

APPENDIX 1

Effectiveness of Community Water Fluoridation

Methodological Approaches of “Tier One” and Other Reviews

A vast literature has accumulated on the effectiveness of fluoride in decreasing tooth decay since the 1940s. Conducting a systematic analysis of the evidence of effectiveness was beyond the scope of the FTSG. Instead the committee sought recent comprehensive reviews conducted by expert panels in which precautions were taken to limit review biases. The following questions guided the Fluoride Technical Study Group’s (FTSG) appraisal of the reviews included (based on Andrew Oxman’s work in Sackett, et. al, 1991, p. 380):

1. Were the questions and methods clearly stated?
2. Were the search methods used to locate relevant studies comprehensive?
3. Were explicit methods used to determine which studies to include in the review?
4. Was the methodologic quality of the primary studies assessed?
5. Were the selection and assessment of the primary studies reproducible and free from bias?
6. Were differences in individual study results adequately explained?
7. Were the results of the primary studies combined appropriately?
8. Were the reviewer’s conclusions supported by the data cited?

The following list identifies the reviews considered by the FTSG, and describes the approach each reviewing body used to find, select and rate the quality and quantity of evidence of effectiveness. Among these, there were two formal systematic reviews—the 2002 review by the Task Force on Community Preventive Services and the 2000 review by the NHS Center for Reviews and Dissemination at the University of York.

“Tier One” Reviews

- A. Centers for Disease Control and Prevention. (2001a). Promoting oral health: interventions for preventing dental caries, oral & pharyngeal cancers, and sports-related craniofacial injuries: a report on recommendations of the task force on community preventive services. *Morbidity and Mortality Weekly Report*; RR-21.

Sponsoring entity: Centers for Disease Control and Prevention

Researchers affiliation: Fluoride Recommendations Work Group, CDC

Methods: Explicit search and selection criteria were not established. Relied on judgment of expert panel members. “Evidence was drawn from the most relevant English-language, peer-reviewed scientific publications regarding the current effectiveness of fluoride modalities” (CDC 2001a, p. 19). Members collectively agreed on the quality of evidence. The criteria were adapted from the U.S. Preventative Services Task Force.

Conclusion: “Despite the strengths of early studies of the efficacy of naturally occurring fluoride in community drinking water, the limitations of these studies make summarizing the quality of evidence on community water fluoridation as Grade I [*randomized controlled trials*] inappropriate. The quality of evidence from studies on the effectiveness of adjusting fluoride concentration in community water to optimal levels is Grade II-1 [*included controlled clinical trials without randomization*]. Research limitations are counterbalanced by broadly similar results from numerous well-conducted field studies by other investigators that included thousands of persons throughout the world” (Centers for Disease Control and Prevention [CDC], 2001a, p. 20).

- B. Task Force on Community Preventive Services. (2002). The guide to preventive services interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries. Supplement to the *American Journal of Preventive Medicine* July, 2002, 23: 1-8.

Sponsoring entity: US Department of Health and Human Services, with support from the CDC and other federal agencies, public and private partners.

Researcher affiliations: The Task Force is an independent, non-federal expert committee and consists of 15 members, including a chair, appointed by the Director of the CDC. The Task Force’s membership is multi-disciplinary, and includes perspectives representative of state and local health departments,

managed care, academia, behavioral and social sciences, communications sciences, mental health, epidemiology, quantitative policy analysis, decision and cost-effectiveness analysis, information systems, primary care, and management and policy. The purpose of the Task Force is to “review and assess the quality of available evidence on the effectiveness and cost-effectiveness of essential community preventive health services, and develop recommendations.” (http://www.thecommunityguide.org/home_f.html)

Methods: The Task Force uses an explicit systematic approach to reviewing the evidence on a preventive intervention: Search strategy included multiple electronic database searches, bibliography/reference searches, and consultation with experts.

Inclusion criteria: From 1966 to 12/2000, human, community water fluoridation, published in English, Established Market Economies, two groups with differing exposures to fluoride, tooth-level caries or other caries measures reported.

Quality: Assessed by 2 reviewers.

Suitability of study design: A: prospective before and after measures of tooth level caries and concurrent comparison group, B: studies not in A with post-exposure measures of tooth-level caries and concurrent comparison group, C: other comparison designs and measures. Included only first 2.

Threats to validity: Considered potential selection, confounding and measurement biases; rated good, fair and limited; included only the first two.

Overall: number of studies, suitability of study designs, the quality of execution, the consistency of results and the effect size. 4000 citations reviewed (oral health promotion); 21 met inclusion criteria and minimum quality standards (9 A, 7 B, 5 C).

Conclusion: “Starting or continuing community water fluoridation effectively prevents dental caries in communities at varying levels of baseline caries prevalence (centers 2001b, p. 8): Estimated: % reduction in tooth level caries: 29.1% median decrease (7 A studies); 50.7% median decrease (7 B studies); 17.9% median increase (3 A studies), 59.5% increase (1 B study).

- C. Committee to Coordinate Environmental Health and Related Programs, USPHS. (1991). *Review of Fluoride: Benefits and Risks: Report of the subcommittee on fluoride of the EHPC*. Public Health Service, Department of Health and Human Services.

Sponsoring entity: The review was requested and commissioned by the U.S. Assistant Secretary of Health, DHHS.

Researcher affiliations: The study was conducted by the USPHS Committee to Coordinate Environmental Health and Related Programs (CCEHRP). The CCEHRP is comprised of all USPHS agencies with responsibilities for health programs. These agencies include: the Agency for Toxic Substances and Disease Registry; the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control and Prevention; the Food and Drug Administration; the Health Resources and Services Administration; the Indian Health Service; and the National Institutes of Health. The report was prepared by a specially created sub-committee of the CCEHRP, the Ad Hoc Subcommittee on Fluoride.

Methods: “The Subcommittee performed an extensive examination of the worldwide biomedical literature on fluorides and health. To ensure public input, an announcement was published in the Federal Register on March 1, 1990, soliciting peer reviewed published articles on fluorides.” (USPHS, 1991, p. iv) The Subcommittee addressed the relationship between fluorides and caries with respect to the epidemiological criteria for causality: “detecting an association, seeking a dose-response relationship, replicating the findings under a variety of circumstances and by different investigators, excluding alternative explanations and observer bias, finding biological plausibility for the relationship, and observing the disappearance of the effect when the cause is removed.” (USPHS, p. 18). Previously published comprehensive reviews were updated through 1990. The Subcommittee did not use explicit criterion for assessing the quality of studies, instead addressing threats to validity by examining and excluding alternative explanations for individual study results (for assessment of alternative explanations for studies examining caries reductions, see USPHS, 1991, pp. 26-28).

Conclusion: “The reduction in dental caries among persons exposed to fluorides fulfills all the criteria for a causal relationship: an association was found with a dose-response effect, the findings were

replicated under a great variety of circumstances by different investigators, alternative explanations and observer bias have been excluded, the findings are biologically plausible, and the effect, prevention of dental caries, continues to show that the fluoridation of water supplies substantially reduces the scores of dental caries. The decline over time in difference in caries scores between fluoridated and non-fluoridated areas is due in part to the increased availability of fluorides in non-fluoridated areas, as in toothpaste and other vehicles for fluorides” (USPHS, 1991, p. 35).

- D. World Health Organization. (1994). *Report of a WHO Expert Committee on Oral Health Status and Fluoride Use*. WHO Technical Report Series, No. 846 ed. Geneva, Switzerland.

The Expert Committee on Oral Health Status and Fluoride Use met for seven days in 1993 and adopted a consensus statement. Only a brief statement was made regarding the effectiveness of community water fluoridation. Approach to assessment of evidence of effectiveness was not stated in report. References cited included only reviews, including The USPHS, 1.5, and a comprehensive monograph published in 1991 (Murray, Rugg-Gunn, & Jenkins, 1991).

- E. NHS Centre for Reviews and Dissemination, University of York. (2000). *A Systematic Review of Public Water Fluoridation*. York, UK: York Publishing Services Ltd.

Sponsoring entity: National Health Service Research and Development Division, United Kingdom

Researcher affiliations: NHS Center for Reviews and Dissemination, University of York

Methods: Used an explicit systematic approach to reviewing the evidence. Search strategy included electronic and hand database searches, bibliography searches, World Wide Web and invitations to public and experts to submit references.

Inclusion criteria: Up to February of 2000, human, any language, community water fluoridation, twogroups with differing exposures to fluoride, prospective with at least 2 points in time, percent caries free or tooth-level caries measures reported.

Quality: Assessed by two reviewers.

Selection of study population: A: prospective before and at least two years after measures of tooth level caries and concurrent comparison group, B: prospective studies not in A with post-exposure measures of tooth-level caries and concurrent comparison group, C: other comparison designs and measures. Included only first two.

Threats to validity: Considered potential selection, confounding and measurement biases; rated highest, moderate and lowest quality; included only the first two.

Overall: 3200 citations reviewed; 26 published and 5 unpublished studies met inclusion criteria. All but three were “before-after” study designs—the remaining three were follow-up studies. Summary measure using meta-regression was estimated: absolute reduction in tooth level caries: 2.25 teeth (inter-quartile range 1.28-3.63).

Conclusion: “The best available evidence suggests that fluoridation of drinking water supplies does reduce caries prevalence, both as measured by the proportion of children who are caries free and by the mean change in dmft/DMFT score. The studies were of moderate quality but of limited quantity. The degree to which caries is reduced, however, is not clear from the data available” (NHS Center for Reviews and Dissemination, 2000, p. xii).

Note – Other “Tier One” Reviews were not included because they were published prior to 1990 or did not address the effectiveness of community water fluoridation

Other Reviews

- a. The Lord Mayor's Taskforce on Fluoridation. (1997). The Lord Mayor's Taskforce on Fluoridation - Final Report to Brisbane City Council. Brisbane, Australia.

Sponsoring entity: City of Brisbane, Australia

Researchers affiliation: Panel of members from professional and community bodies, council members and citizens

Methods: Search included electronic database literature searches (*Medline, Biological Abstracts*), Internet searches, solicitations of references from public and experts, and invited presentations by two noted opponents to water fluoridation. Sufficient detail to replicate search strategy was not provided in report. Study inclusion criteria and approaches to weighing the quality of individual studies was not addressed in the main report. A commissioned paper on dental costs and benefits was not available for FTSG review.

Conclusion of review: "Task Force members were satisfied that the weight of evidence from the large number of studies in many different countries pointed overwhelmingly to a protective effect from water fluoridation. As outlined earlier, however, there were sharp differences of opinion about the extent of the benefits" (The Lord Mayor's Taskforce on Fluoridation, 1997, 39).

- b. Expert Panel for Water Fluoridation Review, City of Calgary. (1998). Report of the expert panel for water fluoridation review appointed by the standing committee on operations and environment. Calgary, Canada.

Sponsoring entity: City of Calgary, Calgary Regional Health Authority

Researchers affiliation: University of Calgary

Methods: Search strategy was not detailed in report, but included literature searches by panel members, solicitations of references from public and experts, and invited presentations by two experts, one supporting and another opposing water fluoridation. Focus was on primary studies and review literature since 1989. Quality of evidence standards were established using model of the Canadian Task Force on the Periodic Health Examination but the results of applying these standards to individual studies was not reported. In the report, the evidence of effectiveness was discussed in the context of the pro-con expert presentation. Conclusion: Consensus on effectiveness among panel members could not be reached—four of five members of the panel produced a majority report: "The relative health benefits are now less than they were forty years ago, because of other sources of fluoride in the diet, better oral hygiene and better dental procedures, as well as a general improvements in overall health. However, these other improvements have not reduced the benefits of water fluoridation to the point where it is no longer needed" (Expert Panel for Water Fluoridation Review, 1998, p. 30). The lone dissenter, a bio-statistician, concluded that the "relative importance of beneficial effect of water fluoridation has decreased and may no longer be necessary" (Expert Panel for Water Fluoridation Review, 1998, p. 28).

- c. Locker, D. (1999). Benefits and Risks of Water Fluoridation - An update of the 1996 Federal-Provincial Subcommittee Report. University of Toronto, Canada.

Sponsoring entity: Public Health Branch, Ontario Ministry of Health & First Nations and Inuit Health Branch, Health Canada

Researcher affiliation: Community Dental Health Services Research Unit, University of Toronto

Methods: Used an explicit systematic approach to reviewing the evidence. Search strategy included electronic and hand database searches, bibliography searches, hand searching of high-yield journals, and the World Wide Web.

Inclusion criteria: Between 1/1994 and 11/1999, human, English language, community water fluoridation.

Quality: Assessed by one reviewer. Suitability of study design was the main criterion used to assess quality.

Treats to validity: Considered potential selection, confounding and measurement biases qualitatively; no rating of quality was attempted.

Overall: Unknown number of citations reviewed; 29 published studies met inclusion criteria. All but four were “before-after” study designs—four were cross-sectional studies. In addition to weak study designs, a variety of methodological flaws were identified which could either increase or decrease the effect size. The magnitude of the caries prevention effect was examined using two of the more robust studies conducted in the later 1990s. The reviewer concluded that caries reductions in the 1990s are relatively small in absolute terms, particularly in permanent teeth and that water fluoridation explains only a small part of the variation in caries experience between children.

Conclusion of review: “Given the weaknesses in design and the methodological flaws to which many of the studies were subject, the data from these more recent studies must be treated with some caution. While the balance of evidence overall suggests that water fluoridation does reduce caries experience, the magnitude of the effect is subject to a degree of uncertainty but is unlikely to be large in absolute terms.” And, “The few studies that have assessed rates of dental decay in communities where fluoridation has been discontinued do not suggest that dental decay increases to any significant degree” (Locker, 1999, p. 33).

- d. Natick Fluoridation Study Committee. (1997). Should Natick Fluoridate? A Report to the Town Board of Selectmen. Natick, MA.

Sponsoring entity: Town of Natick, Massachusetts

Researchers affiliation: None. Members of committee were “qualified, scientifically trained and experienced people” formed by town board.

Methods: Search methods: Committee identified proponents (the Board of Health) and opponents (two citizens of Natick) and asked each to supply a limited number of documents containing study reports as well as letters of endorsement for their perspective. “The committee was not constrained to limit its search to the above materials” but search and inclusion criteria were not defined. The report did not identify any attempts to rate the quality of evidence of effectiveness. Examples of reviewer bias were evident in the final report. (e.g. a report by J. Yiamouyiannis claiming no difference in dental caries prevalence in 1986-87 between U.S. children in fluoridated and non-fluoridated communities that was fully discredited by the National Institutes of Health *was* referenced, but none of the several well-designed analytic studies showing significant differences in caries rates from the same dataset were referenced).

Conclusion of Review: “Recent studies of the incidence of cavities in children show little to no difference between fluoridated and non-fluoridated communities.”

Table 1:
Scoring the Reviews

Criterion	A CDC 2001a.	B. Task Force 2002	C. USPHS 1991	D WHO 1994	E. NHS 2000	a. Brisbane 1997	b. Calgary 1998	c. Locker 2000	d. Natick 1997
Were the questions and methods clearly stated?	yes	yes	yes	no	yes	yes	yes	yes	yes
Were the search methods used to locate relevant studies comprehensive?	yes	yes	yes	no	yes	yes	yes	yes	no
Were explicit methods used to determine which studies to include in the review?	no	yes	yes	no	yes	no	no	yes	no
Was the methodologic quality of the primary studies assessed?	yes	yes	yes	no	yes	no	yes	yes	no
Were the selection and assessment of the primary studies reproducible and free from bias?	yes	yes	yes	no	yes	no	no	yes	no
Were differences in individual study results adequately explained?	no	yes	yes	no	yes	yes	yes	yes	no
Were the results of the primary studies combined appropriately?	yes	yes	no	no	yes	no	no	no	no
Were the reviewer's conclusions supported by the data cited?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Number of Affirmatives	6	8	7	1	8	4	5	7	2