiles when he or she sees you.

4 to 6 Months

- Follows sounds with his or her eyes.
- Responds to changes in the tone of your voice.
- Notices toys that make sounds.
- Pays attention to music.
- Babbles in a speech-like way and uses many different sounds, including sounds that begin with p, b, and m.
- Laughs.
- Babbles when excited or unhappy.
- Makes gurgling sounds when alone or playing with you.

7 Months to 1 Year

- Enjoys playing peek-a-boo and pat-a-cake.
- Turns and looks in the direction of sounds.
- Listens when spoken to.
- Understands words for common items such as “cup,” “shoe,” or “juice”.
- Responds to requests (“Come here”).
- Babbles using long and short groups of sounds (“tata, upup, bibibi”).
- Babbles to get and keep attention.
- Communicates using gestures such as waving or holding up arms.

The above is an abridged checklist from the: ***National Institute on Deafness and Other Communication Disorders (www.nidcd.nih.gov).***

Appendix E: Connecticut Early Hearing Detection and Intervention Brochure II[47]

APPOINTMENT CARDS

Audiology Facilities

The following audiology centers have the specialized equipment and experience to conduct hearing tests on infants and children:

Connecticut Children's Medical Center
Hartford, Farmington, and Glastonbury, CT
(860) 545-9642 or (860) 837-6300

Lawrence & Memorial Hospital
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UConn Speech & Hearing Clinic
Storrs, CT (860) 486-2629

Yale New Haven Children's Hospital
New Haven and Trumbull, CT (877) 925-3637

Or visit **www.ehdi-pals.org** for a list of pediatric audiologists by location.

Circle the facility above and fill out below:

Date: Time:

CMV Specialists

Connecticut Children's Medical Center
Infectious Diseases and Immunology
Hartford, CT (860) 545-9490

Yale New Haven Children's Hospital
Pediatric Infectious Diseases
New Haven, CT (877) 925-3637

Circle the facility above and fill out below:

Date: Time:

DPH
Connecticut Department of Public Health

Connecticut Department of Public Health
Early Hearing Detection and Intervention
410 Capitol Avenue, MS # 11 MAT
P.O. Box 340308
Hartford, CT 06134-0308
Voice: (860) 509-8251
Secure Fax: (860) 629-6965
Telecommunications Relay Service 7-1-1
https://portal.ct.gov/ehdi

For more information about hearing screening and congenital CMV:

For more information about services for babies who are deaf or hard of hearing, contact:
Child Development Infoline
1-800-505-7000
www.birth23.org

None of the information contained herein is intended to replace advice by a health care professional.

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Rev. 05/31/2023
Replaces "Your Baby Needs Another Hearing Test/CMV"

Your Baby Needs: A CMV test and a Hearing Test

CMV and Hearing Testing FAQs for Parents and Caregivers

C T E H D I

Established in 2000

Connecticut Department of Public Health
Early Hearing Detection & Intervention (EHDI) Program
Voice: (860) 509-8251 Fax: (860) 629-6965
https://portal.ct.gov/ehdi

[47] "Resources & Forms," CT.gov, 2024, https://portal.ct.gov/DPH/Family-Health/EHDI/Links-Resources-and-Forms.

My baby failed their newborn hearing screening...

WHAT DO I NEED TO DO RIGHT NOW?

Step 1: Before leaving the birth facility, be sure your baby was tested for congenital Cytomegalovirus (CMV). Birth facilities are required by law to test for CMV when a baby fails their newborn hearing screening. **Critical:** Your baby must be tested before 21 days of age to determine if it is congenital. Follow-up with your pediatrician to get the CMV results.

Step 2: Schedule a diagnostic **hearing test** with an audiologist that specializes in pediatric cases today! This test is far more comprehensive than the screening done at birth and is the only way to know if a hearing loss is present. Barring any medical exceptions, your baby should complete their hearing testing before three months of age. To find an audiologist near you, see the included "**Audiology Facilities**" list.

More Information About Congenital CMV

What is congenital Cytomegalovirus (CMV)?
Congenital CMV is a virus that can cause very serious health issues, developmental delays, and is the leading cause of hearing loss in infants, which can develop anytime during the first few years of life. See prevention tips*

What if my baby has congenital CMV?
Ask your pediatrician for a referral to an infectious disease specialist or contact one yourself. See the "CMV Specialists" list for contact info. Also, it is extremely important to have your baby's hearing tested regularly.

Are there any free developmental services available for babies with congenital CMV?
Yes, contact the **Connecticut Birth to Three System (800-505-7000 or www.birth23.org)** to schedule an evaluation.

More Information About Hearing Testing

Why is the early diagnosis of hearing loss so critical to my baby's future?
Babies' brains try to make sense out of the sounds that reach their ears during the course of everyday events. This is the beginning of language development. The earlier a baby with hearing loss is DIAGNOSED and receives hearing-related services, the more likely they are to reach their full social, emotional, and intellectual potential.

"I think my baby can hear; I'm going to wait to have their hearing tested."
DON'T WAIT! Hearing testing should be done as soon as possible after birth, but before three months of age. Many babies with hearing loss can hear some sounds but not enough to develop speech and language properly. You cannot tell by watching and interacting with your baby if they can hear ALL the sounds needed to learn language. Diagnostic hearing testing is the only way to know for sure if your baby has a hearing loss.

What if my baby passes their hearing test?
All children who PASS their hearing screening or hearing test should be screened again, at least once, before 36 months old to catch a late onset of hearing loss that may have otherwise gone unnoticed.

What if my baby has a hearing loss or develops one later?
Contact the **Connecticut Birth to Three System (800-505-7000 or www.birth23.org)** for free hearing intervention services for children up to three years old. It is recommended to enroll as soon as possible or before six months of age. Also, the **American School for the Deaf (860-570-2393 or www.asd-1817.org)** has contracted with the EHDI program to provide free family-to-family and other family-focused supports.

Risk Factors for Hearing Loss

If any of the below conditions are present, or have occured, have your child's hearing monitored regularly due to the increased risk of a hearing loss developing later on:

- Caregiver concern regarding hearing, speech, language, developmental delay or developmental regression.
- Family history of childhood hearing loss.
- **Congenital Cytomegalovirus (CMV).**
- Syndromes: There are many syndromes associated with hearing loss, please visit: **www.hereditaryhearingloss.org**.
- Antibiotics in the Aminoglycosides family (gentamicin or others) for more than 5 days.
- In utero infections, such as herpes, rubella, syphilis, toxoplasmosis, Zika, etc.
- NICU stay > 5 days.
- Skull or facial malformations, congenital microcephaly, microtia, atresia, or head trauma.
- Hyperbilirubinemia exchange transfusion.
- Asphyxia\Hypoxic Ischemic Encephalopathy.
- Extracorporeal membrane oxygenation
- (ECMO).
- Chemotherapy.

*Congenital CMV Prevention Tips

CMV is transmitted through bodily fluids. Help reduce the spread of CMV to those who are pregnant:

- Wash hands often with soap and water, after feeding a child, changing diapers, wiping a child's nose, or handling children's toys.
- Avoid sharing food, drinks, or utensils with children.
- Do not put a child's pacifier or toothbrush in your mouth.
- Do not kiss young children on or close to the mouth.
- Clean toys, changing tables, and countertops often.

Appendix F: Connecticut Early Hearing Detection and Intervention Shared Plan of Care[48]

Connecticut Department of Public Health
Early Hearing Detection & Intervention (EHDI) Program (860) 509-8251

Family Plan of Care for Infants\Children Who are Deaf or Hard of Hearing

Patient Information

Child's Last Name:_____ First:_____ DOB:_____

Child's Address: _____ City: _____ State:_____ Zip_____

Guardian's Name:_____ Relationship to Child:_____

Guardian Primary Phone:_____ Email:_____ Secondary Phone:_____

Medical Summary

Diagnosis

Diagnosis:_____ Date:_____

Diagnosis:_____ Date:_____

Diagnosis:_____ Date:_____

Medications/Supplements

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

Surgeries

Surgery:_____ Date:_____

Surgery:_____ Date:_____

Surgery:_____ Date:_____

Allergies

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

Hearing-Related Care Team

Role	Name	Best way to contact	
Family member(s)		Phone:	Email:
Pediatrician\PCP		Phone:	Email:
ENT		Phone:	Email:
Audiologist		Phone:	Email:
B23 Coordinator		Phone:	Email:
Other:		Phone:	Email:

FRONT

[48] "Resources & Forms," CT.gov, 2024, https://portal.ct.gov/DPH/Family-Health/EHDI/Links-Resources-and-Forms.

Connecticut Department of Public Health
Early Hearing Detection & Intervention (EHDI) Program (860) 509-8251

Family Plan of Care for Infants\Children Who are Deaf or Hard of Hearing

Family Checklist (Medical Home)

Before 1 Month

☐ **Final Newborn Hearing Screening Results (OAE\ABR):** Date: _____

Left Ear:		Right Ear:
☐	Pass	☐
☐	Failed (Must also screen for cCMV before 21 days of age)	☐
☐	Not Tested	☐

Birth Hospital, Midwife, or Provider that conducted the hearing screenings: _____.

☐**Congenital Cytomegalovirus (cCMV) Screening Results:** Date: _____

☐Detected ☐Not detected

Birth Hospital, Midwife, or Provider that conducted the cCMV screenings: _____.

Before 3 Months

☐**Pediatric Diagnostic Audiology Evaluation (most recent):** Date: _____

Left Ear - Type\Degree of Hearing Loss: _____.

Right Ear - Type\Degree of Hearing Loss: _____.

****** To locate a pediatric audiologist near you, visit: www.ehdi-pals.org******

☐Received copy of the hearing evaluation from audiologist. Date: _____
☐**Referred or self-referred to Birth to Three.** Call: 800-505-7000. Date: _____
☐Pediatric ENT for medical clearance and further testing. Date: _____

☐**Recommended by 3-6 months:**
☐Hearing aid fitting. Date: _____
☐Ongoing diagnostic monitoring, as needed. Date: _____
☐**Family referred to Connecticut Family Support Network.** Call: 860-744-4074 Date: _____

Before 6 Months

☐**Enrollment in Birth to Three (Early Intervention, IDEA, Part C\Non-Part C)** Date: _____

Birth to Three supports families to enhance their child's development and connect to their communities. Early Intervention Programs bill public and private insurance and when applicable fees are charged based on a sliding scale. Anyone can refer a child by calling 800-505-7000, or visit www.birth23.org to learn more.

☐Receiving any other intervention/therapy services: _____.
☐Ongoing audiological testing to monitor hearing aids and progression of hearing loss.

☐**Medical Evaluations to determine causes and identify related conditions (ongoing):**
☐Ophthalmology (annually). ***This is critical for children with a hearing loss.*** Date: _____
☐Genetics. Date: _____
☐Other specialists (as needed): _____. Date: _____

☐**Other tests to consider**: CT, MRI, EKG, or Ultrasound. Speak with your provider.

Risk Factors for Hearing Loss

Check all the apply (continue monitoring hearing if present):
☐None Known
☐Caregiver Concern
☐Craniofacial Anomalies
☐**cCMV** *(50% of babies with cCMV develop a hearing loss)*
☐Cultural Positive Postnatal Infections
☐**Family History**
☐Head Trauma
☐Hyperbilirubinemia
☐In-utero Infections
☐Neurodegenerative disorder
☐NICU >5 days
☐Ototoxic Medications
☐Physical Findings – Specify: _____
☐Syndromes – Specify: _____

Congenital Cytomegalovirus (cCMV) Resources:

Connecticut Children's Medical Center
Infectious Diseases and Immunology
Hartford, CT (860) 545-9490

Yale New Haven Children's Hospital
Pediatric Infectious Diseases
New Haven, CT (877) 925-3637

Need Help with this Form or Need More Copies?
Call us at: 860-509-8251 and ask for the EHDI program.
Or visit us at us at: https://portal.ct.gov/ehdi

Parent Support: If your child has a hearing loss, the **American School for the Deaf** offers free and unbiased parent support and guidance. Contact them at: 860-570-2393 or www.asd-1817.org.

Feedback: You comments and suggestions are valuable to us. Please send them to: dph.ehdi@ct.gov.

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Rev. 11/27/2023

BACK

Appendix G: Connecticut Newborn Screening Program Pamphlet[49]

[49] "The State of Connecticut Newborn Screening Program Bloodspot Screening," The Connecticut Newborn Screening Program, 2021, https://portal.ct.gov/-/media/Newborn-Screening-Program/Forms/Newborn-Screening-flyer_English_2021.pdf.

The State of Connecticut Newborn Screening Program
Bloodspot Screening

Make Sure Your Baby is Healthy

Checklist:

- ☐ Ask your doctor, nurse or midwife about Newborn Screening (NBS)
- ☐ Pick a doctor for your baby before your baby is born
- ☐ Make an appointment with your baby's doctor before you leave the hospital
- ☐ Ask if your baby had the NBS test done before you leave the hospital
- ☐ Ask your baby's doctor for the results of your baby's NBS test
- ☐ Give a phone number where you can be reached after you leave the hospital
  - If you do not have a phone, give a friend's or family member's phone number
- ☐ Call the doctor if your baby:
  - has trouble eating
  - vomits often
  - has skin problems
  - is very sleepy all the time
  - looks sick

More Questions?

- Talk to your baby's doctor, nurse or midwife
- Call the Connecticut NBS Program at:
  (860) 920-6628
- Go to:
  - http://savebabies.org/
  - http://www.babysfirsttest.org/
  - http://www.marchofdimes.org/baby/newborn-screening-tests-for-your-baby.aspx
  - http://portal.ct.gov/newbornscreening
- Email: dph.nbstracking@ct.gov

DPH
Connecticut Department of Public Health

Newborn Screening (NBS) is important!

While most babies are born healthy, some babies are born with serious but treatable medical conditions. Your baby will receive three different screening tests while in the hospital:

1. the bloodspot screen checks for conditions that can cause problems with your baby's growth and development and can sometimes cause death if not treated. You may hear someone call this the "PKU" test, but this name is outdated. PKU is just one of over 60 conditions that babies are tested for by bloodspot screening in Connecticut
2. the hearing screen
3. the pulse oximetry screen that checks for serious heart problems

This pamphlet explains Newborn Screening bloodspot screening

Answers To Your Questions about Newborn Screening

Why does my baby need NBS?

- Bloodspot screening tests for conditions that may be hidden at birth. A baby can appear healthy and still have a condition.
- Connecticut NBS tests for over 60 different conditions using a few drops of blood.
- If one of these health problems is not treated, a baby may:
  - become very sick
  - grow poorly
  - have a physical disability
  - have brain damage
  - die
- With early treatment many of these problems can be prevented.

When is the test done?

- One to three days after birth while your baby is still in the hospital.

What if my baby is born at home?

- Your midwife will collect the bloodspot specimen and send it to the State Public Health Lab. Please ask you midwife about hearing and pulse oximetry screening.

How is the test done?

- The hospital staff or a midwife will take a few drops of blood from your baby's heel and apply it to a filter paper card. The card is sent to the State Public Health Lab for testing.

Will the heel-stick used to collect the blood spots hurt my baby?

- A small needle is used to poke your baby's heel. Some babies cry when their heel is pricked, but the discomfort does not last long. The benefits of newborn screening, such as saving your baby's life and preventing health problems, outweigh the temporary discomfort that comes with the heel-stick.

Can I say "no" to this test?

- All babies in born in CT automatically receive bloodspot screening
- You can say "no" to the test if it conflicts with your religious beliefs. If you say no to the test, you will be asked to sign a form stating so.

Is there a cost for bloodspot screening?

- The cost for bloodspot screening is included with the hospital birthing and nursery charges. There is no charge for bloodspot screening for a baby born at home.

How do I get the screening results?

- If your baby screens positive (has an out-of-range result) for a disorder, someone from the Newborn Screening Program will call your baby's doctor to report the result.
- A final report of screening results will be sent to your baby's doctor usually 7-14 days after birth. Ask your baby's doctor for bloodspot testing results at the first visit.

More Answers to Your Questions

What does a screen positive result mean?

- It does not mean that your baby is sick or has a disorder. Further evaluation is needed.
- There are many things that can cause a screen positive or out-of-range result
  - A screen positive or out-of-range result can happen:
    - if you took certain medicines while pregnant
    - if your baby was born early
    - if your baby's blood was collected too soon
    - if your baby had certain treatments while in the hospital
    - for many other reasons
- If your baby has a screen positive or out-of-range result your doctor may:
  - examine your baby
  - ask about conditions that run in your family
  - repeat the blood spot screening
  - order additional tests
  - have your baby see a doctor who specializes in newborn screening related disorders

What happens to any leftover blood after screening?

- When bloodspot screening is complete, a very small amount of blood is sometimes left over. The leftover blood will be stored at the CT Public Health Laboratory to allow for any necessary follow-up testing, to help make sure screening is accurate, and to develop new newborn screening tests for Connecticut. Leftover bloodspots are not used for research unrelated to newborn screening.

What does Connecticut NBS test for?

Adrenoleukodystrophy (ALD): ALD is genetic condition where the body cannot break down certain fatty acids causing them to buildup in the cells. This causes damage to the nervous system (the nerves, spinal card and brain). ALD can also cause a problem with hormone production in the adrenal gland. There are different types of ALD ranging from mild to severe. The most severe form affects mostly boys and can cause severe disability and death. Babies with ALD will be monitored by a doctor over a period of time and treatment started if needed.

Amino Acid (AA) Disorders: Amino Acid disorders are a group of disorders that can affect an infant from birth. The body cannot use proteins in some foods like formula, breast milk and meats. If not treated, AA disorders can cause developmental delay, organ damage, breathing problems, seizures and death. A special diet and medicine can help prevent these problems. The CT NBS program tests for over a dozen AA disorders.

Biotinidase (BIO) Deficiency: The body does not have enough of the enzyme necessary to make the vitamin biotin. This can cause skin rashes, weak muscles, hair loss, trouble seeing and hearing and brain damage. A vitamin can help prevent these problems.

Congenital Adrenal Hyperplasia (CAH): With CAH the adrenal glands do not make enough of the hormones cortisol and aldosterone. Untreated, this can cause severe illness or death. CAH is treatable with medication.

Congenital Hypothyroidism (CH): With CH the body does not make enough thyroid hormone. This can cause growth problems and brain damage. Medication can prevent these problems.

Cystic Fibrosis (CF): is a disease that affects the lungs and digestive system. The body produces thick and sticky mucus that can clog the lungs and pancreas. CF can be life-threatening and people with the condition tend to have a shorter-than-normal life span. In CT, CF bloodspot screening is done through the Yale and UConn laboratories.

Fatty Acid Oxidation (FAO) Disorders: Fatty Acid Oxidation Disorders are a group of rare disorders where the body has trouble using fat for energy. This can cause sleepiness, weak muscles, vomiting, low blood sugar, liver problems and death. A special diet and medication can help prevent these problems. The CT NBS program tests for over a dozen FAO disorders.

Galactosemia (GALT): In classical GALT the body cannot use a sugar found in milk, infant formula, breast milk, and other foods. This can cause eye and liver problems, brain damage and death. A special diet can help prevent these problems.

Hemoglobin (Hb) Disease: There are many types of Hb disease where the body produces abnormal blood cells. This can cause anemia, infection, pain, poor growth and death. Medicine and special medical care can help prevent these problems. The CT NBS program tests for many types of Hb problems. Sickle cell anemia is one type of Hb disease.

Hemoglobin (Hb) Traits: Screening for Hb trait will show if you baby is a carrier of a red blood cell disease. This does not mean that your baby is sick. Your doctor will talk to you about what this means and may order additional blood tests.

Mucopolysaccharidosis I (MPS-I): With MPS-I the body doesn't make enough of an enzyme causing a build-up of certain sugars in the cells. There are different forms of MPS-I. The more severe form starts in infancy and can cause developmental delays, vision problems, damage to the bones, joints, heart and other body systems. Enzyme replacement and bone marrow transplant can help prevent some of these problems.

Pompe Disease: With Pompe the body lacks the enzyme needed to breakdown certain sugars causing a build-up in the cells. The most severe form appears in infancy and causes heart problems, breathing problems, muscle weakness and death. Babies with the severe infantile form of Pompe often appear well at birth but can deteriorate quickly. Enzyme replacement can slow the progression of the disease and improve quality of life.

Organic Acid (OA) Disorders: This is a group of disorders where the body cannot use certain proteins and fats in foods. This can cause vomiting, poor feeding, low blood sugar, sleepiness, seizures and death. A special diet and medicine can help prevent these problems. The CT NBS program tests for over a dozen OA disorders.

Severe Combined Immunodeficiency Disorder (SCID): SCID is a rare genetic disorder that causes life-threatening problems with the immune system (the body cannot fight infection). This can cause serious illness and death. Bone marrow transplant is a treatment for SCID. The CT NBS program tests for several different types of SCID.

Spinal Muscular Atrophy (SMA): SMA is a genetic condition that causes muscle weakness and muscle loss. The most severe form can affect the child's ability to crawl, walk, sit up and control head movements and can lead to breathing problems and death. Medication and gene therapy are treatments that can improve breathing, muscle function and survival.

SEE REVERSE FOR MORE INFORMATION

The Connecticut Newborn Screening Program | Phone: 860.920.6628 | Email: dph.nbstracking@ct.gov