An Economic Evaluation of a Comprehensive School-Based Caries Prevention Program

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I. CariedAway V1 Methodology.

CariedAway V1 Design. The results for the CariedAway V1 study (previously called ForsythKids) is reported using the Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational research. Analysis used data from a prospective cohort of children who participated in a school-based caries prevention program that was conducted in rural and urban elementary schools located in the northeastern United States. The study was conducted from 2004 to 2010, beginning with four schools at study start and ending with fifty. All schools participating in the study had Title 1 status, signifying that over half of enrolled students qualified to receive free or reduced-price meal. In each year of the study, students in participating schools were provided informed consent. Any consenting child was followed longitudinally and received the included treatments.

The study received IRB approval from the Forsyth Institute and the New York University School of Medicine.

CariedAway V1 Data Collection, Calibration, and Standardization. At each study observation, examining dentists dried tooth surfaces with gauze squares and performed clinical visual-tactile full-mouth oral examinations for all teeth and tooth surfaces. The exam also included an assessment of pain, swelling, infection, and abscess. Recorded clinical data included the number of adult and primary teeth present, the number of decayed, missing, filled, or sealed teeth or surfaces (occlusal, lingual, buccal, mesial, and distal), and any evidence of previous dental care received outside of the school (e.g., preexisting sealants or restorations). Demographic data were collected from each participant for age, the total number of preventive visits received, sex, grade, and school.

Data collectors were calibrated by examining ten students independently at baseline and discussing whether caries were present or not. Following this review, data collectors examined another ten students independently and compared results (kappa = 0.75). To standardize delivery of care, hygienists were trained to use Fuji IX glass ionomer in capsules prior to participating in the program. Dentists and hygienists were standardized yearly. Following clinical examinations, which were conducted by a licensed dentist, dental hygienists delivered all preventive treatments.

II. Methods

We estimated the net cost per averted disability-adjusted life year (DALY) over 5 years attributable to CariedAway V1, a comprehensive school-based dental prevention program, relative to (1) school-based sealant-only programs (SSP) sealing permanent first molars (1Ms) soon after they erupt and (2) no school-based programs. Net costs are calculated as follows:

1. **For SSP relative to no school-based program.** SSP cost minus the avoided costs for fillings and the opportunity cost for parents to take his or her child for dental care because the child received SSP sealants.
2. **For CariedAway V1 relative to no school-based programs.** CariedAway V1 cost minus the avoided costs for fillings and the opportunity cost for parents to take his or her child for dental care because the child received CariedAway V1 comprehensive dental prevention.
3. **For CariedAway V1 relative to a SSP.** The net cost for CariedAway V1 relative to no school-based program, minus the net cost for a SSP relative to no school-based program.

The calculations for averted fillings and productivity losses vary by (1) the program under consideration (CariedAway V1 or a SSP), and (2) whether permanent first molars or posterior teeth are considered. This is because SSPs applies sealants on only permanent first molars, while CariedAway V1 applies sealants on all sound teeth. Additionally, CariedAway V1 not only applies sealants, but also arrests active asymptomatic caries using glass ionomer. However, no materials for caries arrest are provided after enrollment in CariedAway V1 ends (modeled here as any cycles after the first year). As a result, the calculations for averted fillings and productivity losses also vary by whether a child is currently enrolled in CariedAway V1 or is post-enrollment in CariedAway V1.

The averted fillings and productivity losses in each cycle when only first molars are considered are calculated as the following:

1. **For a SSP relative to no school-based program.** SSP effectiveness * (1 – prob(untreated)) * [(1M increment * filling cost) + (1M incidence * productivity losses)]
2. **For CariedAway V1 relative to no school-based program.**

a. During CariedAway V1 (Year 1) relative to no school-based program: CariedAway V1 effectiveness * (1-prob(untreated)) * Prob(symptomatic) * [(1M increment * filling cost) + (1M incidence * productivity losses)]
b. After CariedAway V1 (Year 2 onwards) relative to no school-based program: CariedAway V1 effectiveness * (1-prob(untreated)) * [(1M increment * filling cost) + (1M incidence * productivity losses)]

3. **For CariedAway V1 relative to a SSP.** CariedAway V1 averted fillings and productivity losses relative to no school-based program, minus SSP averted fillings and productivity losses relative to no school-based program.

The averted fillings and productivity losses in each cycle when non-1M posterior teeth are considered are calculated as the following:

1. **For a SSP relative to no school-based program. 0**
2. **For CariedAway V1 relative to no school-based program.** The sum of the following:
    a. During CariedAway V1 (Year 1) relative to no school-based program: CariedAway V1 effectiveness * (1-prob(untreated)) * Prob(symptomatic) * [(Non-1M increment * filling cost) + (Non-1M incidence * productivity losses)]
    b. After CariedAway V1 (Year 2 onwards) relative to no school-based program: CariedAway V1 effectiveness * (1-prob(untreated)) * [(Non-1M increment * filling cost) + (Non-1M incidence * productivity losses)]
3. **For CariedAway V1 relative to a SSP.** CariedAway V1 averted fillings and productivity losses relative to no school-based program.

Note here that there are no averted fillings and productivity losses for a SSP relative to a no school-based program scenario because SSPs do not address posterior teeth that are not permanent first molars. As a result, the averted fillings and productivity losses for CariedAway V1 relative to no school-based programs is equivalent to the averted fillings and productivity losses for CariedAway V1 relative to a SSP.

The averted DALY per child in each cycle when only first molars are considered are calculated as follows (*DALYW* refers to the DALY weight for toothache, 0.012):

1. **For a SSP relative to no school-based program.** *SSP effectiveness * 1M incidence * prob(untreated) * prob(toothache) * DALYW*
2. **For CariedAway V1 relative to no school-based program**
    1. During CariedAway V1 (Year 1) relative to no school-based program**:** *CariedAway V1 effectiveness * 1M incidence * prob(symptomatic cavity) * prob(untreated) * DALYW*
    2. After CariedAway V1 (Year 2 onwards) relative to no school-based program: *CariedAway V1 effectiveness * 1M incidence * prob(untreated) * prob(toothache) * DALYW*

    whereby only symptomatic cavities are not directly treated by CariedAway V1 during implementation.
3. **For CariedAway V1 relative to a SSP.** Averted DALYs per child due to a SSP relative to no school-based program minus averted DALYS per child due to CariedAway V1 relative to no school-based program.

The averted DALYs per child when non-1M posterior teeth are considered are calculated as follows:

1. **For a SSP relative to no school-based program.** 0
2. **For CariedAway V1 relative to no school-based program.**
    a. During CariedAway V1 (Year 1) relative to no school-based program: *CariedAway V1 effectiveness * non-1M incidence * prob(symptomatic cavity) * prob(untreated) * DALYW*
    b. After CariedAway V1 (Year 2 onwards) relative to no school-based program: *CariedAway V1 effectiveness * non-1M incidence * prob(untreated) * prob(toothache) * DALYW*
3. **For CariedAway V1 relative to a SSP.** Averted DALYS per child due to CariedAway V1 relative to no school-based program.

As in the calculation of averted fillings and productivity losses for CariedAway V1 for non-1M posterior teeth, CariedAway V1 is the only program out of the three programs considered that treats and prevents caries in non-1M posterior teeth.

Details on how cavity incidence and increment were estimated and how the other parameter values were derived are below.

Cavity Attack Rate. I calculate the first molar attack rates from (1) the caries increment data from children's initial CariedAway V1 visit to calibrate the model to the caries increment and incidence among the CariedAway V1 population targeted and (2) the caries increment data from children's subsequent visits after the first visit.

Permanent first molar attack rate. To calculate the caries attack rate for permanent first molars, I follow Griffin et al. [3]. I take the data on increment for children ages 7 to 11 years on the initial CariedAway V1 visit and first estimate the cumulative probability of a permanent first molar developing a cavity by summing increment by year of age and dividing by the number of first molars. Because children coming into CariedAway V1 could have had dental care prior to entering into CariedAway V1, I include both first molars with untreated decay and first molars with any fillings into the increment calculation. I exclude children who have evidence of sealant application prior to the initial CariedAway V1 visit. We then calculated the annual cumulative probability of a permanent first molar remaining sound for each age group.

Because the Markov model operates on 6-month cycles to match the 6-month treatment cycles of the CariedAway V1 program, we then convert the annual cumulative probability of a permanent first molar remaining sound for each age group to the six-month probability of a permanent first molar remaining sound. This is done by raising the cumulative annual probability to 1 divided by the number of six-month cycles the first molar has been in the mouth. We then obtain the six-month first molar attack rate for each age group by subtracting the six-month probability of a permanent first molar remaining sound from 1. The weighted six-month first molar attack rate across age groups is 0.0185.

For the sake of comparison to show how the CariedAway V1 population varies in caries increment from the population used in Griffin et al. [4], we calculate the annual first molar attack rate for the CariedAway V1 program. The weighted annual first molar attack rate across age groups is 0.0366, which is substantially lower than the annual first molar attack rate in Griffin et al. [4] of 0.078.

Non-1M posterior teeth attack rate. Similar to the first molar attack rate calculation described above, I take the data on increment for children ages 7 to 11 years without sealants at the initial CariedAway V1 visit and estimate the cumulative probability of a non-1M posterior tooth developing a cavity by summing increment by year of age and dividing by the number of non-1M posterior teeth. However, I examine caries increment across *all* non-1M posterior teeth and include both deciduous and adult teeth to reflect that CariedAway V1 treats all teeth at risk of caries with asymptomatic lesions. I then follow the process for converting the cumulative probability of a tooth developing a cavity into the six-month attack rate described above to obtain the six-month posterior attack rate. The weighted six-month posterior attack rate (including first molars) across age groups is 0.0538, whereas the weighted annual posterior attack rate is 0.103. The weighted six-month non-1M posterior attack rate excluding permanent first molars across age groups is 0.0404, while the weighted annual non-1M posterior attack rate is 0.077.

The large difference between the non-1M posterior caries attack rate and the permanent first molar caries attack rate demonstrates that focusing only upon permanent first molars alone can underestimate the population risk for caries. Though including both deciduous and adult teeth into the calculation for the non-1M posterior caries attack rate can underestimate the population risk for caries as well, since non-permanent teeth with caries can fall out, we note that there is a need in the literature to address the impact of preventive dental programs on the population risk for caries across the whole mouth.

Calculating 1M Cavity Incidence and Increment

We follow the calculation for 1M cavity incidence and increment described in Griffin et al. (2016)'s appendix using the 1M attack rate calculated using the CariedAway V1 data described above.

Calculating Posterior Teeth Cavity Incidence and Increment

We follow the calculation for cavity incidence and increment described in Griffin et al. (2016)'s appendix, but by (1) considering instead that there are 65,536 possible events with sixteen non-1M posterior teeth that can transition between sound (S) and having a cavity (C) in each cycle, and (2) using the six month non-1M posterior attack rate calculated using the CariedAway V1 data described above.

Assumptions adopted from Griffin et al. (2016)

1. The probability per cycle that a sound tooth develops a cavity is constant.
2. Sealants protect teeth against cavities for 4 years.
3. All first molars erupt at age 6.

4. All four permanent first molars are sealed by the school-based sealant-only program.
5. All cavities occur at the beginning of each cycle. Symptomatic cavities can be filled or remain untreated for the duration of the cycle. This assumption was made for model tractability.
6. A child who develops cavities and has them filled will visit the dentist once regardless of the number of cavities.
7. All untreated cavities that are untreated in cycle *i* are filled in cycle *i+1.*

Assumptions differing from Griffin et al. (2016)

1. Model 1 follows Griffin et al. (2016) by assuming that all cavities in the permanent teeth occur in the pits and fissures of first molars. Model 2 assumes that cavities can occur in any tooth, whether deciduous or permanent.
2. When the CariedAway V1 program is ongoing, asymptomatic cavities are treated with interim therapeutic restorations (ITRs) that are fully effective over the time period.
3. Symptomatic caries lead to toothache with a probability of 1.

The Griffin et al. (2016) model is derived from a tooth-specific Markov model introduced by Griffin et al. (2014), aggregated across teeth to the person level. The tooth-specific model specifies the state transitions for each tooth under each type of treatment. By imposing the simple assumption that all non-1M posterior teeth face the same posterior attack rate and all 1M teeth face the same 1M attack rate, the Markov models at the tooth-level for all posterior tooth are collapsed to the person level. Hence, the resulting patient-level model is then only concerned with the number of posterior teeth and the number of 1M teeth with untreated caries. Opportunity costs of dental visits for restorative care are then calculated at the person level, under the assumption that any child with caries that cannot be treated under a school-based dental program would visit the dentist only once to receive fillings (regardless of the number of fillings).

Probability a carious tooth is symptomatic. We estimate the probability that a carious tooth is symptomatic from the CariedAway V1 program. As in the calculation for the permanent first molar and posterior attack rates, we take the data for children ages 7 to 11 years at the initial CariedAway V1 visit without any sealants and estimate the probability that a carious tooth is symptomatic. Again, we exclude children with sealants at the first visit because including them would underestimate the population risk for symptomatic caries. We estimate that the probability of having a symptomatic cavity given a carious tooth is 6.7%.

Because the CariedAway V1 program arrests asymptomatic caries and prevents caries, it is possible that the probability that a carious tooth observed under CariedAway V1 is symptomatic increases with the number of CariedAway V1 cycles administered, holding fixed the population of children being treated by CariedAway V1. This is because as the overall number of untreated caries decreases due to both prevention and arrest, any remaining untreated caries become more likely to be symptomatic. However, this is difficult to observe in practice given that 50% of children have only two CariedAway V1 visits.

Effectiveness of school-based sealant-only programs. The effectiveness of school-based sealant-only programs are given in Griffin et al. (2016) over one-year cycles. To convert this to half year cycles, we assume caries occur at a constant rate within each year. As a result, the rate within the first year is -ln(1-.315) and the probability that teeth with sealants would develop cavities after six months is 17.2%.

Effectiveness of CariedAway V1 for caries prevention. Because the CariedAway V1 program did not include a control group, there are no causal estimates available for the effectiveness of the CariedAway V1 program in preventing caries. The literature is still in the early stages of evaluating the effectiveness of comprehensive school-based dental prevention programs. Hence, I assume that sealants used in the CariedAway V1 program has the same effectiveness in preventing caries as those estimated in Griffin et al. (2016) in the years after placement.

Effectiveness of CariedAway V1 for caries arrest. The baseline assumption is that ITRs are fully effective in arresting caries. A systematic review with meta-analysis found no significant differences between interim therapeutic restorations and traditional amalgam restorations placed in primary dentition [3]. Furthermore, the longevity of interim therapeutic restorations is equal to or greater than that of amalgam restorations [3]. Because traditional restorations are modeled in Griffin et al. (2016) to be fully effective in arresting caries, we also model interim therapeutic restorations placed during the CariedAway V1 program to be fully effective in arresting caries.

III. <u>Analysis</u>

We estimated the cost effectiveness of CariedAway V1 and SSPs relative to a base case scenario (no school-based programs) using base-case parameters and with the following parameters:

1. CariedAway V1 ITRs have only an 80% effectiveness at arresting caries, whereby teeth exhibiting caries progression despite application of ITRs are referred to a private dentist for follow-up care. (We assume that there is still a probability of not receiving dental care once the referral is made.)
2. No productivity losses associated with a dental visit

For one-way sensitivity analyses, we also allowed each parameter value to vary between 50% to 150% of its base-case value to show whether the analysis was sensitive to individual base-case parameter assumptions.

To account for uncertainty in parameter estimates, we carried out a probabilistic sensitivity analysis using Monte Carlo simulation in which all parameters varied simultaneously. Parameter values used in each simulation were based on a random draw with replacement from each parameter's distribution. The distributions for random variables align with those used in Griffin et al. (detailed in their Appendix), after accounting for the six-month cycle lengths of the model and assuming that caries occur at a constant rate within each year. Distribution assumptions are shown in Table 1.

The probabilistic sensitivity analysis was conducted for a population of 1,000 children by using 1,000 replications. From the simulation data, we then determine the mean and 95% confidence interval for net SSP cost, averted years living with a toothache per child, averted fillings, and cost per averted DALY.

As in Griffin et al. (2016), we evaluate the relative cost savings and relative cost-effectiveness ratios (cost per averted DALYs) by using a cost-effectiveness threshold value of $54,639, which is the 2014 U.S. gross domestic product (GDP) per capita.

Appendix Table 1. Distribution assumptions for probabilistic sensitivity analysis.

Parameter	Base value (SD)	Distribution in Probabilistic Sensitivity Analysis	Data Source
First molar cavity attack rate	3.66%	Constant	CariedAway V1 data
Posterior teeth (non-first molar) cavity attack rate	4.04%	Constant	CariedAway V1 data
Probability new cavity remains untreated	27.2% (1.2%)	Beta distribution Beta(4.216, 11.28)	Converted from Griffin et al. (2016) to half-year cycles
School-sealant effectiveness for cycles 1 and 2 (six months per cycle) (Year 1)	43.8% (5.8%)	Beta distribution Beta(31.47, 40.25)	Converted from Griffin et al. (2016) to half-year cycles
School-sealant effectiveness for cycles 3 and 4 (Year 2)	35.1% (9.3%)	Beta distribution Beta(8.83, 16.31)	Converted from Griffin et al. (2016) to half-year cycles
School-sealant effectiveness for cycles 5 and 6 (Year 3)	22.6% (16.8%)	Beta distribution Beta(1.17, 4.02)	Converted from Griffin et al. (2016) to half-year cycles
School-sealant effectiveness for cycles 7 and 8 (Year 4)	13.9% (8.5%)	Beta distribution Beta(2.17, 13.52)	Converted from Griffin et al. (2016) to half-year cycles
School-sealant effectiveness for cycles 9 and 10 (Year 5)	0%	Constant	Assumption given limited data on effectiveness after 4 years
Probability child with untreated cavity has toothache	47.2% (5.8%)	Beta distribution Beta(34.25, 38.34)	From Griffin et al. (2016)
Probability child with untreated cavity is symptomatic	6.7%	Constant	CariedAway V1 data
Loss in health/well-being due to toothache	0.012	Constant	From Griffin et al. (2016)
School-based sealant-only program resource costs	$63.33	Constant	From Griffin et al. (2016)

CariedAway V1 annual program resource costs	$185	Constant	Bukhari (2016)
Cost per filling	$139.18 ($23.99)	Uniform distribution Uniform(130.696, 147.664)	From Griffin et al. (2016)
Productivity losses	$21.34 ($3.33)	Normal distribution Normal(21.34, 11.0889)	From Griffin et al. (2016)