Congenital Cytomegalovirus Infection (cCMV): Natural History, Diagnostic Testing & Available Treatments



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# Disclosures

- Advisory Panel Pfizer, Avalere
- Advisory Council Moderna, Valneva
- Site PI, multicenter clinical trials Regeneron, Pfizer, GSK
- Site Sub-I, multicenter clinical trials Novavax

## **Congenital and Perinatal Infections**

Т	Toxoplasma gondii
0	Other: varicella, parvovirus, Zika
R	Rubella
С	Cytomegalovirus
Η	Herpes simplex, hepatitis B, hepatitis C, HIV
S	Syphilis

# **Congenital CMV**

- Most common congenital infection
  - 0.5%-0.7% of live births in US
    - 1 in 150-200 live-births
    - 20,000-31,500 newborns annually
  - Asymptomatic ~ 90%
  - Symptomatic ~ 10%

 A leading cause of sensorineural hearing loss (SNHL) and neurodevelopmental delay

# Cytomegalovirus



- Herpesvirus family
  - Capacity to infect multiple types of cells
  - Life-long persistent infection
    - Latency
    - Periods of active replication
      - Intermittent shedding from infected cells
        - Urine, saliva, cervicovaginal secretions, semen, breast milk, tears, blood products, transplanted organs
        - CMV can survive on hands and contaminated surfaces

# **CMV: Transmission**



#### Horizontal

- Children in childcare and childcare workers saliva
- Adolescents and young adults young children and sexual
- Transfusion and Transplantation infected blood product or organ
- Vertical
  - Congenital transplacental
  - Perinatal during birth, breast milk



### Young Children are an Important Source of CMV for Young Adults and Pregnant Women

#### • NHANES

- Prevalence of CMV IgG antibody
  - 2011-12
  - 2017-18
- Higher seroprevalence: ethnic/racial minority groups, exposure to breast milk and/or other children
- Shedding is highest in 1-2 y/o
  - Day care centers

Clinical Infectious Diseases

Changes in Cytomegalovirus Seroprevalence Among U.S. Children Aged 1–5 Years: The National Health and Nutrition Examination Surveys

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	2011–2012 <sup>ª</sup>	2017–2018 <sup>ª</sup>	
Characteristic	Prevalence, % (95% Cl)	Prevalence, % (95% Cl)	
Overall	20.7 (14.0, 29.0)	28.2 (23.1, 34.0)	
Age, y			
1	12.3 (6.4, 20.6)	23.3 (16.4, 31.5)	
2–3	20.0 (11.7, 30.7)	24.5 (16.2, 34.4)	
4–5	24.2 (16.6, 33.2)	33.9 (24.0, 44.9)	

# Cytomegalovirus



- Over 50% of US population infected by age 40 yrs
- 1-4% of women will become infected with CMV during a pregnancy
- 50-75% of cCMV occurs in infants born to mothers infected before they became pregnant
  - cCMV prevalence increases with increasing maternal seroprevalence

### In utero CMV Transmission from Mother to Fetus



Primary infection

- 30% transmission rate
- Approximately equal rate regardless of trimester infection occurs

- More severe outcomes with infection in 1<sup>st</sup> trimester

### In utero CMV Transmission from Mother to Fetus



- Non-primary infection
  - Reactivation
    - Lower transmission rate, but increasing percentage of cases based on CMV prevalence
    - Infant less likely to be symptomatic
  - Reinfection
    - Immunity not complete
    - New serotype
    - Risk of cCMV may be as high as primary infection

# Healthy persons – minimal manifestations

Cytomegalovirus

- Pregnant women, > 90% of primary infections are asymptomatic
- Serious disease
  - Congenital infection
  - Immunosuppressed persons
    - Solid organ or bone marrow transplants, AIDS

# **Symptomatic congenital CMV: Manifestations**

- Intrauterine growth restriction (IUGR)
- Thrombocytopenia, purpura
- Hepatitis, pneumonitis
- Jaundice
- Hepatosplenomegaly
- Microcephaly
- Intracerebral calcifications
- Retinitis
- Mortality: ~ 4%













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#### Racial and Ethnic Differences in the Prevalence of Congenital Cytomegalovirus Infection

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- **2007-2012**
- 100,322 infants from 7 medical centers
- Prevalence (per 1000 live births)
  - Overall 4.5
  - Black 9.5
  - Multiracial 7.8
  - Hispanic 3.0
  - Non-Hispanic white 2.7
  - Asian 1
- Symptomatic (9.6%) and SNHL (7.8%) same across groups





Table III. Unadjusted race and ethnicity	l and aPORs for cC	MV infection by
	POR (95% CI)	aPOR (95% CI)*
Infant race and ethnicity		
Black, non-Hispanic	3.5 (2.8-4.5)	1.9 (1.4-2.5)
Multiracial	2.9 (1.8-4.8)	1.9 (1.1-3.0)
White, Hispanic	1.1 (0.8-1.5)	0.7 (0.5-1.0)
Asian	0.4 (0.1-1.0)	0.6 (0.2-1.2)
White, non-Hispanic	1.0	1.0

aPOR, Adjusted prevalence OR.

\*Model included race and ethnicity, insurance status, and maternal age.

J Pediatr 2018;200:196-201

## **Congenital CMV: Outcomes**

#### Symptomatic infection

- 40-60% develop permanent sequelae
  - Sensorineural hearing loss
  - Vestibular dysfunction
  - Cognitive impairment
  - Developmental delays
  - Retinitis
- Asymptomatic infection
  - Sensorineural hearing loss
  - Vestibular dysfunction

## **SNHL with cCMV**

- Most common sequelae
- Loss is variable
  - Mild unilateral to profound bilateral
  - Fluctuate
  - Delayed-onset
- Pathogenesis: may be a combination of viralmediated damage and host inflammatory response





#### Figure 1. Estimates of Causes of Deafness at Birth and at Four Years in the United States.

The incidence of deafness at birth in the United States, and its prevalence at four years of age, were obtained by adjusting estimates from the United Kingdom<sup>11,12</sup> (where, in contrast with the United States, follow-up is nearly complete) to include unilateral hearing loss. The overall proportion of genetic cases at four years of age was estimated by sentinel phenotype analysis.<sup>13</sup> Estimates for specific causes were obtained from previously published data (as documented in the Supplementary Appendix, available with the full text of this article at www.nejm.org). No studies were available in which universal newborn testing was performed for more than one specific cause of deafness in the same population sample. CMV denotes cytomegalovirus, mtA1555G the mitochondrial A1555G mutation, and EVA enlargement of the vestibular aqueduct.

# Natural History of Hearing Loss in cCMV

Hearing Loss	Symptomatic	Asymptomatic
Total	33-40%	7-10%
Characteristics of Loss		
Bilateral	67-71%	43-48%
<b>Delayed onset</b>	<b>18-27%</b>	9-38%
Median age (and range of delayed onset)	33 mos (6-197 mos)	44 mos (24-182 mos)
Progressive	<b>18-54%</b>	<b>20-54%</b>
Fluctuating	21-22%	24-48%
Severe-profound loss	75%	78%

Summary from 4 studies. Antiviral Res 2021;191:1-5

## Cumulative Percentage of Sensorineural Hearing Loss by Age

Age	Symptomatic	A <u>symptomati</u>	
Birth – 1 month	43.5%	25.5%	
3 months	55.3%	31.4%	
6 months	67.2%	43.1%	
2 years	82.4%	47.1%	
3 years	88.2%	58.8%	
4 years	89.4%	72.5%	
6 years	95.3%	86.6%	
7 – 15 years	100%	100%	

*J Am Acad Audiol* 2000;11(5):283-90

#### Vestibular, Gaze, and Balance Disorders in Asymptomatic Congenital Cytomegalovirus Infection

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- Comprehensive vestibular, gaze, and balance assessments
- 40 children with asymptomatic cCMV
  - 17.5% with SNHL (2 each with mild, moderate-severe and profound) vs 33 Controls
- RESULTS: Vestibular disorders in 45% of cohort
  - 46% had difficulties maintaining gaze during head movement
  - 1/3 1/2 with difficulties maintaining balance

# Cognitive Impairment and Cerebral Palsy in Symptomatic cCMV

Outcome	Percentage
IQ < 70	40%
Motor deficits	<b>20%</b>
Seizures	19%

J Pediatr 2014;164:855-859 Pediatr Infect Dis J 2016;35:924-926 Antiviral Res 2021;191:1-5

Effect on Brain Development Based on Trimester of Infection

- 1<sup>st</sup> trimester
  - Neural stem cells which differentiate into neurons and glia are infected

 Interruption of organogenesis, abnormal neuronal migration



#### FIGURE 2

Typical fetal brain development and resultant congenital cytomegalovirus-associated neuropathology by timing of maternal infection and vertical transmission. Processes of fetal neurodevelopment distal to timing of fetal infection may be affected by CMV-associated placental injury, inflammatory response, and fetal central nervous system infection.<sup>91,113,114</sup>

#### Intelligence and Academic Achievement With Asymptomatic Congenital Cytomegalovirus Infection

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- Longitudinal study of infants identified by newborn screening vs controls through childhood and adolescence (92) vs unmatched controls (42) born within 6 days of infant
- 20 patients (11 by age 2 yrs, 9 moderate to profound) and 3 controls (9-15 yrs) developed SNHL

- Results:
  - No differences in IQ, vocabulary or academic achievement scores in subjects with normal hearing at age 2 yrs
  - Subjects with SNHL
    - full-scale intelligence score 7.0 points lower
    - Receptive vocabulary scores 13.1 points lower

### Maternal-infant transmission of CMV

- Transplacental (Congenital)
- Intrapartum (Perinatal) incubation period: 3-4 weeks
  - Cervical secretions
    - CMV positive: 5% 24%, transmission rate: 26% 56%
- Postpartum (Postnatal) incubation period: 3-4 weeks
  - Human milk
    - CMV positive: 13% 32%, transmission rate: 29% 59%
- No sequalae of perinatal or postnatal infection

# **Diagnosis of Congenital CMV**

 Virologic detection within 3 weeks of birth is necessary to differentiate cCMV from perinatal or postnatal infection transmission

#### CMV DNA PCR has replaced culture

- Urine or saliva sensitivity 97-100%
  - Saliva wait 1 hour after breast feeding
    - False positive rate 0.03-0.14%<sup>1</sup>
  - Saliva positive; confirm with urine
- Respiratory tract, blood, CSF, amniotic fluid
- Serologic diagnosis
  - IgG no value, maternal transfer
  - IgM false positives common



### **cCMV** Treatment

- Randomized, placebo-controlled trial
  - 6 wks vs 6 mos; 96 participants
- End points
  - Primary: change in better ear at 6 months
  - Secondary: total ear hearing and developmental outcomes at 12, 24 mos
- Outcome:
  - No improvement in short term (P=0.24 at 6 mos)
  - Modest improvement in hearing and developmental outcomes in longer term

#### Valganciclovir for Symptomatic Congenital Cytomegalovirus Disease

D.W. Kimberlin, P.M. Jester, P.J. Sánchez, A. Ahmed, R. Arav-Boger, M.G. Michaels, N. Ashouri, J.A. Englund, B. Estrada, R.F. Jacobs, J.R. Romero, S.K. Sood, M.S. Whitworth, M.J. Abzug, M.T. Caserta, S. Fowler, J. Lujan-Zilbermann, G.A. Storch, R.L. DeBiasi, J.-Y. Han, A. Palmer, L.B. Weiner, J.A. Bocchini, P.H. Dennehy, A. Finn, P.D. Griffiths, S. Luck, K. Gutierrez, N. Halasa, J. Homans, A.L. Shane, M. Sharland, K. Simonsen, J.A. Vanchiere, C.R. Woods, D.L. Sabo, I. Aban, H. Kuo, S.H. James, M.N. Prichard, J. Griffin, D. Giles, E.P. Acosta, and R.J. Whitley, for the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group



Figure 2. Cytomegalovirus DNA Viral Load in Whole Blood in Participants Receiving the Study Therapy. Participants with a viral load of less than 100 were assessed as having a viral load of 10 (i.e., 1.0 in the graph). P values are for the between-group comparisons at the respective time points.

#### Valganciclovir for Symptomatic Congenital Cytomegalovirus Disease

D.W. Kimberlin, P.M. Jester, P.J. Sánchez, A. Ahmed, R. Arav-Boger, M.G. Michaels, N. Ashouri, J.A. Englund, B. Estrada, R.F. Jacobs, J.R. Romero, S.K. Sood, M.S. Whitworth, M.J. Abzug, M.T. Caserta, S. Fowler, J. Lujan-Zilbermann, G.A. Storch, R.L. DeBiasi, J.-Y. Han, A. Palmer, L.B. Weiner, J.A. Bocchini, P.H. Dennehy, A. Finn, P.D. Griffiths, S. Luck, K. Gutierrez, N. Halasa, J. Homans, A.L. Shane, M. Sharland, K. Simonsen, J.A. Vanchiere, C.R. Woods, D.L. Sabo, I. Aban, H. Kuo, S.H. James, M.N. Prichard, J. Griffin, D. Giles, E.P. Acosta, and R.J. Whitley, for the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group

### **cCMV** Treatment

- Total-ear hearing improved or remained normal
  - 12 mos (73% vs 57%. P=0.001) [OR = 3.04, 95% CI 1.26 to 7.35]
  - 24 mos (77% vs 64%, P=0.04) [OR = 2.61, 95% CI 1.05 to 6.31]
- Bayley III Components at 24 mos
  - Cognitive composite (P=0.02)
  - Language composite (P=0.004)
  - Receptive-communication (P=0.003)
  - Expressive-communication (P=0.02)
  - Gross motor (P=0.02)

# Standardizing manifestations to improve analysis of treatment outcomes

- Mildly symptomatic
  - Presence of 1-2 isolated manifestations, often transient
- Moderately to severely symptomatic
  - Presence of multiple attributable manifestations or central nervous system manifestations or both
- Asymptomatic
  - Normal or isolated SNHL in newborn period

# Current Recommendations for Antiviral Therapy of Infants with cCMV

- Moderate to severe symptomatic disease
  - Valganciclovir (16mg/kg/dose, PO, BID for 6 months)
    - Begin treatment <1 month of age</li>
    - Side-effects: neutropenia (~20%), elevated LFT's
  - Can use ganciclovir IV if PO not indicated
- Mild disease or isolated SNHL should not receive antiviral treatment

#### **TABLE 1** On-Going and Recently Completed Studies of Congenital Cytomegalovirus Related Therapeutics, Prevention, and Vaccines

Clinical Trial Number, Principal Investigator, Institution or Sponsor	Phase	Intervention	Primary Objective	Population
Antiviral medication for infants with cCMV				
NCT03301415 National Institute of Allergy and Infectious Diseases <sup>115</sup>	Phase 2	Valganciclovir, 16 mg/kg per dose provided orally twice daily for 4 mo	To evaluate valganciclovir as a treatment to prevent development of SNHL in infants with asymptomatic cCMV infection	229 newborns with asymptomatic cCMV without baseline SNHL
NCT03107871 Albert Park, University of Utah, National Institute of Deafness and Other Communication Disorders, Genentech, Inc. <sup>116</sup>	Phase 2	Valganciclovir, 16 mg/kg per dose or placebo provided orally twice daily for 6 mo	To determine if valganciclovir treatment reduces the mean slope of total hearing thresholds over the 20 mo after randomization compared with placebo in cCMV-infected asymptomatic infants with isolated hearing loss	52 infants with asymptomatic cCMV and isolated SNHL
NCT02005822 Ann C.T.M. Vossen, Leiden University Medical Center, Netherlands <sup>117</sup>	Phase 3	Valganciclovir, 16 mg/kg per dose provided orally twice daily for 6 wk	To investigate whether early treatment with oral valganciclovir of infants with both congenital cytomegalovirus infection and sensorineural hearing loss can prevent progression of hearing loss	37 infants with cCMV and SNHL

Maternal immunoglobulin to prevent vertical transmission				
NCT05170269 Biotest AG	Phase 3	Cytotect CP Biotest (BT097), 200 U/kg IV weekly every 2 wk until at least GW 17	To demonstrate efficacy and safety of Cytotect CP Biotest in preventing maternal-fetal transmission of CMV	80 pregnant women with primary CMV infection
Maternal behavioral intervention to prevent CMV infection				
NCT04615715 Karen Fowler, University of Alabama at Birmingham <sup>49</sup>	NA	Prenatal clinic-based CMV risk-reduction behavioral intervention versus control	To evaluate whether a brief prenatal clinic-based CMV risk-reduction behavioral intervention will prevent maternal CMV infections during pregnancy in women	840 pregnant women
Antiviral medication for congenitally infected fetuses				
NCT04732260 Yves Ville, Assistance Publique - Hôpitaux de Paris, France <sup>118</sup>	NA	1 tablet of Letermovir (240 mg or 480 mg /d) for 3 d	To measure the Letermovir transplacental transfer in the second trimester and its accumulation in the amniotic fluid and the placenta in the second trimester	10 pregnant women undergoing termination of pregnancy for fetal abnormality

#### Pediatrics 2022;150(2):e2021055896

CMV vaccine trials				
NCT03486834 Merk Sharp and Dohme Corp. <sup>119</sup>	Phase 2	Vaccine V160 vs placebo	To evaluate the safety, tolerability, and efficacy of the CMV vaccine (V160) and whether administration of a 3-dose regimen reduce the incidence of primary CMV infection compared with placebo	2200 healthy seronegative women aged 16 to 35 y with direct exposure to young children
NCT05089630 GlaxoSmithKline <sup>120</sup>	Phases 1 and 2	Recombinant protein subunit vaccine	To assess the safety, reactogenicity, and immunogenicity of the candidate CMV recombinant protein subunit, regardless of baseline CMV sero-status	320 healthy adults 18 to 50 y of age
NCT05085366 ModernaTX, Inc. <sup>121</sup>	Phase 3	mRNA-1647 vaccine versus placebo	To evaluate the efficacy of mRNA 1647 vaccine in CMV-seronegative female participants and to evaluate the safety and reactogenicity of mRNA-1647 vaccine in all participants	6900 healthy seronegative participants aged $\geq$ 20 y old with direct exposure to at least 1 child $\leq$ 5 y old

# **Use of Valacyclovir During Pregnancy**

- 100 women with preconceptionally or 1<sup>st</sup> trimester primary CMV infection
- Oral valaciclovir vs placebo, amniocentesis at 21-22 weeks.
- cCMV: Valaciclovir 11% Placebo 30% (p=0.027)
- Symptomatic fetuses, treated in utero from diagnosis (median 25.9 wks' gestation) until delivery or termination, severe CNS disease not included
- 43 treated, 34 asymptomatic at birth (82%, vs literature – 43%), all asymptomatic at 12 months

Valaciclovir to prevent vertical transmission of cytomegalovirus after maternal primary infection during pregnancy: a randomised, double-blind, placebo-controlled trial

Keren Shahar-Nissan\*, Joseph Pardo\*, Orit Peled, Irit Krause, Efraim Bilavsky, Arnon Wiznitzer, Eran Hadar†, Jacob Amir†

Lancet 2020;396(10253):779-785

In utero treatment of congenital cytomegalovirus infection with valacyclovir in a multicenter, open-label, phase II study

Marianne Leruez-Ville, MD, PhD; Idir Ghout, MSc; Laurence Bussières, PhD; Julien Stirnemann, MD, PhD; Jean-François Magny, MD; Sophie Couderc, MD; Laurent J. Salomon, MD, PhD; Tiffany Guilleminot, BA; Philippe Aegerter, MD, PhD; Guillaume Benoist, MD, PhD; Norbert Winer, MD; Olivier Picone, MD, PhD; François Jacquemard, MD; Yves Ville, MD, FRCOG

Am J Obstet Gynecol 2016;215(4):462.e461-462.e410

American Academy of Pediatrics Committee on Infectious Disease Recommendations for Infants with cCMV

- Asymptomatic or Symptomatic Disease
  - Hearing testing at 4, 6, 9, 12, 15, 18, 24, 36 mos
  - Standard hearing assessments at 4, 5, 6, 8, 10 yrs



American Academy of Pediatrics

AAP 2021 Red Book, pg 298

### Prevention

- Increasing awareness
- Education
  - Hygiene prevention measures



#### **CMV Fact Sheet for Pregnant Women and Parents**



Tests on a baby's saliva, urine, or blood done within

two to three weeks after birth can confirm if the baby

Babies who show signs of congenital CMV at birth

problems and hearing loss but should be used with

Some babies with congenital CMV but without signs

of disease at birth may still have or develop hearing

loss. Hearing loss may be present at birth or may

develop later in babies who passed their newborn

hearing test. Sometimes, hearing loss worsens with

Children with congenital CMV should have regular

hearing checks. Children with hearing loss should receive services such as speech or occupational

therapy. These services help ensure they develop

language, social, and communication skills.

may be treated with medicines called antivirals.

Babies with signs of congenital CMV at birth are

more likely to have long-term health problems.

Antivirals may decrease the severity of health

Long-term health problems may occur

lack of coordination or weakness

Hearing checks and therapies are

has concenital CMV.

Early treatment may help

caution due to side effects

such as:

hearing loss

vision loss

seizures

age.

recommended

The earlier your child can get hearing checks

he or she can benefit

from them.

and therapies, the more

intellectual disability

Most people have been infected with cytomegalovirus (CMV), but do not have symptoms If a pregnant woman is infected with CMV, she can pass it to her developing baby. This is called congenital CMV, and it can cause birth defects and other health problems.

#### For pregnant women You can pass CMV to your baby

If you are pregnant and have CMV, the virus in your blood can cross through your placenta and infect your developing baby. This is more likely to happen if you have a first-time CMV infection while pregnant but can also happen if you have a subsequent infection during pregnancy.

#### You are not likely to be tested for CMV

It is not recommended that doctors routinely test pregnant women for CMV infection. This is because laboratory tests cannot predict which developing babies will become infected with CMV or have longterm health problems.

#### You may be able to reduce your risk

You may be able to lessen your risk of getting CMV by reducing contact with saliva and urine from babies and young children. The saliva and urine of children with CMV have high amounts of the virus. You can avoid getting a child's saliva in your mouth by for example, not sharing food, utensils, or cups with a child. Also, you should wash your hands after changing diapers. These cannot eliminate your risk of getting CMV, but may lessen the chances of getting it.

#### For parents

About 1 out of every 200 babies is born with congenital CMV. About 1 out of 5 of these babies will have birth defects or other long-term health problems

#### Babies with congenital CMV may

show signs at birth Some signs that a baby might have congenital CMV infection when they are born are: Small head size

- Seizures
- Rash
- Liver, spleen, and lung problems



#### For more information, visit: www.cdc.gov/cmv

National Center for Immunization and Respiratory Diseases (NCIRD)

#### https://www.nationalcmv.org

#### https://www.cdc.gov/cmv/fact-sheets/parents-pregnant-women.html

