National Oral Health Conference – Cincinnati, April 18, 2016

A Tale of 2 Evidence-Based Reviews:
Current Evidence on Community Water Fluoridation:

Background on Cochrane and Community Preventive Services Task Force conclusions and recommendations regarding Community Water Fluoridation

Howard Pollick, BDS, MPH
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A Tale of ~~2~~ 3 Evidence-Based Reviews:
Current Evidence on Community Water Fluoridation:

Background on Cochrane and Community Preventive Services Task Force and USPHS conclusions and recommendations regarding Community Water Fluoridation

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Comparing three recent reviews

US Community Preventive Services Task Force – 2013

http://www.thecommunityguide.org/oral/fluoridation.html

USPHS/CDC New Guidelines – 2015

http://www.publichealthreports.org/documents/PHS_2015_Fluoride_Guidelines.pdf

Cochrane Review – 2015

http://www.cochrane.org/CD010856/ORAL_water-fluoridation-prevent-tooth-decay

Community Preventive Services Task Force

- The Community Preventive Services Task Force established in 1996 by the U.S. DHHS
- The Task Force is an independent, nonfederal, unpaid panel of public health and prevention experts that provides evidence-based findings and recommendations about community preventive services, programs, and policies to improve health. Its members represent a broad range of research, practice, and policy expertise in community preventive services, public health, health promotion, and disease prevention.
- To identify population health interventions that are scientifically proven to save lives, increase lifespans, and improve quality of life.
- Produces recommendations (and identifies evidence gaps) to help inform the decision making of federal, state, and local health departments, other government agencies, communities, healthcare providers, employers, schools and research organizations.

Community Preventive Services Task Force – 2013

- Reaffirmed and updated its 2000 recommendation for water fluoridation
- **Strong** evidence of effectiveness in reducing tooth decay (dental caries) across populations.

- http://www.thecommunityguide.org/oral/fluoridation.htm

Community Preventive Services Task Force – 2013

- Based on 28 studies about the effect of CWF on caries; 16 about oral health disparities, and 117 about dental fluorosis.
- Most of these studies were included in an existing systematic review - McDonagh 2000 (York)
  - search period 1966-1999; 26 studies on caries; 13 on oral health disparities; 88 on fluorosis
- Combined with more recent evidence
  - search period 1999-2012; 2 on caries; 3 on oral health disparities and 29 on fluorosis

The Guide to Community Preventive Services
THE COMMUNITY GUIDE
What Works to Promote Health

CWF Effectiveness

Community Preventive Services Task Force (2013):

Findings: In fluoridated communities there was:

Increase in percent of **caries-free** individuals
- Median: 14.6%; range -5.0% to 64% (11 studies)
- Median: 25.1%; range 19.8% to 31.6% (1 study)

Decrease in number of dmft/DMFT
- Median 2.25 teeth; range 0.5 to 4.4 (10 studies)

Task Force recommended CWF to prevent or control caries in communities

*CWF Effectiveness

Community Preventive Services Task Force (2016):

Economic Evaluation of Community Water Fluoridation
A Community Guide Systematic Review

–Search period from January 1995 to November 2013
–Ten studies
–Per person annual cost for communities with more than 20,000 population was less than $1
–Benefit–cost ratios ranged up to 135:1 for large communities

American Journal of Preventive Medicine
Available online 6 January 2016. In Press, Corrected Proof

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National Center for Chronic Disease Prevention and Health Promotion, CDC

National Oral Health Conference, April 27, 2015. Kansas City

HHS Recommendation on Community Water Fluoridation

CENTERS FOR DISEASE CONTROL AND PREVENTION

Community Water Fluoridation HHS Recommendations

- 2010 - HHS panel of federal scientists reviewed relevant evidence to update 1962 recommendations
- 2011 - Proposed HHS recommendation: 0.7 mg/L fluoride in water
- Intent of the action
  - Balance the health benefits of preventing tooth decay across the lifespan while reducing fluoride exposure in children
- Status
  - 0.7 mg/L has been widely implemented by public water systems.
  - Of all persons receiving fluoridated drinking water in the U.S. about 68% were receiving water with 0.7 mg/L fluoride by Summer 2011 – just 6 months after the proposed recommendation was announced

Community Water Fluoridation HHS Recommendations

- April 27, 2015: Online in Public Health Reports. July-August 2015
  - U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation. U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. Public Health Reports / July–August 2015 / Volume 130. 318-331.

- May 1, 2015: Federal Register
- Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries
  - https://www.federalregister.gov/articles/2015/05/01/2015-10201/public-health-service-recommendation-for-fluoride-concentration-in-drinking-water-for-prevention-of

2015 HHS Community Water Fluoridation Recommendations

- Recommendation
- Rationale
- Importance of Community Water Fluoridation
- Trends in Availability of Fluoride Sources
- Dental Fluorosis
- Relationship Between Dental Caries and Fluorosis at Varying Water Fluoridation Concentrations
- Relationship of Water Intake and Outdoor Temperature Among Children and Adolescents in the United States
- Process
- Comments That Opposed the Recommendation as Too High
- Dental Fluorosis
- Bone Fractures and Skeletal Fluorosis
- Carcinogenicity
- IQ and Other Neurological Effects
- Endocrine Disruption
- Effectiveness of Community Water Fluoridation in Caries Prevention
- Cost-Effectiveness of Community Water Fluoridation
- Safety of Fluoride Additives
- Ethics of Community Water Fluoridation
- Comments That Opposed the Recommendation as Too Low
- Comments That Supported the Recommendation
- Monitoring Implementation of the New Recommendation
- Summary and Conclusions
- References
- Appendix A—HHS Federal Panel on Community Water Fluoridation

mg/L: milligrams per Liter

2015 HHS Community Water Fluoridation Recommendations

- "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"
- I would have preferred *standardized* to 0.7

mg/L: milligrams per Liter

Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- June 18, 2015
- Water Fluoridation for the prevention of dental caries
- **Objectives**
- To evaluate the effects of water fluoridation (artificial or natural) on the prevention of dental caries.
- Water with a fluoride concentration of 0.4 parts per million (ppm) or less (arbitrary cut-off defined a priori) was classified as non-fluoridated.
- Reviewed 20 studies examined tooth decay, most of which (70%) were conducted prior to 1975.
- *Compared to 28 studies from the 2013 Community Preventive Services Task Force Review*
- Cochrane did not review outcomes other than caries and dental fluorosis

- For caries data, only prospective studies
- concurrent control
- comparing at least two populations
  - one receiving fluoridated water and the other non-fluoridated water
  - Groups comparable in terms of fluoridated water at baseline.

- "due to the nature of the research question, randomised controlled trials are unfeasible"

Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- Findings on caries and CWF
- **35% reduction** in decayed, missing or filled baby teeth - mean difference was 1.8 dmft
- -absolute during period of the study or yearly?
- **26% reduction** in decayed, missing or filled permanent teeth - mean difference was 1.2 DMFT
- ***15% increase in children with no decay***
- *applicability of the results to current lifestyles is unclear* because the majority of the studies were conducted before fluoride toothpastes and the other preventative measures were widely used

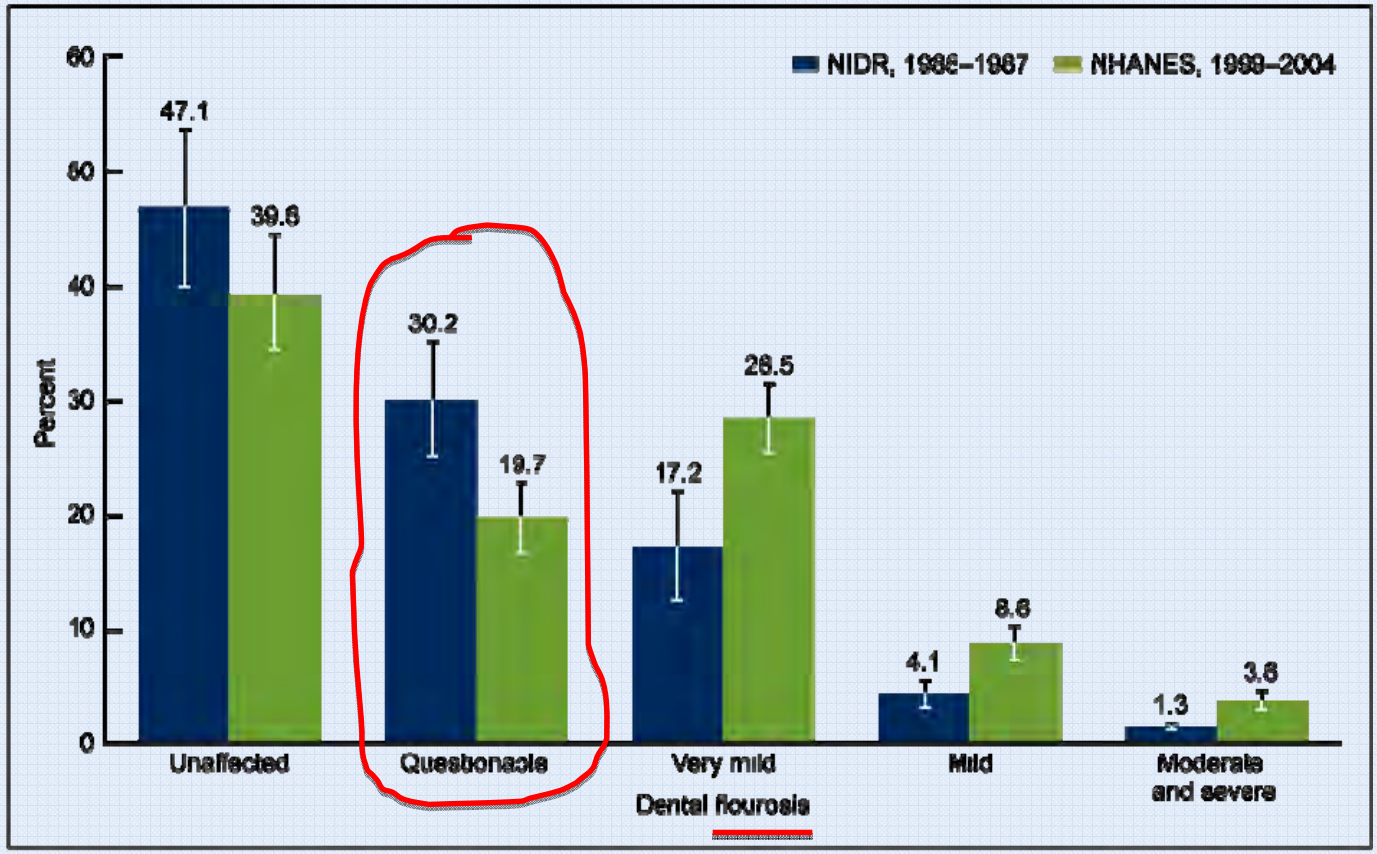
- For studies assessing the *cessation* of water fluoridation, groups had to be from fluoridated areas at baseline
- with one group subsequently having fluoride removed from the water.
- *insufficient information* available to understand the effect of stopping water fluoridation programmes on tooth decay

- **Water fluoridation and dental fluorosis**

- **Objectives**
- To evaluate the effects of water fluoridation (artificial or natural) on dental fluorosis.
- *However, that was changed*
- Fluoride at any concentration present in drinking water – up to 5 ppm
- Reviewed 135 studies on dental fluorosis.

Dental fluorosis types, by severity:
12-15 year-olds: the need to monitor exposure to fluoride.

Figure 3. Change in dental fluorosis prevalence among children aged 12–15 participating in two national surveys: United States, 1986–1987 and 1999–2004



NOTES: Dental fluorosis is defined as having very mild, mild, moderate, or severe forms and is based on Dean's Fluorosis Index. Percentages do not sum to 100 due to rounding. Error bars represent 95% confidence intervals.

SOURCES: CDC/NCHS, National Health and Nutrition Examination Survey, 1999–2004 and National Institute of Dental Research, National Survey of Oral Health in U.S. School Children, 1986–1987.

Enamel Fluorosis and Tooth Decay


Normal


Questionable


Very Mild

Decay is more common, disfiguring and serious


Mild


Tooth Decay


Tooth Decay and abscesses

Photographs of enamel fluorosis from Forum on Water Fluoridation in Ireland, 2002

Dental fluorosis types, by severity:
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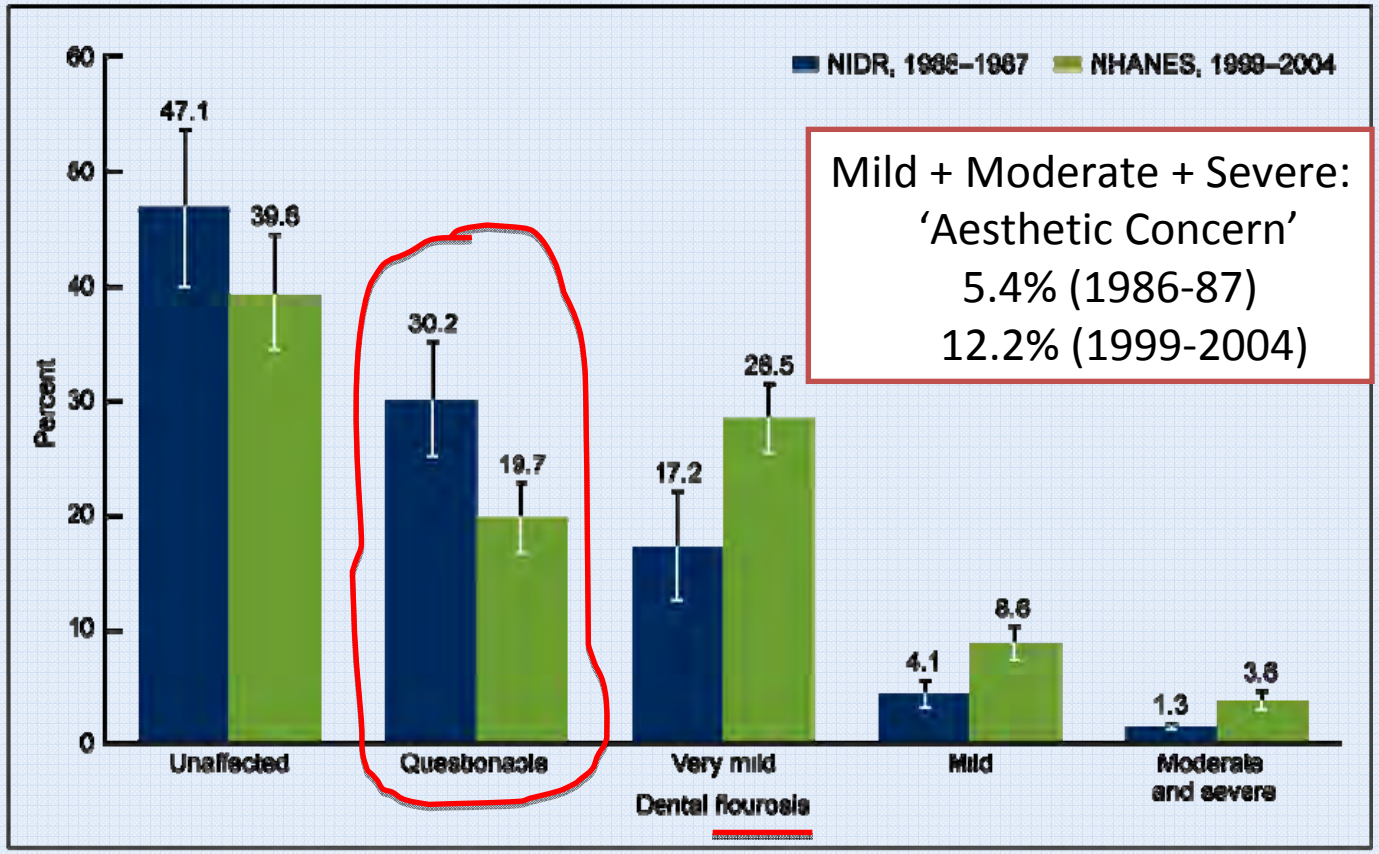

Mild + Moderate + Severe:
'Aesthetic Concern'
5.4% (1986-87)
12.2% (1999-2004)

NOTES: Dental fluorosis is defined as having very mild, mild, moderate, or severe forms and is based on Dean's Fluorosis Index. Percentages do not sum to 100 due to rounding. Error bars represent 95% confidence intervals.

SOURCES: CDC/NCHS, National Health and Nutrition Examination Survey, 1999–2004 and National Institute of Dental Research, National Survey of Oral Health in U.S. School Children, 1986–1987.

Cochrane Oral Health

Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- Cochrane definition of dental fluorosis
  - classified children with a DDE, TSIF, TFI score greater than zero or
  - Dean's classification of 'questionable' or higher as having dental fluorosis.

- *Traditionally Dean's 'questionable' category has **not** been included in prevalence of dental fluorosis*

- *20-30% of U.S. 12-15 year-olds had questionable dental fluorosis*

Cochrane Oral Health

Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- Cochrane definition of dental fluorosis of aesthetic concern
- Any dental fluorosis scoring ≥3 (TFI), ≥2 (TSIF) and
- 'mild' or worse (Dean's)
- *Note that studies of the public perception of aesthetic concern show that less than 15% of mild dental fluorosis is considered to be aesthetically objectionable*

Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- McDonagh et al. 2000 York systematic review:
  - at a fluoride level of **1 ppm** an estimated 12.5% people would have fluorosis that they *would* find aesthetically concerning.

- Cochrane 2015:
  - At a fluoride level of **0.7 ppm** in the water, approximately 12% of the people evaluated had fluorosis that *could* cause concern about their appearance.

CDC Comments Regarding the Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- July 2, 2015
- One key difference between this USPHS review and the Cochrane review is that Cochrane used **more restrictive criteria** for including studies in their analyses
- Although valid, peer-reviewed studies document the effectiveness of community water fluoridation in children and adults even after the use of fluoride toothpaste became widespread, **these studies were not considered by Cochrane**

July 2, 2015
CDC Comments Regarding the Cochrane Review of
Water Fluoridation for the Prevention of Dental Caries

- <u>Effectiveness of Water Fluoridation in Reducing Caries in **Children:**</u>

- estimates of fewer teeth affected by cavities in fluoridated communities and a higher percentage of caries-free children are similar to findings of other evidence-based reviews (e.g., the Task Force in 2013).

✓ Cochrane

✓ Task Force

✓ USPHS

July 2, 2015
CDC Comments Regarding the Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- <u>Effectiveness of Water Fluoridation in Reducing Caries in **Adults:**</u>
- No studies met Cochrane's criteria regarding the effectiveness of water fluoridation in adults.
- Cochrane includes only studies where the outcomes are evaluated at two points in time in the same sample of adults. Clearly, such an evaluation over a long time period could be difficult.
- Research published in the peer-reviewed literature (in Australia and the United States) found differences in caries experience (i.e., numbers of teeth or tooth surfaces with caries) between adults who have access to community water fluoridation and those who do not.

X Cochrane

✓ Task Force

✓ USPHS

July 2, 2015
CDC Comments Regarding the Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

Effectiveness of Water Fluoridation in Reducing Caries in **Adults**:

✓Task Force

✓USPHS

•lower caries levels in adults who were exposed to fluoridation even after other sources of fluoride, such as fluoride toothpaste, became widely available

Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of fluoride in preventing caries in adults. J Dent Res 2007;86:410-5.
Meta-analysis of 5 cross-sectional studies published after 1979 and among adults with lifetime residency in F and NF communities (N=2530)
Tooth decay reduced overall by 27% (95% CI 19–34%)

Slade GD, Sanders AE, Do L, Roberts-Thompson K, Spencer AJ. Effects of fluoridated drinking water on dental caries in Australian adults. J Dent Res 2013;92:376-82.

July 2, 2015

CDC Comments Regarding the Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

Evidence supporting water fluoridation is ***strong***

✓Task Force

✓USPHS

XCochrane - these studies did not meet Cochrane's criteria for inclusion

- Rugg-Gunn AJ, Do L. Effectiveness of water fluoridation in caries prevention. Community Dent Oral Epidemiol 2012;40 (Suppl. 2):55-64.
- Brunelle JA, Carlos JP. Recent trends in dental caries in U.S. children and the effect of water fluoridation. J Dent Res 1990;69 (Spec Iss):723-727
- Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of fluoride in preventing caries in adults. J Dent Res 2007;86:410-5.
- Slade GD, Sanders AE, Do L, Roberts-Thompson K, Spencer AJ. Effects of fluoridated drinking water on dental caries in Australian adults. J Dent Res 2013;92:376-82.

July 2, 2015
CDC Comments Regarding the Cochrane Review of Water Fluoridation for the Prevention of Dental Caries

- Cochrane concluded that there was insufficient information to show that fluoridation works to reduce differences in tooth decay across socio-economic groups.

- CDC: Data from national surveys in the U.S. show that prevalence of tooth decay for groups of adolescents defined by poverty status or race/ethnicity has continued to decline over time.

- CDC: The biggest advantage of community water fluoridation is that it is the best method of delivering fluoride to all members of the community, regardless of age, education, income level or access to routine dental care.

April 8, 2016

Latest Critique of the Cochrane Review

"The Cochrane Review's conclusion that 'there is very little contemporary evidence that has evaluated the effectiveness of water fluoridation for the prevention of caries' is self-fulfilling due to its omission of contemporary studies designed for surveillance of public health programmes."


Critique of the review of 'Water fluoridation for the prevention of dental caries' published by the Cochrane Collaboration in 2015

A. J. Rugg-Gunn,*[1] A. J. Spencer,[2] H. P. Whelton,[3] C. Jones,[4] J. F. Beal,[5] P. Castle,[6] P. V. Cooney,[7] J. Johnson,[8] M. P. Kelly,[9] M. A. Lennon,[10] J. McGinley,[11] D. O'Mullane,[12] H. D. Sgan-Cohen,[13] P. P. Sharma,[14] W. M. Thomson,[15] S. M. Woodward[16] and S. P. Zusman[17]

Rugg-Gunn AJ et al. (17 authors)

British Dental Journal **220**, 335 - 340 (2016)
Published online: 8 April 2016

Identified Evidence Gaps

- Task Force (2000):
- What is the effectiveness of CWF in reducing socioeconomic or racial and ethnic disparities in caries burden?

- Task Force (2013):
  - Inconsistent results (3 studies)

- Cochrane (2015):
- There was insufficient information available to find out whether the introduction of a water fluoridation programme changed existing differences in tooth decay across socioeconomic groups.

Identified Evidence Gaps

- Task Force (2000):
- What is the effectiveness of CWF among adults (aged >18 years)?
- How effective is CWF in preventing root-surface caries?
- Task Force (2013):
  - Because all the included studies examined the effectiveness of CWF in children, research on the effectiveness among adults is needed
- Cochrane:
- No studies met the review's inclusion criteria that investigated the effectiveness of water fluoridation for preventing tooth decay in adults.

The Guide to Community Preventive Services
THE COMMUNITY GUIDE
What Works to Promote Health

Identified Evidence Gaps

- Task Force (2013):
- More research also is needed to understand the following.

- The contribution of fluoride from sources other than water
- The effects of bottled water use (with fluoride naturally present, added, or removed) on caries incidence in fluoridated communities
- Role of water hardness and calcium related to the bioavailability of fluoride among individuals and communities
- Effect of CWF over and above other caries preventive measures, namely dental sealants and fluoride varnishes
- Accumulation of fluoride in calcified tissues (predominantly bone) over time
- Other potential positive or negative health effects

Identified Evidence Gaps

- Both the Cochrane Review and the latest review conducted by the Task Force identified the need for more research to address the effectiveness of fluoridation in the current environment of widespread use of fluoride toothpaste and other measures to prevent tooth decay, such as fluoride varnish and dental sealants.

Filling the gaps:
CDC monitors benefits and risks of CWF

NHANES (from 2013):

- Fluoride content of home water samples for children
- Exposure to other sources of fluoride (toothpaste, fluoride drops and tablets)
- Dentist-assessed measures of caries, fluorosis, and dental sealants
- Researchers will continue to examine data for tooth decay as well as dental fluorosis on a national level and for selected socioeconomic and racial groups.

NHANES: National Health and Nutrition Examination Survey

Questions???

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Safety
Review by National Research Council (2006)

- Focused on naturally-occurring fluoride concentrations in drinking water of 2–4 mg/L
- Notably higher than recommendations for CWF (~1 mg/L)
- Found substantial evidence only for increased risk of severe dental fluorosis
- Noted prevalence of severe dental fluorosis was near zero with fluoride concentrations in drinking water of <2.0 mg/L
- Concluded that lifetime exposure to fluoride at drinking water concentrations of 4.0 mg/L is likely to increase bone fractures compared to exposures at 1.0 mg/L

www.nap.edu/catalog.php?record_id=11571
CWF: community water fluoridation
mg/L: milligram per Liter

Concerns: Measures of Intelligence

- **NRC review (2006)**
  - Considered several Chinese studies reporting lowered IQ among children exposed to higher fluoride concentrations (2.5 – 4.1 mg/L) in drinking water
  - Stated that "the significance of these Chinese studies is uncertain" because important procedural details were omitted; called for more research
- **Meta-analysis (Choi, 2012)**
  - Found association; lower IQ scores among children residing primarily in rural China **with high fluoride concentrations** in drinking water
  - Authors noted low quality of included studies; called for studies with measures of exposure at the individual level over time
  - Findings cited to support "raised fluoride concentrations" in drinking water as a potential developmental neurotoxicant (Grandjean and Landrigan, 2014)
- **Cohort study (Broadbent, 2014)**
  - Found **no association between fluoride exposure** during childhood and repeated IQ measures during childhood and at age 38 years.

Concerns: Attention Deficit and Hyperactivity Disorder (ADHD)

Ecologic study (Malin, 2015)

- Found that prevalence of ADHD was higher in states with higher percentages of persons receiving fluoridated water (CWF)
- Exposure to CWF was measured at the state level
- **No control for other possible explanatory factors for ADHD**
  - prenatal exposures to alcohol or tobacco, other environmental exposures (e.g., lead), premature delivery, and low birth weight

Malin AJ, Till C. Environmental Health 2015;14(17).
CWF: community water fluoridation
http://www.cdc.gov/ncbddd/adhd/facts.html

Malin AJ, Till C. Environmental Health 2015;14(17).
CWF: community water fluoridation
http://www.cdc.gov/ncbddd/adhd/facts.html

Concerns: Hypothyroidism

- **Ecologic study (Peckham, 2015)**
  - Found a higher prevalence of hypothyroidism among primary care practices located in fluoridated vs. non-fluoridated areas in England
  - **No control for other explanatory factors at the individual level, such as iodine sufficiency, or common risk factors**
- **NRC review (2006)**
  - Considered potential association between fluoride exposure (2 – 4 mg/L) and changes in thyroid function
  - Noted **limitations of available studies** of the effects of fluoride exposure on endocrine functions
    - Many did not measure actual hormone concentrations; some did not report nutritional status or other potential confounders
  - Called for better measurement of fluoride exposure, other potential explanatory factors, and outcomes at the individual level

Health 2015
CWF: community water fluoridation

Summary

- All three recent reviews agreed that CWF has been demonstrated to reduce the burden of tooth decay.
- There are evidence gaps.
- Surveillance of dental caries, dental fluorosis, and fluoride intake will monitor changes that might occur following the implementation of the recommendation to 0.7 mg/L.