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# Adjusted fluoride concentrations and control ranges in 34 states — 2006–2010 and 2015

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# Abstract

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, CDC'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 to 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.,  $\pm 0.2$  mg/L) were >83% versus 68% for 0.2 mg/L wide ( $\pm 0.1$  mg/L). In 2015, 70% of adjusted systems maintained averages within  $\pm 0.1$  mg/L of their system's annual average for 9 of 12 months, 67% used the 0.7 mg/L target and 45% used it with a  $\pm 0.1$  mg/L control range. Adoption of the 0.7 mg/L target was underway but not completed in 2015. Control ranges narrower than  $\pm 0.2$  mg/L may be feasible for monthly average fluoride concentration.

# Keywords

Fluoridation; quality; control range; recommendation

# **INTRODUCTION – BACKGROUND**

In January 2011, the Department of Health and Human Services (HHS) 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 (DHHS 2011). By summer 2011 – well before the April 2015 publication of the updated recommendation – many fluoride-adjusted community water systems (adjusted systems) had already begun

#### RESOURCES

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CDC's Community Water Fluoridation resources website: http://www.cdc.gov/fluoridation/index.htm CDC's My Water's Fluoride website: https://nccd.cdc.gov/DOH\_MWF/Default/Default.aspx

ASTDD's Best Practice Report http://www.astdd.org/use-of-fluoride-community-water-fluoridation/#5

AWWA Water Fluoridation Principles and Practices, Manual of Water Supply Practices – M4, Fifth Edition. 2004 (ISBN 1-58321-311-2).

adjusting fluoride to the 0.7 mg/L concentration now recommended 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 of 2010 (PHS 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 plus or minus 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 (PHS 1962, CDC 1986, CDC 1995).

Community water fluoridation has been recognized as one of 10 great public health achievements of the 20<sup>th</sup> century (CDC 1999) and providing water with a fluoride concentration consistently close to the optimal fluoride concentration throughout the year is key for prevention of tooth decay (CDC 2013a, CDC 2013b, ASTDD 2015). 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 American 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 (twelve 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 nor size of population served, however, a few authors have suggested that these factors may be important to consider in establishing a control range (Kuthy et al. 1985, Lalumandier et al. 2001, Teefy 2013). With publication of the updated recommendation for a single optimal fluoride concentration of 0.7 mg/L across the US, regardless of outdoor temperature, data to inform choice of an appropriate control range need to be considered.

Studies published prior to 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 such as fluoride toothpastes and mouth rinses have become widely available since water fluoridation was first introduced (Community Preventive Services Task Force 2013), is cost saving for communities of 1,000 population (costs less than the economic benefit) and savings increase with the size of the community population (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 marking or spots on the enamel of teeth (Beltrán-Aguilar et al. 2010, NIDCR 1989). Dental fluorosis can only occur in children while teeth are developing under the gums (Aoba & Feyerskov 2002). The now-recommended 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 (PHS 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 mg/L wide to 0.8 mg/L wide (PHS 1962, Maier 1963). For example, in the warmest areas of the US the control range was 0.6-0.8 mg/L (i.e.,  $0.7 \text{ mg/L} \pm 0.1 \text{ mg/L}$ ) 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  $\pm 0.1$  mg/L even for cooler areas with optimal fluoride concentration above 0.7 mg/L (Richards et al. 1967, Hann 1968, Long & Stowe 1973, EPA 1976), 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) 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., stateestablished). Target fluoride concentrations used by adjusted systems can be found in CDC's My Water's Fluoride web site, 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). It should be noted that these databases may not contain complete information from every area, and states that waited for the April 2015 publication of the final recommendation may have been in the process of revising their optimal concentration and control range at this time of this study.

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 to this analysis and suggest consideration of hypothetical control ranges as narrow as  $\pm 0.1 \text{ mg/L}$ . In a 1998 survey, 25.9% of 1,280 water plant operators in 12 states reported that their systems were able to maintain fluoride concentrations within  $\pm 0.1 \text{ mg/L}$  of the target, an additional 49.3% between  $\pm 0.1$  to  $\pm 0.2 \text{ mg/L}$ , and 19.5% between  $\pm 0.2$  to  $\pm 0.3 \text{ mg/L}$  (Lalumandier et al. 2001). In the same study, 33.5% of operators of larger plants producing >1 million gallons of water per day (MGD) and 21.3% of operators of smaller plants producing 1 MGD reported ability to maintain fluoride concentrations within  $\pm 0.1 \text{ mg/L}$  of the target.

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 at the time of study. In Vermont, the control

range was  $\pm 0.2$  mg/L around the target fluoride concentration of 1.0 mg/L, and in New Hampshire 0.1 mg/L below to 0.5 mg/L above the three target fluoride concentrations of 1.0, 1.1 and 1.2 mg/L. A study (Kuthy et al. 1985) using data from Illinois Environmental Protection Agency laboratory tests conducted monthly for 249 adjusted systems during 1977–1981 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  $\pm 0.1$  mg/L of the target fluoride concentration, 92.5% within  $\pm 0.15$  mg/L, and 98% within  $\pm 0.2$  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  $\pm 0.1$  mg/L and 98% were within  $\pm 0.15$  mg/L of the target fluoride concentration of 0.85 mg/L. This study (Teefy 2013) 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  $\pm 0.3$  mg/L as of November 2013.

The purpose of this study is 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  $\pm 0.3$ ,  $\pm 0.2$ ,  $\pm 0.15$ , and  $\pm 0.1$  mg/L around the target. The first two aims of the study are to describe overall and by size of population served: 1) the number and percentage of system-months for which the average fluoride concentration was within, below, or above each of the six control ranges and 2) 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 (100%) months among the subset of adjusted systems that reported average fluoride concentration for all 60 months in the five-year study period. The third aim is to 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  $\pm 0.3$ 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). State personnel calculate the monthly average concentration from 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 to EPA Safe Drinking Water Information System (SDWIS) public water system identification number (PWSID) 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 (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 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 non-transient non-community systems by EPA's definition. For the first study aim, adjusted systems with at least one month of data for average fluoride concentration reported to WFRS during 2006–2010 were included. For the second study aim, only adjusted systems with average fluoride concentration data in WFRS for all 60 months during 2006–2010 were included. For the third study aim, 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 the first two study aims, authors compared the average fluoride concentration for each adjusted system for each month from January 2006 through December 2010 to six control ranges: the state-established control range ("state-established") 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  $\pm 0.3$ ,  $\pm 0.2$ ,  $\pm 0.15$ , and  $\pm 0.1$  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 the third aim, analyses of data from 2015 focus on the same hypothetical ranges, and specific state-established control ranges of  $\pm 0.1$  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 only for the four-year period of 2006–2009 would contribute 48 systemmonths 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 is presented overall and by system size. For the second study aim, 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 the third study aim, 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 a) changes in state-established target fluoride concentrations between the proposed (January 2011) and final (April 2015) updated recommendation and b) a major WFRS modernization in July 2011. To characterize the data from WFRS during the study period, authors report: 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 and IQR are reported to 1/100 mg/L as are the vast majority of monthly average fluoride concentrations in WFRS, although WFRS can store averages recorded to 1/1000 mg/L; percentages are reported to the percentage point, except for Figure 6 in which tenths of a percentage point are shown to aid comparisons to CDC's Fluoridation Statistics Report. Because the adjusted systems included in this study were a large convenience sample from all adjusted systems, sampling error of the average fluoride concentrations could not be characterized from WFRS data, and non-sampling error such as

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selection bias may be the more predominant error type in this study, neither standard errors nor statistical tests of hypotheses are reported. Although this study included a large subset of the adjusted systems in the US, 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 target fluoride concentration and 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 that used a target fluoride concentration of 1.1 mg/L target fluoride concentration of 1.0 during 2007–2010 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 2–4 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).

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  $\pm 0.3$ mg/L (91%) and lowest for  $\pm 0.1$  mg/L (68%), with differences by system size of 7–10 percentage points; there was no consistent ordering by size of population served (Figure 4). For state-established and hypothetical control ranges wider than  $\pm 0.2$  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  $\pm 0.2$  mg/L and narrower. The 30% of adjusted systems using state-established control ranges of  $-0.1/\pm0.5$ ,  $\pm 0.3$ , and  $\pm 0.2$  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  $\pm 0.3$  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 90% 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 below to 0.5 mg/L above the target fluoride concentration were lower than for the symmetrical  $\pm 0.3$  mg/L control range of the same width (84% and 32% versus 94% and 53%). As expected, the percentage of adjusted systems maintaining average fluoride concentrations within the control range was smaller for narrower control ranges of  $\pm 0.2, \pm 0.15$  and  $\pm 0.1 \text{ mg/L}$  than the  $\pm 0.3 \text{ mg/L}$ , state-established, and asymmetrical -0.1 to +0.5 mg/L control ranges. The percentages for the control range of  $\pm 0.2 \text{ mg/L}$  were similar (e.g., 85% for 45 of 60 months and 34% for all 60 months), however, to those for the wider asymmetrical control range of -0.1 to +0.5 mg/L. For the narrowest control range of  $\pm 0.1$ mg/L, only 59% maintained average fluoride concentration within that control range for 45 of 60 months, compared to 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  $\pm 0.2$  mg/L and data for all 60 months, almost three-quarters 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 5–21 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  $\pm 0.1$  and  $\pm 0.15$  mg/L, and for 54 or fewer of 60 months.

#### Study Aim 3: Target and average fluoride concentration and control range in 2015

By December 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  $\pm 0.1$  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 -0.1to +0.2 mg/L (7%), and target fluoride concentration of 0.8 mg/L with a control range 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  $\pm 0.1$  mg/L around their annual average fluoride concentration for at least 9 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 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  $\pm 0.1$  mg/L, and higher for the wider control ranges, again with the same decreasing pattern by increasing number of months in 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  $\pm 0.2$  mg/L for more than three-quarters 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  $\pm 0.15$  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.

Findings for Aim 2 were consistent with expectations that the percentage maintaining concentrations within narrower ranges would be 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. The finding that more adjusted systems maintained average fluoride concentrations within  $\pm 0.2$  mg/L of the target fluoride concentration over time than within  $\pm 0.1$  mg/L of the target fluoride concentration aligns with findings from two recent studies (Teefy 2013, Brown et al. 2014). Teefy (2013) concluded that maintaining fluoride concentration within a  $\pm 0.1$  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  $\pm 0.15$  mg/L of the target fluoride concentration. Brown, et al. (2014) found that only four of 40 adjusted systems (10%) maintained fluoride concentrations within  $\pm 0.1$  mg/L for 100% of the daily samples during one year, although all 40 (100%) systems had fluoride concentrations within  $\pm 0.2$  mg/L and 36 (90%) had fluoride concentrations within  $\pm 0.15$ mg/L of the target for 80% of the daily samples. Similarly, findings for Aim 2 from 990 adjusted systems with data for 60 months in 2006-2010 found 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  $\pm 0.1$  mg/L for all 60 months (100% of 60 months, and 82% and 66% maintained average fluoride concentration within  $\pm 0.2 \text{ mg/L}$  and  $\pm 0.15 \text{ mg/L}$ , respectively, for 48 of 60 months (i.e., 80% of 60 months).

Findings from 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. Based on 2015 data, it appears that a majority of adjusted systems maintain average fluoride concentration within  $\pm 0.1$  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 adjusted systems with state-established control range of  $\pm 0.1$  mg/L may be due to a transition period as adjusted systems begin to operate even 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  $\pm 0.15$  mg/L and  $\pm 0.1$  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, nor the percentage of adjusted systems maintaining average fluoride concentration within each control range for most of the study period, except for the narrowest control range of  $\pm 0.15$  and  $\pm 0.1$  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; 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 of time. 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 three-quarters 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. That WFRS data also are used by ADA, ASTDD and CDC to present awards for fluoridation quality to states and individual adjusted systems suggests 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 PHS (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  $\pm 0.15$  mg/L or  $\pm 0.1$  mg/L and the adjusted systems included in the study were not a probability sample of all adjusted systems in the US nor of those reporting data to WFRS. Thus, caution is advised in extrapolation of these findings to target fluoride concentrations of 0.7 mg/L, control ranges of  $\pm 0.15$  mg/L or  $\pm 0.1$  mg/L, to adjusted systems in states that did not participate in WFRS during this time period, or to all adjusted systems in the US. Also, these findings based on monthly average fluoride concentration convey neither the variability of - nor the 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  $\pm 0.1$  mg/L around a target of 0.7 mg/L. For example, in February 2016,

Connecticut's 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 October 1, 2016 (CGA 2016).

Once 2017 data are available, future analyses of WFRS data could report 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 (DHHS 2011, PHS 2015), the control range implemented around the target fluoride concentration, and the percentage of time that adjusted systems 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 concentration 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  $\pm 0.2 \text{ mg/L}$  more than three-quarters of the time. Differences by system size were small but may need to be considered for control ranges of  $\pm 0.2 \text{ mg/L}$  and narrower. By the end of 2015, 70% of adjusted systems had maintained average fluoride concentration within  $\pm 0.1 \text{ mg/L}$  of their system's annual average fluoride concentration for 9 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  $\pm 0.1 \text{ mg/L}$ . 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  $\pm 0.2 \text{ mg/L}$  may be feasible for monthly average fluoride concentrations. Findings from this study may be used to inform choice of monthly control ranges around target fluoride concentrations — such as the updated US Public Health Service recommended concentration of 0.7 mg/L fluoride in drinking water for prevention of dental caries — and development of quality measures for water fluoridation programs.

# Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

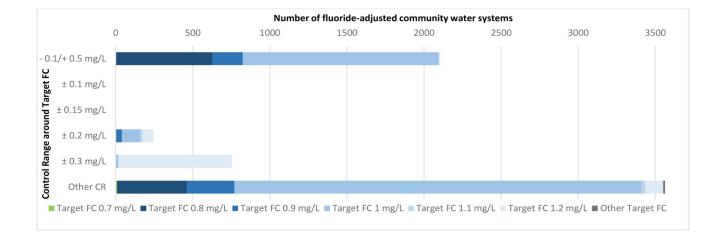
# Acknowledgments

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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.

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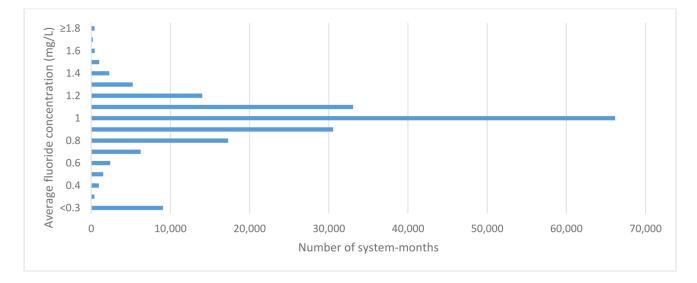
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## Figure 1.

Target fluoride concentration and control range recorded for 6,667 adjusted community water systems in 34 states – Water Fluoridation Reporting System 2006–2010 FC Fluoride concentration

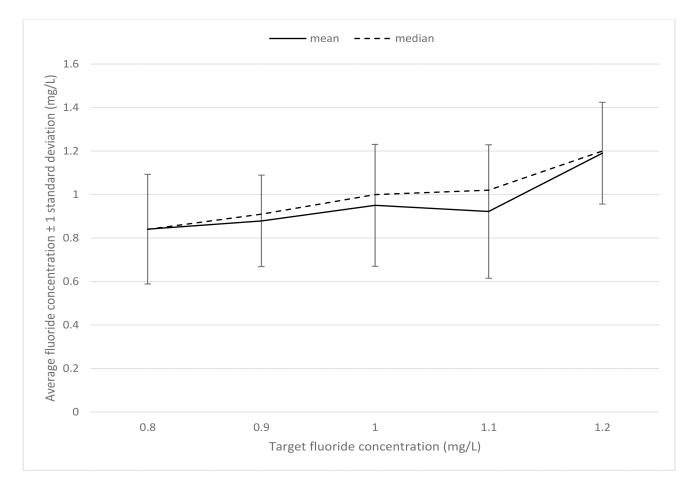
Barker et al.



# Figure 2.

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

Barker et al.



# Figure 3.

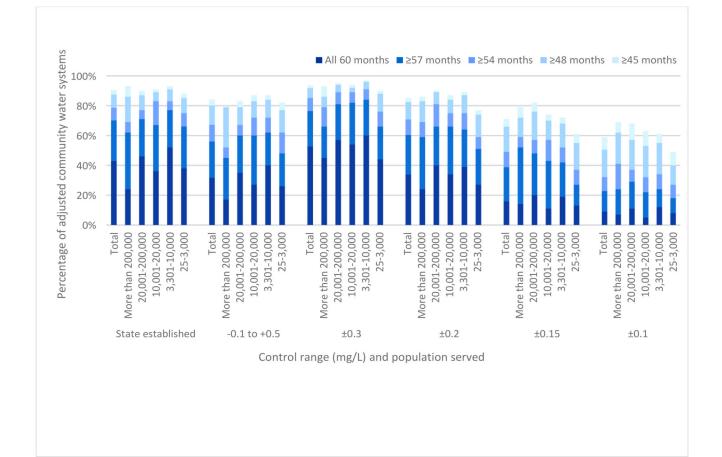
Monthly average ( $\pm 1$  standard deviation) and median fluoride concentration among adjusted community water systems by target fluoride concentration – Water Fluoridation Reporting System, 2006–2010

		0	10	20	30	40	50	60	70	80	90	
	Total						87				1	
q	More than 200,000						07					
she	20,001-200,000						89					
abli												
State established	10,001-20,000						90					
ate	3,301-10,000						91					
St	25-3,000						85					
	Total						84					
	More than 200,000											
Ŀ.							78					
0+	20,001-200,000						84					
-0.1 to +0.5	10,001-20,000						86					
0	3,301-10,000						87					-
	25-3,000						81					-
	Total						91					
	More than 200,000						91					
	20,001-200,000						94					
±0.3	10,001-20,000						94					
• • •	3,301-10,000						94					
	25-3,000					_	87		_			
	Total						85					
	More than 200,000						87					
)	20,001-200,000						89					
±0.2	10,001-20,000						88					
ŦI	3,301-10,000						88					
±0.2 ±0.3	25-3,000						81					
	Total						76					
	More than 200,000						81					
	20,001-200,000											
±0.15	10,001-20,000						81					
±0.							79					
	3,301-10,000						/9					
	25-3,000						71					
	Total						68					
	More than 200,000						71					
	20,001-200,000						71					
±0.1							/1					
+1	10,001-20,000						69					
	3,301-10,000						69					
	25-3,000						65					-

## Figure 4.

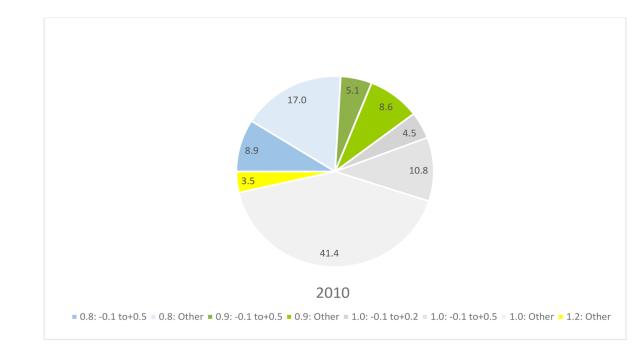
Percentage of system-months in which average fluoride concentration for each month was below, within and above selected control ranges around the target fluoride concentration among adjusted community water systems during 2006–2010, overall and by population served

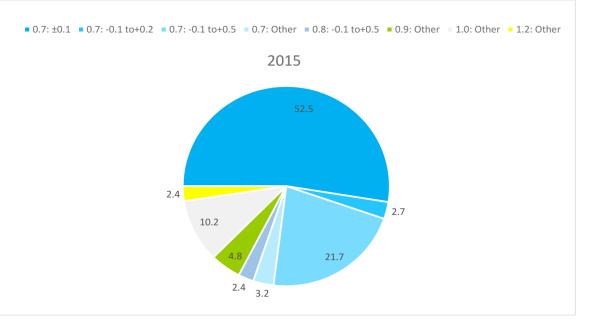
Barker et al.



#### Figure 5.

Percentage of adjusted community water systems that maintained average fluoride concentration within selected control ranges around the target fluoride concentration for all 60, 57, 54, 48 or 45 of 60 months during 2006–2010 among 990 adjusted systems with data for all 60 months, overall and by population size





#### 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.

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 (percentage of adjusted systems)	Maximum Possible number of system- months	Number (percentage) of system- months with data	Number of states with data in WFRS for one or more systems
Community Water Systems listed in the Water Fluoridation Reporting System (WFRS) <sup><math>a</math></sup>	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 <sup>b</sup>	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 <sup><math>C</math></sup>	6,645 (97%)	398,700	364,300 (89%)	50 states and DC
Any monthly data in WFRS <sup>d</sup>	5,467 (80%)	328,020	297,289 (73%)	In 34 states
Monthly average fluoride concentration in WFRS for at least one month during 2006–2010	4,251 (62%)	255,060	191,266 (47%)	In 34 states
Monthly average fluoride concentration in WFRS for all 60 months during 2006–2010	990 (15%)	59,400	59,400 (15%)	In 23 states

<sup>d</sup> The number of systems in WFRS is larger than the number of active community water systems in SDWIS because: 1) systems listed in WFRS for any month during 2006–2010 are included; 2) some of the systems listed in WFRS are non-transient non-community 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 concentration may have changed during the study period.

<sup>d</sup>During 2006–2010, thirty-four 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 due to starting or stopping adjustment of fluoride during the study period, either permanently, or temporarily for equipment maintenance or material supply shortage.

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

Control Range	Number of Adjusted Systems using Control Range	Number of States in which these Adjusted Systems are Located
-0.1/+0.5 mg/L	893	18
±0.3 mg/L	160	6
±0.2 mg/L	202	10

Percentage of adjusted community water systems maintaining average fluoride concentration within hypothetical and state-established control ranges for 9, 11 and 12 months during 2015.

		12 months	11 months	9 months
Hypothetical c	ontrol range arour	nd annual average f	luoride concentration	on (n=2,560)
Lower limit	Upper limit			
-0.1 mg/L	+0.1 mg/L	38%	54%	70%
-0.1 mg/L	+0.2 mg/L	48%	64%	82%
-0.1 mg/L	+0.5 mg/L	50%	67%	87%
		12 months	11 months	9 months
State established of	control range arou		11 months oncentration of 0.7	
State established of <i>Lower limit</i>	control range aroun			
	U			
Lower limit	Upper limit	nd target fluoride c	oncentration of 0.7	mg/L (n=1,646)

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Number and percentage of adjusted community water systems that maintained average fluoride concentration within selected control ranges around the target fluoride concentration for 60, 57, 54, 48 or 45 of 60 months during 2006–2010 among 990 adjusted systems with data for all 60 months

Number of adjusted community water systems that maintained average fluoride concentration within control range for:

		months	months	months	months	months
State es	State established	424	693	778	866	896
Hypc	Hypothetical					
Lower limit	Upper limit					
Target – 0.1	Target + 0.5	313	553	664	793	833
Target – 0.3	Target + 0.3	520	757	843	606	926
Target – 0.2	Target + 0.2	334	597	701	817	843
Target – 0.15	Target + 0.15	156	383	486	652	704
Target – 0.1	Target + 0.1	88	225	317	499	581
Control range		60 months	57 months	54 months	48 months	45 months
State es	State established	43%	70%	79%	87%	91%
Hypc	Hypothetical					
Lower limit	Upper limit					
Target – 0.1	Target + 0.5	32%	56%	67%	80%	84%
Target – 0.3	Target $+ 0.3$	53%	76%	85%	92%	94%
Target – 0.2	Target + 0.2	34%	60%	71%	83%	85%
Target – 0.15	Target + 0.15	16%	39%	49%	66%	71%
Tarøet – 0.1	Taroet + 0 1	%6	23%	32%	50%	59%