FLUORIDATION RULES STATEMENT OF NEED AND REASONABLENESS (SONAR)

DEPARTMENT OF HEALTH

DIVISION OF ENVIRONMENTAL HEALTH

Proposed Amendment to Rules Governing Fluoridation of Municipal Water Supplies, Minnesota Rules 4720.0030, subpart 2.

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STATEMENT OF NEED AND REASONABLENESS (SONAR) FLUORIDATION

I. INTRODUCTION

The Minnesota Department of Health (MDH) proposes to update its Public Water Supply Fluoridation Rule (the rule). Recent research shows that MDH can simply lower the fluoride concentration that municipal public water supplies must maintain and still adequately protect public health. Lowering the fluoride concentration will also protect citizens from excessive fluoride and the adverse consequences that excessive fluoride causes. Measured within a range of concentrations, this lowered concentration will also reduce municipal expense.

Municipal public water supplies measure fluoride concentration in two ways: the *average* concentration that municipal water supplies must maintain over time and the *range* that the concentration that municipal water supplies must stay within. MDH proposes to set three new fluoride levels for municipal public water supplies when fluoride is not naturally present:

- an average fluoride concentration of 0.7 milligrams per liter (mg/L);
- a minimum fluoride concentration of 0.5 mg/L; and
- a maximum fluoride concentration of 0.9 mg/L

(Concentrations are expressed in milligrams per liter, which are the same as parts per million.)

Historical background

Community water fluoridation is the controlled addition of fluoride to a community water supply to achieve the optimal fluoride concentration for dental caries prevention. The optimal fluoride concentration is the fluoride concentration that provides the best balance of protection from dental caries, while limiting the risk of dental fluorosis. Fluoridation has contributed greatly to the decline in both occurrence and severity of tooth decay (dental caries), which is one of the greatest public health accomplishments during the second half of the 20th century.

In 1962, studies showed that adding fluoride to public drinking water supplies effectively reduced dental caries. The U.S. Public Health Service (PHS) responded by issuing its national recommendations for optimal fluoride concentrations in drinking water as an effective public health intervention.[1] State and local governments then respond to the national recommendation by deciding whether to fluoridate water supplies.

The state of Minnesota followed the PHS recommendation in 1967, when the Legislature required that both publicly and privately owned municipal water supplies control the fluoride content in community water supplies. The Legislature further required that the state board of health determine and adopt the proper fluoride amounts by rule,[2] which the state board did in

[1] US National Library of Medicine National Institutes of Health Public Health Reports U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries Report. U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation, Public Health Reports, July–August 2015, Volume 130, page 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/

[2] Minnesota Laws 1967, chapter 603, section 739, https://www.revisor.mn.gov/laws/1967/0/Session+Law/Chapter/603/pdf/

1970.[3] The 1970 standards required that water supplies maintain an average concentration of 1.2 mg/L; it set the range as neither less than 0.9 mg/L nor more than 1.5 mg/L.

In 1977, the Legislature abolished the state board of health and transferred all its powers and duties to the commissioner of health, who therefore now holds the authority to adopt the rules.[4] MDH has not revised the 1970 concentrations since.

The PHS reports how much dental caries has decreased. Scientific evidence shows that community water fluoridation has effectively prevented and controlled dental caries across all age groups. Adolescents with dental caries in at least one permanent tooth have decreased from 90 percent among those 12 to 17 years old in the 1960s to 60 percent among those 12 to 19 years old from 1999–2004. Over that time, the number of permanent teeth affected by dental caries declined from 6.2 to 2.6 per person, respectively. Adults also have benefited. The average number of affected teeth decreased from 18 per person among 35 to 44-year-old adults in the 1960s to 10 among 35-to-49-year-old adults from 1999 to 2004.[3] One of the main reasons in favor of community water fluoridation is that it prevents dental caries equitably for everyone in the population.[5]

Current state of fluoridation and public health

Currently, oral health practices have changed. People now use the additional fluoride sources that have become available since water fluoridation was first introduced. Two widely used examples are fluoride toothpastes and mouth rinses. This means that fluoride contributed from drinking water, when compared to total fluoride exposure, has changed.[6] Two recent national studies have shown an increase in rates of dental fluorosis that was very mild or worse since the 1980s.

Dental fluorosis in children aged 8 years and younger has increased from unmonitored, long-term swallowing of fluoride toothpastes and mouth rinses. Children aged 8 and younger are those at risk because permanent teeth are developing then. Most dental fluorosis in the United States is the very mild or mild form, which appears as barely visible white lacy markings or spots on teeth enamel. Children older than 8 years, adolescents, and adults cannot develop dental fluorosis.[7]

Studies conducted in the 1930s showed that the severity of tooth decay was lower and dental fluorosis was higher in areas with more fluoride in the drinking water. In response to these findings, community-water fluoridation programs were developed to add fluoride to drinking water to reach an optimal level for preventing tooth decay, while limiting the chance of developing dental fluorosis.[8] Reviews of studies conducted after other sources of fluoride were

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[3] Minnesota Administrative Rules 4720.0030, subpart 2, which became effective January 1, 1970. https://www.revisor.mn.gov/rules/4720.0030/

[4] Minnesota Laws 1977, chapter 305, section 39, https://www.revisor.mn.gov/laws/1977/0/Session+Law/Chapter/305/pdf/

[5] Community water fluoridation: Studying the impact of fluoride cessation in Calgary https://obrieniph.ucalgary.ca/fluoride2016-2

[6] Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm

[7] Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm

[8] Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm

introduced, especially fluoride toothpaste, showed beneficial effects from community water fluoridation were still apparent over time.[9]

An extreme overexposure to fluoride leads to severe skeletal fluorosis, a bone disease caused by excessive fluoride intake over a long time. In advanced stages, skeletal fluorosis can cause pain or damage to bones and joints. Fortunately, this is a rare condition in the United States.[6] To protect against it, the U.S. Environmental Protection Agency (EPA), which sets regulatory standards for drinking water safety, has set the current enforceable maximum fluoride concentration at 4.0 mg/L (or parts per million).[9]

Although tooth decay has notably declined, it remains one of the most common chronic diseases among children ages 6 to 19 years. It can lead to pain, infections, and difficulty eating and sleeping—all of which affect school performance.[10] In 2015, the Minnesota Department of Health Oral Health Program led an open-mouth assessment of caries experience and dental sealants in third grade students in Minnesota public schools.[11] In 2015, 17 percent, or nearly 2 out of every 10, Minnesota third graders had untreated tooth decay. The United States median (1998–2015) was 20 percent or 2 out of every 10 third graders.[12]

Thus, we know that fluoridation remains important. MDH needs to update these rules for two reasons: first, to reflect current evidence-based research; and second, to conform the rules to current practice. The 1962 national drinking water standards for community water fluoridation were a range of 0.7–1.2 mg/L, which did not have a corresponding target optimal concentration. In 2011, the Centers for Disease Control (CDC),[13] through the U.S. Public Health Service (PHS), recommended that the U.S. update and replace these 1962 drinking water standards with a target optimal concentration of 0.7 mg/L; the CDC did not propose a corresponding range with the concentration. In 2015, the CDC made its proposed target optimal concentration of 0.7 mg/L its final recommendation number, again through the PHS.

With this rule revision MDH proposes to set the average fluoride concentration for municipal public water supplies when fluoride is not naturally present to 0.7 milligrams per liter (mg/L). MDH further proposes to regulate this average within a range between a minimum fluoride concentration of 0.5 mg/L and a maximum fluoride concentration of 0.9 mg/L. MDH chose this concentration of 0.7 mg/L as the optimal target because the CDC's current evidence-based research supports it and thus the CDC recommended it. MDH independently adjusted its range to correspond to the 2015 CDC recommended average fluoride concentration for reasons described below.

Community water supplies underwrite water fluoridation costs. Such costs run from 1 to 3 dollars per million gallons for every 0.1 mg/L fluoride added to raw water.[14] This amounts to up

[9] U.S. Code of Federal Regulations, 40 C.F.R. § 141.62(b)(1) – Maximum contaminant levels for inorganic contaminants, Fluoride, https://www.govregs.com/regulations/40/141.62

[10] National Center for Health Statistics, Prevalence and Severity of Dental Fluorosis in the United States, 199-2004 https://www.cdc.gov/nchs/products/databriefs/db53.htm

[11] Tooth decay in Minnesota children https://data.web.health.state.mn.us/tooth-decay

[12] Tooth decay in Minnesota children https://data.web.health.state.mn.us/tooth-decay#toothDecayPicto

[13] The Centers for Disease Control and Prevention (CDC) is a federal agency under the U.S. Department of Health and Human Services that serves as "the nation's health department."

[14] Rindal D, Thoele MJ, Using Analysis of Raw Water Samples to Inform Proposed Adjustment of Fluoride Levels in Minnesota's Public Water Systems. Poster Number 66, Abstract number 81. National Oral Health Conference, Kansas City, Missouri, April 27, 2015.

to tens of thousands of dollars per year in chemical costs for larger municipalities using source waters that are low in natural fluoride, making cost saving another consideration for revising MDH's fluoridation rules.

Methodology

MDH started calculating the revised target optimal fluoride concentration with the CDC's current evidence-based research in 2017. MDH also pursued improving the balance between maintaining tooth decay prevention and reducing the enamel fluorosis risks associated with higher fluoride exposure.[15]

To calculate its proposed range, MDH's fluoridation engineer first reviewed the available peer-reviewed literature.[16] Two studies proved most reliable:

1. US PHS 2015 recommendation, which contained the CDC recommendation; and
2. "Adjusted Fluoride Concentrations and Control Ranges in 34 States: 2006-12010 and 2015", a peer-reviewed article by Barker, Duchon, et al., which validated the CDC recommendation, published in AWWA Journal in 2017.

This review persuaded MDH's fluoridation engineer that an optimal target concentration of 0.7 mg/L based on the 2015 CDC recommendation is reasonable and necessary. Treating the water supplies, however, inevitably causes the fluoride levels to fluctuate. Measuring compliance requires that MDH use a control range around the target concentration. The PHS (now the CDC)[17] last provided control-range recommendations in 1986 that it based on the 1962 PHS recommendations. Those 1986 published levels were 0.1 mg/L below to 0.5 mg/L above an optimal target concentration. The 2015 CDC recommendation did not include such operational control ranges.[18]

Updating the calculations

Authority	Target Concentration	Minimum	Maximum	Control Range
Original CDC (1962)	N/A	0.7	1.2	-0.1 to +0.5=0.6 mg/L (1986)
MN Rules / MDH (1970)	1.2	0.9	1.5	0.6 mg/L
CDC (2015)	0.7	None	None	N/A
CDC (2018)	0.7	0.6	1.0	0.4 mg/L
MN Rules / MDH (2019)	0.7	0.5	0.9	-0.2 to +0.2=0.4 mg/L

[15] Per discussion with Merry Jo Thoele, Supervisor, Oral Health Unit, MDH
[16] David Rindal P.E., MDH Fluoride Compliance Engineer
[17] As the PHS became the CDC in June, 1970, this SONAR roughly refers to either of them as interchangeably.
[18] US National Library of Medicine National Institutes of Health Public Health Reports U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries Report. U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation, Public Health Reports, July–August 2015, Volume 130, page 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/

The MDH fluoridation engineer based MDH's proposed control range on three sources: previous PHS recommendations; existing Minnesota Rule 4720.0030, which includes a range; and advice from the MDH Oral Health Program.

Reviewing the historical numbers, the MDH fluoridation engineer first noted that the control ranges for both the original CDC and Minnesota Rules 4720.0030 spanned 0.6 mg/L. This means that the variations of allowed levels above and below Minnesota's 1970 target concentration are 0.6 [The CDC's range of +0.5/ to -0.1 equals 0.6 and MR 4720.0030's minimum of 0.9 mg/L to a maximum of 1.5 also equals 0.6.] These ranges are 50% of Minnesota's current target optimal concentration of 1.2 mg/L.

The MDH fluoridation engineer sought to keep the revised range around the new proposed target optimum concentration of 0.7 mg/L consistent with the relative variability of the existing rule. Thus, to maintain a 50% range, he calculated a proposed symmetric control range of +/-25%, or +/-0.2 mg/L. [50% of 0.7 = .35 (or .40 when rounded up) creates a symmetric range of =/- 0.2]

The resulting proposed range then became either 0.2 mg/L more or 0.2 mg/L less than the optimal target concentration and having a control range of approximately 50%, which is consistent with existing Minnesota Rules 4720.0030. Furthermore, as a practical matter, existing drinking-water treatment systems can hold concentrations steady within this range.

The Minnesota Department of Health Oral Health Program supports using the target optimal concentration of less than or equal to 0.7 mg/L to adequately protect against dental caries. Subsequently, research published by Barker, Duchon, et al., corroborated the MDH control range determination of +/-0.2 mg/L.[19] This is the narrowest range that allows all public water supplies, without considering their size or complexity, to comply with the proposed rule, while still allowing existing drinking-water treatment systems the flexibility they need for operations.

Conforming the concentrations to current practice

For its concentrations, MDH proposes, as described in Methodology above, to set the average fluoride concentration for municipal public water supplies, when fluoride is not naturally present, to 0.7 milligrams per liter (mg/L). MDH will regulate this average within a range between a minimum fluoride concentration of 0.5 mg/L and a maximum fluoride concentration of 0.9 mg/L. MDH arrived at these numbers using a combination of federal recommendations and MDH's independent calculations.

In 2011, the CDC, through the PHS, announced its proposed target optimal concentration of 0.7 mg/L as its intended replacement for the 1962 Drinking Water Standards for community water fluoridation, which ranged from 0.7–1.2 mg/L. The PHS did not propose a corresponding range for public water supplies to meet. While waiting for the CDC to release its final recommended target concentration, MDH's fluoridation engineer calculated MDH's range of 0.5 mg/L to 0.9 mg/L as described above in Methodology. MDH, anticipating the CDC announcement of final concentration number would be forthcoming, then publicized both the CDC's proposed target concentration and MDH's calculated range among its approximately 730 municipal public water supplies. The regulated parties too believed the CDC recommendations would soon become the final target concentration and expressed their approval of MDH's proposed new concentrations range by requesting variances under Minnesota law to begin operating immediately within the lowered numbers. MDH began granting variances on May 21, 2015. In 2015, the CDC made its recommended target optimal concentration of 0.7 mg/L its final standard.

In the meantime, the proposed fluoride concentrations have become current practice. Approximately 550 of 730 regulated municipal water supplies are currently operating under duly granted variances. MDH began rulemaking in 2017 to formally adopt these changes. MDH published its proposed fluoride concentrations in its Request for Comments, which appeared in the *State Register* on July 3, 2017. MDH also notified affected parties of the Request for Comments through multiple means.

Since MDH announced its planned adoption of 0.7 mg/L as its target optimal concentration to be regulated within a range of 0.5 mg/L to 0.9 mg/L, the CDC has proposed its new range of 0.6 mg/L to 1.0 mg/L, as announced in the July 13, 2018 issue of the *Federal Register.*[20] MDH's fluoridation engineer considered the CDC's new range and deemed MDH's own calculated ranges to be sufficient to adequately prevent both dental caries and dental fluorosis. Raising the low end of the range would require more supplies to add fluoride to the water and file the requisite reports with MDH. This would increase both municipal supplies' costs and MDH's administrative burden. Raising the upper end would require all 625 fluoridating municipal supplies to add more fluoride. MDH's fluoridation engineer finds no increased benefit that justifies the additional resources that such an incremental change would require from both MDH and the regulated parties. Thus, MDH stands behind its selected optimal concentration of 0.7mg/L within its chosen range of 0.5 to 0.9mg/L.

II. ALTERNATIVE FORMAT REQUEST

Upon request, MDH can make this SONAR available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact Anita Smith, Drinking Water Protection, Minnesota Department of Health, P.O. Box 64975, St. Paul, Minnesota 55164-0975, Phone: (651) 201-4665, Fax (651) 201-4701 or health.dwp-rules@state.mn.us.

III. STATUTORY AUTHORITY FOR MODIFYING THE RULES

MDH's statutory authority to amend the rules is stated in Minnesota Statutes:

A. Minnesota Statutes, section 144.12, subdivision 1, states: "The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health."

B. Minnesota Statutes, section 144.45 states: For the purpose of promoting public health through prevention of tooth decay, the person, firm, corporation, or municipality having jurisdiction over a municipal water supply, whether publicly or privately owned or operated, shall control the quantities of fluoride in the water so as to maintain a fluoride content prescribed by the state commissioner of health.

   In the manner provided by law, the state commissioner of health shall promulgate rules relating to the fluoridation of public water supplies which shall include, but not be limited to the following:

   (1) The means by which fluoride is controlled;
   (2) The methods of testing the fluoride content; and

[20] Operational Control Range around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride, Federal Register, Volume 83, Number 135, pages 32667–32668. The CDC's public comment closed on October 11, 2018, https://www.federalregister.gov/documents/2018/07/13

(3) The records to be kept relating to fluoridation."

Under these statutes, MDH has the necessary statutory authority to amend the rules. This rulemaking amends existing rules and thus, Minnesota Statutes, section 14.125, does not apply.

IV. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, states eight regulatory factors that state agencies must analyze in a SONAR. Paragraphs (A) through (H) that follow address them. Section VI, the Rule-by-Rule Analysis, also addresses some of these factors.

A. Classes of Persons Probably Affected by the Proposed Rule

A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Classes of Persons Affected by the Proposed Rule

The existing rules apply to persons and entities in charge of municipal public water supplies. The proposed revisions to the rule will likely affect:

- Local units of government that own water supplies, which must comply;
- Municipal public water supply customers who consume the water;
- Municipal public water supply owners, which also must comply;
- Drinking-water treatment chemical distributors that supply fluoride additive;
- Drinking-water treatment engineers who must design fluoridation systems;
- Public water supply operators who must oversee fluoridation systems;
- Primary health care providers, e.g. pediatricians; physician assistants; nurse practitioners; who care for children's health;
- Oral health professionals who seek to prevent or treat dental caries;
- Dental public health organizations who look after population health and policies to pay for it; and
- Dental health professional organizations who service their members' needs.

Classes of Persons Who Will Bear the Costs of the Proposed Rule

Municipal public water supply owners might have one-time costs to purchase replacement pumps. Fluoridation-pump costs run between several hundred and several thousand dollars. Community water supplies, however, have typically incurred less than $1,500 in costs, as shown by invoices submitted to MDH for pump-expense reimbursement from Community Fluoridation Equipment grant programs.[21]

Classes of Persons Who Will Benefit from the Proposed Rule

- Minnesota residents: Every person who lives, studies, or works in a municipality in Minnesota will benefit from the proposed rule. Community water fluoridation,

[21] The 2010/2011 fluoridation equipment grant results show that, $17,575 of awarded grant funding, with a 20% match requirement, covered 11 pumps (plus other items like tanks and scale). So, even with the match, the average pump cost was less than $1,500 per system. Rindal D, Community Fluoridation Optimization through a Statewide Competitive Funding Process. Poster Number 12, Abstract number 63. National Oral Health Conference, Milwaukee, Wisconsin, April 30, 2012.

by adjusting the added fluoride to an optimal concentration to prevent tooth decay, continues to effectively reduce tooth decay across populations. The proposed revised fluoride concentrations will adjust fluoride levels to the proper amounts to avoid overexposure and underexposure. Proper fluoride amounts provide the best public health protection possible.

- Minnesota public water supplies: Most municipal public water supplies within the state of Minnesota will benefit from the proposed rule. Although fluoride occurs naturally in community drinking water sources throughout Minnesota, at concentrations ranging from non-detectable to 3.8 mg/L, the naturally occurring range is usually lower than the optimal concentration needed to prevent tooth decay. Most Minnesota municipal public water supplies must add fluoride to the water to reach an optimal concentration. The rule proposes a new optimal target concentration that is lower than the existing target concentration of 1.2 mg/L. Lowering the range will prevent unnecessary expense for those now using higher amounts. Some will not have to add fluoride at all. Therefore, most Minnesota municipal public water supplies will reduce the fluoride quantity they add to the water and thus lower their corresponding fluoride chemical supply costs. Current fluoride costs are roughly 2 dollars per million gallons for every additional 0.1 mg/L fluoride added to natural fluoride levels.

B. Probable Costs to Agencies and Effect on State Revenues

The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Probable costs to the agency of implementation and enforcement

The probable costs to MDH for implementing the proposed rule amendments will be negligible. Existing agency staff will be able to handle each water fluoridation plant's monthly reports. The Minnesota Public Health Laboratory and existing agency staff will continue to perform comparative analyses on quarterly samples submitted by municipal PWSs. Similarly, MDH staff will continue to receive and evaluate monthly reports submitted by municipal PWSs. Because these monitoring requirements exist under current rule, the agency will only need to replace the existing concentrations with the proposed concentrations to implement the amended rule.

Probable costs to any other agency of implementation and enforcement

MDH is the only agency that has duties under this rule. No other state agency or local public health agencies will incur costs.

Anticipated effect on state revenues

The proposed rule amendments will not affect state revenues.

C. Less Costly or Less Intrusive Methods

A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

MDH has proposed the least costly and least intrusive methods necessary for achieving the purpose of the rule, namely prescribing the lowest fluoride content in water that still promotes public health by preventing tooth decay.

1. Less costly methods

MDH considered reducing fluoride content to less than 0.5 milligrams per liter for the lower limit. However, when the Public Health Service analyzed data from the 1986–87 Oral Health of United States Children survey, it found that dental caries (tooth decay) gradually declined as fluoride content in water increased from negligible to 0.7 mg/L. Reductions leveled off when concentrations ranged from 0.7 to 1.2 mg/L, making further additions needless. MDH chose 0.5 mg/L as the lower limit to continue preventing dental caries, while allowing water supplies flexibility in their operations.

2. Less intrusive methods

The existing rule and proposed amendments will ensure that water supplies can operate flexibly. Setting the proposed levels of added fluoride at appropriate levels will allow water supplies to maintain a singular target level and be able to measure fluoride levels. Thus, fluoride treatment will be feasible for municipalities that operate under the rules. MDH chose this new proposed range as less intrusive than requiring a narrower operational range, which would require municipal water supplies to control and manage fluoridation treatment more precisely. A narrower range would also need more oversight and a corresponding increase to the agency's regulatory burden, without providing justifiable benefits to public health.

MDH has concluded that no less intrusive methods are available to accomplish the goals of the rules. It asserts that the proposed revisions are necessary and reasonable.

D. Alternative Methods Considered

A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

As discussed above in Methodology, MDH considered the CDC's new proposed new range of 0.6 mg/L to 1.0 mg/L, which it announced in the July 13, 2018 issue of the *Federal Register.*[22] MDH's fluoridation engineer determined MDH's own calculated ranges would be sufficient to adequately prevent both dental caries and dental fluorosis. Raising the low end of the range would require more supplies to add fluoride to the water and file the requisite reports with MDH. This would also increase MDH's administrative burden. Raising the upper end would require all 625 fluoridating municipal supplies to add more fluoride. MDH's fluoridation engineer does not see an increased benefit that justifies the additional resources that such an incremental change would require from both MDH and the regulated parties.

[22] Operational Control Range around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride, Federal Register, Volume 83, Number 135, pages 32667–32668. The CDC's public comment closed on October 11, 2018, https://www.federalregister.gov/documents/2018/07/13

E. Costs of complying with the Proposed Rule

The probable costs of complying with the proposed rule, including the portion of the total costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

Any costs of complying with the proposed rule will be borne by municipal public water supply owners or local units of government. MDH expects that affected parties will incur costs because their current methods for adding fluoride and monitoring fluoride level cannot accommodate lower chemical levels. The industry refers to these levels as "feed rates," which are necessary to achieve the proposed target fluoride content. Therefore, some municipal water supplies may need to make minimal capital improvements by purchasing a new pump. MDH's fluoridation engineer estimates, based on overseeing the last five years of fluoridation-equipment grants that affected municipal public water supplies would spend approximately $1,000 apiece for new pumps and pump-related expenses.

F. Probable Cost or Consequences of not adopting the Proposed Rule

The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

Probable costs of not adopting the proposed rules

Some members of the public could suffer preventable aesthetic and health consequences from not adopting the proposed rule. Some citizens will suffer preventable damage to their teeth from dental fluorosis from added fluoride levels that exceed the lower amount prescribed by the current rule. Affected people could also incur monetary costs from dental treatments to address cosmetic or, in rare cases, health-based conditions from failing to adopt the proposed rule.

Failure to adopt the proposed rule will also cause community water supplies to pay more than they need to from continuing to add excess fluoride to reach the unnecessarily high levels in the current rule. Such costs run from 1 to 3 dollars per million gallons for every 0.1 mg/L fluoride added to raw water. This amounts to up to tens of thousands of dollars per year in chemical costs for larger municipalities using source waters that are low in natural fluoride. The difference in chemical cost from fluoridating to a target of 0.7 mg/L rather than 1.2 mg/L is approximately 8 dollars per million gallons. Therefore, the chemical cost savings to community PWSs may range from negligible to $200,000 per year.

Portion of costs borne by identifiable categories of affected parties

MDH discussed the parties who would benefit from the rule and how they would benefit under factor A of the regulatory analysis above.

Minnesota public water supplies owners would pay unnecessary expenses from unwarranted chemical use.

G. Difference between the Proposed Rule and Existing Federal Regulations

An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

Fluoridating community drinking water is a state issue. No existing federal regulations require adding fluoride to drinking water. The federal Safe Drinking Water Act (SDWA) includes fluoride as a primary regulated contaminant. Fluoride has a maximum contaminant limit (MCL) of 4.0 mg/L and a secondary MCL (SMCL) of 2.0 mg/L. MDH has the sole delegated authority for SDWA enforcement.

H. Cumulative Effect of the Rule

An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

There are no federal regulations on community drinking water fluoridation. No other existing state regulations regulate water fluoridation so no state regulations conflict with this fluoridation rule.

V. ADDITIONAL STATUTORY REQUIREMENTS

A. Performance-Based Rules

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting MDH's regulatory objectives and maximum flexibility for the regulated party and MDH in meeting those goals.

MDH staff reviewed the following questions:

1. Are there special situations we should consider in developing the rules?
2. Are there ways to reduce the burdens of the rules?
3. Do you have any other insights on how to improve the rules?

This simple rule change only revises the concentration target optimum concentration and range for community water fluoridation. The range of allowed concentrations recognizes that fluoride levels will fluctuate over time due to treatment process and measured levels will vary accordingly. Municipal water supplies must comply.

B. Additional Notice

Minnesota law (Minnesota Statutes, sections 14.131 and 14.23) requires that the SONAR contain a description of MDH's efforts to provide additional notice to persons who may be affected by the proposed amendments to the rules. The additional notice plan consists of the following steps:

1. Mailing the proposed rules and the notice of hearing to all persons who have registered on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.
2. Posting the proposed rules, the notice of hearing, the SONAR, and a description of the new target optimal concentration on MDH's website at: Minnesota Fluoridation Rule Revision website at http://www.health.state.mn.us/divs/eh/water/com/fluoride/rulemaking/index.html.
3. Mailing the proposed rules and the notice of hearing to the 730 regulated municipal water supplies.

4. Providing a copy of the notice of hearing, the SONAR, the fact sheet containing a summary of the substantive amendments, and a Web link to the proposed rules via e-mail through MDH's GovDelivery subscriber service and Workspace, MDH's other subscriber-based secure portal.[23] These 897 recipients are the various individuals, groups, and organizations that have signed for updates about Minnesota's fluoridation laws and this rulemaking.
5. Notifying the Minnesota Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This will include sending the proposed rules, SONAR, notice of hearing, and summary of substantive amendments to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

C. Consultation with Minnesota Management and Budget on Local Government Impact

Minnesota Statutes, section 14.131, requires agencies to consult with Minnesota Management and Budget (MMB) to help evaluate the fiscal impact and benefits of the proposed rules on local governments. MDH delivered a copy of the proposed rules and SONAR to the Executive Budget Officer on April 26, 2019.

MDH does not anticipate local agencies will incur costs because of the proposed rules because their fluoridation systems for water supplies already exist. As described in section IV.E. above, compliance costs will be minimal at most.

D. Cost Determination for Small Business or Small City

As required by Minnesota Statues, section 14.127, the department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city. Besides purchasing a pump, as mentioned above, the only obligation that might affect small businesses or small cities is reporting. The time commitment to do so in these rare cases is negligible. Since MDH or mandated reporters (as discussed in Section IV.E) will bear any other costs, which will be minimal, the department has determined that the rules will not exceed $25,000 for any small business or small city.

E. Section 14.128 Analysis

Minnesota Statutes, section 14.128 requires agencies to determine whether a local government will have to adopt or amend an ordinance or other regulation to comply with a proposed agency rule and submit this determination for ALJ approval. MDH conducted this analysis and found, since MDH has sole jurisdiction over community water supplies and fluoridation, no local government will have to adopt or amend an ordinance or regulation.

[23] The MDH Workspace is a password-protected portal used by department staff, local health departments, and other emergency preparedness and response partners for planning and response work. MDH used the Workspace when it sent out the Request for Comments to 721 contacts.

F. List of Non-Agency Witnesses

When the rule goes to a public hearing, MDH anticipates having the following non-agency witnesses testify in support of the need for and reasonableness of the proposed amendments to the rules:

1. An oral health expert
2. A drinking water professional

VI. RULE-BY-RULE ANALYSIS

MDH proposes the following amendments to the Fluoridation Rules, Minnesota Rules, chapter 4720.0030, subpart 2. After review, MDH has concluded that the amendments are reasonable and necessary to further the goals of the rules.

PART 4720.0030 FLUORIDATION

4720.0030 Subp. 2. Fluoride Content

MDH proposes to set three fluoride levels for municipal public water supplies when fluoride is not naturally present:

- an average fluoride concentration of 0.7 milligrams per liter (mg/L);
- a minimum fluoride concentration of 0.5 mg/L;
- a maximum fluoride concentration of 0.9 mg/L

An average fluoride concentration of 0.7 mg/L

This addition is reasonable and necessary because a fluoride concentration of 0.7 mg/L in drinking water provides the best balance of protection from dental caries while limiting the risk of dental fluorosis.

A minimum fluoride concentration of 0.5 mg/L

A maximum fluoride concentration of 0.9 mg/L

The minimum and the maximum fluoride concentrations, when read together, create the appropriate control range that is the goal of this amendment. A majority of modern treatment and pumping equipment are more likely achieve control ranges of at least 0.4 mg/L wide (e.g. +/- 0.2 mg/L) than they are control ranges only 0.2 mg/L wide. (Duchon et al. 2017) This addition is reasonable and necessary.

VII. CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

October 7, 2019

Jan K. Malcolm
Commissioner
Minnesota Department of Health

Attachment A: Methods of Notifying and Persons Notified of Request for Comments

- Mailed the Request for Comments to all persons who had registered to be on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

- Posted the Request for Comments and a copy of the draft rules on MDH's Minnesota Fluoridation Rule Revision web site at: Request for Comments: MN Fluoride Rule Revision - EH: Minnesota Department of Health

- Published a summary of the Request for Comments and where people could get further information in publications that reached affected parties.

- Waterline, Fall 2018 quarterly newsletter for water operators, city officials, and others interested in news related to public water supplies in Minnesota. The Waterline includes updates on training sessions along with a registration form for various operator schools as well as feature stories of interest to those in the drinking-water profession. http://www.health.state.mn.us/divs/eh/water/com/waterline/fall2018.html#fluoride

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U.S. Code of Federal Regulations, 40 C.F.R. § 141.62(b)(1) – Maximum contaminant levels for inorganic contaminants, Fluoride, https://www.govregs.com/regulations/40/141.62

Operational Control Range around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride, Federal Register, Volume 83, Number 135, pages 32667–32668. The CDC's public comment closed on October 11, 2018, https://www.federalregister.gov/documents/2018/07/13

Adjusted Fluoride Concentrations and Control Ranges in 34 States: 2006–2010 and 2015

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To inform selection of a control range around the Public Health Service's recommended 0.7 mg/L drinking water fluoride concentration to prevent tooth decay, the Centers for Disease Control and Prevention's Water Fluoridation Reporting System data for 2006–2010 and 2015 were analyzed. Monthly average concentration data from 4,251 fluoride-adjusted community water systems for 191,266 of 255,060 system-months (2006–2010) were compared with control ranges 0.6 mg/L to 0.2 mg/L wide. Percentages of system-months within control ranges ≥0.4 mg/L wide (e.g., ±0.2 mg/L) were >83% versus 68% for 0.2 mg/L wide (±0.1 mg/L). In 2015, 70% of adjusted systems maintained averages within ±0.1 mg/L of their system's annual average for nine of 12 months, 67% used the 0.7 mg/L target and 45% used it with a ±0.1 mg/L control range. Adoption of the 0.7 mg/L target was underway but not completed in 2015. Control ranges narrower than ±0.2 mg/L may be feasible for monthly average fluoride concentration.

Keywords: *control range, fluoridation, quality, recommendation*

In January 2011, the US Department of Health and Human Services published for public comment a proposed update to the US Public Health Service (PHS) recommended optimal fluoride concentration in drinking water for prevention of tooth decay (HHS 2011). By summer 2011, many fluoride-adjusted community water systems (adjusted systems) had already begun adjusting fluoride concentration to the updated recommendation of 0.7 mg/L for all fluoridated community water systems, increasing the percentage of the population served by adjusted systems (directly or through sales to other systems) receiving water with 0.7 mg/L fluoride to 68% from less than 1% in December 2010 (HHS 2015). The previous recommendation, set in 1962, recommended selecting an optimal fluoride concentration within the range of 0.7–1.2 mg/L based on annual average outdoor temperature of geographic areas, and a control range for the selected fluoride concentration—for example, 0.7 mg/L ± 0.1 mg/L (PHS 1962). Recommendations for establishing a control range around the selected optimal concentration have not been updated since 1986, when a control range of 0.1 mg/L below to 0.5 mg/L above the selected fluoride concentration was recommended (CDC 1995, 1986; PHS 1962).

Community water fluoridation has been recognized as one of 10 great public health achievements of the 20th century (CDC 1999), and providing water with a fluoride concentration consistently close to the optimal fluoride concentration throughout the year is an important part of this intervention to prevent tooth decay (ASTDD 2015; CDC 2013a, 2013b). The Water Fluoridation Reporting System (WFRS), hosted by the Centers for Disease Control and Prevention (CDC), records state-established optimal fluoride concentration and control range for adjusted systems in all states and monthly average fluoride concentration for adjusted systems in 34 states. CDC, the Association of State and Territorial Dental Directors (ASTDD), and the American Dental Association (ADA) use data from WFRS to recognize individual adjusted systems and state fluoridation programs with fluoridation quality awards. These awards are based in part on the number of months (12 months for the adjusted system award and nine months for the state fluoridation programs) that average fluoride concentration is within the recommended or state-established control range around the optimal fluoride concentration. The recommended fluoride concentration and control range do not differ by the volume of water produced or the size of population served; however, a few authors have suggested that these factors may be important to consider in establishing a control range (Teefy 2013, Lalumandier et al. 2001, Kuthy et al. 1985). With publication of the updated recommendation for a single optimal fluoride concentration of 0.7 mg/L across the United States, regardless of outdoor temperature, data to inform choice of an appropriate control range needed to be considered.

Studies published before the 1962 recommendation reported an association between children's water intake and outdoor temperature; however, more recent studies have not found outdoor temperature to be an important explanatory factor of children's water intake (Beltrán-Aguilar et al. 2015). Reviews of evidence still find that community water fluoridation provides additional reductions in tooth decay, although other sources of fluoride (e.g., fluoride toothpastes, mouth rinses) have become widely available since water fluoridation was first introduced (Community Preventive Services Task Force 2013). Community water fluoridation saves money for communities with a population of ≥1,000; that is, the cost of water fluoridation is less than the cost of dental treatment that would be needed in the absence of water fluoridation. Further, savings increase with the size of the community population. A 2016 systematic review noted conservatively estimated benefit-to-cost ratios of 1.12 to 1 for communities of 1,000 people, 6.03 to 1 for communities with <5,000 people, and 38.24 to 1 for communities of more than 20,000 people (Ran & Chattopadhyay 2016). The increase in these other sources of fluoride has been accompanied by an overall increase in the prevalence of dental fluorosis, a range of visible changes in the appearance of tooth enamel that can occur only in children while teeth are developing under the gums (Aoba & Fejerskov 2002). Most dental fluorosis in the United States is the very mild or mild form, which appears as barely visible white lacy markings or spots on the enamel of teeth (Beltrán-Aguilar et al. 2010, NIDCR 1989). The updated recommendation of an optimal fluoride concentration of 0.7 mg/L will maintain water fluoridation's protective benefits of preventing tooth decay while limiting the risk of dental fluorosis (HHS 2015).

The previous PHS recommendation described six optimal fluoride concentrations ranging from 0.7 mg/L in the warmest areas of the country to 1.2 mg/L in the coldest areas. The six corresponding control ranges were of different widths—from 0.2 to 0.8 mg/L wide (Maier 1963, PHS 1962). For example, in the warmest areas of the United States, the control range was 0.6–0.8 mg/L (i.e., 0.7 ± 0.1 mg/L) and in the coldest areas, 0.9–1.7 mg/L (an asymmetrical control range of 0.3 mg/L below to 0.5 mg/L above the optimal fluoride concentration of 1.2 mg/L) (PHS 1962). Between 1967 and 1976, four publications proposed using the narrowest control range of ±0.1 mg/L, even for cooler areas with optimal fluoride concentration above 0.7 mg/L (USEPA 1976, Long & Stowe 1973, Hann 1968, Richards et al. 1967), based in part on manufacturers' statements about equipment calibration. Asymmetrical control ranges of 0.1 mg/L below to 0.5 mg/L above (0.6 mg/L wide) for each of the six optimal fluoride concentrations were described in CDC's 1986 water fluoridation manual (CDC 1986) and 1995 *Engineering and Administrative Recommendations for Water Fluoridation* (EARWF) (CDC 1995), but these recommendations were not regulatory. Adjusted systems may have been required to comply with different target fluoride concentrations and control ranges established by the state drinking water administrator and the administrative rules oversight board for the state in which they operate (i.e., state established). Target fluoride concentrations used by adjusted systems can be found in CDC's My Water's Fluoride website, based on data reported by states to WFRS (CDC 2013b). Target fluoride concentration and control range may be established by state or local administrative code, ordinance, or statute (NPHL 2015). State or local governments may have waited for the April 2015 publication of the final recommendation before beginning the process of revising their optimal concentraion and control range.

Few published studies have reported the percentage of time that adjusted systems maintain fluoride concentration within established, recommended, or hypothetical control ranges; however, six studies provide background for this analysis and suggest consideration of hypothetical control ranges as narrow as ±0.1 mg/L. The first study used data from a survey conducted in 1998 and found that 25.9% of 1,280 water plant operators in 12 states reported that their systems were able to maintain fluoride concentrations within ±0.1 mg/L of the target, an additional 49.3% between ±0.1 and 0.2 mg/L, and 19.5% between ±0.2 and 0.3 mg/L (Lalumandier et al. 2001). In the same study, 33.5% of operators of larger plants producing >1 mgd and 21.3% of operators of smaller plants producing ≤1 mgd reported the ability to maintain fluoride concentrations within ±0.1 mg/L of the target.

Three earlier studies in Vermont, New Hampshire, and Illinois analyzed data from finished water samples. The studies in Vermont (Long & Stowe 1973) and New Hampshire (Pelletier 2004) reported, respectively, that 55 and 50% of daily samples from 17 and 11 adjusted systems were within their established control ranges. In Vermont, the control range was ±0.2 mg/L around the target fluoride concentration of 1.0 mg/L, and in New Hampshire –0.1 to +0.5 mg/L around the three target fluoride concentrations of 1.0, 1.1, and 1.2 mg/L. The third study (Kuthy et al. 1985) was conducted using data from Illinois Environmental Protection Agency laboratory tests conducted monthly for 249 adjusted systems during 1977–1981, and it was found that the percentage of monthly samples with fluoride concentrations within the control range of 0.9–1.2 mg/L (no target fluoride concentration was noted) ranged from 35% for those serving the smallest (<250) to 79% for those serving the largest (>20,000) populations. These three studies, conducted more than 10 years ago, represented only a small fraction of the total number of adjusted systems in the United States.

The final two studies provide more recent data from finished water samples (Brown et al. 2014, Teefy 2013). A 2012 study (Brown et al. 2014) highlighted by the 2015 Water Research Foundation report *State of the Science: Community Water Fluoridation* (WRF 2015) reported that 80% of the water samples from 40 adjusted systems—with target fluoride concentrations ranging from 0.7 to 1.05 mg/L and serving different population sizes—were within ±0.1 mg/L of the target fluoride concentration, 92.5% within ±0.15 mg/L, and 98% within ±0.2 mg/L. A 2013 study (Teefy 2013) of one large adjusted system in California reported that between July 2012 and June 2013, 79% of daily samples were within ±0.1 mg/L and 98% were within ±0.15 mg/L of the target fluoride concentration of 0.85 mg/L. This study also noted sources of variation other than equipment calibration, such as source water fluoride concentration and volume of water produced. Both studies cited California's requirement that ≥80% of the samples, recorded daily and reported monthly, have fluoride concentration within the state-established control range, which was 0.1 mg/L below to 0.5 mg/L above the target fluoride concentration at the time of their studies; one study (Teefy 2013) also noted that the control range had changed to ±0.3 mg/L as of November 2013.

The purpose of this study was to provide data to inform selection of control ranges by analyzing data from the five years (2006–2010) preceding the January 2011 notice of the proposed update, and to describe status of average fluoride concentrations and control ranges soon after the April 2015 update. Six control ranges are examined: the state-established control range, the EARWF recommended asymmetrical control range of 0.1 mg/L below to 0.5 mg/L above the target fluoride concentration, and four hypothetical symmetrical control ranges of ±0.3, ±0.2, ±0.15, and ±0.1 mg/L around the target. This study had three aims:

1. Describe, overall and by size of population served, the number and percentage of system-months for which the average fluoride concentration was within, below, or above each of the six control ranges.
2. Describe, overall and by size of population served, the percentage of adjusted systems that had monthly average fluoride concentration within each of the six control ranges for ≥45 of 60 months (≥75%), ≥48 (≥80%), ≥54 (≥90%), ≥57 (≥95%), and all 60 months (100%) among the subset of adjusted systems that reported average fluoride concentration for all 60 months in the five-year study period.
3. Compare the target fluoride concentration and control ranges in use in 2015 to those in use in 2010.

Through these aims, this study describes progress in adoption of the recommended target fluoride concentration through 2015 and potential feasibility of control ranges for monthly average fluoride concentration narrower than 0.6 mg/L in width (e.g., narrower than –0.1 mg/L to +0.5 mg/L or ±0.3 mg/L).

METHODS

Data source and data fields used. The analysis used data for monthly average fluoride concentration for adjusted systems in the 34 states that used WFRS to monitor water fluoridation program quality during 2006–2010 and in 2015 (CDC 2013b). Monthly average concentration is calculated by state personnel using daily measurements; however, the daily measurements are not reported to WFRS. Other data fields used were target fluoride concentration; upper and lower control limits, which together define the state-established control range for each adjusted system; and the population served by each adjusted system, in five categories (25–3,300; 3,301–10,000; 10,001–20,000; 20,001–200,000, and >200,000). State personnel validate data for population served in WFRS after an annual comparison with the US Environmental Protection Agency's (USEPA's) Safe Drinking Water Information System public water system identification number and population data (CDC 2013c). For systems with multiple points at which finished water is produced and not blended before distribution (such as in certain large metropolitan water systems), each point was considered a unique system in this analysis because the average fluoride concentration was reported for and may have differed by each point. Data for gallons of water produced per day were not available from WFRS; therefore, system size was based on the most recent data in WFRS for population served during 2006–2010. If population data were not available during 2006–2010, data from 2012 were used, corresponding to the population data used for the 2012 Fluoridation Statistics report (CDC 2013d). For analyses of changes between 2010 and 2015 (the third aim of this study, or study aim 3), population data from 2015 were used to remove the possible impact of changes in size of population served, or migration between areas served by water systems with different target concentrations or control ranges.

Inclusion and exclusion criteria. Water systems included in this analysis were community water systems that served ≥25 people; adjusted fluoride levels (adjusted systems); and had data in WFRS for target fluoride concentration, control range, and population served. For the sake of brevity, all systems in WFRS are described as community systems in this article, although WFRS and this study included a small number of school and tribal water systems, which are nontransient noncommunity systems by USEPA's definition. For study aim 1, adjusted systems with at least one month of data for average fluoride concentration reported to WFRS during 2006–2010 were included. For study aim 2, only adjusted systems with average fluoride concentration data in WFRS for all 60 months during 2006–2010 were included. For study aim 3, analyses comparing target fluoride concentration and control range during 2010 and 2015 were limited to adjusted systems with data available for both years, or with data for average fluoride concentration for all 12 months during 2015.

Control ranges. For study aims 1 and 2, authors compared the average fluoride concentration for each adjusted system for each month from January 2006 through December 2010 with six control ranges: the state-established control range, which differs among states; the asymmetrical control range of –0.1 mg/L below to +0.5 mg/L above the target fluoride concentration (–0.1/+0.5 mg/L); and four hypothetical symmetrical control ranges of ±0.3, ±0.2, ±0.15, and ±0.1 mg/L around the target concentration. In figures and tables, the EARWF recommended control range of –0.1 mg/L to +0.5 mg/L is grouped with the hypothetical control ranges because some adjusted systems did not use this recommended control range. For study aim 3, analyses of data from 2015 focus on the same hypothetical ranges, and specific state-established control ranges of ±0.1 mg/L, –0.1 to +0.2 mg/L, and –0.1 to +0.5 mg/L that were the control ranges recorded in WFRS for the largest number of adjusted systems in 2015.

Units of analysis. For the first study aim, the unit of analysis was system-months. For example, a single adjusted system that reported average fluoride concentration for each month during 2006–2010 would contribute 60 system-months to the analysis. Another adjusted system that reported data for the four-year period of 2006–2009 would contribute 48 system-months to the analysis. Together these two systems would contribute 108 out of 120 possible system-months to the analysis (60 + 48 = 108 available system-months and 60 + 60 = 120 possible system-months for two adjusted systems). The percentage of system-months within, below, and above each control range are presented overall and by system size. For study aim 2, the unit of analysis was the adjusted system. The number and percentage of adjusted systems that maintained average fluoride concentration within each control range for all 60 months of the study period (100%), and progressively fewer months—≥57 of 60 months (≥95%), ≥54 (≥90%), ≥48 (≥80%), and ≥45 (≥75%)—are reported overall and by system size. For study aim 3, analyses by the hypothetical control range use adjusted systems as the unit of analysis. The annual average fluoride concentration was used as a proxy for the target fluoride concentration because adjusted systems may have been operating with interim target fluoride concentrations not recorded in WFRS during 2015. The unit of analysis for 2015 data by state-established control range was the adjusted system.

Statistical analysis. Authors analyzed WFRS data for 2006–2010 to avoid any potential impact on comparability of data before and after January 2011, arising from (1) changes in state-established target fluoride concentrations between the proposed (January 2011) and final (April 2015) updated recommendation and (2) a major WFRS modernization in July 2011. To characterize the data from WFRS during the study period, the authors reported the number of adjusted systems, jointly by target fluoride concentration and control range used; the distribution of system-months by monthly average fluoride concentration; and the median and average fluoride concentration, interquartile range (IQR), and standard deviation (SD) of the average by target fluoride concentration. Mean, SD, median, and IQR are reported to 1/100 mg/L, as are the majority of monthly average fluoride concentrations in WFRS; percentages are reported to the percentage point, except for Figure 6, in which tenths of a percentage point are shown to aid comparisons with the CDC's *Fluoridation Statistics Report*. Sampling error of the average fluoride concentrations could not be characterized from WFRS data because the adjusted systems included were a large convenience sample from all adjusted systems. Because the more predominant error type may be nonsampling error, such as selection bias, neither standard errors nor statistical tests of hypotheses are reported. Although this study included a large subset of the adjusted systems in the United States, differences in state policies, regulations, and rules require caution in drawing inferences about the performance of adjusted systems in states that did not provide data to WFRS, for other systems that lacked data in WFRS, and to the full population of adjusted systems.

RESULTS

Adjusted systems included in the study. Between 2006 and 2010, WFRS contained data for 57,821 unique community water systems (counting treatment points within multi-point systems as unique systems), of which 56,116 served ≥25 people (Table 1). Of these, 6,821 were adjusted systems; 6,667 adjusted systems had data for both the state-established control range and a target concentration within the control range (Table 1, Figure 1). Less than 1% (n = 22) of these adjusted systems had targets of 0.7 mg/L (n = 10) or >1.2 mg/L (n = 12) and were excluded because there were too few to describe variability at these concentrations meaningfully overall or by each control range and system size considered in this study. Of the 4,251 adjusted systems reporting average fluoride concentration for at least one month during the study period, 990 systems in 23 states reported average fluoride concentration for all 60 months (Table 1).

The 4,251 adjusted systems with average fluoride concentration data for at least one month during 2006–2010 had an average of nine months of data available per year and contributed 191,266 system-months of data, of which about 35% was from adjusted systems with average fluoride concentration of 1.0 mg/L (Figure 2). Standard deviation of average fluoride concentration ranged from 0.21 mg/L among adjusted systems with a target fluoride concentration of 0.9 mg/L (median 0.91, IQR 0.14 mg/L) to 0.31 mg/L among adjusted systems with a target fluoride concentration of 1.1 mg/L (median 1.02, IQR 0.21 mg/L) (Figure 3). For 328 adjusted systems in eight states, the target fluoride concentration changed during the study period; for example, an adjusted system

TABLE 1 Selection of adjusted community water systems from all community water systems listed in CDC's Water Fluoridation Reporting System (WFRS), 2006–2010

Inclusion Criteria	Number of Systems (Adjusted Systems—%)	Maximum Possible Number of System-Months	Number (%) of System-Months With Data	Number of States With Data in WFRS for One or More Systems
Community water systems listed in WFRS[a]	57,821	3,469,260		50 states and DC
Community water systems serving ≥25 people	56,116	3,366,960		50 states and DC
Adjusted systems in WFRS[b]	6,821 (100)	409,260	375,526 (92)	50 states and DC
State-established target fluoride concentration available and within control range in WFRS	6,667 (98)	400,020	365,943 (89)	50 states and DC
Target fluoride concentration in WFRS of 0.8, 0.9, 1.0, 1.1, or 1.2 mg/L[c]	6,645 (97)	398,700	364,300 (89)	50 states and DC
Any monthly data in WFRS[d]	5,467 (80)	328,020	297,289 (73)	34 states
Monthly average fluoride concentration in WFRS for at least one month during 2006–2010	4,251 (62)	255,060	191,266 (47)	34 states
Monthly average fluoride concentration in WFRS for all 60 months during 2006–2010	990 (15)	59,400	59,400 (15)	23 states

CDC—Centers for Disease Control and Prevention, DC—Washington, D.C.

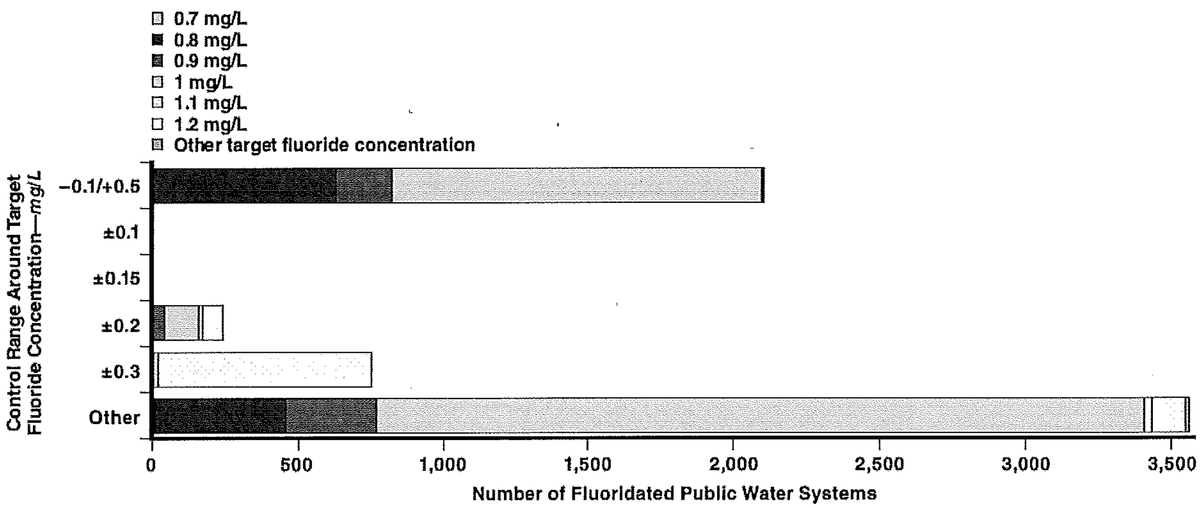
[a]The number of systems in WFRS is larger than the number of active community water systems in the Safe Drinking Water Information System because (1) systems listed in WFRS for any month during 2006-2010 are included; (2) some of the systems listed in WFRS are nontransient noncommunity systems (e.g., school or tribal systems); and (3) for multi-point systems, the individual points were counted as systems because fluoridation may be implemented at the points rather than a central treatment facility.

[b]Adjusted systems are community water systems that adjust the fluoride concentration upward to a concentration optimal for prevention of tooth decay. The number of system-months with data is less than the maximum number of system-months for three reasons: (1) The number of systems can change from month to month as they stop or start service, or merge with another system; (2) systems may have stopped or started adjusting fluoride concentrations during the study period; or (3) systems may have failed to report data for some months during the study period.

[c]Of adjusted systems with at least one month of average fluoride concentration data during 2006-2010, only 10 had a target fluoride concentration of 0.7 mg/L and 12 had target fluoride concentration >1.2 mg/L for the full study period. For some adjusted systems, the target fluoride concentration may have changed during the study period.

[d]During 2006-2010, 34 states provided operational data to WFRS, including data for monthly average fluoride concentration. However, adjusted systems in these states may have data available for fewer than all 12 months as a result of starting or stopping adjustment of fluoride during the study period, either permanently, or temporarily, for equipment maintenance or material supply shortage.

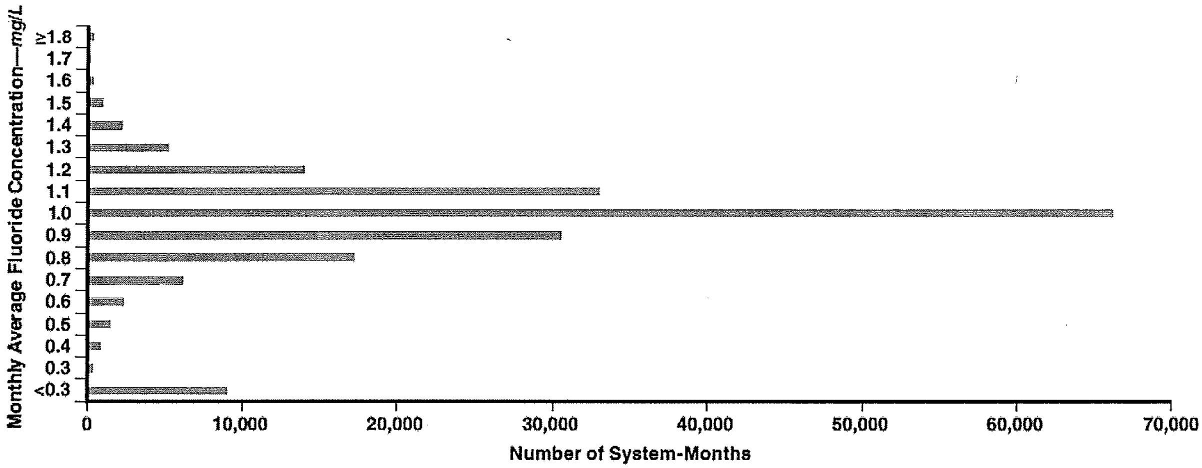
FIGURE 1 Target fluoride concentration and control range recorded for 6,667 adjusted community water systems in 34 states, 2006–2010



FC—fluoride concentration

Analysis of Water Fluoridation Reporting System data, 2006–2010

FIGURE 2 Monthly average fluoride concentration by number of system-months among 4,251 adjusted community water systems in 34 states, 2006–2010

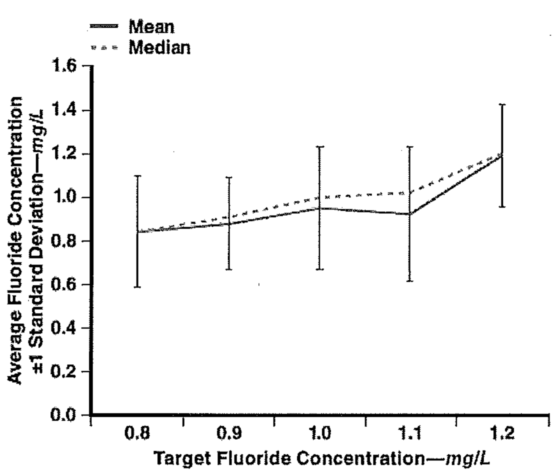


Analysis of Water Fluoridation Reporting System data, 2006–2010

that used a target fluoride concentration of 1.1 mg/L during 2006 and a target fluoride concentration of 1.0 mg/L from 2007 to 2010 would be counted only in the 1.0 mg/L target fluoride concentration category in Figure 1 but would contribute system-months to both categories in Figure 3.

The 2006–2010 analysis included 62% (4,251 of 6,821) of the adjusted systems with any data in WFRS, covering about 51% of the available system-months for the five-year study period (191,266 of 375,526) (Table 1). The number of systems (system-months) included in the analysis from each year ranged from a low of 3,278 (36,050 system-months) in 2006 to a high of 3,854 (41,573 system-months) in 2009. Compared with all adjusted systems that had any data in WFRS during 2006–2010 (n = 6,821), differences of two to four percentage points were found for a few categories of target fluoride concentration, system size, and region (data not shown); however, all 34 states that provided monthly data to WFRS during 2006–2010 were represented among the 4,251 adjusted systems included (Table 1). Of these 4,251 adjusted systems, about 30% (n = 1,255) used a state-established control range that matched either the EARWF recommended asymmetrical control range or one of two hypothetical control ranges (Table 2).

FIGURE 3 Median and mean monthly average (±1 standard deviation) fluoride concentration among adjusted community water systems by target fluoride concentration, 2006–2010



Analysis of Water Fluoridation Reporting System data, 2006–2010

Data were available from 2,707 adjusted systems with target fluoride concentration and control range recorded in WFRS in both 2010 and 2015. No adjusted system had a fluoride concentration of 0.7 mg/L recorded in 2010. Data for average fluoride concentration were available for all 12 months during 2015 from 2,560 adjusted systems (Table 3).

Study aim 1: average fluoride concentration within control range by system-months. Average fluoride concentration was within all six control ranges for most months, overall and for systems of all sizes (Figure 4). The percentage of system-months with average fluoride concentration within each control range was highest for the control range of ±0.3 mg/L (91%) and lowest for ±0.1 mg/L (68%), with differences by system size of seven to 10 percentage points; there was no consistent ordering by size of population served (Figure 4). For state-established and hypothetical control ranges wider than ±0.2 mg/L, the percentage of system-months with average fluoride concentrations below the control range was consistently larger than the percentage of system-months above the control range, and the percentage of system-months above the control range was slightly larger for smaller systems. The difference in percentage above the control range by system size was more pronounced for hypothetical control ranges of ±0.2 mg/L and narrower. The 30% of adjusted systems using state-established control ranges of –0.1/+0.5, ±0.3, and ±0.2 mg/L maintained average fluoride concentration within their established control ranges for 87, 85, and 80% of system-months, respectively (data not shown).

Study aim 2: average fluoride concentration within control range by system. Analysis of data from 990 adjusted systems that reported average fluoride concentration by month for all 60 months of the five years from 2006 through 2010 found that the highest percentage of systems maintaining average concentration within range was for ±0.3 mg/L—the widest symmetrical control range considered—with 94% of these systems maintaining average concentration for at least 45 of 60 months and 53% doing so for all 60 months (Table 4, Figure 5). The next highest percentages were for the state-established control ranges, within which 91% of these systems maintained average fluoride concentration for ≥45 of 60 months, and 43% for all 60 months. These percentages for the asymmetrical control range of –0.1 mg/L to +0.5 mg/L were lower than for the symmetrical ±0.3 mg/L control range of the same width (84% and 32% versus 94% and 53%). The percentage of adjusted systems maintaining average fluoride concentrations within the control range was smaller for narrower control ranges of ±0.2, ±0.15, and ±0.1 mg/L than the ±0.3 mg/L, state-established, and asymmetrical –0.1 to +0.5 mg/L control ranges. The percentages for the control range of ±0.2 mg/L were similar (e.g., 85% for ≥45 of 60 months and 34% for all 60 months) to those for the wider asymmetrical control range of –0.1 to +0.5 mg/L. Only 59% maintained average fluoride concentration within the narrowest control range of ±0.1 mg/L for ≥45 of 60 months, compared with 71% within ±0.15 mg/L for ≥45 of 60 months. Of the subset of 42 adjusted systems with a state-established control range of ±0.2 mg/L and data for all 60 months, almost ¾ of these systems maintained average fluoride concentrations within this control range for ≥48 of the 60 months (data not shown). By system size, differences of seven to 22 percentage points were found in the percentage maintaining average fluoride concentration within control range for ≥45 of 60 months (Figure 5). Relatively consistent ordering of percentage within control range by size of population served was apparent only for the narrowest control ranges of ±0.1 and ±0.15 mg/L, and for ≥54 or fewer of 60 months.

Study aim 3: target and average fluoride concentration and control range in 2015. By Dec. 2015, 2,587 adjusted systems had a recorded target fluoride concentration of 0.7 mg/L, representing 67% of adjusted systems and 80% of the population receiving fluoridated water from adjusted systems (Figure 6). The target fluoride concentration recorded for most adjusted systems in 2010 had changed to 0.7 mg/L by 2015 or remained the same; one changed to a target fluoride concentration higher than the 2010 target fluoride concentration. In 2010, 65% of adjusted systems were using a target fluoride concentration of 1.0 mg/L and another 16% were using a target fluoride concentration of 0.8 mg/L. About 20% reported using the then-recommended control range of –0.1 to +0.5 mg/L. In 2015, 45% of adjusted systems were using both the 0.7 mg/L target fluoride concentration and the ±0.1 mg/L control range. The next most frequently reported combinations were a target fluoride concentration of 0.7 mg/L with control ranges of –0.1 to +0.5 mg/L (13%) or –0.1 to +0.2 mg/L (7%), and target fluoride concentration of 0.8 mg/L with a control range

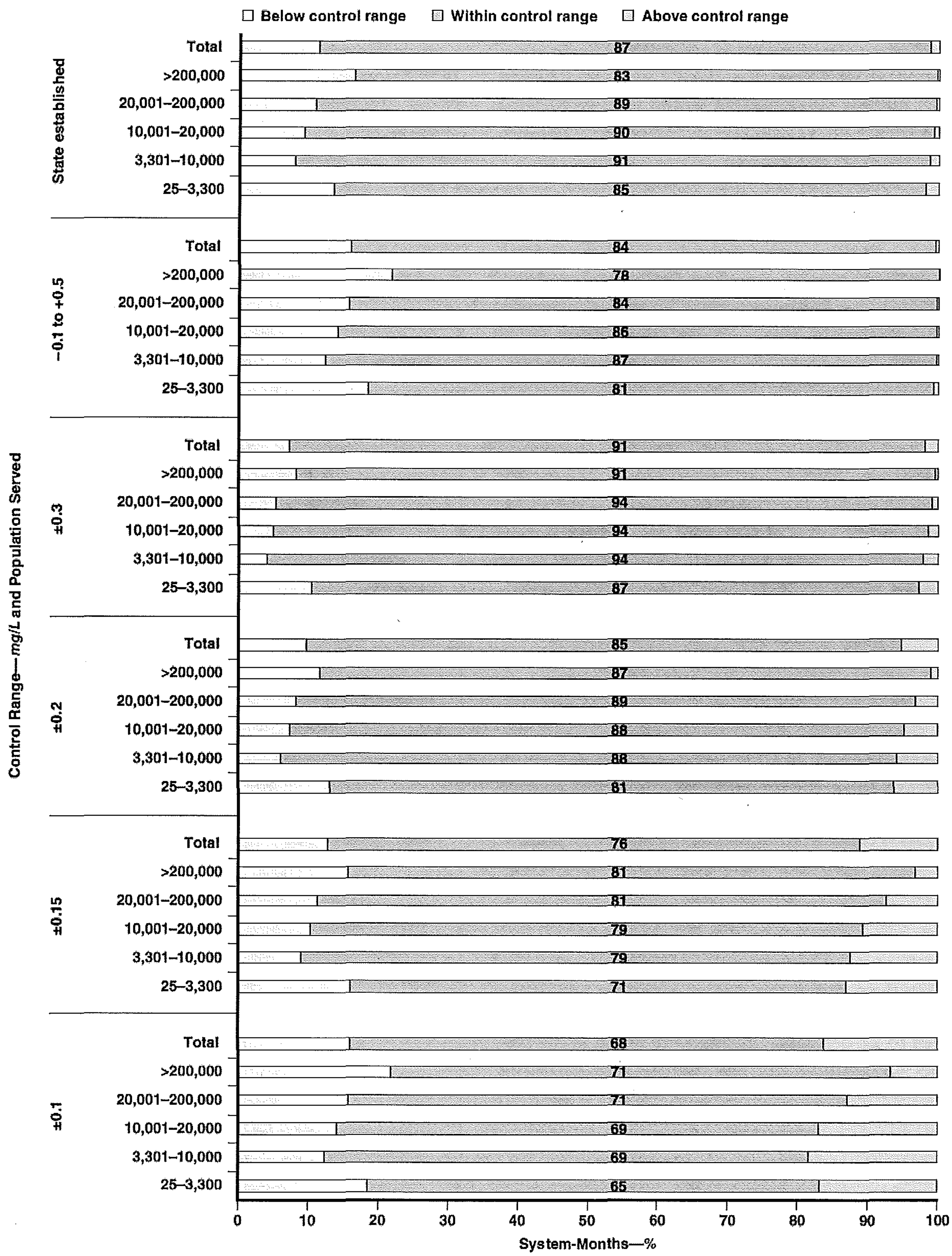
TABLE 2 Number of adjusted community water systems using selected state-established control ranges 2006–2010

Control Range *mg/L*	Adjusted Systems Using Control Range *number*	States in Which Adjusted Systems are Located *number*
–0.1/+0.5	893	18
±0.3	160	6
±0.2	202	10

TABLE 3 Percentage of adjusted community water systems maintaining average fluoride concentration within hypothetical and state-established control ranges during 2015

	12 months %	≥11 months %	≥9 months %
Hypothetical control range around annual average fluoride concentration (n = 2,560)			
Control range—*mg/L*			
±0.1	38	54	70
–0.1/+0.2	48	64	82
–0.1/+0.5	50	67	87
	12 months %	**≥11 months %**	**≥9 months %**
State-established control range around target fluoride concentration of 0.7 mg/L (n = 1,646)			
Control range—*mg/L*			
±0.1	21	30	44
–0.1/+0.2	43	55	69
–0.1/+0.5	50	60	70

FIGURE 4 Percentage of system-months in which average fluoride concentration for each month was below, within, and above selected control ranges, 2006–2010



Analysis of Water Fluoridation Reporting System data by control range around the target fluoride concentration, overall, and by size of population served.

of −0.1 to +0.5 mg/L (8%). Among 2,560 adjusted systems with complete data for all 12 months, 70% maintained average fluoride concentration within the hypothetical control range of ±0.1 mg/L around their annual average fluoride concentration for at least nine months, 54% for at least 11 months, and 38% for all 12 months of 2015 (Table 3). These percentages were higher for the wider control ranges, with similar decreases in percentages by increasing number of months in a range. For state-established control ranges used by adjusted systems operating with a target fluoride concentration of 0.7 mg/L during 2015, these percentages were 44, 30, and 21% for a control range of ±0.1 mg/L and higher for the wider control ranges, again with the same decreasing pattern by increasing number of months in a range (Table 3).

DISCUSSION

Over the five-year period of 2006–2010, adjusted systems with data available in WFRS maintained monthly average fluoride levels within state-established control ranges and hypothetical control ranges as narrow as ±0.2 mg/L for more than ¾ of the study period. This finding is consistent with those of Brown et al. (2014), and conclusions of the 2015 Water Research Foundation report *State of the Science: Community Water Fluoridation* (WRF 2015).

For study aim 1, the percentage of system-months within ±0.15 mg/L was 76%, suggesting that most adjusted systems potentially could have maintained average fluoride concentration within that hypothetical control range had it been their state-established control range. When monthly average fluoride concentration was not within the control range, it was more often below the control range than above it. However, from these data, it is not possible to determine whether the combination of the 0.7 mg/L target fluoride concentration and a narrower control range may change the balance of system-months with monthly fluoride concentration below versus above the control range.

For study aim 2, the authors' findings—that the percentage maintaining concentrations within narrower ranges was smaller than within wider ranges, and that the percentage of systems maintaining average fluoride concentration within range for all 60 months of a five-year period would be smaller than the percentage maintaining concentrations within range for shorter periods of time, such as all 12 months of one year—are not surprising. The finding that more adjusted systems maintained average fluoride concentrations within ±0.2 mg/L of the target fluoride concentration over time than within ±0.1 mg/L of the target fluoride concentration aligns with findings from two recent studies (Brown et al. 2014, Teefy 2013).

TABLE 4 Number and percentage of adjusted community water systems maintaining average fluoride concentration within selected control ranges, 2006–2010[a]

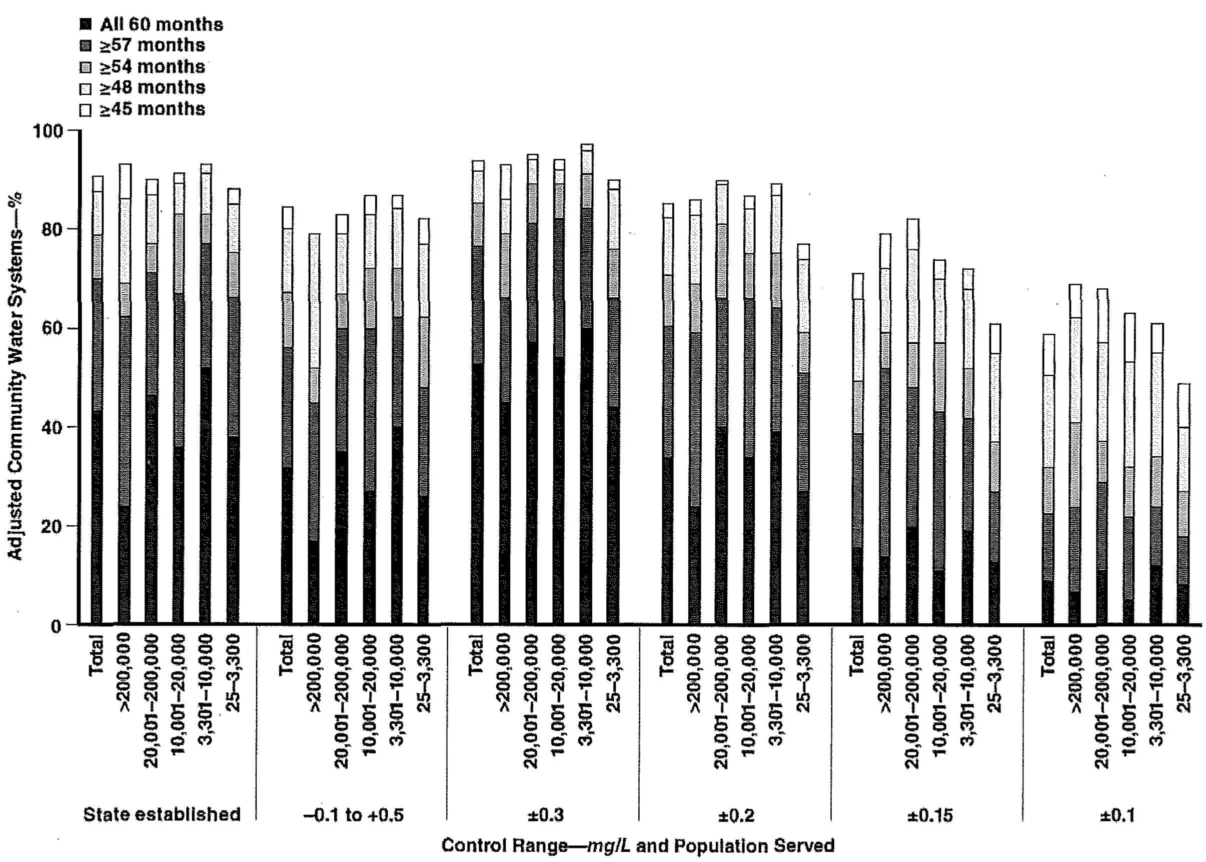
Control range—*mg/L*	60 months	≥57 months	≥54 months	≥48 months	≥45 months
Number					
State-established	424	693	778	866	896
Hypothetical					
−0.1/+0.5	313	553	664	793	833
±0.3	520	757	843	909	926
±0.2	334	597	701	817	843
±0.15	156	383	486	652	704
±0.1	88	225	317	499	581
Percentage					
State-established	43%	70%	79%	87%	91%
Hypothetical					
−0.1/+0.5	32%	56%	67%	80%	84%
±0.3	53%	76%	85%	92%	94%
±0.2	34%	60%	71%	83%	85%
±0.15	16%	39%	49%	66%	71%
±0.1	9%	23%	32%	50%	59%

[a]Around the target fluoride concentration among 990 adjusted systems with data for all 60 months

Teefy (2013) concluded that maintaining fluoride concentration within a ±0.1 mg/L control range every day of the year was challenging for one Northern California system with automated controls; however, 98% of the daily samples analyzed from this system were within ±0.15 mg/L of the target fluoride concentration. Brown et al. (2014) found that only four of 40 adjusted systems (10%) maintained fluoride concentrations within ±0.1 mg/L for 100% of the daily samples during one year, although all 40 (100%) systems had fluoride concentrations within ±0.2 mg/L and 36 (90%) had fluoride concentrations within ±0.15 mg/L of the target for ≥80% of the daily samples. Similarly, findings for study aim 2 from 990 adjusted systems with data for 60 months in 2006–2010 demonstrate lower percentages maintaining monthly average fluoride concentration within the same control ranges for all 60 months; 9% of these adjusted systems maintained average fluoride concentration within ±0.1 mg/L for all 60 months (100% of 60 months), and 82% and 66% maintained average fluoride concentration within ±0.2 mg/L and ±0.15 mg/L, respectively, for ≥48 of 60 months (i.e., ≥80% of 60 months).

Findings from study aim 3 indicate that adoption of the 0.7 mg/L target fluoride concentration has continued since 2011, accompanied by adoption of narrower control ranges. On the basis of 2015 data, it appears that a majority of adjusted systems maintain average fluoride concentration within ±0.1 mg/L of their system's annual average fluoride concentration for at least 11 months of the year. The percentage of adjusted systems that maintain average fluoride concentrations within their state-established control range for nine months of the year was similar for adjusted systems with control ranges of –0.1 to +0.2 mg/L (69%) and the previously recommended control range of –0.1 to +0.5 mg/L (70%). This may be due in part to the lower bound of –0.1 mg/L having been established for many years and adjusted systems operating within a relatively narrow range above the target fluoride concentration for efficient use of fluoride materials, even if the state-established upper bound of the control range was higher. The lower percentage among

FIGURE 5 Percentage of adjusted community water systems that maintained average fluoride concentration within selected control ranges, 2006–2010



Analysis of Water Fluoridation Reporting System data for 990 adjusted systems with data for all 60 months during 2006–2010, by control range around the target fluoride concentration, overall and by size of population served.

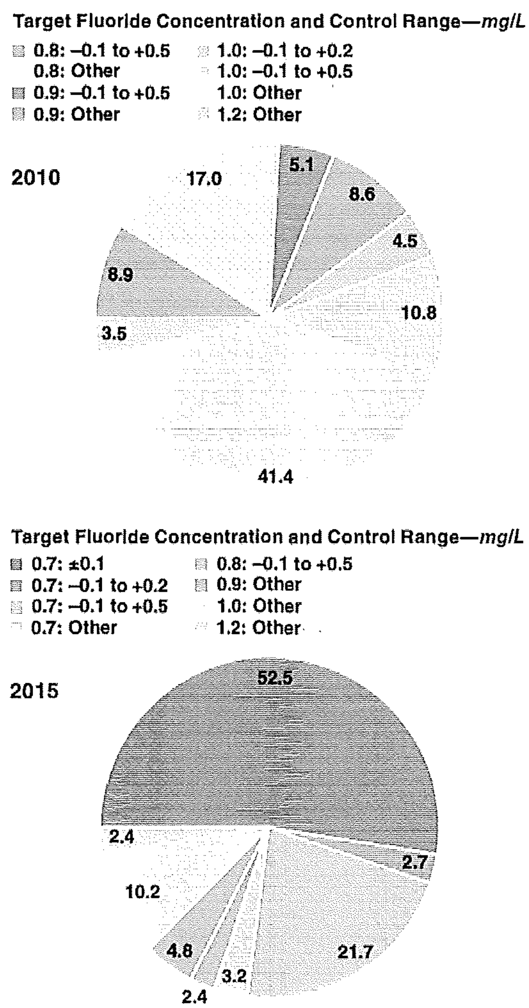
adjusted systems with a state-established control range of ±0.1 mg/L may be due to a transition period as adjusted systems begin to operate more closely to the target fluoride concentration.

Congruent with other research (Lalumandier et al. 2001), this study also found that systems serving populations larger than 3,300 maintained average fluoride concentration within the narrowest hypothetical control ranges of ±0.15 mg/L and ±0.1 mg/L somewhat more consistently than did the smallest systems serving populations of 25–3,300. Among systems serving >3,300 people, differences by system size were not substantial. Further, system size was not directly related to the percentage of system-months with average fluoride concentration within each control range, or the percentage of adjusted systems maintaining average fluoride concentration within each control range for most of the study period, except for the narrowest control ranges of ±0.15 and ±0.1 mg/L for ≥45, ≥48, and ≥54 of 60 months. For all system sizes and control ranges, the percentage within each control range for all 60 months was substantially lower than for ≥57 of 60 months, but authors found no specific temporal pattern that explained this difference; however, sporadic stoppages for maintenance, equipment replacement, or fluoridation product shortages are possible explanations.

Strengths and limitations. To the authors' knowledge, this study is the first to report the amount of time that adjusted systems maintain average fluoride concentration within state-established and recommended control ranges, and narrower hypothetical control ranges, using data from more than 4,000 adjusted systems in 34 US states for a five-year period. Together these adjusted systems served a total population of about 154 million, either directly or through sales of water to other systems, which was about ¾ of the US population served by fluoridated community water systems in 2010 (CDC 2011). The analysis used data for monthly average fluoride concentration submitted by state fluoridation or drinking water personnel to WFRS, which is the only ongoing data system with centrally available data for average fluoride concentration of adjusted systems in a large number of states. These WFRS data are also used by the ADA, ASTDD, and CDC to present awards for fluoridation quality to states and individual adjusted systems, suggesting that these data are suitable for the purposes of this study.

A few limitations of this study should be noted. First, only 11 water systems with any data in WFRS during 2006–2010 had a target fluoride concentration of 0.7 mg/L recorded in WFRS, of which only 10 had data for average fluoride concentration—too few to represent the variation in monthly average fluoride concentration among all adjusted systems that have adopted the optimal concentration now recommended by HHS (2015). The adjusted systems in this analysis were operating to comply with their state-established control ranges—not necessarily the previously recommended or hypothetical ranges presented here. Further, none of the adjusted systems in the 2006–2010 analysis used the hypothetical control ranges of ±0.15 mg/L or ±0.1 mg/L, and the adjusted systems included in the study were not a probability sample of all adjusted systems in the United States or of those reporting data to WFRS. Thus, caution is advised in extrapolation of these findings to target fluoride concentrations of 0.7 mg/L, or control ranges of ±0.15 mg/L or ±0.1 mg/L, to adjusted systems in states that did not participate in WFRS during this period or to all adjusted systems in the United States. Also, these findings, based on monthly average fluoride concentration, convey neither the variability of—nor the

FIGURE 6 Percentage of population receiving fluoridated water from adjusted community water systems by target concentration and control range in 2010 and 2015



The 2015 population served by each water system is used to account for shifts in population over time.

feasibility of maintaining—daily fluoride concentration within the control ranges in this study. Lastly, because the final recommendation was not published until April 2015, and some states were still operating under interim guidance for target fluoride concentration and control range, data from 2015 may not fully reflect the ability of adjusted systems to maintain average fluoride concentration within the narrowest control range of ±0.1 mg/L around a target of 0.7 mg/L. For example, in February 2016, the Connecticut General Assembly proposed a bill to align the state's optimal concentration of fluoride in drinking water to the PHS recommendation. The bill was signed by the governor in May 2016 and took effect on Oct. 1, 2016 (CGA 2016).

Once 2017 data are available, future analyses of WFRS data could report (1) the percentage of adjusted systems that have transitioned to the optimal fluoride concentration of 0.7 mg/L following the proposed and final updated recommendation (HHS 2015, 2011); (2) the control range implemented around the target fluoride concentration; and (3) the percentage of time-adjusted systems that maintain monthly average fluoride concentration within state-established, recommended, or hypothetical control ranges. Neither daily sample data nor state-established performance and quality measures are reported to WFRS; thus, publication of analyses of data available to individual states or groups of states, and their corresponding state monitoring requirements, could be used to inform selection of target fluoride concentrations, control ranges, and quality measures for state drinking water fluoridation programs.

CONCLUSIONS

Authors found that over the five-year period of 2006–2010, fluoride-adjusted community water systems maintained monthly average fluoride levels within state-established control ranges and hypothetical control ranges as narrow as ±0.2 mg/L more than ¾ of the time. Differences by system size were small but may need to be considered for control ranges of ±0.2 mg/L and narrower. By the end of 2015, 70% of adjusted systems had maintained average fluoride concentration within ±0.1 mg/L of their annual average fluoride concentration for nine of the past 12 months, 67% reported using the recommended 0.7 mg/L target, and 45% reported using the 0.7 mg/L target with a control range of ±0.1 mg/L. These findings suggest that adoption of the recommended 0.7 mg/L target fluoride concentration was underway but not completed in 2015 and that control ranges narrower than ±0.2 mg/L may be feasible for monthly average fluoride concentrations. Findings from this study may be used to inform the choice of monthly control ranges around target fluoride concentrations—such as the updated US PHS recommended concentration of 0.7 mg/L fluoride in drinking water for prevention of dental caries (i.e., tooth decay)—and development of quality measures for water fluoridation programs.

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The authors wish to acknowledge insightful comments from Barbara Gooch, Eugenio Beltran, and the editors of and anonymous reviewers for *Journal AWWA*.

DISCLAIMER

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 (CDC).

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PEER REVIEW

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received to both notices, as well as new literature, we revised the previous draft profile (including a revised Minimal Risk Level (MRL)); therefore, on June 21, 2018, ATSDR released a revised draft profile for public comment (83 FR 28849). Because the substantive revisions were limited to the MRLs Appendix, and given the public health demand for the updated toxicological profile, we opted for a 30 day comment period. ATSDR has received requests to extend the comment period for this profile. Accordingly, ATSDR is extending the comment period an additional 30 days. Comments must be submitted by August 20, 2018.

Availability

The Draft Toxicological Profiles are available online at *http://www.atsdr.cdc.gov/ToxProfiles* and at *www.regulations.gov,* Docket No. ATSDR–2015–0004.

Pamela I. Protzel Berman,

Director, Office of Policy, Partnerships and Planning, Agency for Toxic Substances and Disease Registry.

[FR Doc. 2018–15002 Filed 7–12–18; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2018–0064]

Proposed Guidance Regarding Operational Control Range Around Optimal Fluoride Concentration in Community Water Systems That Adjust Fluoride

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice; request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces in this **Federal Register** Notice a proposed operational control range around optimal fluoride concentration in community water systems that adjust fluoride, and monthly adherence to that range. The proposal is based on analysis of available data, provided in the Background document. CDC is opening a docket to obtain comment on the existence of evidence-based concerns about the appropriateness of the proposed operational control range and criteria for adherence based on measurement capacity or feasibility of maintaining a target level. The operational control range specifies upper and lower limits of variation around a target concentration of fluoride. Managers of adjusted water systems at state and local levels need this updated operational control range to ensure the maintenance of consistent monthly averages in fluoride concentration that maximize prevention of tooth decay and minimize the possibility of dental fluorosis. The proposed operational control range is 0.6 mg/L to 1.0 mg/L. CDC bases this guidance on the following considerations: (1) Concentration of fluoride in water shown to prevent tooth decay and (2) Ability of water systems to control variation in fluoride concentration.

DATES: Written comments must be received on or before October 11, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0064 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Oral Health, Centers for Disease Control and Prevention, 4770 Buford Highway, MS S107–8, Atlanta, Georgia 30341. Attn: Docket Number: CDC–2018–0064.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Valerie Robison, D.D.S., M.P.H., Ph.D., Dental Officer, Division of Oral Health, Centers for Disease Control and Prevention, 4770 Buford Highway, MS S107–8, Atlanta, GA 30341. Email: *OPTOL2018@cdc.gov,* telephone: (770) 488–6054.

SUPPLEMENTARY INFORMATION: In 2015, the U.S. Public Health Service (PHS) recommended that community water systems maintain a concentration of 0.7 mg/L to achieve a beneficial fluoride level.[1] This recommendation, which updated and replaced the 1962 Drinking Water Standards related to community water fluoridation, did not include an operational control range associated with the recommended level of 0.7 mg/L.[1 2]

After the 2015 PHS recommendation was issued, several state water fluoridation and drinking water programs contacted the Centers for Disease Control and Prevention (CDC) to request development of revised operational control range guidance around the 0.7 mg/L target level. As part of the range-setting process, these programs requested that CDC consider how consistently water treatment systems can stay within an operational control range on a daily basis. A detailed summary of the information CDC considered in developing a proposed operational control range recommendation is available in the Background document found in the Supplement Material tab of the docket.

Recommended Operational Control Range

Since water systems tend to favor an operating strategy that has a lower feed rate, or the rate at which product is added, CDC recommends an asymmetrical operational control range of 0.6 mg/L to 1.0 mg/L in order for public water systems to consistently meet the recommended concentration of 0.7 mg/L.[3]

The lowest concentration of 0.6 mg/L (−0.1 mg/L below the target level of 0.7 mg/L) will allow public water systems to maintain the oral health benefits of water fluoridation. A lowest concentration of 0.6 mg/L in an operational control range has been in effect since 1962 and water systems have demonstrated experience in meeting it in normal operations.[2 3]

The highest concentration of 1.0 mg/L (+0.3 mg/L above the target level of 0.7 mg/L) will reduce the possibility of dental fluorosis.[4 5]

An operational control range of 0.4 mg/L (−0.1 mg/L to +0.3 mg/L) [actual values (0.6 mg/L to 1.0 mg/l)] will provide operational flexibility. This is based on data demonstrating the ability of water systems to stay successfully within a particular operational control range.[4 6 7] A detailed summary of these findings is available in the Background document.

CDC has received requests for criteria that demonstrate compliance with the operational control range. Published studies have shown that water systems are able to maintain at least 80% of daily measurements during the month within the proposed operational control range.[6 7] Based on these findings, CDC recommends the following operational criteria; the monthly average fluoride level is maintained within the proposed operational control range, and 80% of daily measurements of fluoride are maintained within the proposed operational control range.

In this docket, we are only concerned with the operational control range for water systems that adjust the fluoride level in the water. This request does not apply to water systems that have natural fluoride levels that exceed this recommended level. Further, the issues of whether or not to adjust fluoride in drinking water, as well as the recommended level to which fluoride should be adjusted, have previously been addressed in the **Federal Register** and are not part of this request.[8]

Note: Public water systems must continue to comply with Environmental Protection Agency (EPA) requirements for a special notice for exceedance of the secondary standard of 2 mg/L (40 CFR 141.208) (*https://www.epa.gov/dwregdev/drinking-water-regulations-and-contaminants*).

CDC is seeking public comment on the following:

1. Are there any evidence-based concerns about the appropriateness of the proposed operational control range and criteria for adherence based on measurement capacity or feasibility of maintaining the target level?

References

1. U.S. Public Health Service Recommendations for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. *Public Health Reports.* 2015 July–Aug;130(4):318–331.
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4. Engineering and Administrative Recommendations for Water Fluoridation, MMWR Sept 29,1995/ 44(RR–13:1–40. Fluoride Recommendations Work Group. Recommendations for using fluoride to prevent and control dental caries in the United States. MMWR Recomm Rep. 2001;50(RR–14):1–42.
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6. Brown R, McTigue N, Graf K. Monitoring fluoride: how closely do utilities match target versus actual levels? Opflow, 40;7:10. *https://doi.org/10.5991/OPF.2014.40.0042.*
7. Teefy S. Managing fluoridation within a stringent regulatory framework. Proc 2013 AWWA Water Quality Technology Conference, Oakland, Calif.
8. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. *Fed Regist.* 2015;80(84):24936–24947. Available at: *https://www.federalregister.gov/documents/2015/05/01/2015-10201/public-health-service-recommendation-for-fluoride-concentration-in-drinking-water-for-prevention-of.* Accessed 5/11/2018.

Dated: July 9, 2018.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10531, CMS–R–43, CMS–10102, CMS–10143, CMS–10261, CMS–10500, and CMS–855I]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 13, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395–5806 *OR*

Email: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, "Transcatheter Mitral Valve Repair (TMVR)". The TMVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all-cause mortality and quality of life. In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we

U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FEDERAL PANEL ON COMMUNITY WATER FLUORIDATION

Through this final recommendation, the U.S. Public Health Service (PHS) updates and replaces its 1962 Drinking Water Standards related to community water fluoridation—the controlled addition of a fluoride compound to a community water supply to achieve a concentration optimal for dental caries prevention.[1] For these community water systems that add fluoride, PHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L). In this guidance, the optimal concentration of fluoride in drinking water is the concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier PHS recommendation for fluoride concentrations was based on outdoor air temperature of geographic areas and ranged from 0.7–1.2 mg/L. This updated guidance is intended to apply to community water systems that currently fluoridate, or that will initiate fluoridation, and is based on considerations that include:

- Scientific evidence related to the effectiveness of water fluoridation in caries prevention and control across all age groups,
- Fluoride in drinking water as one of several available fluoride sources,
- Trends in the prevalence and severity of dental fluorosis, and
- Current evidence on fluid intake of children across various outdoor air temperatures.

BACKGROUND

Because fluoridation of public drinking water systems had been demonstrated as effective in reducing dental caries, PHS provided recommendations regarding optimal fluoride concentrations in drinking water for community water systems in 1962.[2,3] The U.S. Department of Health and Human Services (HHS) is releasing this updated PHS recommendation because of new data that address changes in the prevalence of dental fluorosis, the relationship between water intake and outdoor temperature in children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. Although PHS recommends community water fluoridation as an effective public health intervention, the decision to fluoridate water systems is made by state and local governments.

Address correspondence to: Barbara F. Gooch, DMD, MPH, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, 4770 Buford Hwy. NE, MS F-80, Atlanta, GA 30341-3717; tel. 770-488-6054; fax 770-488-6080; e-mail <bgooch@cdc.gov>.

As of December 31, 2012, the U.S. Centers for Disease Control and Prevention (CDC) estimated that approximately 200 million people in the United States were served by 12,341 community water systems that added fluoride to water or purchased water with added fluoride from other systems. For many years, nearly all of these fluoridated systems used fluoride concentrations ranging from 0.8 to 1.2 mg/L; fewer than 1% of these systems used a fluoride concentration at 0.7 mg/L (Unpublished data, Water Fluoridation Reporting System, CDC, 2010). When water systems that add fluoride implement the new PHS recommendation (0.7 mg/L), the fluoride concentration in these systems will be reduced by 0.1–0.5 mg/L, and fluoride intake from water will decline among most people served by these systems.

It is expected that implementation of the new recommendation will lead to a reduction of approximately 25% (range: 12%–42%) in fluoride intake from drinking water alone and a reduction of approximately 14% (range: 5%–29%) in total fluoride intake. These estimates are based on intake among young children at the 90th percentile of drinking water intake for whom drinking water accounts for 40%–70% of total fluoride intake.[4] Furthermore, these estimates are based on a weighted mean fluoride concentration of 0.94 mg/L in systems that added fluoride (or purchased water from systems that added fluoride) in 2009 (Unpublished data, Water Fluoridation Reporting System, CDC, 2009). Community water systems that contain naturally occurring fluoride at concentrations >0.7 mg/L (estimated to serve about 11 million people) will not be directly affected by the new PHS recommendation.

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) sets standards for drinking water quality.[5] EPA is in the process of reviewing the maximum amount of fluoride allowed in drinking water. Upon completion of its review, the EPA will determine if it is appropriate to revise the drinking water standard for fluoride. Currently, the enforceable standard is set at 4.0 mg/L to protect against severe skeletal fluorosis (i.e., a bone disease caused by excessive fluoride intake for a long period of time that in advanced stages can cause pain or damage to bones and joints), which is a rare condition in the United States.[6,7] If the EPA determines that it is appropriate to revise the standard, any revisions could affect certain community water systems that have naturally occurring fluoride. More information about EPA's existing drinking water standards for fluoride can be found on the EPA's website.[8]

RECOMMENDATION

For community water systems that add fluoride to their water, PHS recommends a fluoride concentration of 0.7 mg/L (parts per million [ppm]) to maintain caries prevention benefits and reduce the risk of dental fluorosis.

Rationale

Importance of community water fluoridation. Community water fluoridation is a major factor responsible for the decline in prevalence (occurrence) and severity of dental caries (tooth decay) during the second half of the 20th century.[9] For adolescents, the prevalence of dental caries in at least one permanent tooth (excluding third molars) decreased from 90% among those aged 12–17 years in the 1960s to 60% among those aged 12–19 years in 1999–2004; during that interval, the number of permanent teeth affected by dental caries (i.e., decayed, missing, and filled) declined from 6.2 to 2.6, respectively.[10,11] Adults also have benefited from community water fluoridation; the average number of affected teeth decreased from 18 among 35- to 44-year-old adults in the 1960s to 10 among 35- to 49-year-old adults in 1999–2004.[11,12] Although data were not age-adjusted, age groups in the 1999–2004 survey used a higher upper age limit, and both caries prevalence and number of teeth affected increased with age; thus, these comparisons may underestimate caries decline over time.

Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood.[1,13] In 2009–2010, national survey data showed that untreated dental caries among children varied by race/ethnicity and federal poverty level. About one in four children living below 100% of the federal poverty level had untreated tooth decay,[14] which can result in pain, school absences, and poorer school performance.[15–18]

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity.[19–26] Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults.[20,22,24–26] When analyses were limited to studies conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent.[20,24,27]

Fluoride in saliva and dental plaque works to prevent dental caries primarily through topical remineralization of tooth surfaces.[28,29] Consuming fluoridated water and beverages, and foods prepared or processed with fluoridated water, throughout the day maintains a low concentration of fluoride in saliva and plaque that enhances remineralization. Although other fluoride-containing products are available and contribute to the prevention and control of dental caries, community water fluoridation has been identified as the most cost-effective method of delivering fluoride to all members of the community regardless of age, educational attainment, or income level.[9,30] Studies continue to find that community water fluoridation is cost saving.[21,31–33]

Trends in availability of fluoride sources. Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States.[34] Community water fluoridation began in 1945, reaching 49% of the U.S. population by 1975 and 67% by 2012.[35,36] Toothpaste containing fluoride was first marketed in the United States in 1955.[37] By 1983, more than 90% of children and adolescents 5–19 years of age, and almost 70% of young children 2–4 years of age, reportedly used fluoride toothpaste.[38] By 1986, more than 90% of young children 2–4 years of age were reported to use fluoride toothpaste.[39] And by the 1990s, fluoride toothpaste accounted for more than 90% of the toothpaste market.[40] Other products that provide fluoride now include mouth rinses, dietary fluoride supplements, and professionally applied fluoride compounds. More detailed explanations of these products are published elsewhere.[34,41,42]

More information on major sources of ingested fluoride and their relative contributions to total fluoride exposure in the United States is presented in an EPA report.[4] To protect the majority of the population, EPA uses the 90th percentile of drinking water intake for all age groups to calculate the relative contribution for each fluoride source. The EPA definition of "drinking water" includes tap water ingested alone or with beverages and certain foods reconstituted in the home. Among children aged 6 months to 14 years, drinking water accounts for 40%–70% of total fluoride intake; for adults, drinking water provides 60% of total fluoride intake. Toothpaste that has been swallowed inadvertently is estimated to account for about 20% of total fluoride intake in very young children (1–3 years of age).[4] Other major contributors to total daily fluoride intake are commercial beverages and solid foods.

Dental fluorosis. Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel called dental fluorosis.[43] Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth (excluding the third molars) extends from birth through 8 years of age when the preeruptive maturation of tooth enamel is complete.[34,44,45] The risk for and severity of dental fluorosis depends on the amount, timing, frequency, and duration of the exposure.[34] When communities first began adding fluoride to their public water systems in 1945, drinking water and local foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children.[7,46] At that time, only a few systems fluoridated their water, minimizing the amount of fluoride contributed by processed water to commercial foods and beverages. Since the 1940s, other sources of ingested fluoride such as fluoride toothpaste (if swallowed) and dietary fluoride supplements have become available. Fluoride intake from these products, in addition to water, other beverages, and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis.[47–53] Both the 1962 PHS recommendations and the current updated recommendation for fluoride concentration in community drinking water were set to achieve reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980s, but mostly in very mild or mild forms. Data on the prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES) 1999–2004. NHANES assessed the prevalence and severity of dental fluorosis among people aged 6–49 years. Twenty-three percent (95% confidence interval [CI] 20.1, 26.1) had dental fluorosis, of which the vast majority was very mild or mild. Approximately 2% (95% CI 1.5, 2.5) of people had moderate dental fluorosis, and fewer than 1% (95% CI 0.1, 0.4) had severe fluorosis. The prevalence of dental fluorosis that was very mild or greater was higher among young people and ranged from 41% (95% CI 36.3, 44.9) among adolescents aged 12–15 years to 9% (95% CI 6.1, 11.4) among adults aged 40–49 years.[54]

The prevalence and severity of dental fluorosis among 12- to 15-year-olds in 1999–2004 also were compared with estimates from the Oral Health of United States Children survey, 1986–1987, which was the first national survey to include measures of dental fluorosis.[55] Although these two national surveys differed in sampling and representation (household vs. schoolchildren), findings support the hypothesis that there was an increase in dental fluorosis that was very mild or greater during the time between the two surveys. In 1986–1987 and 1999–2004, the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12–15 years.[54] Similarly, the prevalence of very mild fluorosis (17.2% and 28.5%), mild fluorosis (4.1% and 8.6%), and moderate and severe fluorosis combined (1.3% and 3.6%) among 12- to 15-year-old adolescents during 1986–1987 and 1999–2004, respectively, all showed increases. Estimates limited to severe fluorosis among adolescents in both surveys, however, were statistically unreliable because there were too few cases among survey participants examined. The higher prevalence of dental fluorosis in young people in 1999–2004 may reflect increases in fluoride exposures (intake) across the U.S. population.

Children are at risk for fluorosis in the permanent teeth from birth through 8 years of age. Adolescents who were 12–15 years of age when they participated in the national surveys of 1986–1987 and 1999–2004 would have been at risk for dental fluorosis during 1971–1983 and 1984–2000, respectively.

By 1969, the percentage of the U.S. population receiving fluoridated water was 44% (n=88,475,684). By 1985, this percentage increased about 10 percentage points to 55% (n=130,172,334). By 2000, this percentage was 57% (n=161,924,080). Although the percentage point increases in more recent years appear small (2 percentage points from 1985 to 2000), it is important to note that the total size of the U.S. population also continued to expand during the time period. As a result, the 10-percentage-point increase from 1969 to 1985 reflects an increase of more than 40 million people receiving fluoridated water, whereas the 2-percentage-point increase from 1985 to 2000 represents an increase of more than 30 million people.[36]

Available data do not support additional detailed examination of changes in the percentage of children and adolescents using fluoride toothpaste. As mentioned previously, by 1983, more than 90% of children and adolescents 5–19 years of age, and almost 70% of young children 2–4 years of age, were reportedly using fluoride toothpaste; by 1986, more than 90% of young children were also using fluoride toothpaste.[38,39] As mentioned, recent EPA estimates indicate that toothpaste swallowed inadvertently accounts for about 20% of total fluoride intake in very young children.[4]

More information on fluoride concentrations in drinking water and the risk of severe dental fluorosis in children is presented in an EPA report.[7] EPA's scientific assessments considered new data on dental fluorosis and updated exposure estimates to reflect current conditions. Based on original data from a study that predated widespread water fluoridation in the United States, EPA determined that the benchmark dose for a 0.5% prevalence of severe dental fluorosis was a drinking water fluoride concentration of 2.14 mg/L, with a lower 95% CI of 1.87 mg/L.[7] Categorical regression modeling also indicated that the concentration of fluoride in water associated with a 1% prevalence of severe dental fluorosis decreased over time (1940–2000).[56] These findings are consistent with an increase in exposures from other sources of fluoride and support the conclusion that a fluoride concentration in drinking water of 0.7 mg/L would reduce the chance of dental fluorosis—especially severe dental fluorosis—in the current context of multiple fluoride sources.

The two EPA assessments of fluoride published in 2010 responded to earlier findings of the National Research Council (NRC) of the National Academies of Science, published in 2006.[4,6,7] The NRC had reviewed new data on fluoride at EPA's request and in 2006 recommended that EPA update health and exposure assessments to consider all sources of fluoride and to take into account dental effects—specifically, pitting of teeth (i.e., severe dental fluorosis) in children. The NRC identified severe dental fluorosis as an adverse health effect, because pitting of the enamel compromises its protective function. The NRC's report focused on the potential for adverse effects from naturally occurring fluoride at 2–4 mg/L in drinking water; it did not examine benefits or risks that might occur at lower concentrations typically used for community water fluoridation (0.7–1.2 mg/L).[6] For this PHS recommendation, panel scientists did review the balance of benefits and potential for unwanted effects of water fluoridation at those lower levels.[7]

Relationship between dental caries and fluorosis at varying water fluoridation concentrations. The 1986–1987 Oral Health of United States Children survey has been the only national survey that assessed the child's water fluoride exposure, thus allowing linkage of that exposure to measures of caries and fluorosis.[55] An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children and adolescents. Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7–1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased from 13.5% (standard error [SE] = 1.9) to 41.4% (SE=4.4) as fluoride concentrations in water increased from <0.3 mg/L to >1.2 mg/L.[57]

In Hong Kong, a small decrease of about 0.2 mg/L in the mean fluoride concentration in drinking water in 1978 (from 0.82 mg/L to 0.64 mg/L) was associated with a detectable reduction in fluorosis prevalence by the mid–1980s, from 64% (SE=4.1) to 47% (SE=4.5), based on the upper right central incisor only. Across all age groups, more than 90% of fluorosis cases were very mild or mild.[58] The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase.[59] Although not fully generalizable to the current U.S. context, these findings, along with findings from the 1986–1987 survey of U.S. schoolchildren, suggest that the risk of fluorosis can be reduced and caries prevention maintained toward the lower end (i.e., 0.7 mg/L) of the 1962 PHS recommendations for community water fluoridation.

Relationship of water intake and outdoor temperature among children and adolescents in the United States. The 1962 PHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L (ppm) fluoride, depending on the outdoor air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950s. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more water on warm days.[60–62] Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950s; thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid.[63]

Studies conducted since 2001 suggest that children's water intake does not increase with increases in outdoor air temperature.[64,65] One study conducted among children using nationally representative data from NHANES 1988–1994 did not find an association between either total or plain water intake and outdoor air temperature.[64] Although a similar study using nationally representative data from NHANES 1999–2004 also found no association between total water intake and outdoor temperature among children or adolescents, additional analyses of these data detected a small but statistically significant association between plain water intake and outdoor temperature.[65,66] Temperature explained less than 1% of the variation in plain water intake; thus, these findings support the use of one target concentration for community water fluoridation in all temperature zones of the United States, a standard far simpler to implement than the 1962 temperature-based recommendations. In these analyses, "plain water" was defined as from the tap or bottled water, and "total water" included water from or mixed with other beverages, such as juice, soda, sport drinks, and nondairy milk, as well as water from or mixed with foods.[66]

PROCESS

HHS convened a federal interdepartmental, interagency panel of scientists to review scientific evidence relevant to the 1962 PHS Drinking Water Standards for fluoride concentrations in drinking water in the United States and to update these recommendations based on current science. Panelists included representatives from CDC, the National Institutes of Health, the U.S. Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, EPA, and the U.S. Department of Agriculture.

The panel evaluated recent systematic reviews of the effectiveness of fluoride in drinking water to prevent dental caries, as well as published reports about the epidemiology of dental caries and fluorosis in the United States and the relationship of these conditions with varying water fluoridation concentrations. The panel also reviewed existing recommendations for fluoride in drinking water and newer data on the relationship between water intake in children and outdoor air temperature in the United States—a relationship that had served as the basis for the 1962 recommendations.

Recent systematic reviews of evidence on the effectiveness of community water fluoridation were from the Community Preventive Services Task Force, first published in 2001 and updated in 2013, and the Australian National Health and Medical Research Council in 2007.[21,23,25,26] Both reviews were updates of a comprehensive systematic review of water fluoridation completed by the National Health Service Centre for Reviews and Dissemination, University of York, in 2000.[19,20] In these reviews, estimates of fluoridation effectiveness in preventing caries were limited to children and adolescents and based on comparative studies. Random assignment of individuals usually is not feasible for studies of water fluoridation, because the intervention occurs in the community water system. Another systematic review examined the effectiveness of water fluoridation in preventing dental caries in adults. Findings were based primarily on cross-sectional studies of lifelong residents of communities with fluoridated or non-fluoridated water.[24] Studies in these systematic reviews were not limited to the United States.

Panel scientists accepted an extensive review of fluoride in drinking water by the NRC as the summary of hazard.[6] The NRC review focused on potential adverse effects of naturally occurring fluoride at 2–4 mg/L in drinking water; it found no evidence substantial enough to support effects other than severe dental fluorosis at these levels. A majority of NRC committee members also concluded that lifetime exposure to fluoride at a drinking water concentration of 4.0 mg/L (the enforceable standard established by EPA) is likely to increase bone fracture rates in the population, compared with exposure at 1.0 mg/L.[6] Fluoride concentrations used for water fluoridation have been substantially lower than the enforceable standard EPA established to protect against severe skeletal fluorosis.[2,6]

Conclusions of the panel were summarized, along with their rationale, in the *Federal Register*.[67] PHS guidance is advisory, not regulatory, in nature.

OVERVIEW OF PUBLIC COMMENTS

The public comment period for the Proposed Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries lasted for 93 days; it began with publication of the *Federal Register* notice on January 13, 2011, and was extended from its original deadline of February 14, 2011, to April 15, 2011, to allow adequate time for interested organizations and members of the public to respond. Duplicate comments (e.g., electronic and paper submissions from the same source) were counted as one comment. Although the 51 responses received electronically or postmarked after the deadline (midnight ET, April 15, 2011) were not reviewed, all other comments were considered carefully.

Approximately 19,300 responses were received; of these responses, approximately 18,500 (96%) were nearly identical to a letter submitted by an organization opposing community water fluoridation, often originating from the website of that organization; hereafter, these responses are called "standard letters." Of the remaining 746 unique responses, 79 anecdotes described personal experiences, often citing potentially harmful effects, and 18 consisted of attachments only. Attachments to the unique submissions were examined to ensure that they addressed the recommendation and to determine whether they supported it, opposed it as too low, or opposed it as too high. Although nearly all responses came from the general public, comments also were submitted by organizations, such as those representing dental, public health, or water supply professionals; those that advocate cessation of community water fluoridation; or commercial companies.

Of the unique responses, most opposed the recommendation as still too high and presented multiple concerns. Four CDC scientists (who did not serve on the interagency federal panel) reviewed all unique responses and used an electronic list of descriptors to categorize their contents. Comments were summarized and reported to the full federal panel, along with examples reflecting a range of differing opinions regarding the new recommendation. The following sections summarize frequent comments and provide the federal panel's response, divided into three categories: comments that opposed the recommendation as still too high, comments that opposed the recommendation as too low to achieve prevention of dental caries, and comments that supported the recommendation. Data on the approximate numbers of comments received in support of and opposed to the new recommendation are provided for informational purposes. Responses to these comments are based primarily on conclusions of evidence-based reviews and/or expert panels that reviewed and evaluated the best available science.

Comments that opposed the recommendation as too high

Nearly all submissions opposed community water fluoridation at any concentration; they stated that the new recommendation remains too high, and most asked that all fluoride be removed from drinking water. These submissions included standard letters (about 18,500) and unique responses (about 700 said the new level was too high; of these responses, about 500 specifically asked for all fluoride to be removed). Nearly all of these submissions listed possible adverse health effects as concerns, specifically, severe dental fluorosis, bone fractures, skeletal fluorosis, carcinogenicity, lowered IQ and other neurological effects, and endocrine disruption.

In response to these concerns, PHS again reviewed the scientific information cited to support actions announced in January 2011 by HHS and EPA—and again considered carefully whether or not the proposed recommendations and standards on fluoride in drinking water continue to provide the health benefits of community water fluoridation while minimizing the chance of unwanted health effects from too much fluoride.[4,7,67] After a thorough review of the comments opposing the recommendation, the panel did not identify compelling new information to alter its assessment that the recommended fluoride concentration (0.7 mg/L) provides the best balance of benefit to potential harm.

Dental fluorosis. The standard letters stated that the new recommendation would not eliminate dental fluorosis and cited its current prevalence among U.S. adolescents. In national surveys cited by the initial *Federal Register* notice, however, more than 90% of dental fluorosis in the United States is the very mild or mild form, most often appearing as barely visible lacy white markings or spots on the enamel.[54] EPA considers the severe form of dental fluorosis, with staining and pitting of the tooth surface, as the "adverse health effect" to be prevented.[7] Severe dental fluorosis is rare in the United States, and its prevalence could not be estimated among adolescents in a national survey because there were too few cases among the survey participants examined to achieve statistical reliability.[54] The NRC review noted that prevalence of severe dental fluorosis was near zero at fluoride concentrations <2 mg/L.[6] In addition, the most recent review of community water fluoridation by the Community Preventive Services Task Force concluded that "there is no evidence that [community water fluoridation] results in severe dental fluorosis."[26]

Standard letter submissions also expressed concern that infants fed formula reconstituted with fluoridated drinking water would receive too much fluoride. If an infant is consuming only infant formula mixed with fluoridated water, there may be an increased chance for permanent teeth (when they erupt at about age 6) to have mild dental fluorosis.[68] To lessen this chance, parents may choose to use low-fluoride bottled water some of the time to mix infant formula (e.g., bottled waters labeled as deionized, purified, demineralized, or distilled, and without any fluoride added after purification treatment; the U.S. Food and Drug Administration requires the label to indicate when fluoride is added). Such guidance currently is found on the websites of both CDC and the American Dental Association.[69,70] The PHS recommendation to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation, from birth through 8 years of age for most permanent teeth, and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water.[34,44,45]

Bone fractures and skeletal fluorosis. Some unique comments (about 100) cited fractures or other pathology of bone, while the standard letters expressed concern about skeletal fluorosis and suggested that symptoms of stage II skeletal fluorosis (i.e., a clinical stage associated with chronic pain) are identical to those of arthritis (i.e., sporadic pain and stiffness of the joints). The NRC review found no recent studies to evaluate the prevalence of skeletal fluorosis in U.S. populations exposed to fluoride at the current maximum level of 4.0 mg/L. On the basis of existing epidemiologic literature, the NRC concluded that stage III skeletal fluorosis (i.e., a clinical stage associated with significant bone or joint damage) "appears to be a rare condition in the United States" and stated that the committee "could not determine whether stage II skeletal fluorosis is occurring in U.S. residents who drink water with fluoride at 4 mg/L."[6]

The NRC also recommended that EPA consider additional long-term effects on bones in adults—stage II skeletal fluorosis and bone fractures—as well as the health endpoint that had been evaluated previously (i.e., stage III skeletal fluorosis).[6] In response, the EPA Dose–Response Analysis for Non-Cancer Effects noted that, although existing data were inadequate to model the relationship of fluoride exposure and its impact on bone strength, skeletal effects among adults are unlikely to occur at the fluoride intake level estimated to protect against severe dental fluorosis among children. The EPA report concluded that exposure to concentrations of fluoride in drinking water of ≥4 mg/L appears to be positively associated with the increased relative risk of bone fractures in susceptible populations when compared with populations consuming fluoride concentrations of 1 mg/L.[7] Recently, a large cohort study of older adults in Sweden reported no association between long-term exposure to drinking water with fluoride concentrations up to 2.7 mg/L and hip fracture.[71]

The fluoride intake estimated by EPA to protect against severe dental fluorosis among children during the critical period of enamel formation was determined to be "likely also protective against fluoride-related adverse effects in adults, including skeletal fluorosis and an increased risk of bone fractures." EPA compared its own risk assessments for skeletal effects with those made both by the NRC in 2006 and by the World Health Organization in 2002.[72] EPA concluded that its own dose recommendation is protective compared with each of these other benchmarks and, thus, is "applicable to the entire population since it is also protective for the endpoints of severe fluorosis of primary teeth, skeletal fluorosis, and increased risk of bone fractures in adults."[7]

Carcinogenicity. Some unique comments (about 100) mentioned concerns regarding fluoride as a carcinogen, and the standard letters called attention to one study that reported an association between osteosarcoma (i.e., a type of bone cancer) among young males and estimated fluoride exposure from drinking water, based on residence history.[73] The study examined an initial set of cases from a hospital-based case-control study of osteosarcoma and fluoride exposure. Findings from subsequent cases were published in 2011. This later study assessed fluoride exposure using actual bone fluoride concentration—a more accurate and objective measure than previous estimates based on reported fluoride concentrations in drinking water at locations in the reported residence history. The later study showed no significant association between bone fluoride levels and osteosarcoma risk.[74] This finding is consistent with systematic reviews and three recent ecological studies that found no association between incidence of this rare cancer and the fluoride content of community water.[20,23,25,75–78] Although study authors acknowledged the statistical and methodological limitations of ecological analyses, they also noted that their findings were consistent with the hypothesis that low concentrations of fluoride in water do not increase the risk of osteosarcoma development.

A critical review of fluoride and fluoridating agents of drinking water, accepted by the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) in 2011, used a weight-of-evidence approach and concluded that epidemiological studies did not indicate a clear link between fluoride in drinking water and osteosarcoma or cancer in general. In addition, the committee found that the available data from animal studies, in combination with the epidemiology results, did not support classifying fluoride as a carcinogen.[79] Finally, the Proposition 65 Carcinogen Identification Committee, convened by the Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, determined in 2011 that fluoride and its salts have not clearly been shown to cause cancer.[80]

IQ and other neurological effects. The standard letters and approximately 100 unique responses expressed concern about fluoride's impact on the brain, specifically citing lower IQ in children. Several Chinese studies considered in detail by the NRC review reported lower IQ among children exposed to fluoride in drinking water at mean concentrations of 2.5–4.1 mg/L—several times higher than concentrations recommended for community water fluoridation.[81–83] The NRC found that "the significance of these Chinese studies is uncertain" because important procedural details were omitted, but also stated that findings warranted additional research on the effects of fluoride on intelligence.[6]

Based on animal studies, the NRC committee speculated about potential mechanisms for nervous system changes and called for more research "to clarify the effect of fluoride on brain chemistry and function." These recommendations should be considered in the context of the NRC review, which limited its conclusions regarding adverse effects to water fluoride concentrations of 2–4 mg/L and did "not address the lower exposures commonly experienced by most U.S. citizens."[6] A recent meta-analysis of studies conducted in rural China, including those considered by the NRC report, identified an association between high fluoride exposure (i.e., drinking water concentrations ranging up to 11.5 mg/L) and lower IQ scores; study authors noted the low quality of included studies and the inability to rule out other explanations.[84] A subsequent review cited this meta-analysis to support its identification of "raised fluoride concentrations" in drinking water as a developmental neurotoxicant.[85]

A review by SCHER also considered the neurotoxicity of fluoride in water and determined that there was not enough evidence from well-controlled studies to conclude if fluoride in drinking water at concentrations used for community fluoridation might impair the IQ of children. The review also noted that "a biological plausibility for the link between fluoridated water and IQ has not been established."[79] Findings of a recent prospective study of a birth cohort in New Zealand did not support an association between fluoride exposure, including residence in an area with fluoridated water during early childhood, and IQ measured repeatedly during childhood and at age 38 years.[86]

Endocrine disruption. All of the standard letters and some of the unique comments (about 100) expressed concern that fluoride disrupts endocrine system function, especially for young children or for individuals with high water intake. The 2006 NRC review considered a potential association between fluoride exposure (2–4 mg/L) and changes in the thyroid, parathyroid, and pineal glands in experimental animals and humans. The report noted that available studies of the effects of fluoride exposure on endocrine function have limitations. For example, many studies did not measure actual hormone concentrations, and several studies did not report nutritional status or other factors likely to confound findings. The NRC called for better measurement of exposure to fluoride in epidemiological studies and for further research "to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and factors that determine the response, if any, in a given individual."[6] A 2007 review did not find evidence that consuming drinking water with fluoride at the level used in community water fluoridation presents health risks for people with chronic kidney disease.[87]

Effectiveness of community water fluoridation in caries prevention. In addition to citing potential adverse health effects, the standard letters stated that the benefits of community water fluoridation have never been documented in any randomized controlled trial. There are no randomized, double-blind, controlled trials of water fluoridation because its community-wide nature does not permit randomization of individuals to study and control groups or blinding of participants. However, community trials have been conducted, and these studies were included in systematic reviews of the effectiveness of community water fluoridation.[20,21,23,25,26] As noted, these reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity.

Standard letters also stated that African American and low-income children would not be protected by the recommendation, as they have experienced more tooth decay than other racial/ethnic groups, despite exposure to fluoride through drinking water and other sources. Data from NHANES do not support this statement and, instead, document a decline in the prevalence and severity of dental caries (tooth decay) across racial/ethnic groups. For example, in 1999–2004, compared with 1988–1994, the percentage of adolescents aged 12–19 years who had experienced dental caries in their permanent teeth, by race/ethnicity, was 54% in African American (down from 63%), 58% in non-Hispanic white (down from 68%), and 64% in Mexican American (down from 69%) adolescents.[11] For adolescents whose family income was less than 100% of the federal poverty level, a similar decline occurred: 66% had experienced dental caries in 1999–2004, down from 72% in 1988–1994. Although disparities in caries prevalence among these adolescent groups remain, the prevalence for each group was lower in 1999–2004 than in 1988–1994. Concurrent with these reductions in the prevalence of dental caries, the percentage of the U.S. population receiving fluoridated water increased from 56% (n=144,217,476) in 1992 to 62% (n=180,632,481) in 2004. This change represented an increase of more than 36 million people.[36]

Cost-effectiveness of community water fluoridation. Some unique comments (about 200) called attention to the cost of water fluoridation or stated that it was unnecessary or inefficient given the availability of other fluoride modalities and the amount of water used for purposes other than drinking. Cost-effectiveness studies that included costs incurred in treating all community water with fluoride additives still found fluoridation to be cost saving.[21,88] Although the annual per-person cost varied by size of the water system (from $0.50 in communities of ≥20,000 to $3.70 for communities of ≤5,000, updated to 2010 dollars using the Consumer Price Index [CPI]), it remains only a fraction of the cost of one dental filling. The annual per-person cost savings for those aged 6–65 years ranged from $35.90 to $28.70 for larger and smaller communities, respectively (updated to 2010 dollars using CPI dental services).[88] Studies in the United States and Australia also have documented the cost-effectiveness of community water fluoridation.[21,31–33]

Safety of fluoride additives. Unique comments (about 300) expressed concern that fluoride is a poison and an industrial waste product; standard letters noted the lack of specific data on the safety of silicofluoride compounds used by many water systems for community water fluoridation. All additives used to treat water, including those used for community water fluoridation, are subject to a system of standards, testing, and certification involving participation of the American Water Works Association, NSF International, and the American National Standards Institute (ANSI)—entities that are nonprofit, nongovernmental organizations. Most states require that water utilities use products that have been certified against ANSI/NSF Standard 60: Drinking Water Treatment Chemicals—Health Effects (hereinafter, Standard 60) by an ANSI-accredited laboratory. All fluoride products evaluated against Standard 60 are tested to ensure that the levels of regulated impurities present in the product will not contribute to the treated drinking water more than 10% of the corresponding maximum contaminant level established by EPA for that contaminant.[89] Results from 2000–2011, reported on the NSF International website, found that no contaminants exceeded the concentration allowed by Standard 60.[90]

Although commenters expressed concerns about silicofluorides, studies have shown that these compounds achieve virtually complete dissolution and ionic disassociation at concentrations added to drinking water and, thus, are comparable to the fluoride ion produced by other additives, such as sodium fluoride.[89,91,92] At the pH of drinking water, usually 6.5–8.5, and at a fluoride concentration of 1 mg/L, the degree of hydrolysis of hexafluorosilicic acid has been described as "essentially 100%."[89] Standard 60 provides criteria to develop an allowable concentration when no maximum contaminant level has been established by the EPA. Using this protocol, NSF International calculations showed that a sodium fluorosilicate concentration needed to achieve 1.2 mg/L would result in 0.8 mg/L of silicate, or about 5% of the allowable concentration calculated by NSF International.[90]

SCHER also considered health and environmental risks associated with the use of silicofluoride compounds in community water fluoridation and concurred that in water they are rapidly hydrolyzed to fluoride, and that concentrations of contaminants in drinking water are well below guideline values established by the World Health Organization.[79]

Ethics of community water fluoridation. All standard letters and some unique comments (about 200) stated that water fluoridation is unethical mass medication of the population. To determine if a public health action that may encroach on individual preferences is ethical, a careful analysis of its benefits and risks must occur. In the case of water fluoridation, the literature offers clear evidence of its benefits in reducing dental decay, with documented risk limited to dental fluorosis.[4,7,19–26]

Several aspects of decision-making related to water fluoridation reflect careful analysis and lend support to viewing the measure as a sound public health intervention. State and local governments decide whether or not to implement water fluoridation after considering evidence regarding its benefits and risks. Often, voters themselves make the final decision to adopt or retain community water fluoridation. Although technical support is available from HHS, federal agencies do not initiate efforts to fluoridate individual water systems. In addition, court systems in the United States have thoroughly reviewed legal challenges to community water fluoridation and have viewed it as a proper means of furthering public health and welfare.[93]

Comments that opposed the recommendation as too low

Several unique comments said that 0.7 mg/L is too low to offer adequate protection against tooth decay. Evidence, however, does suggest that 0.7 mg/L will maintain caries preventive benefits. Analysis of data from the 1986–1987 Oral Health of United States Children survey found that reductions in dental caries plateaued at 0.7–1.2 mg/L of fluoride.[57] In addition, fluoride in drinking water is only one of several available fluoride sources, such as toothpaste, mouth rinses, and professionally applied fluoride compounds.

Comments that supported the recommendation

Some submissions specifically endorsed lowering the concentration of fluoride in drinking water for the prevention of dental caries. Other commenters asked for guidance on the operational range for implementing the recommended concentration of 0.7 mg/L and on consistent messaging regarding the recommended change. Currently, CDC is reviewing available data and collaborating with organizations of water supply professionals to update operational guidance. In addition, CDC continues to support local and state infrastructure needed to implement and monitor the recommendation. Examples of this support include maintenance of the Water Fluoridation Reporting System; provision of training opportunities for water supply professionals; assisting state and local health agencies with health promotion and public education related to water fluoridation; and funding research and surveillance activities related to dental caries, dental fluorosis, and fluoride intake (in coordination with other federal agencies, including the National Institute of Dental and Craniofacial Research).

MONITORING IMPLEMENTATION OF THE NEW RECOMMENDATION

Unpublished data from the Water Fluoridation Reporting System show how rapidly the proposed change in recommended concentration has already gained acceptance. In December 2010, about 63% of the population on water systems adjusting fluoride (or buying water from such systems) was at ≥1.0 mg/L and fewer than 1% were at 0.7 mg/L. By summer 2011—only six months after publication of the draft notice—68% of that population was at 0.7 mg/L and about 28% was at ≥1.0 mg/L.

Following broad implementation of the new recommendation, enhanced surveillance during the next decade will detect changes in the prevalence and severity of dental caries and of dental fluorosis that is very mild or greater, nationally and for selected sociodemographic groups. For example, the 2011–2012 NHANES included clinical examination of children and adolescents by dentists to assess decayed, missing, and filled teeth; presence of dental sealants; and dental fluorosis. The 2013–2014 examination added fluoride content of home water (assessed using water taken from a faucet in the home), residence history (needed to estimate fluoride content of home tap water for each child since birth), and questions on use of other fluoride modalities (e.g., toothpaste, prescription drops, and tablets). As findings from these and future examinations become available, they can be accessed through the CDC website.[94]

Definitive evaluation of changes in dental fluorosis prevalence or severity associated with reduction in fluoride concentration in drinking water cannot occur until permanent teeth erupt in the mouths of children who drank that water during the period of tooth development. HHS agencies continue to give priority to the development of valid and reliable measures of fluorosis, as well as technologies that could assess individual fluoride exposure precisely. A recent study documented the validity of fingernail fluoride concentrations at age 2–7 years as a biomarker for dental fluorosis of the permanent teeth at age 10–15 years.[95]

CONCLUSIONS

PHS acknowledges the concerns of commenters and appreciates the efforts of all who submitted responses to the *Federal Register* notice describing its recommendation to lower the fluoride concentration in drinking water for the prevention of dental caries. The full federal panel considered these responses in the context of best available science but did not alter its recommendation that the optimal fluoride concentration in drinking water for prevention of dental caries in the United States be reduced to 0.7 mg/L, from the previous range of 0.7–1.2 mg/L, based on the following information:

- Community water fluoridation remains an effective public health strategy for delivering fluoride to prevent tooth decay and is the most feasible and cost-effective strategy for reaching entire communities.
- In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence.
- Caries preventive benefits can be achieved and the risk of dental fluorosis reduced at 0.7 mg/L.
- Recent data do not show a convincing relationship between water intake and outdoor air temperature. Thus, recommendations for water fluoride concentrations that differ based on outdoor temperature are unnecessary.

Surveillance of dental caries, dental fluorosis, and fluoride intake will monitor changes that might occur, following implementation of the recommendation.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FEDERAL PANEL ON COMMUNITY WATER FLUORIDATION

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