School Fluoride Varnish Delivery Programs

Summary Evidence Table

Abbreviations Used in this Document

Dental Abbreviations

1M: First molar
2M: Second molar
DFS: Decayed (cavitated) and filled tooth surfaces
DiFS: Decayed (including incipient lesions) and filled permanent tooth surfaces
DiMFS: Decayed (including incipient lesions), missing and filled permanent tooth surfaces
DiMFT: Decayed (including incipient lesions), missing, and filled permanent teeth
DMFS: Decayed (cavitated), missing, and filled permanent tooth surfaces
dfs: Decayed (cavitated) and filled primary tooth surfaces
difs: Decayed (including incipient lesions) and filled primary tooth surfaces
dimfs: Decayed (including incipient lesions), missing, and filled primary tooth surfaces
dimft: Decayed (including incipient lesions), missing, and filled primary teeth
dmfs: Decayed (cavitated), missing, and filled primary tooth surfaces
dmft: Decayed, (cavitated) missing, and filled primary teeth
ds: Untreated decayed (cavitated) primary tooth surfaces

Other Abbreviations

AOR: Adjusted odds ratio
Apps: Number of annual applications
BL: Baseline
Calculated: Adjusted by authors for consistent measures across studies
CT: Controlled before-after study design
FU: Follow-up
FV: Fluoride varnish
M: Month
NA: Information not available from study
OH: Oral health
PF: Preventive fraction
RCT: Randomized controlled trial
RR: Relative risk ratio
SD: Standard deviation

SES: Socio-economic status
Tx: Treatment
C: Control
Y: year

Notes

- Prevalence: % of students with at least one affected tooth
- Percentage: % of teeth or tooth surfaces with caries
- Mean: number of teeth or tooth surfaces affected per student
- Incidence: Prevalence or percentage at FU – Prevalence or percentage at BL
- Increment: Mean at FU – Mean at BL
- Relative ratio or risk: Incidence or increment for Tx / Incidence or increment for C
- Only 1 effect measure per study was used in synthesizing evidence across studies. The following criteria were used to select measure in studies with multiple effect measures:
    - Longest FU period
    - Highest application frequency
    - Measure caries at surface vs. tooth level if available
    - Use increment vs. person level incidence if available
    - Include incipient decay in caries measure if available
- Suitability of design includes three categories: greatest, moderate, or least suitable design.
- Quality of Execution: Studies are assessed to have good, fair, or limited quality of execution.
- Participation rate is the number of students receiving intervention treatment divided by number targeted for intervention
- Attrition: Number of students at FU exam divided by number of students at BL
- Statistically significant if $p<0.05$
- The Community Guide only summarizes race/ethnicity for studies conducted in the United States

Study	**Population Characteristics**	**Intervention Characteristics**	**Results**
Author, Year: Abreu-Placeres, 2019	Country: Dominican Republic Country Income: Upper-middle	Setting: School-based	Difference in FV receipt: NA Caries Initiation

Study	Population Characteristics	Intervention Characteristics	Results
Study Design: RCT Unit of randomization: Student Suitability of Design: Greatest Quality of Execution: Fair	Eligibility: age 6 to 7 Y; at least one sound erupting permanent 1M; no systemic condition; verbal consent to participate; and behavior allowed dental evaluation and treatment. Sample size (BL): Intervention 2 apps per Y: 60 Intervention 4 apps per Y: 60 Control: 60 Attrition: 12.8% Participation Rate: NA Demographic: Age: 6 to 7 Y, mean=6.58 Y Female: 51% SES: Low Urbanicity: urban/suburban Optimally fluoridated: No Access to dental care: "Low" BL Caries: Percentage of 1M with Di=29.1%	Provider: Dentist FV apps per Y: 2 and 4 Other Services: OH education and diet counseling; tooth brushing training; toothbrush/ fluoride toothpaste every 3 M; and referrals for dental care for cavitated lesions Comparison: negative (no placebo) Study period: 2015 to 2016 Study funded by: Colgate-Palmolive	Dentition: Erupting sound permanent 1Ms FU: 12 M Outcome: incidence % of permanent 1M surfaces with untreated including incipient decay Effectiveness: Adjusted odds ratio (AOR): 2 apps AOR C vs Tx: 1.06 (95% CI: 0.84 to 1.34; p = 0.638) Calculated Tx vs C: 1/1.06=0.943 4 apps AOR C vs Tx:1.46 (95% CI: 1.18 to 1.81; p<0.001) Calculated Tx vs C: 1/1.46=0.684 Adverse Effects: NA
Author, Year: Arruda et al; 2012	Country: Brazil Country Income: Upper middle Eligibility:	Setting: School-based Provider: Dentist FV apps Y: 2	Difference in FV receipt: NA Caries Initiation

Study	Population Characteristics	Intervention Characteristics	Results
Study Design: RCT Unit of randomization: School Suitability of Design: Greatest Quality of Execution: Good	Consent by parent and child; no orofacial congenital anomaly Sample size (BL): Intervention: 198 Control: 181 Attrition: 44.6% Participation Rate: NA Demographic: Age: Mean=9.14 Y; Range: 7 to 14 Y % Female: 54: SES: 25% in poverty Urbanicity: Rural Optimally fluoridated: No Access to dental care: NA BL Caries: Mean DiFS: Intervention: 6.15; Control: 5.59	Other services: OH education provided to Tx and C groups Comparison: placebo Study period: January 2006 to December 2007 Funding: University of Michigan Office of Vice President and Research Faculty Grants and Awards program funding and by A.O. Arruda Foundation	Dentition: All permanent teeth FU: 12 M Outcome: DiFS increment Effectiveness: C: 7.72 Tx: 4.61 PF was 40% (95%CI: 34.3–45.7%) Calculated RR=0.60 Adverse effects: None reported
Author, Year: Autio-Gold et al; 2001 Study Design: RCT Unit of Randomization:	Counry: USA Country Income: High Eligibility: Children from 10 Head Start schools were invited to participate Sample Size (BL):	Setting: School based and linked Provider: Dentist FV Apps Per Y: 2 Other Services: NA	Difference in FV Receipt: NA Dentition: All primary teeth FU: 9 months Caries Initiation Outcome: Mean dmfs Effectiveness:

Study	Population Characteristics	Intervention Characteristics	Results
Student Suitability of Design: Greatest Quality of Execution: Good	Intervention: 68 Control: 115 Attrition: 19.1% Participation Rate: 82.4% Demographic: Age: Mean=5.5 Y; Range: 3 to 5 Y % Female: 54% SES: NA Race/ethnicity: African-American: Tx: 71.2%, C: 72.8% White: Tx: 25.4%, C: 24.7% Hispanic: Tx: 1.7%, C: 1.2% Asian: Tx: 1.7%, C: 1.2% Urbanicity: Urban/suburban and rural Optimally fluoridated: Yes Access to Dental Care: NA BL Caries: Mean dmfs (SD): Intervention, 2.51 (4.02); Control 2.58 (3.27)	Comparison: Negative Study Period: Prior to 2001 Study Funded by: NA	Mean dmfs: Tx 2.51 at BL and 3.05 at FU; C 2.58 at BL and 4.05 at FU; increment Tx 0.54 vs. C 1.47 Difference in mean dmfs for Tx vs. C significant at FU ($p<0.05$) but not at BL Calculated RR: 0.37 Caries Progression Outcome: % incipient lesions progressing to dentin Effectiveness: Tx 2.4% vs. C 3.6% ($p<0.0001$) Calculated RR=0.67 Caries Regression Outcome: % active incipient lesions becoming inactive Tx 81.2% vs. C 37.8% ($P<0.0001$) Calculated RR=2.15 Adverse Effects: NA
Author, Year: Bergstrom et al, 2014	Country: Sweden Country Income: High	Setting: School-based	Difference in FV Receipt: NA

Study	Population Characteristics	Intervention Characteristics	Results
Study Design: RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Fair	Eligibility: Children who started sixth grade in 2005, 2006 and 2007 from seven secondary schools. No exclusion criteria reported Sample Size (BL): Intervention: 381 Control: 331 Attrition: 16.6% Participation Rate: 84.3% Demographics: Age: Mean=NA; Range: 12-16 Y % Female: 49% SES: 7% from high-risk, 40% from-medium risk and 53% from low-risk areas based on socioeconomic index Urbanicity: Urban/suburban Optimally fluoridated: NA Access to Dental Care: Adolescents took part in dental checkups at public dental clinic at 18 month intervals	Provider: Dental nurses or hygienist FV Apps Per Y: 2 Other Services: supervised tooth brushing without any toothpaste every 6 months Comparison: Negative Study Period[1]: Prior to 2008-2011 Study Funded by: NA	Dentition: Permanent (from distal surface of canine to mesial surface of 2Ms) FU: 42 M Caries Initiation: Outcome: Mean DiFS in approximal tooth surfaces Effectivenes: Increment for Tx was 1.24 and for C was 1.31; Difference in mean for Tx vs C not statistically significant at BL (P=0.671) or FU (P=0.847). Calculated RR = 0.95 Caries Progression Outcome: Mean incipient lesions progressing to cavitated Tx: 0.1 vs. C: 0.09 (Difference not statistically significant; P=0.765) Calculated RR=1.11 Adverse Effects: None reported

Study	Population Characteristics	Intervention Characteristics	Results
	BL Caries: Mean ADiFS (SD): Intervention 0.9 (1.99); Control 0.76 (2.12)		
Author, Year: Bergstrom et al, 2016 Study Design: Retrospective longitudinal cohort Suitability of Design: Moderate Quality of Execution: Fair	Country: Sweden Country Income: High Eligibility: Adolescents born in 1993 and 1998 who were part of FV school program in 2003 and 2008 and those born 1993 who were not part of FV program Sample Size (BL): Intervention: 8111 Control: 5831 Attrition: NA Participation Rate: NA Demographics: Age: Mean=NA; Range: 12-15 Y % Female: 48% SES: NA Urbanicity: Urban/suburban Optimally fluoridated: No Access to Dental Care: Adolescents took part in dental checkups at public dental clinic	Setting: School-based Provider: Dental nurses FV Apps Per Y: 2 Other Services: Two lessons on oral health and tobacco use Comparison: Negative Study Period: Intervention done in 2003 and 2008 Study Funded by: NA	Difference in FV receipt: Adolescents in intervention group on average received 1.98 FV treatments annually compared to 0.64 for usual care group. Caries Initiation Dentition: Permanent (from distal surface of canine to mesial surface of 2Ms) FU: 48 M Outcome: Mean DiFS in approximal tooth surfaces Effectiveness: Increment for Tx was 1.09 and for C was 1.6 Calculated RR = 0.68. General linear models indicated differences in increments significant at $p<0.01$. Adverse Effects: NA

Study	Population Characteristics	Intervention Characteristics	Results
	at 18 month interval where they received 1 FV application. BL caries: Mean ADiFS (SD): Intervention 0.85 (1.8); Control 1.1 (2.03)		
Author, Year: Braun et al, 2016 Study Design: RCT Unit of randomization center/classroom Suitability of Design: Greatest Quality of Execution: Good	Country: USA Country Income: High Eligibility: participants from Navajo Head Start centers. Children <3 y of age and caregivers unable to understand English were excluded, as were children with a fluoride varnish allergy Sample size (BL): Intervention: 443 Control: 424 Attrition: 51.7% Participation Rate: 83.4% Demographic: Age: Range: 3-5 (mean: 3.7) % Female: 51% SES: low Race/ethnicity: Navajo Urbanicity: Rural	Setting: School-based Provider: Trained community oral health specialist Apps per Y 4. Other services: Tx: 5 oral health promotion events for children and 4 for parents All participants: toothbrush and toothpaste during enrollment and follow up visits. Comparison: negative Study period: 2011-2013	Difference in FV receipt: NA Caries Initiation Dentition: All teeth (primary and permanent reported separately) FU: 12, 24 and 36 M Outcomes: Mean DMFS, mean dmfs Effectiveness: FU 36 M: DMFS increment for Tx=1.6 vs. C=1.6 Calculated RR=1 mean dmfs increment for Tx=12.9 vs. C=10.8; calculated RR=1.19 FU 24 M (used in stratification analysis): DMFS increment for Tx=0.4 vs. C=0.4; calculated RR=1

Study	Population Characteristics	Intervention Characteristics	Results
	Optimally fluoridated: NA Access to dental care: 89% past-year dental visit BL caries: Mean dmfs: Intervention=19.9, Control=22.8 Prevalence (dmfs>0): Intervention=86.5%; Control=90.1%		mean dmfs increment for Tx=8.6 vs. C=8.4; calculated RR=1.02 FU 12 M (Used in stratification analysis: DMFS increment for Tx=0.03 vs. C=0.02; calculated RR=1.5 mean dmfs increment for Tx=3.4 vs. C=4.3; calculated RR=0.79 No statistically significant differences when comparing the outcomes for Tx and C groups over time from BL to FU. Adverse effects: None reported.
Author, Year Bravo et al; 1997 Study Design: RCT Unit of randomization: classroom Suitability of Design: Greatest Quality of Execution: Good	Country: Spain Country Income: High Eligibility: NA Sample size (BL): Total 362 (3 arms: FV, negative control, and sealant; BL size by arm: NR); only used FV and control arms in analysis Attrition: 13.3% Participation Rate: 84% (based on 3 arms) Demographic:	Setting: School-based Provider: Dentist and assistant Apps per Y: 2 Comparison: negative control (no placebo) Study period: 1990-1992 Study funded by: NR	Change in FV receipt: NA Caries Initiation: Dentition: Permanent 1Ms FU: 48 M Outcome: % 1M developing caries Effectiveness: RR from cox model=0.46 ($p<0.001$) 24 M effectiveness (used in stratification analysis) Caries Initiation: Dentition: Permanent 1Ms FU: 24 M

Study	Population Characteristics	Intervention Characteristics	Results
	Age: Range: 6 to 8 (mean: 7.28) % Female: 49 SES: low-middle Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: low; no school-based programs BL caries: Mean dft Tx: 2.65 C: 2.63 Mean DMFT Tx: 0.45 C: 0.56		Outcome: DMFS Effectiveness: Increment (fissured + non-fissured) for Tx=1.48 vs. C=2.58; statistically significant difference in increment FV vs. C from multivariable regression (P<0.05) Calculated RR=0.57 Adverse Effects: NA
Author, Year Chu et al., 2002 Study design: RCT Unit of randomization: Student Suitability of design: Greatest Quality of execution: Good	Country: China Country Income: Upper middle Eligibility: Have dentin caries in upper primary anterior teeth. Sample size (BL): Intervention: 73 Control: 73 Attrition: 15.8% Participation: NA Demographic	Setting: School-based (preschool) Provider: Dentist FV apps per Y: 4 Other services: OH education provided by teachers at BL and regularly throughout study Comparison: placebo	Difference in FV receipt: *NA* Caries regression Dentition: Upper primary anterior teeth (incisors and canines) FU: 30 M Outcome: mean ds arrested Effectiveness: Mean ds arrested: Tx=1.54 vs. C=1.27 (difference not statistically significant); calculated RR=1.21.

Study	Population Characteristics	Intervention Characteristics	Results
	Age: Range 3 to 5 Y; mean 4Y % Female: 44% SES: NA Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: 40% had other dental care in 30 months BL Caries: Mean dmf upper anterior tooth surfaces = 4.66	Study period: Likely 1997 to 2000 Study funded by: Authors report there's no conflict of interest.	Adverse effects: none reported
Author, Year: Clark et al; 1985 Study Design: RCT Unit of randomization: Student Suitability of Design: Greatest Quality of Execution: Good	Country: Canada Country Income: High Eligibility: Included 6-7-year-olds attending 17 schools in non-fluoridated communities; no exclusion criteria reported Sample size (BL): Intervention: 280 Control: 275 Attrition: 9.5% Participation Rate: 78.7% Demographic: Age: Mean=NA Range: 6 to 7 Y	Setting: School-based Provider: Dental hygienist FV apps per Y: 2 Other Services: Every child received professional prophylaxis; fluoride dentifrice at home, while some also received daily fluoride supplements. Study period[1]: Prior to 1984	Difference in FV receipt: NA Caries Initiation 20 and 34 M FU Dentition: Permanent 1Ms FU: 32 M Outcome: Mean DMFS Effectiveness: Increment for Tx=2.43 vs. C=3.11; PF=21.9% ($p<0.05$) Calculated RR=0.78 Dentition: Primary 1Ms and 2Ms Outcome: mean dfs Effectiveness: Increment Tx: 1.49 vs. C: 2.06; PF=27.2% (not statistically significant) Calculated RR=0.72

Study	Population Characteristics	Intervention Characteristics	Results
	% Female: NA SES: NA Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: Paper states, "No attempts were made to eliminate exposure to other types of routine cavity prevention". BL caries: Intervention: 0.45; Control BL 0.36	Study funded by: Medical Research Council of Canada Grant	Dentition: Permanent 1Ms FU: 20 M Outcome: Mean DMFS Effectiveness: Increment for Tx=1.73 vs. C=2.02; PF=14.4% (not statistically significant); Calculated RR=0.86 FU: 20M Dentition: Primary 1Ms and 2Ms Outcome: mean dfs Effectiveness: Increment Tx: 1.62 vs. C: 1.74; PF=6.9% (not statistically significant); calculated RR=0.93 Adverse Effects: none reported
Author, Year: Dudowitz, 2018 Study Design: Before-after Suitability of Design: Least Quality of Execution: Fair	Country: USA Country Income: High Eligibility: Select high-need schools and offered services to all children with signed consent forms Sample Size (BL): 2776 Attrition: 77.6% Participation Rate: 60.0%	Setting: School-based Provider: licensed member of dental team FV Apps Per Y: 2 Other Services: 3-tier approach: 1) community wide OH education; 2) Direct	Difference in FV receipt: NA Caries Regression Dentition: Mixed FU: 9 M Outcome: Mean number of white/brown spots changed from 1.7 at BL to 1.3 at FU (P=0.001) Adverse Effects: NA

Study	Population Characteristics	Intervention Characteristics	Results
	Demographics: Age: Mean=8.3 Y; Range: 3.2 -13.9 Y % Female: 52.5% SES: low Race/ethnicity: at least 90% Latino Urbanicity: Urban/suburban Optimally fluoridated: Yes Access to Dental Care: 41% reported no past 6 M dental visit BL caries: 66% had active caries overall, 33.3% had early reversible disease, 26.5% had visible decay, mean number of caries =2.7	preventive care and early intervention at school and 3) linking children in need to more intensive restorative care. Comparison: None Study Period: 2012-2015 Study Funded by: NA	
Author, Year: Effenberger et al; 2021 Study Design: RCT Unit of Randomization: School	Country: South Africa Country Income: Upper middle Eligibility: Included: all children with signed consent and who participated in BL examination. Excluded: Children with chronic stomatitis or ulcerated gums, a history of asthma or known allergies to used materials.	Setting: School-based Provider: Trained local non-professional assistants Annual FV apps: 4 Both arms participated in a	Difference in FV receipt: NA Caries Initiation Dentition: All teeth (primary and permanent teeth reported separately) FU: 12 and 24 M Outcome Measure:

Study	Population Characteristics	Intervention Characteristics	Results
Suitability of Design: Greatest Quality of Execution: Good	Sample size (BL): Intervention: 287 Control: 226 Attrition: 32.9% Participation Rate: NA Demographic: Age: Range: 4 to 8 y; Mean 6.1 y % Female: 48.3 SES: Low Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: No BL caries: Mean dmfs (SD): Intervention=4.8 (4.0); Control=4.9 (4.2) Mean DMFS: intervention=0.1 (0.5); control=0.1 (0.4)	school-based toothbrushing program: received OHE, F toothpaste (1450 ppm) and supervised toothbrushing at BL and FU. Comparison: no treatment Study period: Feb 2018 to Feb 2020	Mean DiMFS, dimfs Effectiveness: FU 24 M: DiMFS increment Tx=1.7 vs. C=2.6 (Significance in increment difference not reported); calculated RR=0.65 dimfs increment Tx=5.5 vs. C=7.1 (Significance in increment difference not reported); calculated RR=0.77 FU 12 M: DiMFS increment Tx=0.6 vs. C=0.7 (Significance in increment difference not reported); calculated RR=0.86 DiMFT increment Tx=0.1 vs. C=0.1 (Significance in increment difference not reported) Calculated RR=1.00 dimfs increment Tx=4.2 vs. C=4 (Significance in increment difference not reported); calculated RR=1.05 Adverse Effects: None reported
Author, Year: Florio, 2001 Study Design:	Country: Brazil Country Income: Upper middle	Setting: School-Linked	Difference in FV receipt: NA

Study	Population Characteristics	Intervention Characteristics	Results
RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Fair	Eligibility: Children from four different public day nursery schools with at least two first permanent molars with restricted enamel decay. 1M with hypoplastic pits, occlusal fillings, or fissure sealants, radiolucent area in proximal surfaces, reaching the enamel-dentin junction or beyond it, were excluded. Sample Size (BL): Intervention 11 Control 11 Attrition: 4.5% Participation Rate: 13.6% Demographic: Age: Mean=6; Range: NA % Female: NA SES: low Urbanicity: Urban/suburban Optimally fluoridated: NA Access to Dental Care: High	Provider: Dentist with assistant FV Apps Per Y: 2 Other Services: professional prophylaxis done each quarter and children had access to restorative care as needed. Comparison: toothbrush training with mouthwash Study Period: Prior to 2001 Study Funded by: NA	Dentition: Permanent 1Ms with restricted enamel decay FU: 12 M Caries progression Outcome: % incipient caries lesions progressing Effectiveness: Tx= 5.5% vs. C=6.1% (Not statistically different) Calculated RR=0.90 Caries Regression Outcome: % incipient caries lesions arrested Effectiveness: Tx=83.3% vs. C=72.7% (Not statistically different) Calculated RR=1.15 Adverse Effects: NA

Study	Population Characteristics	Intervention Characteristics	Results
	BL Caries: at least 2 first permanent molars with restricted enamel decay.		
Author, Year: Grodzka et al, 1982 Study Design: CT Suitability of Design: Greatest Quality of Execution: Fair	Country: Poland Country Income: High Eligibility: Children were from 18 selected prep schools. Sample Size (BL): total 401, not reported by group Attrition: 19.9% Participation Rate: NA Demographics: Age: range: 3-4, mean 3.5 % Female: NA SES: NA Urbanicity: Urban/suburban Optimally fluoridated: NA Access to Dental Care: NA BL Caries: Mean dimft (SD) Intervention =6.79 (3.91), Control=6.62 (3.88) Mean dimfs (SD) Intervention =10.20 (8.29), Control =11.01 (12.9)	Setting: School-based Provider: Dentist FV Apps Per Y: 2 Other Services: NA Comparison: negative Study period[1]: prior to 1982 Study funded by: NA	Difference in FV receipt: NA Caries Initiation Dentition: All primary teeth FU: 24 M Outcome: Mean dimfs Effectiveness: dimfs increment Tx=6.24 vs. C=6.89 (Increment difference not significant, P=0.307) Calculated RR: 0.91 Adverse Effect: NA

Study	Population Characteristics	Intervention Characteristics	Results
Author, Year: Hardman et al; 2007 Study Design: RCT Unit of randomization: School Suitability of Design: Greatest Quality of Execution: Fair	Country: UK Country Income: High Eligibility: NA Sample size (BL) intervention: 420 Control: 412 Attrition: 20.2% Participation Rate: 37.8% Demographic: Age: range: 6-8, mean 6.9 Tx, 7.0 C % Female: 49 SES: low Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: NA; Fluoride milk program started in schools during study BL caries: Prevalence dft Intervention=67.7%, control=60.9% Mean dft Intervention=2.53, Control=2.26	Setting: School-based Provider: Dental therapist FV Apps Per Y: 2 Other Services: Toothbrush and toothpaste containing 1,450ppm F provided to both groups at BL. Comparison: negative control (no placebo) Study period[1]: prior to 2007 Study funded by: NR, one author employed by FV manufacturer.	Difference in FV receipt: NA Caries Initiation Dentition: 1Ms FU: 26 M Outcomes: Incidence DiFS, mean difs Effectiveness: Incidence DiFS Tx 44.9% (=150/334) vs. C 45.8% (=151/330) Incidence not statistically different Calculated RR=0.98 Outcome: Mean difs Effectiveness: Increment Tx=0.71 vs. C=1.12 (increment difference significant, P=0.03) Calculated RR=0.63 Adverse Effects: NA

Study	Population Characteristics	Intervention Characteristics	Results
Author, Year: Hedman et al, 2015 Study Design: RCT Unit of Randomization: School Suitability of Design: Greatest Quality of Execution: Good	Country: Sweden Country Income: High Eligibility: Included schools should have at least 100 students in grades 6-8, situated in above low risk area, and have special room for dental services delivery. Sample Size (BL): Intervention: 270 Control: 264 Attrition: 13.1% Participation Rate: 96.0% Demographic: Age: Mean=NA; Range: 12-16 Y % Female: 45% (Tx) SES: 9% immigrants (Tx) Urbanicity: Urban/suburban Optimally fluoridated: NA Access to Dental Care: Adolescents could attend school dental clinic as needed and those with high risk were offered preventive measures	Setting: School-based Provider: Dental Hygienist FV Apps Per Y: 2 Other Services: recurrent education about oral health and tobacco once each semester High-risk children received preventive measures and dietary advice, OH instructions and F treatments. High-risk children in control schools also received same dental care at dental clinic and could visit dental hygienist for advice and help. Comparison: Negative Study Period: 2009-2011	Difference in FV Receipt: NA Caries Initiation Dentition: Permanent (from distal surface of canine to mesial surface of 2Ms) FU: 24 M Outcome: Mean DiFS in approximal tooth surfaces Effectiveness: Increment for Tx= 0.66 vs. C=0.99 (increment difference not significant, P=0.1); calculated RR was 0.67 Adverse Effects: NA

Study	Population Characteristics	Intervention Characteristics	Results
	and health consultation at school clinic BL Caries: Mean ADiFS (SD) Intervention: 0.11 (0.44) Control: 0.10 (0.38) Prevalence ADFS Intervention: 26.2%, Control: 27.8%	Study Funded by: NA	
Author, Year Jiang et al; 2014 Study Design: RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Good	Country: Hong Kong Country Income: High Eligibility: Children with good general health, not on long-term medication/ with parental consent Excluded: Children with major systemic disease or on long-term medication, and those who were not cooperative and refused examination Sample size (BL): Intervention: 149 Control: 152 Attrition: 6.6% Participation Rate: NA Demographic: Age: mean 16 months	Setting: School-linked Provider: Dental hygienist & Dentist FV apps per Y: 2 Other Services: NA Study period: April 2010-2012 Study funded by: Hong Kong Research Grant Council	Difference in FV receipt: NA Caries initiation Dentition: All primary teeth FU: 24 M Outcome: Mean dimft Effectiveness: Mean dimft increment Tx=0.3 vs. C=0.2 (Difference in increment not statistically significant); calculated RR=1.5 Adverse Effects: None reported

Study	Population Characteristics	Intervention Characteristics	Results
	% Female: intervention 55%, control 57% SES: middle to high Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: NA BL caries: Prevalence dis: 2%		
Author, Year: Kidd et al., 2020 Study Design: Retrospective Cohort Suitability of Design: Moderate Quality of Execution: Good	Country: UK Country Income: High Eligibility: Attended schools in area with high social deprivation Sample size (BL): 31,581 Attrition: NA Participation Rate: 48.9% Demographic: Age: Range: 48 to 72 M; % Female: 49.1% SES: Low Urbanicity: Urban/suburban Optimally fluoridated: No	Setting: School based Provider: Dental nurses FV applications per Y: 2 Other services:	Difference in FV receipt: NA Caries Initiation Dentition: Primary FU: Approximately 24 M Outcome: Obvious caries experience Effectiveness: Multivariable regression model controlling for socio-demographic characteristics, other program interventions and social deprivation status found that odds ratios for 2-year caries initiation in adolescents receiving 5+ applications vs. 0 applications were 1.25 for least deprived, 1.15 for next-least deprived, 0.92 for moderately deprived,

Study	Population Characteristics	Intervention Characteristics	Results
	Access to dental care: 70% had dental visit during study BL caries: Prevalence: 29.8%	Comparison: No FV applications (Study controlled for other interventions) Study period: Intervention likely done from 2012-2015 Study funded by Scottish government	0.80 for next to most deprived, and 1.09 for most deprived. Trend in OR by social deprivation level statistically significant. Adverse Effects: NA
Author, Year: Liu et al; 2012 Study Design: RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Good	Country: China Country Income: Upper middle Eligibility: Included: children with at least one molar with deep fissures or enamel level caries; Excluded: molars with dentin level caries Sample size (BL): Intervention 124 Control 128 Attrition: 4.8% Participation Rate: NA	Setting: School-based Provider: Dentist FV Apps Per Y: 2 Other services: none Comparison: negative control (placebo) Study period: April 2008-2010	Difference in FV receipt: NA Caries Initiation Dentition: Permanent 1Ms FU 24 M Outcome: Incidence of dentin caries (% molar surfaces developing dentin caries) Effectiveness: % molar surfaces developing dentin caries for Tx=2.4% vs. C=4.6% (Difference in incidence significant at p=0.002); calculated RR=0.52

Study	Population Characteristics	Intervention Characteristics	Results
	Demographic: Age: mean 9.1 % Female: Intervention 56%, Control 46% SES: NA Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: 40% of intervention and 34% of control reported dental visit history BL caries: 35% of teeth in both groups had enamel caries (teeth with dentin caries were excluded)		Adverse Events: None reported
Author, Year McMahon, 2020 Study Design: RCT Unit of randomization: Student Suitability of Design: Greatest Quality of Execution: Good	Country: UK Country Income: High Eligibility: No contraindications for FV, (i.e., hypersensitivity to colophony and/or any other constituents; No history of bronchial asthma requiring hospitalization; No history of allergic episodes requiring hospital admission; and No signs of distress on the day of BL inspection or signs of verbal or non-verbal reluctance.	Setting: School-based Provider: NA FV apps Y: 2 Other services: daily supervised toothbrushing (1,000 ppm fluoride toothpaste) in nursery school; free tooth brush and paste for home use; community-based	Difference in FV Receipt: Receipt of 3 or more fluoride varnish applications over 2 in intervention group was 84% compared to 6% in control group Caries initiation: Dentition: all primary teeth FU: 24M Outcome: Mean dmfs Effectiveness: dmfs increment Tx=1 vs. C=0.9 (Difference not significant); calculated RR=1.11

Study	Population Characteristics	Intervention Characteristics	Results
	Sample size (BL): Intervention 643 Control 641 Attrition: 10.4% Participation Rate: 38.6% Demographic: Age: All children age 3 (mean=3.54 Y) % Female: 50 SES: participants socially deprived (5 levels of social deprivation and all participants from 2 highest socially deprived scale) Urbanicity: Urban/suburban (greater Glasgow) Optimally fluoridated: No Access to dental care: 8% and 6% of T and C, respectively received FV outside of program BL caries: dmft Prevalence:17% Mean: Intervention=0.6, Control=0.5	dental health support workers; and oral health advice within primary dental services Comparison: children not receiving FV but receiving other service Study period: 2012-2015 Study funded by: NA	Adverse Effects: None reported
Author, Year: Milsom, 2011	Country: UK Country Income: High	Setting: School-based	Difference in FV receipt: NA Caries initiation

Study	Population Characteristics	Intervention Characteristics	Results
Study Design: RCT Unit of Randomization: School Suitability of Design: Greatest Quality of Execution: Good	Eligibility: Attended state maintained primary schools. Could not have: 1) history of asthma or severe allergic reaction that required hospitalization; 2) fixed orthodontic appliance involving > 4 teeth; 3) participated in another clinical study within 3 M of initial examination, and 4) ulcerative gingivitis/stomatitis. Sample size (BL): Intervention: 1473 Control: 1494 Attrition: 12.7% Participation Rate: 48.1% Demographic: Age: Range: 7 to 8 Y; mean 8.1 Y % Female: 50% SES: Deprived area Urbanicity: Urban/suburban and rural Optimally fluoridated: No Access to dental care: NA	Provider: Dentist first year and dental therapist therafter FV Apps Per Y: 3 Other services NA. Comparison: No treatment Study period: 2006 to 2009	Dentition: Permanent 1Ms FU: 36 M Outcome: Mean DFS Effectiveness: Mean DFS increment Tx=0.66 vs. C=0.63 (Increment did not statistically differ); calculated RR=1.05 Adverse Effect: 12 (0.8%) of 1,473 participants reported minor and self-limiting reactions, including nausea (7), vomiting and diarrhea (1), high temperature (1), swollen tongue (1), sore mouth (1), and mouth ulcer (1)

Study	Population Characteristics	Intervention Characteristics	Results
	BL caries: Median DFS=0; median dmft=3		
Author, Year,: Moberg-Skold, 2005 Study Design: RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Fair	Country: Sweden Country Income: High Eligibility: Schools in high, medium, and low caries risk are where risk determined by social determinants of health. Present findings for all children and those in high- risk areas Sample size (BL): Intervention: All 190; High caries risk area 44 Control: All 181, High risk 40 Attrition: 11.2% Participation Rate: NA Demographic: Age: 13 to 16 Y % Female: 48 SES: varied Urbanicity: Urban/suburban Optimally fluoridated: Low-risk group yes, other risk groups no	Setting: School-based Provider: Dental nurses and dental hygienists FV Apps Per Y: 2 Other services: OH education and had annual dental visit Comparison: Negative control Study period: 1998-2001	FV receipt: NA Dentition: Permanent teeth from distal surface of canine to mesial surface of 2nd molars Caries Initiation FU: 36 M Outcome: Mean DiFS in approximal tooth surfaces Effectiveness: All children: Increment Tx= 0.79 vs. C=1.85 (Increment statistically differed $p<0.001$); calculated RR=0.43 High-risk children Increment Tx= 0.95 vs. C= 3.06 (Increment statistically differed $p<0.001$); calculated RR=0.31 Caries Progression Outcome: Mean incipient lesions progressing Effectiveness: All children: Tx=0.1 vs. C=0.4

Study	Population Characteristics	Intervention Characteristics	Results
	Access to dental care: Annual dental exam where FV delivered to controls BL caries: Mean DFT: Low risk: 0.60 High risk: 2.65		(Progression significantly different); calculated RR=0.25 High-risk children: Tx=0.18 vs. C=0.9 (Progression significantly different); calculated RR=0.20 Adverse effects: None reported
Author, Year: Modeer et al, 1984 Study Design: RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Good	Country: Sweden Country Income: High Eligibility: Children selected from 3 different schools, no specific inclusion/exclusion criteria mentioned Sample Size (BL): Intervention: 118 Control: 118 Attrition: 17.8% Participation Rate: NA Demographic: Age: Mean=14 Y; Range: NA % Female: 43% (Tx) SES: NA	Setting: School-based Provider: Trained dental nurse and hygienist FV Apps Per Y: 4 Other Services: Both groups participated in routine fluoride mouth rinse every 14 days with 0.2% NaF Comparison: Negative Study Period[1]: Prior to 1984	Difference in FV Receipt: NA Dentition: Permanent teeth from distal surface of canine to mesial surface of 2nd molars FU: 36 months Caries Initiation Outcome: Mean DiFS in approximal tooth surfaces Effectiveness Increment Tx=3.7 vs. C=4.8 (Significance not reported) Calculated RR=0.77 Caries Progression Outcome: % incipient lesions progressing Effectiveness:

Study	Population Characteristics	Intervention Characteristics	Results
	Urbanicity: Rural (Outskirts of Stockholm) Optimally fluoridated: No Access to Dental Care: "High" BL Caries: Mean ADiFS Intervention: 4.1; Control: 5.3 Prevalence ADiFS Intervention:12.4%; Control: 14.9%	Study Funded by: NA	Tx=60.6% vs. C=64.4% (Not statistically different) Calculated RR=0.94 Caries Regression Outcome: % caries lesions regressing Effectiveness: Tx= 5.7% vs. C=5.9% (Not statistically different) Calculated RR=0.97 Adverse Effects: NA
Author, Year: Munoz-Millan et al; 2018 Study Design: RCT Randomization Unit: Student Suitability of Design: Greatest Quality of Execution: Good	Country: Chile Country Income: High Eligibility: <u>Included:</u> Children without cavitated caries or previous dental treatments. <u>Excluded:</u> Children with systemic diseases, disabilities or developmental enamel defects and those with temporary residences. Sample size (BL): Intervention: 131 Control: 144 Attrition: 31.3%	Setting: School-based Provider: Dentist FV Apps Per Y: 2 Other services: Both arms received OH education every 6 M; assessment of teeth, dental hygiene and dietary habits; instructions on brushing teeth and use of fluoride toothpaste; daily supervised tooth brushing; printed materials; free toothbrush and toothpaste (500 ppm	Difference in FV receipt: NA Caries initiation Dentition: All primary teeth FU: 24 M Outcome: Mean dmft Effectiveness: Mean dmft increment Tx=1.7 vs. C=2.5 Increment difference not significant, P=0.51 Calculated RR=0.68 Adverse effect: none reported

Study	Population Characteristics	Intervention Characteristics	Results
	Participation Rate: NA Demographic: Age: Range: 2 to 3 Y; Mean 32.4 M for T, 33.5 M for C % Female: 54.5 SES: Low Urbanicity: Rural Optimally fluoridated: No Access to dental care: 28% of students in treatment and 21% in control group had outside dental care during study BL caries: Only included children without caries Note: 53% of population screened for eligibility had caries and were excluded.	F). All preschools brushed children's teeth at least once a day. Comparison: Placebo Study period: May 2012 to Dec 2014	
Author, Year: Pitchika; 2013 Study Design: CT Suitability of Design:	Country: Germany Country Income: High Eligibility: Healthy 2- to 3-year-olds with parental consent Sample size (BL):	Setting: School-based Provider: Dentist or hygienist FV Apps Per Y: 2 Other services: daily supervised brushing	Difference in FV receipt: NA Caries Initiation: Dentition: All primary teeth FU: 24 M Outcome: Mean dimfs Effectiveness: Mean dimfs increment

Study	Population Characteristics	Intervention Characteristics	Results
Greatest Quality of Execution: Fair	Intervention: 195 Control: 179 Attrition: 17.6% Participation Rate: NA Demographic: Age: Range: 2 to 3 Y; Mean NA % Female: NA SES: 90% subjects low to moderate SES Urbanicity: Rural Optimally fluoridated: No Access to dental care: 1 dental visit per year to reduce dental anxiety BL caries: Prevalence: dmfs: Overall 19.2%	with fluoride toothpaste; dietary counseling; OH instruction to parents Comparison: Negative control Study period: 2009 or after Study funded by: NA	Tx= 3.6 vs. C= 4 (Difference in increment not significant) Calculated RR=0.90 Adverse Effects: NA
Author; Year: Sirivichayakul et al., 2023 Study design: RCT Unit of randomization: Student	Country: Thailand Country Income: Upper middle Eligibility: Healthy children with at least one quadrant showing sound contact surfaces of posterior teeth. Distal surfaces of the canine or 1M, or mesial surfaces of the	Setting: School based Provider: Dentist FV apps per Y: 2 Other services:	Difference in FV receipt: NA Dentition: approximal surfaces of primary canines through second molars FU: 12 and 18 M Dentition:

Study	Population Characteristics	Intervention Characteristics	Results
Suitability of design: Greatest Quality of Execution: Good	1M or 2M showing clinically sound and radiographically sound or initial carious lesion. Sample size (BL): Intervention: 62 Control: 64 Attrition: 16.7% Participation: 45.7% Demographic Age: Range 4 to 6 Y; Mean: 5Y % Female: 51.6% SES: NA Urbanicity: Urban/suburban Optimally fluoridated: No Access to dental care: NA BL caries: Mean dmft (SD): Intervention 5.4 (4.8), Control 5.1 (4.0)	Dietary advice; oral hygiene instruction & supplies; OR education materials; dental care referral Comparison: Placebo Study period: March 2019 to Oct 2020 Study funded by: NA	Caries Initiation Outcome: % sound surfaces developing cavitated caries 12 M: Tx 8.9% vs. C 13.8% (Difference significant at P=0.003) Calculated RR=0.64 18 M: Tx12.7% vs. C 20.3% (Difference significant at P<0.001) Calculated RR=0.63 Caries Progression % surfaces with incipient caries progressing to dentin 12 M Tx 24.5% vs. C 26.7% (Not statistically different P=0.76) Calculated RR=0.92 18 M Tx 33.0% vs. C 36.9% (Not statistically different, P=0.26) Calculated RR=0.89 Adverse effects: NA
Author, Year: Souza et al, 2021 Study Design: RCT	Country: Brazil Country Income: Upper middle Eligibility: Healthy children age 6-7 with at least 1 smooth surface active caries lesion from	Setting: School-based Provider: Trained examiners (likely dentists)	Difference in FV Receipt: NA Caries Initiation Dentition: Permanent

Study	Population Characteristics	Intervention Characteristics	Results
Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Good	5 selected schools, children taking antibiotics, undergoing ortho treatment or had received professional FV application 6 months prior to study were excluded. Sample Size (BL): Intervention: 20 Control: 20 Attrition: 10.0% Participation Rate: NA Demographic: Age: Mean=NA; Range: 6 to 8 Y % Female: 40% SES: NA Urbanicity: Urban/suburban Optimally fluoridated: Yes Access to Dental Care: NA BL Caries: 5.2% of the total surfaces had active caries	FV Apps Per Y: 5 (1 per week for 4 consecutive weeks and then single application at 6 months) Other Services: Children were educated about cariogenic diet and oral hygiene during school visits. Comparison: Placebo Study Period[1]: Prior to 2021 Study Funded by: Acknowledgements to FGM-DentsCare (Joinville-SC, Brazil) for manufacturing the experimental materials.	FU: 18 Mo Outcome Measure: Incidence % smooth surfaces developing decay (including incipient lesions) Effectiveness: Incidence TX: 2.3% C: 6.9% Difference not statistically significant Calculated RR=0.33 Adverse Effects: None reported
Author, Year: Tagliaferro et al; 2011	Country: Brazil Country Income: Upper middle Eligibility:	Setting: School-based Provider: Dental hygienist & Main	Difference in FV receipt: NA Caries Initiation

Study	Population Characteristics	Intervention Characteristics	Results
Study Design: RCT Unit of Randomization: School Suitability of Design: Greatest Quality of Execution: Good	Included: 6-8 years old children, with at least two sound permanent first molars; presenting dmft >=3 or at least one active cavitated lesion or dmfs + DMFS=0 and parental consent Excluded: Children with systematic diseases, communication, and/or neuromuscular problems, fixed orthodontic appliances, severe hypoplasia/fluorosis, and/or allergy to the colophony component of the varnish. Sample size (BL): Intervention: 109 Control: 110 Attrition: 19.2% Participation Rate: NA Demographic: Age: Mean= 7 Y Range: 6 to 8 years % Female: 52.0 SES: 72% of families had an income of 1 to 4 times the Brazilian minimum wage Urbanicity: Urban/suburban	Researcher (likely dentist) FV apps per Y: 2 Other Services: OH education 1 hour sessions every 3 months, covering dental caries, periodontal diseases, dental plaque and fluoride. Oral hygiene instructions, supervised tooth brushing and dietary counseling were presented to children means of lectures, videos, educational games and oral quizzes Study period[1]: Prior to 2011 Study funded by: NA	Dentition: occlusal surfaces of permanent 1Ms FU: 24 M Outcome: mean DMFS Effectiveness: All children: Calculated increment based on pooled increments for high-risk and low-risk groups: Tx 0.20 vs. C 0.26 Significance not reported Calculated RR=0.76 High-risk children: Increment Tx 0.29 vs. C 0.39 (increment difference not statistically significant) Calculated RR=0.74 Adverse Effects: none reported

Study	Population Characteristics	Intervention Characteristics	Results
	Optimally fluoridated: Yes Access to dental care: Could access restorative and preventive care in a clinic BL caries: mean dmft (SD) Highrisk Control: 4.53 (3.04) Intervention: 4.28 (2.54) Low risk 0 for botx controls and intervention		
Author, Year: Turska-Szybka, 2021 Study Design: RCT Unit of Randomization: Blocks of children Suitability of Design: Greatest Quality of Execution: Good	Country: Poland Country Income: High Eligibility: Inclusion: (i) all primary teeth erupted, and (ii) the presence of at least 1 noncavitated or cavitated lesion. Exclusion: (i) medical problems or were on medication that could affect their oral health, (ii) a history of severe allergic episodes, and (iii) cognitive disabilities and/or special needs. (iv) children with > 10 tooth surfaces with dentin lesions and those taking antibiotics within the last 2 weeks prior to the BL examination.	Setting: School-linked Provider: Dentist FV apps per Y: 4 Other services: All children received OH education, toothbrushing, and caries examinations at baseline. No dietary restrictions or any other fluoride supplements were recommended or prescribed during the study duration. The parents were	Difference in FV receipt: NA Caries Initiation Dentition: primary teeth FU: 12 M Outcome: Mean dimfs Effectiveness: Mean dimfs increment Tx 1.8 vs. C 4.9 (Increment difference statistically significant, $P<0.05$) Calculated RR: 0.37 Adverse Effects: minor reports discontent with color of varnish

Study	Population Characteristics	Intervention Characteristics	Results
	Sample size (BL): Intervention: 60 Control: 60 Attrition: 5.8% Participation Rate: NA Demographic: Age: range 36 to 71 M, mean intervention = 51, control =46 % Female: intervention 41.7, control 48.3 SES: NA Urbanicity: Urban/suburban Access to dental care: NA BL caries: Mean dimft (SD) Intervention 11.0 (17.7) Control: 10.7 (5.4)	also informed about the need for restorative treatment for those children exhibiting dentin lesions. Comparison: negative control (no placebo) Study period: August 2017-August 2018 Study funded by: manufacturer paid for varnish used in the study	
Author, Year: Wang et al; 2021 Study Design: RCT Unit of Randomization: Class	Country: China Country Income: Upper middle Eligibility: Exclusion: acute or chronic systematic disorders, gingivitis or ulcers, allergy history, participation in other trials in 24 M, fluorosis, hypoplastic defects, sealed 1M	Setting: School-based Provider: Dentist and assistant FV apps per Y: 2	Difference in FV receipt: NA Caries Initiation Dentition: Permanent 1Ms FU: 24 and 36 M Outcome: Mean DFS. Effectiveness: 36 M

Study	Population Characteristics	Intervention Characteristics	Results
Suitability of Design: Greatest Quality of Execution: Good	Sample size (BL): Intervention: 2657 Control: 2740 Attrition: 7.3% Participation Rate: NA Demographic: Age: range 6 to 7 Y, mean intervention = 6.81 Y, control =6.85 % Female: 46 SES: low Urbanicity: rural Optimally fluoridated No Access to dental care: low BL caries: caries prevalence in primary dentition: Intervention: 87.3% Control: 85.7% Mean DFS 1st molars 0.03 in Intervention and 0.04 in Control (about 67.5% had erupted 1st molars)	Other services: Supervised toothbrushing and OH education provided to both groups. Comparison: negative control (no placebo) Study period: October 2014-December 2017 Study funded by: NA	Model-based increment per year Tx 0.25 vs. C 0.38 Increment difference significant at p<0.001 Calculated RR=0.66 24 M Model-based increment per year Tx 0.19 vs. C 0.3 Increment difference significant at p<0.001 Calculated RR=0.63 Adverse Effects: None significant. Only one child complained about the taste of the fluoride varnish
Author, Year: Wu, 2020 Study Design:	Country: China Country Income: Upper middle Eligibility:	Setting: School-based Provider: Dentist FV apps per Y:	Difference in FV receipt: NA Caries Initiation Dentition Permanent 1Ms

Study	Population Characteristics	Intervention Characteristics	Results
RCT Unit of Randomization: Student Suitability of Design: Greatest Quality of Execution: Good	Included: 9 schools randomly selected from 325 schools; Excluded: Children with systemic diseases, a long history of medication use and a history of allergies. Sample size (BL): Intervention: 999 Control: 1004 Attrition: 12.7% Participation Rate: NA Demographic: Age: 6 to 8 years Female: 45.7% SES: low Urbanicity: rural Optimally fluoridated NA Access to dental care: low BL caries: Prevalence of caries in 1Ms: 24%	2 Other services: OH education (healthy diet, oral hygiene, toothbrush and fluoride toothpaste, and brushing instruction) provided to Tx and C every 6 months. Comparison: no treatment Study period: November 2014 to November 2017	FU 36 M Outcomes: Mean DiMFS Effectiveness: DiMFS increment Tx 1.46 vs. C 1.85 Difference in means not significant at BL (p=0.285) but significant at FU (p=0.009) Calculated RR=0.79 Adverse event: none reported
Author, Year: Zimmer et al; 1999 Study Design:	Country: Germany Country income: High Eligibility: NA	Setting: School-based Provider: Dentist (likely) FV apps per Y:	Difference in FV receipt: NA Caries Initiation Dentition: all permanent teeth FU: 48 M

Study	Population Characteristics	Intervention Characteristics	Results
RCT Unit of randomization: School Suitability of Design: Greatest Quality of Execution: Fair	Sample size (BL): 419 total Attrition: 24.1% Participation Rate: 76.5% Demographic: Age: 7.1 mean for group which received >=2 FV applications per year, NR for other groups % Female: 49.8 SES: low Urbanicity: Urban/suburban Optimally fluoridated No Access to dental care: NA BL caries: mean DMFT = 0.48 in group who received >=2 treatments per year, 0.39 in group who received <2 treatments per year, 0.38 in control	2+ group: 4 times first year and 3 the following years. <2 Other services: All groups received OHE and supervised toothbrushing annually. Comparison: negative control (no placebo) Study period: 1991-1995 Study funded by: NA	Outcome: Mean DMFT Effectiveness: All students: Increment Tx 1.04 vs. C 1.39 Statistical significance not reported Calculated RR=0.75 ≥2 applications per Y Increment Tx 0.88 vs. C 1.39 Difference statistically significant (p<0.05) Calculated RR=0.63 <2 applications per Y Increment Tx 1.28 vs. C 1.39 Difference not statistically significant Calculated RR=0.92 Adverse Effects: NA