



ECONOMIC ANALYSIS FOR ADDING NEWBORN SCREENING FOR CONGENITAL CYTOMEGALOVIRUS

Caitlin Maloney, MPHc John Thompson PhD, MPH, MPA Newborn Screening Program

Washington State NBS Criteria

1. Available Screening Technology: Sensitive, specific and timely tests are available that can be adapted to mass screening.

2. Diagnostic Testing and Treatment Available: Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

3. Prevention Potential and Medical Rationale: The newborn identification of the condition allows early diagnosis and intervention. Important considerations:

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.

4. Public Health Rationale: Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.

5. Cost-benefit/Cost-effectiveness: The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:

- The prevalence of the condition among newborns.
- The positive and negative predictive values of the screening and diagnostic tests.
- Variability of clinical presentation by those who have the condition.
- The impact of ambiguous results. For example the emotional and economic impact on the family and medical system.
- Adverse effects or unintended consequences of screening.

Strategy

Decision Tree

 Status quo (no screening) vs. universal (dried blood spot) vs. hearing targeted (failed hearing screen)

Research

- Primary literature and expert opinion
- NBS programs with state-mandated congenital CMV (cCMV) education and/or screening

Sensitivity analysis

• High and low estimates for parameters

No Screening

Universal

Screening

Death at Sx presentation Early ID - early onset sx ... 3.68 Ha Screening Hadel 1.45 52.50 Antiviral treatment (moderately to severely sx) \$/1 34.67 Surviving at Sx Presentation 1.55 48.83 Late onset hearing loss No antiviral treatment £.55 4.96 Birthrate Prevalence # cCMV 1.15 14.16 \$4,000 420.00 Death at Asx presentation 1.00 1 in: 200 1.11 0.00 No late onset hearing loss 15 9.20 Late onset hearing loss (no chance for surveillance) Late ID - late onset sy 6.00 45.94 367.50 Surviving at Asx Presentation 1.115 367.50 1.55 No late onset hearing loss ANS 321.56 a de -de Deaths 2.76 e nevs Antiviral treatment (moderately to severely sx) Universal Screening Mudel 8.01 65.57 True (+) Seculturity 1.19 315.00 Survivina Late onset hearing loss # cCMV Prevalence 1.55475 312.24 1.45 30.\$3 420.00 1.115 No antiviral treatment; surveillance for hearing loss 1 in: 200 246.67 < 6.15 No late onset hearing loss 1.115 215.44 Death at Sx presentation ... 0.92 Early ID - early onset sx Antiviral treatment (moderately to severely sx) False (-) 1.415 13.13 8.14 \$.67 Surviving at Sx Presentation 105.00 s.73 Birthrate 1.55 12.21 \$4,000 No antiviral treatment False (+) Late onset hearing loss 1.15 3.54 100.19 Death at Asx presentation 1.24 1.0 1.555 No cCMV Late ID - late onset sx 1.115 \$35\$0.00 91.88 Late onset hearing loss (no chance for surveillance) No late onset hearing loss 6.405 11.4# 1.65 2.30 Surviving at Asx Presentation True (-) 91.## Spesificile ×.55 \$3479.\$1 No Late onset hearing loss 1.597 1.115 \$0.39 and a ~h all de ale Deaths 0.46 Antiviral treatment (moderately to severely sx) Hearing Targeted Screening Mudel 8.11 10.93 Fail NBHS Seculturity 52.50 \$ \$15 Surviving Prevalence # cCMV 52.04 A. 55%75 420.00 1.05 1 in: 200 iviral treatment; early intervention for early hearing loss \$.15 41.11 Death at Sx presentation 1.11 3.22 Early ID - early onset st Antiviral treatment (moderately to severely sx) Pass NBHS 30.33 45.94 £ 515 8.14 1.00 367.50 Surviving at Sx Presentation Birthrate 42.72 1.55 \$4,000 No antiviral treatment False (+) 12.39 Late onset hearing loss \$.15 752.22 Death at Asx presentation 4.95 No cOMV 1.555 Late ID - late onset sx 111 0.00 \$35\$0.00 321.56 1.115 No late onset hearing loss Late onset hearing loss (no chance for surveillance) 1.45 40.20 1.51 7.43 Surviving at Asx Presentation True (-) 321.56 raifiaily ×.07 \$2\$27.7\$ No late onset hearing loss 1.555

££/5 2\$1.37

ande

Hearing Targeted Screening

Decision Tree

cCMV does not fit traditional newborn screening (NBS) rationale

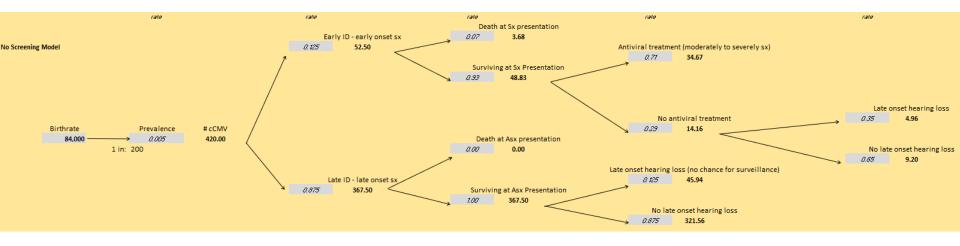
- No quantifiable difference in morbidity and mortality at this time
- Antiviral treatment may provide short-term relief, but will not reverse or prevent symptoms

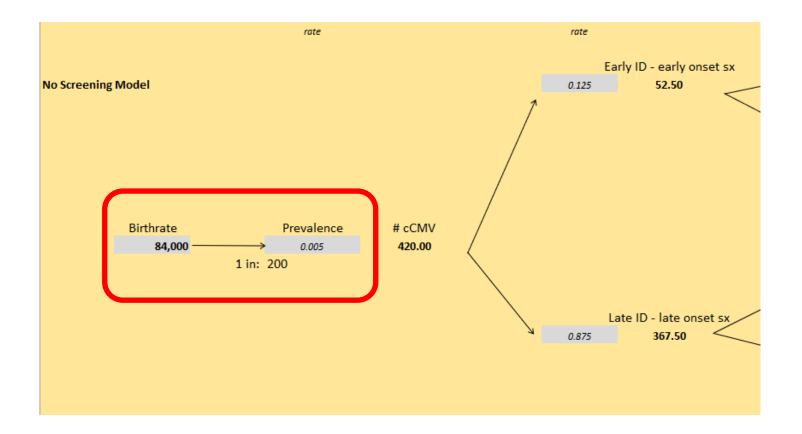
Decision Tree

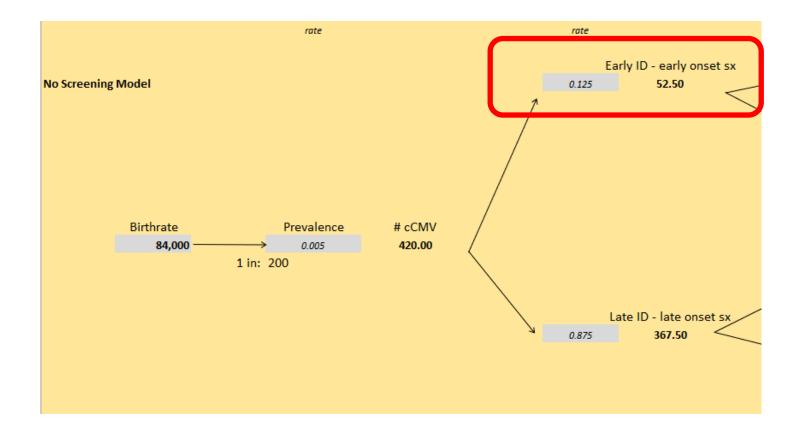
cCMV does not fit traditional newborn screening (NBS) rationale

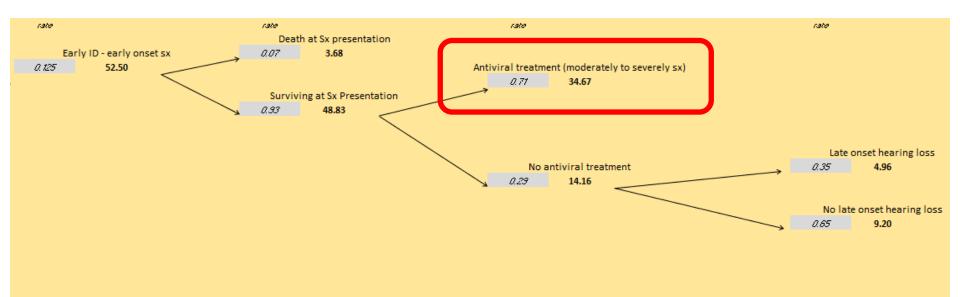
- No quantifiable difference in morbidity and mortality at this time
- Antiviral treatment may provide short-term relief, but will not reverse or prevent symptoms

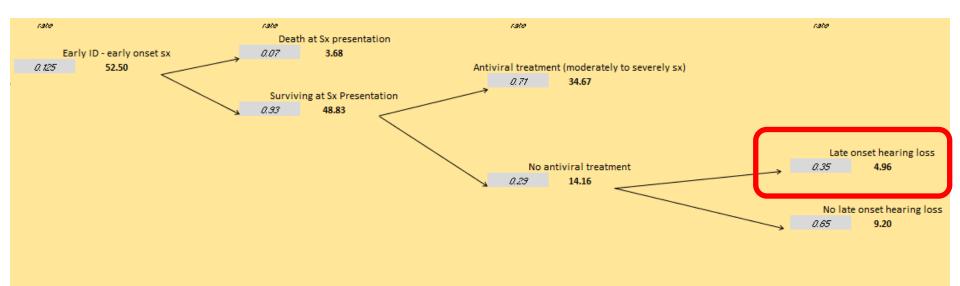
Focus: early identification for infants with asymptomatic cCMV infections for surveillance and early intervention through EHDDI

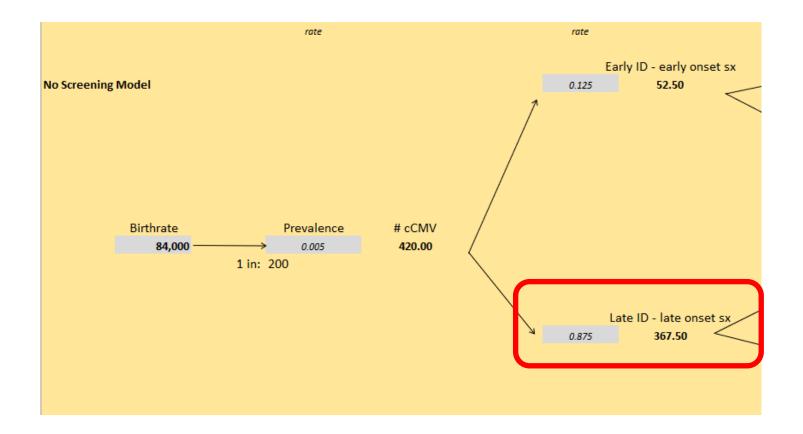


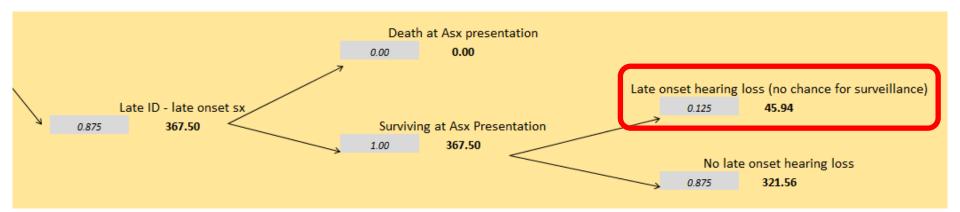


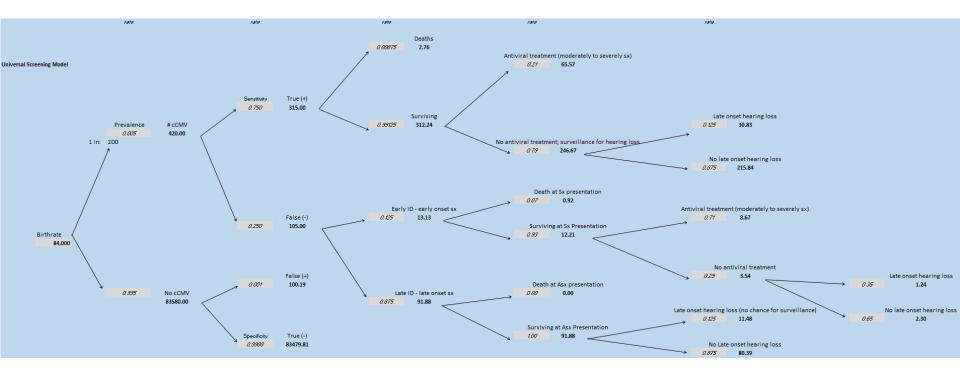


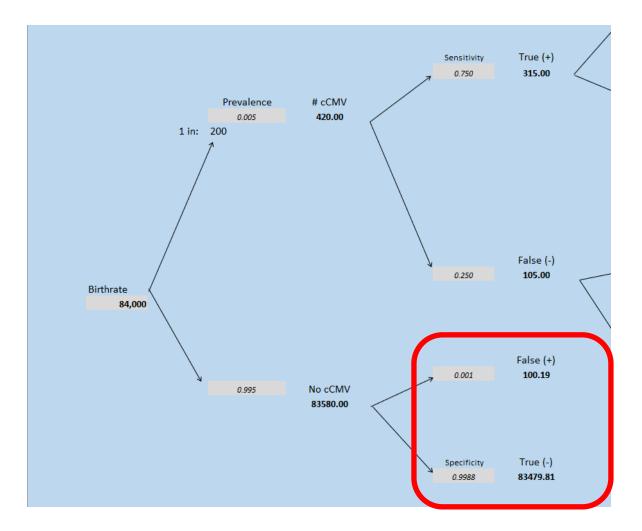


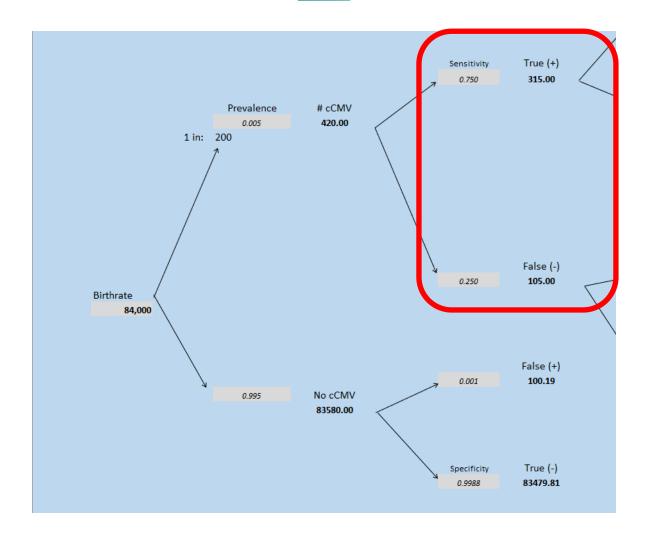


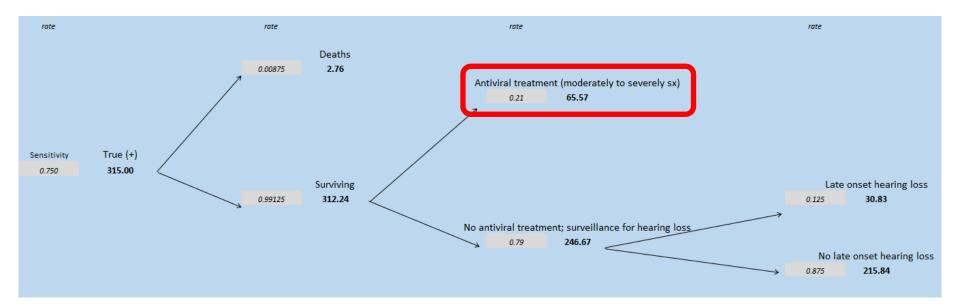


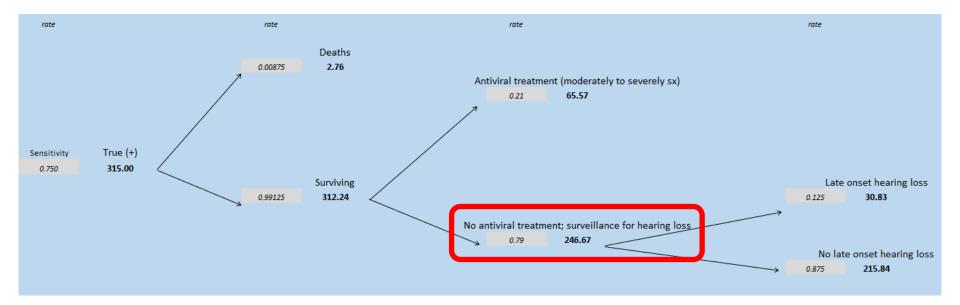


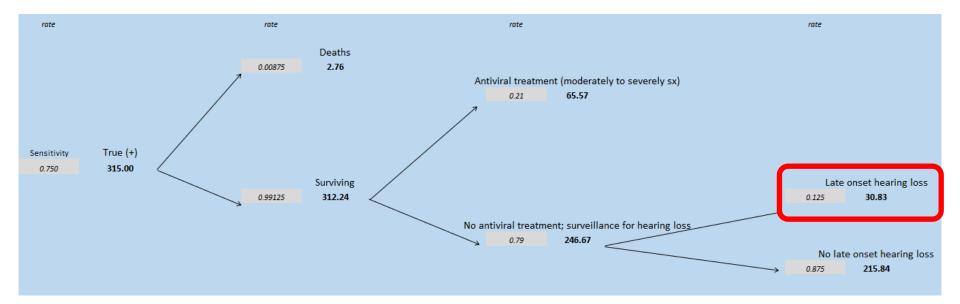


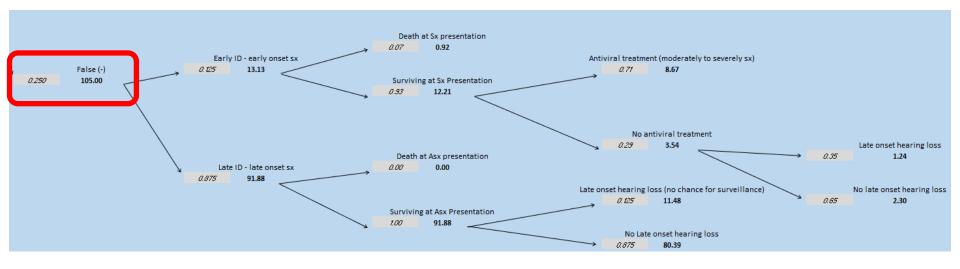


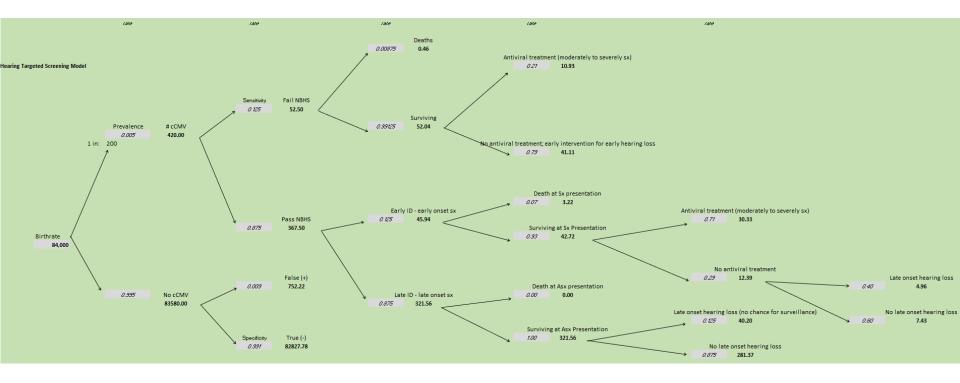


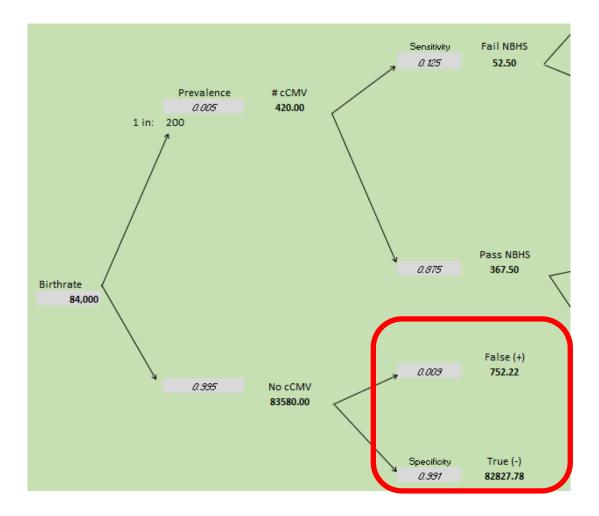


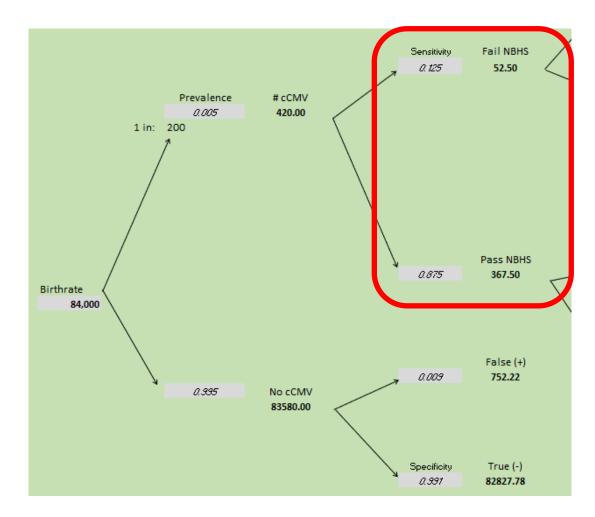


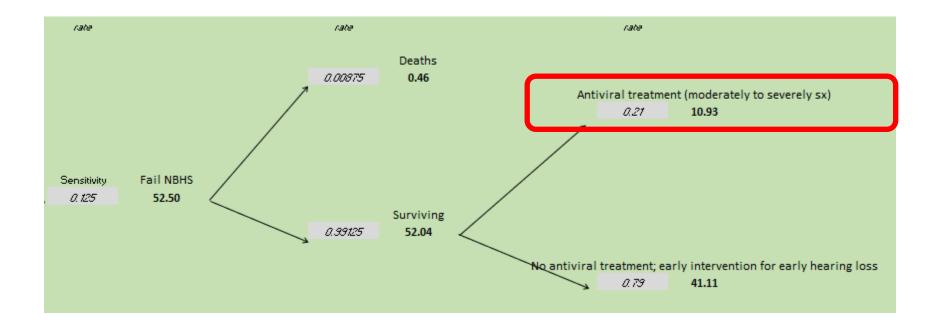


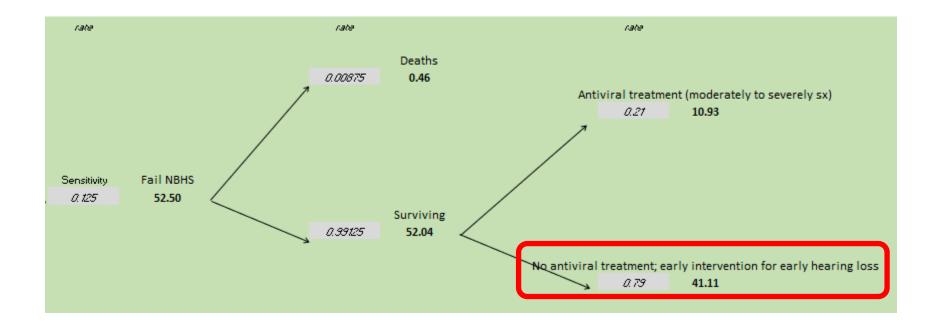


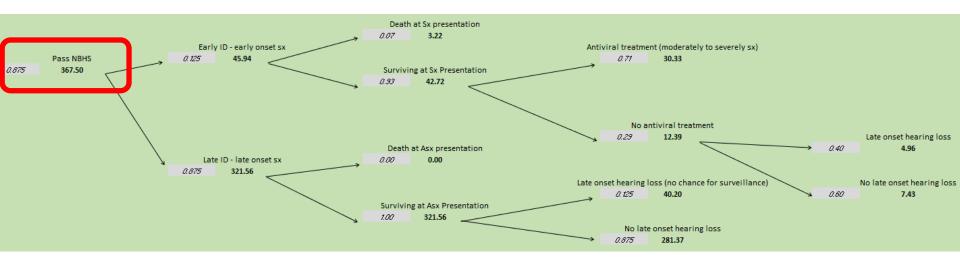












No Screening vs. Universal Screening

No screening Deaths # of babies with dx testing # of babies treated with antivirals Surviving with LOHL and early intervention Surviving with no HL but 6 years of surveilland	
	ce
Universal screening Deaths # of babies with dx testing # of babies treated with antivirals Surviving with LOHL and early intervention Surviving with no HL but 6 years of surveilland	ce

No Screening vs. Universal Screening

No screening	Deaths	3.68
	# of babies with dx testing	52.50
	# of babies treated with antivirals	34.67
	Surviving with LOHL and early intervention	4.96
	Surviving with no HL but 6 years of surveillance	9.20
Universal screening	Deaths	3.68
	# of babies with dx testing	415.19
	# of babies treated with antivirals	74.24
	Surviving with LOHL and early intervention	32.07
	Surviving with no HL but 6 years of surveillance	215.84

No Screening vs. Universal Screening

No screening	Deaths	3.68
	# of babies with dx testing	52.50
	# of babies treated with antivirals	34.67
	Surviving with LOHL and early intervention	4.96
	Surviving with no HL but 6 years of surveillance	9.20
Universal screening	Deaths	3.68
	# of babies with dx testing	415.19
	# of babies treated with antivirals	74.24
	Surviving with LOHL and early intervention	32.07
	Surviving with no HL but 6 years of surveillance	215.84
SHIFT		
	Deaths averted	0.00
	Additional babies with dx testing	362.69
	Additional babies treated with antivirals	39.57
	Additional babies surviving with LOHL and early intervention	27.12
	Surviving with no HL but 6 years of surveillance	206.63

Benefits vs. Costs: Universal Screening

BENEFITS		
	Value per life saved	\$11,600,000
	Value per baby with early identification for hearing loss	\$44,200
COSTS		
	Cost per baby NBS	\$31.10
	Cost per baby diagnostic testing (CMV DNA test)	\$487.50
	Cost per baby antiviral treatment	\$5,868.61
	Cost per baby surveillance for hearing loss	\$1,826.19

Benefits vs. Costs: Universal Screening

Value per life saved Total value of lives saved Value per baby with early identification for HL Total value of LOHL intervention	\$ \$	11,600,000.00 44,200.00		Totals \$0.00
Total value of lives saved Value per baby with early identification for HL				\$0.00
Value per baby with early identification for HL	\$	44 200 00		\$0.00
	\$	44 200 00		
Total value of LOHL intervention		44,200.00		
Total value of LOTIL intervention			\$	1,198,583.21
Total benefits				\$1,198,583.21
				Totals
Cost per baby NBS	\$	31.10		
Total cost NBS			\$	2,612,121.22
Cost per baby dx testing (CMV DNA test)	\$	487.50		
Total cost dx testing			\$	176,812.25
Cost per baby antiviral treatment	\$	5,868.61		
Total cost antiviral treatment			\$	232,231.90
Cost per baby surveillance for HL	\$	1,826.19		
· · · ·			\$	426,876.02
Total costs			\$	3,448,041.39
	Total benefits Cost per baby NBS Total cost NBS Cost per baby dx testing (CMV DNA test) Total cost dx testing Cost per baby antiviral treatment Total cost antiviral treatment Cost per baby surveillance for HL Total cost surveillance for HL Total cost surveillance for HL	Cost per baby NBS \$ Total cost NBS \$ Cost per baby dx testing (CMV DNA test) \$ Total cost dx testing CMV DNA test) \$ Total cost dx testing \$ Cost per baby antiviral treatment \$ Total cost antiviral treatment \$ Total cost antiviral treatment \$ Total cost antiviral treatment \$ Total cost surveillance for HL \$	Cost per baby NBS\$ 31.10Total cost NBS\$ 487.50Cost per baby dx testing (CMV DNA test)\$ 487.50Total cost dx testing\$ 5,868.61Total cost antiviral treatment\$ 5,868.61Total cost antiviral treatment\$ 1,826.19Total cost surveillance for HL\$ 1,826.19	Cost per baby NBS\$ 31.10Total cost NBS\$ 31.10Cost per baby dx testing (CMV DNA test)\$ 487.50Total cost dx testing\$ 5,868.61Cost per baby antiviral treatment\$ 5,868.61Total cost antiviral treatment\$ 1,826.19Cost per baby surveillance for HL\$ 1,826.19Total cost surveillance for HL\$ \$

Benefits vs. Costs: Universal Screening

BENEFITS			Totals
	Value per life saved	\$ 11,600,000.00	
	Total value of lives saved		\$0.00
	Value per baby with early identification for HL	\$ 44,200.00	
	Total value of LOHL intervention		\$ 1,198,583.21
	Total benefits		\$1,198,583.21
COSTS			Totals
	Cost per baby NBS	\$ 31.10	
	Total cost NBS		\$ 2,612,121.22
	Cost per baby dx testing (CMV DNA test)	\$ 487.50	
	Total cost dx testing		\$ 176,812.25
	Cost per baby antiviral treatment	\$ 5,868.61	
	Total cost antiviral treatment		\$ 232,231.90
	Cost per baby surveillance for HL	\$ 1,826.19	
	Total cost surveillance for HL		\$ 426,876.02
	Total costs		\$ 3,448,041.39

Benefit/Cost ratio = 0.35

Net benefit = -\$2,249,458.18

No Screening vs. Targeted Screening

No screening	Deaths # of babies with dx testing # of babies treated with antivirals Surviving with LOHL and early intervention Surviving with no HL but 6 years of surveillance
Targeted screening	Deaths # of babies with dx testing # of babies treated with antivirals Surviving with LOHL and early intervention

No Screening vs. Targeted Screening

No screening	Deaths	3.68
	# of babies with dx testing	52.50
	# of babies treated with antivirals	34.67
	Surviving with LOHL and early intervention	4.96
	Surviving with no HL but 6 years of surveillance	9.20
Targeted screening	Deaths	3.68
	# of babies with dx testing	804.72
	# of babies treated with antivirals	41.26
	Surviving with LOHL and early intervention	4.96

No Screening vs. Targeted Screening

No screening	Deaths	3.68
	# of babies with dx testing	52.50
	# of babies treated with antivirals	34.67
	Surviving with LOHL and early intervention	4.96
	Surviving with no HL but 6 years of surveillance	9.20
Targeted screening	Deaths	3.68
	# of babies with dx testing	804.72
	# of babies treated with antivirals	41.26
	Surviving with LOHL and early intervention	4.96
SHIFT		
	Deaths averted	0.00
	Additional babies with dx testing	752.22
	Additional babies treated with antivirals	6.60
	Additional babies surviving with LOHL and early intervention	0.00

Benefits vs. Costs: Targeted Screening

BENEFITS		
	Value per life saved	\$11,600,000
	Value per baby with early identification for HL	\$44,200
COSTS		
	Cost per baby NBS	\$4.03
	Cost per baby dx testing (CMV DNA test)	\$487.50
	Cost per baby antiviral treatment	\$5,868.61
	Cost per baby surveillance for HL	\$1,826.19

Benefits vs. Costs: Targeted Screening

BENEFITS		I.		Totals
DEINEFITS		<u> </u>	44 699 999 99	Totals
	Value per life saved	\$	11,600,000.00	
	Total value of lives saved			\$0.00
	Value per baby with early identification for HL	\$	44,200.00	
	Total value of LOHL intervention			\$0.00
	Total benefits			\$0.00
COSTS				Totals
	Cost per baby NBS	\$	4.03	
	Total cost NBS			\$ 338,707.97
	Cost per baby dx testing (CMV DNA test)	\$	487.50	
	Total cost dx testing			\$ 366,707.25
	Cost per baby antiviral treatment	\$	5,868.61	
	Total cost antiviral treatment			\$ 38,705.32
	Cost per baby surveillance for HL	\$	1,826.19	
	Total cost surveillance for HL			\$0.00
	Total costs			\$ 744,120.53

Benefits vs. Costs: Targeted Screening

				Totals
Value per life saved	\$	11,600,000.00		
Total value of lives saved				\$0.00
Value per baby with early identification for HL	\$	44,200.00		
Total value of LOHL intervention				\$0.00
Total benefits				\$0.00
				Totals
Cost per baby NBS	\$	4.03		
Total cost NBS			\$	338,707.97
Cost per baby dx testing (CMV DNA test)	\$	487.50		
Total cost dx testing			\$	366,707.25
Cost per baby antiviral treatment	\$	5,868.61		
Total cost antiviral treatment			\$	38,705.32
Cost per baby surveillance for HL	\$	1,826.19		
Total cost surveillance for HL				\$0.00
Total costs			\$	744,120.53
	Total value of lives savedValue per baby with early identification for HLTotal value of LOHL interventionTotal benefitsCost per baby NBSTotal cost NBSCost per baby dx testing (CMV DNA test)Total cost dx testingCost per baby antiviral treatmentTotal cost antiviral treatmentCost per baby surveillance for HLTotal cost surveillance for HL	Total value of lives saved Value per baby with early identification for HL \$ Total value of LOHL intervention * Total benefits * Cost per baby NBS \$ Total cost NBS \$ Cost per baby dx testing (CMV DNA test) \$ Total cost dx testing * Cost per baby antiviral treatment \$ Total cost antiviral treatment \$ Total cost surveillance for HL \$	Total value of lives savedValue per baby with early identification for HL\$ 44,200.00Total value of LOHL interventionTotal benefitsTotal benefits	Total value of lives savedValue per baby with early identification for HL\$ 44,200.00Total value of LOHL interventionTotal benefitsTotal benefits

Benefit/Cost ratio = 0.00

Net benefit = -\$744,120.53

Parameters

Parameter	Base			
birthrate	84,000			
birth prevalence	1:200			
sensitivity	75.00%			
specificity	99.88%			
cost of universal NBS	\$31.10			
cost of diagnostic test	\$487.50			
cost antiviral treatment	\$5,868.61			
cost surveillance for hearing loss	\$1,826.19			
% surviving with antiviral treatment	21.00%			
% asymptomatic with late onset hearing loss	12.50%			
value per baby with early intervention for late onset hearing loss	\$44,200.00			

Parameters

Parameter	Base
birthrate	84,000
birth prevalence	1:200
sensitivity	75.00%
specificity	99.88%
cost of universal NBS	\$31.10
cost of diagnostic test	\$487.50
cost antiviral treatment	\$5,868.61
cost surveillance for hearing loss	\$1,826.19
% surviving with antiviral treatment	21.00%
% asymptomatic with late onset hearing loss	12.50%
value per baby with early intervention for late onset hearing loss	\$44,200.00

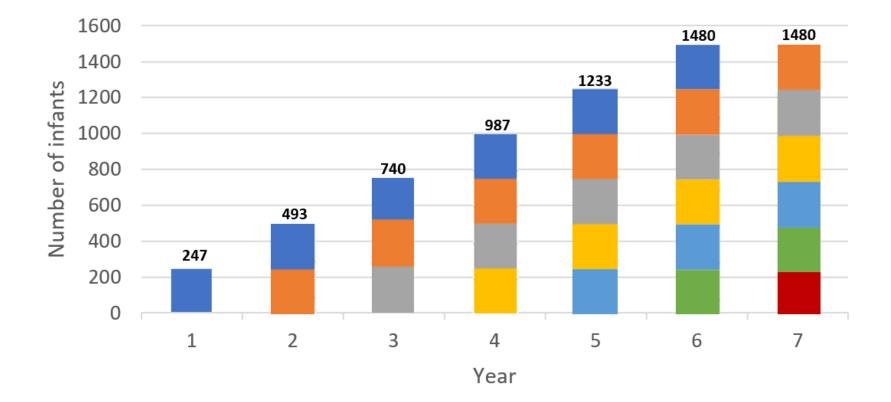
Emotional impact on individuals and families

Surveillance for Hearing Loss

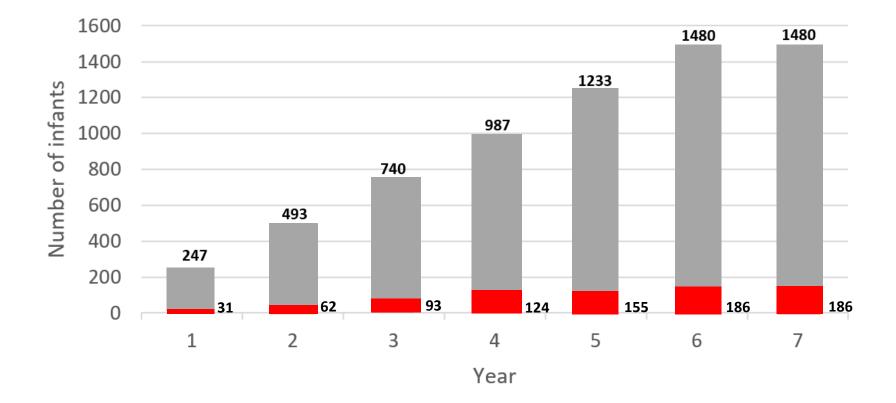
months of age	3	6	9	12	15	18	21	24	27	30	33	36	42	48	54	60	66	72
ABR	Х																	
OAEs	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х					
Tympanometry	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
VRA		Х	Х	Х	Х	Х	Х											
Condition play audiometry								Х	Х	Х	Х	Х	Х					
Select picture								Х	Х	Х	Х	Х	Х					
Standard audiometry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

Based on Utah's EHDI hearing assessment schedule

Surveilling cCMV Positive Infants for Hearing Loss



cCMV Positive Infants Who Develop Late Onset Hearing Loss



Emotional impact on individuals and families

- 31 infants benefit from surveillance and early identification
- 216 infants will go through surveillance and not receive benefits from early identification

Emotional impact on individuals and families

- 31 infants benefit from surveillance and early identification
- 216 infants will go through surveillance and not receive benefits from early identification

Wages lost for parents and families

Emotional impact on individuals and families

- 31 infants benefit from surveillance and early identification
- 216 infants will go through surveillance and not receive benefits from early identification

Wages lost for parents and families

CMV infections prevented from prenatal education and outreach

Acknowledgements

Advocates

- Washington CMV Project
 CDC
- Scott Grosse
- Tatiana Lanzieri

Clinical perspective

- Gail Demmler-Harrison
- Mallory Baker
- Marcie Rider
- Karin Neidt

Newborn Screening

- Ontario: Lauren Gallagher, Jessica Dunn
- Idaho: KD Carlson, Claudia Coatney
- Utah: Stephanie Mcvicar
- Minnesota: Jill Simonetti

Questions?



To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

Sensitivity Analysis

		1	B/C ratio		
	B/C ratio swing low		0.35		B/C ratio swing high
		low	base	high	
birthrate	0.35	73,000	84,000	95,000	0.35
birth prevalence - 1 in:	0.29	250	200	71	0.69
sensitivity	0.34	73.20%	75.00%	85.70%	0.38
specificity	0.34	99.76%	99.88%	100.00%	0.35
cost of universal NBS	0.56	\$15.55	\$31.10	\$46.65	0.25
cost of dx test	0.36	\$243.75	\$487.50	\$4,875.00	0.24
cost antiviral tx	0.36	\$2,934.31	\$5,868.61	\$58,686.10	0.22
cost surveillance for HL	0.37	\$792.89	\$1,826.19	\$2,516.07	0.33
% surviving with antiviral tx	0.42	10.50%	21.00%	42.00%	0.23
% asx with LOHL	0.15	6.25%	12.50%	25.00%	0.74
value per baby with EI for LOHL	0.17	\$22,100.00	\$44,200.00	\$88,400.00	0.70