SENES Oak Ridge Inc.
Center for Risk Analysis
F. Owen Hoffman, Ph.D., President

Specialists in Energy, Nuclear And Environmental Sciences.

Custom Applications in Human Health and Ecological Assessment.

January 31, 2000

Mr. John E. Hoagland
Deputy Director of Public Works
City of Escondido
201 North Broadway
Escondido, CA 92025

Re: Consulting Agreement-Independent Review of California Oral Health Needs Assessment (A-2336)

Dear Mr. Hoagland:

I am enclosing an original and five photocopies of my review of the California Oral Health Needs Assessment. I apologize. for my delay in completing this review; we have had more work the last few months than I had anticipated. If you or others at the City of Escondido have any questions about the review, or if I or *SENES* Oak Ridge, Inc., can be of further assistance to the City of Escondido, please do not hesitate to call me at (865) 483-6111. (The 865 area code is relatively new, and some people have reported difficulty with it; if that should happen, try the old area code, 423).

Sincerely,

Kathleen M. Thiessen

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Review of

the California Oral Health Needs Assessment 1993-94

Prepared for the City of Escondido

January 31, 2000

Prepared by

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Summary

The intent of this paper is to provide the City of Escondido with an independent review of the California Oral Health Needs Assessment 1993-94. In the review context, I have concentrated on the issues that are expected to be most important: the relationship between prevalence of dental caries (cavities in teeth) and such factors as use of fluoridated water, use of fluoride supplements, use of dental sealants, prevalence of specific infant feeding practices, and occurrence of Baby Bottle Tooth Decay. It must be emphasized, however, that this review is not exhaustive and is concerned primarily with the scientific merits of one particular study; I have not addressed more general issues such as the pros and cons of water fluoridation or the use of fluoride supplements.

I would like to commend the originators of the study for their obvious care and thoroughness in designing the study and collecting the data. The data collected during the California Oral Health Needs Assessment 1993-94 constitute a valuable resource for addressing a number of important questions.

However, the data analysis as reported by Pollick et al. (1994) stands in need of improvement in two key areas:

1. All sources of uncertainty should be considered, including sample representativeness, errors or ambiguity in data collection or recording, and absence or incompleteness of relevant data. In particular, uncertainties in individual fluoride exposures should be addressed. Regional fluoridation status should not be used as a surrogate for total fluoride exposure due to the potential for misclassification of individuals.

2. Analysis of endpoints such as caries experience should include both incidence (caries or no caries) and severity (number of caries) and should account, on an individual basis, for all factors that might affect the endpoint, including total fluoride exposure, presence of dental sealants, history of dental visits, history of Baby Bottle Tooth Decay, and economic factors.

The results of the study as reported by Pollick et al. (1994) do not support its primary conclusion, namely that increased fluoridation of public water supplies and increased supplementation of fluoride in nonfluoridated areas are warranted. The differences in caries incidence (percentage of children with and without caries) with fluoridation status as reported by Pollick et al. (1994) are probably due to other factors, primarily economic status and presence or absence of dental sealants.

1. Introduction

The intent of this paper is to provide the City of Escondido with an independent review of the California Oral Health Needs Assessment 1993-94, as described in a December 1994[1] draft report, entitled *Report of the California Oral Health Needs Assessment 1993-94* (Pollick et al., 1994), and two companion summary reports, one published in September 1995, entitled *Our Children's Teeth: Beyond Brushing and Braces* (CDHS, 1995), and one published in 1997, entitled A *Neglected Epidemic* (DHF, 1997). The California Oral Health Needs Assessment 1993-94 collected data on the dental health of preschool, elementary, and high school children to determine the extent to which national oral health objectives (as specified in pp. 349-364 of *Healthy People 2000;* USDHHS, 1991) were being met; to provide a baseline for evaluation of efforts to meet these objectives; and to assess complementary areas such as demographics, oral health status, risk reduction factors, and systems for delivery of community-wide preventive and treatment services[2].

The health objectives specified in *Healthy People 2000* that are addressed by the California Oral Health Needs Assessment 1993-94 are concerned primarily with water fluoridation, use of fluoride supplements, Baby Bottle Tooth Decay and associated infant feeding practices, prevalence of dental caries (cavities), and use of dental sealants[3]. The present review of the California Oral Health Needs Assessment 1993-94 addresses these issues in that context. It must be emphasized, however, that this review is concerned primarily with the scientific merits of one particular study; the review does not address more general issues such as the pros and cons of water fluoridation or the use of fluoride supplements.

Materials reviewed in this report include the primary technical document referred to above (Pollick et al., 1994), plus the two summary reports (CDHS, 1995; DHF, 1997) and a number of additional documents supplied to me, including copies of correspondence, newspaper clippings, etc. I have concentrated primarily on scientific issues (e.g., study design, appropriateness of sampling and data collection methods, and analysis of the results-whether the results follow logically from the data). This review is not exhaustive; rather, I have concentrated on the issues that are expected to be most important: the relationship between caries prevalence and such factors as use of fluoridated water, use of fluoride supplements, use of dental sealants,

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[1] The title page of the report gives a date of December 1994. The footer on most pages in the report indicates a draft of October 18, 1994, with earlier dates in some sections.

[2] "Study Design," pp. 1-2. Page numbering begins with "1" in each chapter in the December 1994 draft report. For the convenience of the reader of this review, when I refer to a page in that report, I have given a chapter designation (title or abbreviated title) and the page number(s) within that chapter.

[3] "Study Design," pp. 1-2. Other oral health objectives specified in *Healthy People 2000* that are not addressed by the California Oral Health Needs Assessment 1993-94 include the prevalence of missing teeth or edentulism (toothlessness) in adults, the prevalence of gingivitis and destructive periodontal disease in adults, the reduction of deaths due to cancer of the oral cavity and pharynx, availability of dental care for residents of institutions, use of oral health services by adults, identification and treatment of infants with cleft lips and/or palates, and use of protective equipment in sports and recreational activities (USDHHS, 1991).

prevalence of specific infant feeding practices, and occurrence of Baby Bottle Tooth Decay. A list of specific concerns submitted to me with the reports is addressed at the end of this review.

2. Summary of the study and technical report

The California Oral Health Needs Assessment 1993-94 was carried out by The Dental Health Foundation under a contract with the California Department of Health Services, Maternal and Child Health Branch[4]. The study team collected data on the dental health of preschool, elementary, and high school children in 10 major geographic regions of California during the period from October 1993 through January 1994. The data collected during the assessment were to be used to determine the extent to which national public health objectives were being met and to provide a baseline for evaluation of efforts to meet these objectives[5]. A professional advisory committee developed the protocol for the project, including the sampling design, types of data to be collected, and the methods for data collection and reporting.[6]

The sampling was done by school and by grade within schools (K-3 at elementary schools, and grade 10 in high schools). Preschools and public elementary and high schools were selected by geographical region, fluoridation status of the community, and racial or ethnic composition of the schools[7]. Selection of schools was designed purposely to ensure that enough students were examined from each type of fluoridation status (urban fluoridated, urban nonfluoridated, and rural), each type of preschool (Head Start vs. non-Head Start) or high school (regular vs. continuation), and each major racial or ethnic group (classified by "Asian," "Black/African American," "Latino/Hispanic," "White/Caucasian," or "Other"). Selected schools were then asked to participate, and parental consent was requested for all children within the participating schools. The study included "[o]nly those schools, parents and children/students who had provided written consent."[8] Due to the process used to select the schools, and due to the selfselection of the children (i.e., the children or their parents chose whether or not to participate), the study group cannot be expected to conform to the demographics of the statewide population of children of the relevant age-groups. However, it is worthwhile to note that most major segments of the state's preschool or public school population (at least in terms of fluoridation status, Head Start status, or racial/ethnic background) were likely to have been represented by a sufficiently large sample to provide meaningful data for many uses.

Data for the participating students were collected in two ways: (1) by questionnaire completed by the parent or guardian for preschool and elementary school children or by the student and parent or guardian for high school students, and (2) by examination of the child by a dental professional. Information requested by questionnaire included the use of fluoride toothpaste or fluoride supplements, dental visits, dental insurance status, birthplace and residence history, race/ethnicity, education level of parents or guardians, family income and size,

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4 "Study Design," p. 1.
5 "Study Design," p. 1.
6 "Study Design," p. 2.
7 "Study Design," pp. 2-4.
8 "Study Design," p. 9.

ability of the parent or guardian to take time off from work to take the child to a dentist, the parent or guardian's perception of the child's current oral health status, and (for preschool children) infant feeding practices[9]. The draft report (Pollick et al., 1994) refers the reader to copies of the questionnaires'°, and the Table of Contents for the Appendices at the end of the report includes the questionnaires and parental consent forms, but copies of the questionnaires and consent forms were not included in my copy of the draft report and have not been included in this review.

Dental professionals evaluated each participating child according to a preestablished protocol (copy provided in the Appendices of the draft report). Children were evaluated for presence or absence of the expected teeth (dependent on the child's age), condition of teeth and tooth surfaces (e.g., soundness, evidence of caries, evidence of restorations or crowns, presence of sealants), dental treatment needs (e.g., no treatment needed, restorations needed, etc.), lesions of the lips or oral mucosa (e.g., ulcers, gingivitis, swelling, cleft lip or palate), periodontal status, fluorosis, and orthodontic needs[11]. Examiners were instructed, when in doubt, to assign the less serious disease or need category[12]. Both dentists (examiners) and data recorders were trained and standardized for this specific projec[13]. Reliability data showed 96% agreement when children were examined or data recorded by more than one individua[14]. However, it must be pointed out that examiners knew (or could easily have known) the fluoridation status of the children when they were examined (a "blind" study would probably be impractical, as it would require transport of children to some set of central locations, such that the examiner could not know, without asking, where a child lived or went to school). It is not known to me whether the examiners had access to a child's questionnaire at the time of the examination.

In all. 6643 children from 156 schools participated in the assessment[15]. Data were analyzed by type of region (fluoridated urban, nonfluoridated urban, or rural[16]). Detailed demographic data are provided for each age group. Results for most endpoints were corrected for factors that reflect the differences between the sample group and the larger population from which the sample was drawn. For example, the sample of children in grades K-3 included 24.1 % white/Caucasian children[17], while the entire K-3 population of California includes 43.8% white/Caucasian children[18]. The results obtained for the sample were therefore adjusted to give the expected results for the statewide ethnic distribution of children. Thus, in most cases, results of the study are reported as percentages, not of the sample, but of the total population of children,

[9] "Study Design," p. 9.
[10] "Study Design," p. 9. "
[11] "Appendices," pp. 3-7. 12
[12] "Appendices," p. 7. "
[13] "Study Design," p. 9. "
[14] "Study Design," p. 10.
[15] "Study Design," p. 10-11.
[16] "Study Design," p. 13.
[17] "Study Design," p. 10.
[18] "Study Design," p. 14.

based on the sample. The report does not contain the actual data or summaries of unadjusted data, other than for the demographics of the study group.

The results of the study are described separately for preschool, elementary, and high school children. The main conclusions from each group are also discussed in sections entitled "Findings and Recommendations," "Findings and the Healthy People 2000 Objectives," and "Priorities," as well as the Executive Summary. The chief conclusion reported is the need for increased fluoridation of public water supplie[19]. This conclusion is based on (1) the assertion in *Healthy People* 2000 that, "Community water fluoridation is the single most effective and efficient means of preventing dental caries in children and adults, regardless of race or income level" **(USDHHS,** 1991, p. 357, citing Burt, 1989); (2) comparison of the mean number of decayed, extracted or missing, and filled teeth per child in fluoridated vs. nonfluoridated areas; (3) the prevailing levels of water fluoridation and fluoride supplementation in California; (4) a survey of the perceptions of health care providers and community leaders about fluoridation[20]; and (5) comparison of the rates of fluorosis in fluoridated vs. nonfluoridated areas. Other major recommendations involve reduction of the incidence of Baby Bottle Tooth Decay (BBTD), reduction in the amount of treated and untreated decay in the various age groups of children, and reduction in periodontal disease in high school-age children, particularly with respect to meeting the objectives outlined in *Healthy People 2000.*

3. Evaluation of the study

I would like to commend the originators of the study for their obvious care and thoroughness in designing the study and collecting the data. They have taken pains to ensure adequate representation of the most important (in terms of size) population subgroups, as determined by geographic region, race or ethnicity, and economic level. They appear to have asked most of the relevant questions of the parents of the study group, and they appear to have collected most of the important data. The data represent a significant investment on the part of the State of California and constitute a valuable resource for addressing a variety of important questions. I would like to encourage the appropriate organizations to make the raw data available to the broader scientific community.

The analysis of the data, as reported by Pollick et al. (1994), is extensive and provides an imposing array of statistics. I would submit, however, that there are several ways in which the data analysis could be improved, and in which the data as presented by Pollick et al. (1994) do not necessarily support the conclusions reported by Pollick et al. (1994), the CDH (1995), or the DHF (1997).

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[19] "Findings and Recommendations," pp. 1-6; "Executive Summary," pp. 1-3.

[20] This survey is described only in the Executive Summary (p. 2) and the Findings and Recommendations (pp. 2-3) of Pollick et al. (1994), plus p. 3 of CDC (1995) and in DHF (1997). No information was available to me regarding the selection of survey recipients, the overall response rate of people receiving the survey, or the specific content of the survey.

First, most of the results are reported in terms of percentages based on population distributions (of ethnicity, etc.), rather than sample percentages or the actual numbers obtained. The intention was good-in order to have an adequate sample size for some smaller population subgroups, these subgroups were "oversampled." Therefore, the sample distributions do not reflect the overall population distribution. Since the goal was to determine various frequencies in the entire population, rather than in the sample population, the results were adjusted to fit the population distribution. Use of percentages rather than actual sample numbers can be misleading in many situations, however. For example, there might be no real difference between 60% and 70% if the sample size is 10 (i.e., results of 6 vs. 7 out of 10), but a substantial difference if the sample size is 1000 (i.e., results of 600 vs. 700 out of 1000). This issue was addressed to an extent by exclusion of results based on samples of less than 25 children. However, adjustment of sample results to provide results supposedly indicative of the population, without any qualifiers, implies that the sample is sufficiently representative of the whole population; this is demonstrably not the case in this study.

The authors of the reports state, "This is not a representative sample of all of California's children" (CDHS, 1995; p. 2), and "the survey is not geographically representative of all California children."[21] Enrollment in preschools is not mandated; therefore samples from children enrolled in preschools are not necessarily representative of all children of this age[22]. "The sample chosen for grades K-3 and grade 10 is representative of children in public schools rather than of all children[23]"; children in private schools were expected to have "fewer unmet needs."[24] Larger schools were preferentially selected[25], and girls were over represented in the sample, especially for high schools[26]. Participating schools and students were self-selected to an extent (schools were first selected by the investigators), meaning that first the school administrators and secondly each child or the child's parents chose whether or not to participate. "It must be assumed that school administrators, teachers and parents/guardians who were willing to participate were those who perceived the greatest need for the children to receive a free dental screening."[27] "To overcome this bias in the survey, some data are presented by poor and non-poor status"[28] or, for preschool children, by Head Start vs. non-Head Start status. In addition, the examinations were not carried out blindly; in other words, examiners knew or could easily have known the fluoridation status of each community in which they examined children.

The authors clearly do not consider the sample to be entirely representative, and certainly not randomly selected, and they expect that there is a bias toward children who need dental attention. It is not appropriate, therefore, for the results to be adjusted to population norms and treated as

[21] "Study Design," p. 2.
[22] "Study Design," p. 3.
[23] "Study Design," p. 4.
[24] "Study Design," p. 4. -5
[25] "Study Design." p. 9.
[26] "Study Design," pp. 16-17.
[27] "Study Design," p. 13. -8
[28] "Study Design," p. 13.

defining the situation for the entire population of California children in the relevant age groups. A better approach would be to retain the stratification (i.e., separation by location, ethnicity, economic status, etc.) in the sample to the extent possible and to describe with each set of results its expected relevance (or lack of relevance) to the larger population or to specific population subgroups. For example, if a bias toward a need for dental care is expected, then the results could be reported as a likely "worst-case" situation for the group in question. It might or might not be possible to estimate the other end of the range in which the true situation is expected to fall.

Thus, the results as reported by Pollick et al. (1994) and CDHS (1995) do not account for uncertainty due to lack of representativeness of the sample. To put it another way, there is no statement of the degree of confidence to be placed in the results. For example, rather than reporting that 54% of California 15-year-olds have at least one decayed tooth[29] (in need of a restoration), it would be appropriate to say that at most 54% are expected to have at least one decayed tooth, and that given the perceived bias toward a need for dental care and the exclusion of the 10% of the student population with "fewer unmet needs" (i.e., the private school students), the actual fraction of California 15-year-olds in need of restorations is expected to be lower. It might or might not be possible from the available information to estimate how much lower.

Uncertainty in the results may also occur due to errors or ambiguities in data collection or recording or to absence or incompleteness of relevant data (e.g., relevant information does not exist or is not available, or questions later determined to be relevant were not included in the surveys). Uncertainty due to problems in data collection or recording are probably small in this study, especially in comparison to the uncertainties due to lack of sample representativeness, although the opportunity for bias in the data collection (due to knowledge of the local fluoridation status) cannot be ignored. The examinations of the children were carried out by dental professionals, and reliability tests showed 96% agreement when children were examined or data recorded by more than one individual[30]. Uncertainties due to errors or ambiguities in the data obtained by questionnaire from parents do not seem to have been quantified; these could likely be larger than uncertainties due to differences in the dental examinations or in the recording of either type of data.

A potentially significant source of uncertainty for this study is the actual fluoride intake by each individual child. The results are reported by region, based on fluoridation status of the region (i.e., fluoridated, nonfluoridated, and rural). However, a range of fluoride concentrations in water supplies exists for the nonfluoridated and rural regions, including a few communities known to have optimally fluoridated water supplies". In addition, most (80% or more) of the children in all areas used fluoridated toothpaste[32], and variable fractions of the children in all regions used fluoride supplements[33]. Other major factors influencing the amount of fluoride in the diets of

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[29] "High Schools Report," p. 18.
[30] "Study Design," p. 10. "
[31] "Study Design," p. 3. "
[32] "Preschool Report," pp. 40-41; "Elementary Schools Report," pp. 38-40; "High Schools Report," pp. 40-43. "
[33] "Preschool Report," pp. 40-41; "Elementary Schools Report," pp. 38-40; "High Schools Report," pp. 40-43.

individuals have not been addressed (although some of them probably could have been addressed in the questionnaires). These factors include use of bottled drinking water (often but not always without fluoride); use of soft drinks, bottled juices made from concentrates, and processed foods, all of which reflect the fluoridation status of their area of origin, rather than their area of consumption; consumption of high-fluoride foods such as tea or some seafoods; and use of cigarettes (which admittedly should not occur in children age 15 or younger but likely does in some). Pollick et al. (1994) report higher levels of mild and moderate fluorosis[34] in nonfluoridated urban regions than in fluoridated region[35], which, even allowing for the problems with sample representativeness discussed above and for the fact that residence history was not included in the comparison by regional fluoridation status, suggests that the source of residential tap water is not a reliable indicator of actual fluoride intake by an individual.

In other words, then, to report results on the basis of fluoridation status of the local tap water (as a surrogate for expected average fluoride intake of the group), rather than on the basis of the estimated fluoride intake of each individual, is potentially misleading, because of the likelihood of misclassification. For example, there may be no real difference in fluoride intake between a child drinking tap water in a fluoridated community and a child drinking substantial quantities of soft drinks in a nonfluoridated community, or between a child drinking bottled (nonfluoridated) water in a fluoridated community and a child drinking tap water in a nonfluoridated community. For any assessment of the effects of fluoride on children, it is essential to consider the actual exposure variable-the intake of fluoride by each individual-rather than a potentially misleading surrogate for the exposure variable. I would strongly encourage reanalysis of the data taking into account individual fluoride intake to the best extent that it can be quantified, and allowing for the uncertainty in typical dietary intakes of fluoride where intake cannot be quantified on an individual basis.

Measuring the primary exposure of interest is one of the basic criteria for a valid epidemiological study (e.g., Lyon, 1999), and adequate accounting for uncertainty in exposure-related data is vital to the meaningful analysis of epidemiological data. For example, a National Research Council panel recently determined that the nine-year, $18-million, Hanford Thyroid Disease Study should be reanalyzed to account more completely for uncertainty in individual exposure estimates (NRC, 1999). In addition, if study results are determined in terms of confidence ranges (accounting for uncertainty), rather than point estimates, it is much easier to see whether real differences exist (e.g., confidence ranges of the results for two different exposure situations do not overlap) or whether apparent differences between point estimates may, in fact, be due to "noise" in the system or in the measuring capabilities.

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[34] Dental fluorosis is a discoloration or “mottling” of the tooth enamel due to the high intake of fluoride by an individual during childhood (CDC 1999); the prevalence and severity of dental fluorosis are related to the level of fluoride intake.

[35] “Findings and Recommendations,” p. 4; “High Schools Report,” p.35

Although the results as reported by Pollick et al. (1994) and CDHS (1995) do not adequately account for uncertainties, particularly with respect to sample representativeness and individual fluoride intake, it should still be possible, within these limitations, to address several issues that are not discussed in the 1994 report. These include the correlations, if any, between caries incidence and use of fluoridated toothpaste, use of fluoride supplements, or presence of dental sealants, and between incidence of Baby Bottle Tooth Decay (BBTD) and incidence of caries in other teeth. The presence of dental sealants (in older children) or of BBTD (in younger children) was determined in the oral examinations; information on usage of fluoridated toothpaste and fluoride supplements was obtained by questionnaire. The 1994 report contains only the estimated frequencies of usage of toothpaste, supplements, or sealants in the population of children based on the study group; no information or discussion is provided concerning the effectiveness of these measures, although these would seem to be extremely important matters in this context. In other words, the major endpoint of importance (caries prevalence) has not been analyzed with respect to some of the most important factors assumed to affect it.

If, in fact, "fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children" (CDC, 1999), then some relationship is expected between the use of fluoridated toothpaste or fluoridated supplements (topical as opposed to systemic) and caries incidence, and these should be more important determiners than the amount of fluoride in the drinking water. According to *Healthy People* 2000, "approximately 90 percent of the decay in children's teeth occurred in pits and fissures, and almost two-thirds was found on the chewing surfaces alone. Pit-and-fissure sealants . . . have existed for many years. If sealants were applied routinely to susceptible tooth surfaces, most incremental tooth decay among American children could be prevented" (USDHHS, 1991, p. 357; see also DHF, 1997, p. 14). Thus any study of the effectiveness of a particular measure in preventing dental caries must control for the presence of dental sealants, or the results will be meaningless. The data on dental caries in California children should be reanalyzed to account for the effects or lack of effects of total fluoride intake, use of topical fluorides (e.g., toothpaste, rinses), and presence of sealants.

Similarly, the incidence of BBTD and the use of various infant feeding practices are each summarized with respect to parental education, regional fluoridation status, and family economic status, but the incidence of BBTD is not summarized with respect to infant feeding practice. If, in fact, incidence of BBTD is related to infant feeding practice, it should be easy to show it from the data obtained in the study; however, the relationship cannot be adequately assessed from the information in the 1994 report. In addition, from the information that is in the report, it seems that perhaps one-third to one-half of the preschool children with caries have BBTD (depending on region, approximately 30 to 55% of all preschool children are estimated to have at least one decayed, extracted, or filled teeth[36], while approximately 14 to 30% are estimated to have BBTD[37]). Therefore, any evaluation of the effectiveness of various measures must control for the

[36] "Preschool Report," pp. 23-26.
[37] "Preschool Report," pp. 29-31.

occurrence of BBTD vs. other types of decay. The preschool data should be reanalyzed to evaluate the relationship between BBTD and infant feeding practices, and to control for **BBTD** in analyzing the effectiveness of other measures intended to prevent dental caries. In addition, if children with BBTD are thought to be more prone to developing caries in other teeth (DHF, 1997, p. 9), then history of BBTD vs. caries incidence should be examined for preschool and elementary children.

Given the issues described above, the primary conclusion reported for the study does not necessarily follow from the data as reported by Pollick et al. (1994), namely, that increased fluoridation of public water supplies and increased supplementation of fluoride in nonfluoridated areas are warranted. First, comparisons have been made only by regional fluoridation status, rather than on the basis of total fluoride intake or exposure. Second, a number of factors that are assumed to affect caries incidence have not been accounted for: (1) use or non-use of fluoridated toothpaste or fluoride supplements; (2) a history of regular dental visits or lack thereof; (3) presence or absence of dental sealants; and (4) the presence of BBTD in preschoolers. Third, minimal attention has been given to the possibility of harm due to exposure to fluoride (including but not limited to dental fluorosis). Given the amount of public concern that fluoride (or excess fluoride) may cause harm to at least some individuals, the conclusion to increase fluoride usage should be drawn only if the study also establishes that no adverse effects will result.

Finally, the authors of the report draw their conclusions based on the average number of decayed teeth (dt or DT; teeth presently needing a filling or other treatment; Figure 1 and Table 1) or of decayed, extracted or missing, and filled teeth (deft, dft, or DMFT; teeth presently needing treatment plus teeth treated in the past; Figure 2 and Table 2 [38]). When the data are examined on the basis of children with and without decay (present or past), the results are rather different (Figures 3 and 4; Tables 3 and 4 [39]). In fact, the data shows essentially no difference with respect to fluoridation status for preschool children and small to moderate differences for high school or elementary school children, respectively. The only significant difference in findings with respect to fluoridation status is the use of dental sealants in elementary and high school children (Figure 5 and Table 5), especially for non-poor elementary school children[40]. In short, most of the data (with the possible exception of some measures of dietary fluoride intake) are probably in hand to address the effect of water fluoridation on caries prevention in the study group, but the data and results as presented by Pollick et al. (1994) do not show any significant effect. This is not necessarily to say that fluoridation is not beneficial. However, the data as reported in this study do not show any increased advantage of fluoridated urban regions over rural or nonfluoridated urban regions.

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[38] Compare with the figures on p. 1 of "Executive Summary" or pp. 1-2 of "Findings and Recommendations."

[39] Note that the health objectives listed in *Healthy People 2000* (USDHHS, 1991, pp. 352-353) are given in terms of children with or without caries, rather than in terms of average caries experience per child.

[40] Although Pollick et al. (1994) suggest. "Fluoridation of water supplies may be a prerequisite to achieving this objective [of increased usage of sealants in 15-year olds], since data show higher sealant prevalence in fluoridated regions" ("Objectives," p. 23), there is clearly no intrinsic reason why addition of fluoride to water should cause children to obtain sealants in Greater numbers.

It is important to consider the differences in the results from comparisons made on the basis of average decayed (or decayed, extracted or missing, and filled) teeth per child and results from comparisons of percentages of children with and without caries (Figures 1-4; Tables 1-4). In the first case, a few children with many decayed teeth can affect the average for the whole group. The latter comparison gives a better indicator of the group experience, in **terms of helping** to identify factors that affect whether or not a child develops caries. It is obviously important also to identify factors that affect how many caries a child develops; possibilities include individual factors such as heredity, dietary habits and general nutrition, oral hygiene, use of dental sealants, and economic level. It is not correct, for example, to conclude that children in fluoridated areas have fewer cavities per child when (a) the actual individual fluoride exposures have not been evaluated, and (b) factors that might have contributed to the high caries experience of a few children or to the low caries experience of many children have not been fully explored. For instance, rural preschoolers have a higher rate of caries per child than urban preschoolers (controlled for Head Start status but not for overall economic status), but this may be due to other reasons such as economic factors, rather than to the lack of fluoridated water; the average caries per child shown for children in fluoridated vs. nonfluoridated urban areas are probably not significantly different. Similarly, the lower caries experience per child for elementary and high school students in fluoridated areas could well be due to the higher usage of dental sealants, rather than to the water fluoridation.

The main conclusion that can be drawn from the data as shown in Figures 3-6 and Tables 3-6 is that economic factors appear to be important in dental health of children. Clear differences in caries experience and in the incidence of BBTD are seen between Head Start and non-Head Start preschoolers. Approximately 97% of the Head Start preschoolers in the study group are considered to be from poor families (defined as below 200% of the Federal Poverty Level, based on family size), while only 54% of the non-Head Start preschoolers examined (estimated to correspond to 40% of the non-Head Start preschoolers in the larger population) are considered poor`'. Rural non-Head Start preschoolers show similar results to Head Start preschoolers from all regions, suggesting that economic differences, or at least ease in reaching a dentist, may be a factor for these children as well. The use of dental sealants also seems to be related to economic level, especially for the elementary age children (the difference is much smaller for high school students).

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[41] "Preschool Report," p. 3.

Table 1. Average number of decayed teeth per child (dt or DT; teeth currently needing treatment)[a].

Group of children Region:	Mean decayed teeth per child Fluoridated	Non-fluoridated	Rural	All regions
All preschoolers	0.66	0.82	1.86	0.82
Head Start preschoolers	1.58	1.65	1.94	1.66
Non-Head Start preschoolers	0.62	0.77	1.85	0.78
Grades K-3	1.05	2.13	1.73	1.98
Grade 10 (Regular high schools)	0.95	2.05	1.80	1.86

[a] Data from "Preschool Report," pp. 15-18; "Elementary Schools Report," pp. 19-22; "High Schools Report," pp. 18-21.

Table 2. Average number of decayed, extracted or fussing, and filled teeth per child (deft, dft, or DMFT; teeth currently needing treatment or treated in the past[a].

Group of children Region:	Mean decaved. extracted or missing, and filled teeth per child Fluoridated	Non-Fluoridated	Rural	All regions
All preschoolers	1.05	1.23	3.15	1.26
Head Start preschoolers	2.62	3.02	4.10	3.06
Non-Head Start preschoolers	0.97	1.14	2.97	1.16
Grades K-3	2.70	3.87	3.67	3.71
Grade 10 (Regular high schools)	2.75	4.24	3.75	3.98

[a] Data from "Preschool Report." pp. 23-26; "Elementary Schools Report," p. 26; "High Schools Report." p. 27.

Table 3. Percentage of children with no decayed teeth (0 dt or DT; no teeth currently needing treatment[a]).

Group of children	Children with 0 decayed teeth (%)			
Region:	Fluoridated	Non-Fluoridated	Rural	**A**ll regions
All preschoolers	73.9	73.2	54.2	72.8
Head Start preschoolers	56.0	53.3	60.7	54.3
Non-Head Start preschoolers	74.9	74.3	53.0	73.8
Grades K-3	63.4	44.5	51.3	47.2
Grade 10 (Regular high schools)	57.0	43.1	54.3	45.8

[a] Data from "Preschool Report," pp. 15-18; "Elementary Schools Report," pp. 19-22; "High Schools Report," pp. 18-21.
[b] Note that the percentage of children in a given category needing treatment for at least one tooth is equal to 100 minus the number shown.

Table 4. Percentage of children with no decayed, extracted or missing, or filled teeth (0 deft, dft, or DMFT; no teeth currently needing treatment or treated in the past)[a].

Group of children	Children with 0 decaved. extracted or missing, or filled teeth (%)[b]			
Region:	Fluoridated	Non-Fluoridated	Rural	All regions
All preschoolers	69.5	69.5	43.5	68.8
Head Start preschoolers	44.3	40.0	41.9	40.7
Non-Head Start preschoolers	70.8	71.0	43.9	70.3
Grades K-3	41.3	29.0	32.6	30.8
Grade 10 (Regular high schools)	27.6	21.8	25.5	22.9

[a] Data from "Preschool Report," pp. 23-26; "Elementary Schools Report," p. 24; "High Schools Report." pp. 25-26.
[b] Note that the percentage of children in a given category needing treatment for at least one tooth or having at least one previously treated tooth is equal to 100 minus the number shown.

Table 5. Percentage of children with sealants on at least one permanent molar[a].

Group of children	Children with sealants (%)			
Region:	Fluoridated	Non-Fluoridated	Rural	All regions
Grade 3[b] (all incomes)	31.6	6.1	5.9	11.5
poor	10.8	4.0	3.4	4.9
non-poor	51.8	11.8	16.8	25.7
Age 15 (all incomes)	25.7	8.7	15.5	12.6
poor	24.2	6.5	13.4	9.8
non-poor	26.7	10.6	18.6	14.8

[a] Data from "Elementary Schools Report," p. 43; "High Schools Report," p. 44.
[b] Similar results were also reported for Age 8.

Table 6. Percentage of children with Baby Bottle Tooth Decay (BBTD)[a].

Group of children	Children with BBTD (%)			
Region:	Fluoridated	Non-Fluoridated	Rural	All regions
All preschoolers	14.9	13.2	29.4	13.9
Head Start preschoolers	28.3	33.7	34.0	33.0
Non-Head Start preschoolers	14.2	12.2	28.5	12.9

[a] Data from "Preschool Report," pp. 29-31.

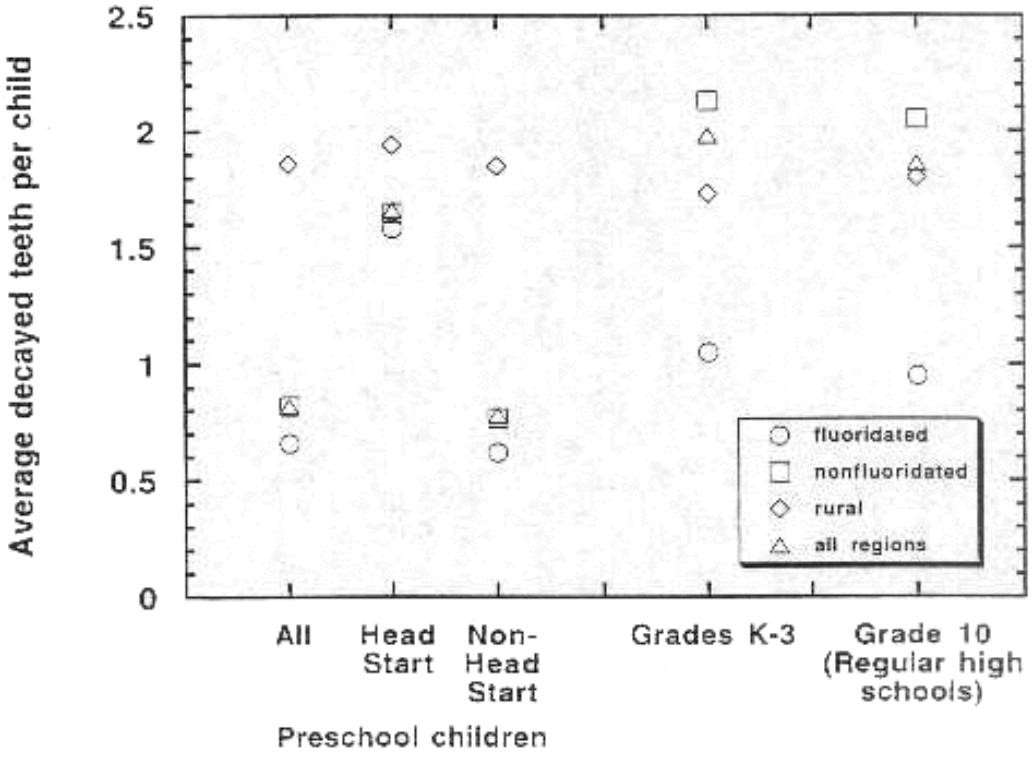

Figure 1. Average number of decayed teeth per child (dt or DT; teeth currently needing treatment). Data are shown in Table 1 and are taken from "Preschool Report," pp. 15-18; "Elementary Schools Report," pp. 19-22; and "High Schools Report," pp. 18-21.

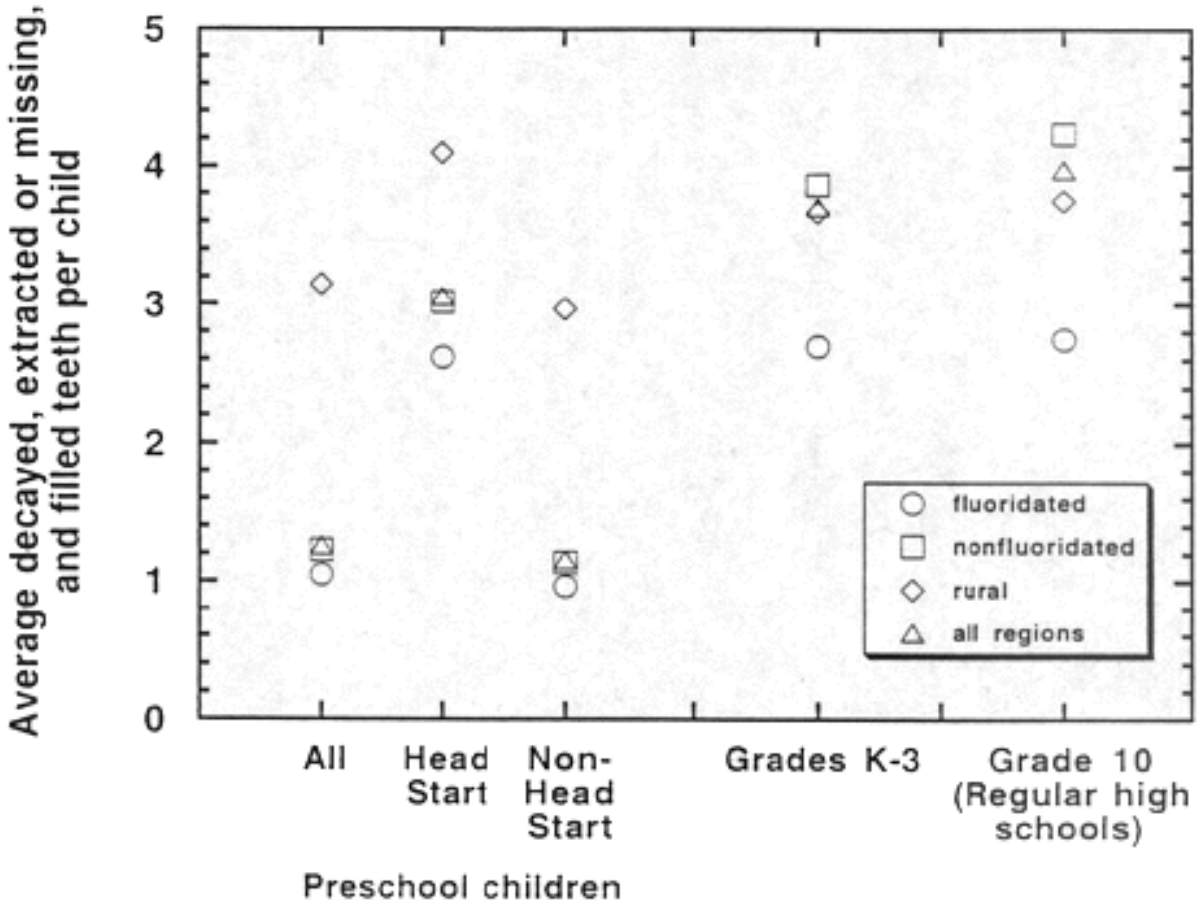

Figure 2. Average number of decayed, extracted or missing, and filled teeth per child (deft, dft, or DMFT; teeth currently needing treatment or treated in the past). Data are shown in Table 2 and are taken from "Preschool Report," pp. 23-26; "Elementary Schools Report," p. 26; and "High Schools Report," p. 27.

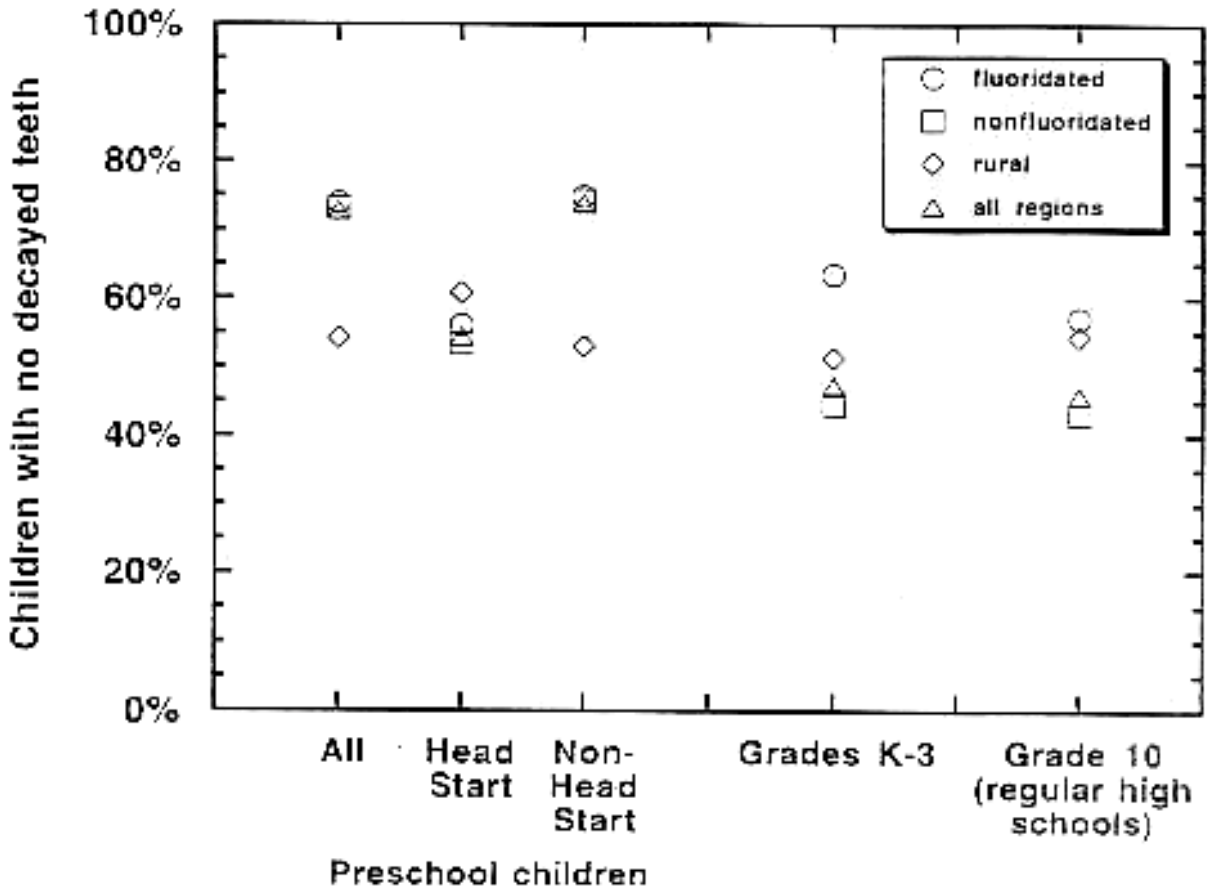

Figure 3. Percentage of children with no decayed teeth (0 dt or DT; no teeth currently needing treatment). Data are shown in Table 3 and are taken from "Preschool Report," pp. 15-18; "Elementary Schools Report," pp. 19-22; and "High Schools Report," pp. 18-21.

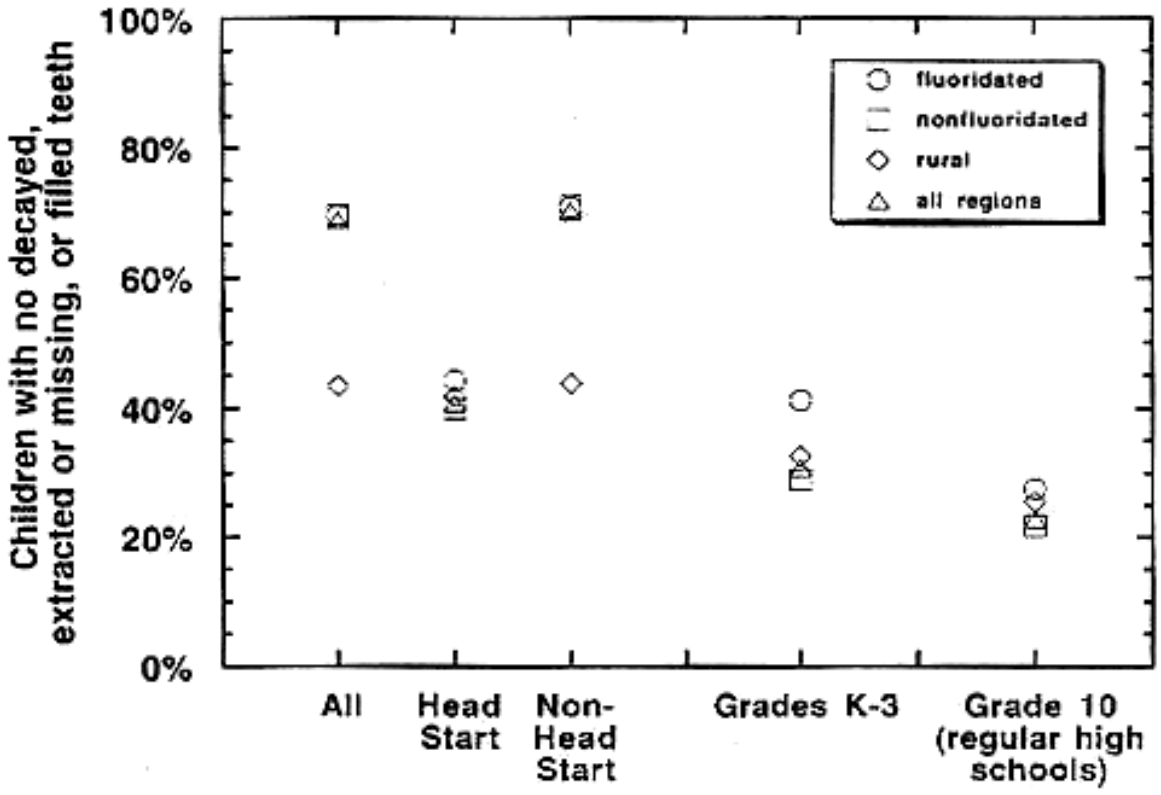

Figure 4. Percentage of children with no decayed, extracted or missing, or filled teeth (0 deft, dft, or DMFT; no teeth currently needing treatment or treated in the past). Data are shown in Table 4 and are taken from "Preschool Report," pp. 23-26; "Elementary Schools Report," p. 24; and "High Schools Report," pp. 25-26.

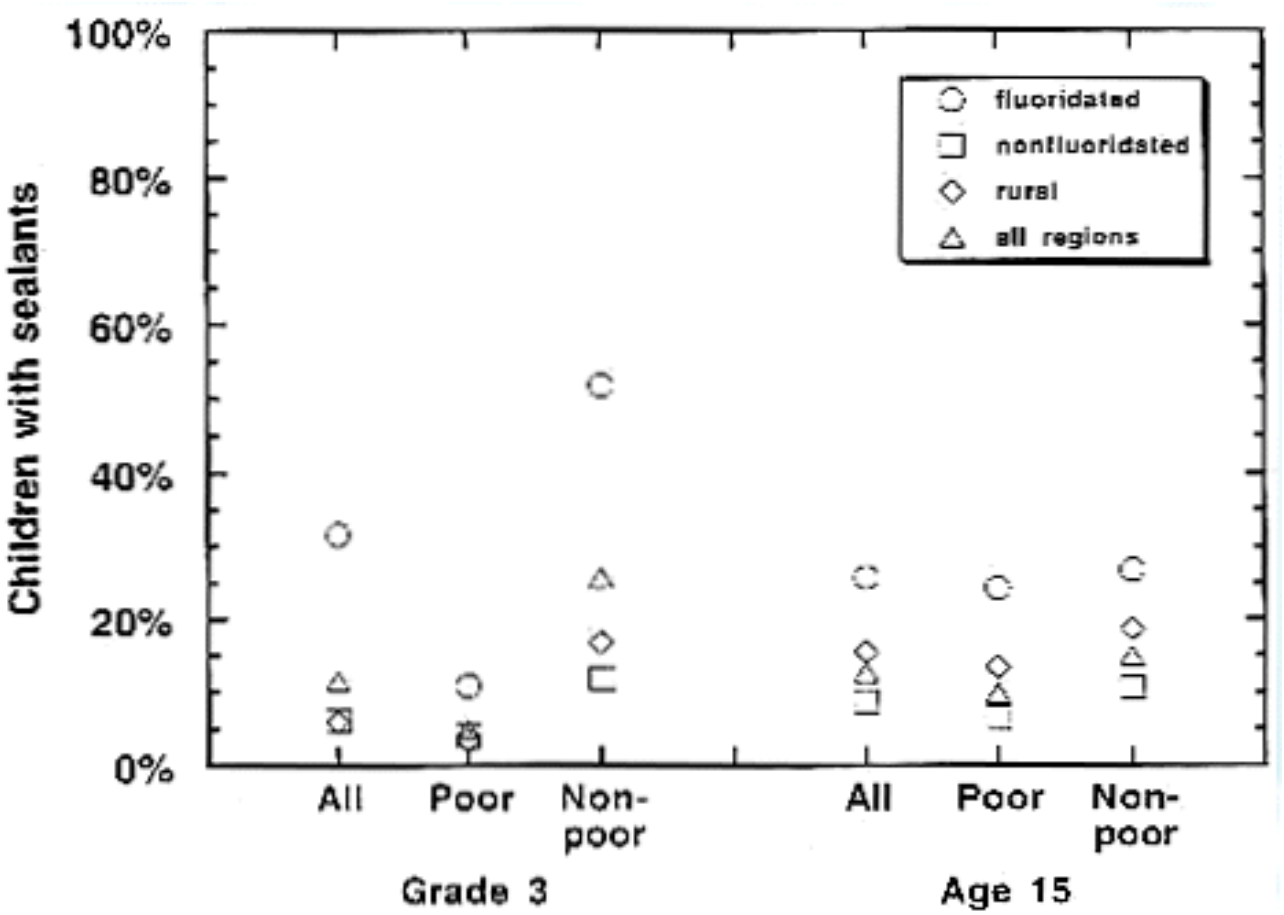

Figure 5. Percentage of children with sealants on at least one permanent molar. Data are shown in Table 5 and are taken from "Elementary Schools Report," p. 43; and "High Schools Report," p. 44.

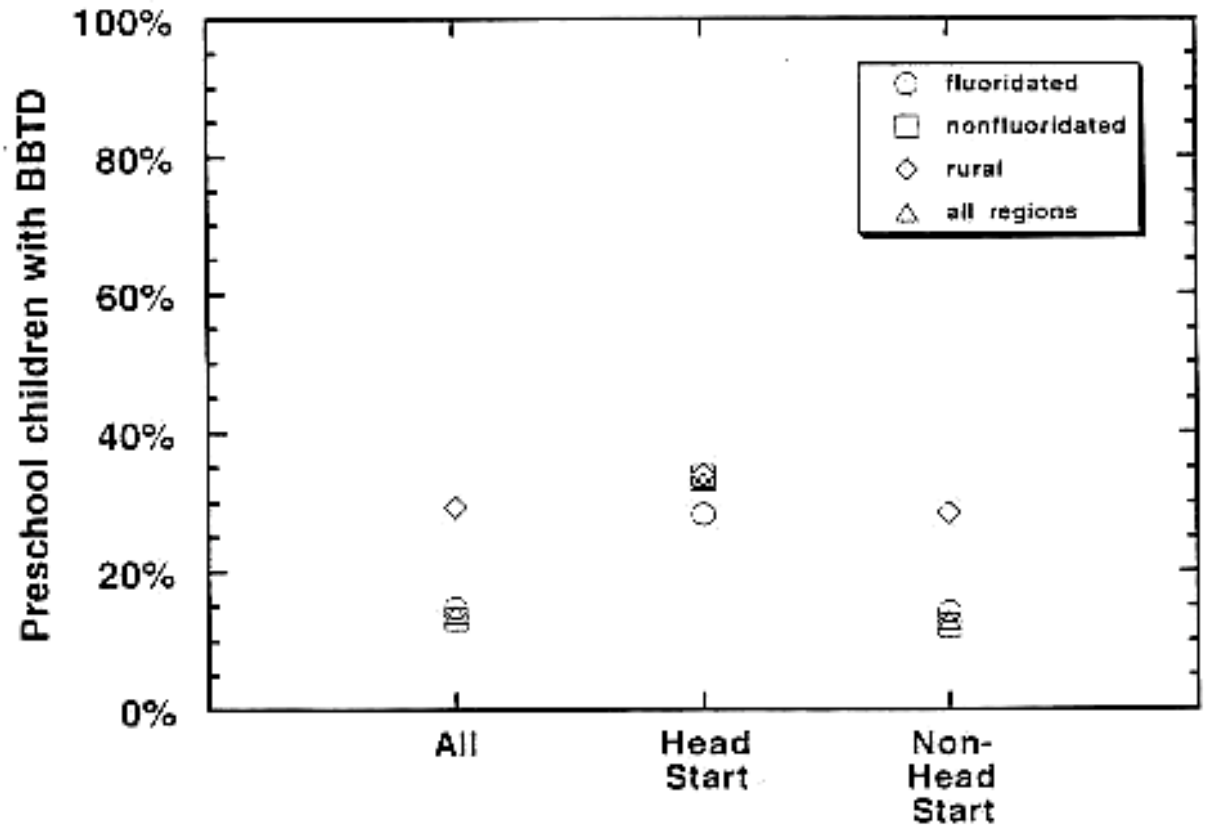

Figure 6. Percentage of children with Baby Bottle Tooth Decay (BBTD). Data are shown in Table 6 and are taken from "Preschool Report," pp. 29-31.

4. Conclusions from the review

The data collected during the California Oral Health Needs Assessment 1993-94 constitute a valuable resource for addressing a number of important questions. The data analysis as reported by Pollick et al. (1994), however, stands in need of improvement in two key areas:

3. All sources of uncertainty should be considered, including sample representativeness, errors or ambiguity in data collection or recording, and absence or incompleteness of relevant data. In particular, uncertainties in individual fluoride exposures should be addressed. Regional fluoridation status should not be used as a surrogate for total fluoride exposure due to the potential for misclassification of individuals.

4. Analysis of endpoints such as caries experience should include both incidence (caries or no caries) and severity (number of caries) and should account, on an individual basis, for all factors that might affect the endpoint, including total fluoride exposure, presence of dental sealants, history of dental visits, history of Baby Bottle Tooth Decay, and economic factors.

The results of the study as reported by Pollick et al. (1994) do not support the primary conclusion of the report, namely that increased fluoridation of public water supplies and increased supplementation of fluoride in nonfluoridated areas are warranted. The differences in caries incidence (percentage of children with and without caries) with fluoridation status as reported by Pollick et al. (1994) are probably due to other factors, primarily economic status and presence or absence of dental sealants.

5. Responses to specific concerns

A series of specific concerns was submitted to me with the technical reports. These are listed below, together with my responses to them.

(1) Verification that the Oral Health Needs Assessment establishes that any or all subsets of the population are experiencing a deficiency of fluoride, or- that children under eight years old are not already getting the fluoridation objective of I mg/day of fluoride.

The California Oral Health Needs Assessment 1993-94, as reported by Pollick et al. (1994), does not quantify the fluoride exposure of children, either on an individual basis or on an average basis by regional fluoridation status. Source of residential tap water is used as a surrogate for fluoride exposure, but differences within or among regions are not addressed or established.

(2) Verification that the Oral Health Needs Assessment either establishes or takes into consideration total fluoride exposure from all sources.

The California Oral Health Needs Assessment 1993-94, as reported by Pollick et al. (1994), does not establish total fluoride exposure on an individual or average basis and does not consider all sources of fluoride exposure. Fluoridation status of residential tap water is considered, as is usage of fluoridate toothpaste and fluoride supplements. However, the latter (use of toothpaste and/or supplements) is addressed only in terms of percent usage in various groups, not in terms of any effect that it has or does not have on caries prevalence. Fluoride intake from other sources such as bottled soft drinks is not considered.

(3) Verification that the Oral Health Needs Assessment adequately addresses all alternative methods of delivering fluoride other than addition to the water supply.

The California Oral Health Needs Assessment 1993-94, as reported by Pollick et al., (1994), addresses alternative methods of delivering fluoride in terms of percent usage of selected methods (e.g., use of fluoridated toothpaste or fluoride supplements). It might not address all alternative methods, and it could possibly underrepresent use of fluoride rinses, etc., at dental visits if some parents did not specifically know that such rinses were used. The California Oral Health Needs Assessment 1993-94 does not address the effectiveness of these methods with respect to reduction of caries incidence. It does quote *Healthy People 2000* to say that water fluoridation is the single most effective and efficient means of preventing dental caries in children and adults".

(4) Verification that the Oral Health Needs Assessment adheres to Bradford Hill's Principles of Medical Statistics--"... in order to eliminate bias the sample studied must be representative of the total population from which it is drawn. " Verification that the Oral Health Needs Assessment is in compliance with contract (Exhibit B-1) that establishes the sample is to be as representative of the general population as possible. Verification that the sample is representative of geographical area, age, educational status, racial composition, poverty, level, lifetime residency, and dental sealants.

Regarding Bradford Hill's principles, for statistical inference about a population, the sample should be randomly and independently selected and large enough if it is to be representative of the population. The California Oral Health Needs Assessment 1993-94 reports indicate that the sample is not representative with respect to randomness or to distribution across races, economic levels, geographic regions, etc., nor were the data collected blindly, that is, without knowledge of a child's fluoridation status. The sample is representative in the sense that large enough samples of most major population subgroups were obtained-i.e., no major subgroup was omitted. However, due to lack of randomness and other shortcomings, the sample data cannot be statistically manipulated to give valid estimates of population characteristics. Rather, different methods are needed that account subjectively for incomplete or only partially relevant data to

[42] "Executive Summary," p. 1; "Findings and Recommendations," p. 1 (both citing USDHHS, 1991, p. 3571.

produce what are known as subjective confidence intervals. These data could be useful at least to give a "worst-case" estimate and to evaluate such things as correlations (or lack thereof) between

caries prevalence and such factors as total fluoride exposure; use of fluoridated toothpaste or fluoride supplements, Baby Bottle Tooth Decay, use of dental sealants, and history of dental visits, or between Baby Bottle Tooth Decay and various infant feeding practices.

Regarding compliance with the contract, if the samples, which were to an extent self-selected, are thought to be biased toward perceived need for dental work43, then they are not statistically valid in the sense of obtaining "reliable oral health status data" for the relevant groups. While useful information can still be obtained, purely statistical estimates of population status would have to be considered suspect.

(5) The question of prejudice in awarding a contract (without competitive bids) to an organization whose founding purpose is to promote the very solution being recommended.

This area is properly the concern of the funding agency or an entity such as the state legislature that oversees the funding agency. Typically in my experience (more with federal than with state agencies), contracts above some minimum size (often $25,000) must be competitively bid, unless the agency can make a very good case (based on extremely specialized expertise or familiarity with a given situation) for awarding a sole-source contract. The question of independence (objectivity, absence of conflict of interest) should also be the concern of the funding agency or state legislature. If the intent is to seek facts, rather than to support an opinion, independence is a necessity. At the very least, if a contracting organization's independence is in question, having a balanced oversight or review panel can help promote objectivity in a study.

(6) The question of bias and conflict of interest by author R. Isman who, while under indictment with the Oregon State Supreme Court for election code violations concerning an Oregon fuoridation ballot issue, became California's State Dental Director, and in his new position admits to using the DHF "...to do the business of the State, " and became author, planner, as well as critical reviewer of the study used to lobby AB733 through the CA State Legislature.

Critical review of a major study should always be carried out independently of the funders or investigators; otherwise its utility is compromised. Persons involved with a funding agency should not normally be involved in the work funded. The report by Pollick et al. (1994) lists Robert Isman as an author, and in the Acknowledgments lists him as the State Dental Director and acknowledges his efforts in planning and critical review. The DHF report (1997) lists him as a State of California consultant. A strict definition of conflict of interest requirements might be limited to whether or not Dr. Isman was paid by The Dental Health Foundation; specific instances of suspected conflict of interest are properly the area of the funding agency and the state

[43] "Study Design," p.13

legislature. However, in general, perception of conflict of interest compromises the **c**redibility of a project.

(7) The question of bias and conflict of interest given that the CA State Department of Health Services and The Dental Health foundation, awarder and contractor of the Oral Health Needs Assessment, respectively, are integral members of the CA Fluoridation Task Force, an advocacy coalition established to promote fluoridation.

This issue is properly the area of the state legislature. If the state wants factual answers to its questions, whatever those answers may be, then independence is essential. Additionally, having an analysis carried out by two or more independent groups of investigators can help to ensure the credibility of a study.

(8) The widespread public use of the results of the draft report, even though not published or peer-reviewed in the six years since its completion-- "The Committee will explore ways to utilize the Oral Health Needs Assessment Report's findings ....; assist in developing strategy to present the information to the public prior to peer review. " Dec. 3, 1994, Fluoridation Task Force minutes.

There is a certain risk involved in relying too heavily on results of a study that has not been properly peer-reviewed (e.g., see NRC, 1999). Risks include making decisions on an inadequate basis, making wrong decisions, misallocating resources (e.g., taxpayers' money), and having to back down on statements made prematurely or with too much confidence. I am in favor of disclosing preliminary results in major studies, in the interest of openness with the public, but such disclosure must emphasize the preliminary nature of the results, the potential for the findings to change, and the types of information still needed. I am also in favor of thorough and independent peer reviews being part of major studies (as well as analysis by two or more investigators when possible); such review helps to ensure overall credibility of a study, to make sure that important details are not missed, to maintain the integrity of the investigators and the funding or oversight agencies, and to promote responsible use of resources.

(9) The question of whether the CA Oral Health Needs Assessment was performed in full compliance with the Contract and Scope of Work (including omission of final report).

This is properly the area of the funding agency and the state legislature. The scope of work in the contract does specify a final report, but to my knowledge only the draft report (Pollick et al., 1994) was completed. The DHF report (DHF, 1997, reference #8 on p. 24) lists a report by Pollick et al., published by the DHF in 1997, with the same title as Pollick et al. (1994). It is not known to me whether the reports are substantially different.

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