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AD HOC COMMITTEE

REPORT ON

DENTAL FLUOROSIS

July 21, 1982

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AD HOC COMMITTEE ON DENTAL FLUOROSIS:
DRAFT REPORT TO THE CHIEF DENTAL OFFICER, PHS

I. Introduction

In 1946, the PHS published guidelines in the form of drinking water standards that set an upper limit of 1.5 ppm for fluoride, presumably to avoid objectional fluorosis on the basis of data from Dean's studies. In 1962, the revised PHS drinking water standards raised the upper limit for fluoride to twice the local optimum concentration (1). The exact reasons for that change are not available to the committee, but this guideline was still clearly intended to limit the occurrence of dental fluorosis that was of only cosmetic significance.

The Safe Drinking Water Act (P.L. 93-523), passed in 1974, directed the EPA to promulgate primary drinking water regulations for limiting contaminants that might "have any adverse effect on the health of persons" (2). The EPA included fluoride under this health effect category and adopted the twice-optimum upper limit (now "maximum contaminant level") from the 1962 standards (3).

The U.S. Environmental Protection Agency (EPA), under a provision of the Safe Drinking Water Act, 42 U.S.C. 300f, has promulgated regulations which in part require all communities with water supplies naturally containing fluoride in excess of twice the optimum concentration to lower the fluoride content of their water (2,3). A 1980 amendment has extended the exemptions from compliance with this requirement until January 1, 1984, or until January 1, 1986, if the water system in question agrees to comply with the regulations by becoming a part of a regional water system.

On June 4, 1981, the South Carolina Department of Health and Environmental Control, pursuant to the Administrative procedure Act, 5 U.S.C. 553(c), filed a petition requesting the EPA to exercise its rulemaking authority to repeal 40 CFR 141.11(c), that portion of the National Interim Primary Drinking Water Regulations establishing Maximum Contaminant Levels (MCLs) for fluoride. The Adminstrator of EPA acknowledged receipt of the petition and agreed to consider the petitioners request as part of the process of developing Revised National Primary Drinking Water Regulations (4).

As a result of the South Carolina petition, the EPA offered an accelerated review of the fluoride limit to be completed by August 1982 (15). The review is to be carried out in cooperation with the Office of the Surgeon General, Public Health Service, the American Dental Association, and other interested parties.

The purpose of this Committee is to review current scientific data related to the effects of fluoride ingested through drinking water and provide advice to the EPA on the validity and significance of these data relative to dental fluorosis.

II. Health considerations of fluoride ingestion

A. Effect on general health

Investigations comparing morbidity and mortality rates between fluoridated and non-fluoridated areas are numerous. In one comprehensive study carried out in 1954, persons exposed to 8.0 ppm of naturally occurring fluoride present in the drinking water of Bartlett, Texas, were compared with a similar group of individuals exposed to 0.4 ppm naturally occurring fluoride in the drinking water of Cameron, Texas, 25 miles from Bartlett. Except for a higher incidence of dental fluorosis in Bartlett, the findings showed no significant differences in morbidity for a wide range of systemic abnormalities (5). Comparative mortality rates were studied in 1961 in 18 selected fluoridated and non-fluoridated Canadian communities at the request of the Ontario Committee of Inquiry. The Committee concluded "...the mortality rates under consideration are not influenced by the fluoride concentration of the water supply (6). In an exhaustive review of the subject, the Report of the Royal Commissioner into the fluoridation of Public Water Supplies, Hobart, Tasmania concluded in 1968 "the studies referred to (in the report) do not support any suggestion that fluoridation has or could have an adverse effect on morbidity or mortality (7).

B. Effect on dental health

1. Fluoride ingestion at optimum concentration

Fluoridation of community water supplies to the recommended concentration has been firmly established as a safe and effective public health measure for the prevention of dental caries. The procedure has consistently been demonstrated to reduce the prevalence of dental caries by approximately 50 to 65 percent (8-12). Extensive investigations have been carried out to determine what constitutes an optimum concentration of fluoride for a community water supply. Foremost among these investigations was the classic 21-city study reported by Dean in 1946 (13). The water supplies of the cities contained naturally-occurring fluorides at concentrations ranging from zero to 2.6 parts per million (ppm). Dean concluded from these data that a fluoride concentration of about 1.0 ppm constituted an optimum amount. This optimal concentration is generally defined as that concentration which concomitantly provides maximal protection against dental caries consistant with minimal dental fluorosis. With only two exceptions, the 21 cities surveyed by Dean were located within a confined geographic area (the midwest). Later work by Galagan and his co-workers demonstrated that the optimum fluoride concentration varied from one geographic area to another, depending on annual average maximum daily air temperature

(14-16). Temperature influenced fluid intake and, hence, the amount of fluoride ingested. Galagan and Vermillion provided a table of recommended optimum fluoride concentrations, ranging from 0.7 ppm in the warmest temperature zones of the United States to 1.2 ppm for the coldest temperature zones (17).

2. Summary of studies of fluoride ingestion at higher-than optimum concentration:
(a) Fluorosis findings

Water fluoride concentrations ranging from about optimum to less than 2 times optimum:

The percentages of children showing moderate fluorosis ranged from about 1 percent to about 13 percent. Most studies showed about 3 percent or less.

The percentages of children showing severe fluorosis ranged from zero to about 3 percent.

Water fluoride concentrations ranging from 2 times optimum to less than 3 times optimum:

The percentages of children showing moderate fluorosis ranged from about 4 percent to about 16 percent.

The percentages of children showing severe fluorosis ranged from zero to about 5 percent.

Water fluoride concentrations ranging from about 3 times optimum to less than 4 times optimum:

The percentages of children showing moderate fluorosis ranged from about 5 percent to about 34 percent.

The percentages of children showing severe fluorosis ranged from zero to about 8 percent. Most studies showed about 3 percent or less.

Water fluoride concentrations ranging from about 4 times optimum to less than 5 times optimum:

The percentages of children showing moderate fluorosis ranged from 6 percent to 40 percent. Most studies showed about 20 percent or more.

The percentages of children showing severe fluorosis ranged from zero to about 23 percent.

Water fluoride concentrations of about 5 times optimum and above:

The percentages of children showing moderate fluorosis ranged from about 11 percent to about 50 percent.

The percentages of children showing severe fluorosis ranged from about 18 percent to about 58 percent.

It is not likely, nor is there evidence to show, that cosmetic changes in the appearance of the tooth are in any way harmful to the tooth. These changes range from scarcely noticable color change to pitting of the enamel surface. Depending on the fluoride concentration of the water and certain other factors such as individual susceptibility and amounts of water ingested during the calcification stage of tooth development, the pits may appear as isolated single pits, or as areas of multiple confluent pits. The presence of increasing degrees of confluent pitting results in the loss of progressively larger areas of enamel until, ultimately, the entire enamel surface has a corroded appearance and may present an altered morphological shape. Such extensively involved teeth are subject to greater than normal surface attrition.

(b) Caries prevalence findings*
Table 2 presents mean DMF tooth and surface scores for the children, according to water fluoride level. For DMF teeth, the mean score at the optimum fluoride level was 2.17 DMFT per child. By comparison, the scores at all three higher than optimal levels were substantially lower. Scores at 2 and 4 times optimal were similar, at 1.38 and 1.49 DMFT per child, respectively. The lowest score, 1.02 DMFT per child, occurred among children at the 3X optimal level. With regard to DMF surfaces, the relationship in the size of the scores among the various water fluoride levels was the same as that for DMF teeth. The mean DMFS score at the optimal fluoride level was 3.14 per child, whereas, at the fluoride levels of 2,3 and 4 times optimal, the respective scores were 1.97, 1.41 and 2.02 DMFS per child. Statistical comparisons between all pairs of DMFT and DMFS scores were made, using Scheffe's method for multiple comparisons. This analysis showed that, for both DMFT

and DMFS, the caries scores at all three higher than optimal fluoride levels were significantly lower than the score at the optimal level. However, none of the differences in scores among the higher than optimal fluoride groups were statistically significant, even though scores for both DMFT and DMFS at 3 times optimum were noticeably lower than the corresponding scores at 2 and 4 times optimum.

With regard to the findings of other investigators on the relationship between fluoride concentrations in drinking water and the prevalence of dental caries, Dean reported that there was little if any additional reduction in dental caries at fluoride concentrations above the optimum (13). More recent reports, however, are in agreement with the NIDR findings in that caries preventive benefits are realized from consuming water containing fluoride at higher than the recommended optimum concentrations (18-22). Some data indicate that children with severe dental fluorosis have a higher prevalence of dental caries when compared with children having lesser degrees of dental fluorosis (23,24). However, because of the limited data available, it is not clear whether or not the caries prevalence of children with severe fluorosis continues to be lower than that of children who consume optimally fluoridated water.

C. Psychological effects

Few people would disagree that the cosmetic effects of dental fluorosis become progressively less desirable as the fluoride concentration exceeds the recommended optimal level. However, the point at which the effects become cosmetically undesirable, and ultimately become unacceptable, is a highly subjective issue and is one that would undoubtedly vary greatly from community to community and from individual to individual depending upon how the residents perceive the condition. The committee found no controlled studies that evaluated the psychological effects of dental fluorosis.

III. Conclusions

A. An optimum concentration of fluoride in drinking water is best defined as that concentration which provides the highest level of protection against dental caries consistent with a minimal prevalence of clinically observable dental fluorosis.

B. The traditional method that takes into account the effect of air temperature on water consumption for estimating optimum fluoride concentrations remains scientifically valid. Standards established by that method specify optimum concentrations of fluoride ranging from 0.7 to 1.2 ppm. for various geographic areas within the U.S. depending on the annual average of the maximum daily air temperatures.

C. It has been well documented that persons born and reared in communities with optimum concentrations of fluoride in their drinking water supplies have on an average 50 to 65 percent less dental caries than persons reared in communities with lower fluoride levels in their drinking water.

D. No sound evidence exists which shows that drinking water with the various concentrations of fluoride found naturally in public water supplies in the U.S. has any adverse effect on general health.

E. No sound evidence exists which shows that drinking water with the various concentrations of fluoride found naturally in public water supplies in the U.S. has any adverse effect on dental health as measured by loss of function and tooth mortality.

F. Some data indicates that children with severe dental fluorosis have a higher prevalence of dental caries when compared with children having lesser degrees of dental fluorosis (23,24). However, because of the limited data available, it is not clear whether or not the caries prevalence of children with severe fluorosis continues to be lower than that of children who consume optimally fluoridated water.

G. As the natural fluoride concentration in water supplies increases beyond the recommended optimum, an increasing percentage of individuals exhibit dental fluorosis which may range from scarcely noticeable color change to confluent pitting of the enamel surface. Although conspicuous color changes definitely warrant concern, whether and to what extent these changes are considered cosmetically objectionable is subjective, varying by individual and community.

H. Overall, data suggest that at fluoride concentrations in drinking water as great as three times optimum, dental fluorosis is largely limited to color changes. At the fluoride concentration of four times optimum, some data suggest a marked increase in the prevalence of severe fluorosis, whereas other data indicate that the prevalence of severe fluorosis continues to be low. Because of the equivocal nature of the data at four times optimum, the dose-response curve for severe fluorosis between three and four times the optimum has not been clearly defined.

I. To minimize the occurrence of undesirable cosmetic effects, it is most prudent to maintain the upper limit of fluoride in drinking water at two times the recommended optimum concentration.

In its deliberations the committee noted that additional research is needed to further clarify the dose-response relationship at fluoride concentrations exceeding approximately 3 times the recommended optimum. The committee recognized that much of the research to date on dental effects has focused upon childhood populations and feels that more information is needed to clearly define any later dental consequences among adults of the use of water with high concentrations during the years of tooth development.

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