



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)

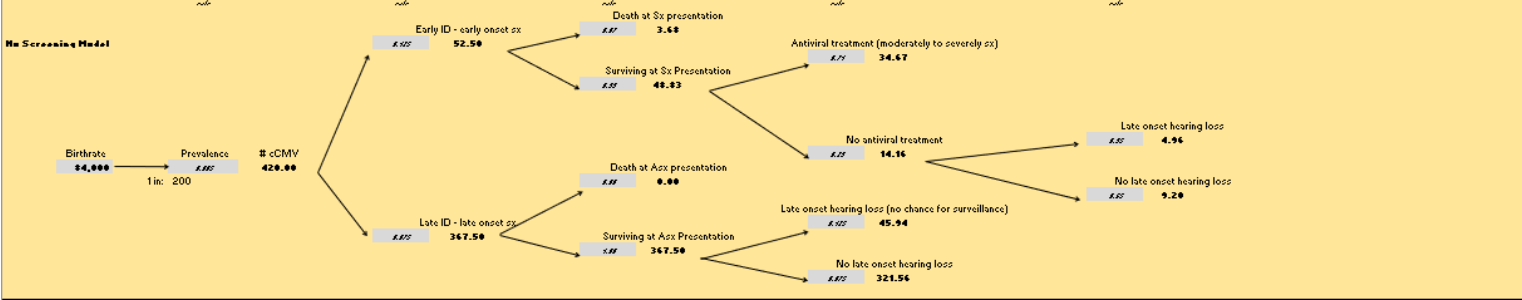
Research

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

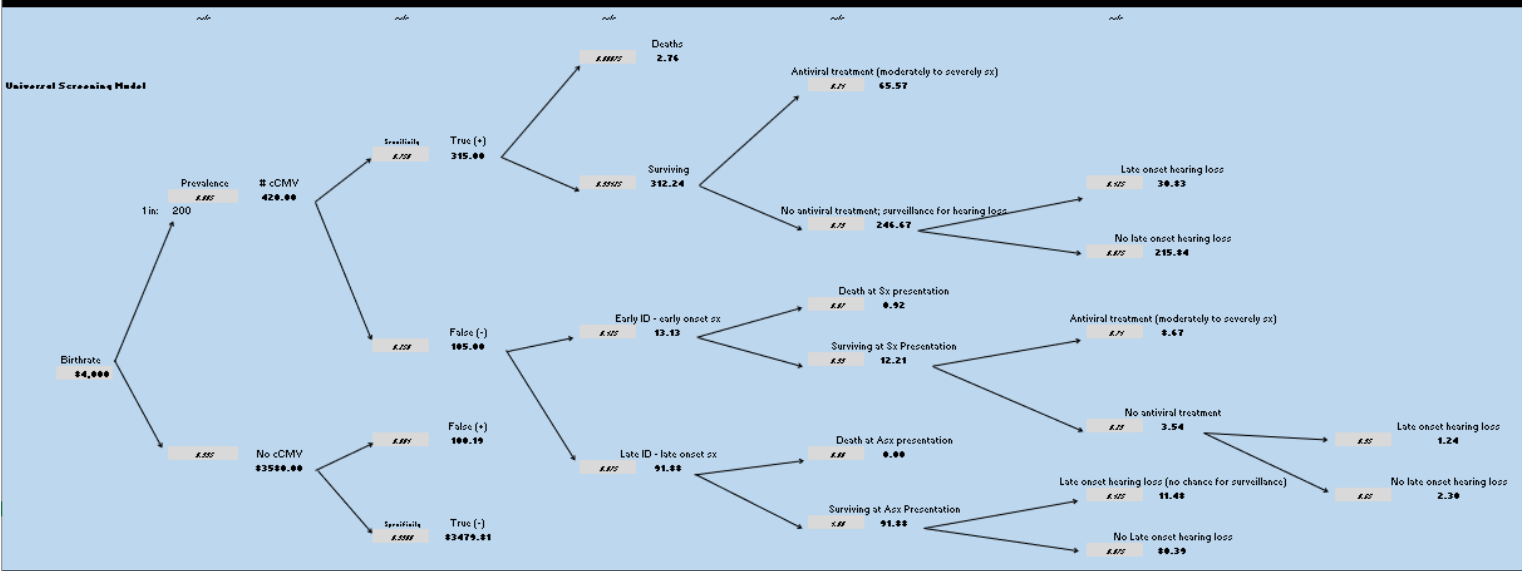
Sensitivity analysis

- High and low estimates for parameters

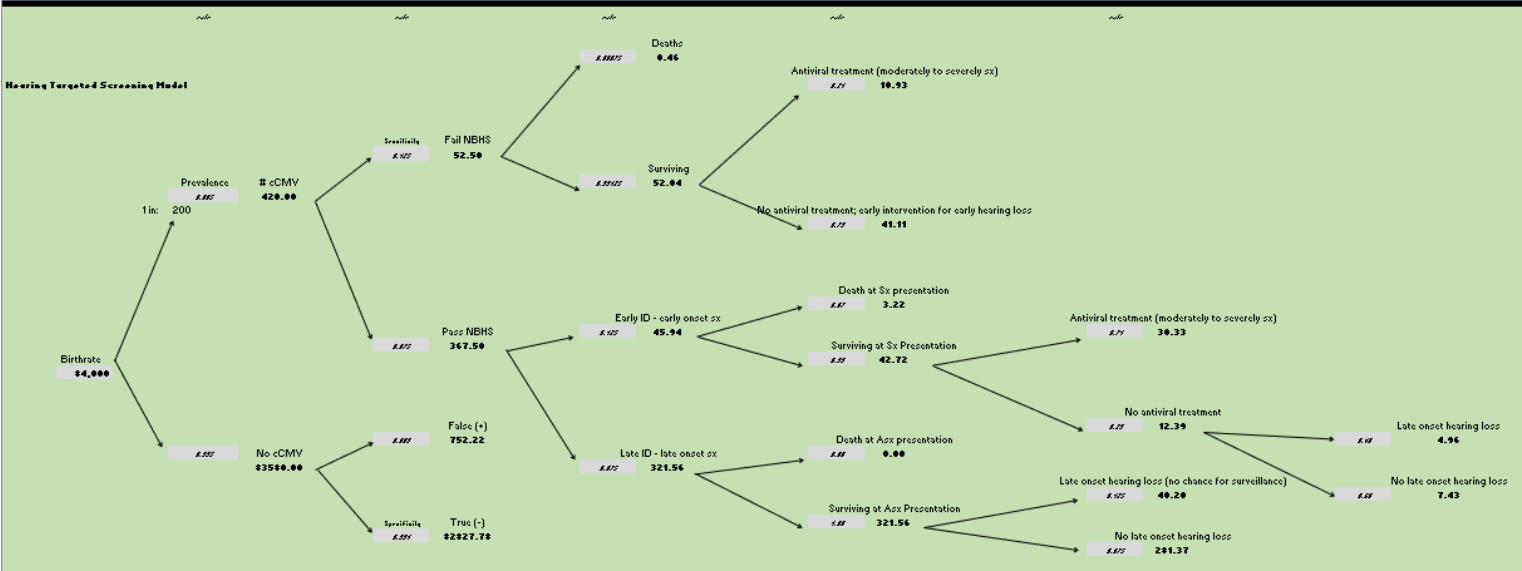
No Screening



Universal Screening



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

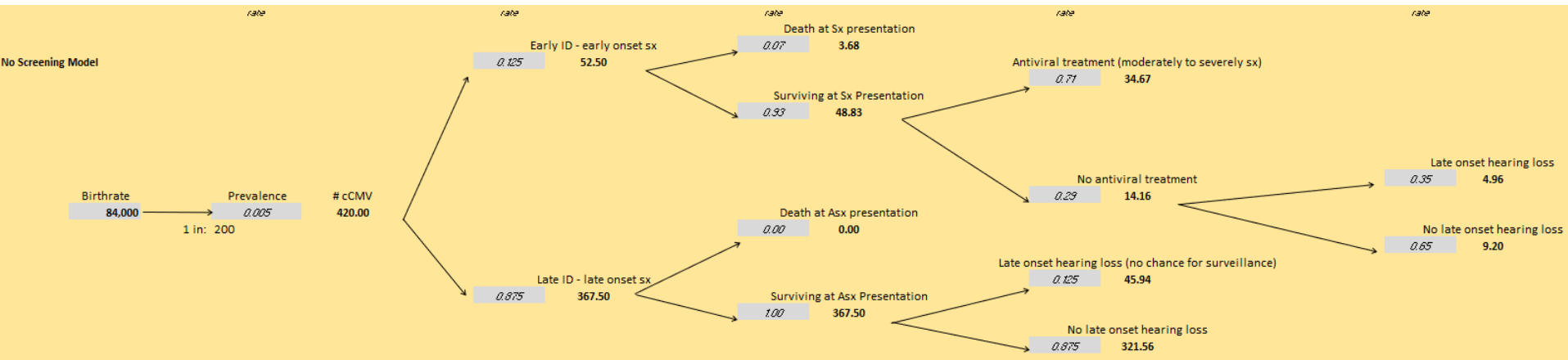
Decision Tree

cCMV does not fit traditional newborn screening (NBS) rationale

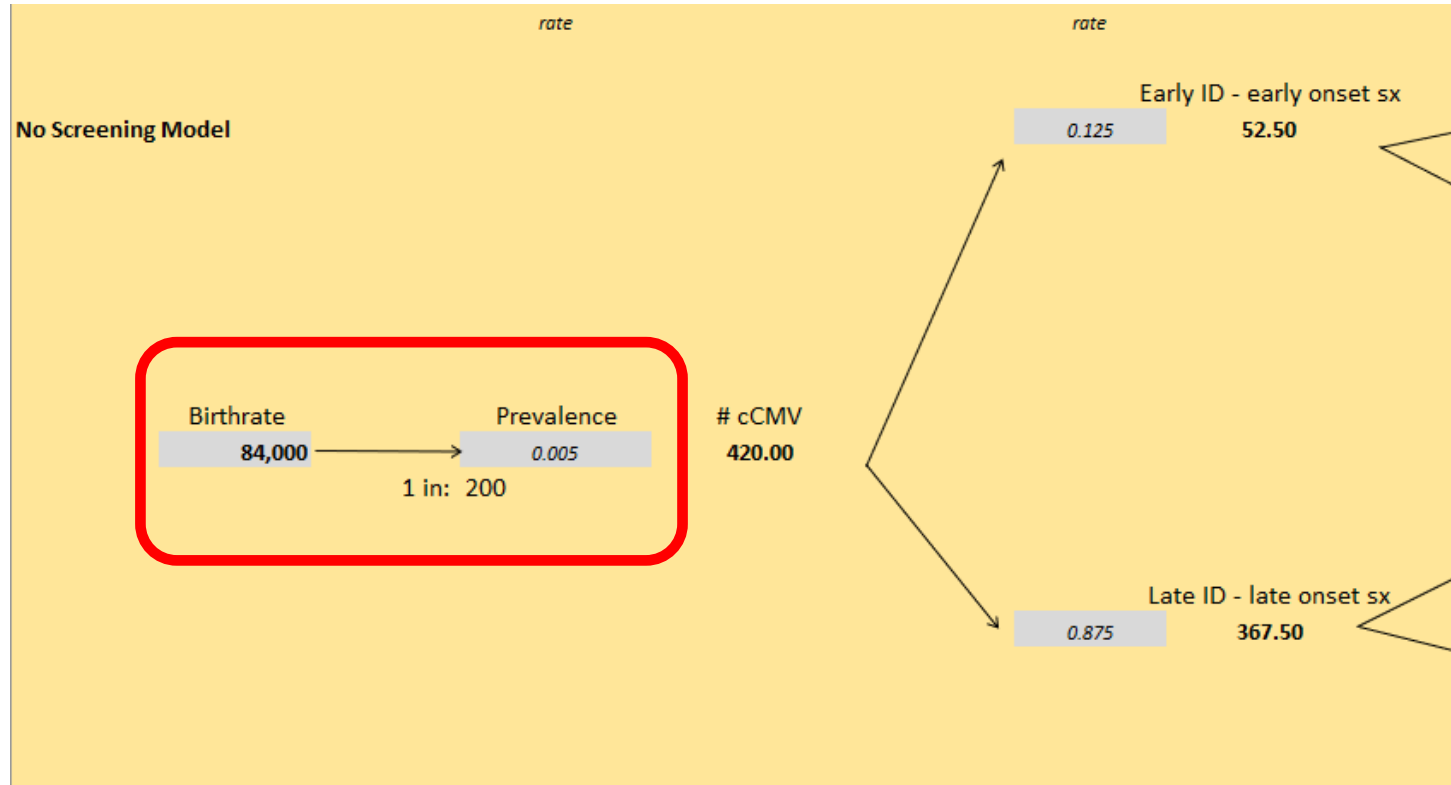
- No quantifiable difference in morbidity and mortality at this time
- Antiviral treatment may provide short-term relief, but will not reverse or prevent symptoms

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

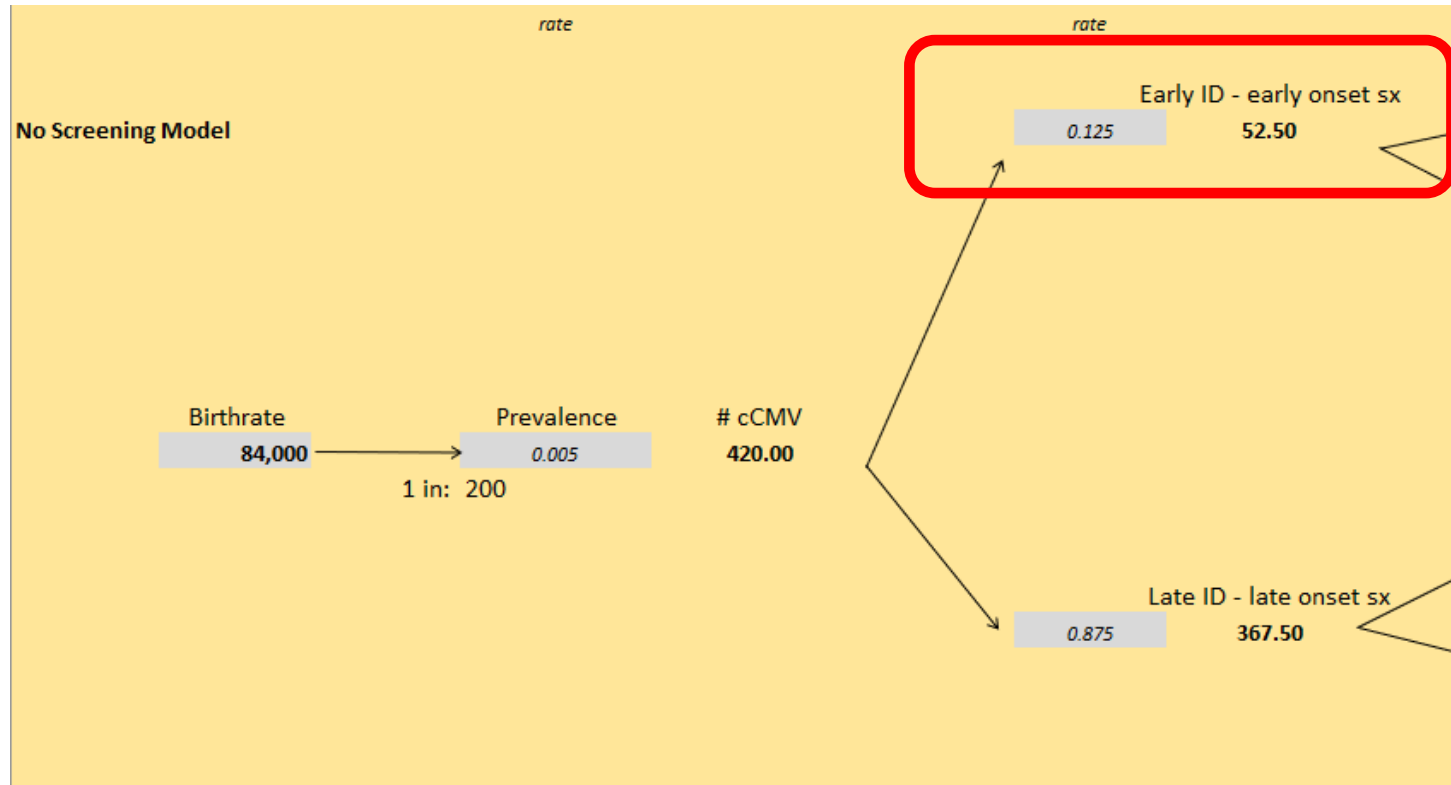
No Screening Model



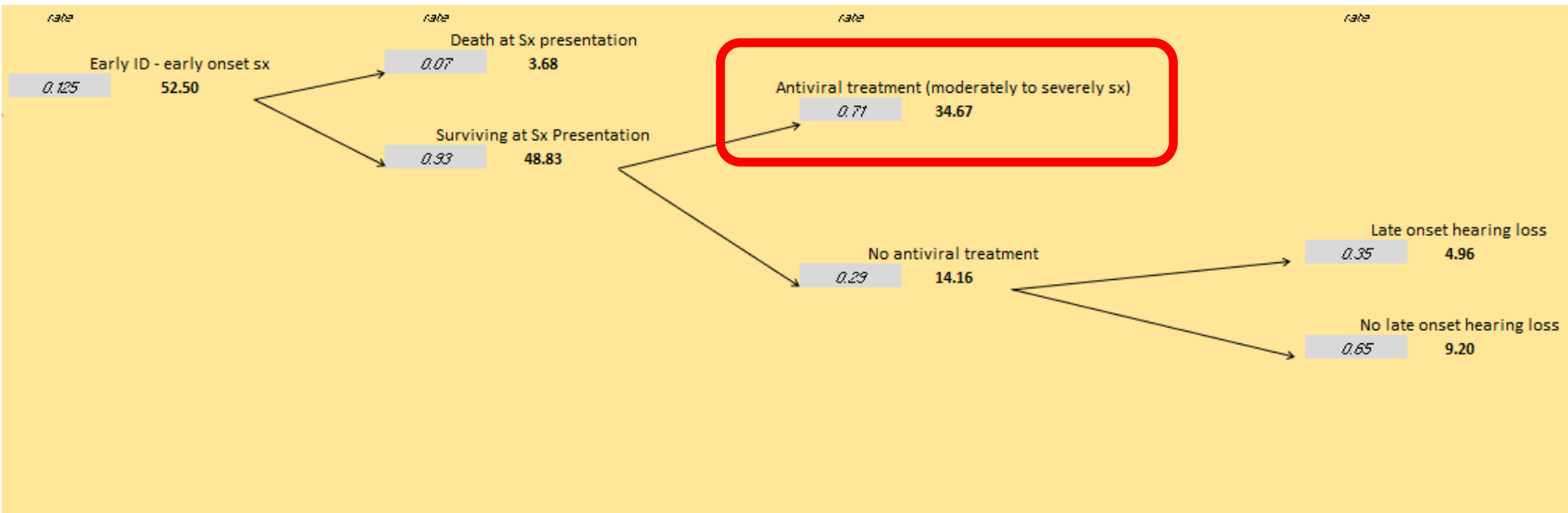
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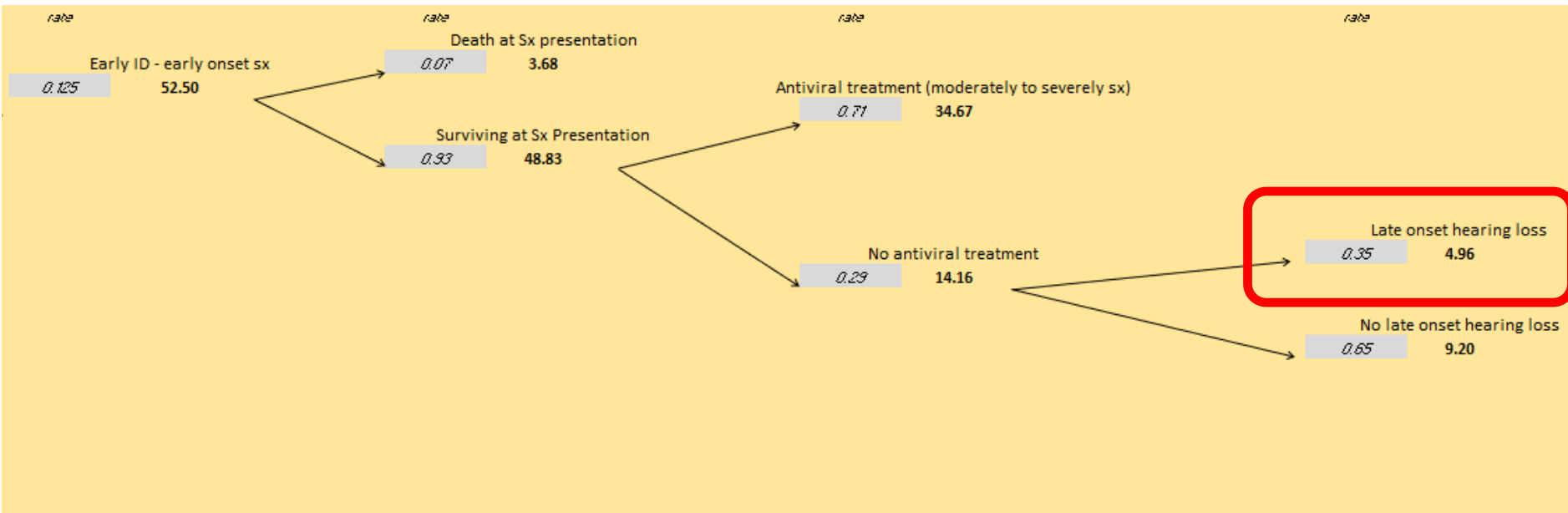
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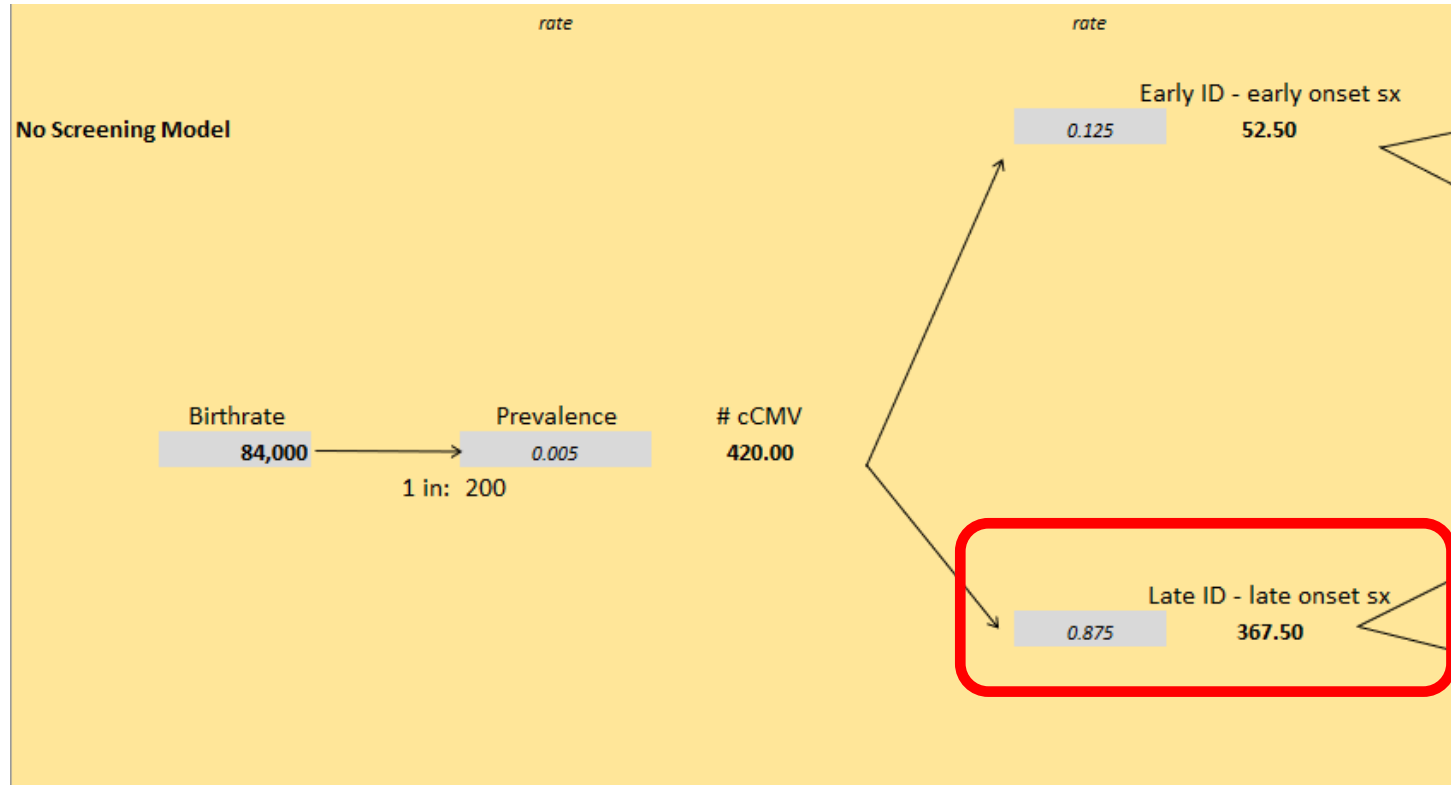
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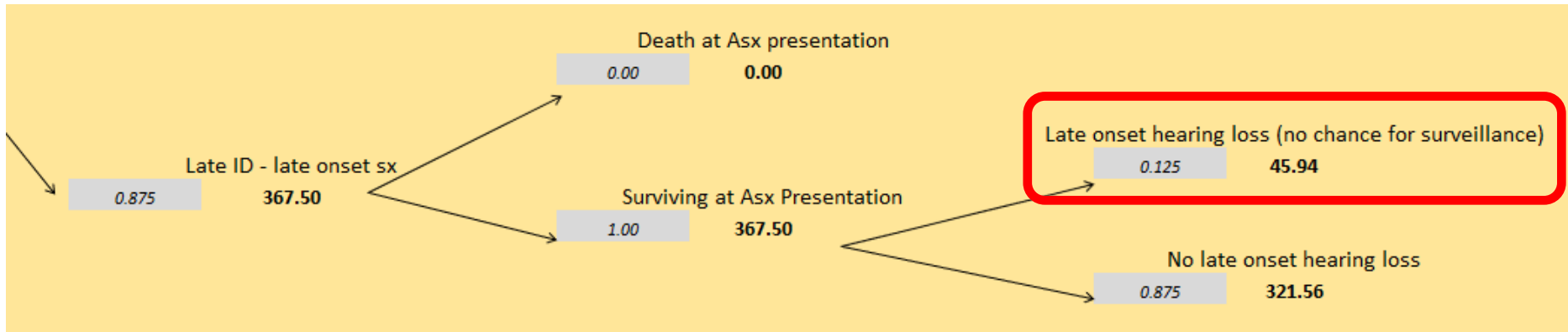
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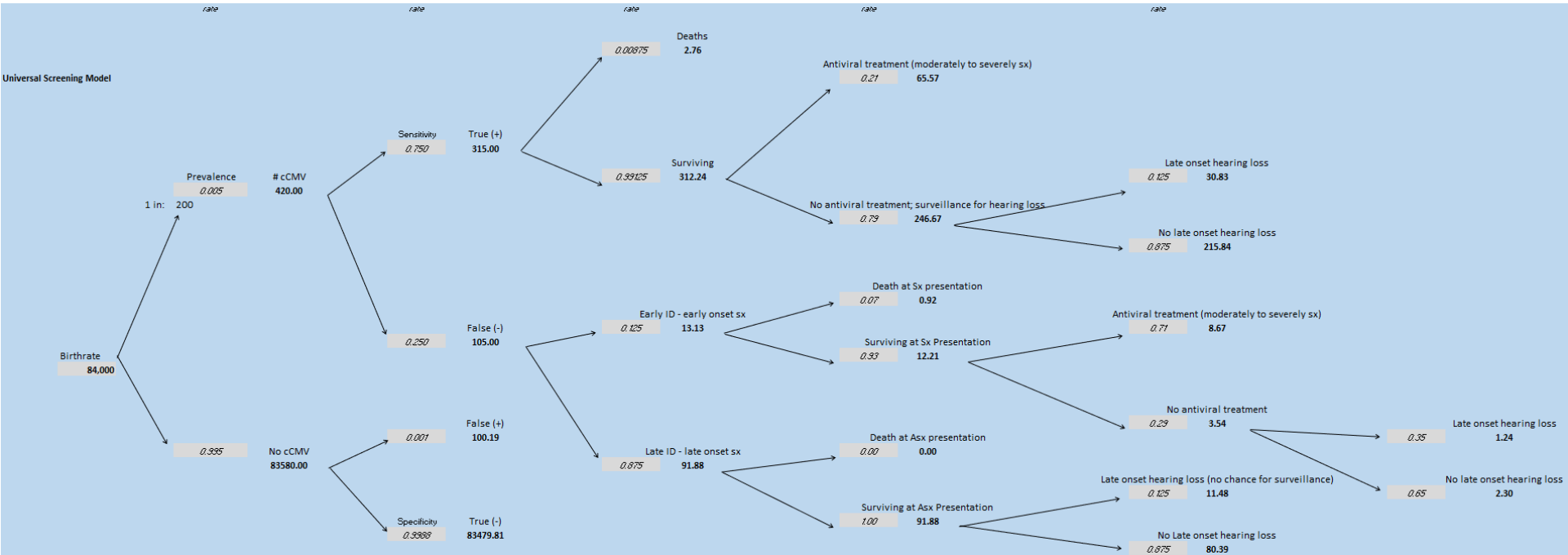
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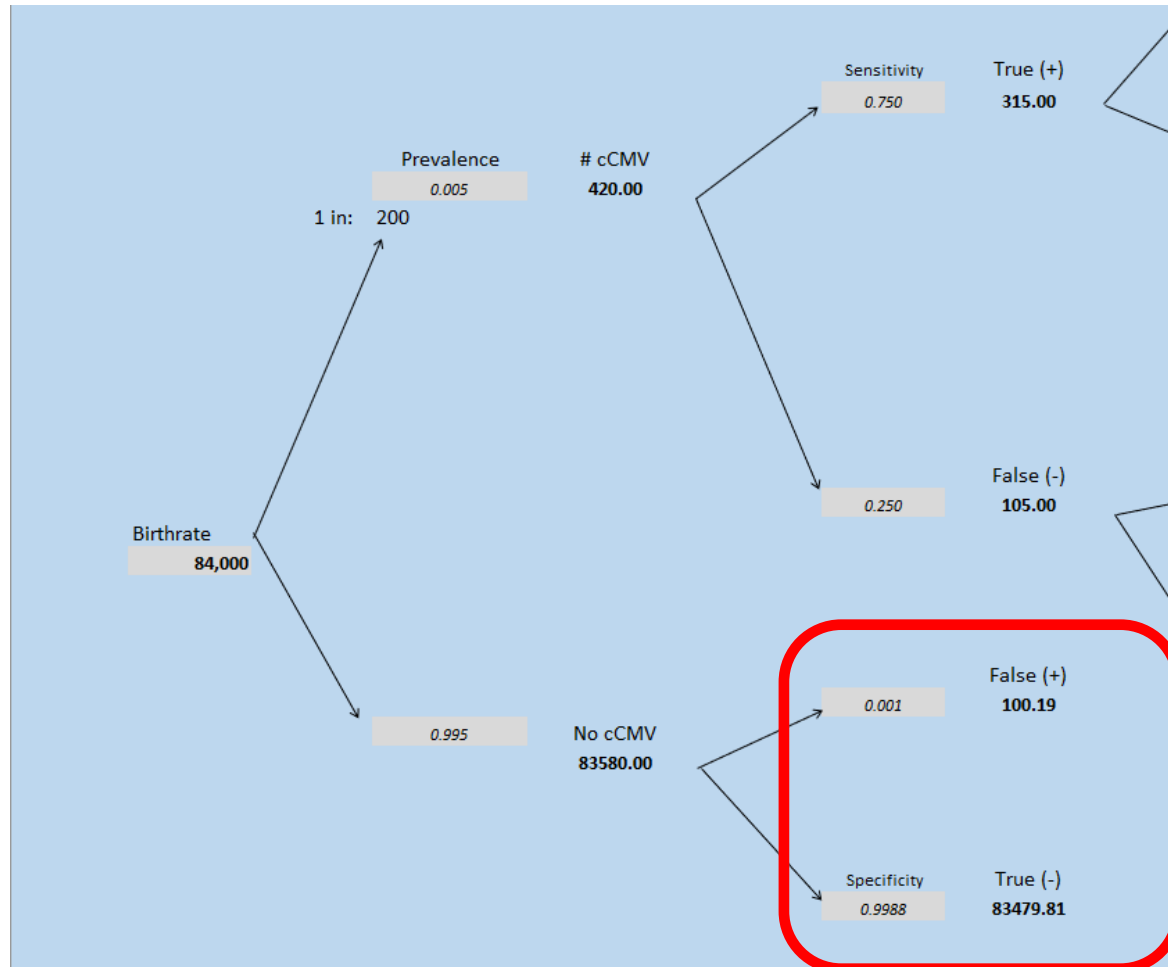
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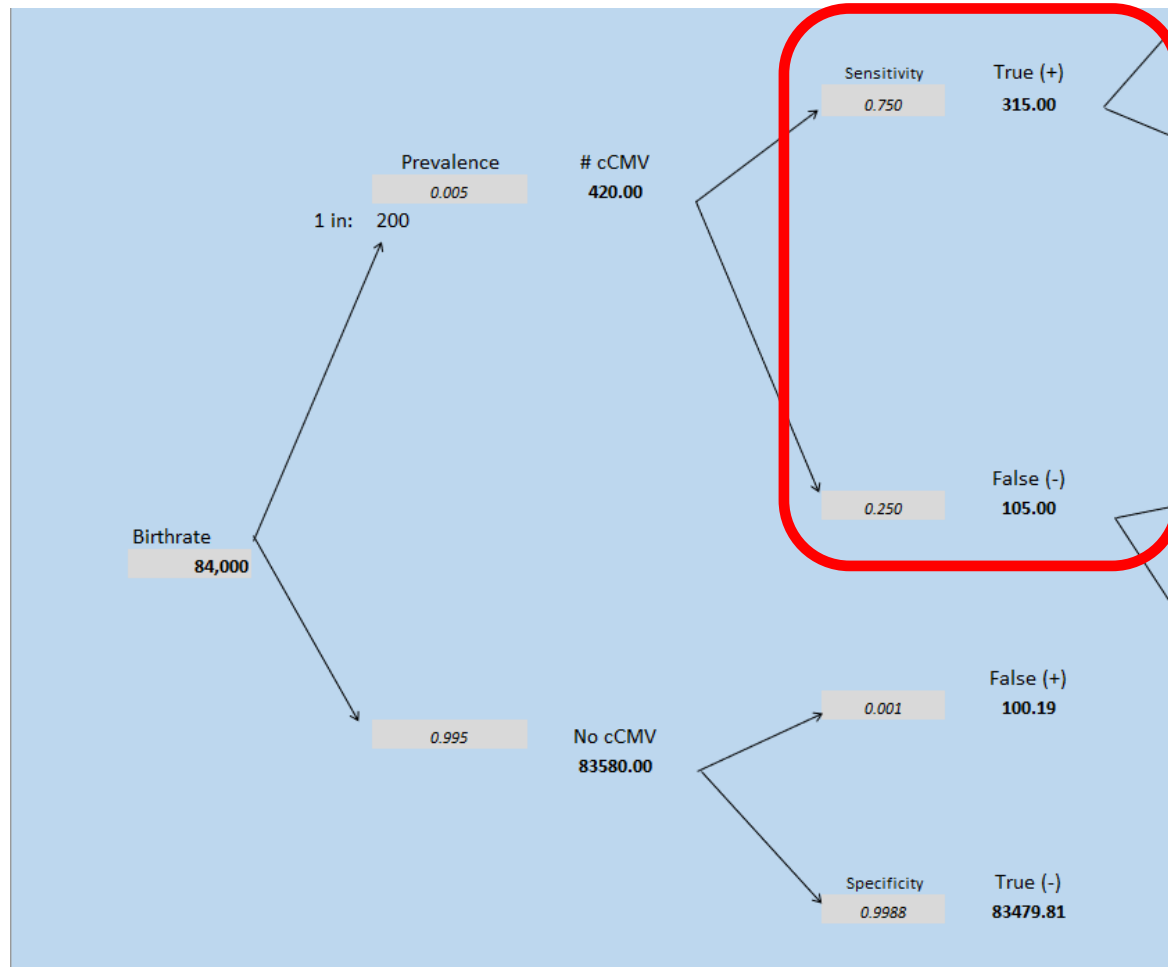
Universal Screening Model



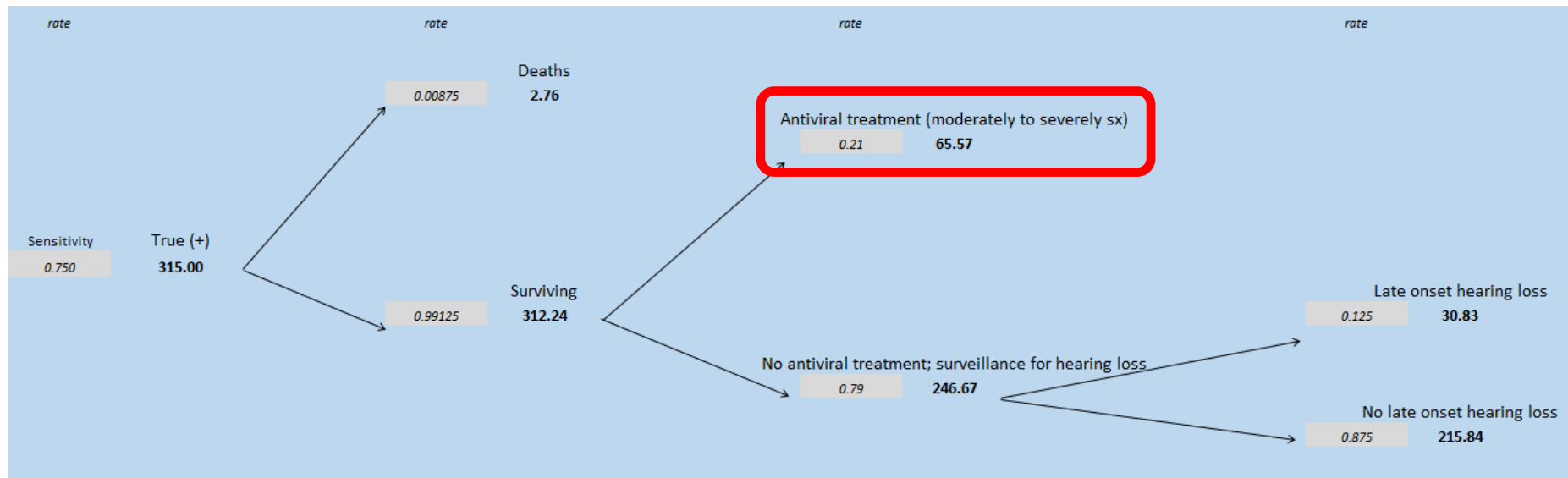
Universal Screening Model



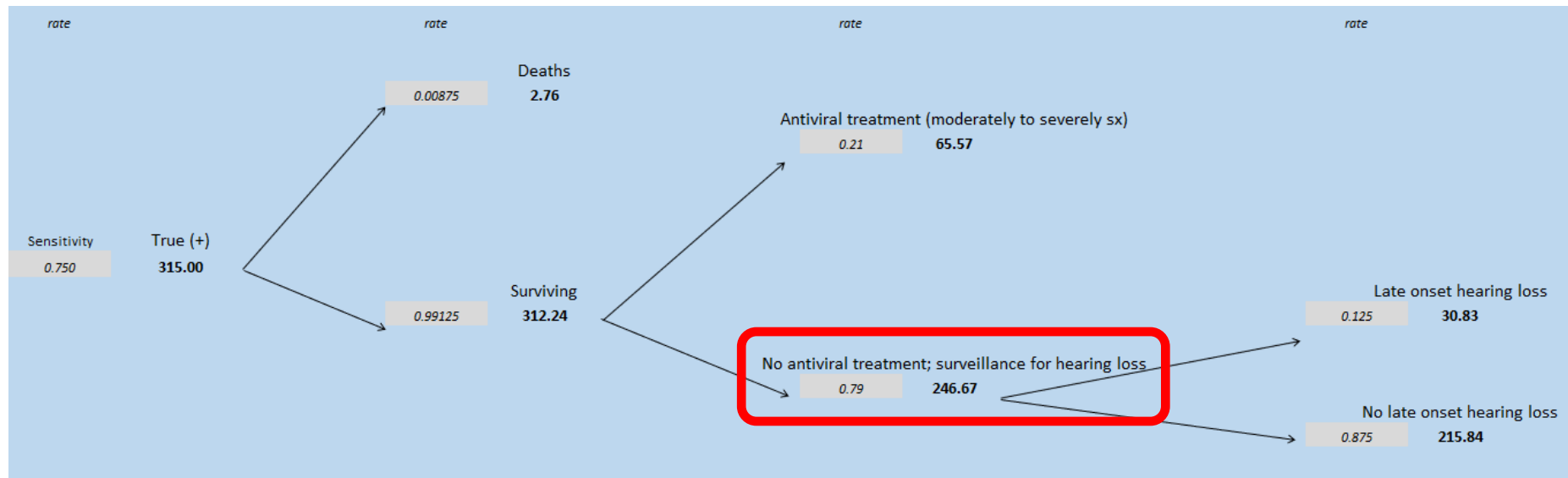
Universal Screening Model



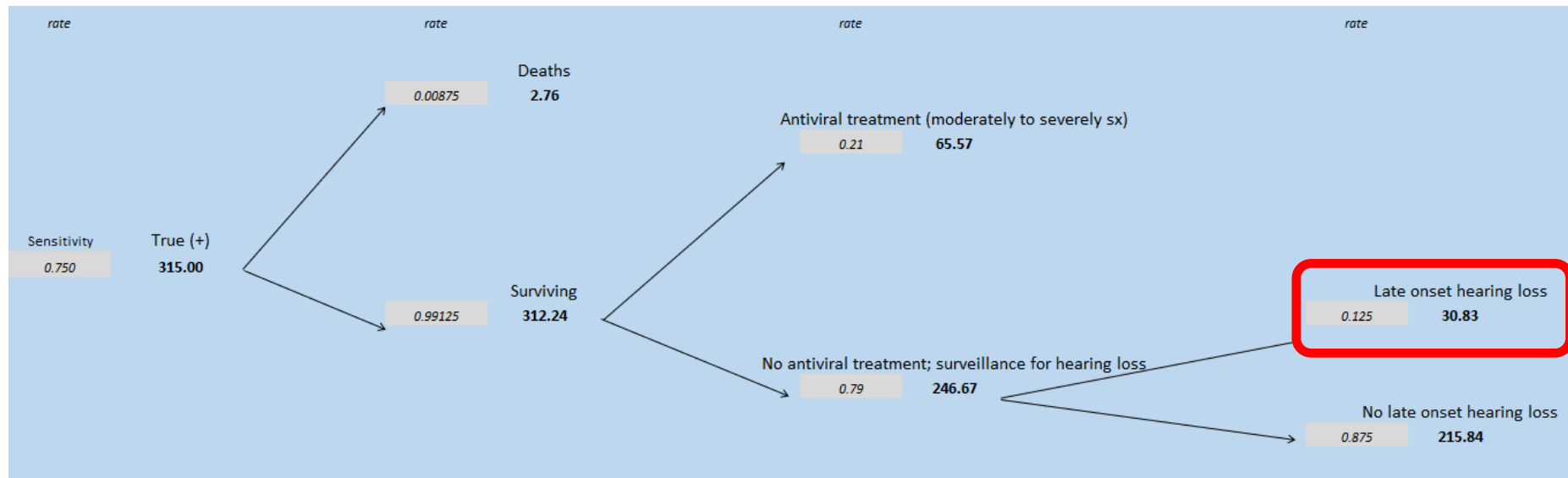
Universal Screening Model



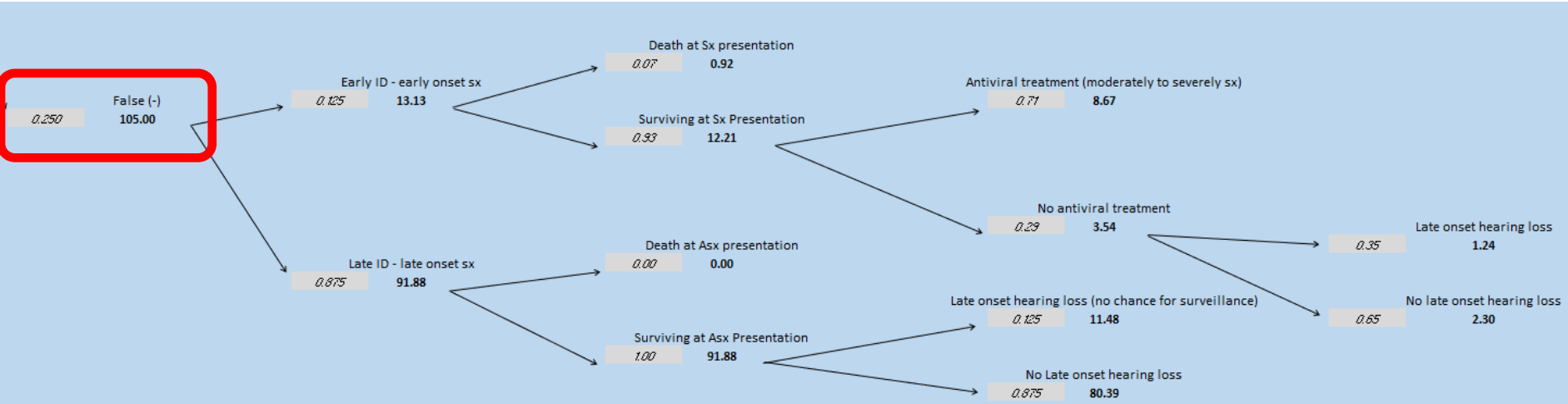
Universal Screening Model



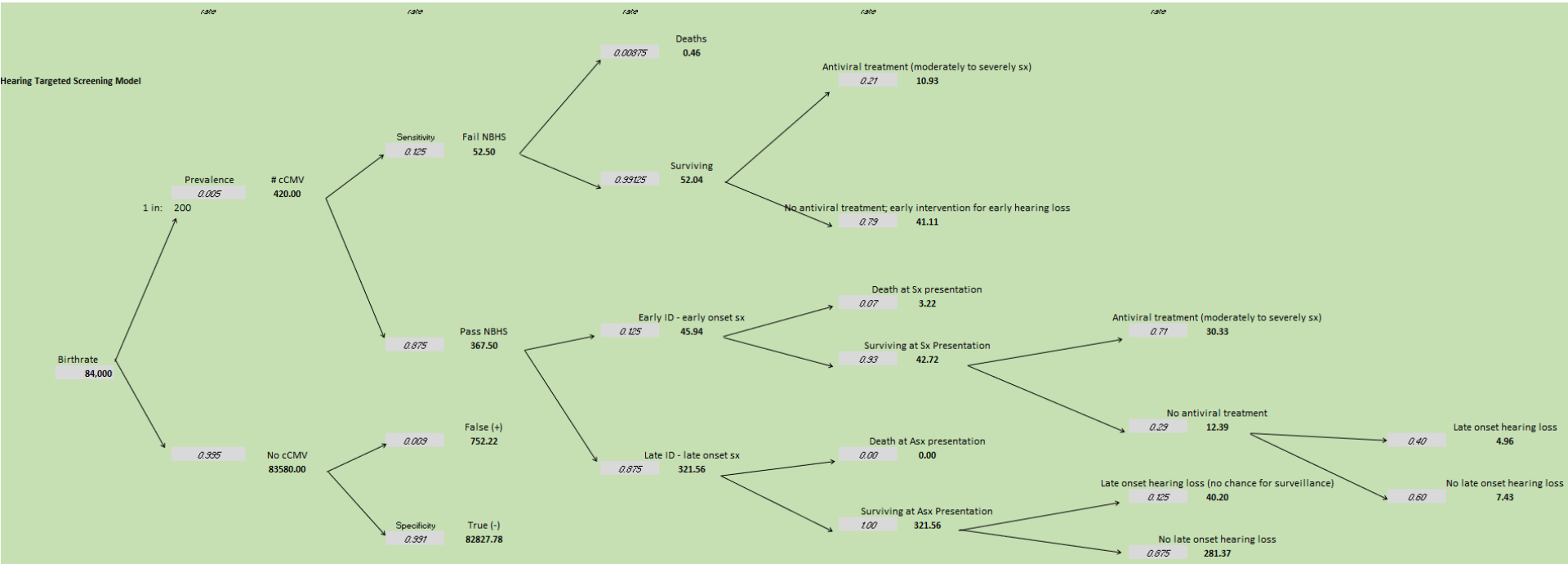
Universal Screening Model



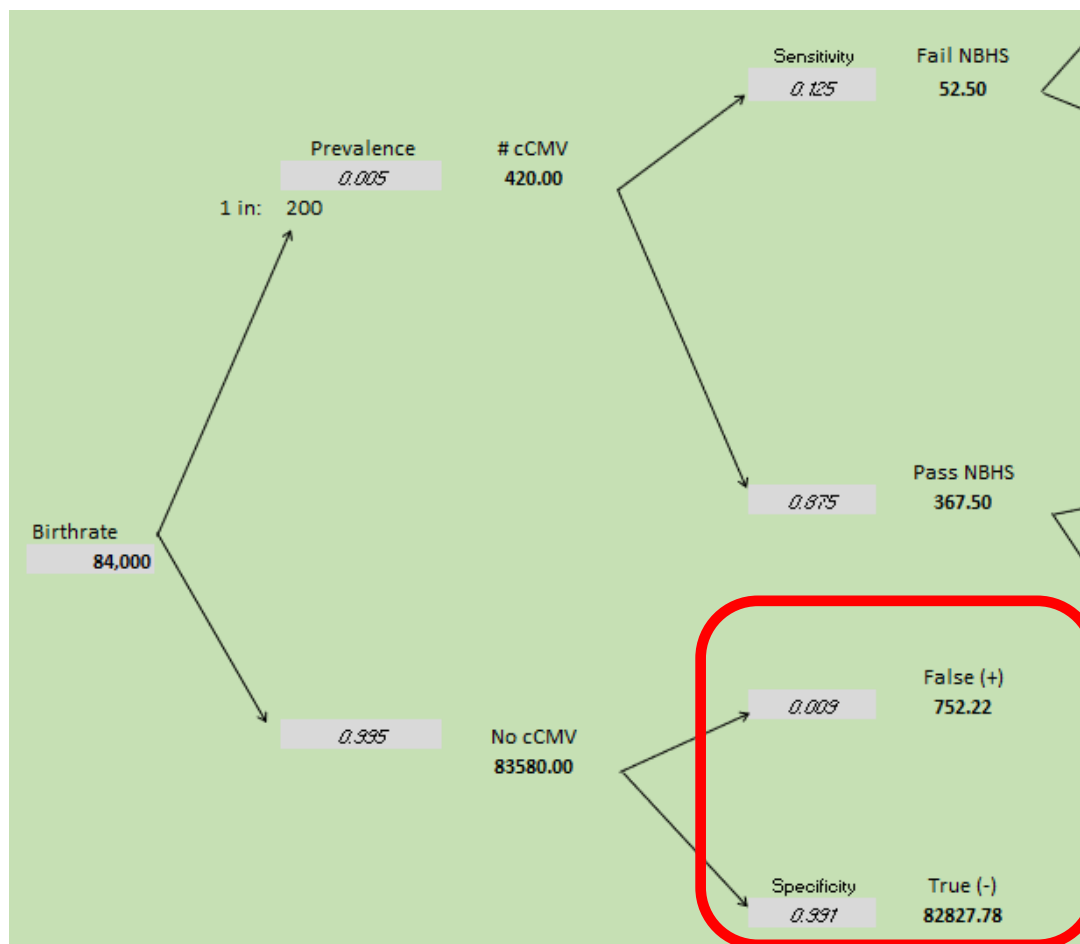
Universal Screening Model



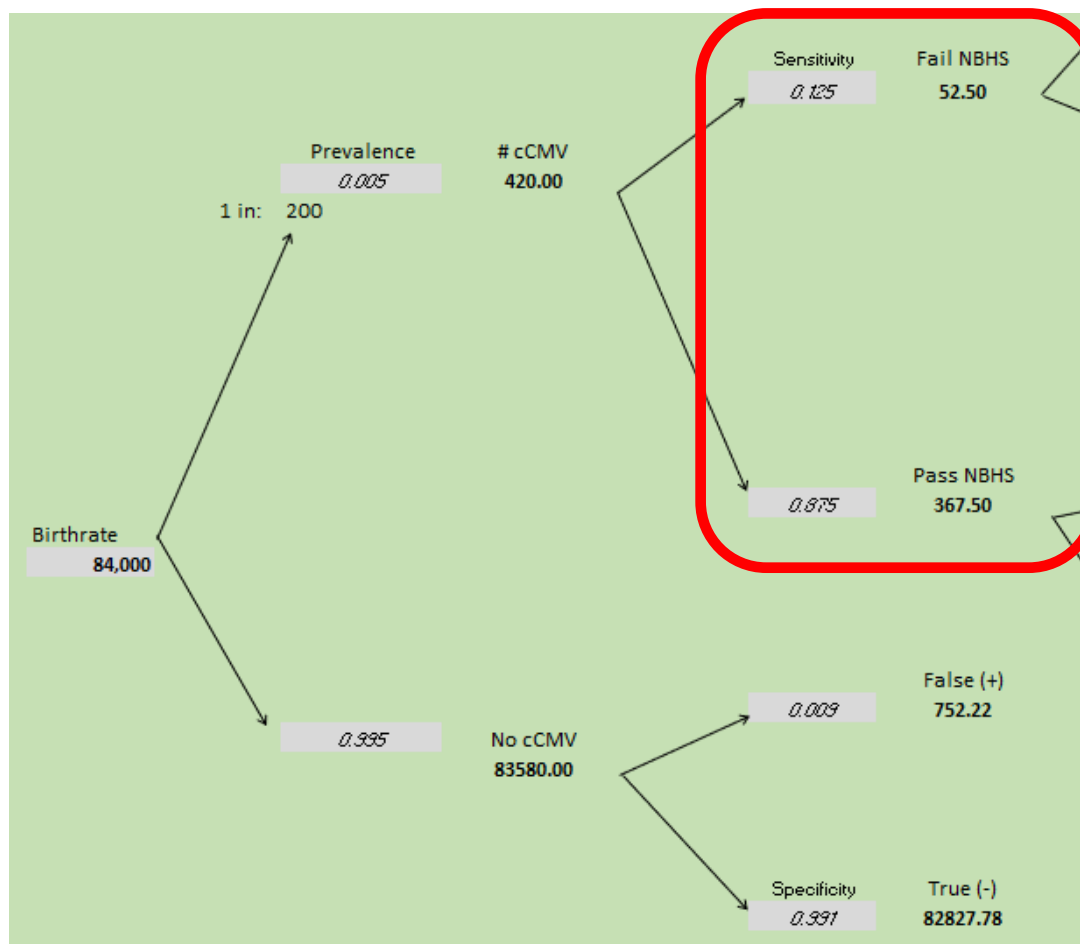
Hearing Targeted Screening Model



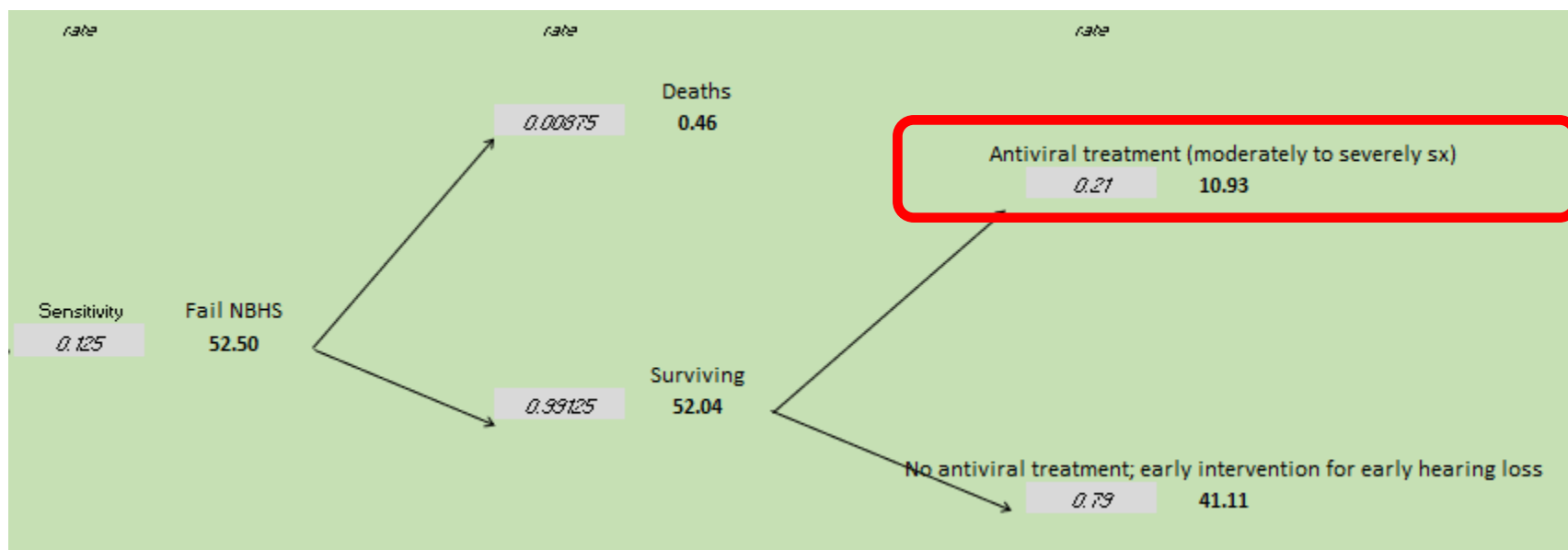
Hearing Targeted Screening Model



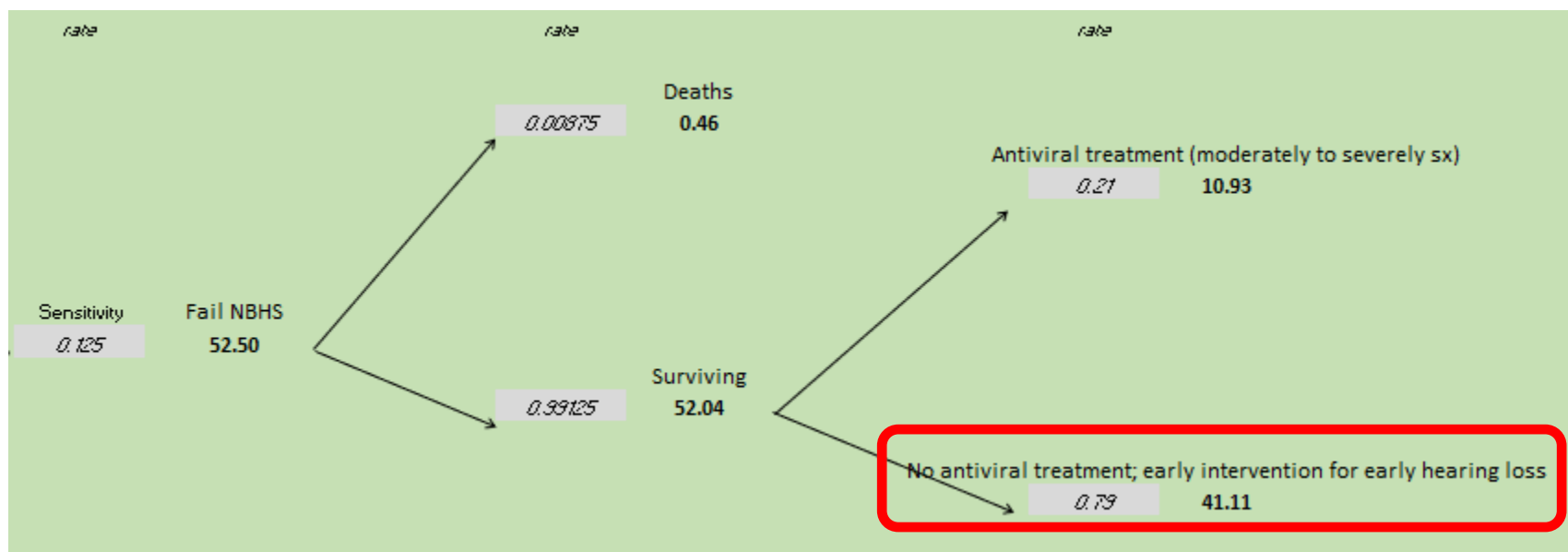
Hearing Targeted Screening Model



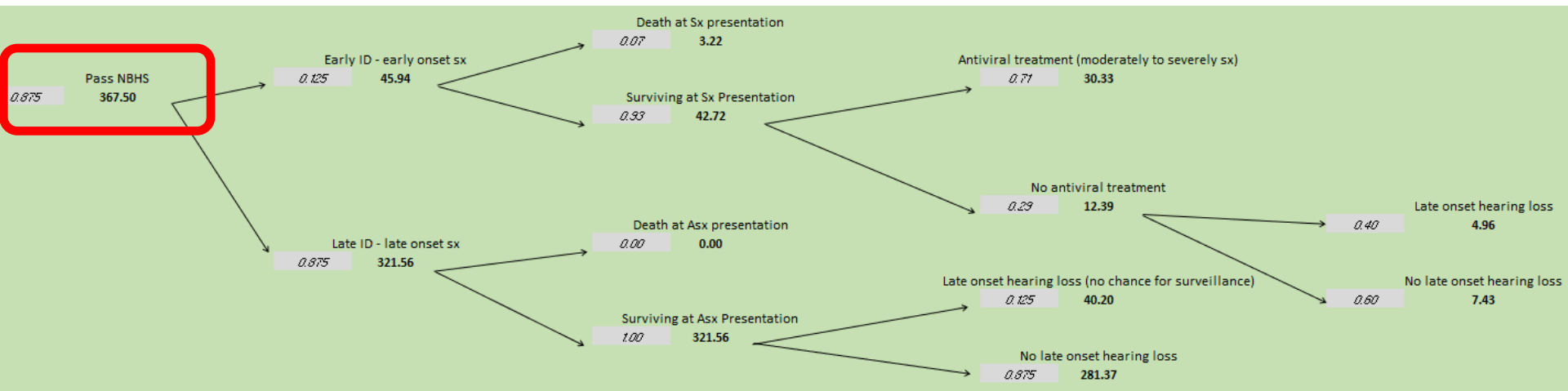
Hearing Targeted Screening Model



Hearing Targeted Screening Model



Hearing Targeted Screening Model



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 surveillance

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 surveillance

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
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	# 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

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

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		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

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		\$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

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

Intangible Benefits and Costs

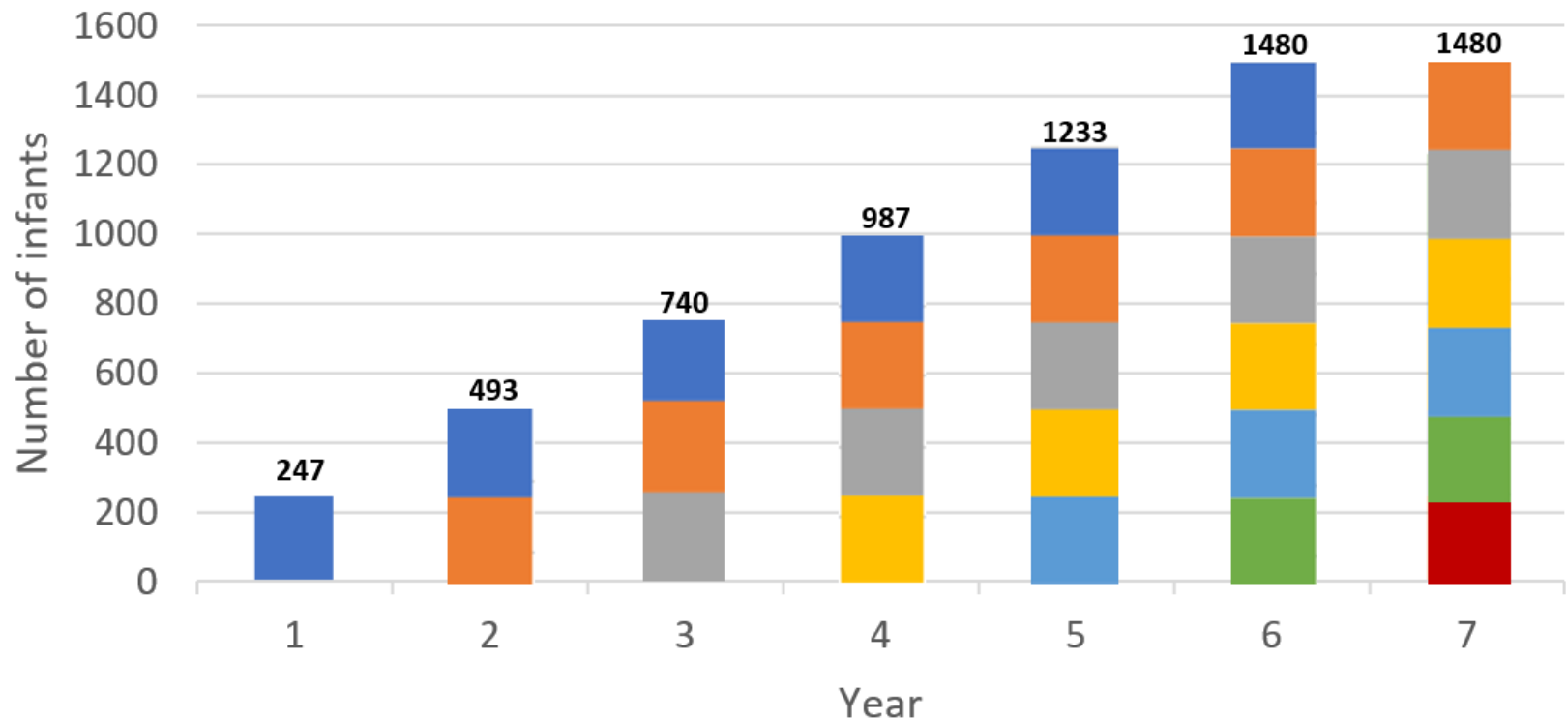
Emotional impact on individuals and families

Surveillance for Hearing Loss

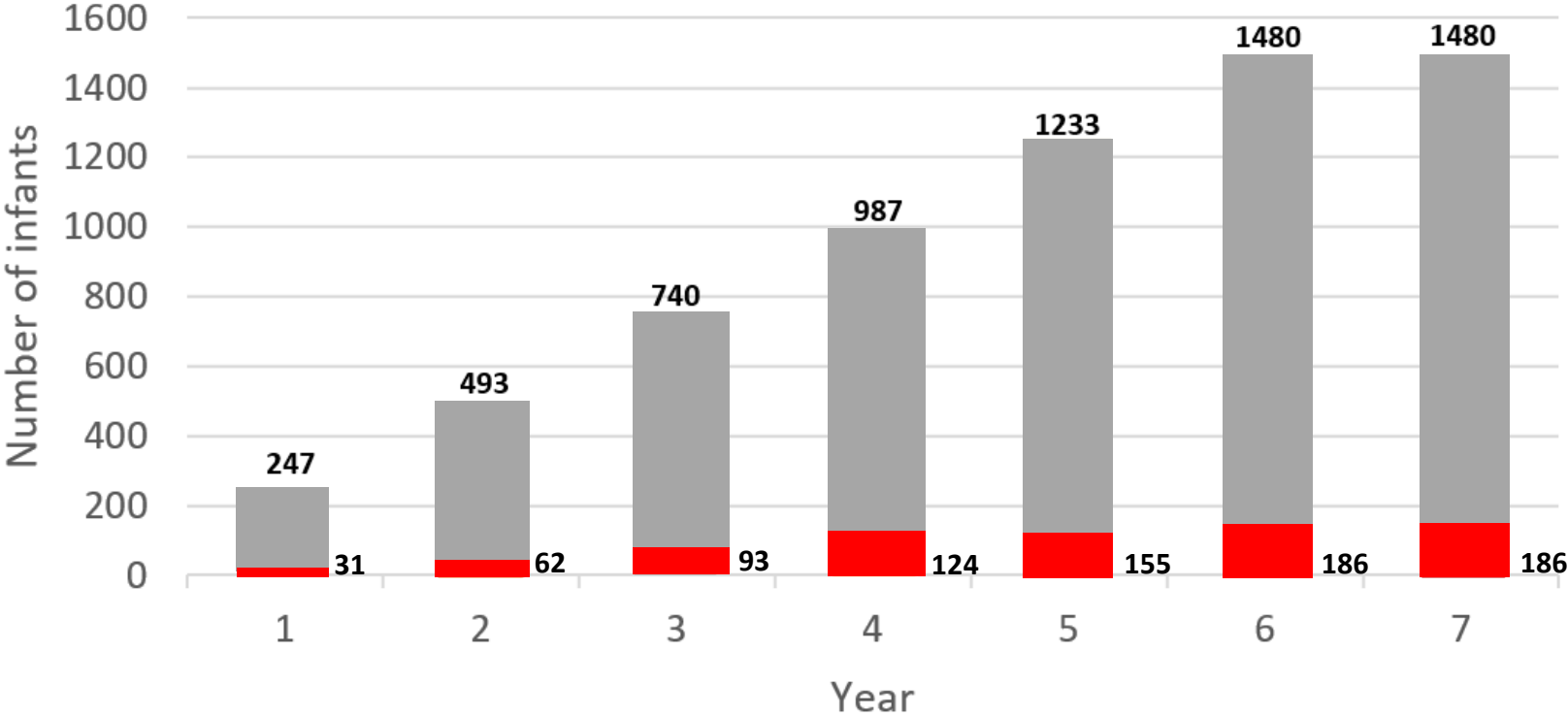
months of age	3	6	9	12	15	18	21	24	27	30	33	36	42	48	54	60	66	72
ABR	X																	
OAEs	X	X	X	X	X	X	X	X	X	X	X	X	X					
Tympanometry	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
VRA		X	X	X	X	X	X											
Condition play audiometry								X	X	X	X	X	X					
Select picture								X	X	X	X	X	X					
Standard audiometry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

Based on Utah's EHDI hearing assessment schedule

Surveilling cCMV Positive Infants for Hearing Loss



cCMV Positive Infants Who Develop Late Onset Hearing Loss



Intangible Benefits and Costs

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

Intangible Benefits and Costs

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

Intangible Benefits and Costs

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?





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Sensitivity Analysis

			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