









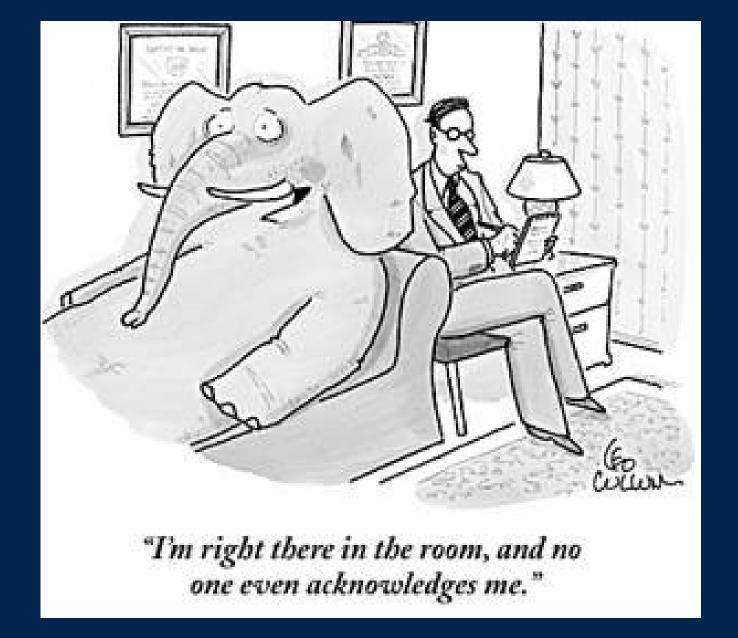






Baylor College of Medicine CMV 101
Congenital Cytomegalovirus Infection
The Elephant in our Living Room

Gail J Demmler Harrison MD
Professor of Pediatrics, Section Infectious Diseases
Baylor College of Medicine
and
Texas Children's Hospital
Houston, Texas USA







Objectives CMV 101

- See the elephant in our living room
 - Maternal CMV infection during pregnancy
 - Newborns with congenital CMV
 - Recognize congenital CMV is common
 - Learn how newborns with CMV may present
- Know latest updates on progress in reducing impact of congenital CMV
 - Diagnosis and newborn screening congenital CMV
 - Clinical management and antiviral treatment
 - Prevention
 - Awareness & public policy



Disclosures

- I will discuss off label use of ganciclovir, valganciclovir, valacyclovir and CMV hyperimmune globulin, with findings supported by clinical trials, expert opinion, and guidance from AAP
- I receive research support from NIH, CDC, Merck
 & Co and data from this support will be discussed



Why ELEPHANTS and CMV?

CMV is a **BIG** public health and medical problem for our newborns and children, that no one really talks about - CMV is the elephant in our living room.

Elephants are battling their own CMV-related virus, called Elephant Endotheliotropic Herpes Virus (EEHV), which threatens their elephant babies' health and survival



CMV 101

Elephant Friends as Helpers

Baby Tupelo & Mother Tess



Baby Baylor & Mother Shanti





THE FETUS AND NEWBORN WITH CMV

Approximately 4 Million Births Annually in the U.S.A.



40,000 Congenitally Infected Infants Each Year

6,000 Symptomatic *in utero* or at birth; neurologic or sensory sequelae; fetal or neonatal death 8%









34,000 Asymptomatic or mildly symptomatic at birth; 10-20% hearing and 1-2% vision loss







Pregnant Women In the United States



55% to 85% CMV seropositive

0.1% to 1% recurrent CMV maternal infection

CMV in utero fetus congenital CMV newborn

<1% babies have symptoms or signs at birth

symptoms rare hearing loss disabilities? 15% to 45% CMV seronegative

1% to 4% to 7% primary CMV maternal infection

40% CMV in utero fetus congenital CMV newborn

10% -15% have signs and symptoms of disease as fetus or newborn

> *5% to 8% die 85% to 90% broad range disabilities*

85%-90% of babies have minimal or no signs or symptoms in utero or at birth

smaller size or GA 10% to 20% hearing loss other disabilities?





CMV 101 – What is symptomatic congenital CMV (ScCMV)?





Symptomatic congenital CMV

- "Tip of the iceberg"
- Classic signs and symptoms body somatic
 - IUGR or SGA 58%
 - Jaundice w/ direct hyperbilirubinemia at birth 40%
 - Skin rash petechiae or purpura 72%
 - Enlarged liver and spleen 50%
 - Low platelets 70%
 - Abnormal liver enzymes 20%

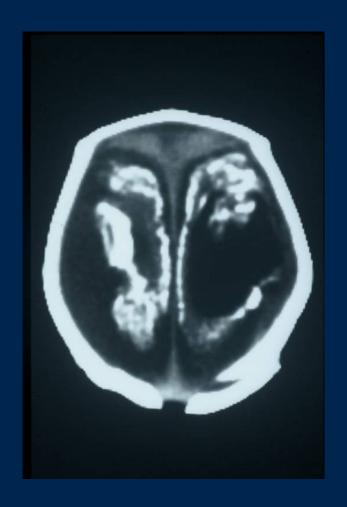


Symptomatic congenital CMV

- "Tip of the iceberg"
- Classic signs and symptoms- brain- 85% ScCMV
 - Microcephaly 40-50%
 - Enlarged ventricles 55%
 - Calcifications of brain usually periventricular 60%
 - Periventricular white matter lucency 27%
 - Cortical maldevelopment of brain
 - Motor and tone disabilities
 - Hemiparesis
 - Lanzieri et al J Perinatol 2017

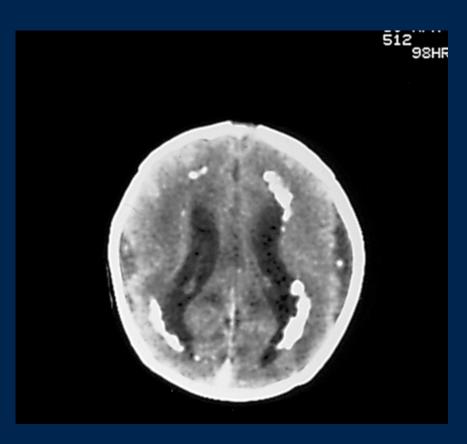


Severe ScCMV with CNS involvement





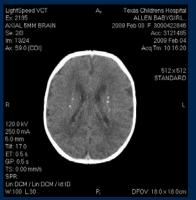
Classic congenital CMV with CNS involvement



Unenhanced CT scan
 of brain showed
 ventriculomegaly, linear
 periventricular Ca+,
 cerebral atrophy

Mild to moderate ScCMV - Variations of CNS involvement

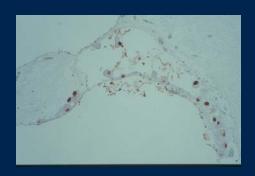




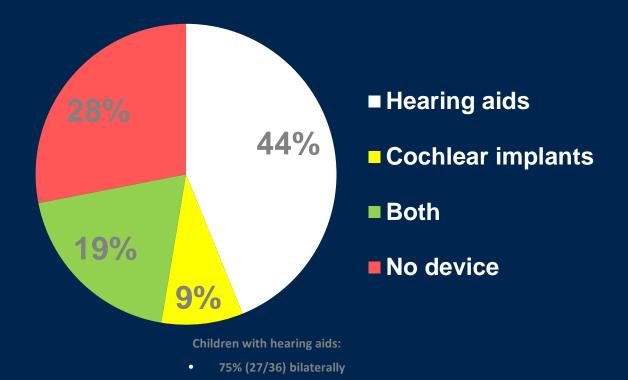
- Ventriculomegaly
- Punctate or beaded periventricular Ca+
- Periventricular leukomalacia

Symptomatic congenital CMV

- "Tip of the iceberg"
- Classic signs and symptoms- sensory
 - Vision loss/Ocular abnormalities ~ 50%
 - Retinitis/retinal scars 25%, optic atrophy 12%, cortical blindness 15%, strabismus 25%
 - Unilateral or bilateral
 - Hearing loss ~ 75%
 - Sensorineural
 - Progressive
 - Unilateral or bilateral
 - Congenital or later onset



Hearing Devices Interventions for Children with Symptomatic cCMV and SNHL (n=57)



Children with cochlear implants:

- 31% (5/16) bilaterally
- 43% (7/16) received first implant by age 2 years



Primarily Neurological Phenotype

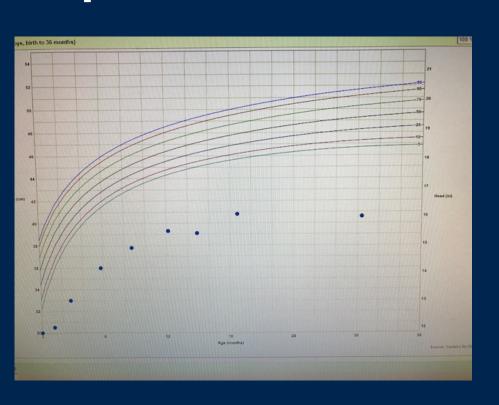
- -Emerging recognition that ScCMV may present with only clinical neurological signs at birth or manifest later
- Microcephaly
- Seizures
- Hemiparesis
- Motor and tone disabilities
- Diagnosis often delayed past newborn period

Primarily Neurological Phenotype

Emerging recognition that cCMV can present with only neuro-imaging abnormalities

- Microcephaly
- Cortical maldevelopment
- Neuronal migration abnormalities
- Polymicrogyria PMG unilateral or bilateral
- Ca+ not as common?

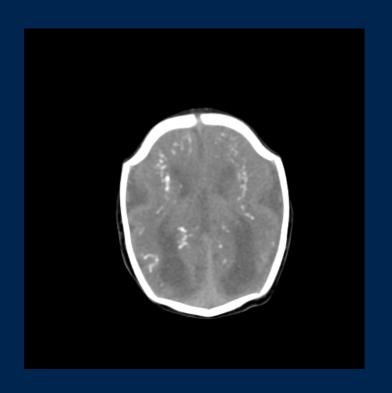
Early presentation and diagnosis at birth- primary neurological presentation

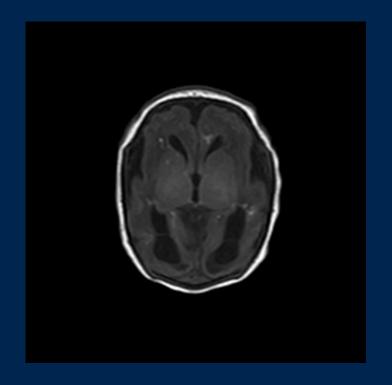


• 38 week GA boy, diagnosed 20 WK FUS abnormal brain, at delivery microcephaly, hypotonia, seizures developed 6 months age, cortical vision impairment, global delay now at age 2 years

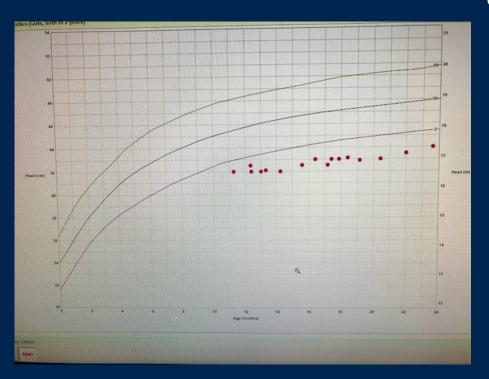


Early diagnosis at birth – primary neurological presentation





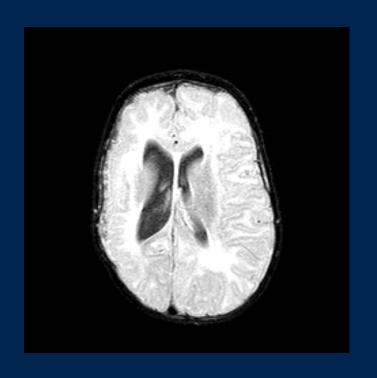
Late presentation and delayed diagnosis-primary neurological presentation

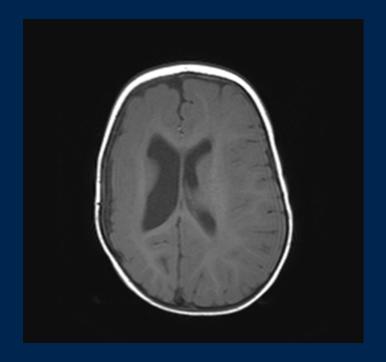


 36 week GA girl presented at age 10 months with microcephaly, left side hemiparesis, intractable seizures, unilateral SNHL, unilateral vision loss, mildmoderate delays now at age 5 years



MRI showed unilateral PMG





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Hearing loss Disabilities?



1% to 4% primary CMV maternal infection

40% CMV in utero fetus congenital CMV newborn

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*

0 10

85%-90% of babies have minimal or no signs or symptoms in utero or at birth

10% to 15% have hearing loss other disabilities?





CMV 101Treatment for Symptomatic Congenital CMV

Antiviral medications for CMV

Ganciclovir IV

Valganciclovir oral

Foscarnet and cidofovir- also anti CMV medications- usually NOT used to treat congenital CMV; secondary line antivirals

No CMV medication is "FDA approved" to treat congenital CMV

Treatment of symptomatic congenital CMV is supported by randomized clinical trials and recommended by expert opinion, AAP



CMV 101Treatment for Symptomatic Congenital CMV

Indications to Consider Treatment - Treat immediate signs and symptoms at birth or neonatal period — Case by case

Viral sepsis & high CMV viral load in plasma/blood

Pneumonia/pneumonitis

Acute chorioretinitis that threatens sight

Severe persistent thrombocytopenia that increases risk for life threatening hemorrhages

Hepatitis- severe where there is risk of liver damage



CMV 101Treatment for Symptomatic Congenital CMV

Indications to Consider Treatment -- Treat to reduce or prevent *long term sequelae* in newborns with CNS or sensory involvement- randomized clinical trials

Reduce risk of progressive or late onset sensorineural hearing loss

Improve developmental and speech/language disabilities

Microcephaly- improve head circumference growth



CMV 101 IV Ganciclovir Treatment for ScCMV with CNS involvement-THE FIRST STEP!



- 1991-1999 Phase III randomized trial CASG NIH
 - 100 newborns enrolled & randomized to receive ganciclovir 6mg/kg/dose every 12 hours IV for 6 weeks or no ganciclovir
 - 42 of the 100 newborns were followed & evaluated fully at 6 months- limitation of the study
 - Randomized to receive IV gancicloivr or no ganciclovir
 - Kimberlin et al J Ped 2003, Kimberlin et al JCV 2010



CMV 101- Ganciclovir Treatment for SCMV with CNS involvement

Benefits

- Significant improvement in
- Median weight gain (1.2 kg vs. 1.0 kg, P = 0.02) at 6 weeks age
- Median head circumference growth (3.6 cm vs. 2.5 cm, P < 0.01) between baseline birth and 6 wks of age for ganciclovir treated groups
- Reduced risk of hearing loss progressing or for late onset hearing loss to occur in treated group at 6 months and 12 months (P<.01) of age
- Improved developmental milestones in treated group measured on DDS at 6 months (P=0.02) and 12 months (P=0.007) of age

Medication side effect

- 63% of ganciclovir treated infants had <u>reversible</u> neutropenia (low blood count ANC) during treatment
- IV central line needed for 6 weeks

Oliver et al J Clin Virol 2009. Kimberlin et al











CMV 101- Neonatal Treatment for Symptomatic Congenital CMV w/ and w/o CNS involvement-Randomized Phase III Trial – Next Big Step

- 2008-2011
- 96 subjects with congenital CMV disease, with and without CNS disease
- Randomized 6 weeks vs 6 months treatment
- Oral valganciclovir 16mg/kg/dose every 12 hr

Kimberlin, et al CASG JID 2008 and N Eng J Med 2015; Redbook COID 2015; Michaels, et al 2003 Ped Inf Dis J;



Neonatal Treatment for Symptomatic Congenital CMV w/ and w/o CNS involvement-Randomized Phase III Trial

- At 24 months follow up
 - 6 month treated group had superior language composite and receptive communication skills on Bayley III Developmental Scales
 - (P=0.003 to P=0.004)
 - Improved or normal hearing better for 6 months treatment than for 6 weeks treatment
 - (P=0.04)
- Medication side effect
 - 19% neutropenia

Kimberlin, et al CASG JID 2008 and N Eng J Med 2015; Redbook COID 2015; Michaels, et al 2003 Ped Inf Dis J;



AAP Committee on Infectious Diseases and International Consensus Recommendations

- Neonates with symptomatic congenital CMV, with or without CNS involvement, should receive oral valganciclovir solution at 16 mg/kg /dose every 12 hours for 6 months
- Start treatment within first month of life
- Monitor CBC diff plat, hepatic function, renal function
- Adjust valganciclovir dosing with weight gain
- Makes outpatient management feasible and affordable
- Red Book 2018-2021 Report of COID 31st edition; Rawlinson W et al. Lancet Infect Dis 2017; 17(6): e177-188; Luck S, et al. Pediatr Infect Dis J 2017 Dec; 36(12): 1205-1213.



CMV 101- Antiviral treatment – are the effects long lasting?

- Follow up in clinical trials has been only for 6 months to 2 years
- It is not known how long the apparent benefits of antiviral therapy will last
- Is antiviral therapy helpful for the "worse ear" or the "good ear" or both or neither?
- Do we need to treat longer than 6 months for long term benefits?
 - Park et al Abstract CMV Public Health and Policy Meeting, Burlington, VT, 2018



Symptomatic Congenital CMV-Other Interventions are helpful

- Antiviral treatment now standard care
- Speech language therapy
 Hearing aids, cochlear implants
- Educational accommodations
- Physiotherapy, mobility aids, orthotics, orthopedics
- Seizure treatments
- Vision aids and therapies, strabismus surgery
- Nutritional interventions for growth disorders









Pregnant Women In the United States



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5% to 8% die 85% to 90% broad range disabilities *85%-90% of babies have minimal or no signs or symptoms in utero or at birth*

smaller size or GA 10% to 20% hearing loss other disabilities?





CMV 101-What is asymptomatic congenital CMV (AcCMV) infection?

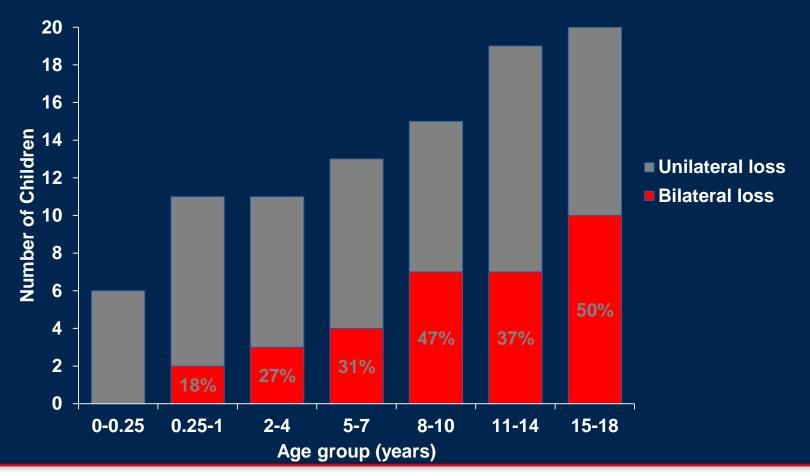
- "Silent majority" of cCMV
- Normal appearing newborn
 - AcCMV with normal newborn hearing screen
 - Normal hearing retained
 - Late onset hearing loss may develop
 - AcCMV with referred newborn hearing screen and congenital sensorineural hearing loss, unilateral or bilateral



CMV 101-AcCMV long term sequelae

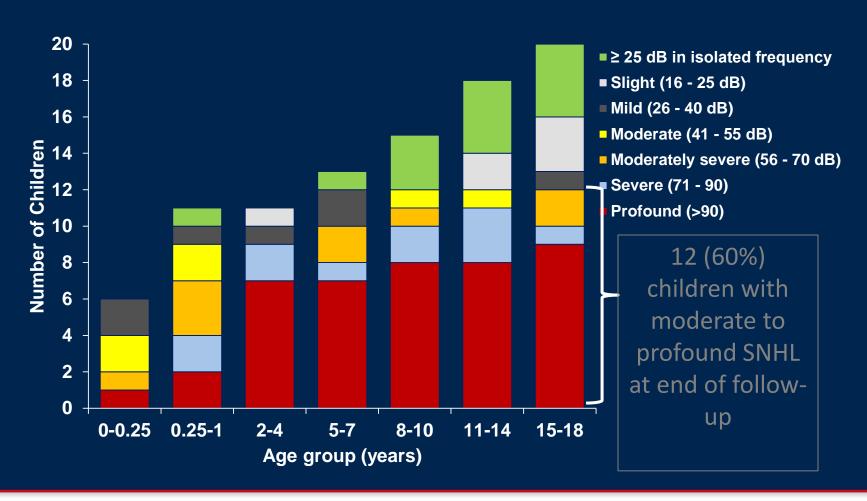
 At risk for hearing loss, congenital, progressive, or late onset past newborn period- 10-25%

Cumulative Number and Proportion of Children with Asymptomatic cCMV Infection with Bilateral and Unilateral SNHL by Age Group (n=20) Lanzieri et al Pediatrics 2017 Nov; 140(5)



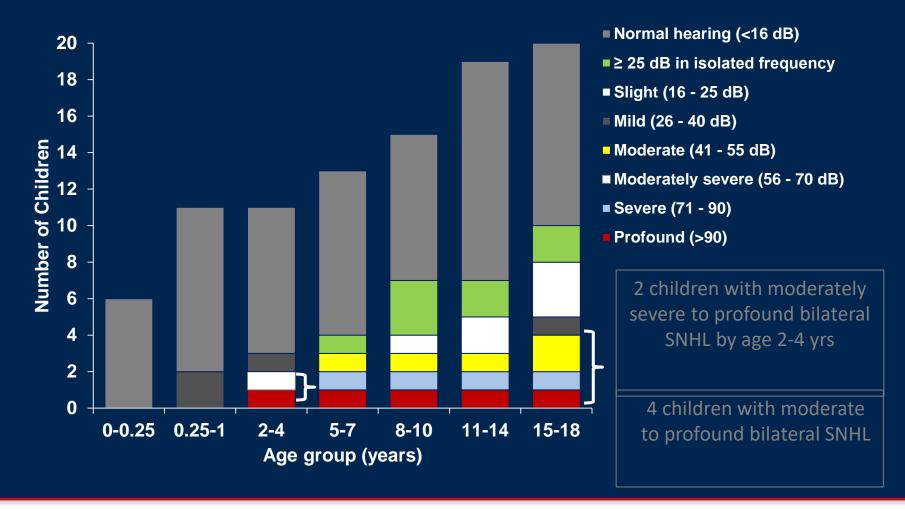


Severity of SNHL in the Worse Ear by Age Group (n=20)

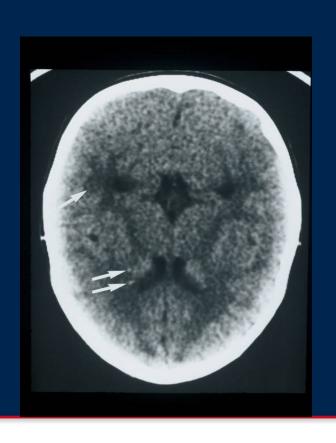




Severity of SNHL in the Better Ear by Age Group (n=20)



CMV 101-AcCMV Cranial CT images may have mild abnormalities 25%



 Periventricular leukomalacia

Punctate periventricular calcifications

 Mild enlargement of ventricles



CMV 101-AcCMV long term outcomes

- Normal cognitive development ages 5 and 18 years compared to children without cCMV
- Normal academic achievement in school compared to children without cCMV
- Does presence of SNHL influence outcomes?
- What is known about behaviors, such as ADHD?
- Does presence of SNHL influence behaviors?

Lopez, et al Pediatrics 2017 Nov; 140(5); Wright G abstract at CMV Public Health and Policy Meeting, Burlington VT.

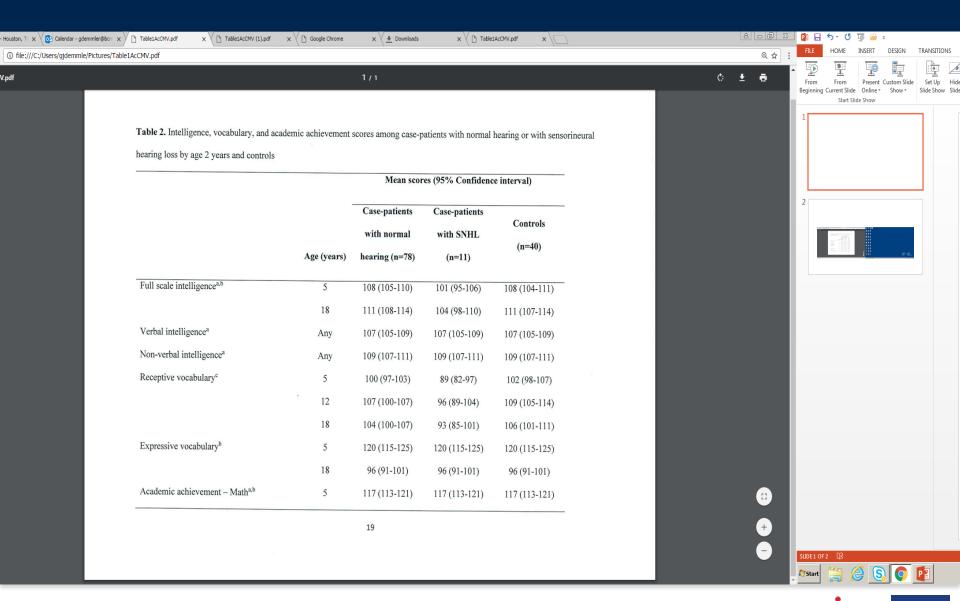


CMV 101-AcCMV long term outcomes

- Children w/ AcCMV w/ and w/o hearing loss by age 2 years
 - Full scale IQ * mild differences noted *
 - Verbal
 - Nonverbal
 - Receptive vocabulary * differences noted *
 - Expressive vocabulary
 - Academic achievement Math
 - Academic achievement Reading

Lopez, et al Pediatrics 2017 Nov; 140(5).









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CMV in utero fetus congenital CMV l newborn

<1% babies have symptoms or signs at birth

Hearing loss Disabilities?

15% to 45% CMV seronegative

1% to 4% primary CMV maternal infection

40% CMV in utero fetus congenital CMV newborn

*

10% -15% have signs and symptoms of disease as fetus or newborn

5 to 8% die - 85% to 90% survivors neurodevelopmental *85%-90% of babies have minimal or no signs or symptoms in utero or at birth





CMV 101-Should we screen newborns for congenital CMV?

- Targeted Newborn Screening for Congenital CMV
 - Failed Newborn Hearing Screening
 - Many hospitals and a few states in U.S. routine
- Universal Newborn Screening for Congenital CMV
 - All newborns
 - Recommended Uniform (Universal) Screening Panel (RUSP)- must be accepted on this panel for most states

Greenlee J. Abstract at CMV Public Health Policy Meeting, Burlington VT 2018



CMV 101-Newborn screening tests for CMV to detect babies with AcCMV



Detection of CMV in urine or saliva

- CMV Culture or Shell Vial, DNA PCR, LAMP, or rapid POC lateral flow immunoassay (?)
- Must be first 21 days of life critical time window of diagnostic opportunity

Detection of CMV in blood – Dried Blood Spot (DBS)

DNA PCR test – as newborn or retrospective diagnosis





CMV 101 AcCMV-The "Silent Majority"- Treatment?

- Antiviral treatment of AcCMV not currently recommended, unless failed newborn hearing screen, then consider? Controversial?
- Clinical trials will begin this year to determine if babies AcCMV with only hearing loss at birth will benefit from antiviral treatment
- Clinical trials are planned to determine if AcCMV with normal newborn hearing will benefit from antiviral treatment to reduce later onset SNHL



CMV 101 AcCMV-The "Silent Majority"- Management

- Anticipatory guidance at risk for progressive and later onset SNHL
- Regular hearing evaluations
 - Every 6 months for 3 years, then annually
- Speech/language therapy
- Educational accommodations if needed



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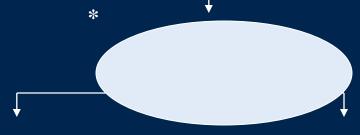
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> **Hearing loss Disabilities?**

15% to 45% CMV seronegative

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10% -15% have signs and symptoms of disease as fetus or newborn

5 to 8% die - 85% to 90% survivors neurodevelonmental

85%-90% of babies have minimal or no signs or symptoms in utero or at birth

10% to 20% have hearing loss





CMV 101-Prenatal Testing or Screening to Diagnose Maternal CMV Infection during Pregnancy

- Maternal Serology <u>NOT ROUTINE</u>
- CMV IgG positive or seroconversion (IgG negative to IgG positive)
 - CMV IgM positive
 - CMV avidity index
 - Low indicates recent infection < 4 months ago
 - High indicates CMV infection > 4 -6 months ago

Revello et al J Clin Virol 2011; Lazzarotto et al Clin Microbiol 2011; Yinon J Obstet Gynaecol Can 2010

- Second Trimester- Fetal Ultrasound- <u>ROUTINE</u>
 - Echogenic bowel, IUGR, hydrops, brain abnormalities may be first indication of CMV infection in utero

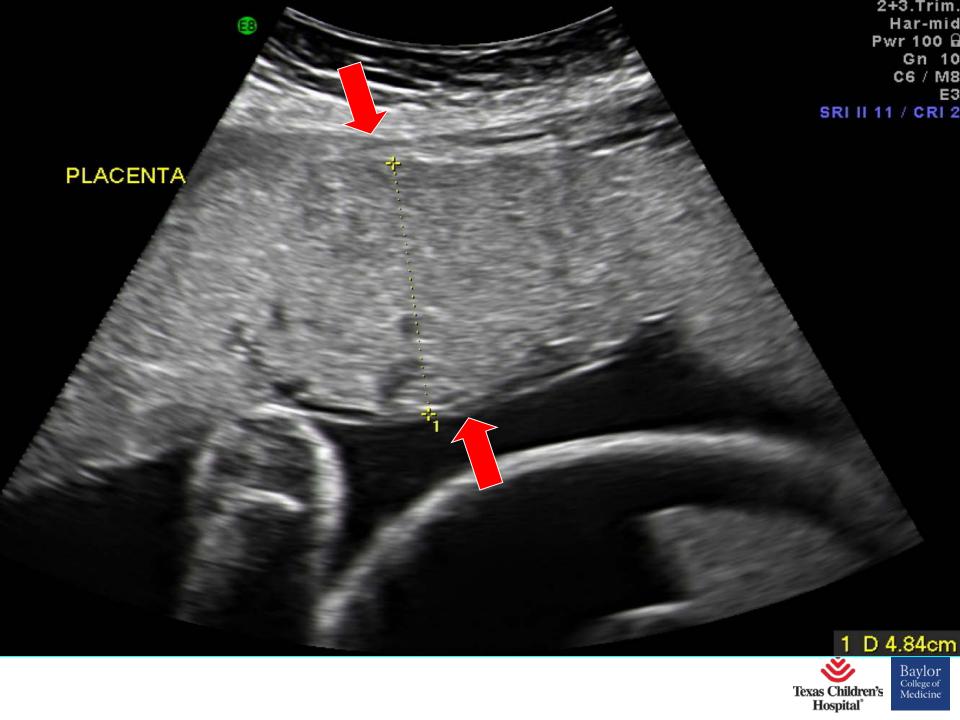
Goetzinger et al Obstet Gynecol 2011



CMV 101- Case Cytomegalovirus Infection of a Fetus

- 24 y.o G2P1Ab0
- Ultrasound 20 and repeat 24 weeks gestationthickened placenta, cerebral echogenic foci, fetal ascites, hepatosplenomegaly
- Maternal studies: CMV IgG +, CMV IgM +, CMV avidity low Recent primary infection
- Amniocentesis: + PCR/culture for CMV; viral load > 1 X 10⁶ copies/ml

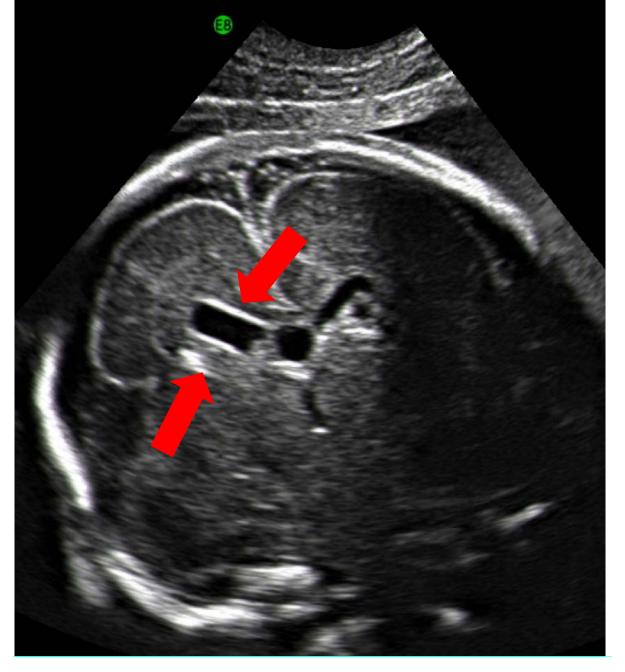
















CMV 101-CMV Prenatal Treatment-Observational Study-Nonrandomized-HOPEFUL!

- In 45 pregnant women with CMV infection during pregnancy and positive amniocentesis for in utero CMV infection Fetal CMV disease was reduced
 - 31 women received CMV IVIG and 1/31 (3%) infant born with CMV disease
 - 14 women did not receive CMV IVIG 7/14 (50%) infants born with CMV disease
 - P=0.001
- In 84 pregnant women with primary CMV infection during pregnancy and no amniocentesis performed Fetal transmission was reduced
 - 37 women received CMV IVIG 6/37 (16%) baby born with CMV
 - 47 women did not receive CMV IVIG 19/47 (40%) baby born with CMV
 - P=0.04

Nigro et al N Engl J Med 2005; Nigro et al J Perinatol 2008; case series; anecdotal reports



CMV 101-CMV Prenatal Treatment-Randomized Trial-CAUTIOUS!

- In 123 pregnant women with proven primary CMV infection 5 to 26 weeks GA
- Randomized to receive monthly CMV IVIG infusions or placebo infusions
- 61 pregnant women with primary CMV infection during pregnancy randomized to receive CMV IVIG
 - 18 /61 (30%) transmitted CMV to their fetus/newborn
- 62 pregnant women randomized to receive placebo infusions
 - 27/62 (44%) transmitted CMV to their fetus/newborn
 - 14% difference in CMV transmission rates
 - P=0.13

NO SIGNIFICANT DIFFERENCE in treatment vs placebo in this trial

LIMITATIONS- underpowered to detect smaller differences, enrollment in second half pregnancy for some subjects? too late

Revello et al N Engl J Med 2014



CMV 101-USA randomized clinical trial-enrolling now-WILL THIS STUDY ANSWER THE QUESTION?

Improving pregnancy outcomes by advancing the science and practice of obstetric care

MFMU Network is seeking referrals for "A Randomized Trial to Prevent Congenital Cytomegalovirus Infection (CMV)"

The MFMU Network is seeking referrals from Maternal Fetal Medicine specialists to an ongoing clinical trial "A Randomized Trial to Prevent Congenital Cytomegalovirus Infection (CMV)". This trial will test the hypothesis that CMV hyperimmune globulin prevents congenital CMV infection as compared to placebo. The trial will enroll pregnant women at <23 weeks' gestation with serologic evidence of primary CMV infection.

Serology results will be confirmed at a central laboratory and delivery must occur at one of the 14 MFMU centers. This is a preventative trial: those with evidence of fetal CMV infection by ultrasound will not be eligible.

There are 14 centers within the MFMU Network doing this trial

http://clinicaltrials.gov/ct2/show/NCT01376778?term=congenital+cmv&ra nk=4



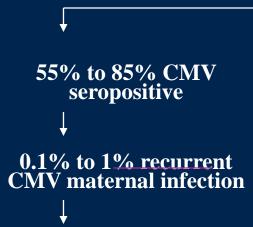
CMV 101- Antenatal treatment with antiviral medications

- Treatment of CMV primary infection and fetal infection with <u>valacyclovir</u> given to the mother
 - Levels achieved in amniotic fluid
 - Reduces viral load titers in infected fetus
 - No measureable effect on fetal disease/outcome
- Treatment of CMV primary infection and fetal infection with <u>valgancicloivir</u> given to the mother
 - Clinical trials being considered?

STUDIES IN FRANCE by Vliles, et al



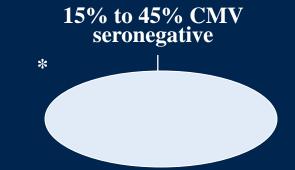
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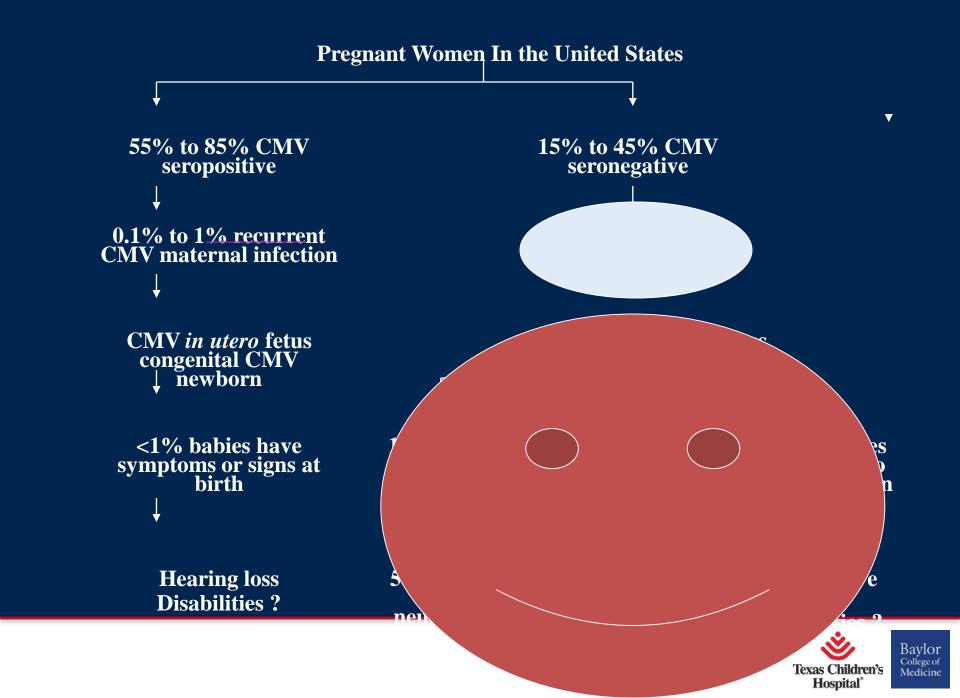
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10% to 15% have hearing loss other disabilities?





CMV 101- CMV Prevention

CMV vaccine to prevent maternal CMV infection

- CMV vaccine research ongoing since 1970s, many candidates evaluated, none so far successful
- CMV Vaccine a priority for 21st Century in USA by Institute of Medicine*
- Many CMV vaccine candidates under evaluation, active R&D pipeline, currently early clinical trials with results!
- NO licensed CMV vaccine available yet
- * IOM Committee to Study Priorities for Vaccine Development for 21st Century Nat Academics Press 2000



CMV 101-

Can we prevent maternal CMV through other ways?



- CMV is transmitted through close contact with others who have CMV infected body fluids
- Toddlers are "HOT ZONES" for CMV
- Annual seroconversion rates 15% day care workers and 50% in households with toddlers shedding CMV in saliva/urine
- Reduce risk by reducing contact with CMV infected secretions





CMV 101"CMV Knowledge Vaccine" "Information Vaccination"

- An Ounce of CMV Awareness
- Three Simple Precautions
 - Do not kiss young children on or near mouth
 - Do not share food or drink or pacifiers or toothbrushes with young children
 - Wash hands after <u>all</u> diaper changes and after wiping runny noses/drooling

Not recommended now routinely by obstetricians and by ACOG – "too burdensome" "unproven"

Recommended now by CMV experts, International Consensus Guidelines, AAP, supported by clinical trials

Adler et a J Pediatr 2004; Cannon Br Med J 2005; Harvey et al 2008; Revello et al J Clin Virol 2011; Vauloop-Fellous et al J Clin Virol 2009, Rawlinson et al Lancet ID, 2017

www.http://www.texaschildrensblog.org/2011/01/cmv-every-pregnant-woman-should-know-about-this-virus/











Who should know?

- Pregnant mothers with contact with young children
 - Toddlers/ pre schoolers in household
 - Day care center workers
 - Should CMV information be required for licensure?
 - Pre school teachers
 - Speech/language therapists
 - Health care workers- routine universal precautions sufficient to prevent transmission in hospital
 - Other?

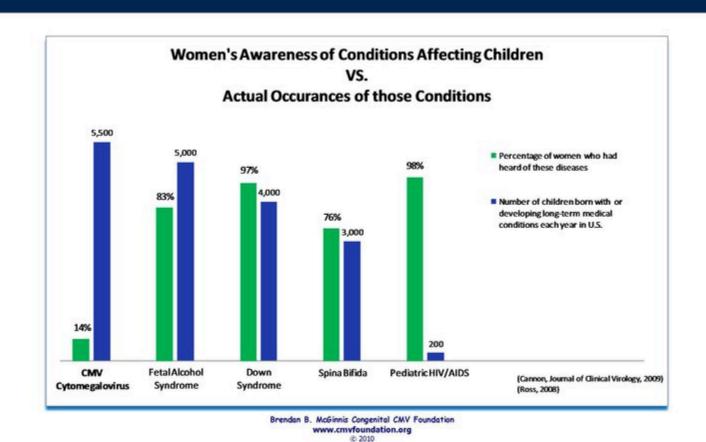






CMV 101-CMV Awareness...... We Can Do Better





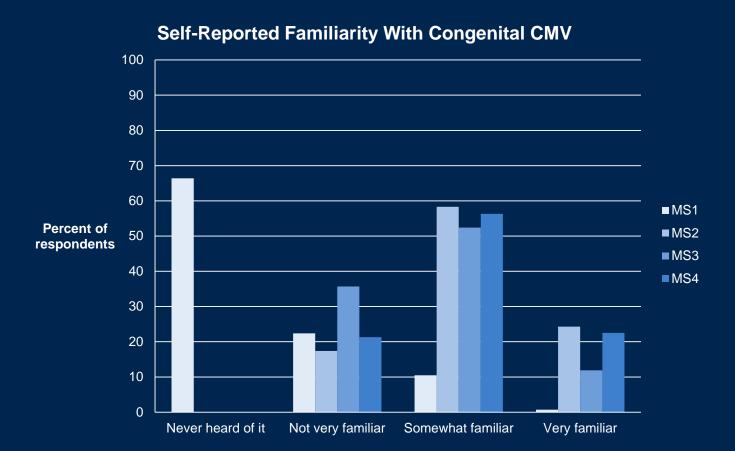




Survey of Congenital Cytomegalovirus (cCMV) Knowledge Among BCM Medical Student, Houston Texas

- Most "young doctors to be" have never even heard of CMV!

Baer HR, Corwin HE, Caviness AC, Demmler-Harrison GJ, J Clin Virol 2014



CMV 101- CMV Awareness There are many sites on the internet... there are a few books...but you have to first know CMV exists

- CMV Action UK
- Congenital CMV Association of Australia
- www.cdc.gov/cmv
- www.ncbi.nlm.nih.gov
- www.nationalcmv.org
- www.cmvawareness.org
- www.nationalcmvfoundation.org
- www.authorlisasaunder.com
- www.bcm.edu/pedi/infect/cmv
- http://www.texaschildrensblog.org/cm v-every-pregnant-woman-shouldknow-about-this-virus





















CMV 101-CMV-It's The Law- First in Utah!





- UTAH- H.B. 81 (2013 General Session) <u>UCA 26-10-10</u>, whose Chief Sponsor was Representative Ronda Rudd Menlove, went into effect on July 1, 2013. http://www.health.utah.gov/cshcn/CHSS/CMV.html
- This law (Act for Cytomegalovirus Public Education and Testing)
 - directs the Utah Department of Health to create a public education program to inform pregnant women and women who may become pregnant about the occurrence of CMV, the transmission of CMV, the birth defects that CMV can cause, methods of diagnosis, and available preventative measures.
 - directs medical practitioners to test infants, who fail two
 newborn hearing screening tests, for congenital CMV and
 inform the parents of those infants about the possible birth defects
 that CMV can cause and the available treatment methods.

CMV-It's The Law in Texas!





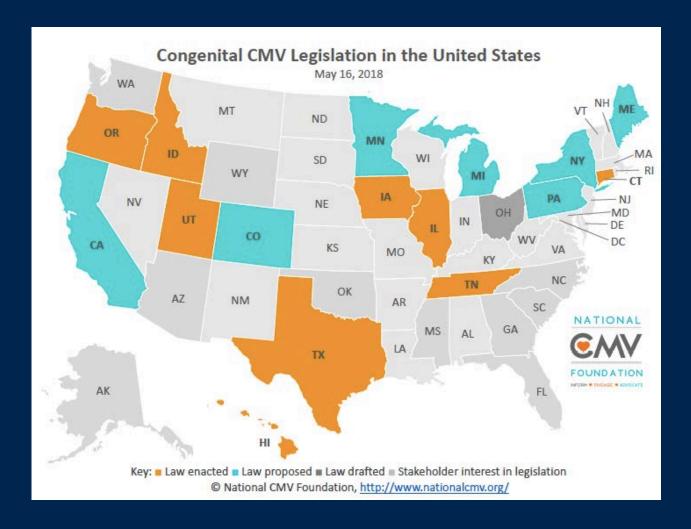




- TEXAS S.B. 791 (passed this 84TH Legislative Session, 2015)
- Signed by Governor June 19, 2015.
- Madeline Leigh Armstrong Act for CMV Education and Awareness
- Went into effect on September 1, 2015. This law directs the Texas DSHS to create educational materials and an education outreach program to public and health care professionals on congenital CMV (incidence, transmission to pregnant women, available preventive measures for pregnant women and women who may become pregnant, birth defects caused by congenital CMV, available and resources for families of children born with congenital)
- Texas DSHS is developed educational materials in 2016
- TMA TPS have plans for education programs 2017-2018



Congenital CMV Legislation in the United States as of August 2018 www.nationalcmv.org







Congenital CMV challenge..... to take the next steps forward!



"If we stumble, it will not be because we lack for technology, vision or motivation.

It will be because we cannot set a direction and march <u>collectively</u> into the future."

History of the Future 2004

Maternal CMV Screening in Pregnancy

CMV Knowledge Vaccine - Information Vaccination

Newborn cCMV Screening for Early Diagnosis

Antiviral Treatments for cCMV

CMV Vaccine





"Good Bye"
It's time to say "good-bye" to the elephant in our living room!



Thank you!







The End





