

Evidence Supporting the 2011 “Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries”

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Pittsburgh, PA, April 11, 2011



Objective of this Presentation

To summarize the evidence used in the deliberation of the scientific panel for the:

“Proposed HHS Recommendation for Fluoride Concentration for Drinking Water for Prevention of Dental Caries”

Available at:

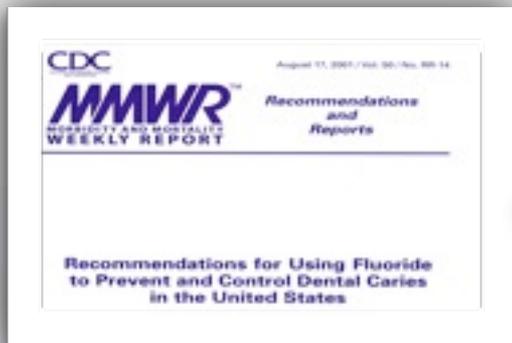
<http://www.hhs.gov/news/press/2011press/01/20110107a.html>

<http://www.gpo.gov/fdsys/pkg/FR-2011-01-13/pdf/2011-637.pdf>

Period for public comments extended until April 15, 2011

Timeline

2001

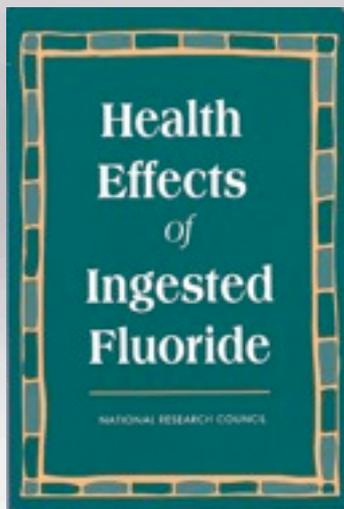


2006-9 CDC
F Expert
Panel

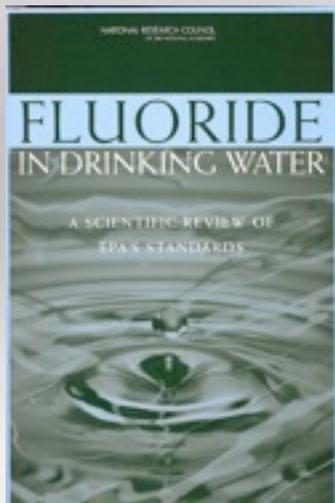
2010 HHS
Panel

2011 HHS
Proposed
Recommendations

1993



2006



2010 August
HHS-EPA
Scientific
Review and
Discussion

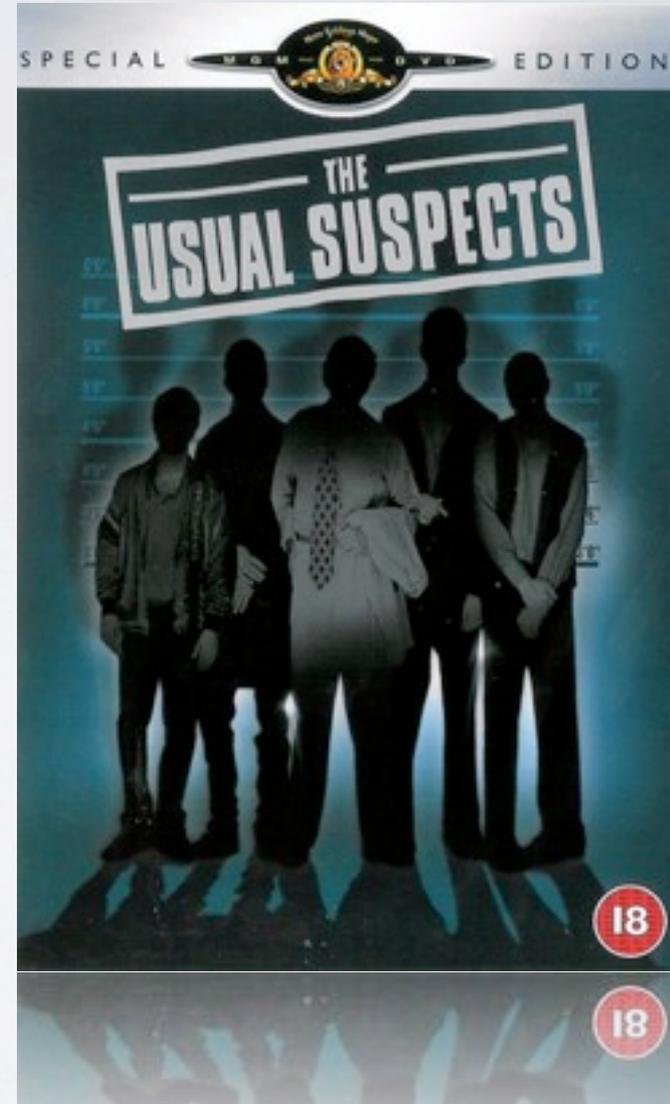
EPA's D-R
and RC
Research

2011 EPA
D-R and RC
Publications

“The current method of determining the optimal concentration of fluoride in community drinking water, which depends on the average maximum annual ambient air temperature, should be reevaluated because of the social and environmental changes that have occurred since it was adopted in 1962.....Such research will either validate the current method for determining optimal fluoride concentration... or indicate improved methods” (page 29)

CDC FLUORIDE EXPERT PANEL

- Brian Burt
- Jay Kumar
- Steve Levy
- Jane McGinley
- Howard Pollick
- Gary Rozier
- John Stamm
- Gary Whitford



HHS FEDERAL PANEL ON FLUORIDE

- Peter Briss (Chair)
- Laurie Barker (CDC)
- Eugenio Beltrán (CDC)
- Mary Beth Bigley (OSG)
- Linda Birnbaum (NIEHS)
- John Bucher (NTP)
- Amit Chattopadhyay (NIDCR)
- Joyce Donahue (EPA)
- Elizabeth Doyle (EPA)
- Isabel García (NIDCR)
- Barbara Gooch (CDC)

- Jesse Goodman (FDA)
- J Nadine Gracia (HHS)
- Susan Griffin (CDC)
- Laurence Grummer-Strawn (CDC)
- Jay Hirschman (USDA)
- Frederick Hyman (FDA)
- Timothy Iafolla (NIDCR)
- William Kohn (CDC)
- Richard Manski (AHRQ)
- Benson Silverman (FDA)
- Thomas Sinks (ATSDR)

SUMMARY: The Department of Health and Human Services (HHS) seeks public comment on proposed new guidance which will update and replace the 1962 U.S. Public Health Service Drinking Water Standards related to recommendations for fluoride concentrations in drinking water. The U.S. Public Health Service recommendations for optimal fluoride concentrations were based on ambient air temperature of geographic areas and ranged from 0.7–1.2 mg/L.

HHS proposes that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level. For the purpose of this guidance, the optimal concentration of fluoride in drinking water is that concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. Community water fluoridation is the adjusting and monitoring of fluoride in drinking water to reach the optimal concentration (Truman BI, *et al*, 2002).

This updated guidance is intended to apply to community water systems that

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The U.S. Public Health Service has provided recommendations regarding optimal fluoride concentrations in drinking water from community water systems (CWS)² for the prevention of dental caries (US DHEW, 1962). HHS proposes to update and replace these recommendations because of new data that address changes in the prevalence of dental fluorosis, fluid intake among children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. As of December 31, 2008, the Centers for Disease Control and Prevention (CDC) estimated that 16,977 community water systems provided fluoridated water to

fluoridation and use of other fluoride-containing products.

Recommendation

HHS proposes that community water systems adjust their fluoride content to 0.7 mg/L [parts per million (ppm)].

Rationale

Importance of community water fluoridation:

Community water fluoridation is a major factor responsible for the decline of the prevalence and severity of dental caries (tooth decay) during the second half of the 20th century. From the early 1970's to the present, the prevalence of dental caries in at least one permanent tooth (excluding third molars) among adolescents, aged 12–17 years,³ has decreased from 90% to 60% and the average number of teeth affected by dental caries (*i.e.*, decayed, missing and filled) from 6.2 to 2.6 (Kelly JE, 1975, Dye B, *et al*, 2007). Adults have also benefited from community water fluoridation. Among adults, aged 35–44 years,⁴ the average number of affected teeth decreased from 18 in the early

Evidence Reviewed by the HHS Panel

- Historical aspects of water fluoridation:
 - Determining 1 ppm as the optimal fluoride level.
 - 1962 USPHS Optimal Fluoride Recommendations.
- Prevalence, severity and trends of dental fluorosis in the U.S.
- Effectiveness of water fluoridation
- Evidence for continuing an ambient temperature-based recommendation (fluid intake)
- Dental caries and dental fluorosis
- EPA studies on dose-response and relative contribution
- Effects on dental caries of reducing/eliminating water fluoridation on dental caries and fluorosis

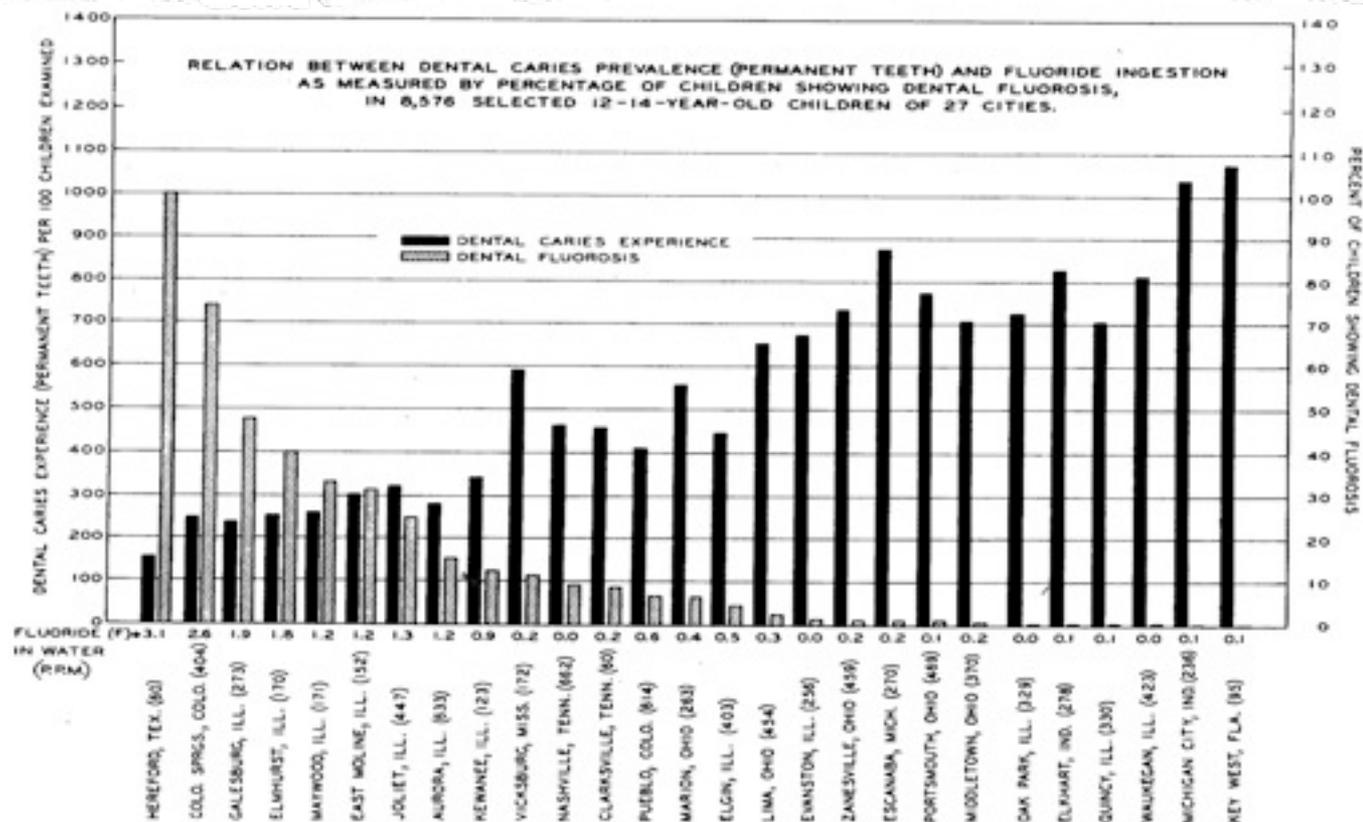


FIGURE 2. Dental caries experience of permanent teeth related to endemic dental fluorosis. (Unpublished data from the files of H. Trendley Dean.)

“The minimum threshold [for enamel fluorosis] has not yet been definitely established but studies to date would suggest that amounts below 1 p.p.m., expressed in terms of fluoride (F), are of no public health significance.”

Dean & Elvove. Some epidemiological aspects of chronic endemic dental fluorosis. Public health reports
1936

“Strikingly low dental caries prevalence was found associated with the continuous use of domestic waters whose fluoride (F) content was as low as about 1 part per million, a concentration which under the conditions prevailing in the localities studies produced only sporadic instances of the mildest forms of dental fluorosis of no practical esthetic significance.”

Dean HT, Arnold FA Jr, Elvove, E. Domestic water and dental caries experience in 4,425 white children, aged 12 to 14 years of 13 cities in 4 states. Pub Health Rep 1942, 57:1155-79.

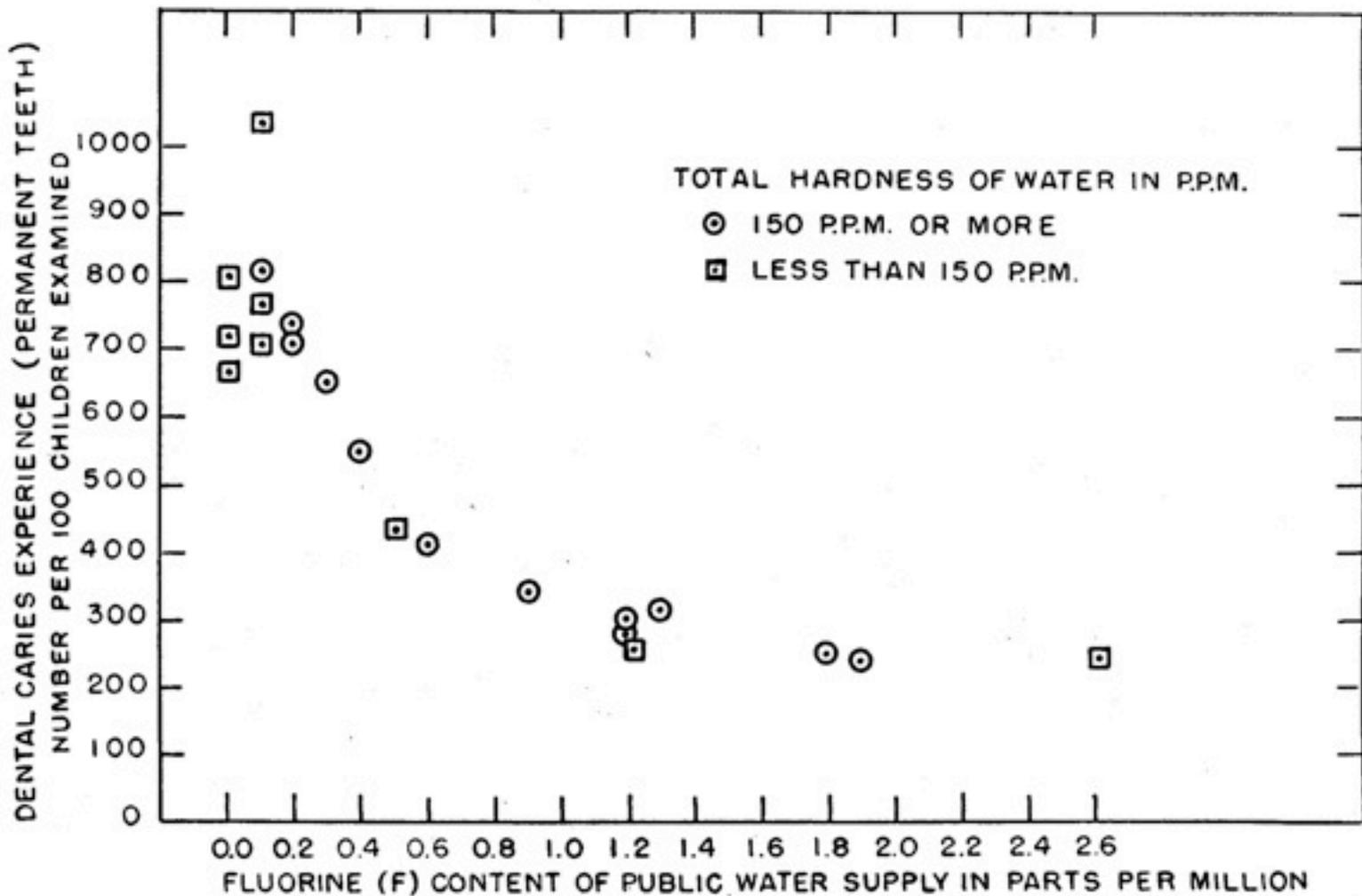
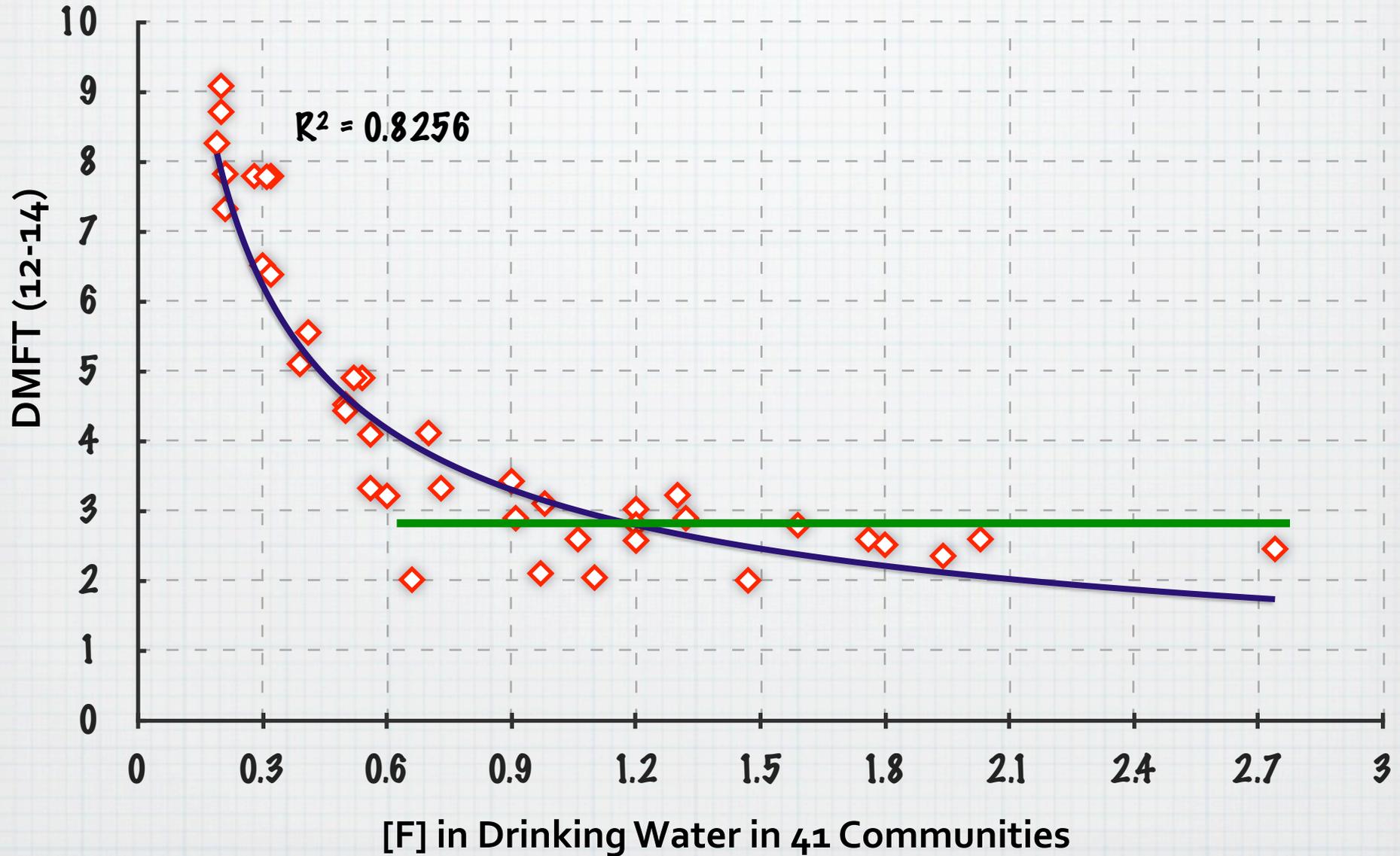


FIGURE 1. Variation in dental caries experience rates observed in 7,257 selected white school children, aged 12-14 years, in 21 cities of four states, according to fluoride concentration and hardness value of the public water supply. (Dean¹⁶)

Mean DMFT by F levels in Drinking Water in the 1950s

Dean + Eklund & Striffler



Galagan and Vermillion, 1957

that for every degree increase in maximum daily temperature between 50° and 100° F. water intake increased, on the average, by 0.062 ounces per pound of body weight. For example, the aver-

The relationship between maximum temperature and water intake for the California children was described by the estimation equation "ounces of water per pound of body weight = $-0.038 + 0.0062 \text{ temperature}$." The validity of this equation should perhaps be checked by studies in other areas of the country, but in the meantime it can be used to illustrate the calculation of optimum fluoride concentrations. As will be

U.S. Public Health Service Drinking Water Standards (1962)

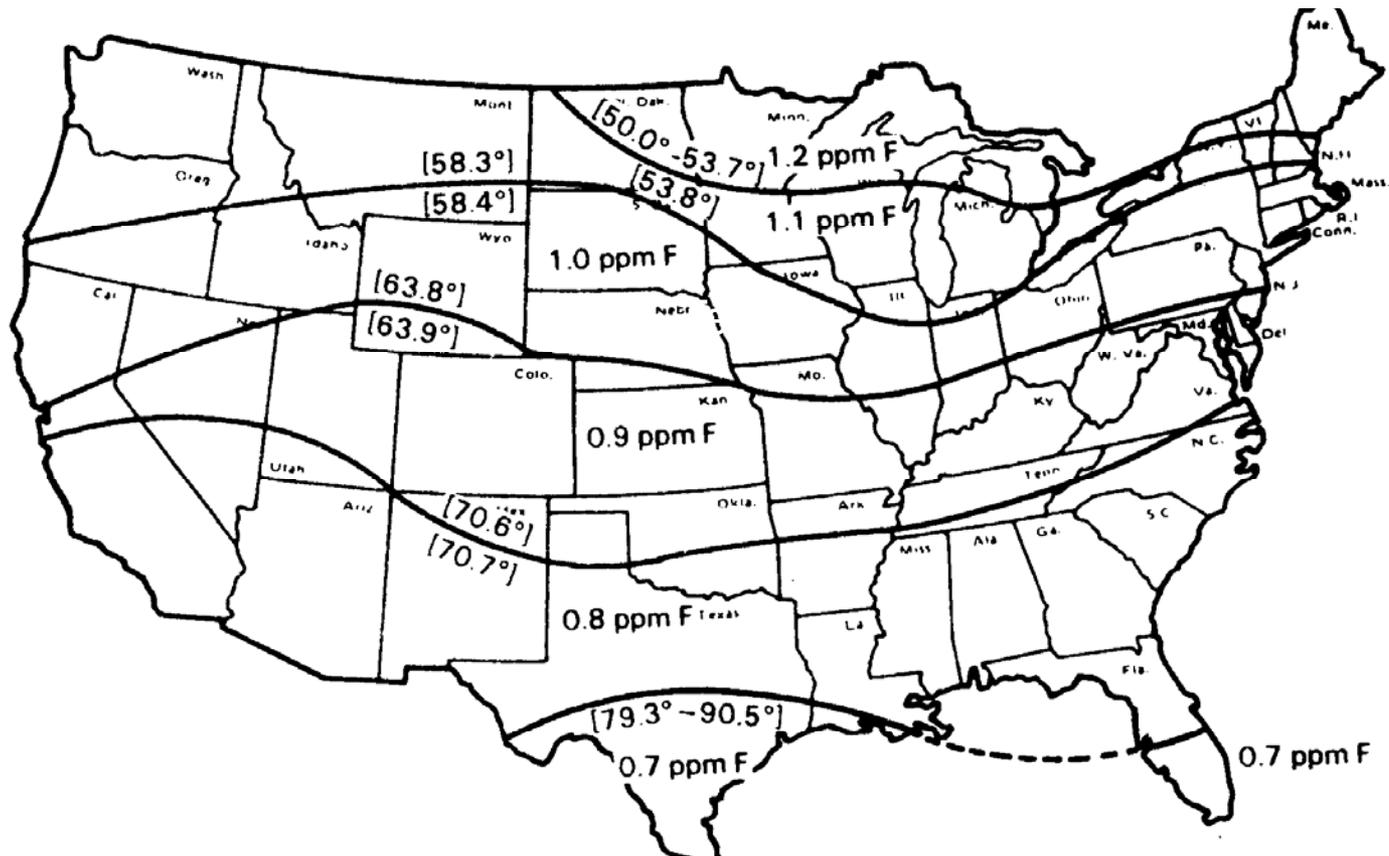
TABLE 1.

Annual average of maximum daily air temperatures ¹	Recommended control limits— Fluoride concentrations in mg/l		
	Lower	Optimum	Upper
50.0-53.7	0.9	1.2	1.7
53.8-58.3	0.8	1.1	1.5
58.4-63.8	0.8	1.0	1.3
63.9-70.6	0.7	0.9	1.2
70.7-79.2	0.7	0.8	1.0
79.3-90.5	0.6	0.7	0.8

¹ Based on temperature data obtained for a minimum of five years.

¹ Based on temperature data obtained for a minimum of five years.

U.S. Public Health Service Drinking Water Standards (1962)

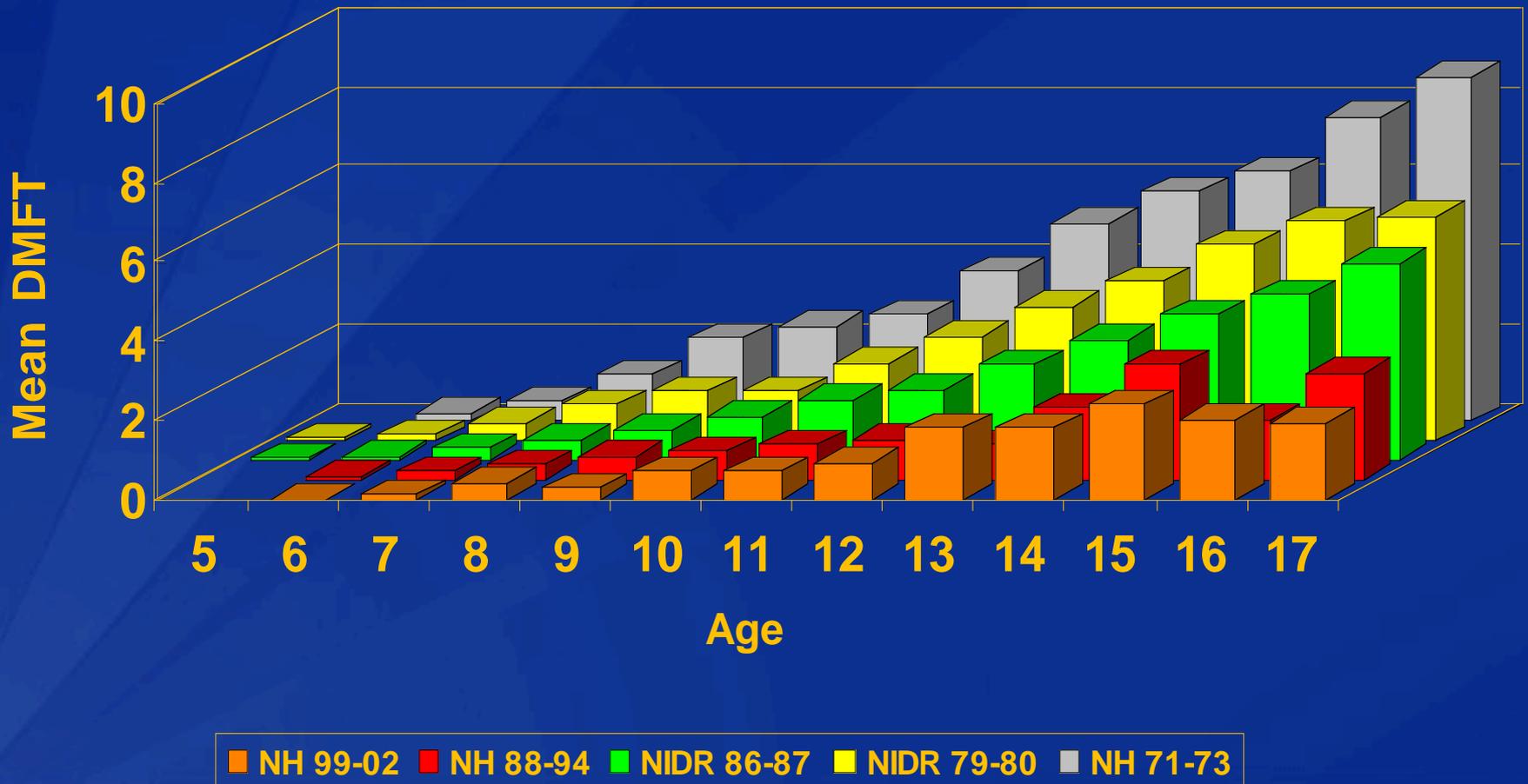


EFFECTIVENESS OF WATER FLUORIDATION

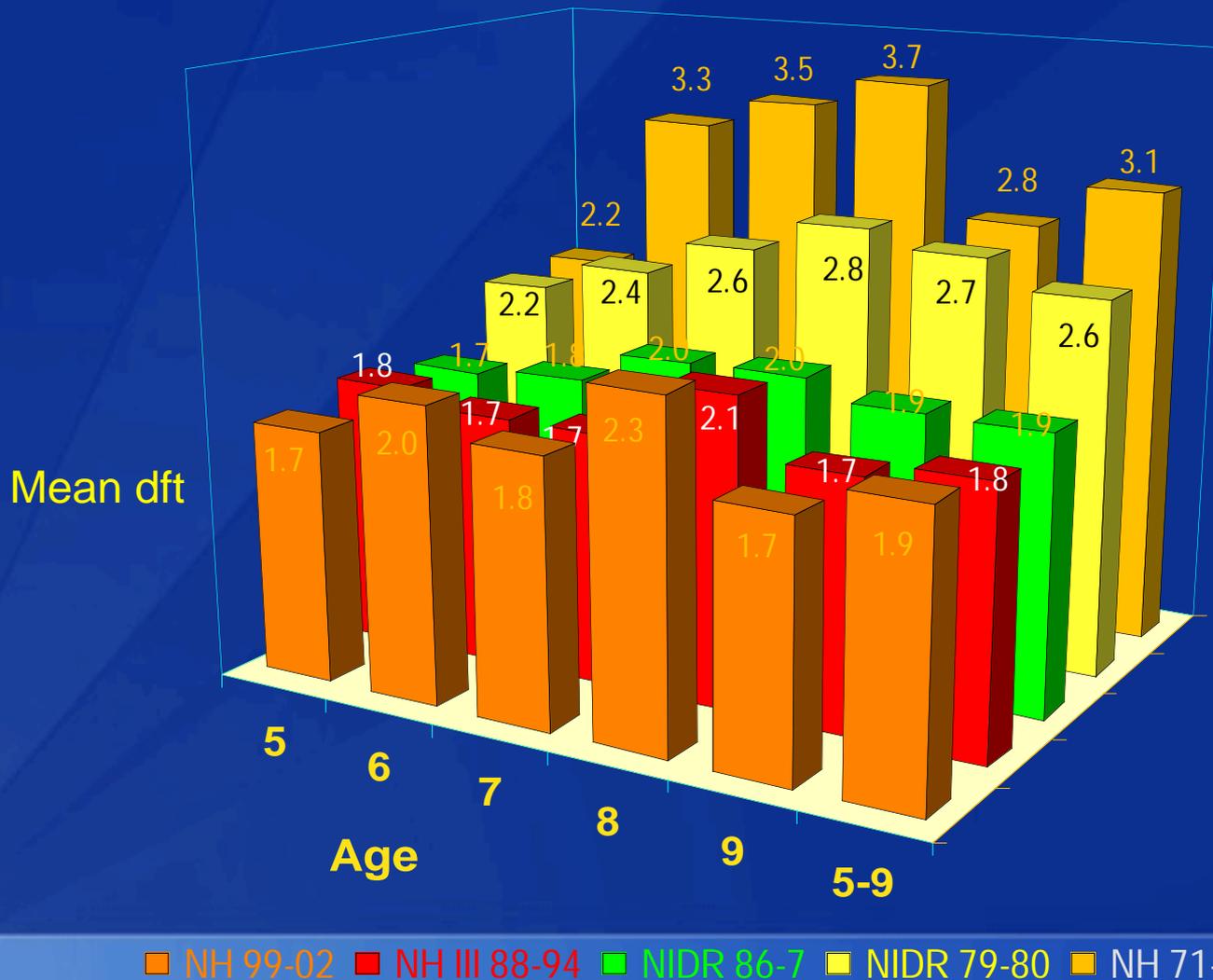
Reviews on Effectiveness

Reviews	# studies	Outcome	Other
“York”	26	Median diff=14.6% Median diff DMF=2.25	Effectiveness observed after 1974
Community Guide	21	Pre-post: Me=-29.1% (-110.5 to 66.9) Post only: Me=-50.7% (- only) Stop WF: Me=17.9% (-42.2 to 31.7)	
Griffin et al 2008	9	PF (5)=27.2% (95%CI 19.4-34.3)	Adults also

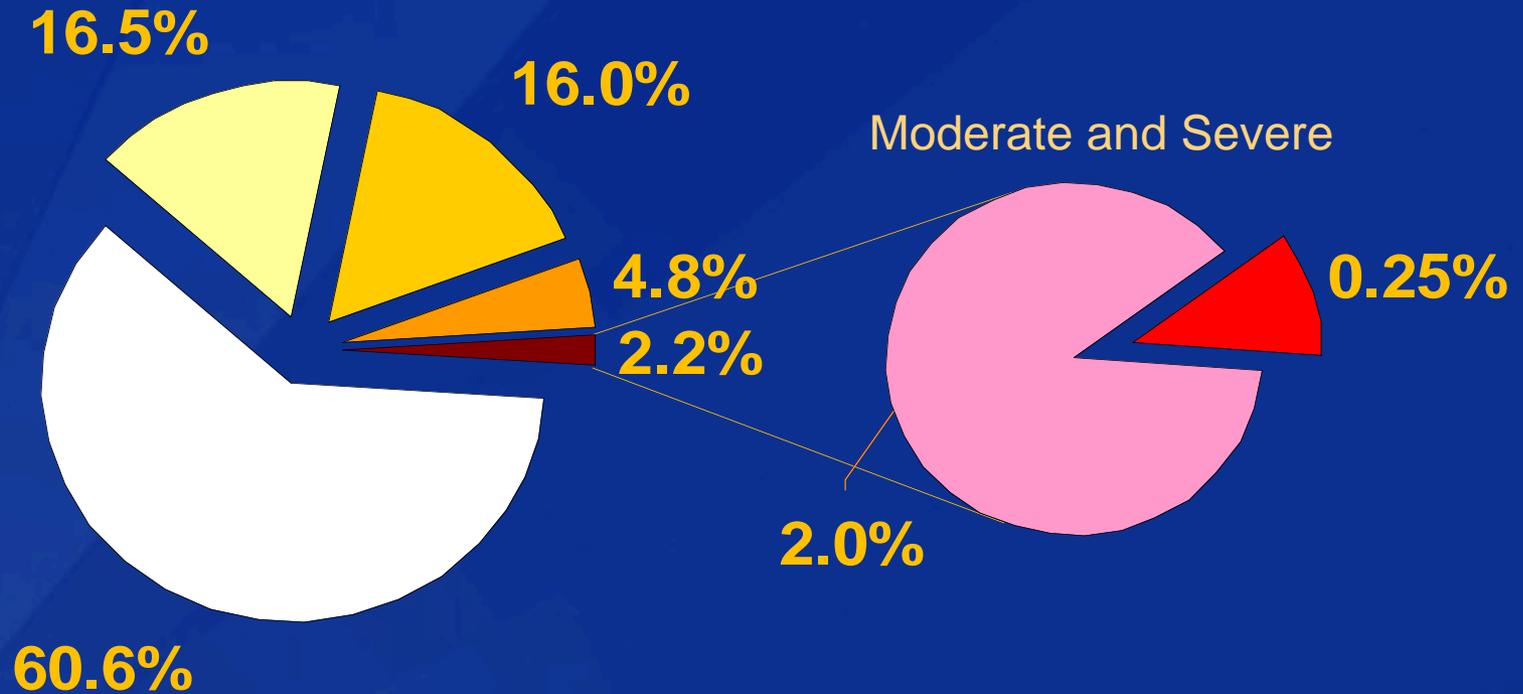
Trends in Dental Caries Prevalence in the Permanent Dentition (DMFT). United States, 1970s to 1990s



Trends in Dental Caries in the Primary Dentition (dft). United States, from 1970s to 1980s



Enamel Fluorosis in the United States Among Participants Aged 6-49 Years, NHANES 1999-2004



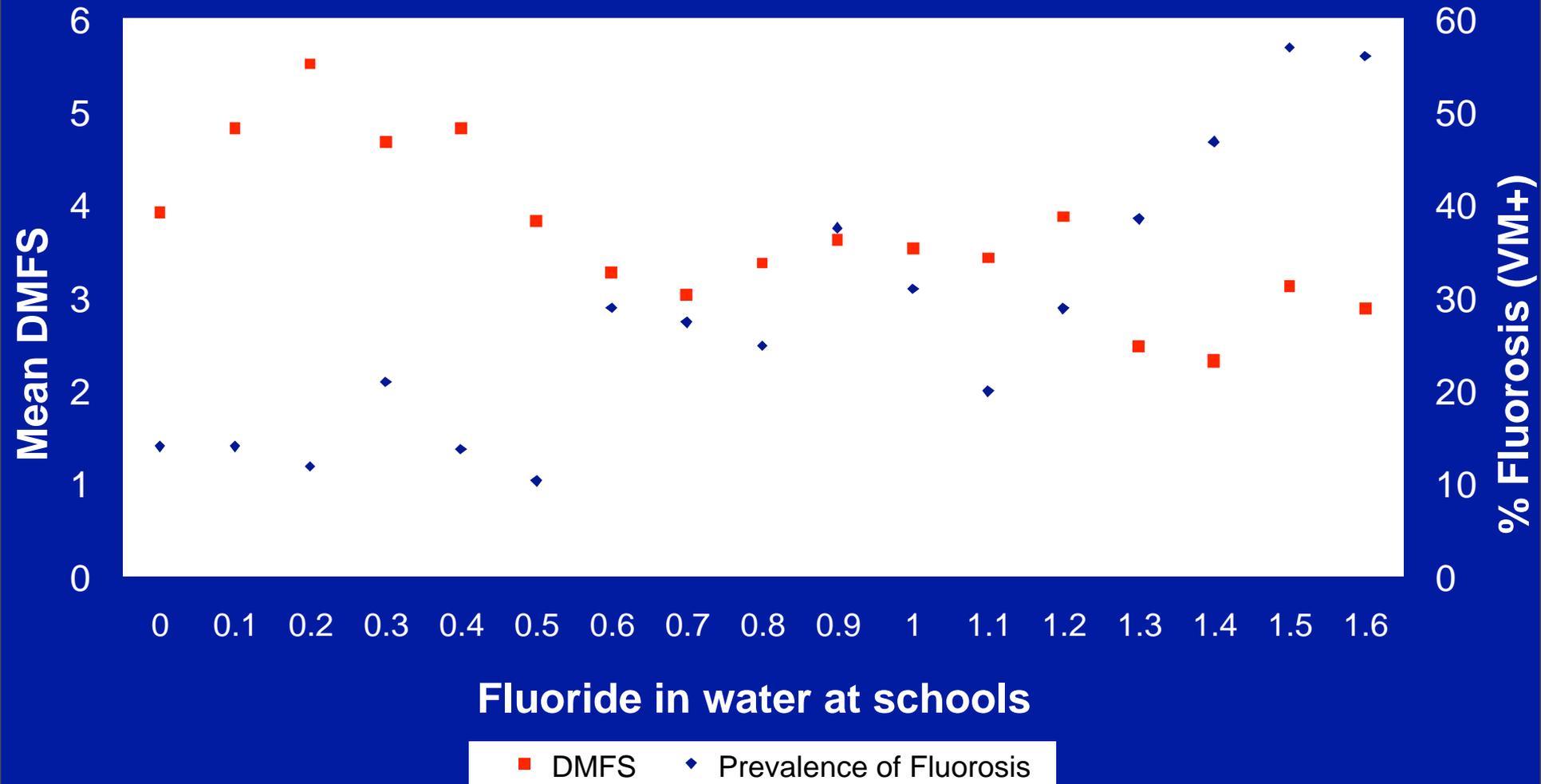
■ Unaffected ■ Questionable ■ Very Mild ■ Mild ■ Moderate ■ Severe

Prevalence and Severity of Enamel Fluorosis (Dean's Fluorosis Index) Among School Children Aged 12-14 years in the 1930s in Seven Communities Studied by Dean

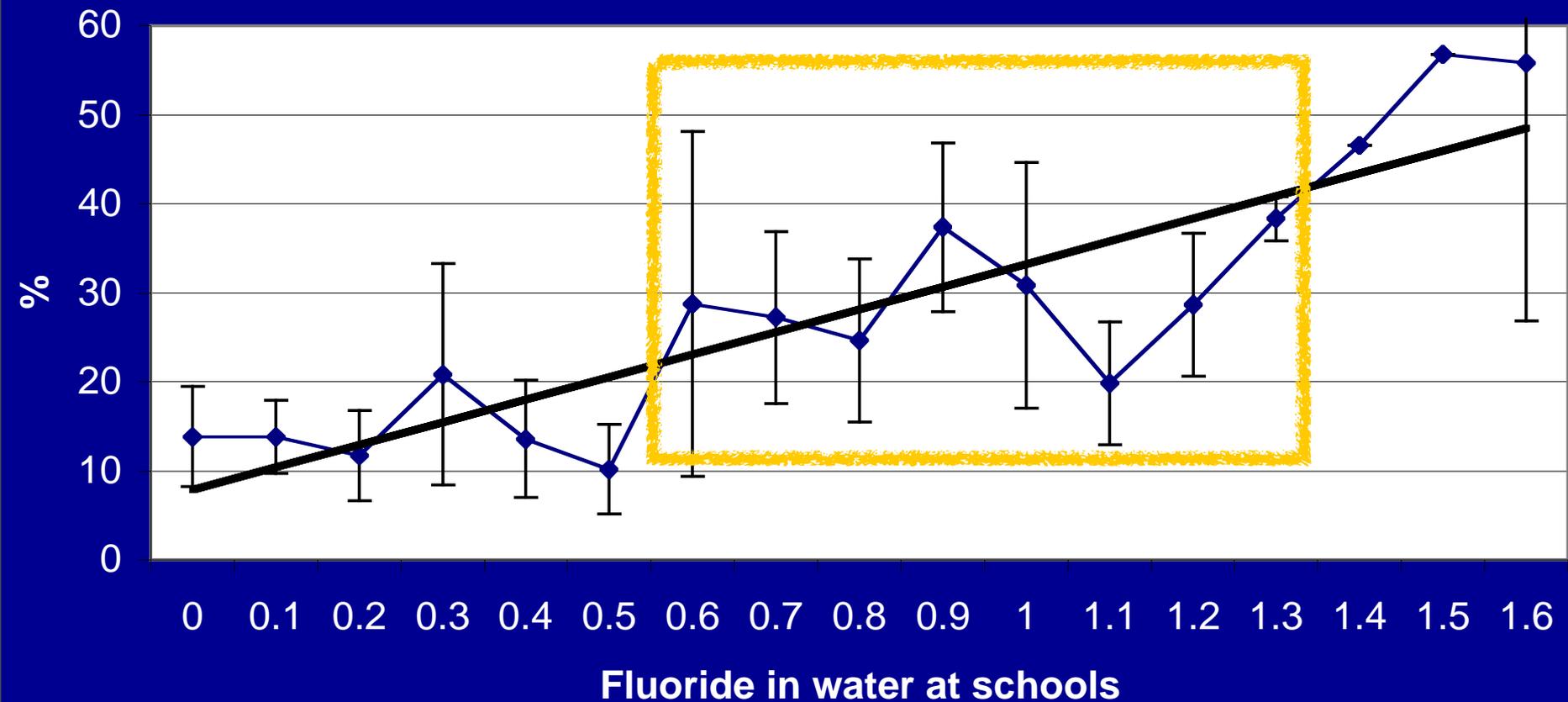
	Pueblo, CO	Kewanee, IL	Aurora, IL	Joliet, IL	Maywood, IL,	Elmhurst, IL	Galesburg, IL
[F] in water	0.6-0.7	0.9	1.2	1.2-1.3	1.4	1.8	1.9
Sample size	614	123	633	447	171	170	273
Dean's Index:							
Unaffected	72.3%	52.8%	53.2%	40.5%	39.2%	28.2%	25.3%
Questionable	21.2%	35.0%	31.8%	34.2%	27.5%	31.8%	27.1%
Very mild	6.2%	10.6%	13.9%	22.2%	29.2%	30.0%	40.3%
Mild	0.3%	1.6%	1.1%	3.1%	4.1%	8.8%	6.2%
Moderate	0.0%	0.0%	0.0%	0.0%	0.0%	1.2%	1.1%
Severe	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Questionable to Severe	27.7%	47.2%	46.8%	59.5%	60.8%	71.8%	74.7%
Very mild to severe	6.5%	12.2%	15.0%	25.3%	33.3%	40.0%	47.6%

Source: Dean HT. The investigation of physiological effects by the epidemiological method. In: Moulton FR, ed. Fluorine and Dental Health. Washington DC: American Association for the Advancement of Science;1942:23-31.

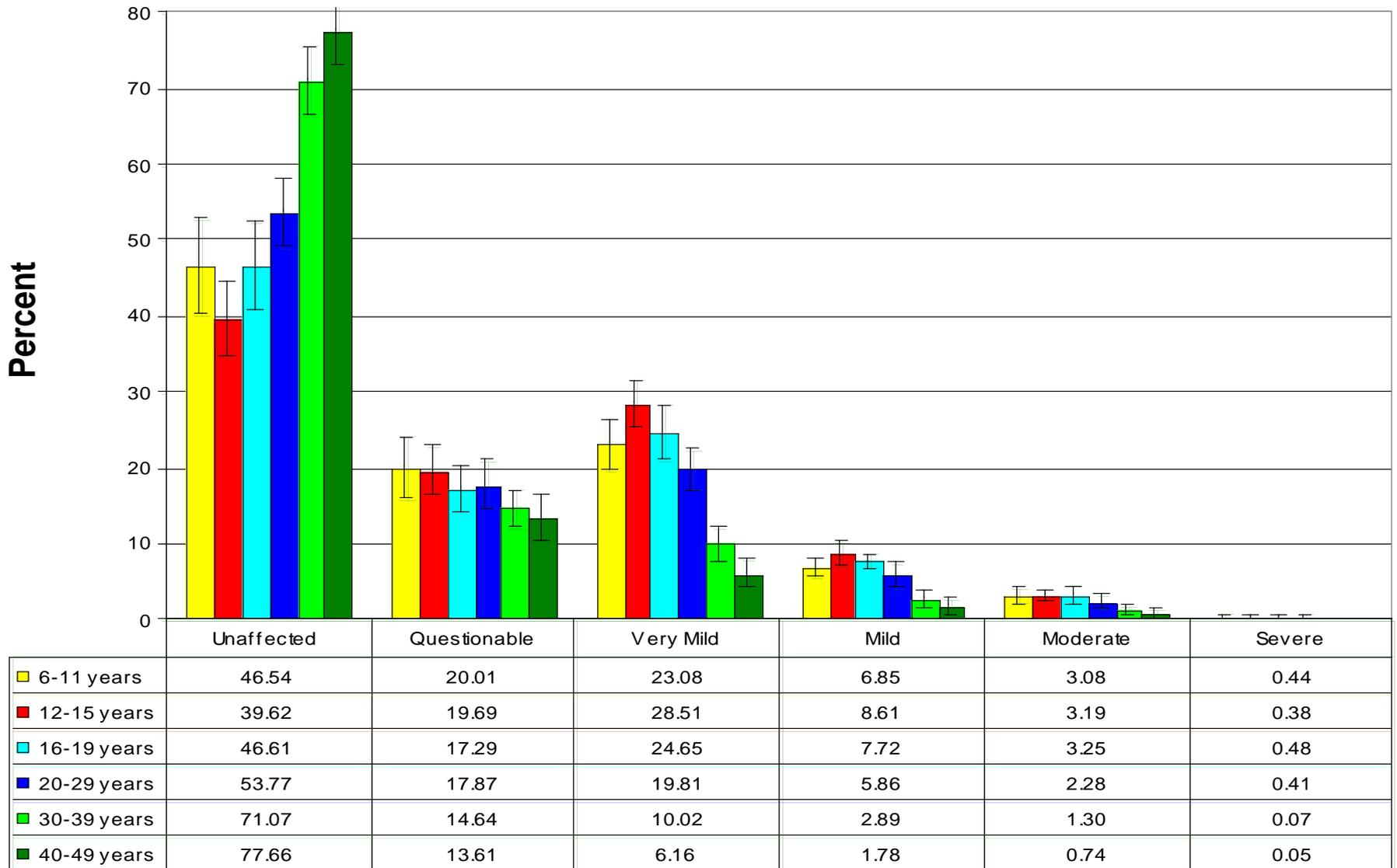
Enamel Fluorosis and Dental Caries at Different Levels of Fluoride in water at Schools. Heller, Eklund & Burt. JPHD 1997;57:136-43



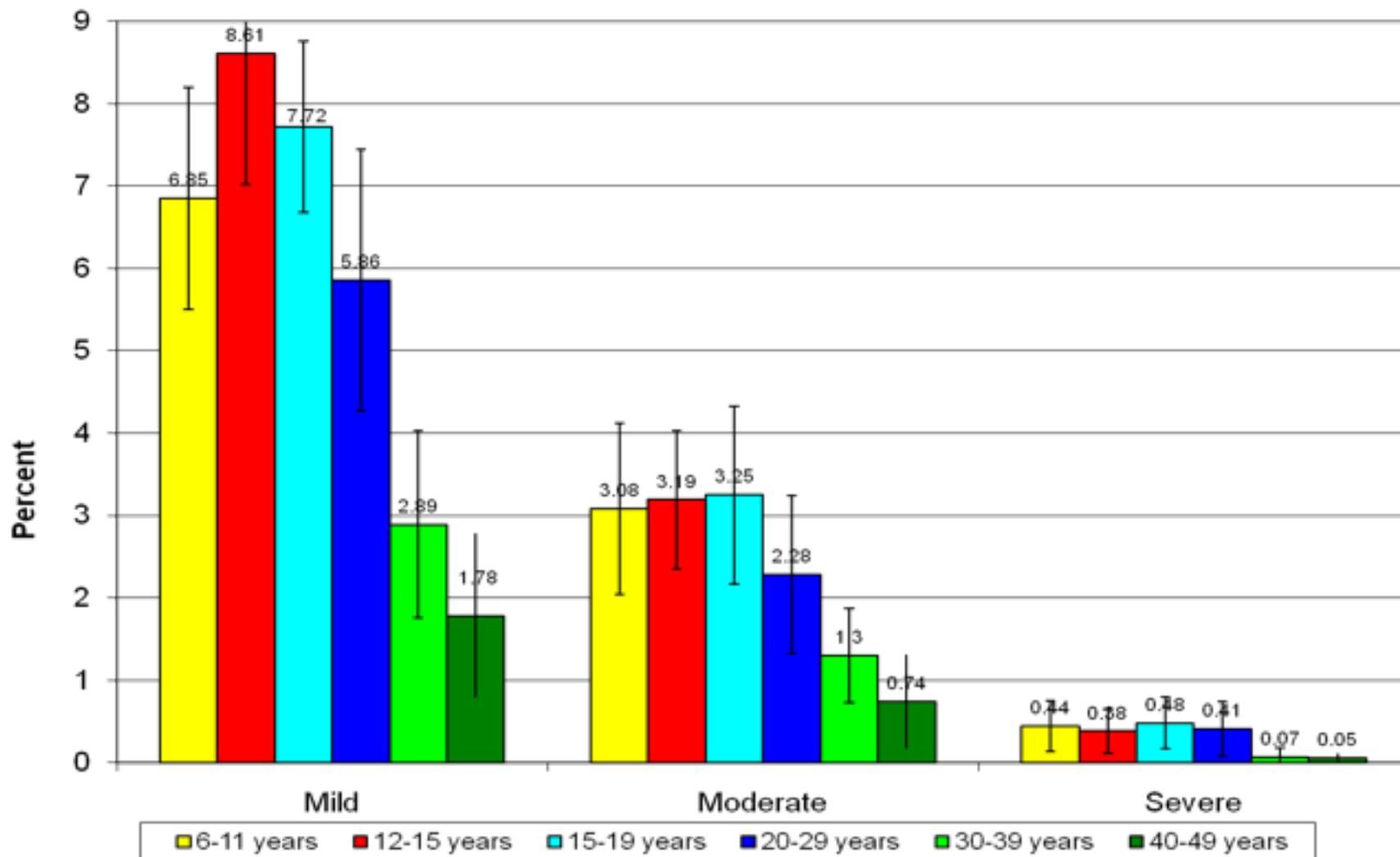
Enamel Fluorosis at Different Levels of Fluoride in water at Schools. Heller, Eklund & Burt. JPHD 1997;57:136-43



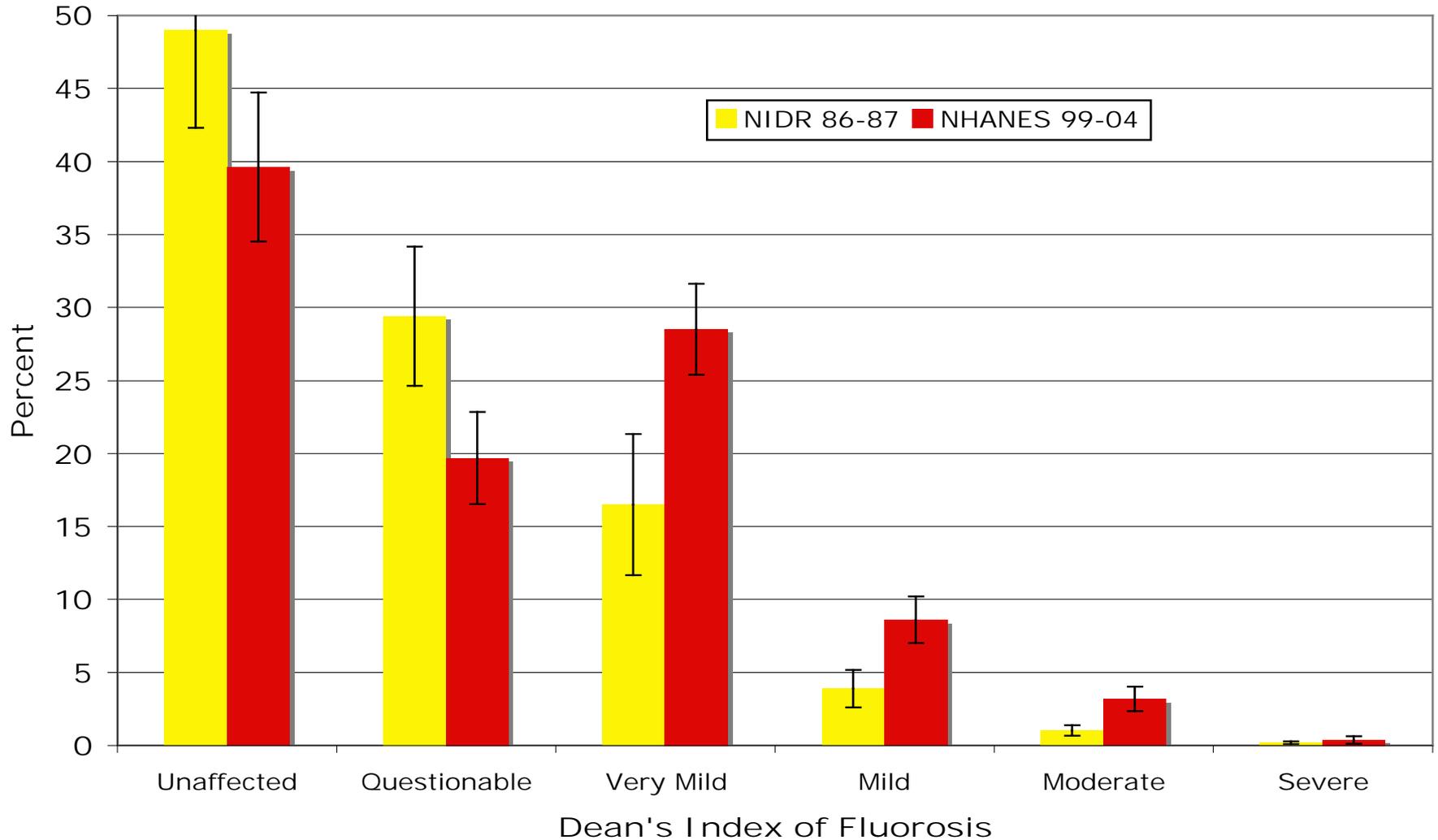
Prevalence and Severity of Enamel Fluorosis Among Participants of the National Health and Nutrition Examination Survey Aged 6-49 Years. United States, 1999-2004



Prevalence and Severity of Mild to Severe Enamel Fluorosis Among NHANES Participants Aged 6-49, by Age Group. United States, 1999-2004

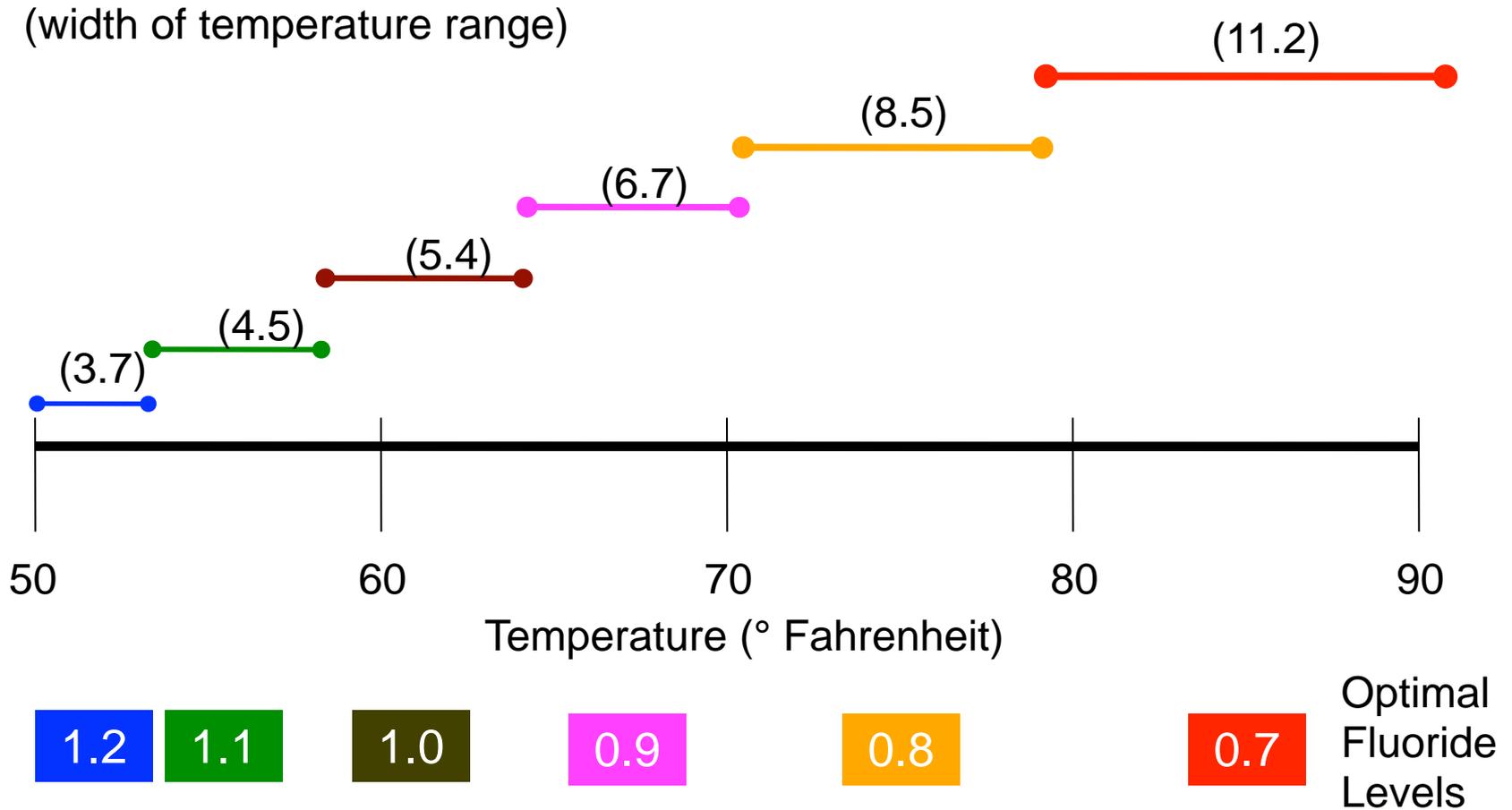


Changes in Enamel Fluorosis Prevalence and Severity from 1986-7 to 1999-2004 Among Adolescents Aged 12-15 at the NIDR and NHANES Surveys



EFFECTS OF AMBIENT TEMPERATURE

Temperature Zones Used for Recommending Optimum Fluoride Levels in Water



NHANES
1999-2004

NOAA data
bases

Have:
Dietary recall
Dental Caries
Fluorosis

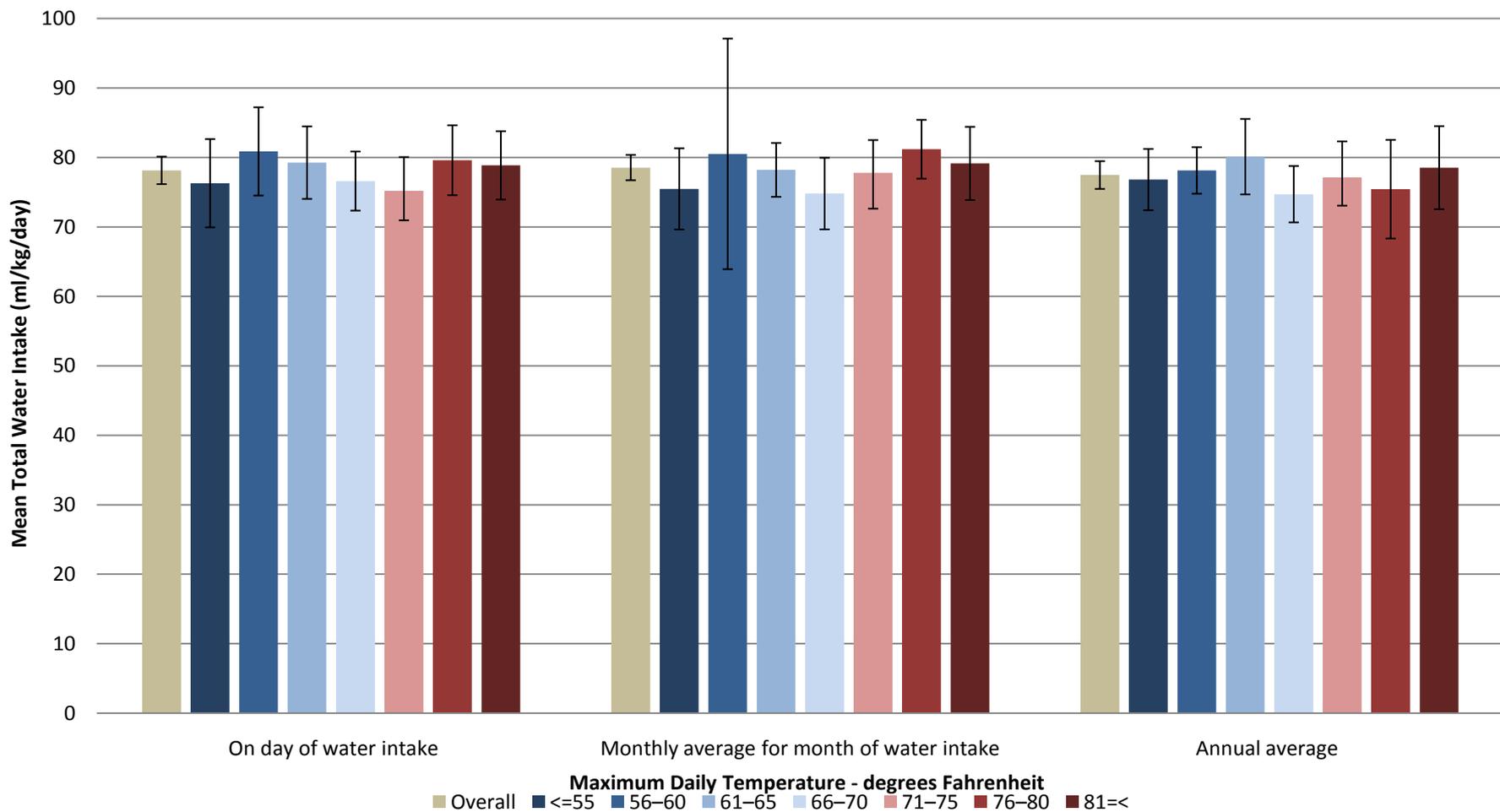
How do we link these?

Have:
Daily, &
Monthly and
Annual
"Normals"

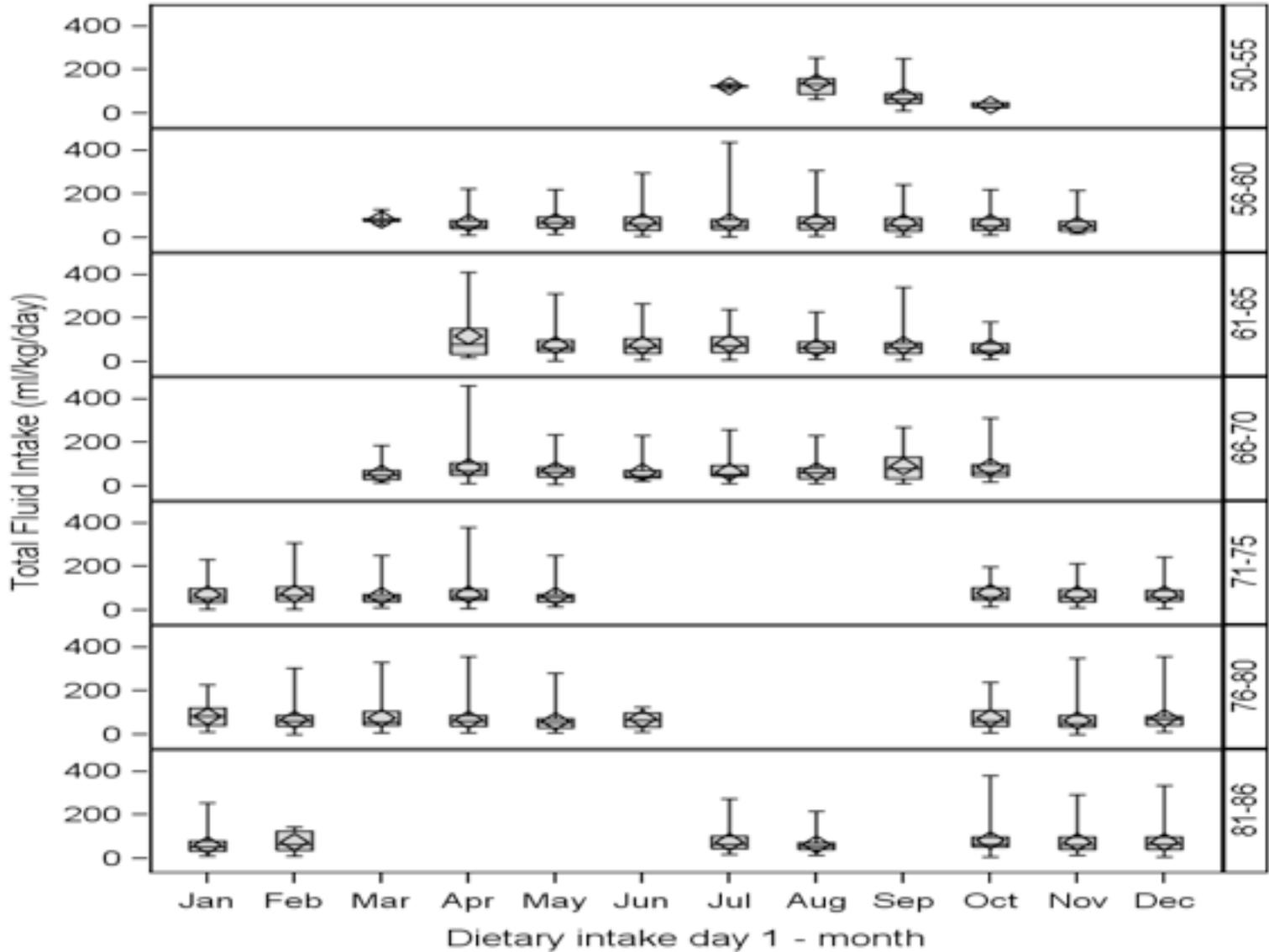
No:
[F] in water

NCHS Resource Data Center

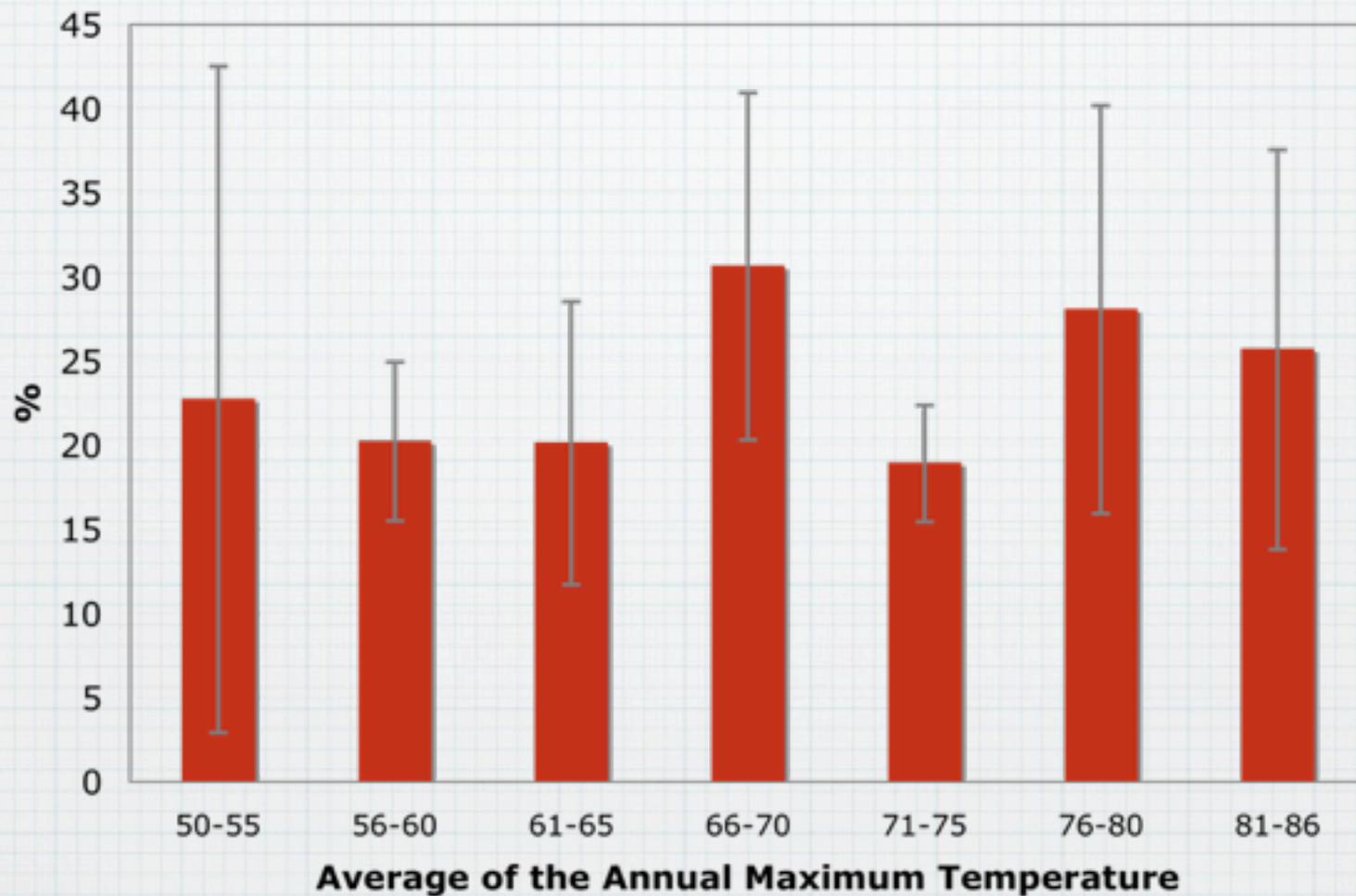
Total water intake in milliliters per kilogram of body weight per day by maximum daily temperature among children aged 1 to 10 years — United States 1999–2004



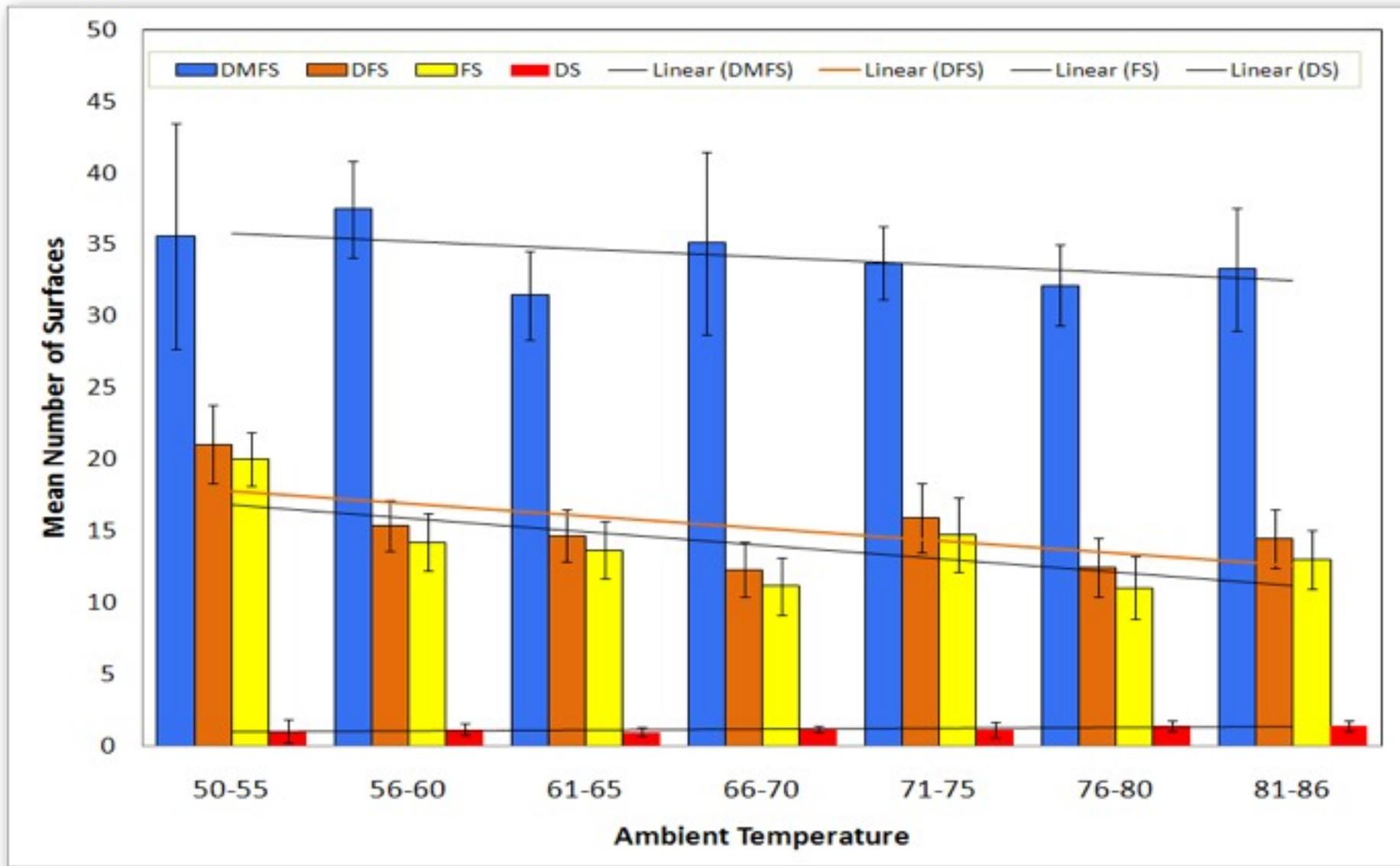
**Total Fluid Intake by Month and Temperature zones - Age 0-14 -
 - whiskers indicate range, outliers excluded**



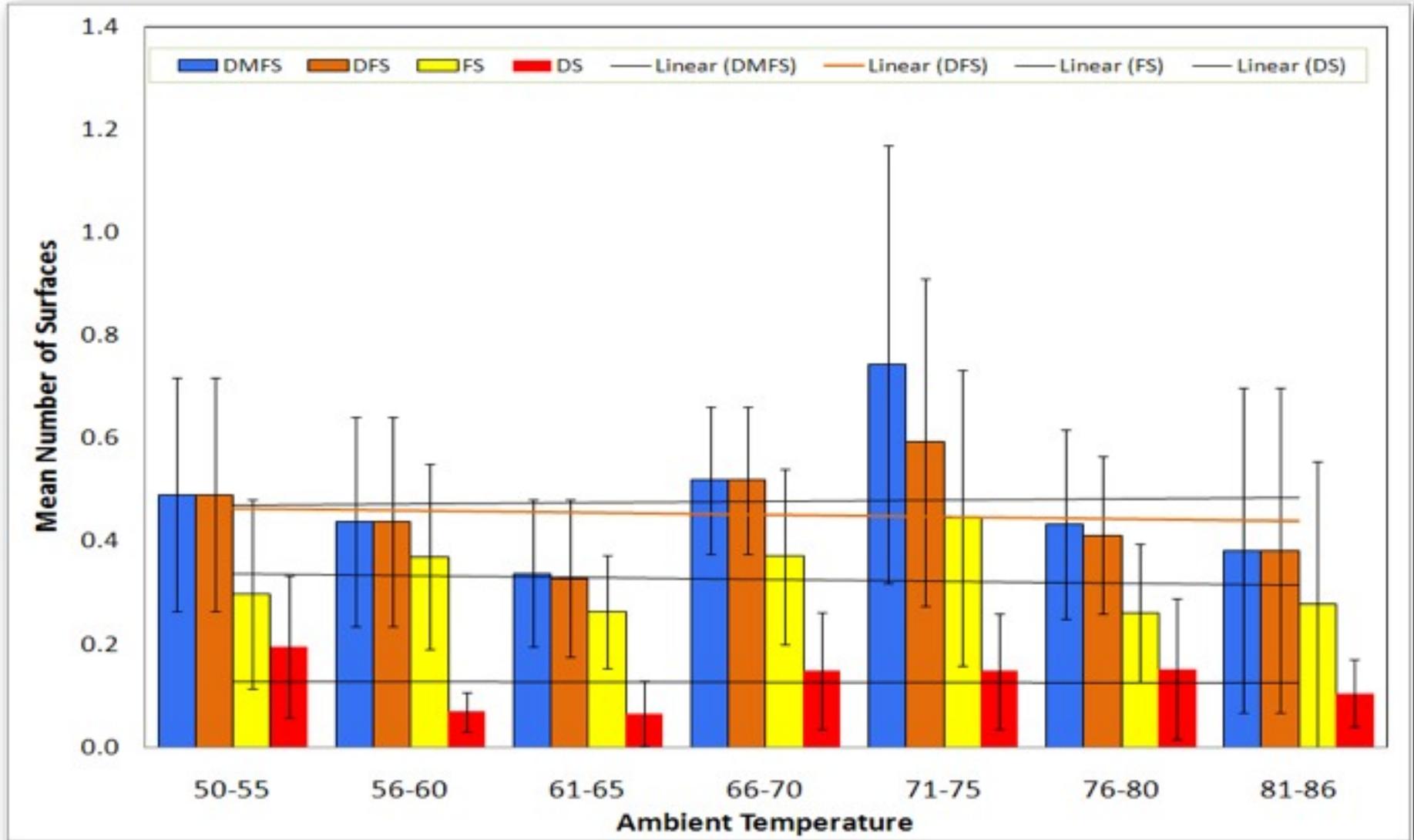
Enamel Fluorosis Prevalence (Very Mild and higher) by Seven Ambient Temperature Zones Defined by the Average of the Annual Maximum Temperature Among NHANES Participants Aged 6-49 years. U.S., 1999-2004.



Mean number of decayed, missing and filled surfaces on permanent teeth by 7 ambient temperature zones (defined by 30-year normals for annual maximum daily temperature) - United States, 1999-2004.



Mean number of decayed, missing and filled surfaces on permanent teeth by 7 ambient temperature (defined by 30-year normals for annual maximum daily temperature), Ages 1-10 - United States, 1999-2004.



Major Findings

- Water fluoridation remains effective in preventing dental caries
- Increase in enamel fluorosis prevalence and severity (since mid 1980s), associated with F ingestion from different sources
- Severe fluorosis continues to be rare
- No clear association of ambient temperature and fluid intake suggesting one recommendation not a range
- No data on $[F^-] \cdot H_2O$, dental caries and fluorosis after Heller
- Lower levels of disease, multiple sources of fluoride and no effect of ambient temperature

Issues

- Limitation: incomplete and dated data put together
- Strength: “big picture”

To do List

- Strengthen surveillance of populations at risk
- Assessment of fluoride exposures among those at risk of severe fluorosis
- Update information on effectiveness of water fluoridation by levels of exposure before modification of recommendation
- Repeat Dean's studies
- New technologies on fluoride exposure

The data presented in this presentation is the collective effort of the following individuals:

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Woosung Sohn

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Kip Duchon

National Institute of Dental and Craniofacial Research:

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

National Center for Chronic Disease Prevention and Health Promotion
Division of Oral Health

