

Implementation and Outcomes of a New CMV Screening Protocol at Boston Children's Hospital

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Disclosure

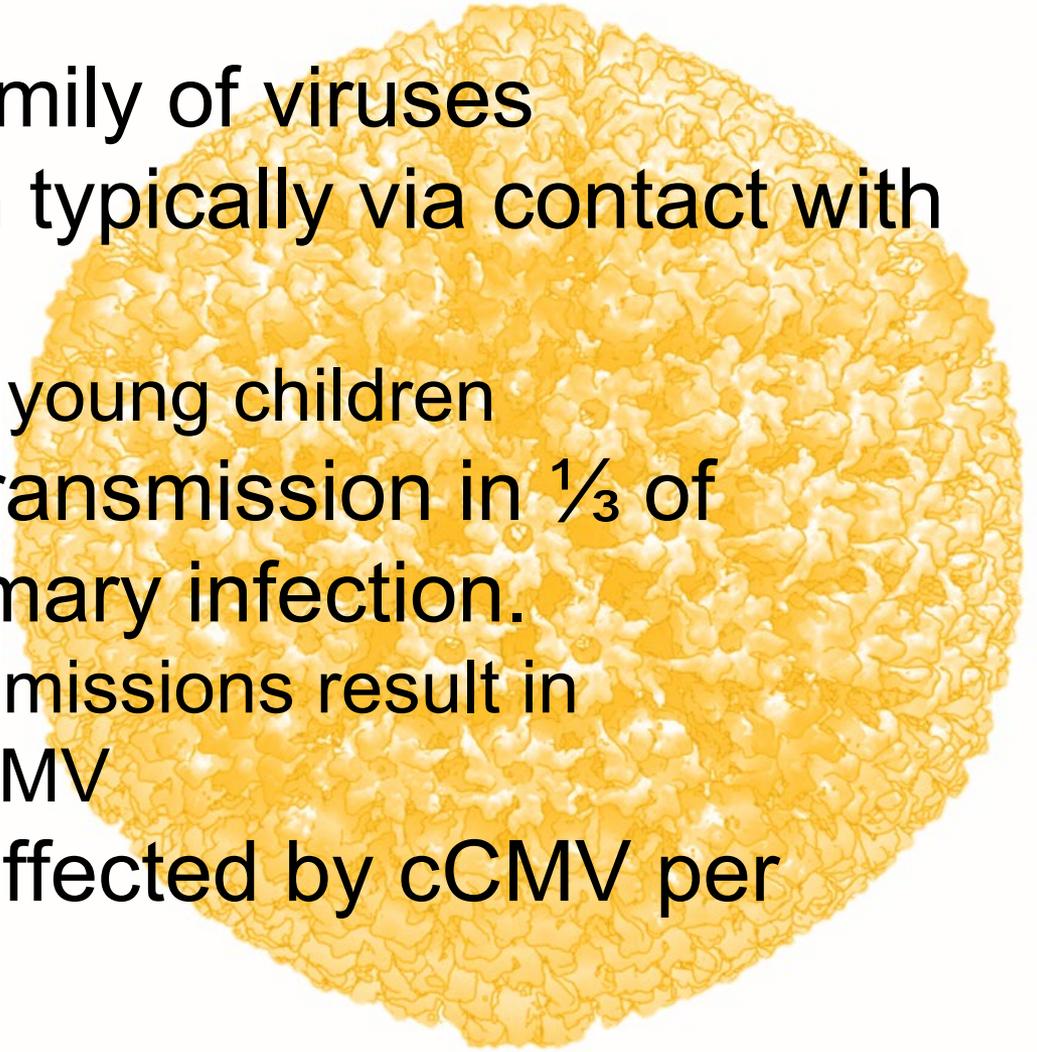
- Derek Stiles is an employee of Boston Children's Hospital.
- Kaitlyn Fitzpatrick is an employee of Boston Children's Hospital.

Presentation Outline



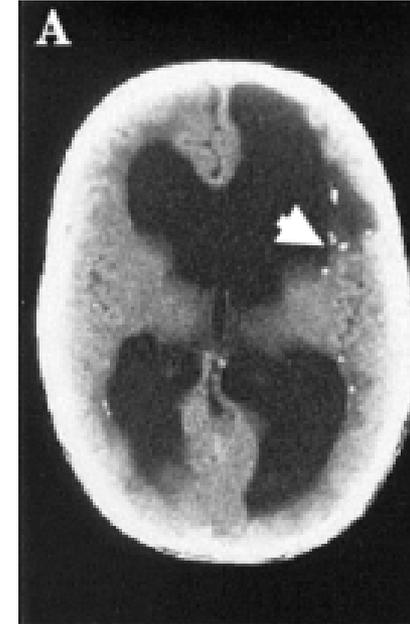
Cytomegalovirus

- *Herpesviridae* family of viruses
- Primary infection typically via contact with bodily fluids
 - most likely from young children
- Transplacental transmission in $\frac{1}{3}$ of mothers with primary infection.
 - $\frac{1}{2}$ of those transmissions result in symptomatic cCMV
- ~8000 children affected by cCMV per year



Effects of cCMV

- Developmental Delay
- Microcephaly
- Motor Delay
- Seizures
- Vision Loss
- Hearing Loss
 - Increased levels and longer duration of urinary excretion of CMV are associated with development of hearing loss
 - Virus causes inflammatory response in endolymph

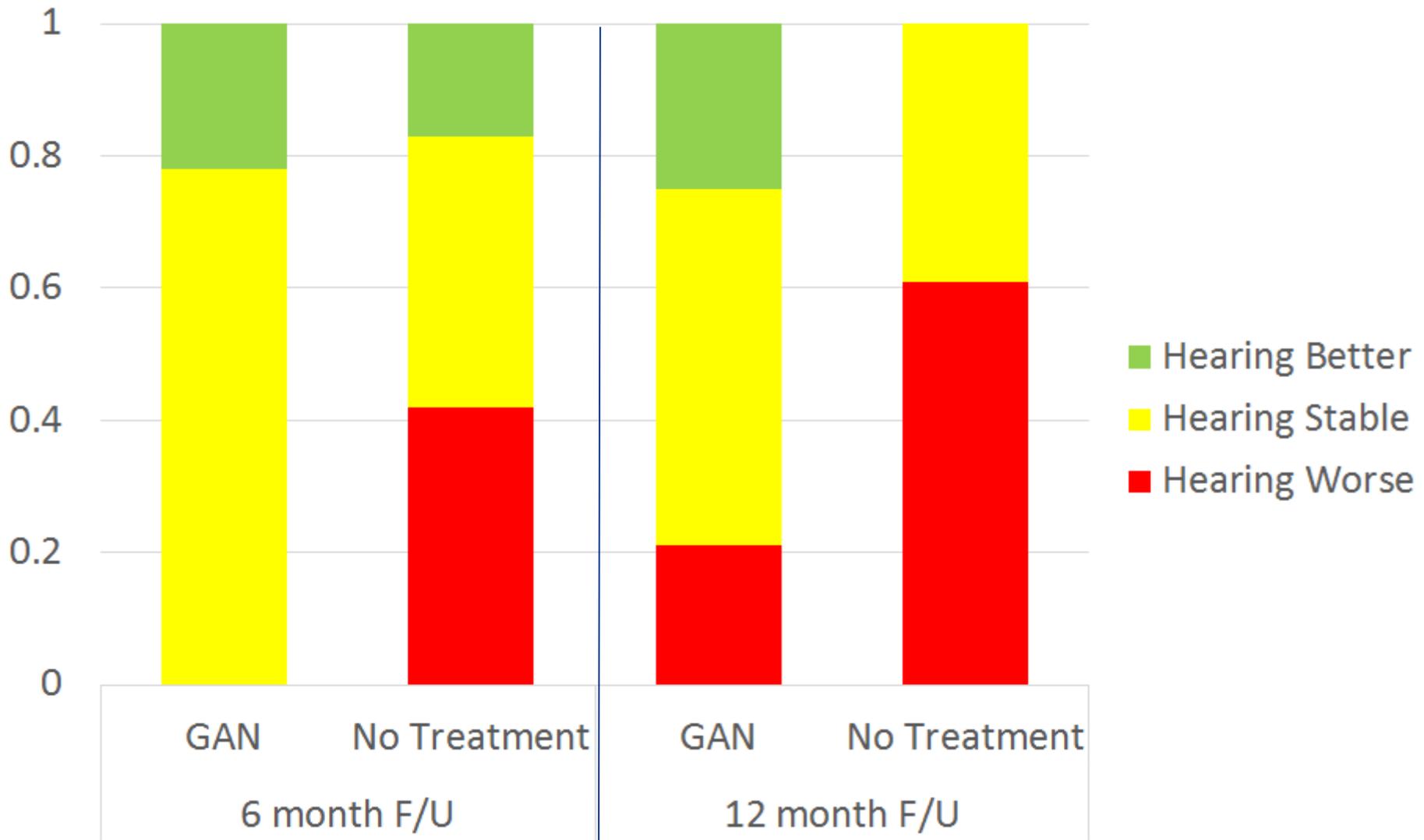


Treatment of cCMV

- Antiviral medications, including Valganciclovir, may prevent or slow the progression of hearing loss and vision loss

The hallmark study (Kimberlin et al 2003) included infants less than 1 month of age (median age 8 days for treated infants)

Kimberlin et al, 2003



Basic Issue

What do you do when there is no state mandate for newborn CMV screening?



Implementation

- Guideline developed & approved by staff in 2015
- Buccal swab training
- Requesting lab orders in Electronic Medical Record




Boston Children's Hospital

Audiology Patient Management Guideline
Document: pmg_pftnts_cmv_4.docx

Infants with CMV

Purpose

Cytomegalovirus (CMV) is an infection associated with progressive hearing loss in children. Treatments are now available that may prevent or slow the progression of hearing loss in children identified with this infection, especially if treatments are started within the first 3 weeks of life, necessitating early screening for CMV. The purpose of this guideline is to describe the management of infants who are at risk of CMV and those identified with CMV.

Populations Intended

This guideline applies to infants who referred their newborn hearing screening.

Expected Outcome

This guideline will improve identification rates of infants with CMV and provide consistency in management across sites.

Procedures

When an infant presents for newborn hearing screening following referral at the birth hospital, the audiologist must ask the parent whether the child was screened for CMV, and if so, what the results were. If the parent is not sure, the audiologist may refer to the list of hospitals known to perform CMV screenings on infants who refer their newborn hearing screening (Appendix A).

If the patient did test positive for CMV, they will require hearing evaluations (ABR or behavioral as appropriate) every three months for the first year of life. If the CMV-positive patient has normal hearing after the first year of life, they are scheduled for annual evaluations thereafter. If the CMV-positive patient has hearing loss, they are followed per management guidelines for children with hearing loss.

If the patient did not test positive for CMV, the audiologist completes the newborn unseated ABR. If the results are consistent with normal hearing, the patient is released with recommendations per protocol for newborn management. If hearing loss is identified (of any type), the audiologist requests a nurse to complete a CMV swab. If the CMV swab comes back positive, appointments with ORL and Infectious Disease are scheduled and the patient receives audiologic evaluations every 3 months for the first year as described in the previous paragraph. If the CMV swab comes back negative, the child is followed per the newborn management protocol.

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cCMV Patient Management Guideline

- Children up to 12 months of age demonstrating hearing loss will be offered a CMV screening
- Buccal swab collected by nursing staff or audiologist
- Attending Physician and Physician Assistant informed of request
- Results communicated to family by telephone by Physician Assistant
- CMV+ Screening Results trigger immediate referrals to Infectious Disease Department
- CMV Diagnostic Testing administered by Infectious Disease

cCMV Patient Management Guideline

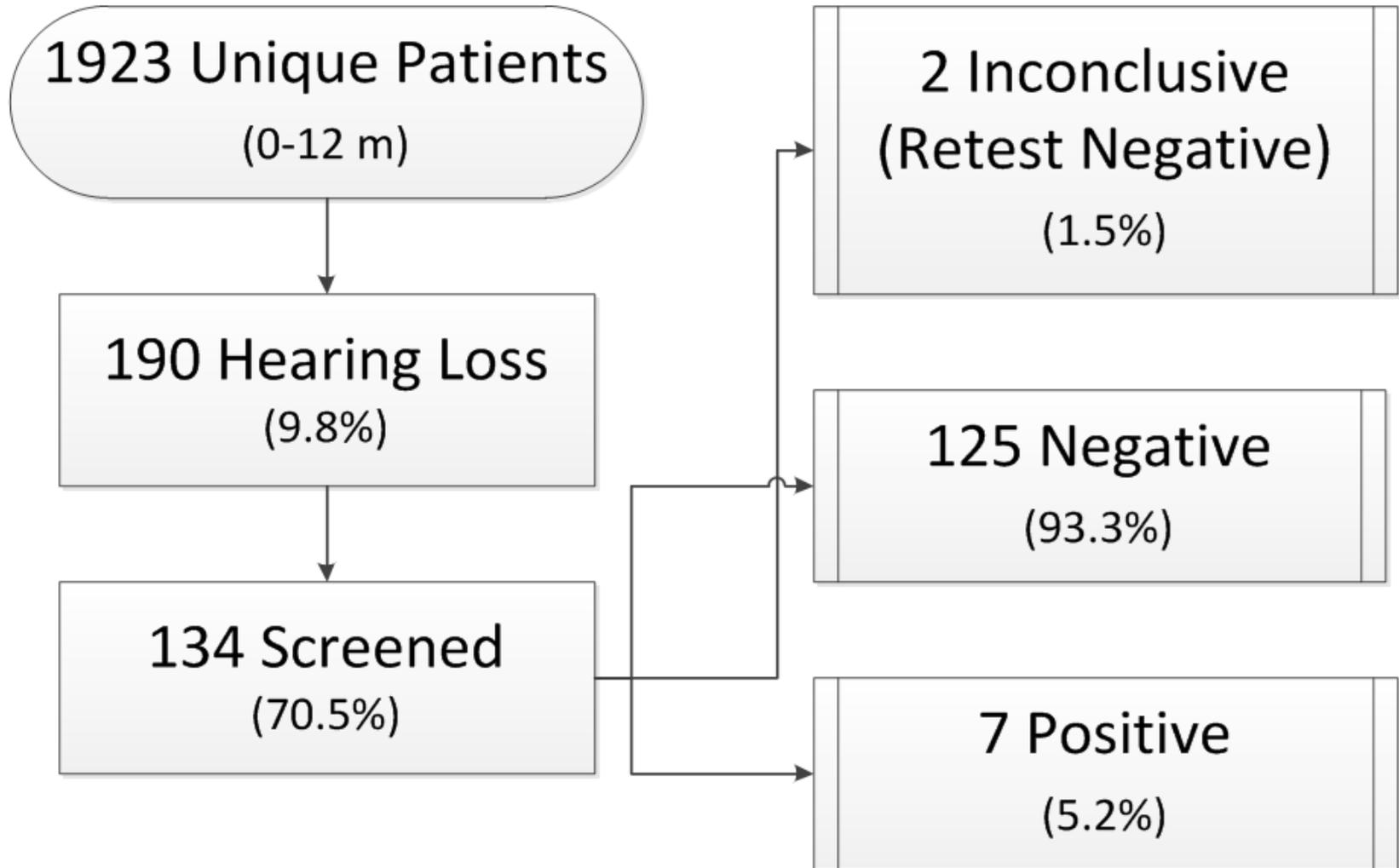
CMV+ // Normal Hearing

- Hearing tests every three months until 1 year old
- Annual thereafter (if hearing stays normal)

CMV+ // Hearing Loss

- Hearing tests every three months until 1 year old
- Audiological management as appropriate for degree and type of loss

Our Tracking Data (4/15-1/18)



CMV+ at Children's

CHILD	AGE OF SWAB	HEARING LEVEL	LATERALITY	LENGTH OF VALGANCYCLOVIR	TECHNOLOGY
*AM	31 days	Mild	Right	False Positive; No Treatment	n/a
*NG	46 days	Mild	Bilateral	319 days	Hearing Aids
*LA	63 days	Profound	Bilateral	298 days	Cochlear Implants
*LL	84 days	Mild to Severe	Bilateral	Recommended; Lost to F/U	Hearing Aids
*BK	98 days	Mild	Bilateral	Not Recommended; CMV of unknown timing	n/a
*HA	163 days	Mild to Moderate	Right	Family denied	Not pursued

Without Universal Screening, It's a Community Effort



- Obstetrics
 - Maternal diagnosis
- Birth Hospital
 - Newborn Hearing Screening
 - Symptomatic Infants
- Infectious Disease

CHILD	AGE OF SWAB	HEARING LEVEL	LATERALITY	LENGTH OF VALGAN-CYCLOVIR	TECHNOLOGY
JA	In Utero	Severe to Profound	Bilateral	150 days	Hearing Aids
MF	6 hours	Mild to Mod-Severe	Bilateral	395 days	Hearing Aids
AS	2 days	Mod-Severe to Severe	Right	172 days	Hearing Aid
LH	2 days	Severe to Profound	Right	257 days	
GK	3 days	Mild to Severe HiFreq	Right	179 days	
*AM	31 days	Mild	Right	False Positive; No Treatment	n/a
*NG	46 days	Mild	Bilateral	319 days	Hearing Aids
*LA	63 days	Profound	Bilateral	298 days	Cochlear Implants
*LL	84 days	Mild to Severe	Bilateral	Recommended; Lost to F/U	Hearing Aids
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Observations

- Our process did not prevent any child from acquiring hearing loss
- Our process possibly prevented progression of hearing loss

cCMV Management

- Establish care with several specialty programs:
 - Audiology
 - Infectious Disease
 - Neurology
 - Ophthalmology
 - Otolaryngology

- Enrollment in Early Intervention

CMV Screening Challenges

- Challenges with Acquisition
 - Parent refusal
 - Insurance Coverage
 - Implemented Letter of Medical Necessity
 - Audiologist does not collect swab
 - Forgets
 - Assumes etiology based on presentation
 - Child presents with diagnoses that address hearing loss etiology (e.g., hypoxia, middle ear dysfunction, Pierre Robin sequence)
- Challenges post-Acquisition
 - Parent stress level
 - False positives
 - Loss to follow-up

Summary and Implications

- More birth hospitals electing to perform CMV swab on infants who refer NBHS
 - Leads to earlier diagnosis, treatment, and intervention
- Asymptomatic infants still are missed
- Late-onset hearing losses or losses undetectable by NBHS: How can we know whether congenital CMV was the etiology?

Summary and Implications

Almost all challenges would be solved with universal cCMV newborn screening.



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