

Maine CDC CMV Report



Submitted to the Joint Standing Committee on Health and Human Services



Paul R. LePage, Governor

Maine Center for
Disease Control and Prevention
An Office of the
Department of Health and Human Services

Ricker Hamilton, Commissioner

2017 Report

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EXECUTIVE SUMMARY

December 2017

Background

In 2017, the Maine State Legislature's Committee on Health and Human Services (HHS) directed the Maine Center for Disease Control and Prevention (Maine CDC) to convene a workgroup to review issues surrounding Cytomegalovirus (CMV) exposure at birth or in utero.

“The tasks associated with the workgroup include, but are not limited to making recommendations about:

- *Solutions for infants afflicted with CMV during and after birth,*
- *The most effective public educational resources to inform pregnant women and women who may become pregnant about information regarding the incidence of CMV,*
- *The transmission of CMV during and before pregnancy,*
- *Birth defects caused by CMV,*
- *Methods of diagnosing CMV, and*
- *Available preventative measures and resources for the family of an infant born with CMV.*

The workgroup will meet four times over the year and the work completed will result in recommendations which will be reported to the Legislature by January 31, 2018.”

What is CMV?

Cytomegalovirus, or CMV, is a common virus that infects people of all ages. In the United States, nearly one in three children are already infected with CMV by age five years. Once CMV is in a person's body, it stays there for life and can reactivate.

Most people infected with CMV show no signs or symptoms. That's because a healthy person's immune system usually keeps the virus from causing illness. However, CMV infection can cause serious health problems for people with weakened immune systems, as well as babies infected with the virus before they are born called congenital CMV (cCMV).

cCMV Prevalence In Maine

- An average of 12,500 babies are born in Maine each year, average for recent years.
- 250 newborns do not pass their hearing screening in Maine and are referred for audiology follow-up.
- 1,050 newborns pass their hearing screening, but have reported risk factors for cCMV.
 - This includes infants that have a diagnosis of cCMV, but passed a hearing screen
 - Recommended follow-up is three months to 36 months
- 62 (0.49%) babies are diagnosed with cCMV in Maine in a typical year.

CMV Workgroup Recommendations

1. Provide education on the causes, symptoms and prevention of cCMV to all parents, caregivers, and providers working with children, infants, and pregnant women.
2. Convene a workgroup to develop and disseminate educational information and materials to key stakeholder groups.
3. Require a targeted screening approach with the long-term goal of universal screening.
4. Explore the option of utilizing bloodspot tests to screen for cCMV.

Background and Introduction

In 2017, the Maine State Legislature's Committee on Health and Human Services (HHS) directed the Maine Center for Disease Control and Prevention (Maine CDC) to convene a workgroup to review issues surrounding Cytomegalovirus (CMV) exposure at birth or in utero. *"The tasks associated with the workgroup include, but are not limited to making recommendations about:*

- *Solutions for infants afflicted with CMV during and after birth,*
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- *The transmission of CMV during and before pregnancy,*
- *Birth defects caused by CMV,*
- *Methods of diagnosing CMV, and*
- *Available preventative measures and resources for the family of an infant born with CMV.*

The workgroup will meet four times over the year and the work completed will result in recommendations which will be reported to the Legislature by January 31, 2018."

In response to this directive, the Maine CDC convened a group of parents, pediatricians, obstetricians, otorhinolaryngologists, audiologists, pediatric audiologists, delivery nurses, midwives, infectious disease specialists, child development experts, Maine CDC Epidemiologist and Medical Director as well as the state employees in the newborn screening program. See Appendix 1 for a complete list.

The group met four times in 2017 to discuss the CMV issues and develop a recommendation report: May 1, July 10, September 11, and November 28. These meetings were facilitated by Market Decisions Research and this contractor prepared the final report.

This report summarizes the information gleaned by the workgroup and shares its final recommendations with the HHS Committee.

What is CMV and What are Its Health Effects?

U.S. CDC Information on CMV¹

Prevalence

Over half of adults by age 40 have been infected with CMV. The virus stays in the body for life and can reactivate. For most people, CMV goes undetected and never creates any illness. However, people with weakened immune systems and babies infected with the virus before they are born (congenital CMV) are vulnerable to problems due to the virus.

About one out of every 200 babies in the U.S. (0.4% to 1%) is born with congenital CMV (cCMV) infection. Of those with the infection, one in five babies will become ill or have long-term health problems. Congenital CMV is the most common viral cause of birth defects and leading non-genetic cause of hearing loss in the U.S., it is more common than better known causes of birth defects such as down syndrome, spina bifida, and fetal alcohol syndrome.

Transmission

CMV is transmitted via body fluids, such as urine, saliva, blood, tears, semen, and breastmilk. People infected with CMV can spread the virus in the following ways:

- From direct contact with urine or saliva, especially from babies and young children
- Through sexual contact
- From breastmilk
- Through transplanted organs and blood transfusions
- From mother to child during pregnancy (congenital)

CMV is common among healthy children one to three years of age who attend daycare and can easily spread the CMV virus among their peers. CMV is not generally harmful to these children and most do not exhibit signs or symptoms of infection. Contact with the saliva or urine of young children is a major cause of CMV infection among pregnant women, especially mothers, daycare workers, preschool teachers, therapists, and nurses. Regular hand washing, particularly after changing diapers, is a commonly recommended step to decrease the spread of infections, and may reduce exposures to CMV.

Symptoms

Most babies with cCMV infection never show signs of infection or have health problems. However, some babies with cCMV do have health problems at birth or may develop them later during infancy or childhood. In rare cases, it can cause pregnancy loss or infant death.

The signs of cCMV at birth include:

- Premature birth
- Liver, lung and spleen problems
- Small size at birth
- Small head size
- Seizures

¹ Cytomegalovirus (CMV) and Congenital CMV Infection <https://www.cdc.gov/cmV/overview.html>

Some babies with signs of cCMV infection at birth may have long-term health problems, such as:

- Hearing loss
- Vision loss
- Intellectual disability
- Lack of coordination
- Weakness or problems using muscles
- Seizures

Hearing loss may be present at birth or may develop later in babies who passed their newborn hearing test.² However, not all babies with hearing loss have cCMV.

Studies show that:

- 10% of infants with cCMV will have immediate signs at birth, and
- 40% to 60% of infants with cCMV will have hearing loss, cognitive impairment, retinitis, and or cerebral palsy that may present in the days, weeks, and months after birth.³

Diagnosis

Congenital CMV infection can be diagnosed by testing a newborn baby's saliva, urine, or blood. To confirm a diagnosis, specimens must be collected for testing within two to three weeks after the baby is born.

Currently, universal screening of babies for cCMV is not carried out. Most providers who screen for cCMV, do so after a baby fails two hearing screenings.

Treatment and Management

Medicines, called antivirals, may decrease the risk of health problems and hearing loss in some infected babies who show signs of congenital CMV infection at birth. However, the *use of antivirals for treating babies with congenital CMV infection who have no signs at birth is not currently recommended.*

Babies with congenital CMV infection, with or without signs at birth, should have regular hearing checks and developmental screenings.

² Cytomegalovirus (CMV) and Congenital CMV Infection <https://www.cdc.gov/cmV/overview.html>

³ A Targeted Approach for Congenital Cytomegalovirus Screening Within Newborn Hearing Screening" Karen Fowler, DrPH

Scientific and Medical Community Guidance on CMV

The workgroup reviewed the following:

- Peer reviewed journal articles on CMV.
- Recommendations from a convening of international experts on CMV and cCMV.
- Findings from other states that have implemented screening.
- Practice guidelines from U.S. CDC and American College of Obstetricians and Gynecologists.

The medical community, as well as scientific literature, support the following:

- **Education about CMV transmission is important** and can help reduce the spread of infection.
- Universal screening of **pregnant women** is not recommended.
- **Screening of newborns is recommended.** Targeted screening is helpful in identifying cases, but misses 43% of cCMV cases.
- **Early referral and treatment of infected newborns is strongly recommended and improved health outcomes for those who have been verified.**

Journal Articles Reviewed
Demmler-Harrison, G. J. (2016). Congenital Cytomegalovirus Infection. <i>JAMA Pediatrics</i> , 170(12), 1142. doi:10.1001/jamapediatrics.2016.2892
Diener, M. L., Zick, C. D., Mcvigar, S. B., Boettger, J., & Park, A. H. (2017). Outcomes From a Hearing-Targeted Cytomegalovirus Screening Program. <i>Pediatrics</i> , 139(2). doi:10.1542/peds.2016-0789
Fowler, K. B., Mccollister, F. P., Sabo, D. L., Shoup, A. G., Owen, K. E., Woodruff, J. L., . . . Boppana, S. B. (2017). A Targeted Approach for Congenital Cytomegalovirus Screening Within Newborn Hearing Screening. <i>Pediatrics</i> , 139(2). doi:10.1542/peds.2016-2128
Gantt, S., Dionne, F., Kozak, F. K., Goshen, O., Goldfarb, D. M., Park, A. H., . . . Fowler, K. (2016). Cost-effectiveness of Universal and Targeted Newborn Screening for Congenital Cytomegalovirus Infection. <i>JAMA Pediatrics</i> , 170(12), 1173. doi:10.1001/jamapediatrics.2016.2016
Rawlinson, W. D., Boppana, S., Fowler, K. B., Kimberlin, D. W., Lazzarotto, T., Alain, S., Daly, K., Doutré, S., Gibson, L., Giles, M. L., Greenlee, J., Hamilton, S. T., Harrison, G. J., Hui, L., Jones, C. A., Palasanthiran, P., Schleiss, M. R., Shand, A., Van Zuylen, W. J. (2017). Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy. <i>Lancet Infectious Diseases</i> . doi:10.1016/S1473-3099(17)30143-3 http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(17)30143-3/fulltext

Maine Congenital CMV Prevalence

- An average of 12,500 babies are born in Maine each year, average for recent years.
- 250 newborns do not pass their hearing screening in Maine and are referred for audiology follow-up.
- 1,050 newborns pass their hearing screening, but have reported risk factors for cCMV.
 - This includes infants that have a diagnosis of cCMV, but passed a hearing screen
 - Recommended follow-up is three months to 36 months
- 62 (0.49%) babies are diagnosed with cCMV in Maine in a typical year.

What is Currently Happening in Maine to Address CMV

Education for Providers and Parents

- Unknown prevalence of provider knowledge of cCMV.
- Unknown if education is provided to mothers. There is no evidence of this occurring routinely and if there's consistency in the education across the State.
- Education is not routinely provided to daycare providers or other caregivers of small children.

Maine Birth Hospitals/Health Systems

Some providers currently implement a targeted cCMV screening for newborns who fail two hearing tests, however no common approach has been adopted in Maine.

U.S. States' Legislation on CMV – A Summary of Final Legislative Mandates

The workgroup reviewed efforts to address congenital CMV in other states. The following includes a high-level summary of what states are doing to address CMV.

Both Screening and Education

- Four states, Illinois, Iowa, Oregon and Utah, require both education for the public and providers, as well as targeted newborn screening after two failed hearing tests.

Education

- Seven states require the state to educate the public and professionals about congenital CMV: Hawaii, Idaho, Illinois, Iowa, Oregon, Texas, and Utah.
- Tennessee requires healthcare providers to educate women of childbearing age.
- Only Utah has legislation that is accompanied by ongoing funding (\$70,000 per year). Idaho has proposed \$15,000 per year.

Screening

- Connecticut, Iowa, and Utah require each newborn that fails the newborn hearing screening to be tested for congenital CMV.
- Illinois requires that a CMV test be offered to the parents of every child who fails the newborn hearing screening.

Proposed Legislative Mandates

- Education and Screening: New York and Pennsylvania.
- Education: Michigan and Minnesota.
- In 2017, Maine proposed universal newborn CMV screening. While the legislation did not pass, the legislature established a committee to investigate universal CMV screening to provide a recommendation to the HHS Committee in 2018.

Table 1. Summary of Actions Taken by States to Address Congenital CMV

State	Education	Screening after Failed Hearing Test	Requires Both
Utah	✓	✓	✓
Illinois	✓	✓	✓
Oregon	✓	✓	✓
Iowa	✓	✓	✓
Hawaii	✓		
Texas	✓		
Connecticut		✓	
Tennessee	✓		
Idaho	✓		
Proposed Legislation			
New York	✓	✓	✓
Pennsylvania	✓	✓	✓
Michigan	✓		
Minnesota	✓		

Maine CMV Workgroup Recommendations

Based on the information gathered about CMV, the workgroup identified a comprehensive set of options and identified the critical components/considerations for each. A matrix was created to compare the components of each option. See Tables 2 and 3. From this analysis and using their professional expertise and experience, the group developed the following recommendations.

**There is a Critical Need to Address Congenital CMV with Parents,
Caregivers, and Newborns in Maine**

1. *Provide education on the causes, symptoms and prevention of cCMV to all parents, caregivers, and providers working with children, infants, and pregnant women.*

2. *Convene a workgroup to develop and disseminate educational information and materials to key stakeholder groups, including but not limited to the groups listed in Table 4.*

Early education about CMV among pregnant women, their families and their newborn babies is critical for the following reasons:

- The prevalence of cCMV is higher than many other neonatal conditions that are currently addressed in pre-natal education and screening;
 - The health impacts on the afflicted baby are severe and can impact healthy development;
 - Early intervention can reduce the long-term impact, ultimately supporting healthy development and avoiding future health complications.
 - Most adults, including parents and women of child-bearing age, are not aware of CMV, despite the fact that over 40% currently have the virus.
 - Educating families and care-givers about prevention can reduce the number of cases in Maine.
3. *Require a targeted screening approach with the long-term goal of universal screening.*

The workgroup recommends that providers be required to screen newborn babies for cCMV at the time of birth. The group supports the long-term goal of universal saliva/urine screening because it is currently thought to be the most reliable means of early detection. However, given the practicality and potential cost of universal saliva/urine screening, the group urges the legislature to require targeted screening for newborn babies after two failed hearing tests, or the presence of other risk factors, before hospital discharge.

4. *Explore the option of utilizing bloodspot tests to screen for cCMV.*

Maine has an opportunity to participate in a long-term review of the efficacy of using blood spot to detect cCMV through the University of Minnesota. The workgroup encourages the Maine CDC to explore the benefits and costs of participating in this study or others like it.

Table 2. Comparing Options to Detect Congenital CMV on Key Factors

	Universal Screening Using Saliva/Urine	Universal Screen Using Bloodspot	Universal Screen Using Bloodspot with targeted saliva/urine testing	Targeted Screen Using Saliva (after 2 failed hearing screens or presentation of other risk factors)	Education
Cost and cost considerations	<ul style="list-style-type: none"> • Highest cost • 0.5 – 2 FTEs for managing the process at ME CDC 	<ul style="list-style-type: none"> • Cost for testing bloodspot is incremental to current bloodspot tests • 0.5 – 2 FTEs for managing the process at ME CDC Good reach and cost-effectiveness • Half the cost of universal saliva/urine 	<ul style="list-style-type: none"> • Potentially high cost • Half the cost of universal saliva/urine • Best reach and cost-effectiveness • Cost for testing blood-spot is incremental to current bloodspot tests • 0.5 – 2 FTEs for managing the process at ME CDC 	<ul style="list-style-type: none"> • Lower cost • Not automatic test – needs to be included in neonate tests (technically not mandated) • 0.5 FTE for managing the process at ME CDC 	<ul style="list-style-type: none"> • Costs are low and include staff time, material development, and outreach • Education is necessary, but not sufficient, more is needed.
Implementation Considerations	<ul style="list-style-type: none"> • Labor intensive in sample collection from the newborns • Specimen interference (collection issues with saliva and breastfeeding, also urine) 	<ul style="list-style-type: none"> • Same downsides as Universal Bloodspot with targeted saliva • Explore using bloodspot tests as a way to screen for cCMV 	<ul style="list-style-type: none"> • Laboratories can handle the volume • 1st state to do this 	<ul style="list-style-type: none"> • Specimen interference • Labor intensive 	<ul style="list-style-type: none"> • Materials exist, they can be re-branded for Maine • Education needs to occur in childcares, providers, pregnant women, others who care for pregnant women
Outcomes	<ul style="list-style-type: none"> • False positives can occur 	<ul style="list-style-type: none"> • False positives can occur or positives with no symptoms • Lacks targeted screening/still have to happen if positive blood spot 	<ul style="list-style-type: none"> • Efficacy based on a study with a low number of babies 	<ul style="list-style-type: none"> • Studies show it misses 43% of babies affected with CMV • Can have false positives 	<ul style="list-style-type: none"> • Can be used to support/raise awareness of a new standard of testing

	Universal Screening Using Saliva/Urine	Universal Screen Using Bloodspot	Universal Screen Using Bloodspot with targeted saliva/urine testing	Targeted Screen Using Saliva (after 2 failed hearing screens or presentation of other risk factors)	Education
Benefits	<ul style="list-style-type: none"> Will detect most cases of CMV 	<ul style="list-style-type: none"> Newborns already have the bloodspot test administered No time limitation on usefulness of sample Bloodspot test cannot be used for research According to Dr. Schleiss, will detect most cases of CMV 	<ul style="list-style-type: none"> Newborns already have the bloodspot test administered No time limitation on usefulness of sample Bloodspot test cannot be used for research 	<ul style="list-style-type: none"> Exceeds current standard of care Starting point for introducing test in Maine Other states are doing this Maybe put this in the current Hearing Legislation as a rule change 	<ul style="list-style-type: none"> Can lead to actions that will reduce numbers of infections This would be better than no action, and will be more than what is currently happening

Table 3. Estimated Annual Laboratory Costs CMV Testing for Newborns

Laboratory	Universal Saliva (12,500/year)	Universal Bloodspot (12,500/year) Targeted Saliva (300/year)	Targeted Bloodspot (After 2 failed hearing screens or presentation of other risk factors) (300/year)	Targeted Saliva (After 2 failed hearing screens or presentation of other risk factors) (300/year)
Health and Environmental Testing Laboratory Saliva: \$110.00 DBS: \$110.00	\$1,375,000 plus cost of courier and collection equipment	\$1,375,000 plus cost of courier and collection equipment	\$33,000 plus cost of courier and collection equipment	\$33,000 plus cost of courier and collection equipment
ARUP Saliva: \$75.00 DBS: \$60.00	\$937,500 plus cost of courier and collection equipment	\$750,000 plus cost of courier and collection equipment	\$18,000 plus cost of courier and collection equipment	\$22,500 plus cost of courier and collection equipment
Minnesota Cohort	N/A	\$260,000 plus cost of courier and collection equipment	N/A	N/A

Table 4. Key Audiences for CMV Education, Listed by Role in Prevention, Detection, and Treatment

Prevention	Detection (21-day period)	Treatment/ Follow up	Medical Provider Associations
<ul style="list-style-type: none"> • Public and Partner Websites • Pediatricians • Obstetrics • Provider offices • Midwives • Centering pregnancy groups • Family Practitioners • Daycares/Care Providers • DONA International: Doulas • Women, Infants and Children (WIC) • March of Dimes • Family Planning • Public Health Nursing • CradleME/Maine Families • Licensing-daycares • Birth Roots • Birthing Classes • La Leche League • City Health Departments/Maine Health Districts • Epidemiologists 	<ul style="list-style-type: none"> • Hospitals/Nurseries • Midwives • Audiologists • Ear, Nose and Throat Care (ENT) • Pediatrics • Perinatal Leadership Coalition • Newborn Hearing Program 	<ul style="list-style-type: none"> • Audiologists • Child Development Services • Pediatrics/Family Practitioners • Public Health Nursing • Newborn Hearing Program • Schools/Daycares 	<ul style="list-style-type: none"> • Maine Medical Association • American Academy of Pediatrics • Association of Women's Health, Obstetric and Neonatal Nurses • Maine Osteopathic Association • American Congress of Obstetricians and Gynecologists • American College of Nurse-Midwives • American Academy of Family Physicians • Certified Physician Assistants • Maine Quality Counts • Maine Public Health Association • Maine Primary Care Associates • Maine Association of Certified Professional Midwives

Appendix 1. CMV Workgroup Participants

Area of Specialty	Name
Infectious Disease Specialist	<p>Dr. Siiri Bennett Maine CDC-P</p> <p>Mary Herbert-Grant, MD Eastern Maine Health</p>
Obstetrician	Danielle Salhainey, DO MidCoast Hospital
Pediatrician	<p>Christopher Pezzullo, DO Maine CDC-P Medical Director</p> <p>Andrew Tenenbaum, DO InterMed</p>
Family Physician involved with the management of pregnancy and delivery of newborns	Jack Forbush, DO Osteopathic Center for Family Medicine Hampden, ME
Nurse Midwife	Angela Ripley, CNM Maine General Midwifery
Labor and Delivery Nurse or Nurse Manager	Donna Stevens, RN Women & Infants Health Care Unit Waldo County General Hospital
Parent of a child that has been affected with a birth defect resulting from an infection with CMV	Laura Sweet Parent
Midwife who performs home births	Holly Arends Murphy, CPM Birch Moon Midwifery Penobscot, ME 04476
One (1) physician from each of the 4 birthing hospitals with neonatal intensive care units who provide acute nursery care to newborns affected by CMV	<p>MMC: Chris Murry, DO Otolaryngology</p> <p>MGMC: Stephen Meister, MD Edmund Ervin Pediatric Center Ballard Center</p> <p>EMMC: Mark Brown, MD Neonatal Perinatal Medicine</p>

Area of Specialty	Name
	CMMC: Sheila Carroll, MD Medical Director Pediatrics Lewiston
EHDI Representative from CDC	Maryann Harakall Maternal Child Health Program Director Maine CDC-P Betsy Glencross Maine Newborn Hearing Coordinator Maine CDC-P Duska Thurston, MD EMMC Family Medicine Center and Residency Karen Hopkins Director of Early Childhood Education and Family Services Maine Educational Center for the Deaf and Hard of Hearing
EHDI Audiologists	Nicole Duncan, Au.D., CCC-A, FAAA, PASC Warren Center for Speech and Hearing Bangor Stacia L Thomas, AuD Educational Audiologist Maine Educational Center for the Deaf and Hard of Hearing Falmouth
Child Development Services (CDS)	Roy K. Fowler, M.Ed., Director Child Development Services Augusta
March of Dimes	Abby Rogers, Director of Advocacy and Government Affairs for Maine, New Hampshire and Vermont
Joint Advisory Committee for Newborn Screening Advisory Group Appointed Representative	Christopher Pezzullo, DO Maine CDC-P Medical Director
Newborn Screening Program Staff	Betsy Glencross Newborn Hearing Coordinator Maine CDC-P/Division of Disease Prevention/CSHN

Area of Specialty	Name
	<p>Shirley Helms, RN Bloodspot Screening Coordinator Maine CDC-P/Division of Disease Prevention/CSHN</p> <p>Holly Richards, MPH Newborn Screening Program Manager Maine CDC-P/Division of Disease Prevention/CSHN</p>
Facilitator	<p>Patricia Hart Vice President, Evaluation Market Decisions Research</p>
Sign Language Interpreters	<p>Julia Schafer Mary Jane Grant Sign Language Interpreting Services, LLC</p> <p>Marisa Zastrow Mary Jane Grant Sign Language Interpreting Services, LLC</p>
CMV Expert	<p>Dr. Mark Schleiss University of Minnesota Medical School Director, Division of Infectious Diseases and Immunology Professor, Department of Pediatrics Co-Director, Center for Infectious Diseases and Microbiology Translational Research Investigator, Institute for Molecular Virology</p>



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