NYU

CariedAway: One solution for a global disease

Ryan Richard Ruff, PhD, MPH
Tamarinda Barry Godin, DDS, MPH

1

DISCLOSURES

Research presented in this talk was funded by the Patient Centered Outcomes Research Institute (#PCS-1609-36824) and the National Institutes of Health (R01 MD011526)

The study was approved by the NYU School of Medicine Institutional Review Board (#i17-00578). The views expressed are those of the presenters and may not reflect official policy of New York University.

Principal Investigators: Ruff and Niederman

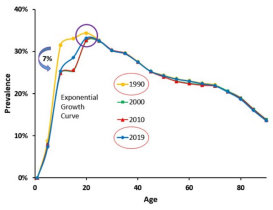
It is registered at www.clinicaltrials.gov, #NCT03442309

NYU

2

PROBLEM #1

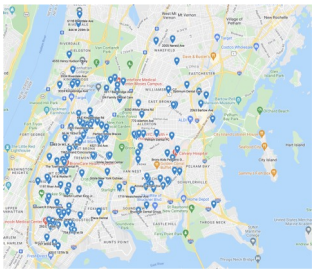
U.S. Caries Across the Life Span
A 30-Year System Outcome Failure*



NYU

3

PROBLEM #2



NYU

4

PROBLEM #3

Original Contributions

Systematic Review

Oral health, academic performance, and school absenteeism in children and adolescents

A systematic review and meta-analysis

Ryan Richard Ruff, MPH, PhD; Sashendra Senthi, MBChB, MPH, PhD; Stephanie R. Susser, MD-CM, MSc, MPH; Atsuko Tsutsui, MD, PhD, MSc

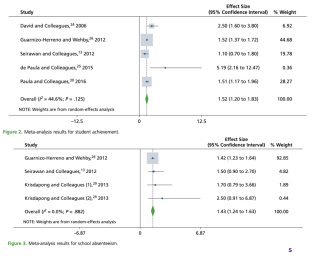


Figure 2. Meta-analysis results for student achievement.

Figure 3. Meta-analysis results for school absenteeism.

NYU

5

5

An imperfect solution

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

School sealant programs are an effective way to reach millions of children with dental sealants to prevent cavities. The Community Preventive Services Task Force strongly recommends using school-based sealant delivery programs to prevent cavities among children.[1] In addition, school sealant programs can be cost-saving within 2 years of placing sealants, and delivering sealants to children at high risk for cavities can be cost-saving to Medicaid.[2]

CDC supports states to put into action school sealant programs that reduce oral disease and improve oral health. As part of CDC's State Actions to Improve Oral Health Outcomes (DP-1810), CDC funds 20 states and one territory for implementing evidence-based preventive interventions to include expanding sealant delivery in low-income and rural schools.

NYU

6

6

"Increased operating costs due to policies requiring dentists' supervision of dental hygienists providing sealants in school settings were a barrier to implementing and expanding SSPs"

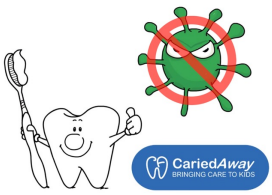
Patel et al, *JADA* 153(10); 2022.

NYU

7

7

CariedAway



NYU

8

8

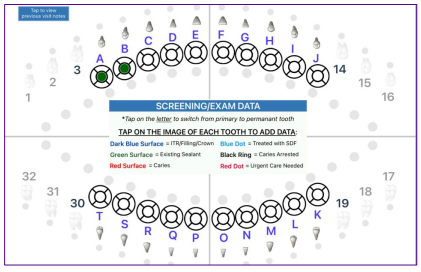
SDF – An introduction

- Silver diamine fluoride is a minimally-invasive medicament used worldwide for the control of dental caries (tooth decay)
- In addition to secondary prevention, growing evidence that SDF is effective for primary prevention
- In the US, SDF is approved by the FDA for hypersensitivity, and was awarded breakthrough therapy status in 2017
- Faster and cheaper than dental sealants, able to be applied by a number of clinical providers
- An excellent alternative for children lacking access to oral healthcare
- Results in permanent staining of decayed teeth and temporary staining of the oral mucosa

9

Implementation Model

10



NYU

11

CariedAway BRINGING CARE TO KIDS

School-Based Caries Prevention Program for Children in Underserved, Low Income, Hispanic Communities

12

Vision

Oral health equity for all children.

Mission

To improve the oral health-related quality of life of New York City's most underserved communities by providing safe, aerosol-free, essential dental caries prevention to children in schools.

13

NYU Dentistry Caried*Away* Provides:

- An oral screening to check the teeth, gums, and mouth
- Tooth cleaning with a toothbrush
  - To remove plaque and food from the biting surfaces of teeth
- Cavity prevention, either:
  - Fluoride varnish on all teeth, sealants and temporary fillings to prevent and arrest cavities
  - Fluoride varnish on all teeth and decay stopping fluoride (silver diamine fluoride) placed on the back teeth to prevent and arrest cavities

14

NYU Dentistry Caried*Away* Provides:

- Dental health education to teach children how to have a healthy mouth
- A toothbrush and full-size tube of fluoride toothpaste
- A report to parents on their child's care
  - Referral to a dentist for further care
  - Assistance in finding a local dentist
- The program follows each child over time using secure electronic records to ensure that oral health is improving

15

Program Planning

- OK, so how does it work?
  - Where do we start?
  - Who is responsible?
  - How long does it take?

16

Program Elements

- Research instrument
  - Electronic health record and survey tools
- Recruitment
- Applications to regulatory entities (city and state)
- Subject enrollment
  - Community engagement
    - Health literacy, cultural competency, and primary language
    - Insurance and immigration concerns
    - Thought leaders

17

Community Engagement

- Communication target
  - School administration, teachers, parent/caregiver, student
- Dissemination channels
  - Interpersonal networks, community and other promotional events
- Content strategies
  - Communication campaign (e.g., marketing mix)
  - Approach (e.g., emotional appeals, message framing, narrative persuasion)

NYU

18

Community Engagement

- Executional strategies (packaging)
  - Paper, e-mail, and telephone marketing, leverage of school media platforms
- Incentives
  - Value: define and demonstrate
  - School, class/peer and individual incentives
- Frequency & Temporality
  - Repeat announcements, reminders, and follow-up communications
  - Timing in relation to health fairs, oral health education, etc.

NYU

19

Program Promotion

- The most important contribution a school can make
  - Demonstrate buy-in
  - Connect students with available services
    - Parents, teachers, staff, students, and community members are invited to:
      - Meet their school's dental team
      - Ask questions about and enroll students in the program
      - Engage in meaningful discussions about good oral health

NYU

20

Program Promotion

Professional Development
- School Administration
- Teachers

Tabling
- Community members
- Parents
- Students

Oral Health Education
- Teachers
- Students

21

Visit Scheduling

- Once our team receives notice of New York State approval, our Clinical Program Coordinator will work with school administrative staff to schedule our first visit
  - Our calendar fills up quickly!
  - We return to schools on a 6-month recall schedule (tricky!)
    - Fall semester: 4 months
    - Spring semester: 6 months

22

Patient Flow/Station Turn-Over

- CariedAway is dedicated to its role in supporting school attendance
  - Make every attempt to minimize the amount of time students spend away from the classroom
  - Care is provided:
    - In as little as 10 minutes
    - Twice per year
    - Eliminating up to 80% of cavities!

23

Space and Storage

- CariedAway strives to provide the greatest impact for New York City school students while minimizing programmatic demands
  - We recognize that physical space is valuable
  - Make every effort to fit our equipment and personnel wherever school's can accommodate us
  - When available, our team works best:
    - In a large classroom or on an auditorium stage*
      - *Subject to availability/circumstances in accordance with COVID-19 guidance

24

Space and Storage

NYU

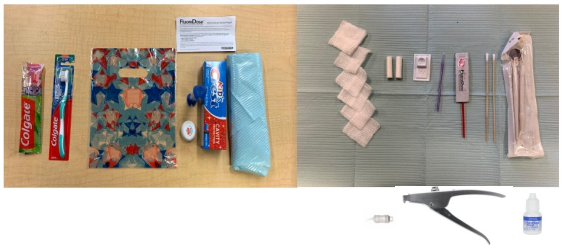
25

25

Mobile SBHC-D Dental Clinic

26

Caries Prevention/Arrest Arsenal



27

Silver Diamine Fluoride (SDF) Application

1. Dispense 1-2 drops of SDF 38% into a disposable well
2. Isolate teeth to be painted using gauze and cotton rolls
3. Remove debris and plaque with a toothbrush
4. Paint SDF on to the biting surfaces of back teeth (30 sec.)
5. Air dry (60 sec.)
6. Wipe excess material away with gauze
7. Repeat as necessary for multiple teeth

28

Isolation

29

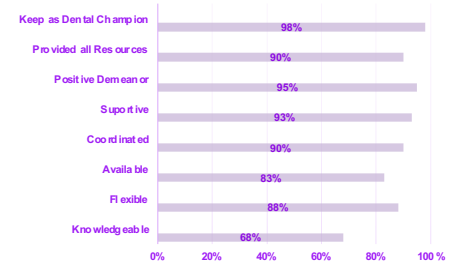
Process evaluation - Dissemination

- Clinical Team Debrief Meeting
  - Consolidated Framework for Implementation Research (CFIR)
    - Inner [i.e., school] setting
      - Culture, structural characteristics, implementation climate and readiness
    - Characteristics of individuals [e.g., "dental champions"]
      - Knowledge and beliefs about the intervention
    - Process
      - Planning, executing, engaging, reflecting and evaluating
- School [Administration] Debrief Meeting

NYU

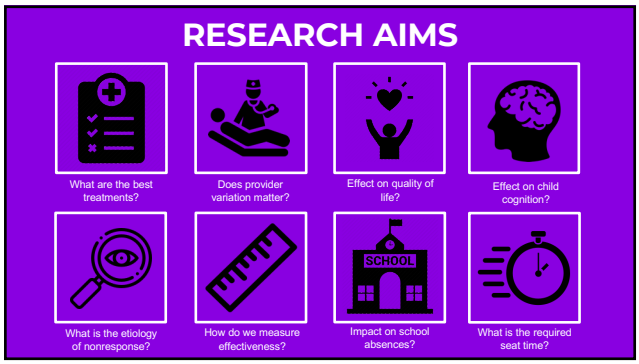
30

Dental Champion Assessment



31

RESEARCH AIMS



32

11%

SEALANT PREVALENCE

Along with an approximate 30% untreated decay prevalence, these statistics suggest a substantial unmet need in the low-income minority child population

NYU

33

33

PRIOR TREATMENT

Table 3: Baseline evidence of prior dental treatment and prevention (N=1398)

	N	%
Treated dentition	374	26.75
Sealant prevalence	156	11.16
Filling prevalence	288	20.6
Sealant by race		
Hispanic	83	0.12
Black	15	0.07
White	4	0.14
Asian	2	0.08
Other	2	0.06
Unreported	50	0.12

NYU

34

34

12%

PREVALENCE OF SEVERE DISEASE, POST-PANDEMIC

Following a two-year suspension due to COVID-19, approximately 12% of study subjects presented with swelling, fistula, or pulpal involvement

NYU

35

35

NEED SEVERITY

Table 5: Risk difference in severe disease post-pandemic, by treatment (N=1398)

	SDF	Sealants	Risk Diff	95% CI
Fistula/swelling/pupal (FSP)	85	86		
No FSP	526	701	0.0298	-.005, .065
Caries	165	215		
No caries	446	572	-0.0031	-.050, .044

NYU

36

36

< 2

POINT DIFFERENCE IN OHRQOL

Children were not significantly different in oral health-related quality of life, whether they received SDF or sealants/ART

NYU

37

37

QUALITY OF LIFE

BMC Oral Health

RESEARCH Open Access

Silver diamine fluoride, atraumatic restorations, and oral health-related quality of life in children aged 5–13 years: results from the CariedAway school-based cluster randomized trial

Ryan Richard Ruff, Tamarinda J Barry Godin, Topaz Murray Small and Richard Niederman

Table 2 COHIP-SF scale and subscale scores, pre/post, by treatment group (means and standard deviations; N = 160)

Scale/subscale	SDF		Sealants + ART	
	Pre	Post	Pre	Post
Oral health	4.98 (3.31)	4.38 (3.66)	5.12 (3.55)	5.61 (3.26)
Functional well-being	2.88 (2.88)	2.08 (2.83)	2.24 (2.54)	2.63 (2.85)
Socio-emotional well-being	4.25 (4.77)	3.73 (4.84)	4.49 (5.16)	3.67 (5.69)
School environment	1.09 (1.51)	0.97 (1.52)	1.39 (2.14)	0.91 (1.71)
Self-image	3.36 (2.34)	3.46 (2.73)	3.41 (3.01)	3.63 (3.03)
COHIP (overall)	16.44 (11.12)	14.62 (11.90)	16.65 (10.56)	16.47 (11.09)

NYU

38

38

50%

AVERAGE 2-YEAR ARREST RATE

Both treatment arms had nearly identical rates of prevention and similar rates of arrest at two years

NYU

39

39

NON-INFERIORITY

JAMA Network Open

Original Investigation | Pediatrics

Effect of Silver Diamine Fluoride on Caries Arrest and Prevention
The CariedAway School-Based Randomized Clinical Trial

Ryan Richard Ruff, PhD; Tamarinda Barry Godin, DDS; Richard Niederman, DMD

Figure 2. Noninferiority Plot for Caries Arrest and Prevention at 2 Years

Outcome	Difference in proportions (95% CI)
Caries prevention	0.01 (−0.04 to 0.06)
Caries arrest	−0.11 (−0.22 to 0.01)

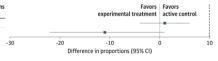


Table 2. Noninferiority Results for Caries Arrest and Prevention After 2 Years

	Experimental group			Control group			Difference			
Outcome	No. (mean)	SD	SE	No. (mean)	SD	SE	No. (mean)	SD	SE	95% CI
Caries arrest	193 (0.56)	0.50	0.04	220 (0.46)	0.50	0.04	413 (−0.11)	1.24	0.06	−0.22 to 0.01
Caries prevention	418 (0.81)	0.39	0.02	567 (0.82)	0.39	0.02	985 (0.01)	0.78	0.03	−0.04 to 0.06

NYU

40

40

1%

DIFFERENCE BETWEEN NURSES AND HYGIENISTS

Nurses were non-inferior to hygienists in the 2-year prevention of caries, with an average of 80%

NYU

41

41

NURSE NON-INFERIORITY

Table 1: Baseline demographics overall and by provider type (N=417)

	Overall		Hygienist/Dentist		Nurses	
	N/Mean	% / SD	N	%	N	%
Subjects	417	100	298	71.46	119	28.54
Female	221	53	167	56.04	54	45.38
Race						
Hispanic	240	57.55	176	59.06	64	53.78
Black	98	23.5	64	21.48	34	28.57
White	10	2.4	8	2.68	2	1.68
Asian	14	3.36	10	3.36	4	3.36
Multiple	5	1.2	4	1.34	1	0.84
Other	11	2.64	7	2.35	4	3.36
DK/Missing	39	9.35	29	9.73	10	8.4
Untreated decay, follow-up	61	14.43	46	15.44	15	12.61
Sealants at baseline	43	10.31	33	11.07	10	8.4
Decayed teeth, follow-up	0.22	0.59	0.23	0.6	0.18	0.54

Table 2: Prevention rates after two years

	Hygienists/Dentists			Nurses			Difference		95% CI	
	N	mean	SE	N	mean	SE	mean	SE	Lower	Upper
Prevention	298	0.81	0.23	119	0.8	0.37	0.01	0.43	-0.07	0.098

NYU

42

42

~4

YEARS OF NON-INFERIORITY

For the full Caried*Away* sample, we showed consistent results for prevention at each study visit

NYU

43

43

Prevalence

Follow-up Obs.	Duration	C	T	C-T	95% L	95% U
1st	490	.67	.64	.029	-.009	.066
2nd	300	.68	.68	.004	-.039	.046
3rd	193	.69	.69	-.004	-.050	.043
4th	181	.72	.76	-.042	-.143	.059

NYU

44

44

Prevalence (NI)

any_all	exp(b)	Std. err.	z	P>|z|	[95% conf.	interval]
visitN	.8183713	.0258861	-6.34	0.000	.7691762	.8707128
treat1	.9462931	.0809619	-0.65	0.519	.8002017	1.119056

NYU

45

45

Incidence

Incidence-rate comparison

	Exposed	Unexposed	Total	
Cases	3495	3239	6734	
Person-time	314883.6	286336.7	601220.3	
Incidence rate	.0110993	.0113119	.0112006	
	Point estimate		[95% Conf.	Interval]
Inc. rate diff.	-.0002125		-.0007484	.0003234
Inc. rate ratio	.9812128		.9351429	1.029575 (exact)
Prev. frac. ex.	.0187872		-.029575	.0648571 (exact)
Prev. frac. pop	.8898396			

Mid p-values for tests of incidence-rate difference:
Adj Pr(Exposed cases <= 3495) = 0.2184 (lower one-sided)
Adj Pr(Exposed cases >= 3495) = 0.7816 (upper one-sided)
Two-sided p-value = 0.4368

NYU

46

46

6

% REDUCTION IN CHRONIC ABSENTEEISM

Caried*Away* schools, averaged across all years of the program, had between 3.5 and 6% lower chronic absenteeism

NYU

47

47

SCHOOL ATTENDANCE

School-based caries prevention and the impact on acute and chronic student absenteeism

Ryan Richard Ruff, PhD, MPH; Rami Habib, BSc; Tamarinda Barry Godin, DDS, MPH; Richard Niederman, DMD

Table 3. Model results for the proportion of chronically absent students.*

VARIABLE	MODEL 1		MODEL 2		MODEL 3	
	1a†	1b‡	2a§	2b‖	3a#	3b‡‡
$\Gamma^{\dagger}$, 95% CI	0.0114*	0.00766*	0.0114*	0.00757*	0.00625	-0.00184
	(0.00542 to 0.0174)	(0.00254 to 0.0128)	(0.00543 to 0.0174)	(0.00245 to 0.0127)	(-0.00296 to 0.0155)	(-0.0112 to 0.00751)
$\alpha^{\P\P}$, 95% CI	0.00210	0.00268	0.00194	0.00343	0.00846	0.00200
	(-0.0244 to 0.0284)	(-0.0240 to 0.0294)	(-0.0245 to 0.0293)	(-0.0233 to 0.0302)	(-0.0277 to 0.0446)	(-0.0244 to 0.0284)
κt, 95% CI	-0.0369*	-0.0329*	-0.0370*	-0.0328*	-0.0329*	-0.0909*
	(-0.0624 to -0.0113)	(-0.0586 to -0.00723)	(-0.0626 to -0.0114)	(-0.0585 to -0.00715)	(-0.0654 to -0.000226)	(-0.0624 to -0.0113)
$\rho^{\P}$, 95% CI	NA¶¶	NA	-0.0283	-0.0295	-0.0498	-0.0681*
			(-0.0900 to 0.0334)	(-0.0890 to 0.0319)	(-0.120 to 0.0255)	(-0.137 to 0.00108)
ρt, 95% CI	NA	NA	NA	NA	0.00881	0.0129*
					(-0.00322 to 0.0209)	(0.00216 to 0.0244)
ρx, 95% CI	NA	NA	NA	NA	0.00758	NA
					(-0.192 to 0.207)	
ρxt, 95% CI	NA	NA	NA	NA	-0.00643	NA
					(-0.0589 to 0.0461)	
Constant, 95% CI	0.322*	0.340*	0.338*	0.361*	0.350*	0.391*
	(0.287 to 0.358)	(0.310 to 0.370)	(0.289 to 0.386)	(0.307 to 0.416)	(0.298 to 0.402)	(0.331 to 0.451)
Observations, No.	193	258	193	258	193	258
Schools, No.	39	52	39	52	39	52

* Superscript letters indicate level of statistical significance (* $P < .01$, † $P < .05$, ‡ $P < .1$). † Model 1a: Time only, no comparators. ‡ Model 1b: Time only, no comparators. § Model 2a: Multigroup, silver diamine fluoride (SDF) vs sealant schools. ‖ Model 2b: Multigroup, with comparators (SDF + sealant schools vs no treatment). # Model 3a: Full model, SDF vs sealant schools. ** Model 3b: Full model, with comparators (higher interactions removed). †† t: School year. ‡‡ x: Time varying treatment year. §§ z: Treatment. ¶¶ NA: Not applicable.

NYU

48

48

STUDY CONCLUSIONS

1. Prevalence of caries is non-inferior over three years, inclusive of all subjects
2. Risk of caries incidence nearly identical across both groups
3. SDF is non-inferior to sealants for caries arrest after two years
4. School-based care may improve academic performance and quality of life
5. Nurses are as effective as hygienists when treating children with SDF in a school program

NYU

49

49

POTENTIAL BIASES

COVID-19

Due to pandemic restrictions, aerosol-generating procedures in traditional dental offices were severely restricted.

UNIQUE POPULATION

Our focus on low-income, minority children was in part due to the historically low utilization of alternative dental care, limiting the role of outside intervention

ANALYTIC ADJUSTMENT

Our analyses for caries arrest and prevention included not only incidence of observed decay but incidence of fillings, which was conservatively considered treatment failure.

NYU

50

50

CariedAway 3.0 – Clinical R&D

Incorporating precision medicine into school-based caries prevention

1. Utilize sequential multiple assignment randomized trials for dynamic treatment regimes
2. Further role of school nurses
3. Applications of machine learning for trajectory evaluation based on patient need

NYU

51

51

PRISMS – Dissemination and Implementation

PRISMS

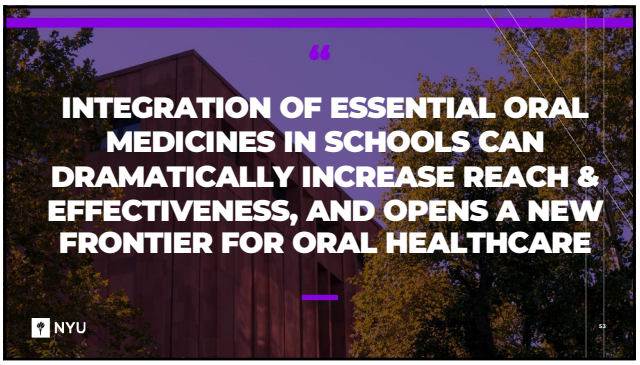
Promoting Implementation of Sustainable Medicine in Schools

1. Identify the policy barriers and facilitators that influence the universal integration of SDF into school-based dental programs
2. Framework for program implementation using SDF
3. Economic simulation

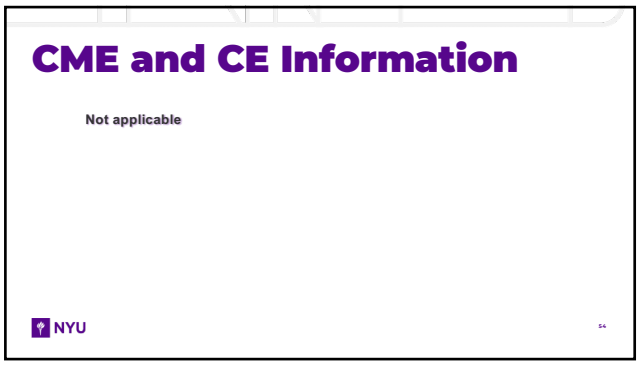
NYU

52

52


INTEGRATION OF ESSENTIAL ORAL MEDICINES IN SCHOOLS CAN DRAMATICALLY INCREASE REACH & EFFECTIVENESS, AND OPENS A NEW FRONTIER FOR ORAL HEALTHCARE
NYU

53


CME and CE Information
Not applicable
NYU

54