

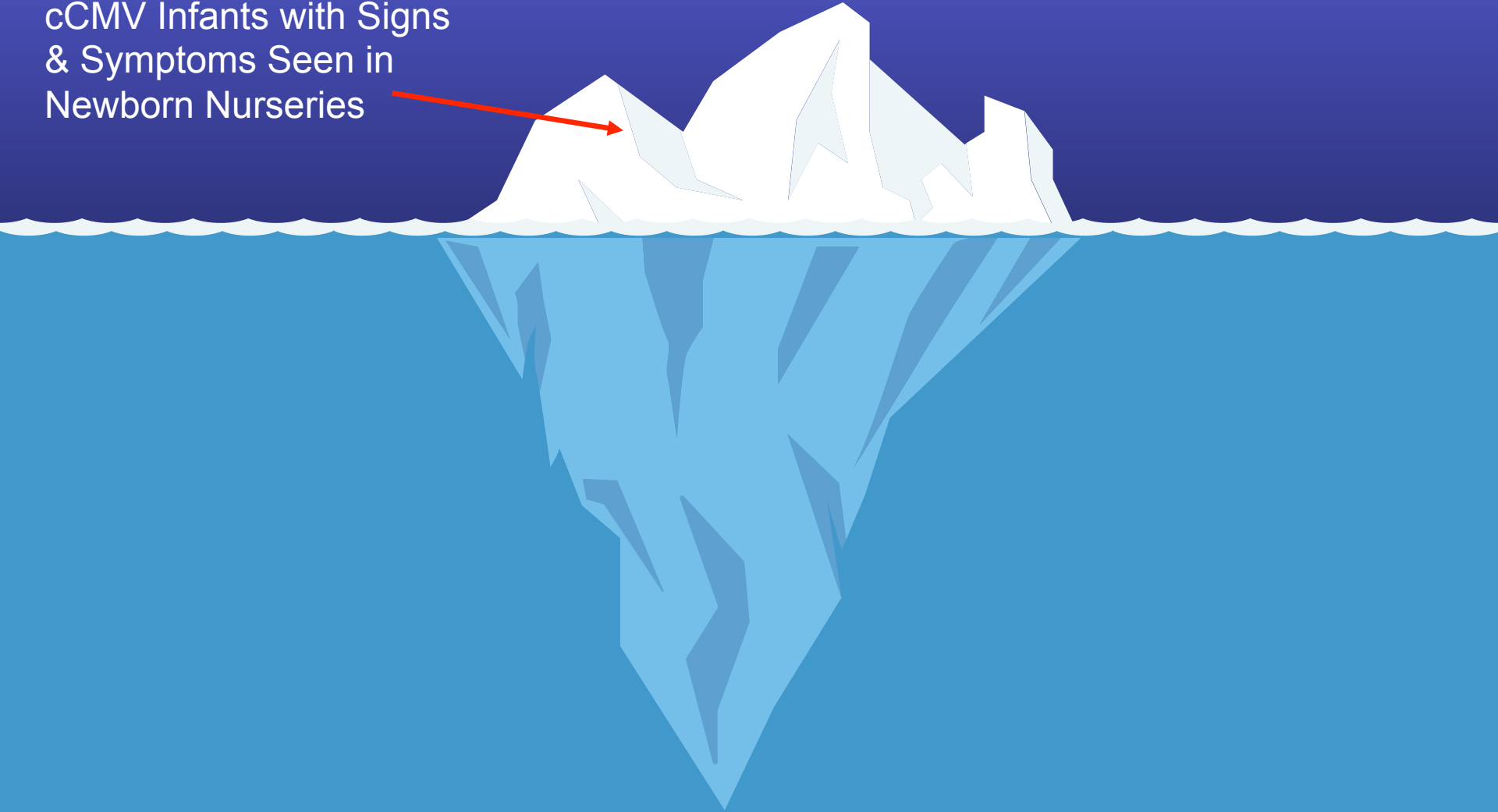
Is Universal Newborn Screening for Congenital Cytomegalovirus Good Public Health Policy?

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Salt Lake City, UT
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Congenital CMV Infection (cCMV) without Newborn CMV Screening - Today

cCMV Infants with Signs
& Symptoms Seen in
Newborn Nurseries

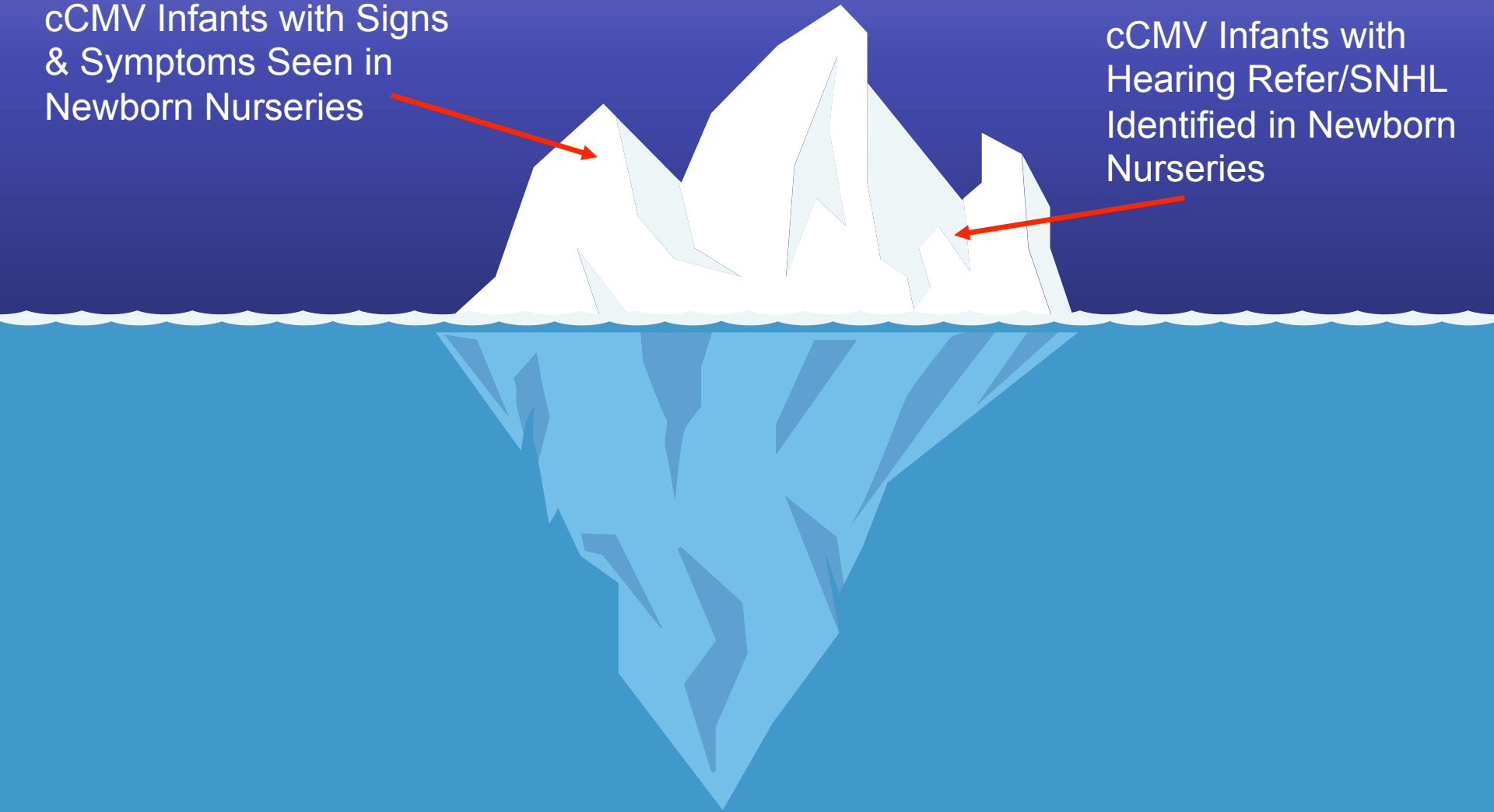


Congenital CMV Infection (cCMV)

Targeted Newborn CMV Screening - Today

cCMV Infants with Signs & Symptoms Seen in Newborn Nurseries

cCMV Infants with Hearing Refer/SNHL Identified in Newborn Nurseries

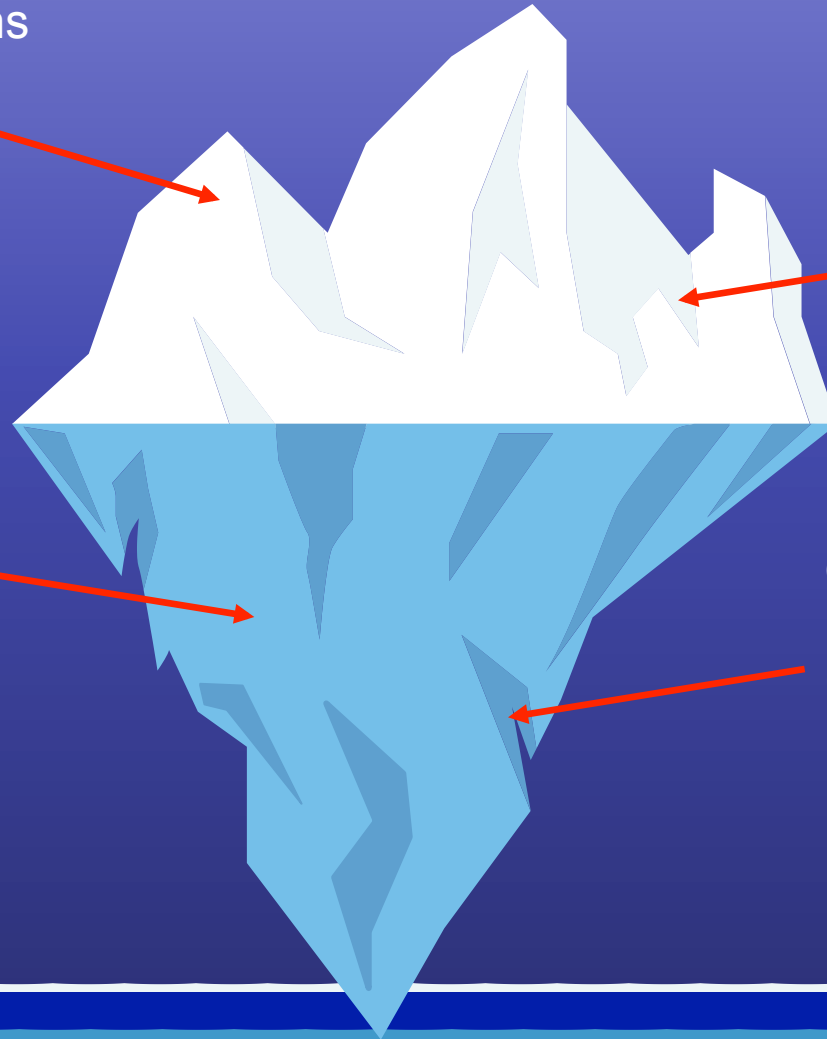


Congenital CMV Infection (cCMV)

Universal Newborn CMV Screening – Future?

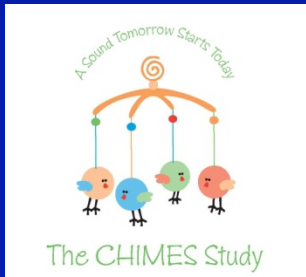
cCMV Infants with Signs & Symptoms Seen in Newborn Nurseries

cCMV Infants with Hearing Refer/SNHL Identified in Newborn Nurseries



cCMV Infants without or only Mild Signs & Symptoms not Identified in Newborn Nurseries

cCMV Infants with Possible Late Onset SNHL



NIDCD Multicenter CHIMES Study

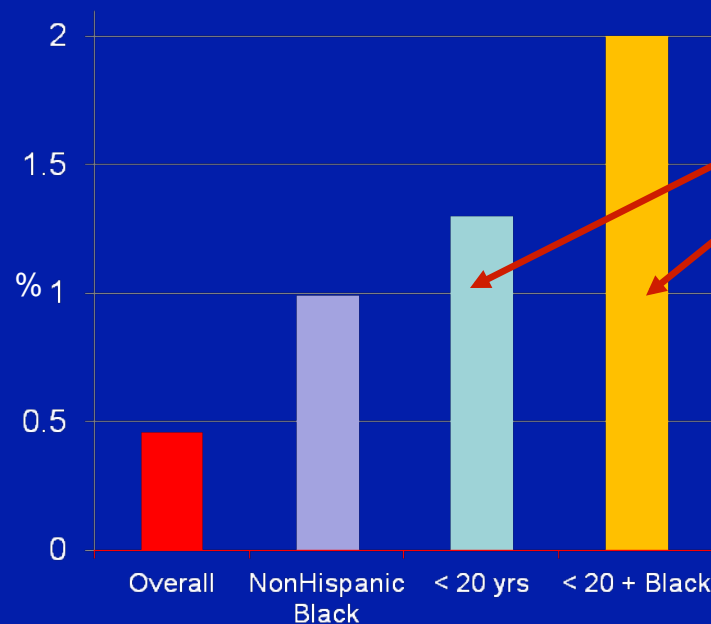
What do we know

Overall prevalence of congenital CMV infection in the CHIMES Study

16,600 – 20,160
infants w cCMV born
in the US each year

Greater No. of Cases
of cCMV than the No.
of Cases for any of the
current Newborn
Screening Panel
Conditions

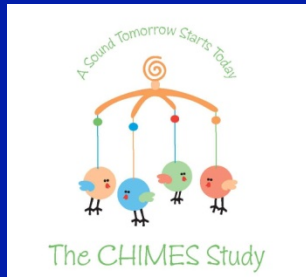
0.46% (95% CI, 0.42 – 0.51)



cCMV rates even
higher in different
subpopulations of
the US.

Fowler K, et al. Racial Disparities and the Prevalence of Congenital Cytomegalovirus (CMV) Infection: Findings from the NIDCD CHIMES Study. PAS/ASPR Joint Meeting Vancouver BC, May 3-6, 2014.

Fowler K, et al. Adolescent Pregnancies and the Risk of Congenital Cytomegalovirus (CMV) Infection: Findings from the NIDCD CHIMES Study. PAS/ASPR Joint Meeting Vancouver BC, May 3-6, 2014.



What do we know

Saliva PCR method for Congenital CMV Screening

Saliva PCR method:

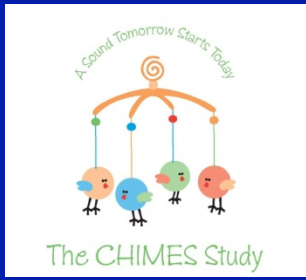
Sensitivity 97.4% – 100%; Specificity 99.9%,
PPV 90.2% – 91.4%; NPV 99.9% - 100%

Advantages of Saliva PCR Method:

- Ease of sample collection
- No DNA extraction step
- Amenable to high throughput for mass screening
- Viral loads as high/higher than urine

Boppana SB, et al. Utility of saliva real-time polymerase chain reaction assays for screening newborns for congenital cytomegalovirus infection. NEJM 364:2111-2118, 2011.

Ross SA, et al. Detection of Congenital Cytomegalovirus Infection by Real-Time Polymerase Chain Reaction of Saliva or Urine. J Infect Dis. June 2014



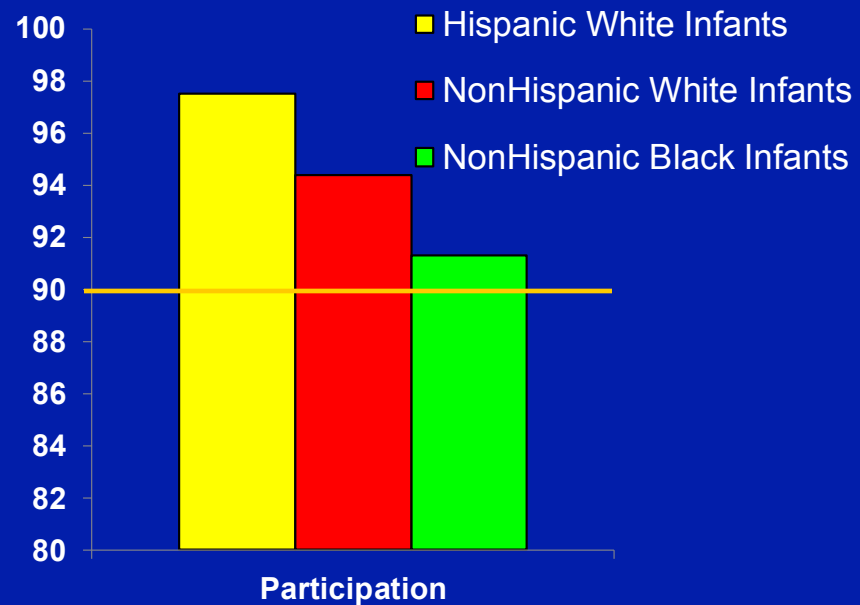
NIDCD Multicenter CHIMES Study

What do we know

Acceptability of Newborn CMV Screening

Recent study in the UK, 99% (407/411) of parents whose newborn referred on newborn hearing screening agreed to be tested for CMV.

Williams, EJ, et al. Feasibility and acceptability of targeted screening for congenital CMV-related hearing loss. Arch Dis Child Fetal Neonatal Ed. 99: F230-36, 2014.



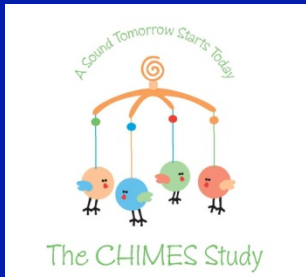
Fowler K, et al. Acceptability of Newborn Cytomegalovirus (CMV) Screening in Minority Women: Findings from the NIDCD CHIMES Study. PAS/ASPR Joint Meeting Vancouver BC, May 3-6, 2014.

What do we know

Anxiety about cCMV infection during pregnancy doesn't increase when women are educated about cCMV infection

Kessler Anxiety Scale (range 10 – 50, with 10 low anxiety & 50 high anxiety) given before CMV education & prevention messages & 12 weeks later (after messages) indicated no differences in anxiety.

	Anxiety Score median (range)
Pre-CMV info/messages	18 (10-35)
After CMV messages	16 (10 -37)



NIDCD Multicenter CHIMES Study

What do we know

A targeted CMV screening approach will identify cCMV - HL

Hearing Refers by CMV Status

CMV Screen	Hearing Refer* % (95% CI)
CMV Positive (n=461)	7.1% (5.0 – 9.9%)
CMV Negative (n=99,317)	0.9% (0.8 – 1.0%)

P < 0.0001

Newborn hearing screening identified 60% (95% CI, 42% - 76%) of CMV-Related SNHL in the newborn period

Fowler KB, et al. A targeted approach for congenital cytomegalovirus (CMV) Screening within newborn hearing screening: Findings from the NIDCD CHIMES Study. PAS/ASPR Joint Meeting Vancouver BC, May 3-6, 2014.

Challenge 1: For Universal Congenital CMV Screening Treatment with ganciclovir or valganciclovir

- Concerns for side effects and for long term safety of antivirals
- Whether children have been followed long enough after Tx to see if this is a long term Tx effect or not
- Increase in diagnostic testing to see if infant would be eligible for Tx

Even if we take antivirals off the table – we still have a therapy!
We still have to manage the HL present at birth and still monitor for late onset loss/progressive losses.

Children with cCMV infection & hearing loss do have therapy options – look to the newborn hearing screening program with early intervention services- *evals for amplification or sensory devices, surgical & medical evals, communication assessment & therapy*

Challenge 2: For Universal Congenital CMV Screening

Lack of current knowledge about CMV and/or lack of understanding of the magnitude of disease burden due to CMV among clinicians and other health care providers

- Continue to dialog with Obstetricians and Pediatricians/the medical home and others who will provide health care and interventions for the infants and children
- Continue to educate women and families – so they ask for information from their obstetrician & pediatrician

Challenge 2: For Universal Congenital CMV Screening

If we can talk about Toxo – can't we talk about

Toxoplasmosis 1 per 10,000 vs. 46 per 10,000 cCMV in the US

CMV?

Education Topics, Obstetrics*

Topics, 1st Trimester: orientation to clinic, HIV and other routine prenatal tests, Risk factors identified by prenatal history, Anticipated course of prenatal care, nutrition and weight gain counseling; special diet, Breastfeeding, **Toxoplasmosis precautions (cats/raw meat)**, sexual activity, exercise, perinatal depression, environmental/work hazards, Travel, use of any medications (including supplements, vitamins, herbs, or OTC drugs, Indications for ultrasound, Childbirth classes/hospital facilities

**UAB prenatal health clinics*

Challenge 2: For Universal Congenital CMV Screening

Take a lesson from Newborn Hearing Screening-
keep moving forward!

After the 1993 NIH Consensus panel on “Early Identification of Hearing Impairment in Infants and Young Children”

Some titles in the scientific literature afterwards –

“Universal Screening for Infant Hearing Impairment: Not Simple, Not Risk-Free, Not Necessarily Beneficial, and Not Presently Justified” *Pediatrics* 1994

“Universal Newborn Hearing Screening: Should We Leap Before We Look?” *Pediatrics* 1999

Challenge 2: For Universal Congenital CMV Screening

As we keep moving forward-we need to dialog with individual health care providers & the boards & members of professional organizations

- the American College of Obstetricians and Gynecologists (ACOG)
- the American Academy of Pediatrics (AAP)
- the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
- the American Academy of Audiology (AAA)
- the American Speech-Language-Hearing Association (ASHA)
- Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPHWA)
- the Alexander Graham Bell Association for the Deaf and Hard of Hearing (AG Bell)
- the Council on Education of the Deaf (CED)

Challenge 3: For Universal Congenital CMV Screening

Continue to educate women of childbearing age and their families about congenital CMV infection

In our currently CDC funded CMV behavioral intervention in pregnant women –only 25% of the young women have heard about CMV – and this is after about 70-75% of them have been consented to be screened for CMV as part of another study 1-3 weeks before!

We must try to simplify our message (without losing the content) and continue to reach out to women and families about congenital CMV infection and the disease burden caused by congenital CMV infection.