

Randomized Trial of Motivational Interviewing to Prevent Early Childhood Caries in Public Housing

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Appendix

Adverse Events Determination Following Each FV Application

In addition to enrolling mother-child dyads (with children under 6 years old) residing in greater Boston area public housing developments, the study also enrolled mothers with more than one eligible child. In such cases, the youngest eligible child was designated as the 'index' child, but study procedures were available to all the family's age-eligible children. A total of 1837 index and non-index children were enrolled across 26 housing developments.

All children were assigned to receive FV, delivered quarterly for two years. Each FV application utilized a 0.40ml unit dose of 3M ESPE CavityShield™ 5% sodium fluoride varnish, using a pre-packaged brush, delivered by a study hygienist.

Adverse events were monitored according to a protocol-specified procedure where study staff contacted each child's parent or legal guardian following each FV application. Typically, contact was by phone using a standardized script. The purpose was to assess whether the child experienced any negative health events since his/her most recent study-related FV application, the nature of any such health events, and whether the child had a corresponding medically-attended visit. To assess safety of FV treatments, study-related AE were considered to include health events with a corresponding medically-attended visit that occurred within a prescribed timeframe (termed the "FV-AE window") following FV application. We aimed to identify AE that occurred within the first 7 calendar days following FV application. Each AE that study staff identified was subsequently adjudicated by the trial's clinician principal investigator (PI) to determine whether it was related to study participation. The NIDCR medical monitor, the DSMB, and the IRB reviewed all AE at least annually. The PI reported SAE within 72 hours of learning of an event to NIDCR's clinical research operations management systems contractor. In Appendix Table 1 data is presented on all enrolled children who had at least one FV application, total number of completed FV applications, mean number of FV applications per child, and the distribution of the number of FV applications per child. Timing of the intervals among repeated FV applications within the trial were also calculated.

Appendix Table 1. Number of children with FV applications.

Total N =	1837
# of children with 0 FV applications	477
# of children with $\geq 1+$ FV application	1,360
Total FV applications completed	5,645
mean FV applications / child ^a	4.15
Mean (SD) days between FV treatments ^a	96.7 (39.4)
Median days (inter-quartile range) between FV treatments	95 (77-114)
Minimum, maximum days between FV treatments	16, 1189
# of FV applications/child	n (%)
1	153 (11.3)
2	204 (15.0)
3	231 (17.0)
4	211 (15.5)
5	187 (13.8)
6	156 (11.5)
7	98 (7.2)
8	90 (6.6)
9	30 (2.2)

^a For those with 2 or more FV applications; by protocol, FV was to be applied quarterly.

In Appendix Table 2, data are presented on the trial’s activities related to contacting parents or legal guardians following each FV application to query for any AE in their children. In addition, the total numbers of study-related SAE and AE in children with at least one FV are included.

Appendix Table 2. FV AE follow-up contacts and Number of AEs among children with at least 1 FV application.

	N (%)
FV applications completed	5,645
AE follow-up:	
Contact attempts	10,089
Successful contacts of FV applications completed (as % FV applications)	4,225 (74.7%)
Average # attempts per contact	2.39
AE/SAE with medically-attended visit:	
All-cause AE/SAE ^a	0
Study-related AE/SAE	0

^a Percentages calculated using corresponding number of successful contacts as the denominator.