

The Cost and Effectiveness of School-Based Preventive Dental Care

Stephen P. Klein, Harry M. Bohannon, Robert M. Bell,
Judith A. Disney, Craig B. Foch, Richard C. Graves

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PREFACE

The National Preventive Dentistry Demonstration Program was conducted to assess the costs and effects of various types and combinations of school-based preventive dental care procedures. The program was supported by two grants from The Robert Wood Johnson Foundation of Princeton, New Jersey. One grant went to The American Fund for Dental Health (AFDH), a national, nonprofit organization dedicated to the support of dental education, service, and research. The other grant went to The Rand Corporation, a nonprofit public institution that conducts policy research and analysis on problems of national security and domestic affairs.

The initial concept for the program was developed and presented to The Robert Wood Johnson Foundation by AFDH. Within the program, AFDH was responsible for providing and supervising the preventive care, collecting most of the data, and conducting annual dental examinations. Rand was responsible for monitoring these activities, developing the data collection forms and procedures, and conducting the data analyses. AFDH and Rand worked together in designing the program, selecting the 10 sites around the country at which it was conducted, preparing reports, and establishing the procedures for other areas of joint responsibility.

The first major activity at a site involved securing parental consent for participation in the program. This was followed by clinical (visual plus tactile) and radiographic dental evaluations of all participants. Children were then assigned to treatment groups. The children who remained in the Program until its completion received four more annual clinical examinations and one more radiographic examination.

This report provides a brief description of the program's procedures and summarizes its major findings and implications. Other program reports present more complete descriptions of the examination procedures,^[41] the reliability of these examinations,^[19] analyses of the baseline data,^[31] the types of preventive dental care provided,^[15] and the cost^[23] and effectiveness of these procedures.^[20] Additional reports deal with prior attempts to assess the cost of preventive dental care^[12] and the results of surveys of the program's teachers and principals^[22] and of the parents who did and did not enroll their children in the program.^[16]

SUMMARY

The National Preventive Dentistry Demonstration Program assessed the cost and effectiveness of various types and combinations of school-based preventive dental care procedures. The program involved 20,052 first, second, and fifth graders from five fluoridated and five non-fluoridated communities. These children were examined at baseline and assigned to one of six treatment regimens. Four years later, 9,566 members of this group were examined again. Analyses of their dental examination data showed that dental health lessons, brushing and flossing, fluoride tablets and mouthrinsing, and professionally applied topical fluorides were not effective in reducing a substantial amount of dental decay, even when all of these procedures were used together. Occlusal sealants prevented one to two carious surfaces in four years. Children who were especially susceptible to decay did not benefit appreciably more from any of the preventive measures than did children in general. Annual direct per capita costs were \$23.00 for sealant or fluoride prophylaxis applications and \$3.29 for fluoride mouthrinsing. Communal water fluoridation was reaffirmed as the most cost-effective means of reducing tooth decay in children.

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I. INTRODUCTION

Numerous articles published over the past thirty years have reported that systemic fluorides, obtained through fluoridated water supplies and tablets, are very effective in preventing dental decay in children.^[1,2] Fluoride protection also can be obtained topically, through toothpaste, mouthrinse, and professionally applied fluoride treatments.^[1-5]

The application of a resin coating, called "pit and fissure sealant," to the occlusal surfaces of the posterior teeth also has been shown to be very successful in preventing decay.^[6,7] Because fluorides are most effective in preventing dental caries on smooth tooth surfaces^[8] whereas sealants are applied primarily to occlusal surfaces, it has been assumed that the *combination* of systemic fluorides, topical fluorides, and sealants would virtually eliminate all dental decay in children.

Arguments in favor of preventive dental care are often supported by comparisons between the estimated costs of the preventive procedures and the costs of restoring (through fillings) the tooth surfaces that would otherwise have been affected by decay.^[9] Several articles have ascribed relatively low costs for these procedures when they are delivered to children in their schools.^[10-12] For example, it has been estimated that the annual costs of a school-based topical fluoride mouthrinse program ranges from \$0.71 to \$9.27 per child,^[13] whereas the cost in 1981 dollars of restoring a surface (through the placement of an amalgam filling) is about \$19.92.^[14]

The National Preventive Dentistry Demonstration Program was undertaken to test two hypotheses: 1) The combination of fluorides and sealants would eliminate almost all dental caries in children; and 2) the cost of school-based preventive dental care would be quite low, especially in comparison with the costs of restoring the surfaces that would have become decayed if this care had not been provided.

II. METHODS

PROGRAM SITES

Announcements about the study were sent to dental schools, dental associations, health departments, and education agencies throughout the United States.^[15] These announcements described the study's procedures and requirements for participation, such as a high student retention rate, no previous involvement in a school-based preventive dental health program, and a willingness on the part of teachers and school district staff to participate. From the 120 sites that applied, 10 were selected that satisfied the requirements and varied on factors that were known to be related to dental decay.

Table 1 lists the 10 sites. Five of them reportedly had optimally fluoridated water supplies for their region (0.8 or 1.0 ppm F ion); the other five were designated as "nonfluoridated" (less than 0.2 ppm F ion). It was discovered shortly after the program began, however, that one of the reportedly nonfluoridated sites (Wichita, Kansas) actually had about 0.4 ppm F ion in its water supply, whereas one of the supposedly fluoridated sites (Hayward, California) had intermittent fluoridation during the 10-year period before the program started. The sites varied in urbanization, average socioeconomic status, percent of children in four racial/ethnic groups (Anglo, Black, Hispanic, and Asian), prevalence of dental decay, and type of local sponsoring agency (e.g., school district and health department).

SAMPLE

Of the children who were eligible to enroll in the study, 82 percent obtained their parents' written consent to receive annual dental examinations and to participate in any one of the project's six treatment regimens.^[15,16] Our study population consisted of the 20,052 first, second, and fifth graders in this group who also received a baseline dental exam between September 1977 and March 1978. The study's four longitudinal cohorts consisted of children in grades 1+2 and 5 at fluoridated sites and grades 1+2 and 5 at nonfluoridated sites. Children who began the study in grade 1 or 2 at a site were combined into one group because of the similarity of their data. The children in all four cohorts received annual dental examinations for four years after baseline, provided they were still enrolled in the study.

The sample used to measure the effectiveness of the preventive procedures consisted of the 9,566 children who received both the baseline and the final examination. The loss of 52 percent of the baseline population in 48 months yielded a relatively low attrition rate per month compared with other studies of school-based preventive dental care.^[4,17] Discontinuing the New York site after the third year accounted for 10 percent of the attrition. The remaining 42 percent of the attrition was due mainly to children leaving their site during the course of the study, not obtaining parental consent to participate in the fourth year (the initial consents were for three years), or having braces placed on their teeth. There was no systematic relationship between attrition rate and treatment group across sites in any of the four cohorts; and there was essentially no difference in average baseline dental decay level between the children who did and did not complete the program.

Table 1
 NUMBER OF CHILDREN AT BASELINE AND AT THE END OF THE PROGRAM,
 BY SITE AND BASELINE GRADE LEVEL

Site	Baseline		End	
	Cohort 1+2	Cohort 5	Cohort 1+2	Cohort 5
Nonfluoridated				
Billerica, Massachusetts	1449	728	1006	423
Tallahassee, Florida	1647	727	816	335
Wichita, Kansas ^a	1259	524	607	287
Monroe, Louisiana	1194	523	750	332
Pierce County, Washington	1351	617	781	311
Total nonfluoridated	6900	3119	3960	1688
Fluoridated				
Chattanooga, Tennessee	1329	576	607	181
New York, New York	1359	628	(b)	(b)
Minneapolis, Minnesota	1510	739	935	394
El Paso, Texas	1409	673	693	346
Hayward, California ^a	1240	570	542	220
Total fluoridated	6847	3186	2777	1141

^aWichita had 0.4 ppm fluoride ion in its water supply, and Hayward had intermittent water fluoridation during the 10-year period before the program began.

^bThe program was discontinued at the New York site after three years of operation primarily because of the extremely high cost of running the study at this site.

Table 1 shows the distribution of children in the baseline population and in the analysis sample by baseline grade level and site. The samples used to assess the costs of the preventive procedures consisted of all the children who received these procedures and were thereby consuming project resources.

Two other groups of children were examined to provide cross-sectional comparison data. The children in one group received only a baseline examination; those in the other group were seen only at the end of the program. The 4,320 children in the first group were drawn from grades 3, 4, 6, 7, and 8 at the same schools as those who were assigned to the program's treatment regimens. The 4,746 children in the second group also attended these schools, but they did not receive any preventive care from the program. These children were in grades 1 through 9 at the time they were examined.

EXAMINATIONS

Annual clinical (visual-tactile) examinations were performed by 31 specially trained dentists, although only 16 members of this group participated after baseline. Usually, six to eight examiners visited a site each year and in most cases, a given examiner went to the same sites each year. Standard examination criteria were used.^[18]

The examiners were very consistent with themselves and each other in their evaluations of whether a tooth surface was affected by decay.^[19] Examination errors (as measured by a surface being classified as carious or filled one year and as sound the next) were not related to whether examiner/child pairings were or were not maintained across years.

Bitewing radiographs were taken at the beginning and again at the end of the study by trained technicians using a mobile X-ray van. Analyses indicated that adding the radiograph data to the clinical results did not change the study's findings. Most of the previous studies on the efficacy of preventive procedures do not include radiographs. Thus, in order to facilitate comparisons with this literature, radiograph results are not presented here, but they may be found in other reports.^[19,20]

RESEARCH DESIGN

Table 2 shows the six treatment regimens used at each site. Each of the first five regimens contained one or more preventive procedures. Two procedures, sealants and fluoride prophylaxis/gel treatments, were provided by a clinic team of dental hygienists and assistants who moved from school to school within a site. This team delivered these services under the general supervision of a dentist. The remaining procedures were administered by classroom teachers or aides.

The treatment regimens differed slightly between fluoridated and nonfluoridated sites. Fluoride tablets were not given at fluoridated sites, and regimen 2 at these sites provided sealants instead of prophylaxis/gel applications. This planned variation in protocol was designed to reflect differences in the types of programs that might be adopted eventually by the two kinds of communities. The children in regimen 6 did not receive any of the preventive measures, but they received the same examinations as the children in the other five regimens. The regimen 6 children therefore served as a longitudinal control group for the other five regimens.

Schools within a site were assigned to regimens in a way that balanced baseline decay level, numbers of children, and racial mix across treatment regimens.^[15] Schools, rather than individual children, were assigned to regimens because some of the procedures, such as fluoride

Table 2
 ASSIGNMENT OF PREVENTIVE PROCEDURES TO THE SIX TREATMENT
 REGIMENS AT NONFLUORIDATED AND FLUORIDATED SITES

Regimen	Preventive Procedure				
	Delton sealant applied and, if needed, reapplied up to 3 times	Acidulated paste prophylaxis and 1.23% F ion gel (2 times/year)	0.2% neutral sodium F mouthrinse (1 time/week)	1 mg F in 2.2 mg of neutral sodium F tablet (5 times/week)	Biweekly brushing and flossing, 10 health lessons per year, and home supply of F dentifrice
Nonfluoridated					
1	X	X	X	X	X
2	-	X	X	X	X
3	X	X	-	-	-
4	-	-	X	X	X
5	-	-	-	-	X
6	-	-	-	-	-
Fluoridated					
1	X	X	X	-	X
2	X	-	X	-	X
3	X	X	-	-	-
4	-	-	X	-	X
5	-	-	-	-	X
6	-	-	-	-	-
Persons providing procedure	Clinic team	Clinic team	Classroom teachers	Classroom teachers	Classroom teachers

NOTE: F = fluoride. An X indicates that the regimen included the procedure. Children in all six regimens received annual dental examinations. All teacher-provided classroom procedures were discontinued after two years in Cohort 5.

mouthrinsing, were delivered more efficiently to children when they were in classroom groups. Table 3 shows the number of children in the four-year continuous residence sample in each regimen.

ANALYSIS OF TREATMENT EFFECTS

The analysis of treatment effectiveness focused on the number of decayed, missing due to decay, and filled permanent tooth surfaces that a child acquired between baseline and the end of the study (about a 48-month period), hereafter referred to as the child's DMFS increment score.

Only 1 to 3 percent of the variation among children in DMFS increment scores was uniquely associated with the school they attended.^[20] This finding, and the fact that each school in a site-regimen combination tended to enroll about the same number of children, meant that regimen means were not sensitive to the choice of the child or school as the unit of analysis. For example, in 20 of the 24 cohort/regimen combinations, the mean four-year DMFS increment score computed using the school as the unit was within 0.09 surfaces of the mean

Table 3
 NUMBER OF CHILDREN IN THE FOUR-YEAR CONTINUOUS
 RESIDENCE SAMPLE, BY TREATMENT
 REGIMEN AND COHORT

Regimen	Nonfluoridated		Fluoridated	
	Cohort 1+2	Cohort 5	Cohort 1+2	Cohort 5
1	666	279	498	201
2	565	260	487	192
3	677	312	432	199
4	692	258	537	195
5	620	284	393	154
6	740	295	430	200
Total	3960	1688	2777	1141

computed using the child as the unit (see App. A). The average difference was 0.05 surfaces. We chose the child as the unit because it allowed us to study whether the treatment procedures were especially effective with children who were unusually susceptible to decay, and it allowed us to control for differences in the background characteristics of children in different schools.

Differences in mean DMFS increment scores between treatment and control regimens were explored through a series of analyses of covariance. This technique allowed us to estimate what the mean DMFS increment score in a regimen would have been if: each regimen had half boys and half girls; each regimen had an equal number of children from each site; there were no differences among regimens in their children's average age, baseline DMFS scores, or socioeconomic status; and the racial/ethnic mix was the same in all six regimens. Thus, differences among regimens do not reflect artificial differences caused by imbalances in the children's background characteristics. Appendix B shows the effects of these adjustments.

Separate analyses were run for four groups of children. Groups were defined on the basis of their site's water supply (fluoridated or nonfluoridated) and baseline grade level (first + second graders or fifth graders). In order to increase the sensitivity of statistical tests, a preventive procedure's effectiveness was assessed with data from all the regimens that used it.^[20] For example, information on the set of classroom components was provided by comparisons between regimens 1 and 3, and between 4 and 6. Because the results of these comparisons did not differ significantly from each other, the reported classroom effect is the average of these two estimates.

Although using the child rather than the school as the unit of analysis had little effect on regimen means, it could bias tests for differences between means. The standard errors generated in the analyses of covariance (and presented in a previous report^[20]) were therefore rescaled to control for the small (0.00 to 0.02) intraschool correlations in the covariate-adjusted DMFS increment scores. The rescaling, using a procedure described by Scott and Holt,^[21] involved multiplying all of a cohort's analysis of covariance standard errors by a constant. The constants were 1.14, 1.29, 1.45, and 1.00 for cohorts 1+2 and 5 at nonfluoridated sites and cohorts 1+2 and 5 at fluoridated sites, respectively.

COST ANALYSIS PROCEDURES

The resources required to provide the treatment regimens were measured conservatively using the following procedures:

Labor: All the members of a site's dental team (coordinator, dentist, hygienists, dental assistants, and clerk) indicated how they spent each 30-minute interval of each workday (i.e., type of activity and in which regimen the activity was conducted). The cost of this time was computed initially on the basis of hourly wage rates.

Direct labor costs excluded time spent by teachers, volunteers, and other school personnel; site staff downtime (such as when children were not available for care), vacation time, and other necessary indirect expenses; and time spent in conducting administrative and research activities, such as the annual dental examinations. Research staff time, such as in providing computer support and in hiring and training site staff, also were not considered in computing direct labor costs.

Capital: This category included the amortized cost of the equipment, such as portable dental chairs and lights, that were used to provide the preventive procedures. These costs were allocated to procedures and then to regimens in proportion to their use of this equipment.

Materials: Essentially all consumable supplies were purchased centrally in bulk for the study and then shipped to the sites. The costs of these materials were allocated to the preventive procedures and then to regimens in proportion to the number of children who consumed them.

III. RESULTS

PROGRAM IMPLEMENTATION

Examination data indicated that sealants were provided to 96 percent of the children scheduled to receive them. Almost all of the remaining 4 percent did not have teeth that were suitable for sealing. Treatment records showed that 79 percent of the children scheduled to receive a total of four gel applications during the middle 24 months of the study received all four, whereas 7 percent received fewer than three, 12 percent received three, and 2 percent received more than four.^[20] The primary reason some children did not receive their full set of gel applications was that they were absent on the days the clinic team visited their school. Questionnaire surveys of teachers and principals conducted during the study, monitoring visits by program staff, and analyses of the quantities of supplies used indicated that school personnel generally understood and followed the protocols for administering the dental health lessons and the brushing, flossing, mouthrinse, and tablet components.^[20,22]

Almost 50 percent of the teachers complained about the amount of time it took to provide the classroom procedures. They estimated that the total number of minutes spent in a typical week was 16 to 30 for biweekly brushing and flossing, 6 to 11 for weekly mouthrinse, and 20 to 25 for daily tablets. Complaints about the time required to administer these procedures were less common at the lower grade levels, even though the procedures took longer for younger children than for older children. Throughout the program, teachers of grades 1, 2, and 3 were more willing to continue to use the classroom procedures than were teachers at the upper grade levels.

TREATMENT EFFECTS

All the children who received both a baseline and a final examination were included in the analysis of treatment effects regardless of whether they received all their scheduled treatments. This approach was adopted in order to assess the effectiveness of the procedures under actual field conditions. Our results may therefore differ from those obtained under the special requirements of a randomized clinical trial.

Table 4 shows the number of surfaces saved from decay by each regimen in four years in comparison with its longitudinal control group. For instance, at fluoridated sites, the mean DMFS increment in cohort 5's longitudinal control group was 3.07 as compared with 1.05 in regimen 1. This 2.02 surface difference corresponds to a 66-percent reduction in decay. It is evident from these data that the children in the sealant regimens (1, 2, and 3 at fluoridated sites, and 1 and 3 at nonfluoridated sites) developed consistently less decay than their respective control groups. There were only two instances in which a nonsealant regimen had a statistically significantly lower mean increment score than its control group: regimens 2 and 4 with cohort 1+2 children at nonfluoridated sites.

Table 5 shows the amount of decay prevented in four years by each procedure, the combination of all of the clinic procedures, and the combination of all of the classroom procedures. The methods used to compute these effects are described by Bell,^[20] and on the basis of preliminary analyses, assume there are no interactions among procedures.

Table 4

DIFFERENCE BETWEEN EACH REGIMEN AND ITS LONGITUDINAL CONTROL GROUP IN
THE MEAN NUMBER OF SURFACES THAT BECAME DECAYED IN FOUR YEARS

Regimen	Nonfluoridated		Fluoridated	
	Cohort 1+2	Cohort 5	Cohort 1+2	Cohort 5
1 Rinse (tablets) + lessons + brushing + sealants + prophy/gel	1.90**	1.91**	1.29**	2.02**
2 Rinse + lessons + brushing + sealants	(a)	(a)	1.00**	1.62**
2 Rinse + tablets + lessons + brushing + prophy/gel	0.68*	0.65	(a)	(a)
3 Sealants + prophy/gel	1.68**	1.83**	1.24**	1.74**
4 Rinse (tablets) + lessons + brushing	0.67*	-0.55	0.04	-0.61
5 Lessons + brushing	0.12	-0.60	-0.25	-0.42

NOTE: Fluoride tablets were given at nonfluoridated sites only. The four-year DMFS increments in decay in the longitudinal control group (regimen 6) at nonfluoridated sites were 3.13 and 4.75 surfaces for cohorts 1+2 and 5, respectively; corresponding values at fluoridated sites were 2.19 and 3.07. A negative value in this table indicates that a treatment group had a larger increment in decay than its longitudinal control group.

* Differs from regimen 6 mean at the 0.01 level.

** Differs from regimen 6 mean at the 0.001 level.

None of the other comparisons with regimen 6 differed at the 0.05 level.

^aRegimen 2 included prophy/gel at nonfluoridated sites and sealants at fluoridated sites.

Table 5

REDUCTIONS IN FOUR-YEAR DMFS INCREMENTS, BY TREATMENT PROCEDURE,
COHORT, AND FLUORIDATION STATUS

Procedure	Nonfluoridated		Fluoridated	
	Cohort 1+2	Cohort 5	Cohort 1+2	Cohort 5
Clinic				
Sealants	1.33**	1.11*	0.96**	2.00**
Prophy/gel	0.12	1.04	0.29	0.18
Total clinic	1.46**	2.15**	1.25**	2.18**
Classroom				
Mouthrinse/tablets ^a	0.44*	0.21	0.29	0.03
Health lessons ^b	0.01	-0.44	-0.24	-0.20
Total classroom	0.45**	-0.24	0.05	-0.16

NOTE: The analysis of a procedure's effect involved children from several regimens; e.g., only regimen 2's data were excluded from the measurement of the mouthrinse effect.

* Differs significantly from zero at 0.05 level.

** Differs significantly from zero at 0.001 level.

^aFluoride tablets were offered only at nonfluoridated sites.

^bIncludes biweekly brushing and flossing plus home supply of fluoride dentifrice.

Table 5 shows that sealants saved 1 to 2 surfaces from decay in four years. The fluoride prophy/gel applications reduced decay by one surface in four years only in the most caries-prone group, cohort 5 at nonfluoridated sites. Figure 1 shows that in this group, the chances are 95 in 100 that the combination of sealants and fluoride prophy/gel applications saved between 1.36 and 2.94 surfaces in four years. The highest average annual benefit of the fluoride mouthrinse was only 0.11 surfaces, and this reduction was obtained with only cohort 1+2 at nonfluoridated sites. The education program, which included biweekly brushing in the classroom without a dentifrice, did not prevent any decay.

A procedure prevented about as much decay in the first two years of the program as it did during the last two.^[20] The two exceptions to this trend were in cohort 5, where the additional reductions in the last two years of the study over the first two were 0.54 surfaces for sealants at fluoridated sites and 0.90 surfaces for prophy/gel at nonfluoridated sites. However, only the latter difference was statistically significant ($p = 0.05$). Although the rinse/tablet component ran for only 1.5 years in cohort 5, the reductions attributable to this component at the end of the first two years were about the same as those observed during the last two years.

The two-year results at the New York site were essentially the same as those at the other four fluoridated sites. The four-year effectiveness of a procedure at one site paralleled very

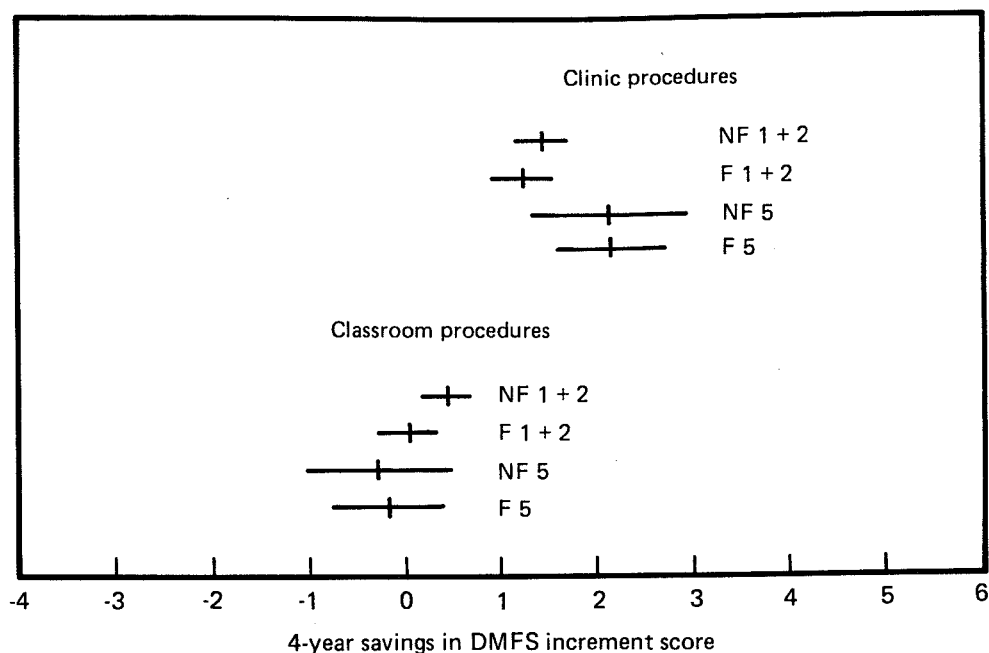


Fig. 1—95 percent confidence interval for clinic and classroom effects by cohort and fluoridation type

closely its effectiveness at the other sites with similar water supplies. Figure 2 illustrates this consistency by showing the 95-percent confidence intervals by site for the combination of prophylaxis and sealant applications. Figure 3 shows the intervals for the combination of all the classroom procedures.

TREATMENT COSTS

Direct treatment costs were calculated for school years 2 and 3.^[23] These two years were chosen in order to eliminate possible biases due to start-up or close-down activities. The two years had very similar costs for a given regimen. There were no differences in the average costs of regimen 2 that were systematically related to fluoridation status even though this regimen involved sealants at fluoridated sites and prophylaxis treatments at nonfluoridated sites. Thus, the data for this regimen were combined across site types. Similarly, the incremental cost of providing fluoride tablets was so negligible that it did not require separate cost analyses for fluoridated and nonfluoridated sites. All costs are reported in 1981 dollars in order to facilitate comparisons with other studies.

There was considerable variation among sites in the direct costs of each regimen. This variation occurred because 1) the sites differed in mean cost of living and thereby local wage rates, 2) state laws at three sites required that a dentist be present to perform or supervise certain tasks, 3) El Paso had high costs for just the regimens that involved classroom procedures because its staff devoted considerable time to developing instructional materials that were shared with the other sites, and 4) New York had atypically high costs for all regimens.

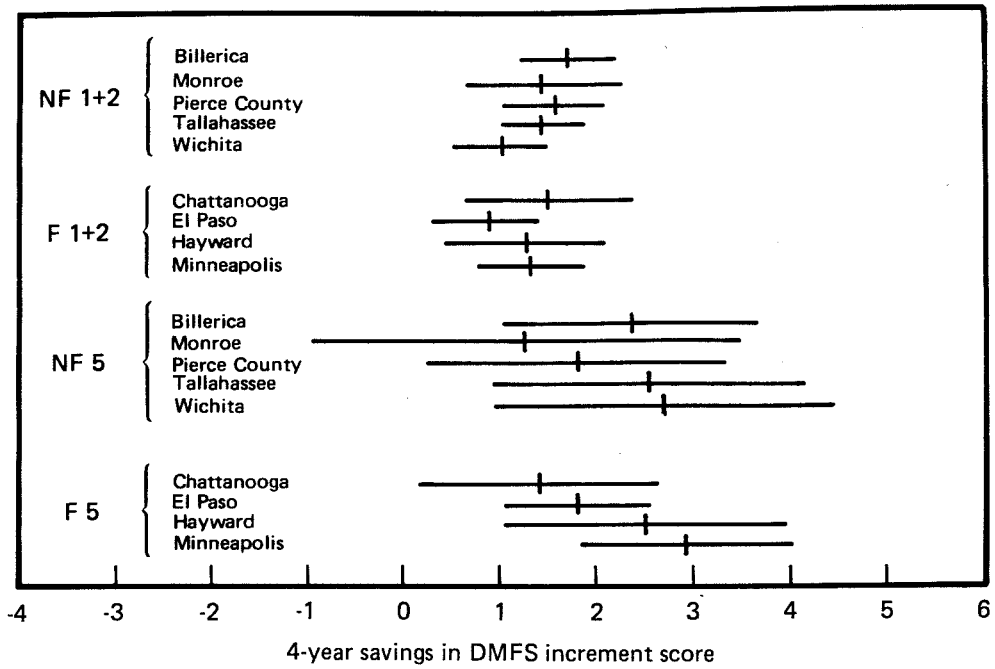


Fig. 2—95 percent confidence intervals for clinic effect, by site and fluoridation status

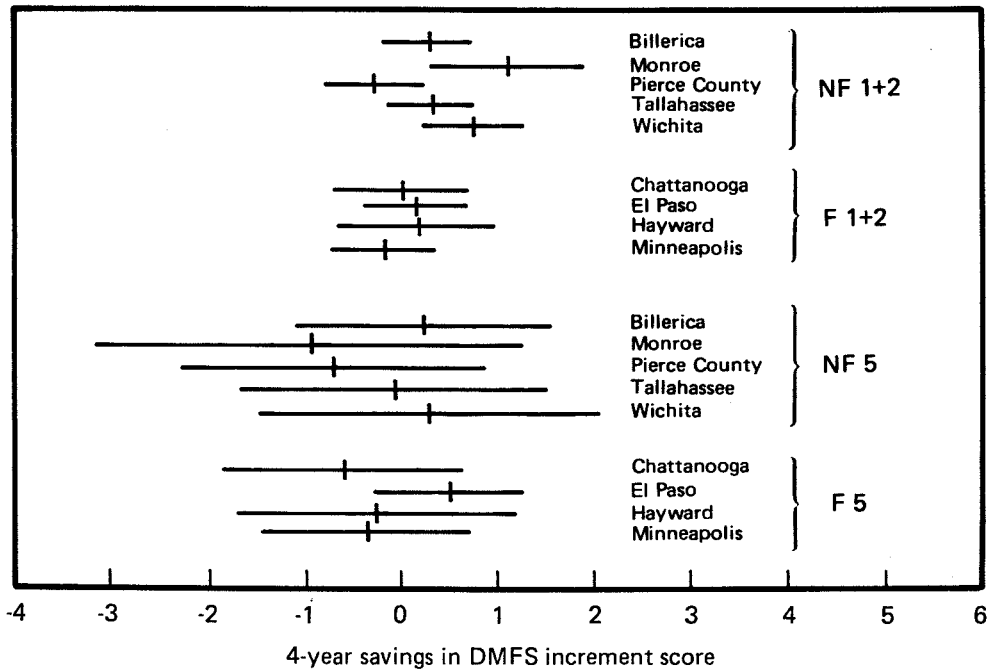


Fig. 3—95 percent confidence intervals for classroom effect, by site and fluoridation status

The intersite variation in actual costs was reduced substantially by spreading the El Paso educational development costs across all 10 sites, eliminating New York's data from the cost analysis, and then adjusting for the other two factors listed above. For example, the following hourly wage rates were assigned to all sites: dentist, \$20; site coordinator, \$13; hygienist, \$10; dental assistant, \$6.50; and clerk, \$6. These rates were very close to the nine-site averages for these job classifications.

Table 6 shows the adjusted annual direct costs per child in each regimen, the nine-site standard deviation, and the cost at New York. This table indicates that it was almost as expensive to provide regimen 1 (\$54.92), which involved all the clinic and classroom procedures, as it was to provide these two groups of procedures separately (regimen 3 @ \$40.02 + regimen 4 @ \$15.15 = \$55.17).

Because there is no real cost-sharing between clinic and classroom procedures, the annual average direct cost of maintaining a child in a sealant or prophylaxis program can be estimated by the difference in cost between regimens 2 and 4 ($\$37.97 - \$15.15 = \$22.82$). This estimate, in comparison to regimen 3's cost of \$40.02, suggests that a \$5.62 annual savings was obtained by combining sealants and prophylaxis into one regimen (because $2 \times \$22.82 = \45.64). A child could have from 0 to 16 teeth sealed, depending upon the number of erupted teeth that had pits and fissures but were not carious or filled. About 10 teeth were sealed per child in four years. Thus, it cost about \$8 to \$9 to seal a tooth and maintain that seal.

The cost of adding fluoride mouthrinsing to a supervised dental health program that already included lessons and brushing was estimated in two ways: a) regimen 4 - regimen 5 = \$3.41 and b) regimen 1 - (regimens 3 + 5) = \$3.16. The average of these two estimates is \$3.29.

Table 6
ADJUSTED ANNUAL DIRECT COSTS PER CHILD
(In \$ 1981)

Regimen	9-Site Average			Total	9-Site Standard Deviation	Average Cost at New York
	Labor	Capital	Supplies			
1 All class & clinic	39.92	4.11	10.89	54.92	7.14	92.55
2 All class + 1 clinic	26.69	2.35	8.92	37.97	5.08	64.01
3 All clinic	31.80	4.26	3.95	40.02	7.25	56.36
4 All class	8.21	--	6.94	15.15	3.57	30.22
5 Lessons + brushing	7.36	--	4.38	11.74	2.22	20.85

NOTE: Regimen 5 included all the classroom procedures with the exception of fluoride (F) mouthrinse at all sites and F tablets at nonfluoridated sites.

IV. DISCUSSION

DECREASING PREVALENCE OF DECAY

The study's most caries-prone children, the cohort 5 longitudinal control group at non-fluoridated sites, averaged fewer than 1.25 newly affected surfaces per year. The mean in each of the other three longitudinal control groups was much less than one surface per year.

These small increases in decay level are consistent with prevalence data that have recently been reported by others.^[24] For example, in the national surveys conducted between 1963 and 1973,^[25-28] 12-year-olds had about 6.6 surfaces affected by decay whereas in the 1979-1980 survey,^[29] 12-year-olds had only 4.2 affected surfaces. This large decline has been found in both nonfluoridated and fluoridated communities and is probably due to several factors, including the increased prevalence of fluorides "in the food chain, especially from the use of fluoridated water in food processing, increased use of infant formulas with measurable fluoride content, and even unintentional ingestion of fluoride dentifrices."^[30]

The study's cross-sectional data also suggest there has been a significant decline in decay level.^[20] For example, the program's 12-year-olds had a mean DMFS score of 6.6 at baseline,^[31] whereas four years later, another group of 12-year-olds at these same schools had a mean of only 5.1 surfaces.^[20] Since the latter group did not participate in any school-based preventive dental care program, this 1.5 surface decline must be due to other causes.

EFFECTIVENESS

The children in the end of program cross-sectional control group (as well as the children in the program's longitudinal control and treatment groups) could have received preventive care from their family dentist and/or used fluoride mouthrinse or tablets at home. However, several results suggest that if such non-program care occurred, it did not significantly bias our estimates of treatment effects. Specifically, 1) only a small percentage of children in the cross-sectional and longitudinal control groups had sealants; 2) there was a high degree of consistency in the size and pattern of treatment effects across sites despite the considerable variation among sites on factors that are correlated with DMFS increment scores and/or the amount of professional dental care received; and 3) if non-program preventive care had had a significant impact, we would not have been able to detect the large sealant effect that was obtained.

Our finding that fluoride mouthrinsing prevented only slightly more than one tenth of a decayed surface per year in cohort 1+2 is consistent with the results obtained with children of comparable age in the only randomized clinical trial of weekly sodium fluoride rinse that has been conducted in a nonfluoridated community in the United States in the past 15 years.^[32] Our results with cohort 1+2 also are consistent with those obtained in the only other large-scale study of fluoride rinsing—the study conducted by the National Institute of Dental Research (NIDR) in 17 nonfluoridated communities across the United States.^[13] NIDR reported that children in grades 1-8 in 1975 who had not rinsed in school had an average of one more carious surface than children in grades 1-8 at these same schools in 1979-1980 who had rinsed for three years—an apparent preventive effect of 0.33 surfaces per year.

If the program had used this same type of historical comparison, we would have attributed a reduction of 0.34 surfaces per year to the rinse. The average DMFS score of 10-to-11-year-olds at our nonfluoridated sites in 1977–1978 who had not rinsed was 1.34 surfaces higher than that of the 10-to-11-year-olds in 1981–1982 who had rinsed for four years. Thus, because of the secular decline in decay, a cross-sectional comparison indicates a reduction of 0.23 surfaces per year greater than the 0.11 reduction that was actually obtained when a longitudinal control group was used. If the NIDR data are corrected for this bias (by subtracting 0.23 surfaces per year from its reported annual reduction), then both the program and NIDR studies attribute a 0.10 to 0.11 reduction per year to fluoride mouthrinsing. The two studies also reported almost identical average costs for a mouthrinse program.

The data from cohort 1+2 provide the most realistic estimate of the size of the mouthrinse effect in an operational program because most of the children who rinse in public schools today are in elementary school. It is simply not feasible to continue the rinse after the sixth grade in most school districts because of difficulties in obtaining student and teacher compliance at the upper grade levels.^[33] If it were possible to continue a rinse program to the ninth grade, then our four-year data would underestimate the size of the benefit derived from the rinse in cohort 5 because this cohort only rinsed for 1.5 years. No such bias existed for the fluoride prophy/gel component, because almost all of the children in both cohorts 1+2 and 5 who were scheduled to receive eight fluoride prophy/gel applications did receive them.

COSTS

Several factors cause the large differences among studies in their estimates of the cost per child for a given preventive procedure. For example, the estimates depend on whether standard accounting techniques are used to assess costs and report them in a particular year's dollars, whether estimates are based on the actual costs of providing the procedure under realistic field conditions, the number of children treated, whether estimates include indirect expenses, and whether all necessary direct expenses are measured.^[12,34–36] Because such factors have a major impact on estimated costs, they must be considered in determining the utility of a given procedure. For example, the usually cited estimate of \$1 per child per year for mouthrinsing^[10] does not include many direct expenses, such as the necessary cost of training and supervising classroom teachers to make sure they dispense the rinse properly.^[37]

Recent empirical studies^[13,35] as well as a U.S. General Accounting Office report^[38] show that when most direct expenses are considered, the cost of rinsing (in 1981 dollars) is about \$3.50 per child per year. However, these estimates do not include necessary indirect costs, which tend to be about 50 percent of direct costs.^[23,35] Readers are therefore cautioned that average total costs of a preventive procedure in an operational school program are likely to be substantially higher than those presented in Table 6.

COSTS VERSUS EFFECTIVENESS

The application of sealants was the only school-based procedure that was consistently effective in reducing decay. However, the average *direct* cost of providing sealants as part of a school-based program (about \$23 per child per year if not provided in conjunction with fluoride prophy/gel applications) was far more than the *total* cost of restoring the 0.25 to 0.50 surfaces that sealants prevented from becoming decayed per year (@ \$19.92 per restoration).

The study strongly reaffirmed the value of communal water fluoridation. The cohort 1+2 longitudinal control group at nonfluoridated sites experienced 0.94 more DMF surfaces in four years than the comparable group at fluoridated sites. There was a 1.68 surface savings due to water fluoridation with the cohort 5 children. The reductions in decay attributable to water fluoridation in both cohorts are therefore almost the same as those obtained in these cohorts with sealants. However, in contrast to the \$23 per year cost of maintaining a child in a sealant program, the annual per capita cost (in 1981 dollars) of water fluoridation in five United States communities ranged from \$0.06 in Denver, Colorado, to \$0.80 in rural West Virginia.^[39]

A comparison of the costs of a school-based sealant program with the cost of restoring the surfaces that would have become decayed without such a program would have to consider several variables that were not quantified in the present research, such as the perceived value of a sound tooth relative to one that has been restored, the discounted value of funds spent to prevent a future problem, and the expected life of a restoration and a sealant. Such a comparison also would have to come to grips with the fact that our bare-bones estimate of the direct cost for a school-based sealant program is about \$40 to \$80 per surface saved from decay when sealants are provided to all children regardless of their susceptibility to tooth decay.

TARGETING PREVENTIVE PROGRAMS

Analyses of the study's baseline data and DMFS increment scores indicated that a small number of children accounted for a disproportionately large amount of the decay.^[31] For example, the 20 percent of the cohort 5 children at fluoridated sites in regimen 6 who had the highest DMFS score increments accounted for 55 percent of all the new decay in that group. These findings, together with the high cost of the preventive procedures, led to a preliminary investigation of the utility of targeting preventive care on high-risk children.

The targeting study used data on the children in regimen 5 to construct a multiple regression equation to predict their DMFS increment scores. Separate equations were constructed for each combination of water supply type and cohort. The variables in each equation included such factors as socioeconomic status, site, and the number of erupted and decayed permanent teeth at baseline.

The regression equations constructed with regimen 5 children were able to predict only 6 to 10 percent of the variance in regimen 6 DMFS increment scores. This finding is consistent with previous attempts to predict DMFS increments.^[40] Despite this low predictability for individual children, the 25 percent who were estimated to have the largest DMFS increments had twice the mean increment of children in general at nonfluoridated sites and three to four times as many at fluoridated sites.^[20] Table 7 shows that the group predicted to have the largest increments benefited only slightly more from the preventive measures than did children in general. The difference was never more than 0.75 surfaces in four years.

It must be noted that the program was not designed to identify children likely to have the highest DMFS score increments. If it had been so designed, we would have gathered data on other variables such as the amount of decay on primary teeth that might have improved the prediction system. Nevertheless, even if a much more successful prediction system were available, several factors would still have to be considered in assessing the utility of a school-based targeting program. Such factors would include: the cost of identifying high-risk children, the relative effectiveness of the preventive procedures with high-risk versus typical-risk children, and the difficulties of reaching the targeted children during the school day. There may also be ethical problems about delivering preventive care to only a small segment of the eligible population.

Table 7
 REDUCTIONS IN FOUR-YEAR DMFS INCREMENTS DUE TO THE CLINIC
 PROCEDURES BY RISK GROUP, COHORT, AND
 FLUORIDATION STATUS

Group	Risk Group			All Children	Difference Between High and All
	Low	Medium	High		
NF 1+2	1.04	1.46	1.54	1.46	0.08
NF 5	1.46	2.31	2.90	2.15	0.75
F 1+2	0.73	1.36	1.59	1.25	0.34
F 5	1.25	2.55	2.75	2.18	0.57

NOTE: NF and F refer to nonfluoridated and fluo-
 ridated sites. Children whose predicted DMFS increment
 fell in the lowest and highest quartiles of the dis-
 tribution of predicted increment scores constituted
 the low- and high-risk groups, respectively.

V. CONCLUSIONS AND IMPLICATIONS

School-based weekly fluoride mouthrinsing, daily fluoride tablets, biannual fluoride paste prophylaxis and gel applications, dental health lessons, and biweekly brushing and flossing were not consistently effective in preventing clinically significant amounts of tooth decay beyond that already prevented by typical home and dental office care. These results, obtained when the procedures were used singly and in combination, were consistent across age groups and sites.

Sealant application was the only procedure that was effective in reducing decay in all four study groups. Although sealants prevented 23 to 65 percent of the decay that occurred in the longitudinal control group, this percentage translated to merely one to two carious surfaces prevented in four years. This is about the same amount of decay that was prevented by community water fluoridation, although sealants only affected pit and fissure surfaces. Because of the considerable difference in costs between sealants and water fluoridation, the latter procedure will continue to play the primary role in preventing dental decay.

The small preventive effect of several of the school-based procedures used in this study appears to have been due in part to the precipitous decline in the prevalence of tooth decay. Nevertheless, most children are still experiencing some decay. It will therefore be important to determine the reasons for the recent decline and its long-range impact in order to plan what types of school and nonschool preventive programs will be needed in the future. The limited resources available for preventive care and the finding that a small percentage of children have most of the decay suggest that research also is needed to assess the feasibility of developing a program that could accurately identify high-risk children and effectively target care on them.

Appendix A

EFFECTS OF USING THE CHILD VERSUS THE SCHOOL AS THE UNIT OF ANALYSIS WHEN THERE IS INTRASCHOOL CORRELATION

Using the child rather than the school as the unit of analysis can potentially cause two problems in the presence of intraschool correlation. First, a child-level analysis might give too much weight to the results from large schools and too little weight to results from small schools. Second, the classical estimates of standard errors may understate the true variation in estimated treatment effects.

This appendix reports the effects of using the child as the unit of analysis. Specifically, it 1) compares *estimated means* for the regimens, using the school versus the child as the unit of analysis; 2) reports how intraschool correlation affected *standard errors* and the resulting significance tests and confidence intervals; and 3) discusses the impact of the unit of analysis on the *pattern of results*. This appendix shows that the choice of the unit of analysis had a negligible effect on estimated means, a small to moderate effect on estimated standard errors, and essentially no effect on the overall pattern of results and conclusions.

EFFECT ON ESTIMATES

Table A.1 compares results of estimating regimen means with the child versus the school as the unit of analysis. Background characteristics (other than site) were not used to adjust the means. Thus, its last column isolates the unique effect of the choice of the unit of analysis on the computation of treatment means.

The sample used to construct this table was restricted to schools that had 10 or more children in a given combination of cohort and regimen. This restriction eliminated less than 1 percent of the 9,566 children in the four-year continuous residence sample. For that reason and because these means have not been adjusted, they differ slightly from those presented in other tables.

These results indicate that using the school rather than the child had almost no effect on regimen means and therefore on the size of treatment effects. In 20 of the 24 comparisons, the four-year mean DMFS increment score computed using the school as the unit was within 0.09 surfaces of the mean computed using the child as the unit. The average difference was 0.05 surfaces.

EFFECT ON STANDARD ERRORS OF ESTIMATES

In this section, we derive a factor for rescaling the standard errors to account for intraschool correlation (based on the methods in Scott and Holt).^[21] The significance levels and confidence intervals in this report reflect the rescaled standard errors as well as reduced degrees of freedom for t-distributions.

Table A.1
 MEAN FOUR-YEAR DMFS INCREMENT IN EACH REGIMEN,
 BY WHETHER THE CHILD OR THE SCHOOL IS USED
 AS THE UNIT OF ANALYSIS

Cohort	Regimen	Unit of Analysis		Difference Between Means
		Child	School	
NF 1+2	1	1.35	1.29	0.06
	2	2.36	2.31	0.05
	3	1.48	1.59	-0.11
	4	2.44	2.48	-0.04
	5	3.04	3.04	0.00
	6	3.10	3.01	0.09
F 1+2	1	0.86	0.86	0.00
	2	1.10	1.08	0.02
	3	0.95	0.99	-0.04
	4	2.18	2.23	-0.05
	5	2.43	2.39	0.04
	6	2.13	2.13	0.00
NF 5	1	2.86	2.72	0.14
	2	4.02	3.87	0.15
	3	2.96	3.00	-0.04
	4	5.23	5.18	0.05
	5	5.23	5.21	0.02
	6	5.12	5.17	-0.05
F 5	1	1.28	1.42	-0.14
	2	1.56	1.55	0.01
	3	1.27	1.24	0.03
	4	3.60	3.60	0.00
	5	3.41	3.47	-0.06
	6	3.24	3.15	0.08

NOTE: A school (and its children) was used to compute the mean for a given combination of cohort, regimen, and site if that school had 10 or more children. Each mean in the table is the mean of the site means. There was no other adjustment for background characteristics.

In each analysis, the mean for a given regimen-cohort was a weighted mean of school means for that regimen-cohort. In the child-level analysis, a school's weight equaled the number of children in that regimen-cohort. In the school-level analysis, each school mean received equal weight.

Theoretical Methods

Suppose that one observes a sample from k clusters (schools) of size m_i for $i = 1, \dots, k$. Suppose further that separate observations within a cluster have correlation $\rho > 0$, but that observations from different clusters are independent. That is, for each i , one observes $\{X_{ij}\}$ for $j = 1, \dots, m_i$, where

$$\text{Corr}(X_{ij}, X_{ij'}) = \rho, \text{ for } j \text{ not equal to } j'$$

and

$$\text{Corr}(X_{ij}, X_{i'j'}) = 0, \text{ for } i \text{ not equal to } i'.$$

The sample mean (the ordinary least squares estimator) is unbiased for estimating the population mean. However, the usual estimate of its variance will be too small by a factor that depends on both ρ and the $\{m_i\}$. Scott and Holt state that the true variance of the sample mean exceeds the usual estimate by a factor of

$$1 + (\bar{m} - 1)\rho, \quad (1)$$

where

$$\bar{m} = (\sum m_i^2) / (\sum m_i). \quad (2)$$

The above factor is an *upper* bound for the adjustment factor for regression coefficients. That upper bound is reached for estimates of site effects, regimen means, and treatment effects because site and regimen are confounded with school. However, for other variables (such as baseline DMFS score), which vary considerably within school, the correct adjustment factor is essentially 1.0 (Section 5 of Scott and Holt).^[21]

Because the values of $\{m_i\}$ are known, one only needs to estimate the intra-cluster correlation coefficient ρ in order to adjust ordinary estimated standard errors. The obvious method for doing so in the simple structure with no covariates is to use the F-statistic from a one-way ANOVA of X_{ij} on the cluster (if the $\{X_{ij}\}$ are normal, F is a sufficient statistic). Reasonably straightforward calculations show that the expected value of the within-cluster sum of squares, with $(M - k)$ degrees of freedom, is

$$E(SSW) = \sigma^2(M - k)(1 - \rho),$$

where $\sigma^2 = \text{Var}(X_{ij})$ is constant and $M = \sum m_i$. Also, the expected value of the between-cluster sum of squares, with $(k - 1)$ d.f., is

$$E(SSB) = \sigma^2(k - 1)[(1 - \rho) + \rho(\bar{m} - \text{Var}(m_i)/M)]$$

$$< \sigma^2(k - 1)[(1 - \rho) + \rho\bar{m}].$$

Thus, for large k ,

$$E(F) \approx 1 + \bar{m}\rho / (1 - \rho),$$

so that an obvious estimate of ρ is

$$\hat{\rho} = (F - 1) / (F - 1 + \bar{m}). \quad (3)$$

In a regression context with several covariates, we need to estimate the intra-cluster correlations of the residuals. We do this by including school as a random effect in the regression. The F-statistic associated with the school effect provides our estimate for ρ , and the number of degrees of freedom associated with the numerator of this F-statistic is the number that should be used for all t-tests from the regression. Note that the correlation of residuals is likely to be much smaller than that for raw values. This helps to explain the importance of using covariates such as baseline DMFS, race, and SES, which explain much of the between-school differences.

Results

Table A.2 shows results of the calculations described above for each combination of cohort and fluoridation status. We computed separate values of m for each combination of site with regimen. The values shown in the table are the means of these values averaged across all site-regimens within a particular combination of cohort and fluoridation status. If a single value of \bar{m} were computed across all the site-regimens, it would be about 5 to 10 percent lower, which would reduce the standard error factors by about 0.01.

The next-to-last line of the table shows the factors by which standard errors in Bell et al.^[20] should be multiplied to make them consistent with the ones in this report. Separate factors are provided for each analysis group. The final line shows the number of degrees of freedom in the between-schools sum of squares that was used to compute the F-statistic, which in turn was used to estimate ρ . That number of degrees of freedom (rather than ∞) should be used for all t-tests involving site and treatment effects.

EFFECT ON THE PATTERN OF RESULTS

Of the significance levels indicated by one or two asterisks in Tables 4 and 5 (Tables 3.1 and 3.2 of Bell et al.),^[20] only four lost an asterisk using the revised standard errors and significance levels. The p -values for regimens 2 and 4 in Column 1 of Table 4 rose from about 0.0004 to about 0.005. The two significant results for prophyl/gel lost their statistical significance at the 0.05 level. The p -values rose from about 0.02 to 0.08 and 0.12 in Columns 2 and 3, respectively.

The pattern and interpretation of the results were not affected by whether the school or child was used as the unit of analysis nor by the rescaling of the standard errors. None of the significance levels changed for sealants or fluoride mouthrinse. The two prophyl/gel effects that were significant at 0.02 had their significance levels increase to about 0.11. The confidence intervals in Fig. 1, the most important figure in the report, remained quite narrow.

Table A.2
ADJUSTMENT FACTORS FOR STANDARD ERRORS BY COHORT
AND FLUORIDATION STATUS

Item	Nonfluoridated		Fluoridated	
	Cohort 1+2	Cohort 5	Cohort 1+2	Cohort 5
F for school effect on DMFS	1.24	1.56	1.92	0.99
F - 1	.24	.56	.92	-.01
\bar{m} (mean school size)	72.0	29.6	54.5	22.4
Intra-cluster correlation, $\hat{\rho}^a$.003	.019	.017	.000
Mean \tilde{m} across site-regimens ^b	91.1	37.4	67.4	27.3
Variance factor ^c	1.30	1.68	2.10	1.00
Std. error factor ^d	1.14	1.29	1.45	1.00
Degrees of freedom ^e	34	29	28	27

^aSee Eq. (3).

^bSee Eq. (2).

^cSee Eq. (1).

^dSquare root of previous line.

^ed.f. for numerator of F-test and for use in subsequent t-tests.

Appendix B

UNADJUSTED BASELINE AND END-OF-PROGRAM SCORES

Table B.1

UNADJUSTED BASELINE AND END-OF-PROGRAM DMFS SCORES,
COVARIATE ADJUSTED 4-YEAR INCREMENTS IN DMFS SCORE,
AND THE ADJUSTED NUMBER AND PERCENTAGE OF SURFACES
SAVED COMPARED WITH THE LONGITUDINAL CONTROL GROUP

Regimen	Mean Unadjusted DMFS Score		Mean Covariate Adjusted	Surfaces Saved Compared With Regimen 6	
	Exam 1	Exam 5	Increment	Number	Percent
Nonfluoridated--Cohort 1+2					
1	1.36	2.78	1.23	1.90	61
2	1.12	3.50	2.45	.68	22
3	1.21	2.85	1.45	1.68	46
4	1.01	3.49	2.46	.67	21
5	1.08	4.14	3.01	.12	4
6	1.09	4.18	3.13	--	--
Nonfluoridated--Cohort 5					
1	4.68	7.77	2.84	1.91	40
2	4.97	9.02	4.10	.65	14
3	4.96	8.03	2.92	1.83	39
4	4.88	10.14	5.30	-0.55	-12
5	4.48	9.77	5.35	-0.60	-13
6	5.03	10.05	4.75	--	--
Fluoridated--Cohort 1+2					
1	.88	1.75	.90	1.29	59
2	.89	1.96	1.19	1.00	46
3	.94	1.84	.95	1.24	57
4	1.20	3.41	2.15	.04	2
5	.92	3.30	2.44	-0.25	-11
6	.73	2.81	2.19	--	--
Fluoridated--Cohort 5					
1	3.23	4.29	1.05	2.02	66
2	3.52	5.07	1.45	1.62	53
3	3.20	4.52	1.33	1.74	57
4	3.70	7.74	3.68	-0.61	-20
5	3.62	7.08	3.49	-0.42	-14
6	3.24	6.44	3.07	--	--

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