



## UNIVERSAL NBS for cCMV

Washington State Department of Health

# cCMV Universal Screening

- Test all babies for cCMV (~84,000 babies/year)
  - Urine
    - Best sample type – highest sensitivity
    - Cumbersome to collect
    - No system for collecting urine for all babies
  - Saliva
    - Good sensitivity
    - Higher false positive rate than urine
    - No system for collecting saliva for all babies

## cCMV Universal Screening

- cCMV DNA can be detected in dried blood specimens
- Viral load in blood is 100x lower than in urine or saliva
  - Current DBS assays require three times the amount of blood as other NBS tests
    - Would likely require an additional blood spot for testing (new total = 6 blood spots)

# cCMV Universal Screening

- Dried blood spot screening test performance
- Sensitivity: 75.0%
  - False(-) rate: 25% (no benefit from NBS)
- Specificity: 99.88%
  - False(+) rate: 0.12%

## Blood spot test - cCMV

Ontario – combined method - 2 lab developed tests

- Real-time qPCR method for cCMV
- MassArray for 2 genes associated with hearing loss

Minnesota – for research use only

- Real-time qPCR method

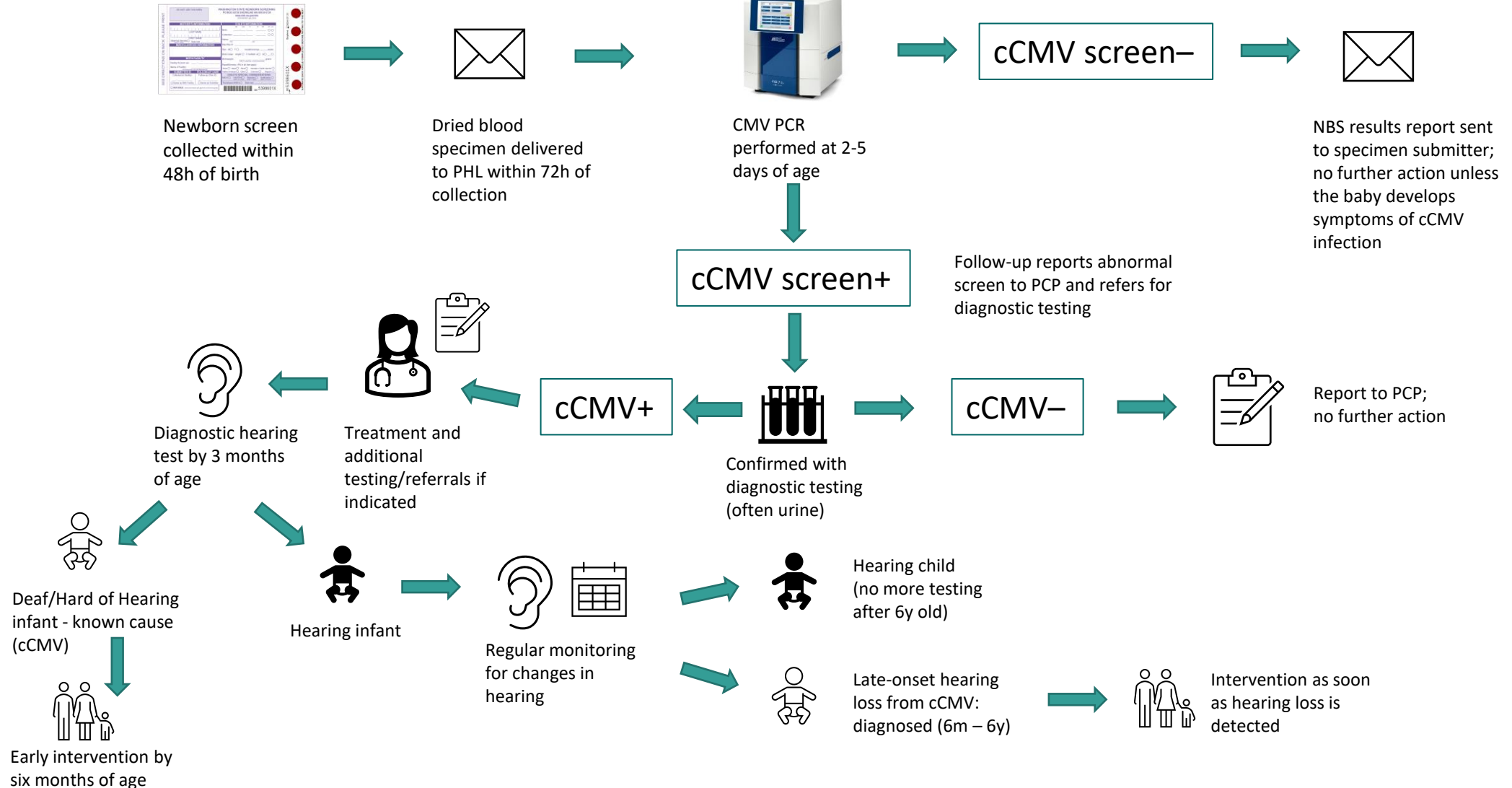
# Blood spot test - cCMV

## Minnesota method

- \$15/baby for the kits
- Cost does not include
  - Instrumentation
  - Salaries/Benefits for NBS staff
    - Laboratory testing
    - Follow-up
    - Long-term follow-up



# Universal cCMV Screening



# Surveillance for late-onset hearing loss

months of age	3	6	9	12	15	18	21	24	27	30	33	36	42	48	54	60	66	72
ABR	X																	
OAEs	X	X	X	X	X	X	X	X	X	X	X	X	X					
Tympanometry	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
VRA		X	X	X	X	X	X											
Condition play audiometry								X	X	X	X	X	X					
Select picture								X	X	X	X	X	X					
Standard audiometry														X	X	X	X	X
Pediatric speech testing														X	X	X	X	X

Based on Utah's EHDI hearing assessment schedule



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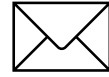
Whose responsibility is this?

Based on Utah's EHDI hearing assessment schedule

# Universal cCMV Screening



Newborn screen collected within 48h of birth



Dried blood specimen delivered to PHL within 72h of collection



CMV PCR performed at 2-5 days of age



cCMV screen-



NBS results report sent to specimen submitter; no further action unless the baby develops symptoms of cCMV infection

Typical Blood Spot Follow-up End

cCMV screen+

Follow-up reports abnormal screen to PCP and refers for diagnostic testing



Diagnostic hearing test by 3 months of age



Treatment and additional testing/referrals if indicated

cCMV+



Confirmed with second sample (often urine)

cCMV-



Report to PCP; no further action



Deaf/Hard of Hearing infant - known cause (cCMV)



Hearing infant



Regular monitoring for changes in hearing



Hearing child (no more testing after 6y old)

N=216/year



Late-onset hearing loss from cCMV: diagnosed (6m - 6y)

N=31/year



Intervention as soon as hearing loss is detected

Typical EHDDI Follow-up End

Early intervention by six months of age

N=247/year

## NBS for cCMV elsewhere

- Targeted screening: UT, IA, VA, NY, CT, IL
- Utah
  - legislation 2013 established a public education program for CMV
  - Work group meets monthly
  - cCMV Clinic at the UofU/Primary Children's Hospital

## NBS for cCMV elsewhere

- Minnesota
  - Vivian act (2107, 2021) – convened advisory committee to review CMV
  - If passed, increase NBS fee by \$43/baby
  - Conditions readiness review
    - Evaluation of public health laboratory and medical system for introducing cCMV screening

# Summary

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- Dried blood spot test is available
  - Requires extra blood (three punches)
  - Low sensitivity (25% of cases missed)
  - Adequate specificity (0.12% false(+) rate)
  - Testing kit available (moderately expensive)
- There are infrastructure needs to perform long-term follow-up for an additional ~250 babies needing surveillance for hearing loss

~Thank you~

Together we protect the lives of  
Washington's youngest citizens.

