WSBH Petition #22. December 4, 2024

Washington State Board of Health

PO Box 47990, Olympia, WA 98504-7990 wsboh@doh.wa.gov

Petitioners: Washington Action for Safe Water and Bill Osmunson DDS MPH

Dear Washington State Board of Health

"Addendum A" is an update to our petition #22 for rule change.[1]

Below are the slides from the December 3, 2024 webinar put on by Kayla Taylor PhD et al of the National Toxicology Program's report on fluoride's developmental neurotoxicity.

[1] Consistent with health and safety issues in Title 246, Title 173, Title 296, WAC 173-340, and WAC 296-62-07521; this petition is made in compliance with RCW 34.05.330 and WAC Chapter 82-05.

Our petition for amendment to WAC 246-290-220

"(8) In keeping with the Federal Safe Drinking Water Act S.433 and the Food Drug and Cosmetic Act, Title 21, the Board of Health does not recommend any substance be added to water with intent to treat humans, unrelated to treatment of water as defined in RCW 18.64.011(14)(15) or 21 U.S. Code § 321(g)(1), unless approved by the Food and Drug Administration in compliance with the U. S. Food, Drug and Cosmetic Act. This recommendation does not apply to substances added to water to make water safer as determined by the U.S. Environmental Protection Administration in compliance with the Safe Drinking Water Act."

Of summary and special note:

1. Page 30. “Children in high fluoride communities have statistically significantly lower IQ.”
2. Page 33. “For every 1 mg/L increase in urinary there is a statistically significant decrease in IQ
3. Page 35 For the NTP Monograph which ended May 1, 2020 the NTP reported
   “Consistent inverse association across:
   - 18 of 19 high quality studies
   - 46 of the 53 low quality studies
4. Conclusion of “Moderate Confidence” took over 4 years to get published
5. Note the Addendum
   Literature since May 1, 2020?

- Addendum updated through October 2023 to match timeframe of meta-analysis (in press)

- 28 new studies
  - 12 of 12 high quality studies reported inverse associations (6 in new study populations)
  - 13 of 16 low quality reported inverse associations

6. Of the 19 high quality studies before 2020 and the 12 high quality studies after 2020, only one of the 31 high quality studies did not report harm from fluoride to the developing brain.

During the January, 2024, the two-week court hearing, the hired expert for the EPA's defense was raising doubt of harm to the developing brain based on the 18 of the19 high quality studies reported by the NTP. I was listening as Judge Chen interrupted the prosecution questions and asked the expert, "so what would change your mind?" The expert responded, "one or two more studies reporting harm." I remember screaming at my computer yelling, "that's what the tobacco companies kept saying about the risk of tobacco smoking in the 1970's."

And now the NTP/OHAT reports there are 12 of 12 more high quality studies reporting harm to the developing brain.

Hundreds of thousands of babies over the last 14 years of our petitions have been harmed in Washington State from fluoridation because the Board of Health has refused to even remove their false endorsement that fluoridation is "safe and effective" and "cost effective."

Once again, read our latest published peer reviewed research that when just the cosmetic risk and 3 IQ points are lost the cost estimate is $556 per person per year on fluoridation. http://dx.doi.org/10.1002/puh2.70009

Below are the slides from the NTP/OHAT webinar and sometimes quality is lost so the same slides are attached.

Sincerely,

Bill Osmunson DDS MPH

Washington Action for Safe Water

NTP Monograph
Fluoride Exposure and Neurodevelopment and Cognition
A Systematic Review

Collaborative for Health and the Environment

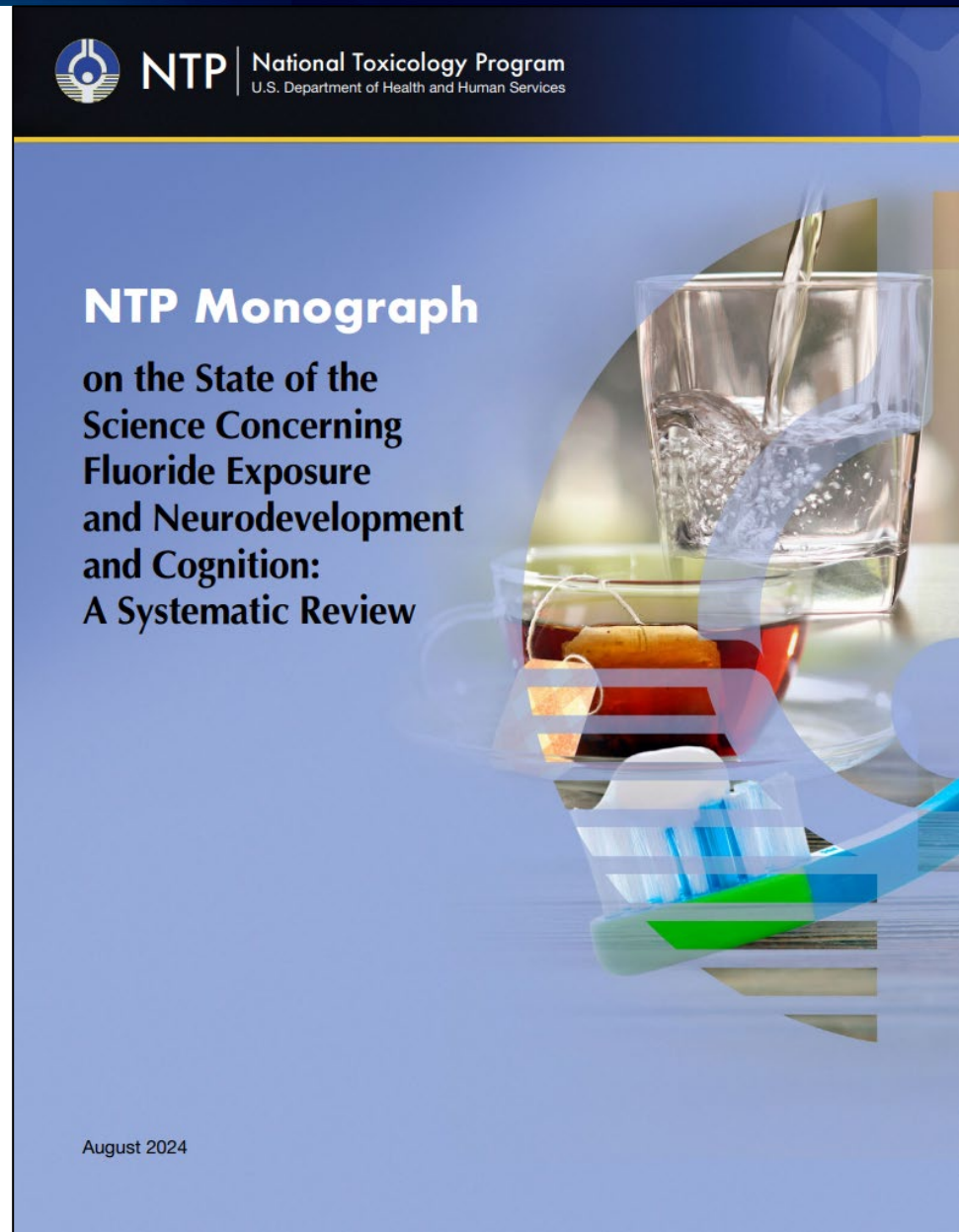
December 3, 2024

Kyla W. Taylor, PhD, John Bucher, PhD, Andrew A. Rooney, PhD

Integrative Health Assessments Branch
Division of Translational Toxicology
National Institute of Environmental Health Sciences

Talk outline

- What is fluoride? The history of U.S. water fluoridation
- NTP Monograph: Fluoride, neurodevelopment, and cognition
- Public health relevance
- Recent federal court ruling and role of the Monograph
- Questions and panel discussion



What is fluoride?

- Naturally occurring mineral
- Topical contact reduces risk of cavities
- Added to drinking water
- Many other sources of exposure

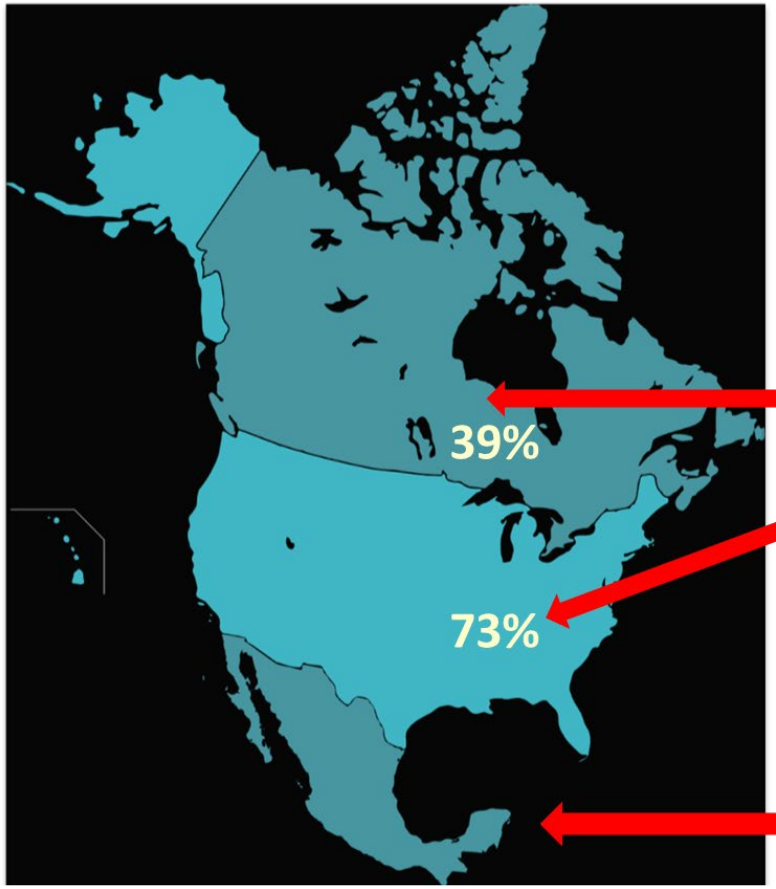
Topical sources

Systemic sources

History of U.S. water fluoridation

- Early 20th century researchers noticed that people living in areas with high levels of fluoride in drinking water had fewer cavities
- First added to drinking water in Grand Rapids, Michigan in 1945
- The U.S. Public Health Service (PHS) first recommended communities add fluoride to drinking water in 1962
- U.S. PHS recommends 0.7 mg/L fluoride added to drinking water
- Community water systems serve about 200 million US residents

Sources of *added* fluoride in North America



Drinking water
Recommended: 0.7 mg fluoride/L

Salt supply is fluoridated

Public Health Agency of Canada, 2017

Adverse health effects and current drinking water standards and recommendations

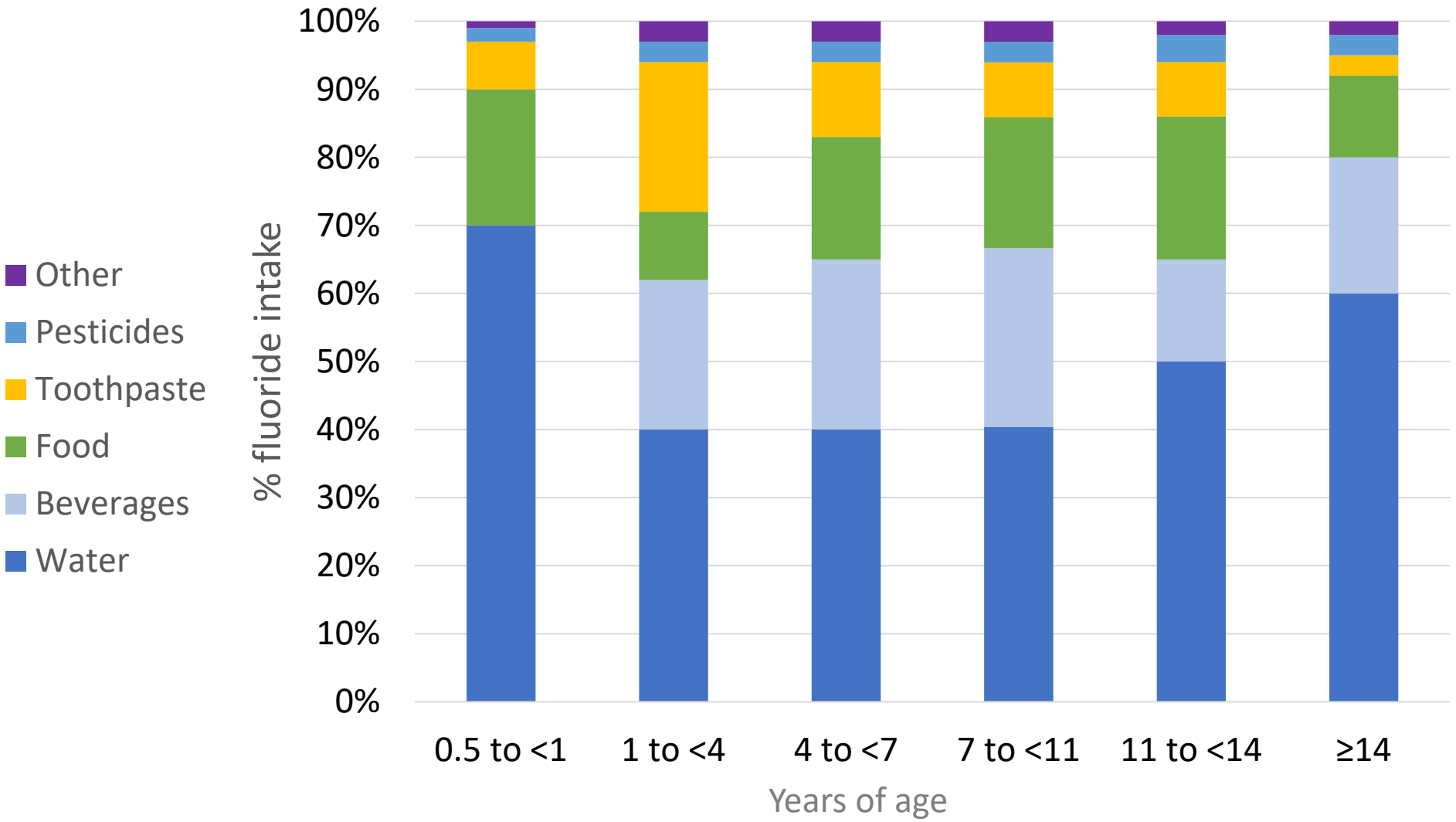
- Skeletal fluorosis
  - Bone disease caused by fluoride accumulation in the bones
  - Causes pain and tenderness of the major joints
- Dental fluorosis
  - Mild: Discoloration
  - Moderate to severe: Pitting

Dental fluorosis is the white discoloration

	Agency	Fluoride drinking water level	US residents served by CWSs above level
Standards (enforceable)	US EPA	4.0 mg/L	> 40,000
Recommendations (non-enforceable)	US EPA	2.0 mg/L	> 1.9 Million
	WHO	1.5 mg/L	> 2.9 Million
	US PHS	0.7 mg/L	>20.5 Million

CWS: Community water system
EPA: Environmental Protection Agency
WHO: World Health Organization
PHS: Public Health Service

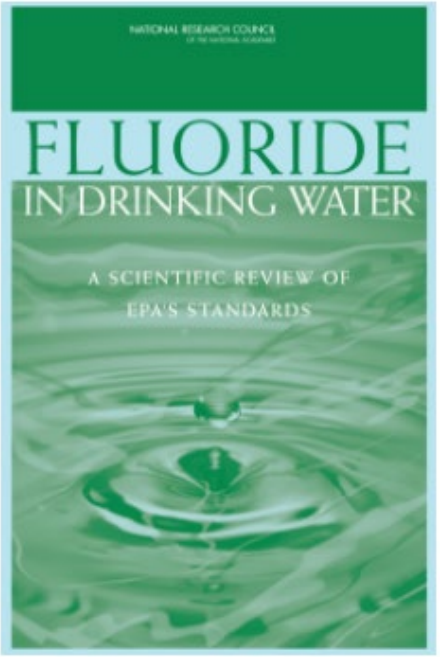
% total fluoride intake in children from various sources, by age



US EPA Fluoride: Exposure and Relative Source Contribution Analysis (2010)

Neurotoxic effects?

- **2006:** National Research Council (NRC) reported evidence of neurotoxic effects of fluoride
- Fetal and developing brains are especially vulnerable to neurotoxicants
- Concern that some pregnant women and children may be getting more fluoride than they need because they now get fluoride from many sources and the combined total intake of fluoride may exceed safe amounts
- Fetal exposure
  - Fluoride from maternal blood crosses placenta
  - Fluoride stored in bone and remobilized into bloodstream during pregnancy
- Formula-fed infants residing in fluoridated communities:
  - 3-4 times greater exposure to fluoride than adults on a per body-weight basis
  - ~70-fold higher fluoride intake than exclusively breastfed infants

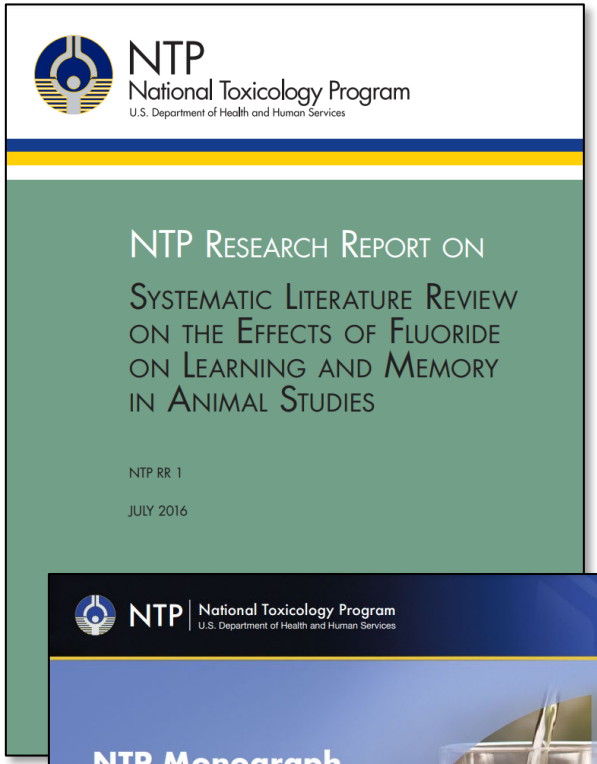


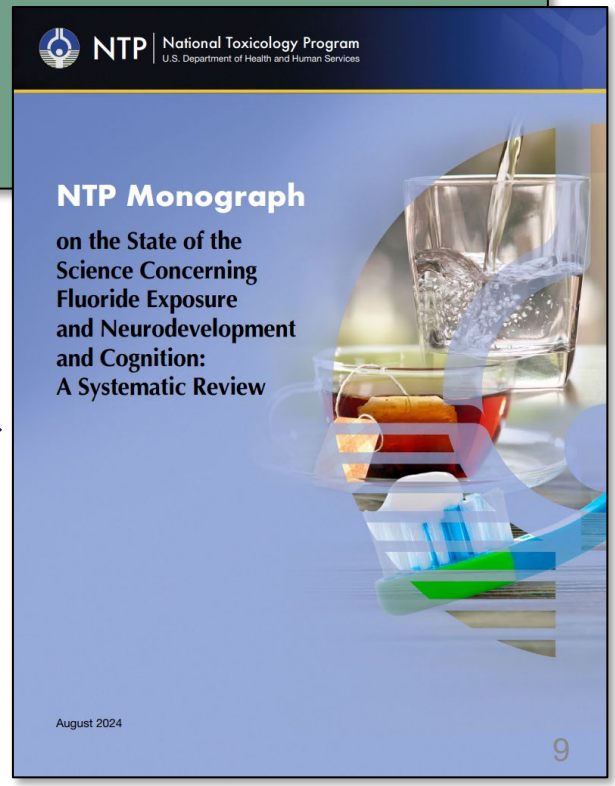
Fluoride as a topic for evaluation at the National Toxicology Program (NTP)

- **2015:** Topic of fluoride exposure & adverse health effects nominated to NTP
- **2016:** NTP Monograph (animal studies only) published
  - Systematic review of animal studies found *low to moderate* evidence of adverse effects on learning and memory

2nd NTP systematic review to evaluate potential neurodevelopmental and cognitive effects of fluoride in the human, animal, and mechanistic/*in vitro* literature

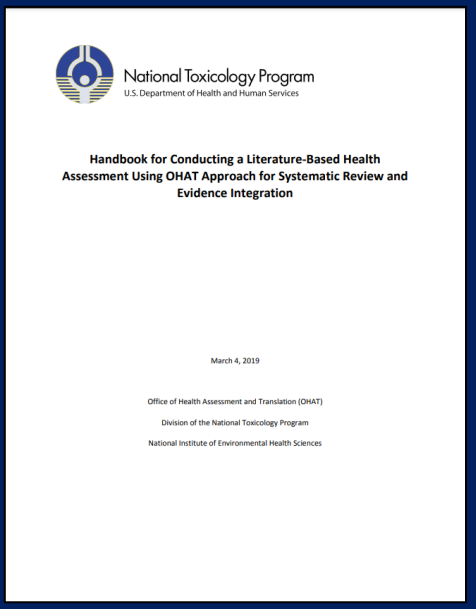
Published August 2024





What is systematic review?

- Transparent and rigorous method for identifying, evaluating, and summarizing every single relevant study published on a topic
- Look for patterns across a body of evidence, and develop conclusions based on the best available evidence
- **OHAT approach to systematic review**, developed in 2014, is a framework for systematic review and evidence integration across human, animal, mechanistic studies
  - Developed to address challenges with reproducibility, transparency
  - Leading edge of bringing systematic review methodology to toxicology and environmental health
- Given **importance and scrutiny** of public health decisions, adherence to standardized methods is essential


National Toxicology Program
U.S. Department of Health and Human Services

Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration

March 4, 2019

Office of Health Assessment and Translation (OHAT)

Division of the National Toxicology Program

National Institute of Environmental Health Sciences


Research

Systematic Review and Evidence Integration for Literature-Based Environmental Health Science Assessments

Andrew A. Rooney, Abee L. Boyles, Mary S. Wolfe, John R. Bucher, and Kristina A. Thayer

Office of Health Assessment and Translation, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, Research Triangle Park, North Carolina, USA

Introduction

Methods

OHAT Handbook: https://ntp.niehs.nih.gov/sites/default/files/ntp/ohat/pubs/handbookmarch2019_508.pdf

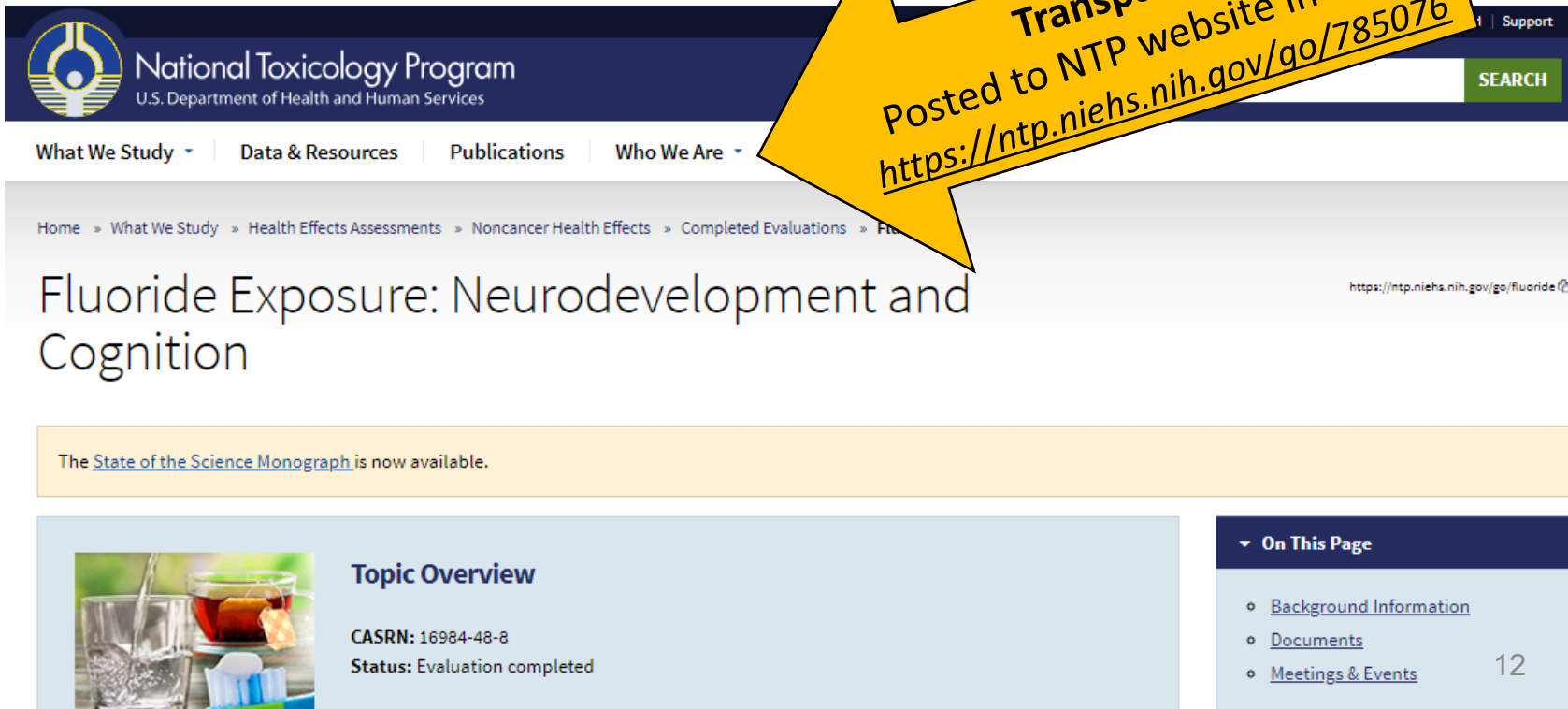
OHAT approach to systematic review

- Systematic Review
  - Planning and protocol development
  - Identify evidence
    - Comprehensive literature search
    - Literature screening
  - Evaluate evidence
    - Extract data
    - Risk of bias assessment

OHAT approach to systematic review

- **Systematic Review**
  - **Planning and protocol development** →
    - Refined research question, developed detailed protocol with input from technical experts
    - Formal peer review of protocol
  - Identify evidence
    - Comprehensive literature search
    - Literature screening
  - Evaluate evidence
    - Extract data
    - Risk of bias assessment

Transparency
Posted to NTP website in 2017
https://ntp.niehs.nih.gov/go/785076



OHAT approach to systematic review

- **Systematic Review**
  - Planning and protocol development
  - **Identify evidence**
    - **Comprehensive literature search**
    - **Literature screening**
  - Evaluate evidence
    - Extract data
    - Risk of bias assessment

- Comprehensive literature search of eight databases through May 1, 2020 (***Addendum update through October 2023***)
  - BIOSIS, EMBASE, PsychINFO, PubMed, Scopus, Web of Science, CNKI, and Wanfang
  - Peer reviewed articles, no language restrictions
- References screened for relevance (2 independent reviewers)
  - Selection based on predefined Population, Exposure, Comparator, and Outcome (PECO) criteria to avoid bias

OHAT approach to systematic review

- **Systematic Review**
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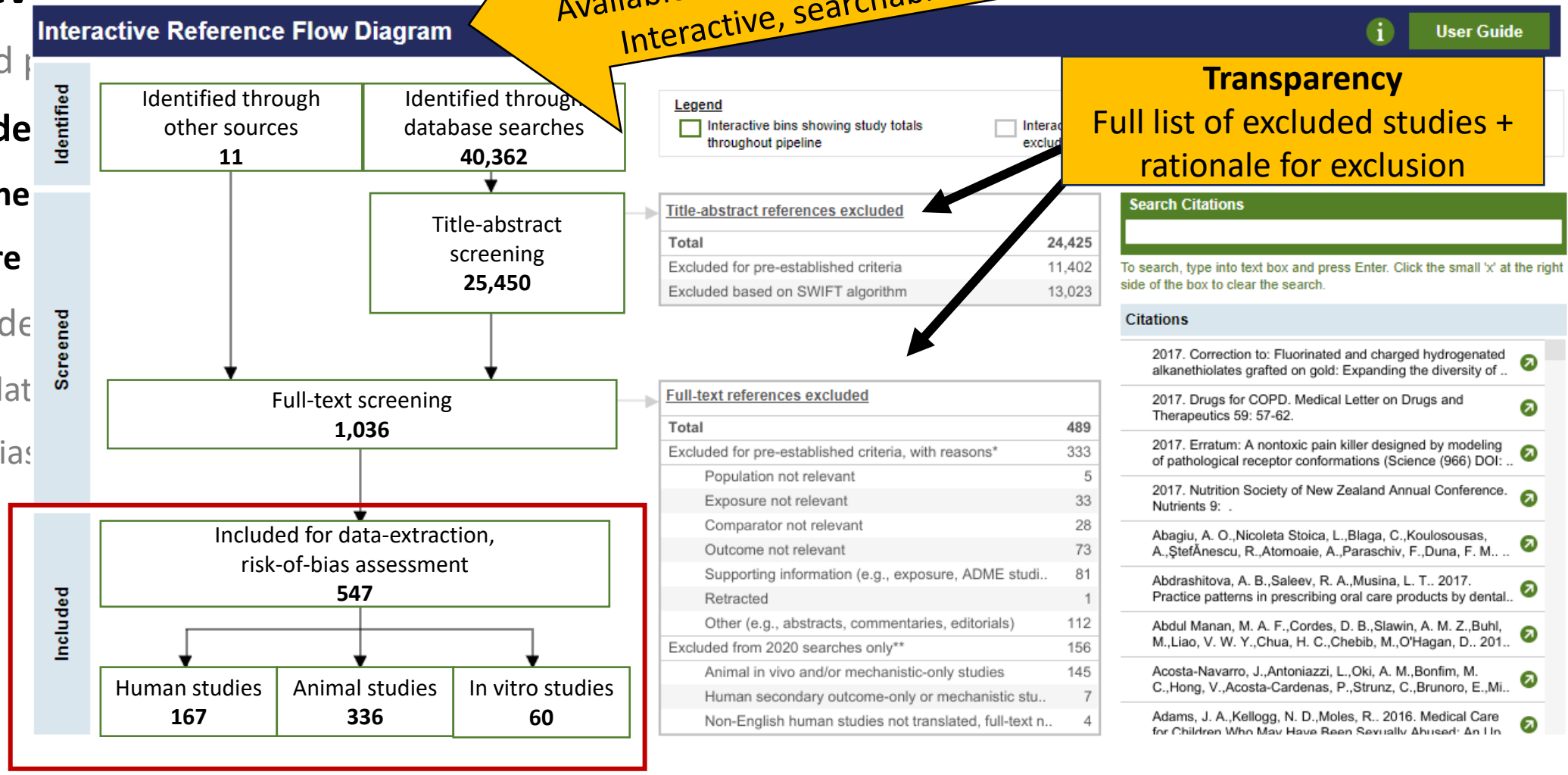
Transparency
Available through NTP website
Interactive, searchable

Transparency
Full list of excluded studies + rationale for exclusion

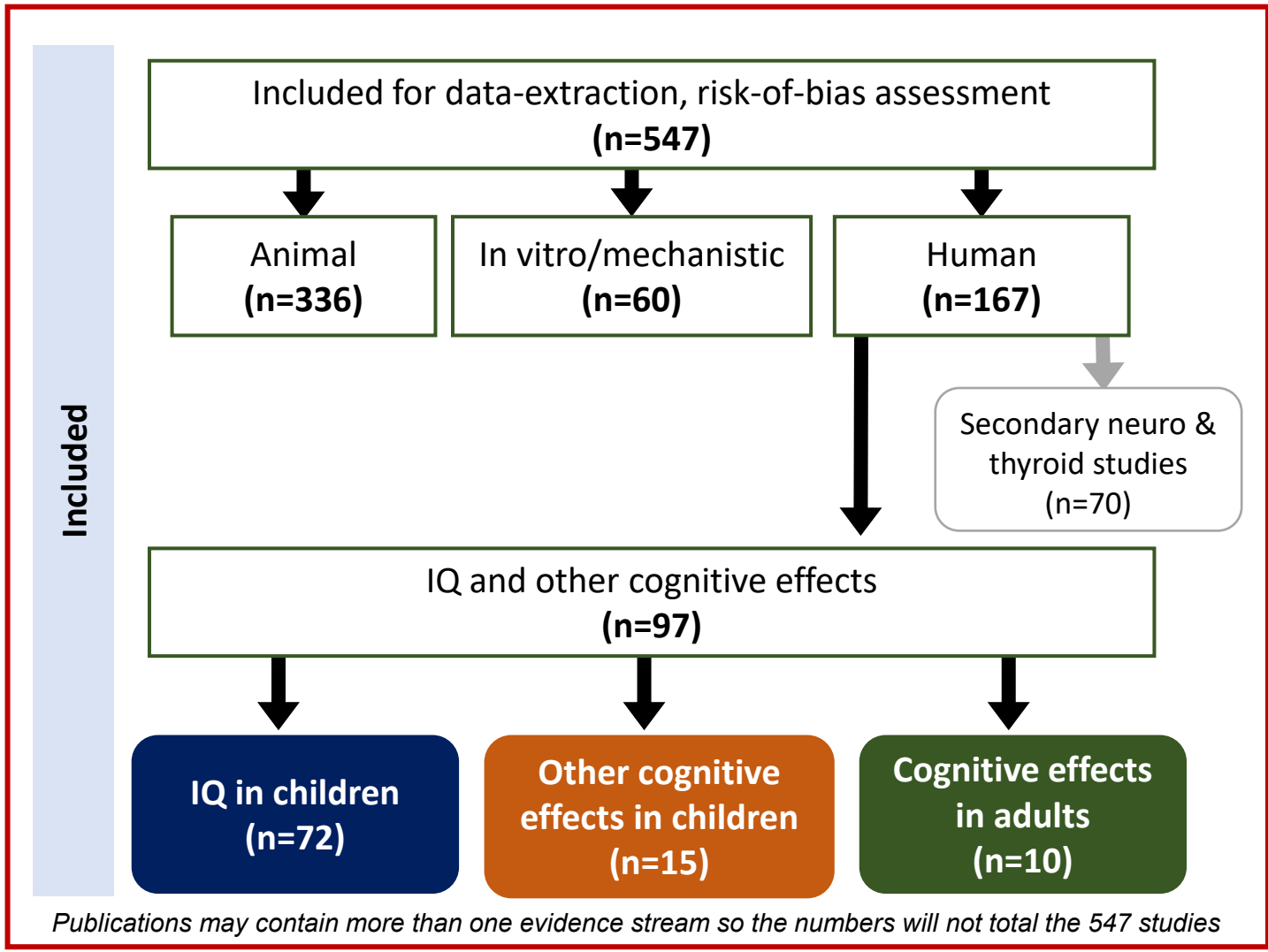


https://hawcproject.org/summary/visual/assessment/405/Figure-2/

Systematic review focuses on the human studies

- 547 human, animal, mechanistic/ in vitro studies considered relevant
- Experimental animal learning and memory data ***inadequate*** to inform assessment of neurodevelopment and cognitive effects in humans
- In vitro/mechanistic studies too heterogeneous and limited to make determination on biological plausibility (e.g., changes in thyroid hormone)

Details for each evidence stream available in NTP Monograph



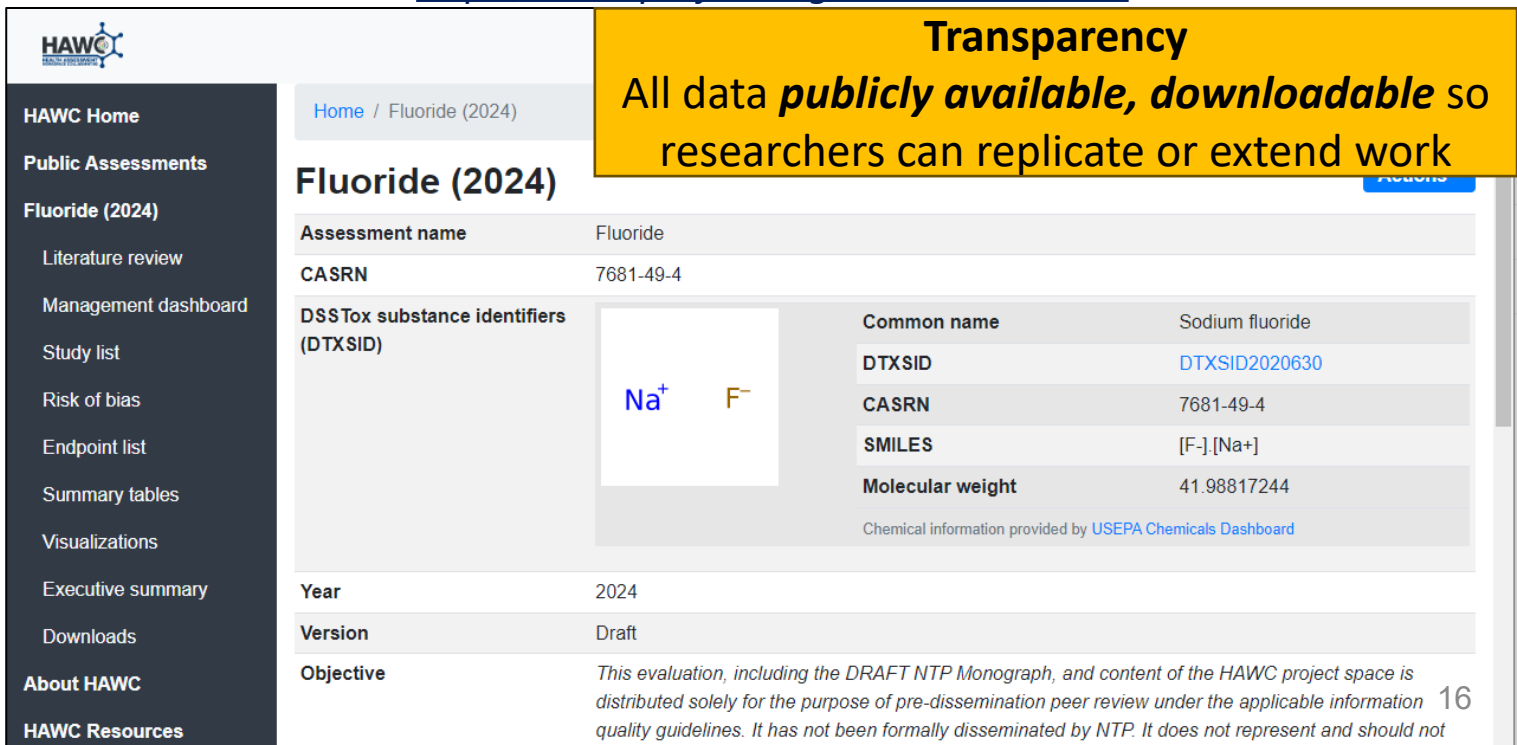
OHAT approach to systematic review

- **Systematic Review**
  - Planning and protocol development
  - Identify evidence
    - Comprehensive literature search
    - Literature screening
  - **Evaluate evidence**
    - **Extract data**
    - Risk of bias assessment

- Open source, web-based application for data extraction and visualizations
- Health Assessment Workspace Collaborative (HAWC) developed at DTT, NIEHS (*Shapiro et al., 2018)*

https://hawcproject.org/assessment/405

Transparency
All data ***publicly available, downloadable*** so researchers can replicate or extend work



OHAT approach to systematic review

- **Systematic Review**
  - Planning and protocol development
  - Identify evidence
    - Comprehensive literature search
    - Literature screening
  - **Evaluate evidence**
    - Extract data
    - **Risk of bias assessment**

- Evaluate **7 risk-of-bias domains**
  - ✓ Confounding bias
  - ✓ Exposure characterization
  - ✓ Outcome assessment
  - Selection bias
  - Attrition bias
  - Selective reporting
  - Other (e.g., statistical analyses)

Key domains: Greatest potential to impact results of a study

Risk of Bias Ratings	
- -	Definitely high
-/NR	Probably high or NR
+	Probably low
++	Definitely low

NR: Not reported

Transparency
Interactive risk of bias ratings and rationale for each individual study available in HAWC

https://hawcproject.org/assessment/405

Identify “high quality” and “low quality” studies

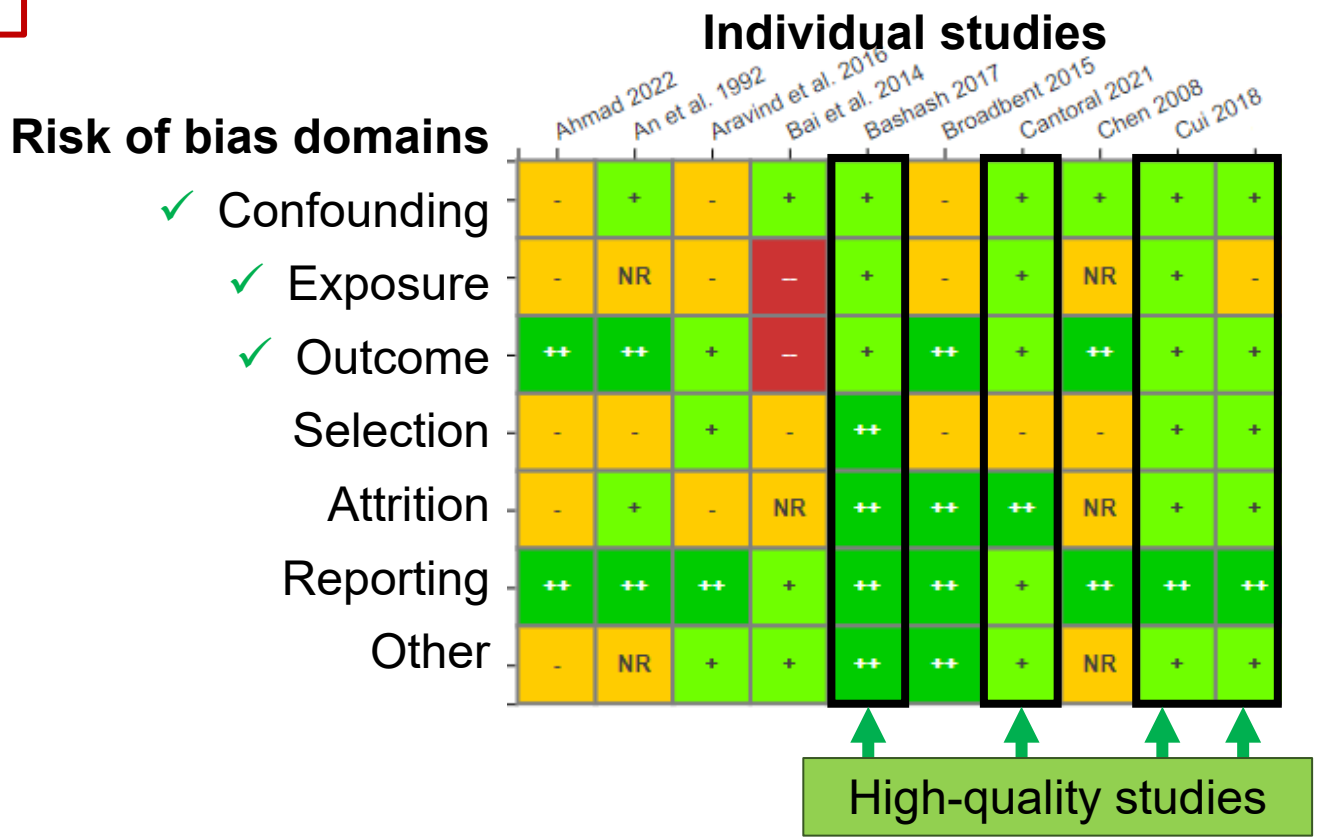
High quality studies represent **the best evidence**, and are basis for the Monograph’s conclusions

- A high-quality study’s **risk of bias ratings** are:

+ ++	For most domains
-	No more than one in a key domain
- -	None in any domain

Risk of Bias Ratings	
- -	Definitely high
-/NR	Probably high or NR
+	Probably low
++	Definitely low

NR: Not reported

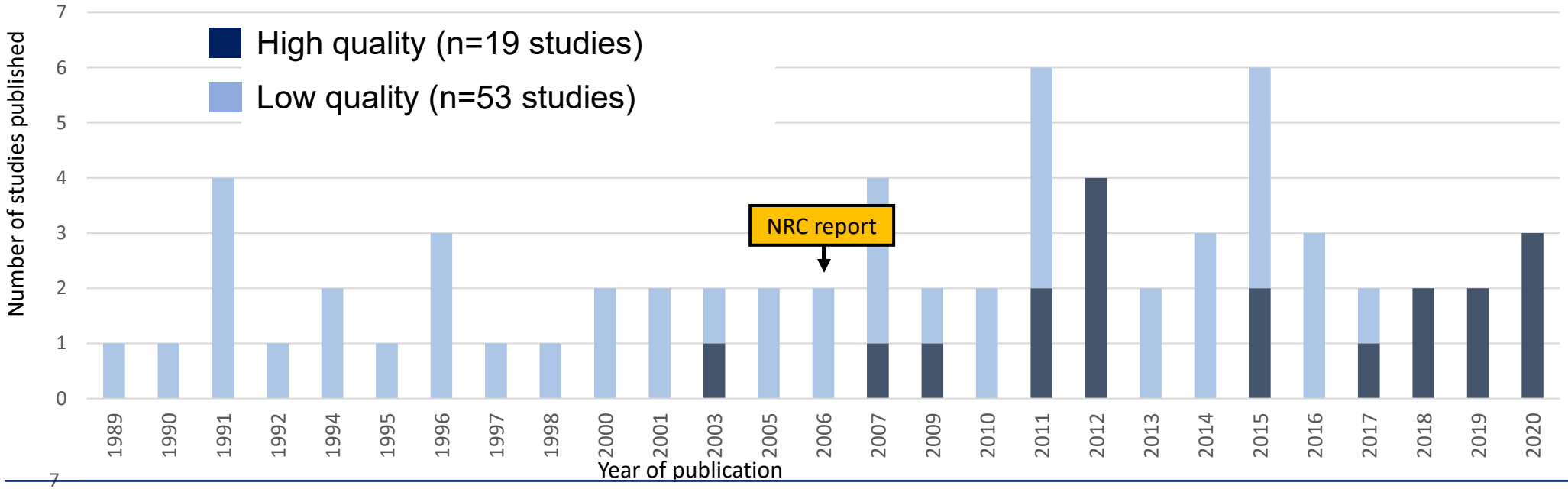


Characteristics of high-quality studies

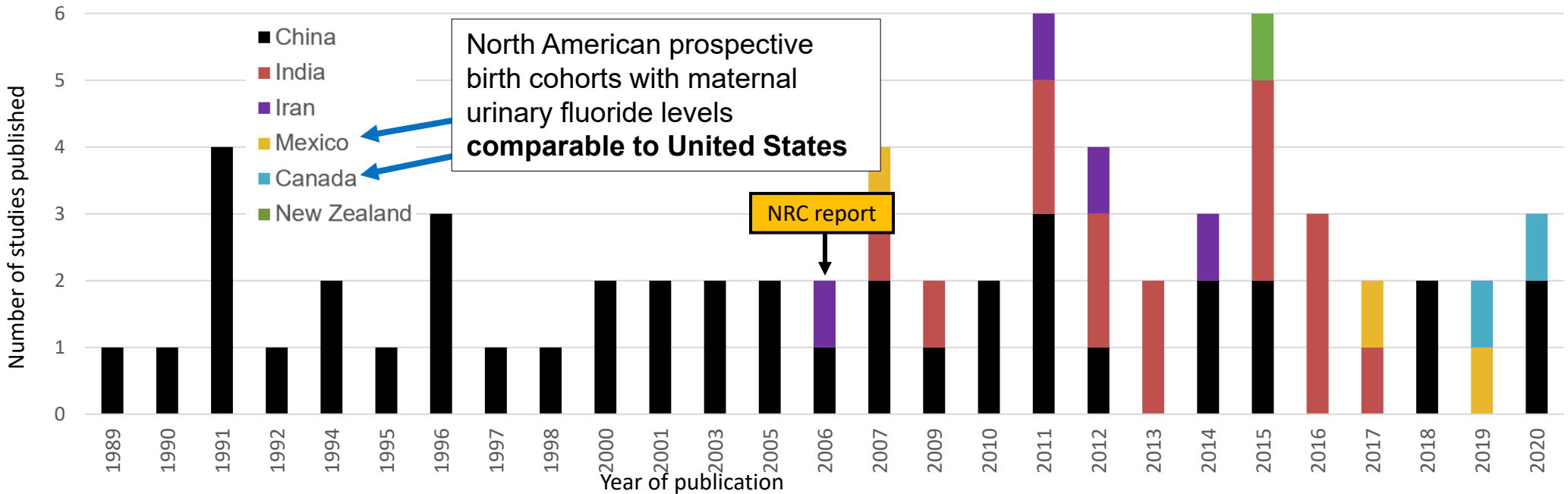
Important for determining confidence

- Most established exposure occurred prior to outcome assessment (i.e., temporality)
  - e.g., prospective cohort studies or prevalence of dental fluorosis in children, limiting study populations to children who lived in an area for long periods of time
- Used IQ tests that were appropriate for the population being studied, outcome assessors were blind to fluoride exposure status
- Accounted for **key confounders** (e.g., age, sex, socioeconomic status) including potential co-exposures to other neurotoxins (e.g., arsenic, lead intake)
- Used individual-level exposure assessment measures (e.g., urine or water)
  - Or, if using group-level data, confirmed regions being compared had differences in fluoride exposure
- Used appropriate sampling techniques for study populations and statistical approaches for analyses
  - e.g., stratified multistage random sampling, regression techniques that account for clustering

Study quality and year of publication in studies of fluoride exposure and children's IQ

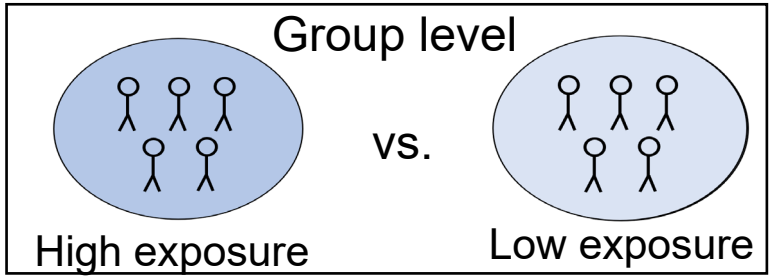


Study location and year of publication in studies of fluoride exposure and children's IQ

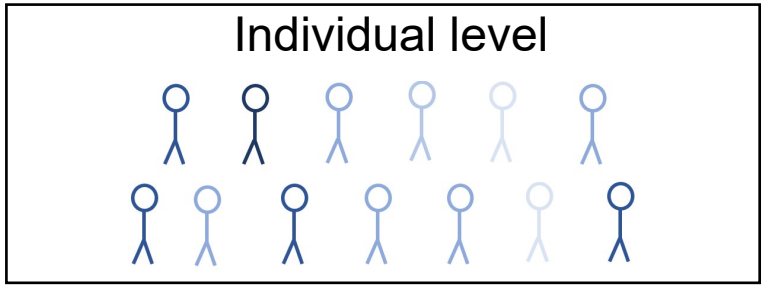


NRC: National Research Council

Exposure data fell into two general categories



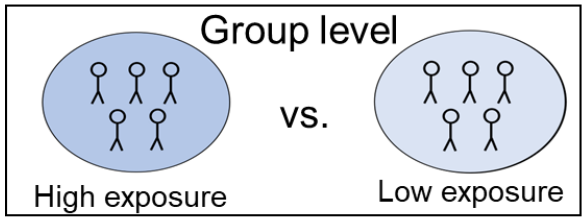
- Reported group-level exposure measures
- Compared mean IQ of children living in “high” fluoride areas to children living in “low” fluoride areas
- Measures included
  - Village or area of residence (endemic vs. non-endemic)
  - Drinking water
  - Children’s urine
  - Severity of dental fluorosis
  - Coal burning



- Reported individual-level exposure measures
- Reported regression coefficients for change in children’s IQ per 1 mg/L increase in urinary fluoride levels
- Measures included
  - Children’s urine
  - Maternal urine
  - Drinking water
  - Fluoride intake
  - Serum

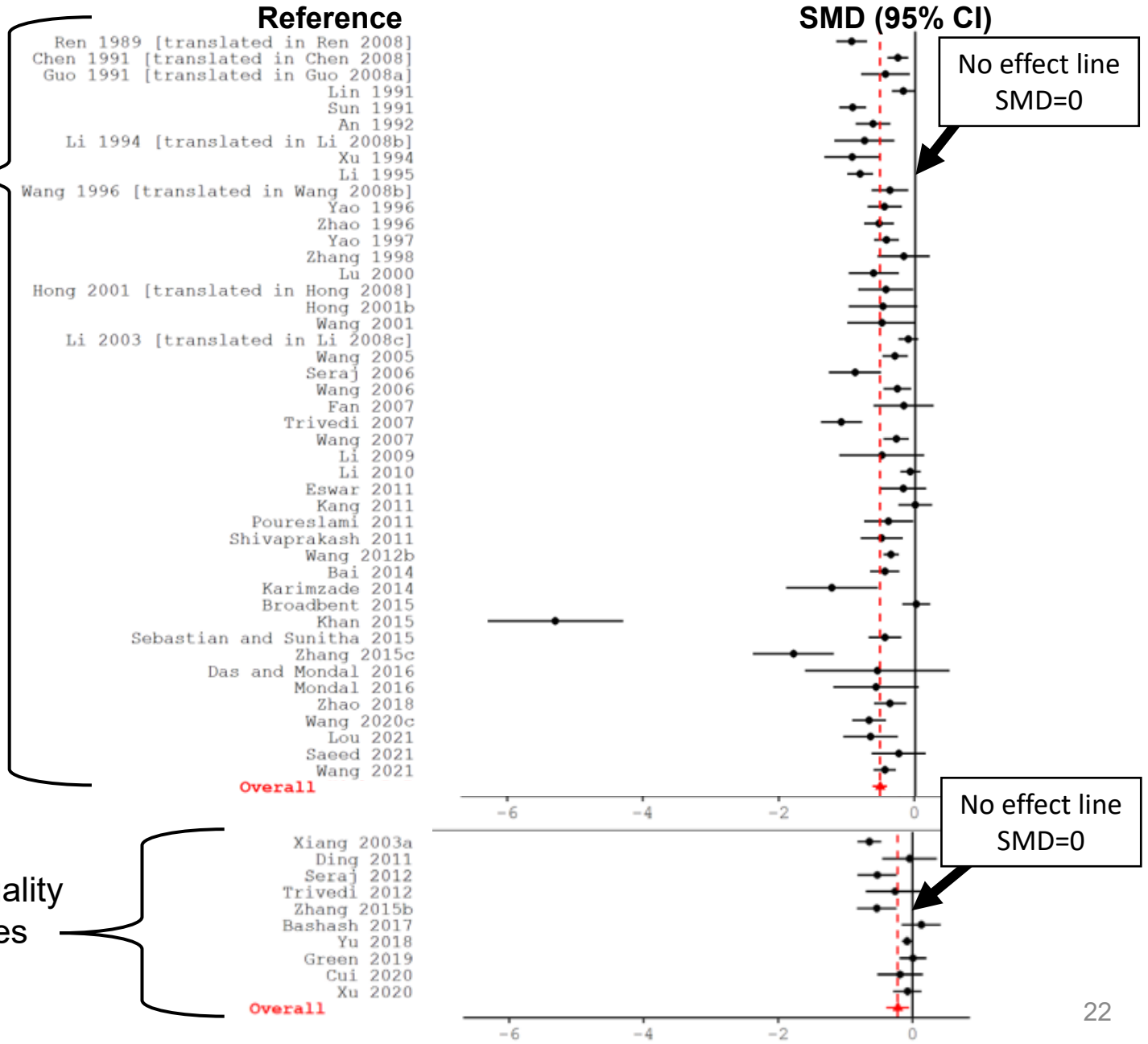
Consistency across high- and low-quality studies

Group-level data



- Standardized mean difference (SMD) for studies comparing children's IQ in a "high" fluoride exposure area vs. a "low" fluoride exposure area

Children in high fluoride communities have statistically significantly **lower IQ**

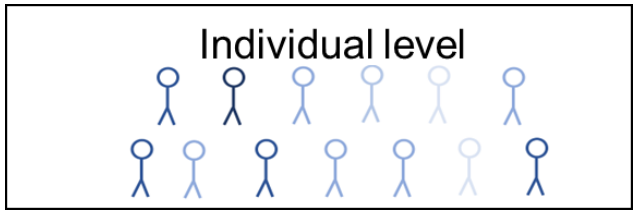


CI: Confidence intervals

Not all high-quality studies reporting group level data are displayed (e.g., studies that did not report data in a way that could be plotted as an SMD)

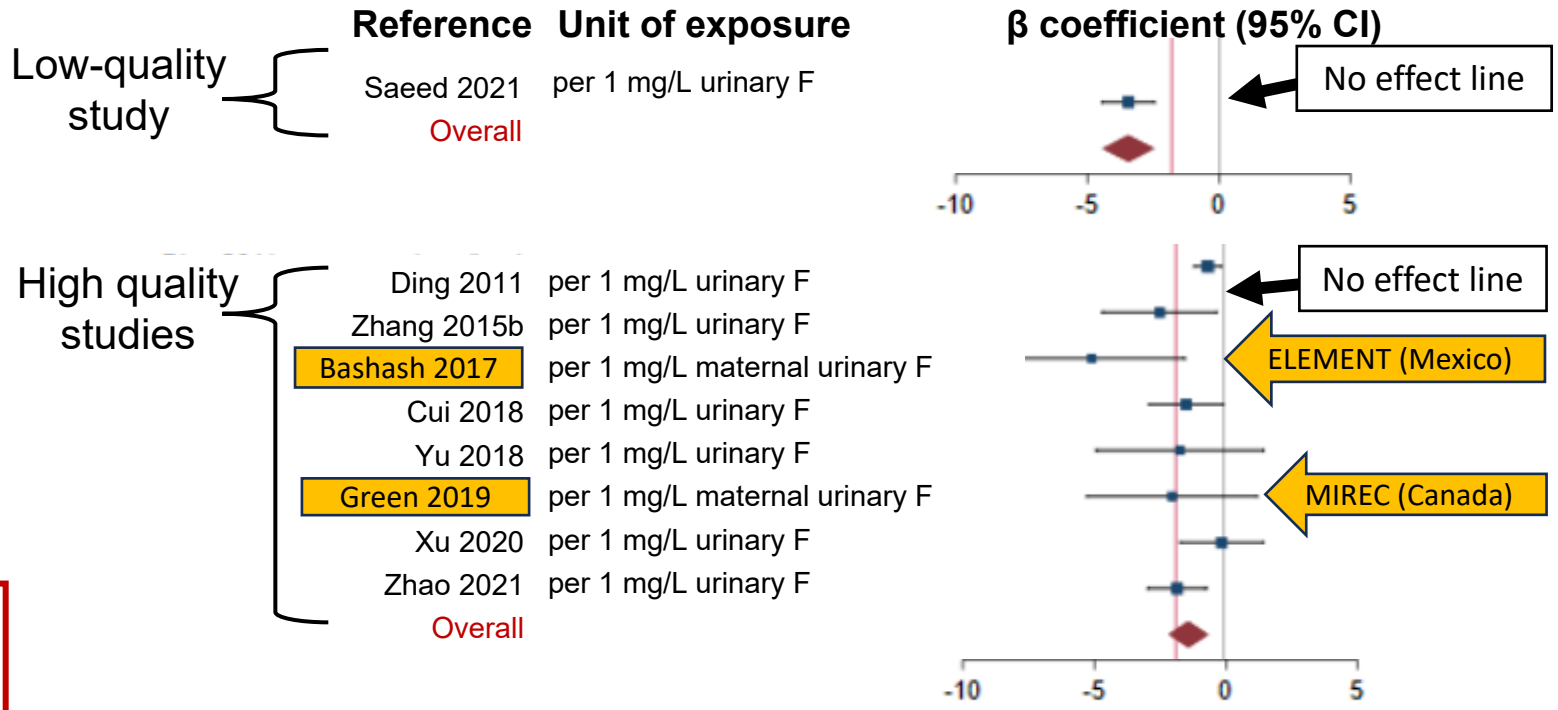
Consistency across high- and low-quality studies

Individual-level data



- Regression coefficients (β) and 95% CIs for change in children's IQ per 1 mg/L increase in maternal or children's urinary fluoride

For every 1 mg/L increase in urinary fluoride there is a statistically significant **decrease children's IQ**



ELEMENT and MIREC cohorts reported maternal urinary fluoride levels **comparable to the United States** (*Ugyturk 2020, Malin 2024*)

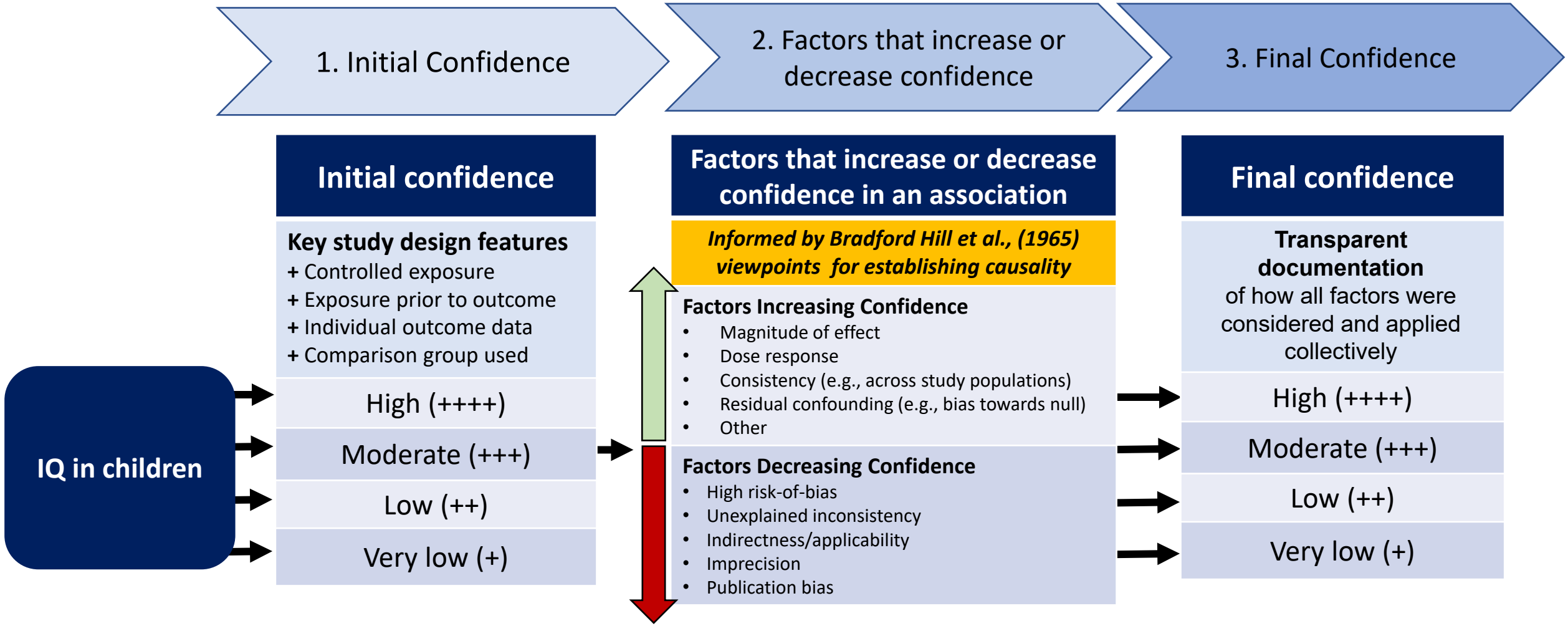
- Green et al 2019 (MIREC): β = **-1.95** (95% CI: -5.19, 1.28)
- Bashash 2017 (ELEMENT): β = **-5.16** (95% CI: −9.12, −1.19)

Interpretation: Per 1 mg/L increase in maternal urinary fluoride, → 2 to 5 point decrease in children's IQ

Confidence ratings

- Rate confidence in bodies of evidence that overall findings ***reflect the true exposure-effect relationship***
- Four-point scale:
  - High confidence
  - Moderate confidence
  - Low confidence
  - Very Low confidence
- Performed for bodies of evidence on outcome basis
- Considers principles that are ***consistent with causation***

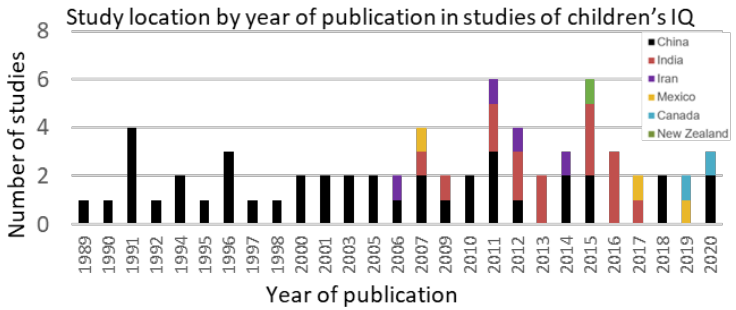
3 steps for determining confidence

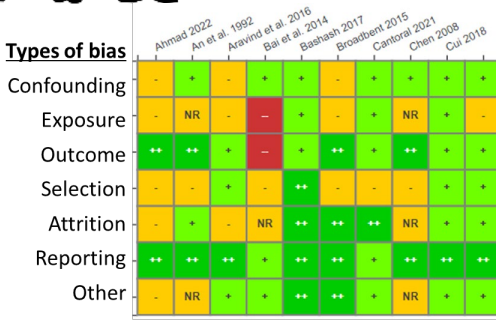


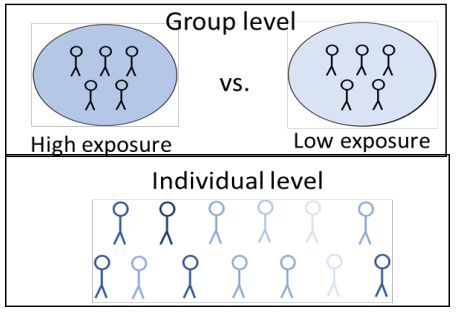
Considerations for confidence ratings

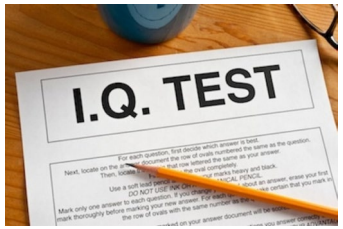
Studies of fluoride exposure and children's IQ

- Consistent inverse association across:
  - 18 of 19 high quality studies
  - 46 of the 53 low quality studies
  - Study populations from different countries
  - Study designs (cross-sectional, prospective cohort)
  - Risk of bias ratings
  - Exposure matrices (water and urine)
  - Type of exposure data (group and individual level data)
  - Timing of exposure (pre- and post-natal)
  - Outcome assessment type (different types of IQ tests)
- Heterogeneity in methods, NOT heterogeneity in results
- Each level of consistency **strengthens** overall confidence
- Determined confounding could not explain these results *(see NTP Monograph for details)*









NTP Conclusion:

Moderate confidence that

higher fluoride exposure is associated with lower IQ children

Extensive peer review

2019–2020

National Academies of Science, Engineering, Medicine (NASEM) committee reviewed initial (2019) & revised (2020) drafts

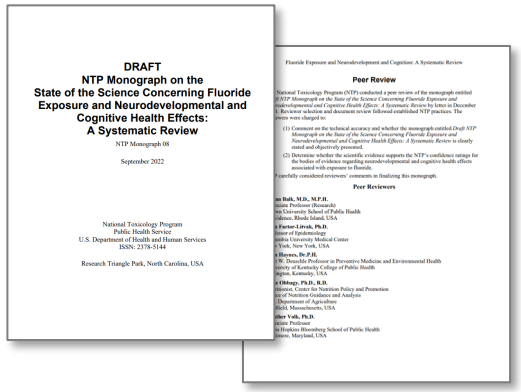
NTP revised Monograph in response to these reviews

2021

External peer review by 5 independent reviewers of 2021 draft NTP Monograph (typical NTP peer review process)

Both **NASEM reviews** & author responses provided

Reviewers ***unanimously*** agree with NTP's conclusions



2022

DTT Scientific Director approves NTP Monograph to be published (May 2022)

NTP/NIEHS Director asks NTP Board of Scientific Counselors (BSC) to review authors' responses to external peer review & *interagency comments on Monograph & meta-analysis (MA)

2023

NTP BSC working group review of author responses to external peer review & *interagency comments on Monograph & MA

Both **NASEM reviews** & author responses provided

Issued recommendations for language refinement & clarification

No major issues identified with methods, analyses, conclusions

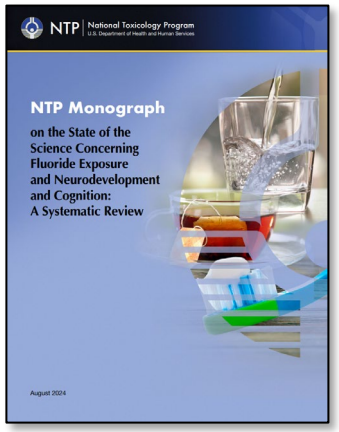
Encouraged rapid publication

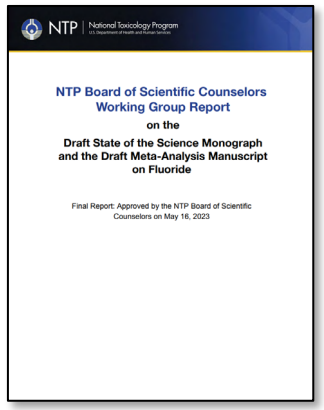
Authors respond to all NTP BSC comments

2024

Final publication
August 2024

(MA in press)





*Agencies and offices that provided comments on Monograph & MA
Office of the Director, NIH
Office of the Assistant Secretary of Health (OASH)
Food and Drug Administration (FDA)
Centers for Disease Control (CDC)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Child Health and Development (NICHD)

Of note…

- Final confidence conclusions based primarily on high-quality studies (i.e., the best evidence)
  - Consideration of low-quality studies does not decrease confidence in overall body of evidence
- Conclusions based primarily on non-US studies where total fluoride exposure approximated *>1.5 mg/L fluoride in drinking water
  - Several high-quality prospective birth cohort studies with maternal urinary fluoride levels comparable to the United States

  **>1.5 mg/L refers to WHO Drinking Water Guideline of 1.5 mg/L; chosen to describe "higher" fluoride exposure in the NTP Monograph based on an overall assessment of the epidemiology literature; represents a useful total fluoride exposure equivalent metric (no alternative safety guidelines for total fluoride exist)*
- Review ***does not***
  - Evaluate benefits of fluoride or provide a risk/benefit analysis
  - Address whether ***sole exposure*** to fluoride at 0.7 mg/L in drinking water is associated with neurodevelopment and cognitive effects
- Targeted research that prospectively examines the association between fluoride exposure and children's IQ in optimally fluoridated areas of the United States would add clarity to the existing data at lower levels

Exposure considerations

- Fluoride in drinking water
  - Provides useful estimates of long-term population exposures
  - May underestimate total exposure because it does not capture the amount of water ingested or other sources of ingested fluoride
- Fluoride in urine
  - Biological measure that captures individual's total fluoride exposure
  - Represents a limited (recent) time-period
  - Multiple measurements would be more robust, e.g., cohort studies with maternal urinary fluoride had multiple measures throughout pregnancy
- Small number of studies at low exposure levels
  - Limited exposure contrasts, which makes it more difficult to detect a true effect, if it exists

Relevance to the United States

- NTP conclusions are relevant to some pregnant women, infants, and children living in the United States
  - People may have total fluoride exposures higher than levels in drinking water
  - **Over 2.9 million people** in the United States served by CWS receive drinking water with >1.5 mg fluoride/L

NEWS & FEATURES

In Millions of Homes, High Fluoride in Tap Water May Be a Concern

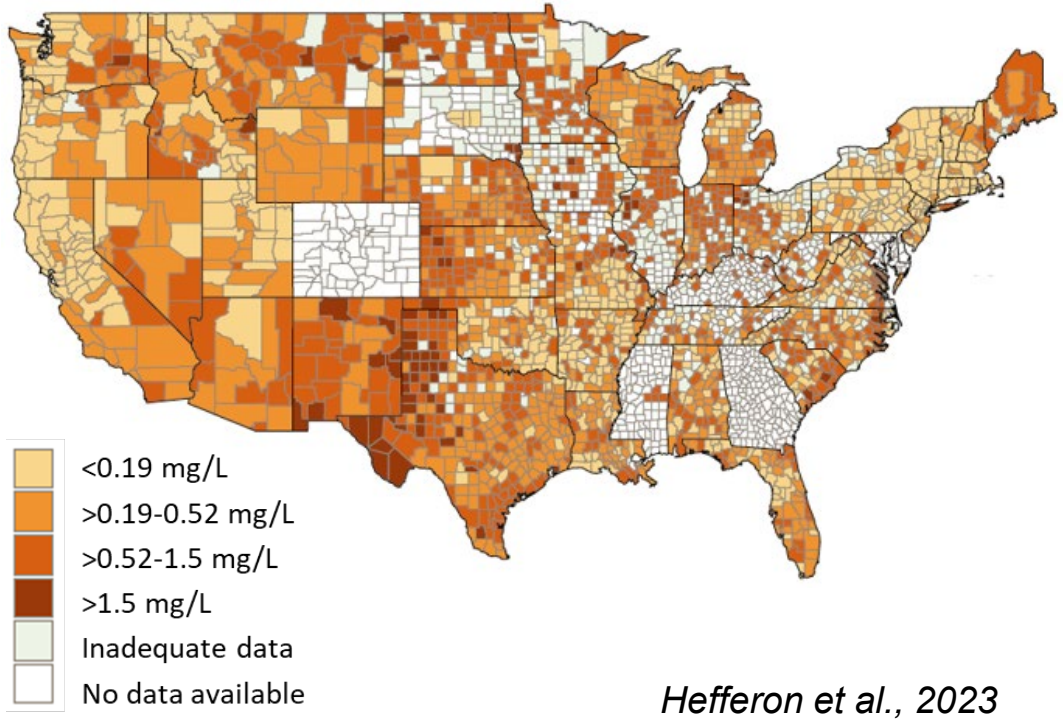
In communities across the U.S., water contains levels of fluoride some experts say could be harm developing brains.

BY MICHAEL SCHULSON
05.06.2024

Top: Water tower in Comfort, Texas. Visual: Marcus Wennrich/ iStock/Getty Images Plus

> *Lost in that debate are the roughly 3 million Americans whose water naturally contains higher concentrations of fluoride — often at levels that could have neurodevelopmental effects.*

Estimated fluoride levels in community water systems by county



Hefferon et al., 2023

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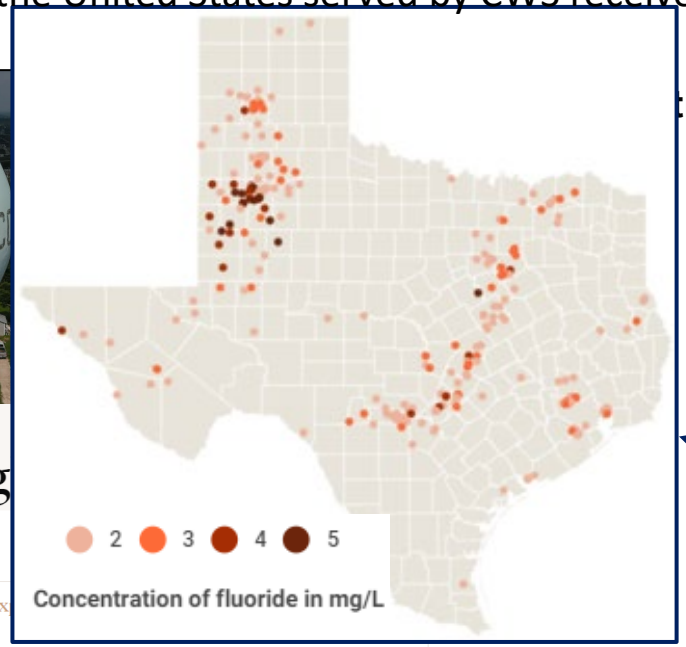
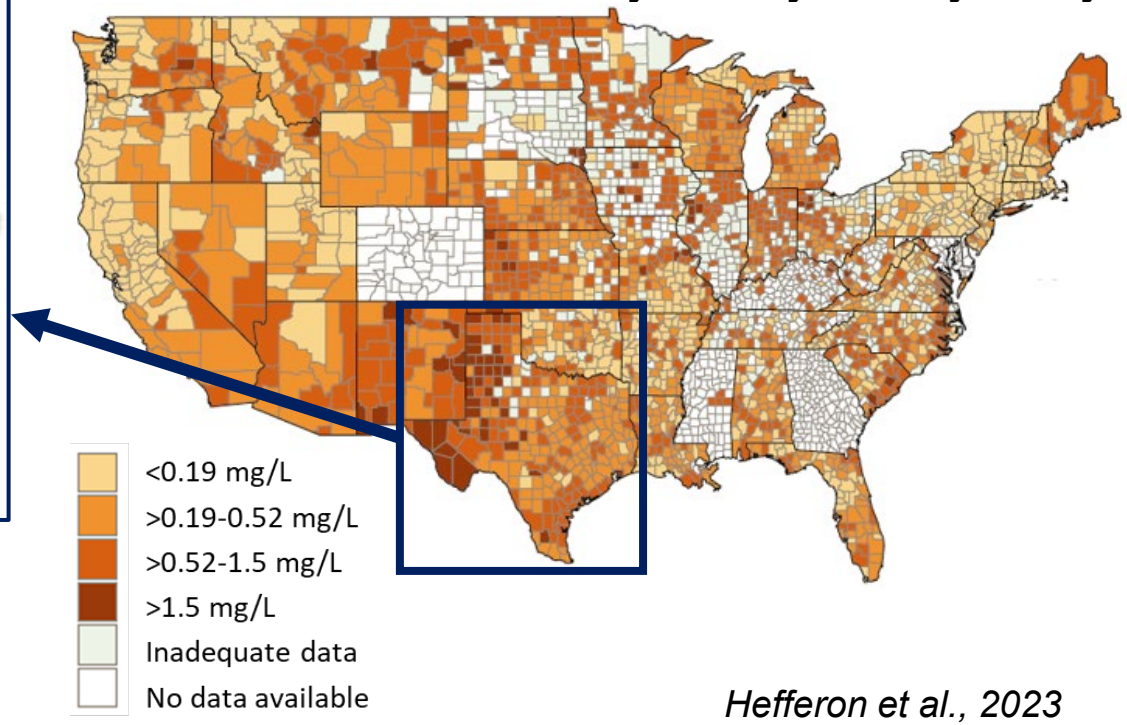
NEWS & FEATURES

In Millions of Homes, Hig
Water May Be a Concern

In communities across the U.S., water contains levels of fluoride some ex

Top: Water tower in Comfort, Texas. Visual: Marcus Wennrich/ iStock/Getty Images Plus





Hefferon et al., 2023

> *Lost in that debate are the roughly 3 million Americans whose water naturally contains higher concentrations of fluoride — often at levels that could have neurodevelopmental effects.*

Fetal and developing brains are especially vulnerable

- Benefits of fluoride are from topical contact with teeth
- No benefit from gestational exposure
- Fetal exposure:
  - Fluoride from maternal blood crosses placenta
  - Fluoride stored in bone and remobilized into bloodstream during pregnancy

The New York Times

Is Fluoridated Drinking Water Safe for Pregnant Women?

New research suggests a link between prenatal fluoride levels and behavioral issues in children. Experts are divided on the study's

By Alice Callahan and Christina Caron

May 22, 2024

- Formula-fed infants residing in fluoridated communities at higher risk of fluoride toxicity
  - 3-4 times greater exposure to fluoride than adults on a per body-weight basis
  - ~70-fold higher fluoride intake than exclusively breastfed infants
  - Retain more fluoride than breastfed infants

NTP Monograph played central role in recent federal trial

- What was the lawsuit about?
  - Plaintiffs petitioned EPA to evaluate fluoride in drinking water, EPA denied the petition and under Amended Toxic Substances Control Act (TSCA), Plaintiffs were entitled to a judicial review
- Monograph relied on by both Plaintiffs and EPA as a "high-quality review"
- What was the Court's ruling?
  - On September 24, 2024, a federal district judge found that the 0.7 mg/L fluoride in drinking water, level considered "optimal" in the United States, poses an ***"unreasonable risk"*** of IQ loss in children which, under the toxics law, requires ***"a regulatory response"***
  - Finding did not conclude with certainty that fluoridated water is injurious to public health
  - Court finds the risk is ***sufficient*** to require the EPA to engage with a regulatory response, but does not dictate what that response must be, decision left to the EPA,
  - TSCA allows wide spectrum of potential risk-management measures from warning labels or public advisories to prohibiting the manufacturing and distribution of a chemical


GREENWIRE

EPA 'in a really tough spot' after landmark fluoride ruling

By Ellie Borst, Miranda Willson | 10/18/2024 01:30 PM EDT

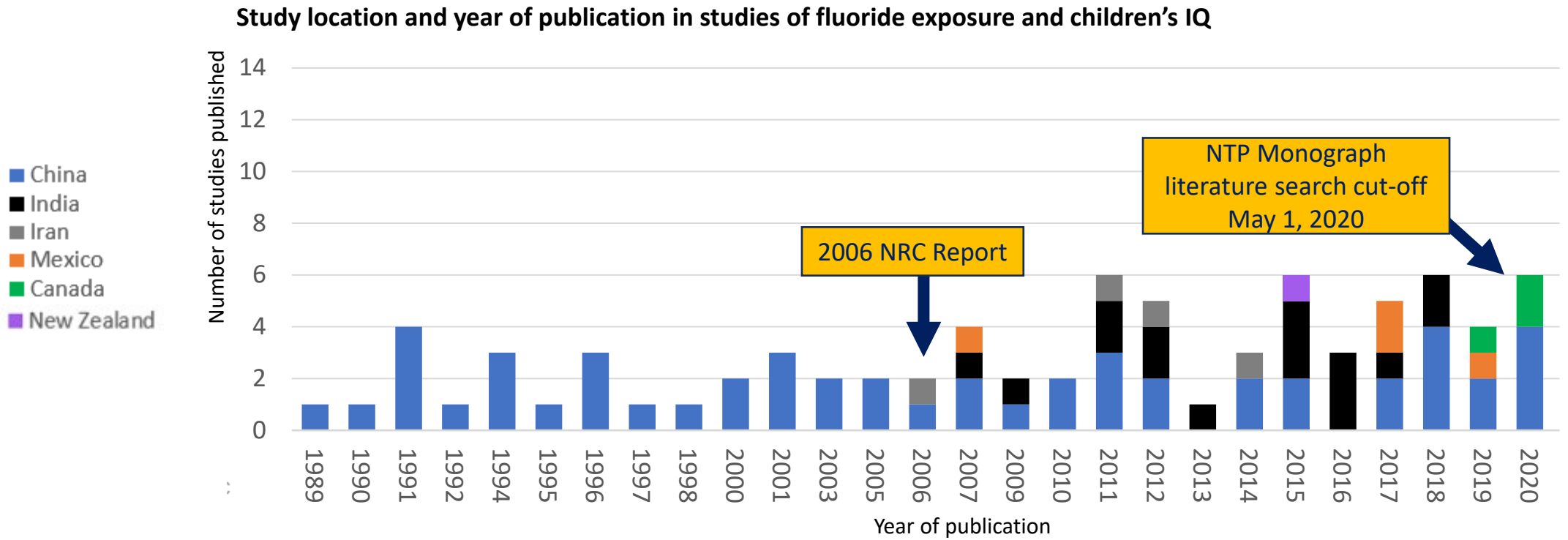
Experts say the precedent-setting court decision backing a Toxic Substances Control Act citizen petition could spur other bids to force new chemical rules.


A district court judge ruled that fluoride in drinking water "poses an unreasonable risk of reduced IQ in children." EPA's regulatory response to the ruling remains unclear. Claudine Hellmuth/E&E News(illustration);EPA(text);Jenn Durfey/Flickr(faucet);Freepik(hands with glass);umanoide/Unsplash(teeth)

Public health community can use the NTP systematic review as part of ongoing evaluations of the role of fluoride in drinking water

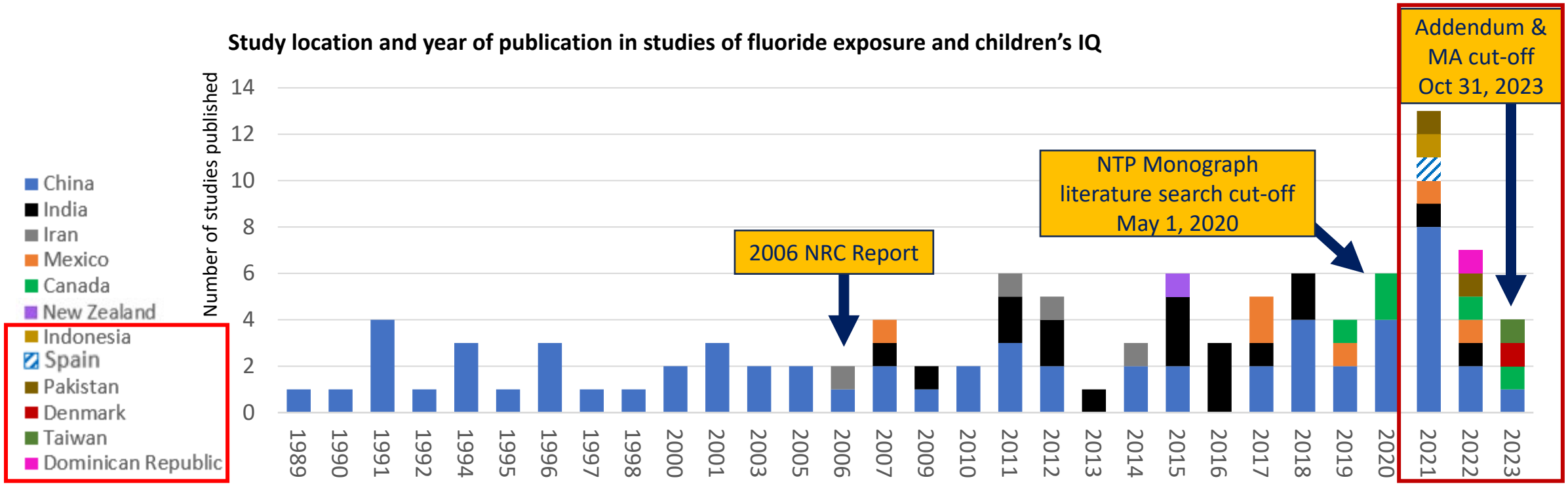
Literature since May 1, 2020?

- Addendum updated through October 2023 to match timeframe of meta-analysis (in press)



Literature since May 1, 2020?

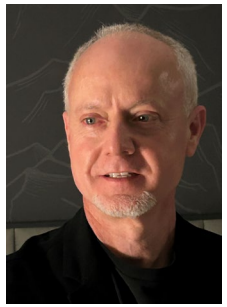
- Addendum updated through October 2023 to match timeframe of meta-analysis (in press)
- 28 new studies
  - 12 of 12 high quality studies reported inverse associations (6 in new study populations)
  - 13 of 16 low quality reported inverse associations



National Institute of Environmental Health Sciences
Division of Translational Toxicology

Acknowledgements

DTT co-authors



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Thank you! Questions?

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Fluoride Exposure and Neurodevelopment and Cognition A Systematic Review

Collaborative for Health and the Environment

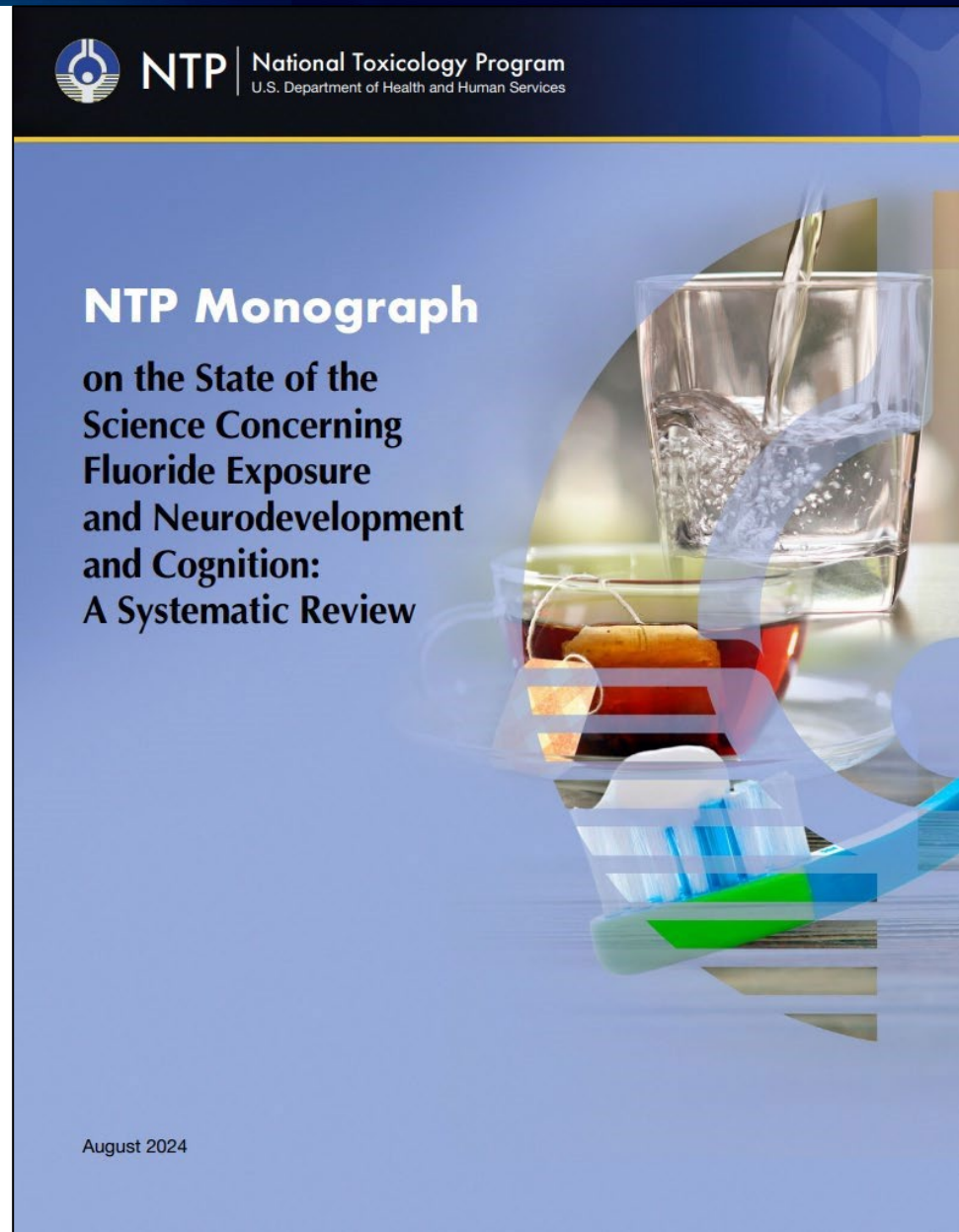
December 3, 2024

Kyla W. Taylor, PhD, John Bucher, PhD, Andrew A. Rooney, PhD

Integrative Health Assessments Branch
Division of Translational Toxicology
National Institute of Environmental Health Sciences

Talk outline

- What is fluoride? The history of U.S. water fluoridation
- NTP Monograph: Fluoride, neurodevelopment, and cognition
- Public health relevance
- Recent federal court ruling and role of the Monograph
- Questions and panel discussion



What is fluoride?

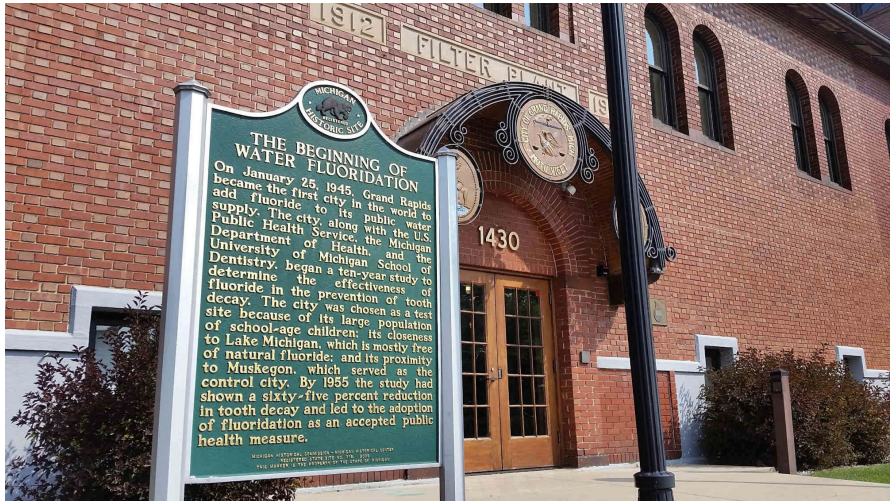
- Naturally occurring mineral
- Topical contact reduces risk of cavities
- Added to drinking water
- Many other sources of exposure

Topical sources

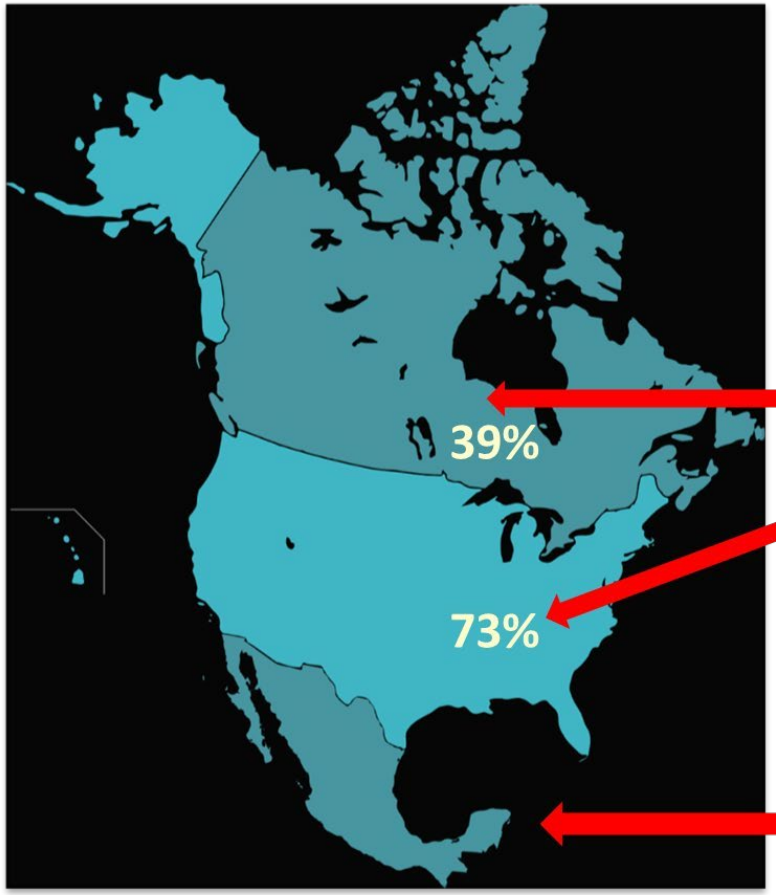
Systemic sources

History of U.S. water fluoridation

- Early 20th century researchers noticed that people living in areas with high levels of fluoride in drinking water had fewer cavities
- First added to drinking water in Grand Rapids, Michigan in 1945
- The U.S. Public Health Service (PHS) first recommended communities add fluoride to drinking water in 1962
- U.S. PHS recommends 0.7 mg/L fluoride added to drinking water
- Community water systems serve about 200 million US residents



Sources of *added* fluoride in North America



Drinking water
Recommended: 0.7 mg fluoride/L

Salt supply is fluoridated

Public Health Agency of Canada, 2017

Public Health Agency of Canada, 2017

Adverse health effects and current drinking water standards and recommendations

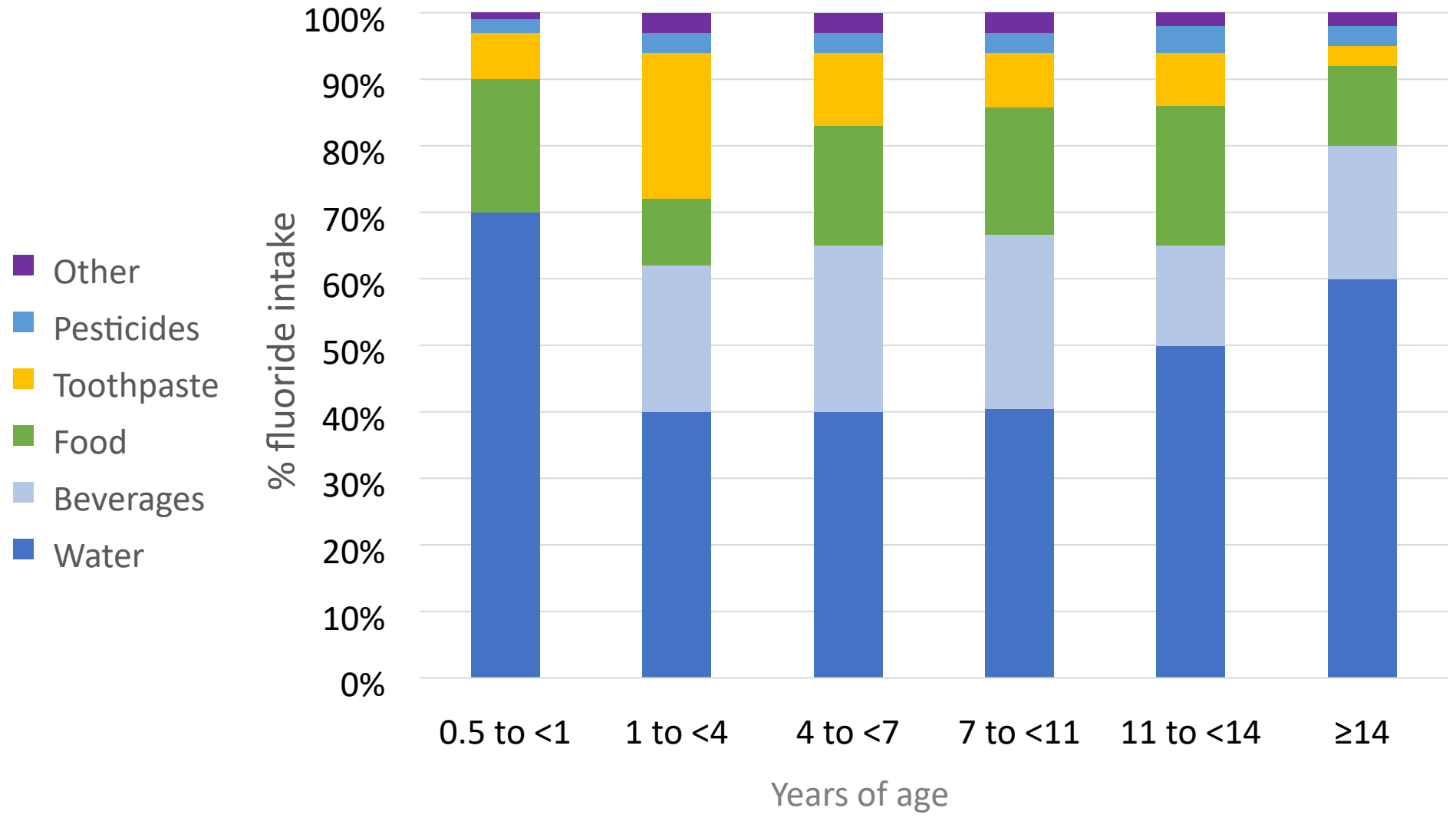
- Skeletal fluorosis
  - Bone disease caused by fluoride accumulation in the bones
  - Causes pain and tenderness of the major joints
- Dental fluorosis
  - Mild: Discoloration
  - Moderate to severe: Pitting

Dental fluorosis is the white discoloration

	Agency	Fluoride drinking water level	US residents served by CWSs above level
Standards (enforceable)	US EPA	4.0 mg/L	> 40,000
Recommendations (non-enforceable)	US EPA	2.0 mg/L	> 1.9 Million
	WHO	1.5 mg/L	> 2.9 Million
	US PHS	0.7 mg/L	>20.5 Million

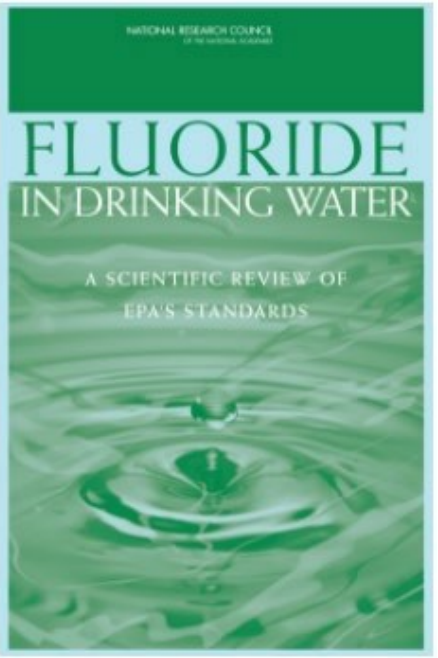
CWS: Community water system
EPA: Environmental Protection Agency
WHO: World Health Organization
PHS: Public Health Service

% total fluoride intake in children from various sources, by age



US EPA Fluoride: Exposure and Relative Source Contribution Analysis (2010)

Neurotoxic effects?



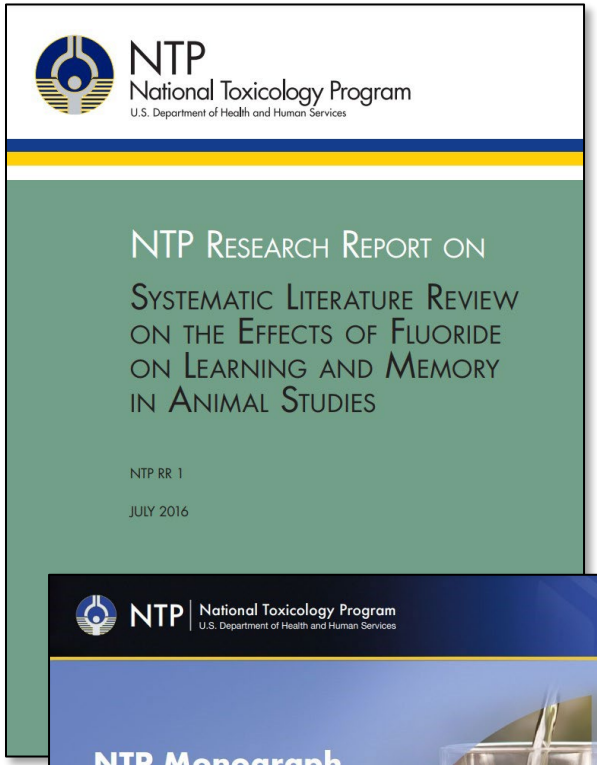
- **2006:** National Research Council (NRC) reported evidence of neurotoxic effects of fluoride
- Fetal and developing brains are especially vulnerable to neurotoxicants
- Concern that some pregnant women and children may be getting more fluoride than they need because they now get fluoride from many sources and the combined total intake of fluoride may exceed safe amounts
- Fetal exposure
  - Fluoride from maternal blood crosses placenta
  - Fluoride stored in bone and remobilized into bloodstream during pregnancy
- Formula-fed infants residing in fluoridated communities:
  - 3-4 times greater exposure to fluoride than adults on a per body-weight basis
  - ~70-fold higher fluoride intake than exclusively breastfed infants

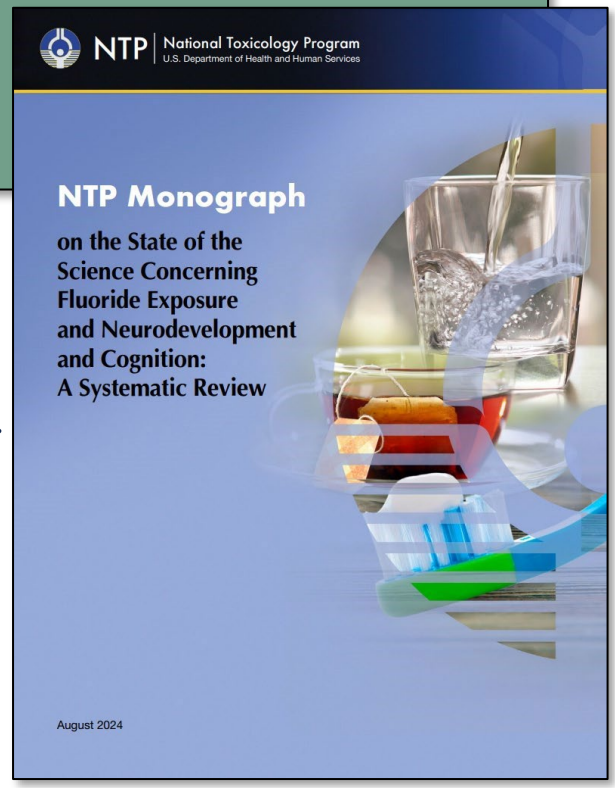
Fluoride as a topic for evaluation at the National Toxicology Program (NTP)

- **2015:** Topic of fluoride exposure & adverse health effects nominated to NTP
- **2016:** NTP Monograph (animal studies only) published
  - Systematic review of animal studies found *low to moderate* evidence of adverse effects on learning and memory

2nd NTP systematic review to evaluate potential neurodevelopmental and cognitive effects of fluoride in the human, animal, and mechanistic/*in vitro* literature

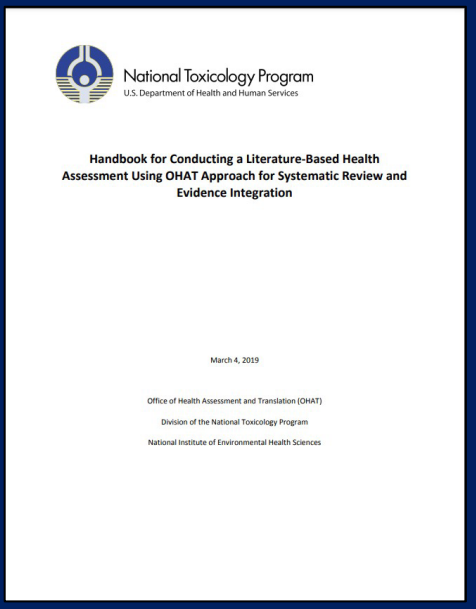
Published August 2024





What is systematic review?

- Transparent and rigorous method for identifying, evaluating, and summarizing every single relevant study published on a topic
- Look for patterns across a body of evidence, and develop conclusions based on the best available evidence
- **OHAT approach to systematic review**, developed in 2014, is a framework for systematic review and evidence integration across human, animal, mechanistic studies
  - Developed to address challenges with reproducibility, transparency
  - Leading edge of bringing systematic review methodology to toxicology and environmental health
- Given **importance and scrutiny** of public health decisions, adherence to standardized methods is essential


National Toxicology Program
U.S. Department of Health and Human Services

Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration

March 4, 2019

Office of Health Assessment and Translation (OHAT)

Division of the National Toxicology Program

National Institute of Environmental Health Sciences


Research

Systematic Review and Evidence Integration for Literature-Based Environmental Health Science Assessments

Andrew A. Rooney, Abee L. Boyles, Mary S. Wolfe, John R. Bucher, and Kristina A. Thayer

Office of Health Assessment and Translation, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, Research Triangle Park, North Carolina, USA

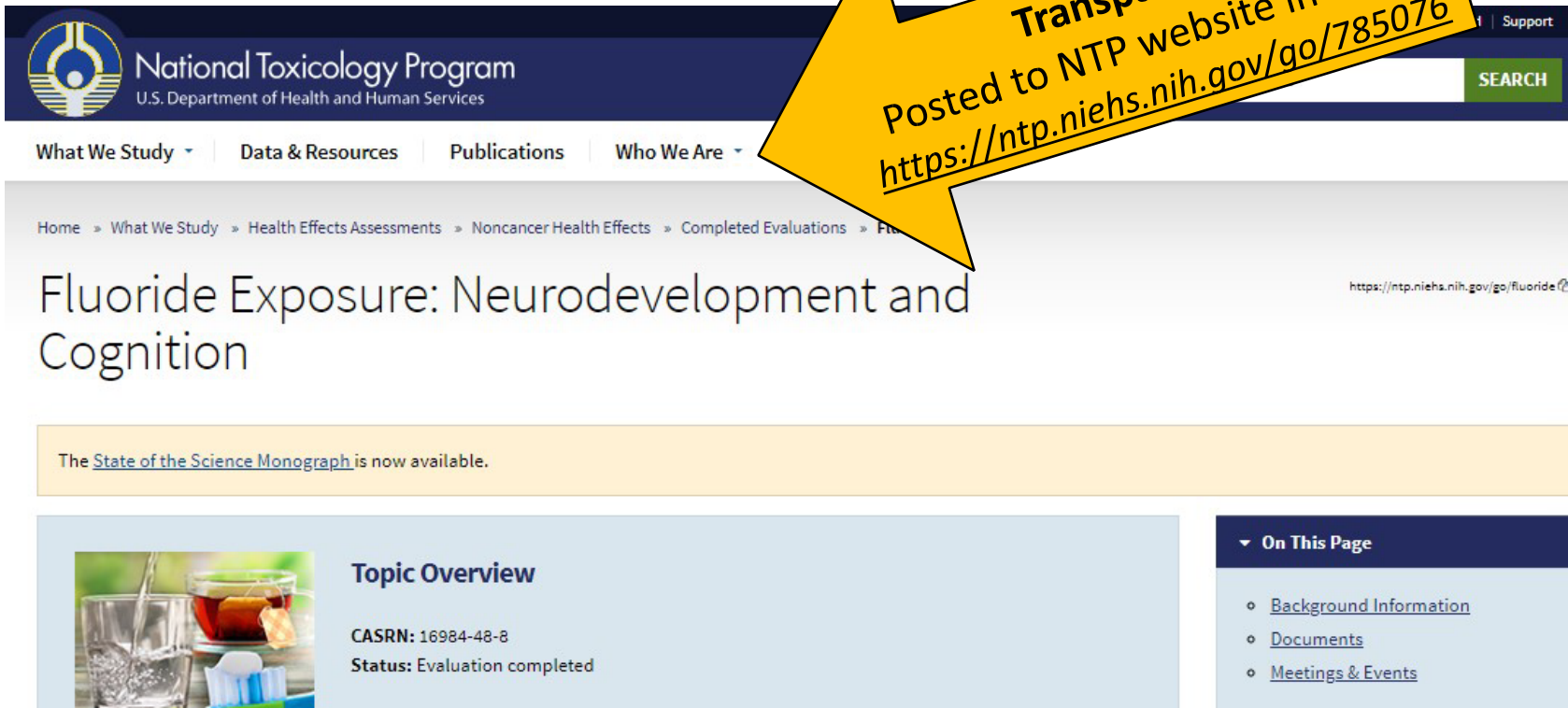
OHAT Handbook: https://ntp.niehs.nih.gov/sites/default/files/ntp/ohat/pubs/handbookmarch2019_508.pdf

Systematic Review
- Planning and protocol development
- Identify evidence
  - Comprehensive literature search
  - Literature screening
- Evaluate evidence
  - Extract data
  - Risk of bias assessment

- **Planning and protocol development** → • Refined research question, developed detailed protocol with input from technical experts
- Identify evidence
  - Comprehensive literature search
  - Literature screening
- Evaluate evidence
  - Extract data
  - Risk of bias assessment

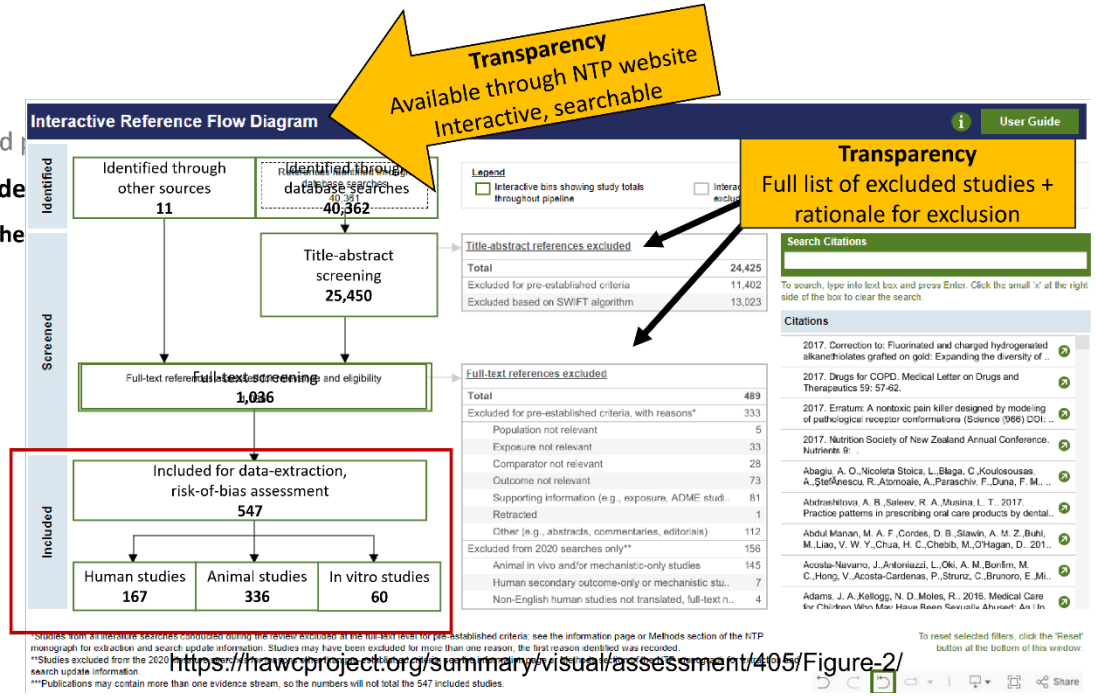
• Formal peer review of protocol

Transparency
Posted to NTP website in 2017
https://ntp.niehs.nih.gov/go/785076



- Planning and protocol development
- **Identify evidence** → • Comprehensive literature search of eight databases through May 1, 2020 (***Addendum update through October 2023***)
  - **Comprehensive literature search**
  - **Literature screening**
    - BIOSIS, EMBASE, PsychINFO, PubMed, Scopus, Web of Science, CNKI, and Wanfang
    - Peer reviewed articles, no language restrictions
    - • References screened for relevance (2 independent reviewers)
- Evaluate evidence
  - Extract data
  - Risk of bias assessment

- Planning and p
- **Identify evide**
  - **Comprehe**



https://hawcproject.org/summary/visual/assessment/405/Figure-2/

  - **Literature screening**

Evaluate evidence

– Selection based on predefined Population, Exposure, Comparator, and Outcome (PECO) criteria to avoid bias

- Extract data
- Risk of bias assessment

Systematic review focuses on the human studies

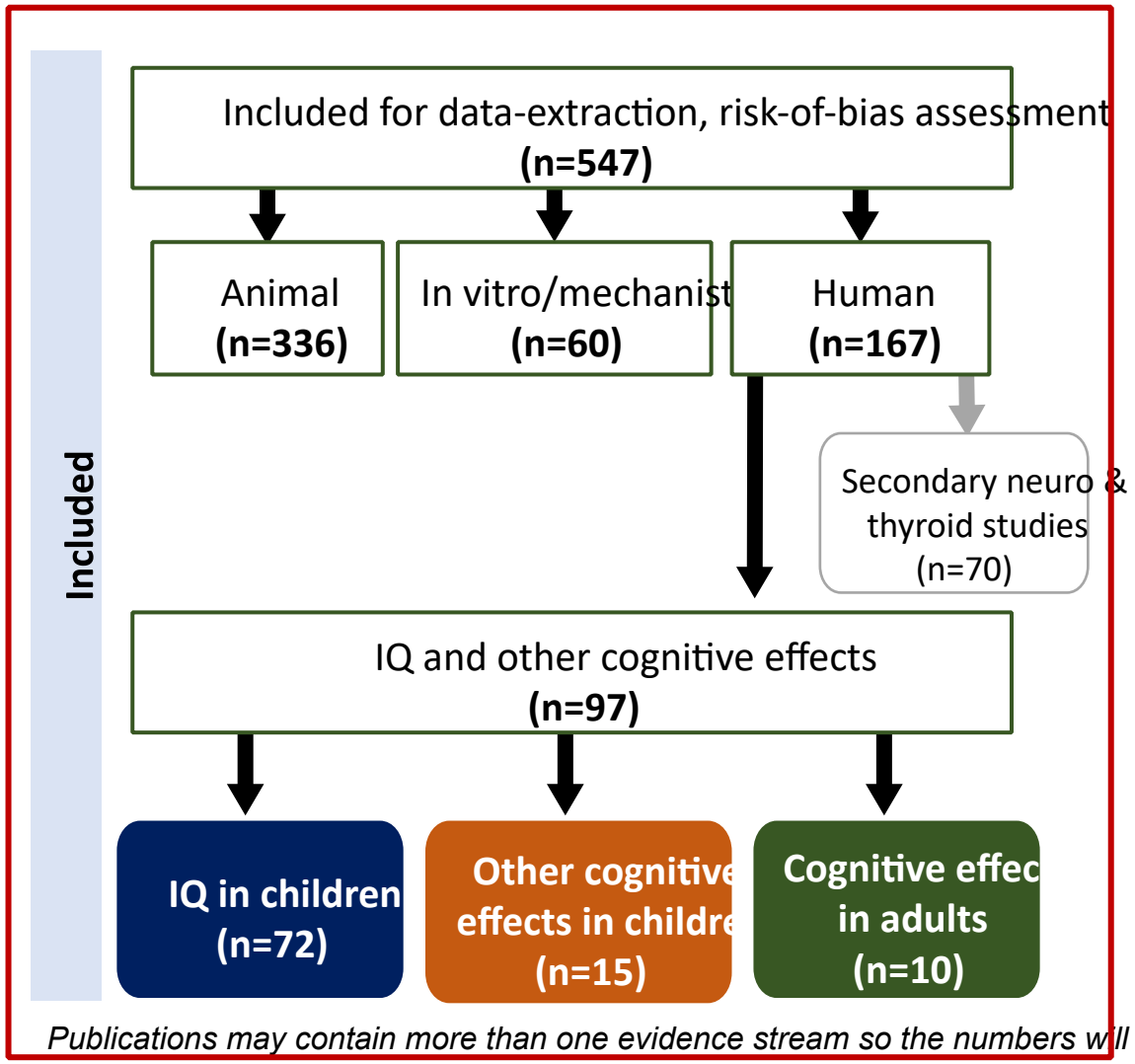
- 547 human, animal, mechanistic/ in vitro studies considered relevant

Details for each evidence stream

available in NTP Monograph

- Experimental animal learning and memory data ***inadequate*** to inform assessment of neurodevelopment and cognitive effects in humans

- In vitro/mechanistic studies too heterogeneous and limited to make determination on biological plausibility (e.g., changes in thyroid hormone)



Publications may contain more than one evidence stream so the numbers will not total the 547

OHAT approach to systematic review

- **Systematic Review**
  - Planning and protocol development
  - Identify evidence
    - Comprehensive literature search
    - Literature screening
  - **Evaluate evidence**
    - **Extract data**
    - Risk of bias assessment

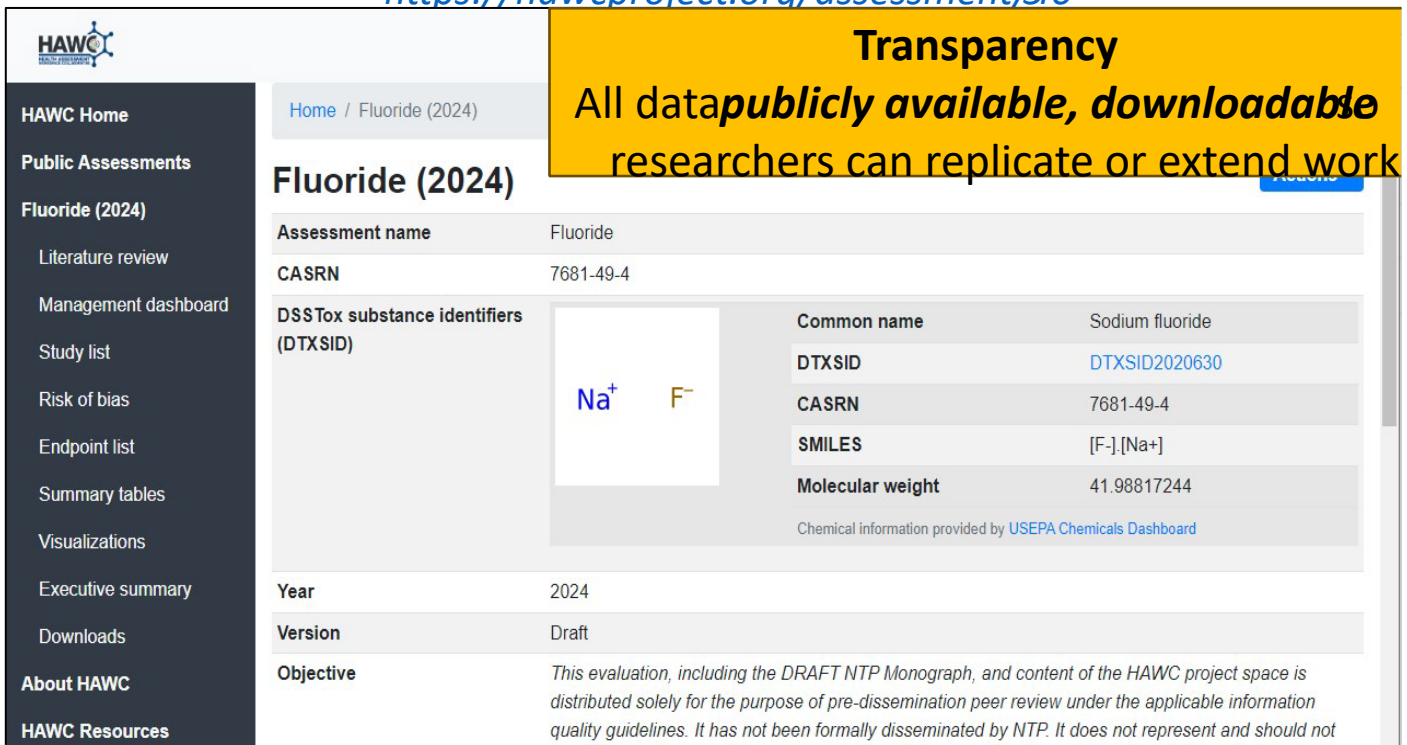
and visualizations

- Health Assessment Workspace Collaborative (HAWC) developed at DTT, NIEHS (*Shapiro et al., 2018*)

https://hawcproject.org/assessment/40

Transparency

All data ***publicly available, downloadable*** so researchers can replicate or extend work



- Open source, web-based application for data extraction

OHAT approach to systematic review

- **Systematic Review**
  - Planning and protocol development
  - Identify evidence
    - Comprehensive literature search
    - Literature screening
  - **Evaluate evidence**
    - Extract data
      - **Risk of bias assessment**

- Evaluate **7 risk-of-bias domains**
  - ✓ Confounding bias
  - ✓ Exposure

  Key domains: Greatest potential to impact results of a study

Risk of Bias Ratings	
- -	Definitely high
-/NR	Probably high or NR
+	Probably low
++	Definitely low

NR: Not reported

characterization ✓ Outcome

assessment ○ Selection bias ○

Attrition bias ○ Selective reporting ○

Other (e.g., statistical analyses)

Transparency Interactive risk of bias ratings and rationale

for each individual study available in HAWC

https://hawcproject.org/assessment/405

High quality studies represent **the best evidence**, and are basis for the Monograph’s conclusions

- A high-quality study’s **risk of bias ratings** are:

+ ++	For most domains
-	No more than one in a key domain
--	None in any domain

Risk of Bias Ratings	
- -	Definitely high
-/NR	Probably high or NR
+	Probably low
++	Definitely low

NR: Not reported

Individual studies

Risk of bias domains	Ahmad 2022	An et al. 1992	Aravind et al. 2018	Bai et al. 2014	Bashash 2017	Broadbent 2015	Cantoral 2021	Chen 2008	Cui 2018	
✓ Confounding	-	+	-	+	+	-	+	+	+	+
✓ Exposure	-	NR	-	–	+	-	+	NR	+	-
✓ Outcome	++	++	+	–	+	++	+	++	+	+
Selection	-	-	+	-	++	-	-	-	+	+
Attrition	-	+	-	NR	++	++	++	NR	+	+
Reporting	++	++	++	+	++	++	+	++	++	++
Other	-	NR	+	+	++	++	+	NR	+	+

High-quality studies

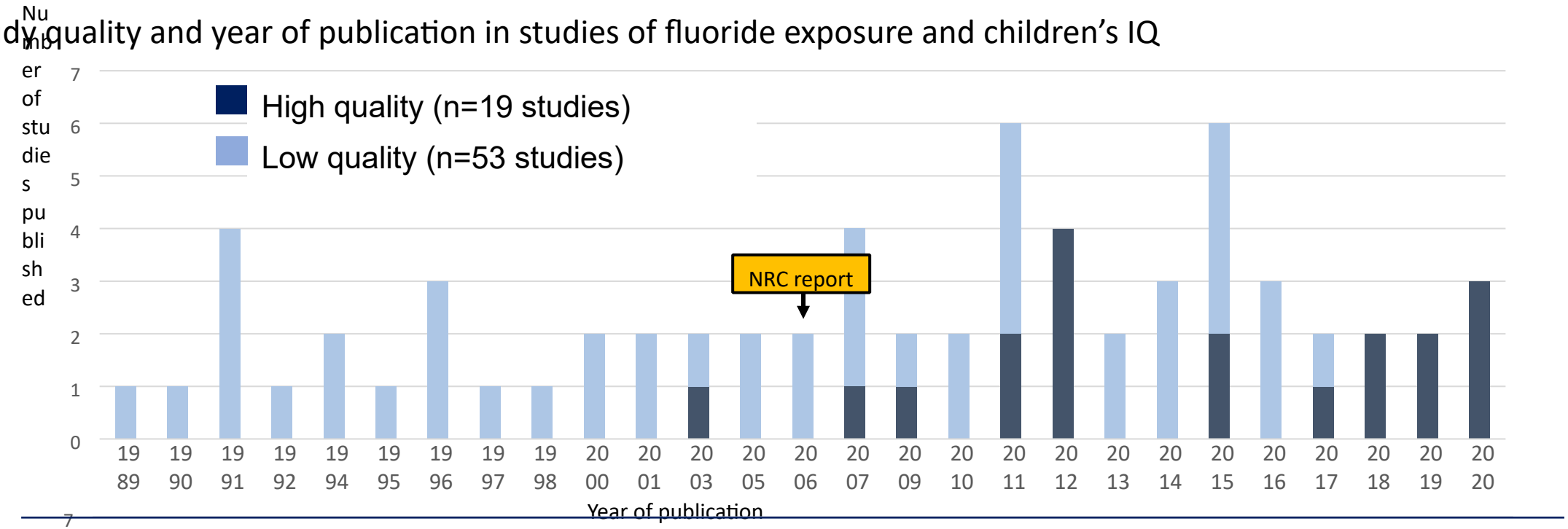
Id uality” and “low quality” studies

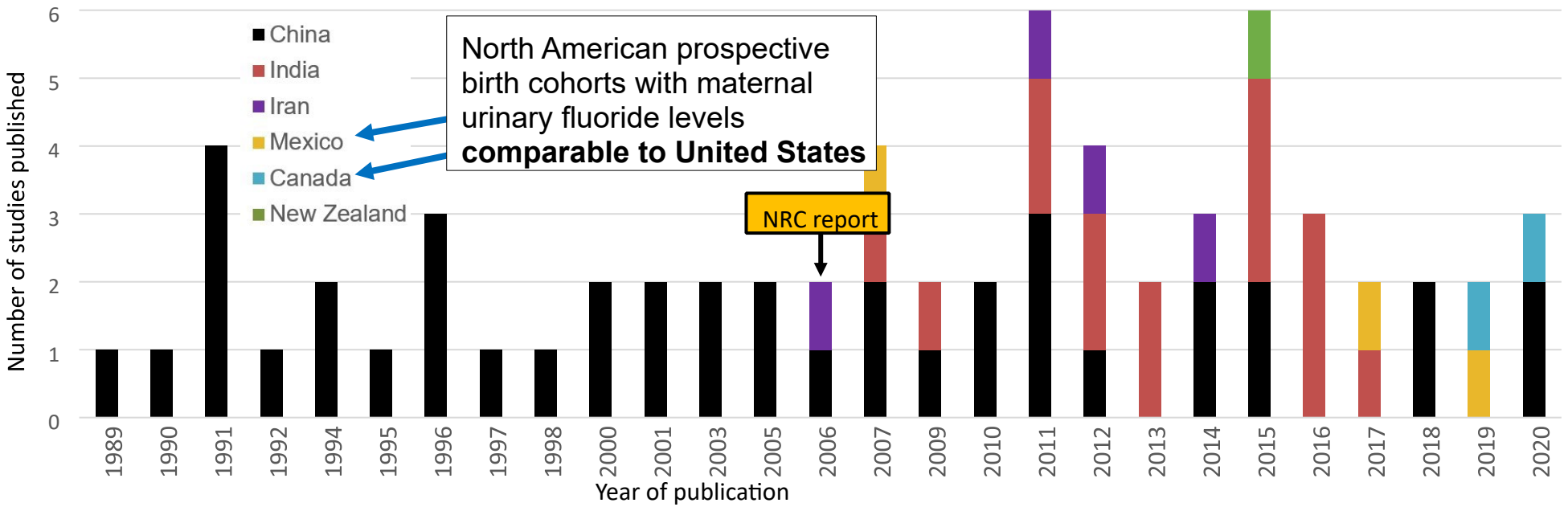
Characteristics of high-quality studies

Important for determining confidence

- Most established exposure occurred prior to outcome assessment (i.e., temporality)
  - e.g., prospective cohort studies or prevalence of dental fluorosis in children, limiting study populations to children who lived in an area for long periods of time
- Used IQ tests that were appropriate for the population being studied, outcome assessors were blind to fluoride exposure status
- Accounted for **key confounders** (e.g., age, sex, socioeconomic status) including potential co-exposures to other neurotoxins (e.g., arsenic, lead intake)
- Used individual-level exposure assessment measures (e.g., urine or water)
  - Or, if using group-level data, confirmed regions being compared had differences in fluoride exposure
- Used appropriate sampling techniques for study populations and statistical approaches for analyses
  - e.g., stratified multistage random sampling, regression techniques that account for clustering

Study quality and year of publication in studies of fluoride exposure and children's IQ

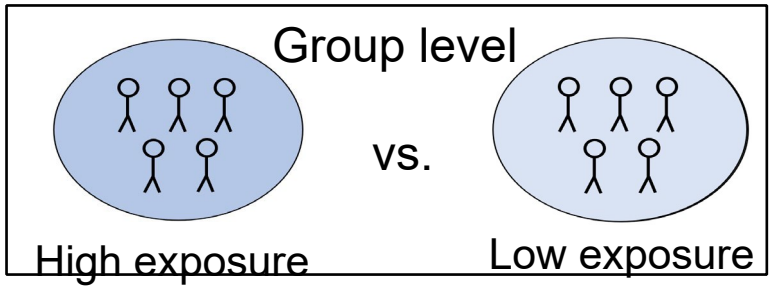




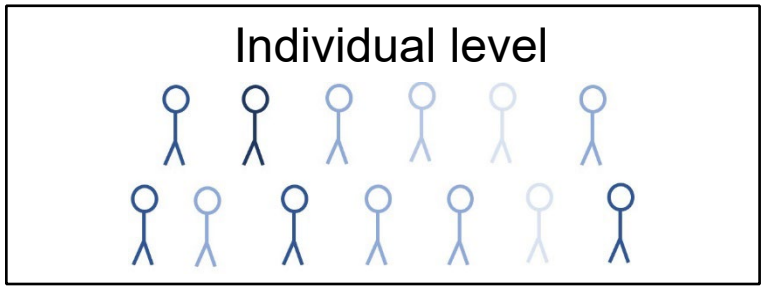
NRC: National Research Council

Study location and year of publication in studies of fluoride exposure and children's IQ

Exposure data fell into two general categories



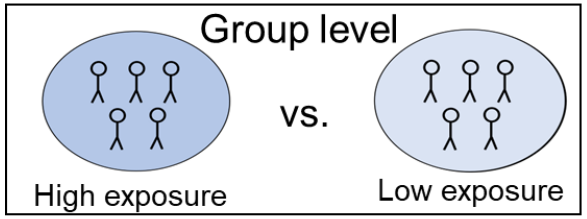
- Reported group-level exposure measures
- Compared mean IQ of children living in "high" fluoride areas to children living in "low" fluoride areas
- Measures included
  - Village or area of residence (endemic vs. non-endemic)
  - Drinking water
  - Children's urine
  - Severity of dental fluorosis
  - Coal burning



- Reported individual-level exposure measures
- Reported regression coefficients for change in children's IQ per 1 mg/L increase in urinary fluoride levels
- Measures included
  - Children's urine
  - Maternal urine
  - Drinking water
  - Fluoride intake
  - Serum

Consistency across high- and low-quality studies

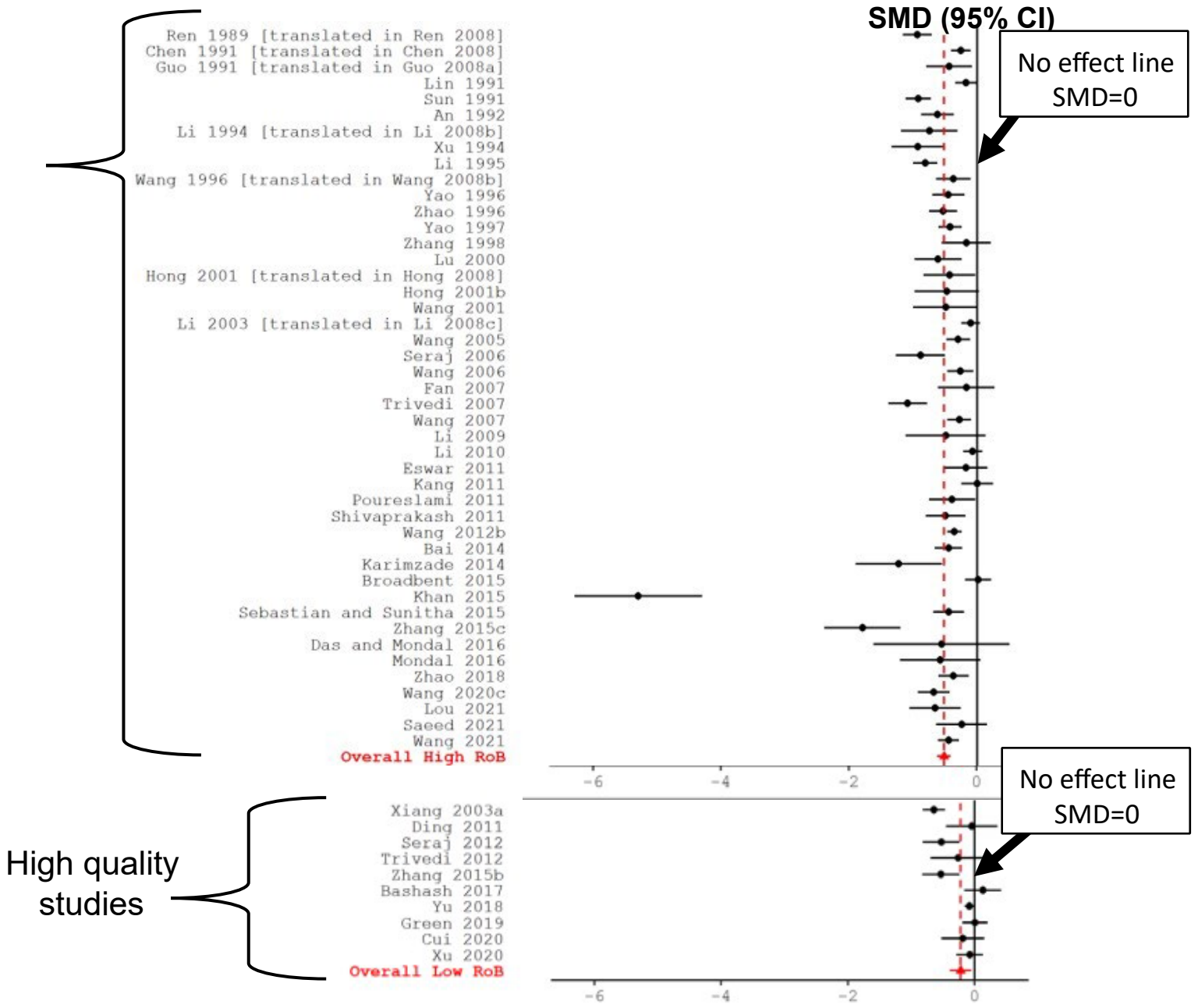
Group-level data



- Standardized mean difference (SMD) for studies comparing children's IQ in a "high" fluoride exposure area vs. a "low" fluoride exposure area

Children in high fluoride communities have statistically significantly **lower IQ**

CI: Confidence intervals



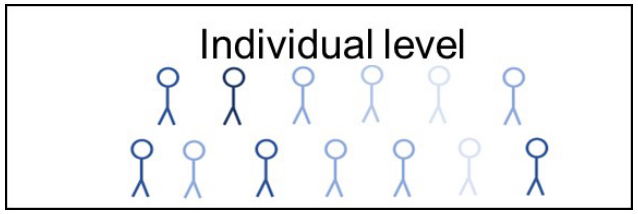
Low quality studies

Not all high-quality studies reporting group level data are displayed (e.g., studies that did not report data in a way that could be plotted as an SMD)

Consistency across high- and low-quality studies

ELEMENT and MIREC cohorts reported maternal urinary fluoride levels **comparable to the United States** (*Ugyturk 2020, Malin 2024*)

Individual-level data

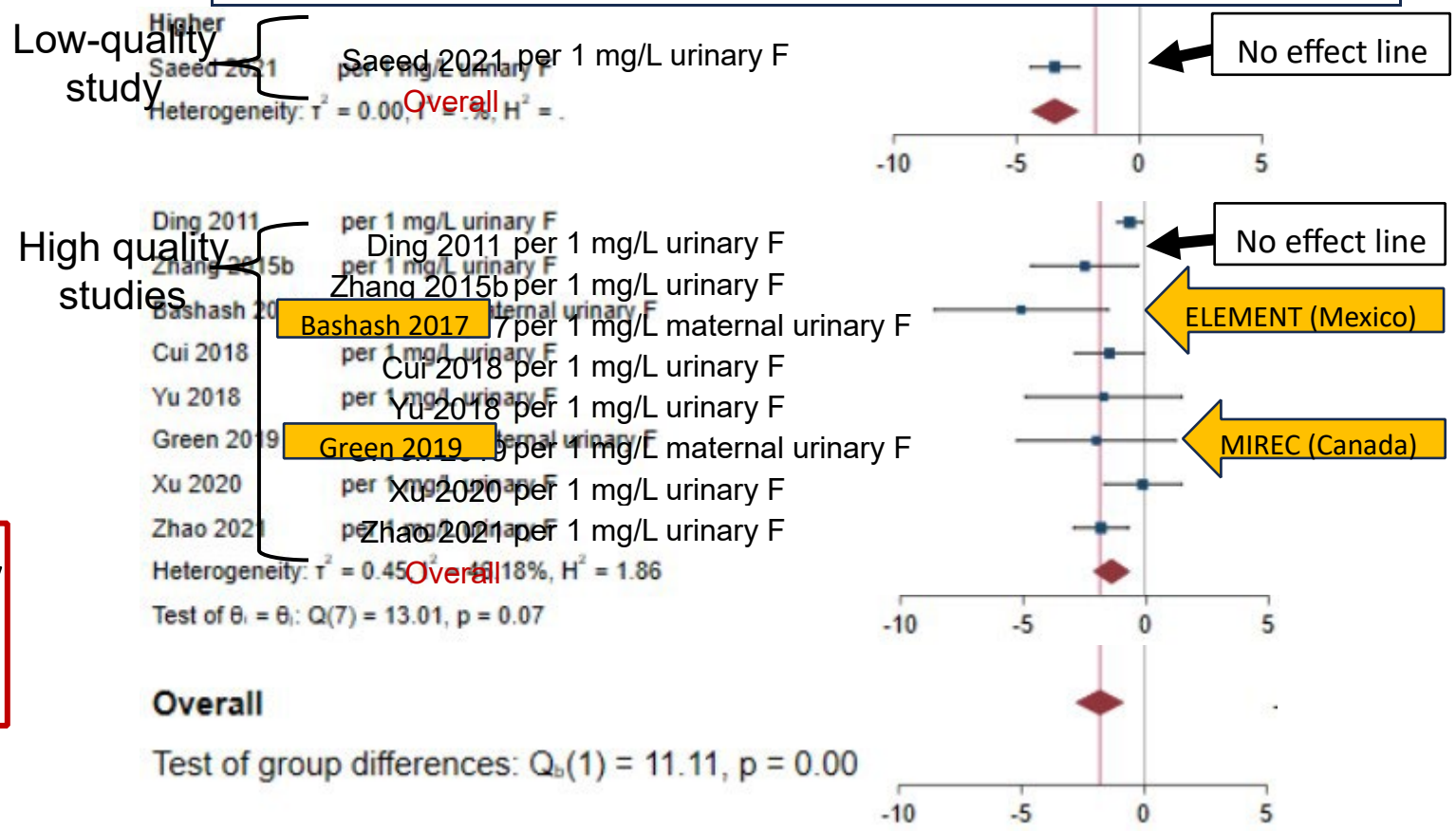


- Green et al 2019 (MIREC): β = **-1.95** (95% CI: -5.19, 1.28)
- Bashash 2017 (ELEMENT): β = **-5.16** (95% CI: −9.12, −1.19)

Interpretation: Per 1 mg/L increase in maternal urinary fluoride, → 2 to 5 point decrease in children's IQ

- Regression coefficients (β) and 95% CIs for change in children's IQ per 1 mg/L increase in maternal or children's urinary fluoride

For every 1 mg/L increase in urinary fluoride there is a statistically significant **decrease children's IQ**



Overall

Test of group differences: $Q_b(1) = 11.11$, $p = 0.00$

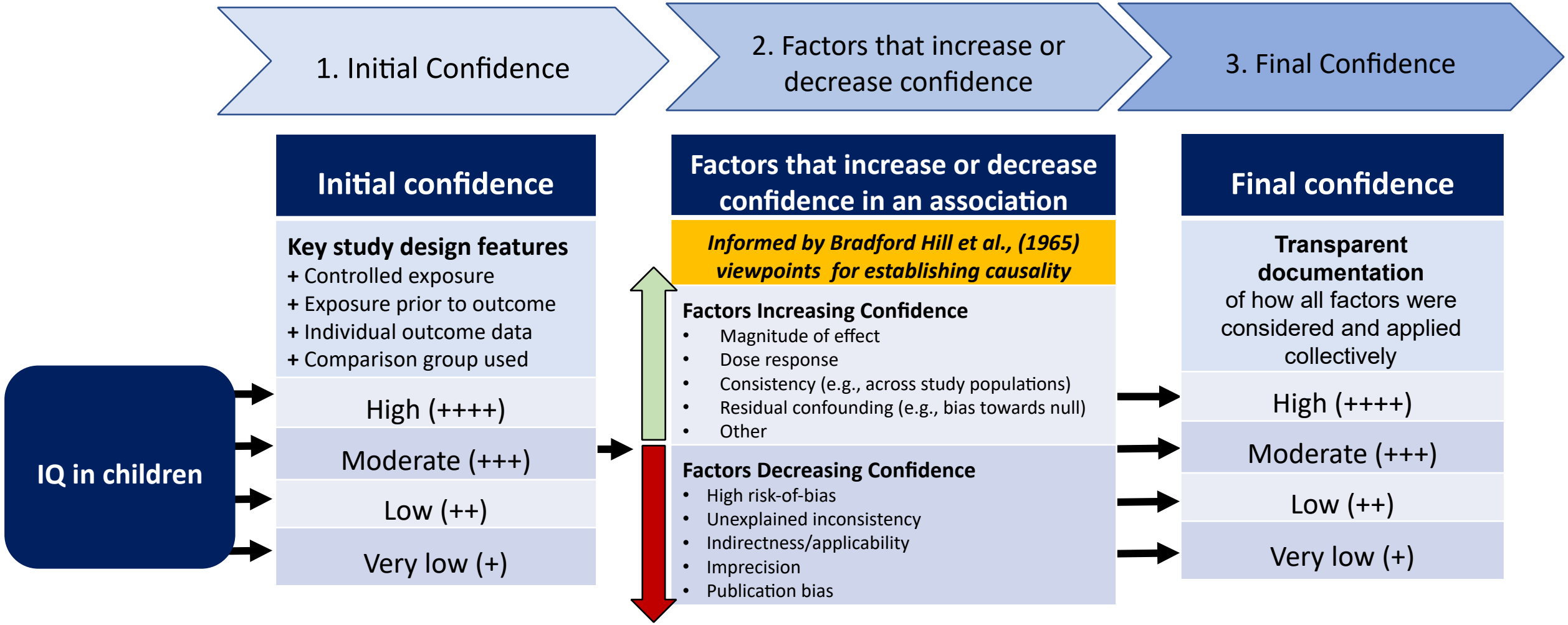
Reference Unit of exposure

β coefficient (95% CI)

Confidence ratings

- Rate confidence in bodies of evidence that overall findings ***reflect the true exposure-effect relationship***
- Four-point scale:
  - High confidence
  - Moderate confidence
  - Low confidence
  - Very Low confidence
- Performed for bodies of evidence on outcome basis
- Considers principles that are ***consistent with causation***

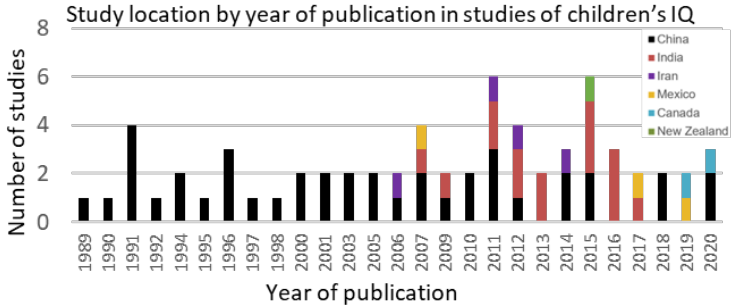
3 steps for determining confidence

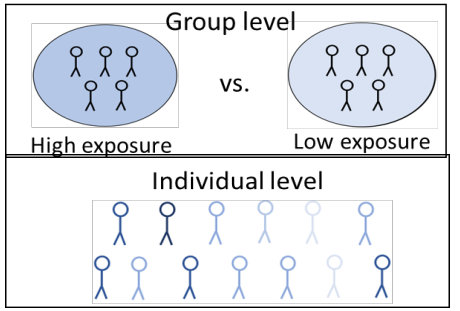


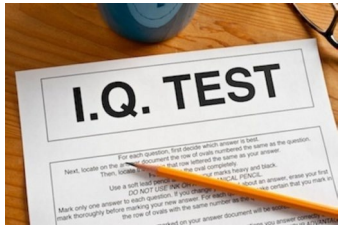
Considerations for confidence ratings

Studies of fluoride exposure and children's IQ

7. Consistent inverse association across:
   - 18 of 19 high quality studies
   - 46 of the 53 low quality studies
   - Study populations from different countries
   - Study designs (cross-sectional, prospective cohort)
   - Risk of bias ratings
   - Exposure matrices (water and urine)
   - Type of exposure data (group and individual level data)
   - Timing of exposure (pre- and post-natal)
   - Outcome assessment type (different types of IQ tests)







8. Heterogeneity in methods, NOT heterogeneity in results
9. Each level of consistency **strengthens** overall confidence
10. Determined confounding could not explain these results *(see NTP Monograph for details)*

NTP Conclusion:

Moderate confidence that

higher fluoride exposure is associated with lower IQ children

Extensive peer review

2019-2020

National Academies of Science, Engineering, Medicine (NASEM) committee reviewed initial (2019) & revised (2020) drafts

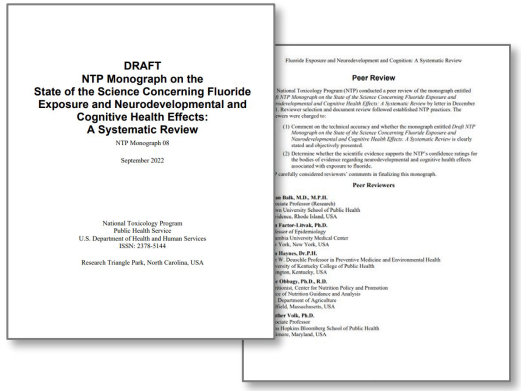
NTP revised Monograph in response to these reviews

2021

External peer review by 5 independent reviewers of 2021 draft NTP Monograph (typical NTP peer review process)

Both **NASEM reviews** & author responses provided

Reviewers ***unanimously*** agree with NTP's conclusions



2022

DTT Scientific Director approves NTP Monograph to be published (May 2022)

NTP/NIEHS Director asks NTP Board of Scientific Counselors (BSC) to review authors' responses to external peer review & *interagency comments on Monograph & meta-analysis (MA)

2023

NTP BSC working group review of author responses to external peer review & *interagency comments on Monograph & MA

Both **NASEM reviews** & author responses provided

Issued recommendations for language refinement & clarification

No major issues identified with methods, analyses, conclusions

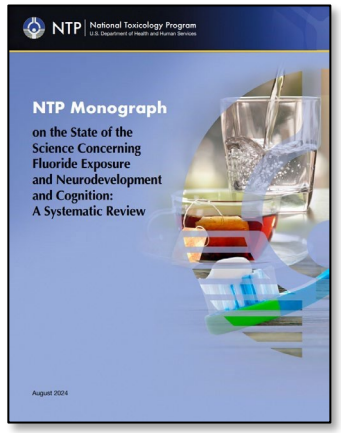
Encouraged rapid publication

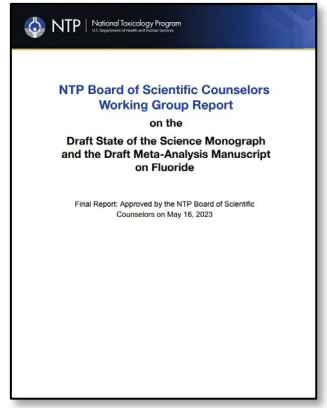
Authors respond to all NTP BSC comments

2024

Final publication
August 2024

(MA in press)





*Agencies and offices that provided comments on Monograph &
Office of the Director, NIH
Office of the Assistant Secretary of Health (OAS
Food and Drug Administration (FDA
Centers for Disease Control (CDC
National Institute of Dental and Craniofacial Research (NID
National Institute of Child Health and Development (NICH

Of note…

- Final confidence conclusions based primarily on high-quality studies (i.e., the best evidence)
  - Consideration of low-quality studies does not decrease confidence in overall body of evidence
- Conclusions based primarily on non-US studies where total fluoride exposure approximated *>1.5 mg/L fluoride in drinking water
  - Several high-quality prospective birth cohort studies with maternal urinary fluoride levels comparable to the United States

  **>1.5 mg/L refers to WHO Drinking Water Guideline of 1.5 mg/L; chosen to describe "higher" fluoride exposure in the NTP Monograph based on an overall assessment of the epidemiology literature; represents a useful total fluoride exposure equivalent metric (no alternative safety guidelines for total fluoride exist)*
- Review ***does not***
  - Evaluate benefits of fluoride or provide a risk/benefit analysis
  - Address whether ***sole exposure*** to fluoride at 0.7 mg/L in drinking water is associated with neurodevelopment and cognitive effects
- Targeted research that prospectively examines the association between fluoride exposure and children's IQ in optimally fluoridated areas of the United States would add clarity to the existing data at lower levels

Exposure considerations

- Fluoride in drinking water
  - Provides useful estimates of long-term population exposures
  - May underestimate total exposure because it does not capture the amount of water ingested or other sources of ingested fluoride

- Fluoride in urine
  - Biological measure that captures individual's total fluoride exposure
  - Represents a limited (recent) time-period
  - Multiple measurements would be more robust, e.g., cohort studies with maternal urinary fluoride had multiple measures throughout pregnancy

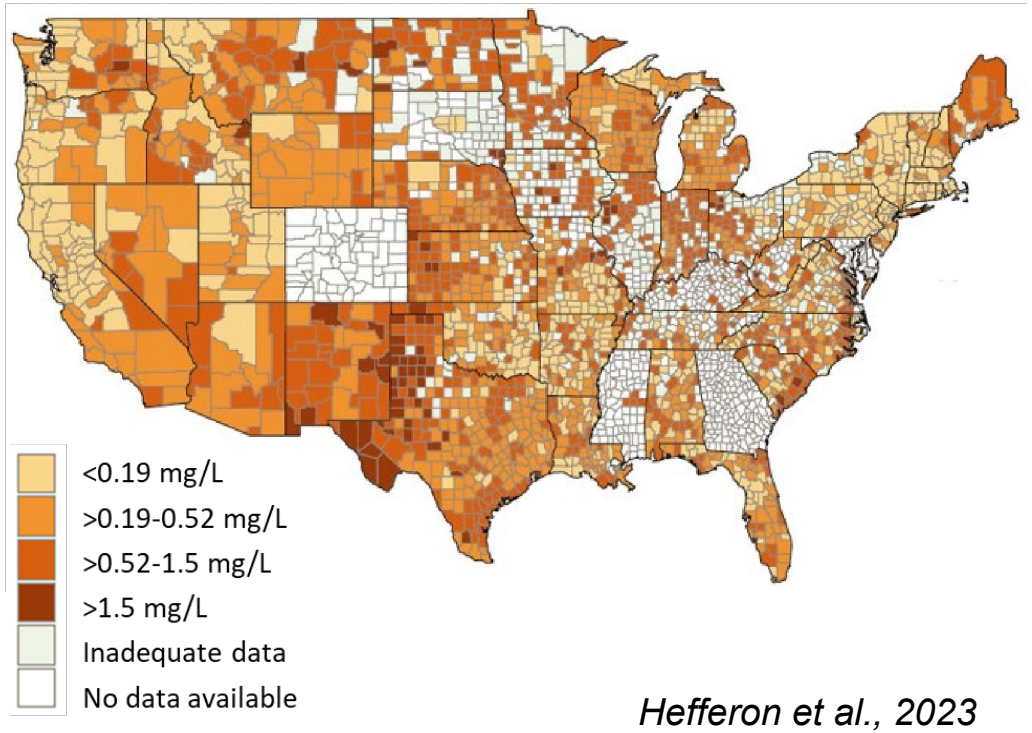
- Small number of studies at low exposure levels
  - Limited exposure contrasts, which makes it more difficult to detect a true effect, if it exists

Relevance to the United States

- NTP conclusions are relevant to some pregnant women, infants, and children living in the United States

– People may have total fluoride exposures higher than levels in drinking water

– **Over 2.9 million people** in the United States served by CWS receive drinking water with >1.5 mg fluoride/L



Hefferon et al., 2023

NEWS & FEATURES

In Millions of Homes, High Fluoride in Tap Water May Be a Concern

In communities across the U.S., water contains levels of fluoride some experts say could be harm developing brains.

Top: Water tower in Comfort, Texas. Visual: Marcus Wennrich/ iStock/Getty Images Plus

BY MICHAEL SCHULSON
05.06.2024

> *Lost in that debate are the roughly 3 million Americans whose water naturally contains higher concentrations of fluoride — often at levels that could have neurodevelopmental effects.*

Estimated fluoride levels in community water systems by county

Relevance to the United States

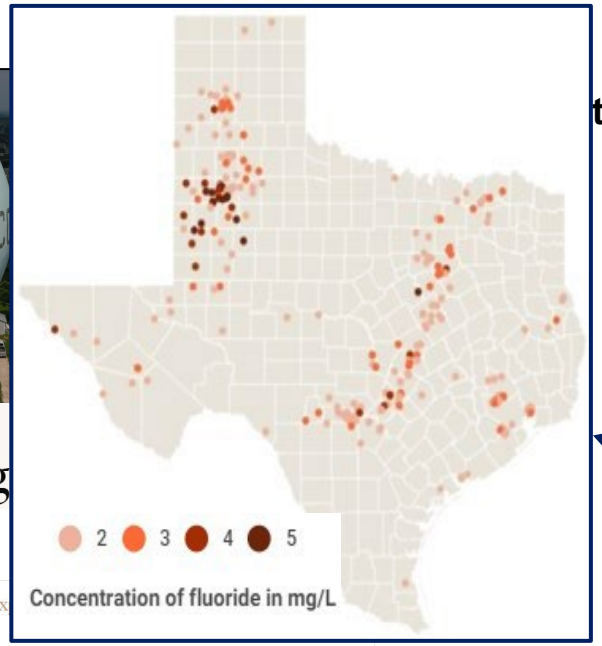
- NTP conclusions are relevant to some pregnant women, infants, and children living in the United States
  - People may have total fluoride exposures higher than levels in drinking water
  - **Over 2.9 million people** in the United States served by CWS receive drinking water with >1.5 mg fluoride/L

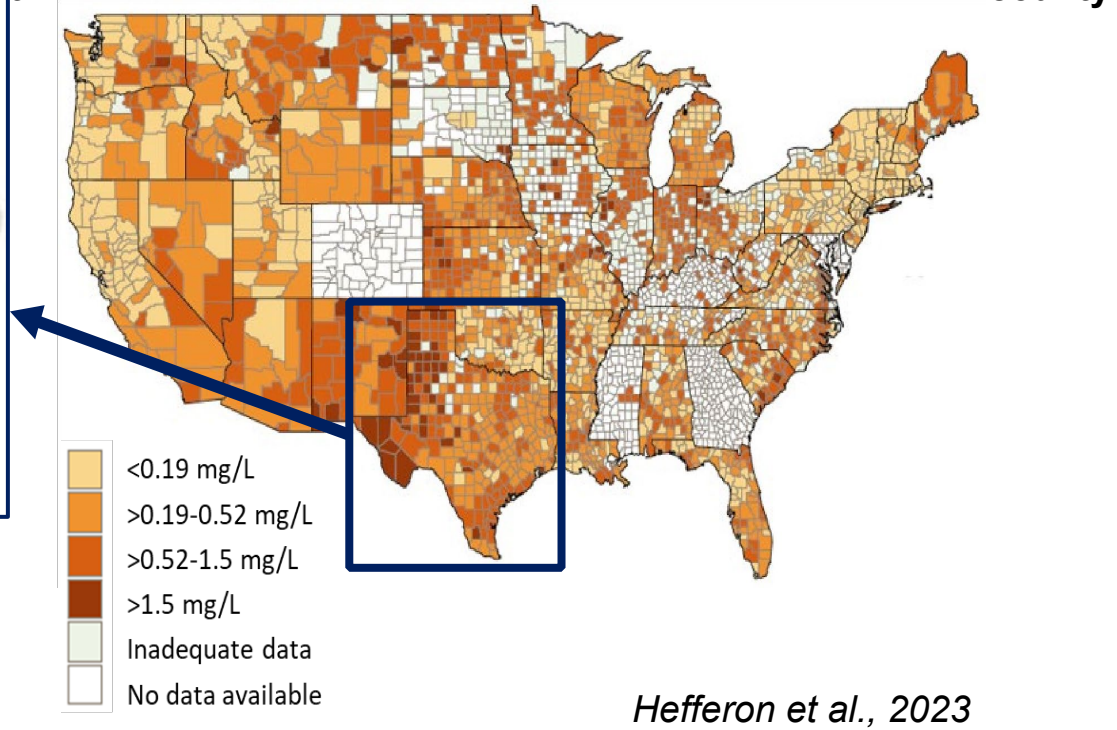
NEWS & FEATURES

In Millions of Homes, Hig
Water May Be a Concern

In communities across the U.S., water contains levels of fluoride some ex

Top: Water tower in Comfort, Texas. Visual: Marcus Wennrich/ iStock/Getty Images Plus





Hefferon et al., 2023

> *Lost in that debate are the roughly 3 million Americans whose water naturally contains higher concentrations of fluoride — often at levels that could have neurodevelopmental effects.*

Fetal and developing brains are especially vulnerable

- Benefits of fluoride are from topical contact with teeth
- No benefit from gestational exposure
- Fetal exposure:
  - Fluoride from maternal blood crosses placenta
  - Fluoride stored in bone and remobilized into bloodstream during pregnancy
- Formula-fed infants residing in fluoridated communities at higher risk of fluoride toxicity
  - 3-4 times greater exposure to fluoride than adults on a per body-weight basis
  - ~70-fold higher fluoride intake than exclusively breastfed infants
  - Retain more fluoride than breastfed infants


The New York Times

Is Fluoridated Drinking Water Safe for Pregnant Women?

New research suggests a link between prenatal fluoride levels and behavioral issues in children. Experts are divided on the study's

By Alice Callahan and Christina Caron

May 22, 2024

NTP Monograph played central role in recent federal trial

- What was the lawsuit about?

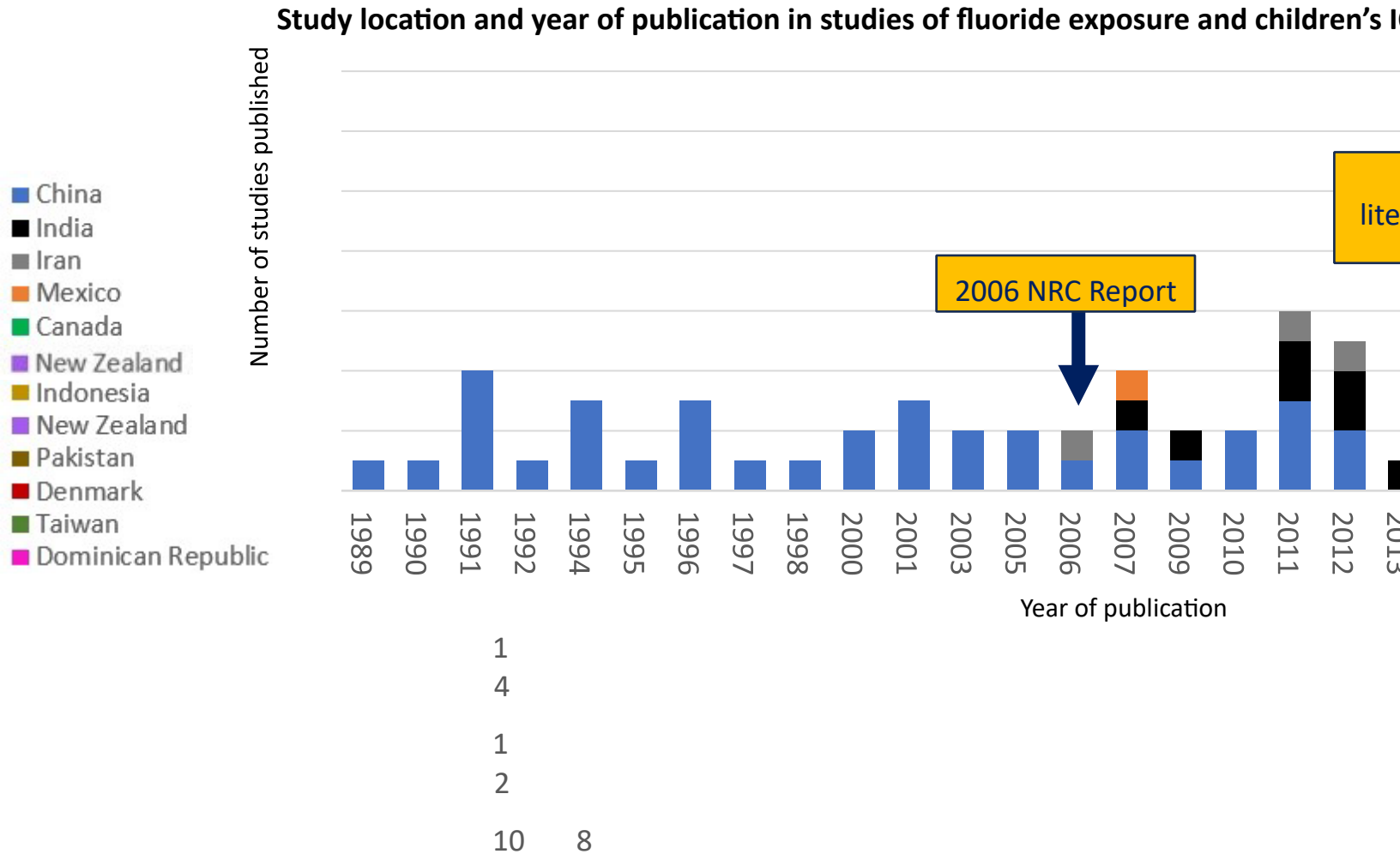
– Plaintiffs petitioned EPA to evaluate fluoride in drinking water, EPA denied the petition and under Amended Toxic Substances Control Act (TSCA), Plaintiffs were entitled to a judicial review • Monograph relied on by both Plaintiffs and EPA as a “high-quality review”

- What was the Court’s ruling?
  - – On September 24, 2024, a federal district judge found that the 0.7 mg/L fluoride in drinking water, level considered “optimal” in the United States, poses an ***“unreasonable risk”*** of IQ loss in children which, under the toxics law, requires ***“a regulatory response”***
  - – Finding did not conclude with certainty that fluoridated water is injurious to public health
  - – Court finds the risk is ***sufficient*** to require the EPA to engage with a regulatory response, but does not dictate what that response must be, decision left to the EPA,
  - – TSCA allows wide spectrum of potential risk-management measures from warning labels or public advisories to prohibiting the manufacturing and distribution of a chemical

Public health community can use the NTP systematic review as part of ongoing evaluations of the role of fluoride in drinking water

Literature since May 1, 2020?

- Addendum updated through October 2023 to match timeframe of meta-analysis (in press)
-



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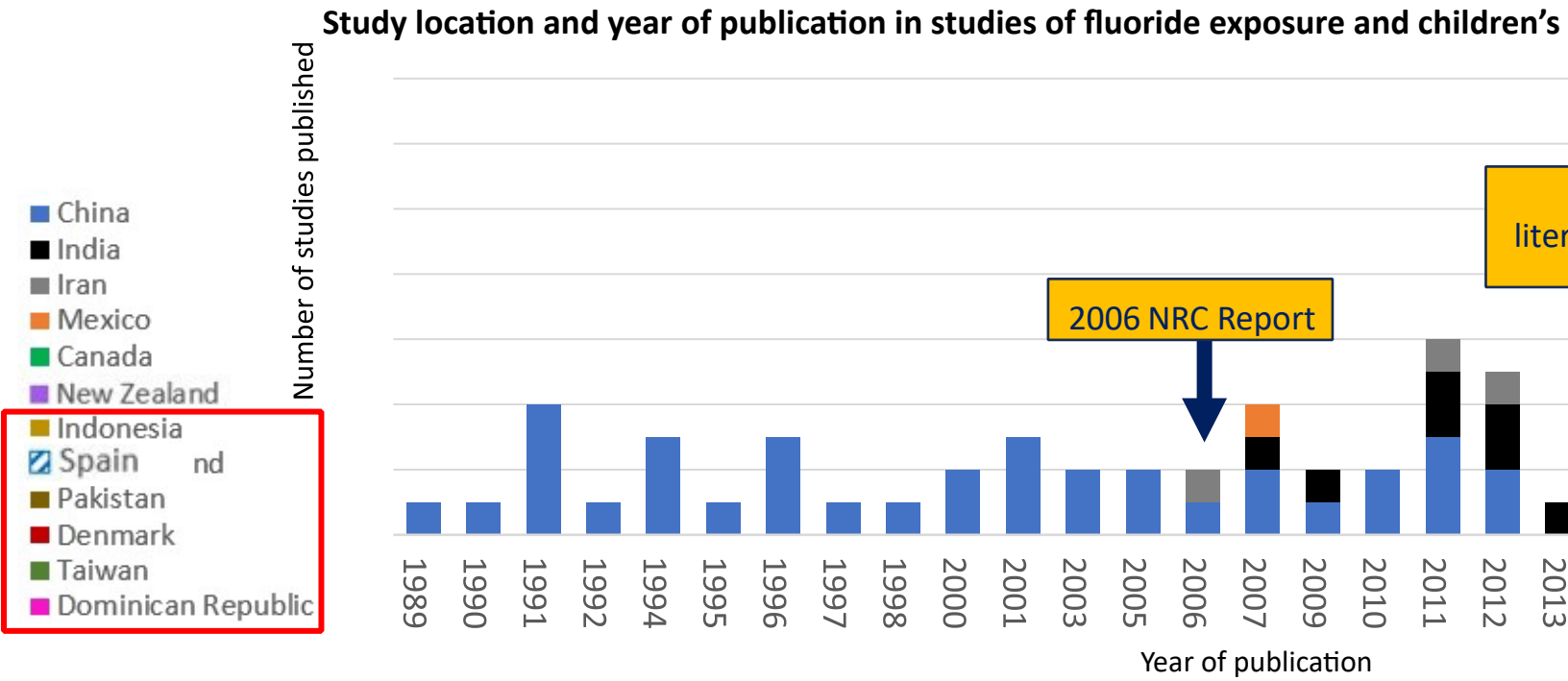
Literature since May 1, 2020?

- Addendum updated through October 2023 to match timeframe of meta-analysis (in press)
- 28 new studies
  - 12 of 12 high quality studies reported inverse associations (6 in new study populations)
  - 13 of 16 low quality reported inverse associations



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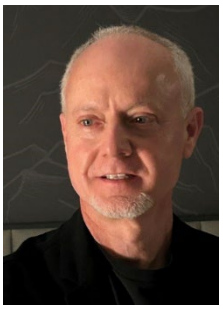
Former Scientific Director of DNTP and Associate Director of NTP



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Thank you!
Questions?

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WSBH Petition #22. December 8, 2024

Washington State Board of Health PO Box 47990, Olympia, WA 98504-7990 wsboh@doh.wa.gov
Petitioners: Washington Action for Safe Water and Bill Osmunson DDS MPH

Dear Washington State Board of Health

"Failing to Assure Safe Water" Addendum B to our petition #22 for rule change.[1]

The Washington State Board of Health (Board) has been charged by the Legislature to assure safe public drinking water.[2] The Board appears to attempt delegating responsibility for determining the complex, scientific pharmacological, toxicological, epidemiological, chemistry, physiological effects, ethics, benefits, risks, costs and laws of fluoridation (CWF, Community Water Fluoridation, the addition of fluoride to public water onto the cities who have the fewest experts and often the least financial resources to make the judgement on fluoridation's safety, efficacy, ethics and cost-benefit-risk analysis.

The Board claims they do not add fluoride to pubic water, implying lack of jurisdiction or responsibility for the Board's advice. Words matter. The time and expense for the determination of safety, efficacy, dosage, ethics, laws and costs of these experts for each of the 281 cities and towns in Washington State is unreasonable. Evaluation of the science takes hundreds of hours and multiplying hundreds of hours by experts, times 281 cities and towns makes evaluation unreasonably expensive.

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[1] Consistent with health and safety issues in Title 246, Title 173, Title 296, WAC 173-340, and WAC 296-62-07521; this petition is made in compliance with RCW 34.05.330 and WAC Chapter 82-05.

Our petition for amendment to WAC 246-290-220

"(8) In keeping with the Federal Safe Drinking Water Act S.433 and the Food Drug and Cosmetic Act, Title 21, the Board of Health does not recommend any substance be added to water with intent to treat humans, unrelated to treatment of water as defined in RCW 18.64.011(14)(15) or 21 U.S. Code § 321(g)(1), unless approved by the Food and Drug Administration in compliance with the U. S. Food, Drug and Cosmetic Act. This recommendation does not apply to substances added to water to make water safer as determined by the U.S. Environmental Protection Administration in compliance with the Safe Drinking Water Act."

[2] Pursuant to RCW 43.20.50 (1) "The state board of health shall provide a forum for the development of public health policy in Washington state. . . ." RCW 43.20.50 (2) "In order to protect public health, the state board of health shall: (a) Adopt rules for group A public water systems . . . necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding: . . . (ii) Drinking water quality standards . . . (b) Adopt rules as necessary for group B public water systems . . ." And further under RCW 70.142.010 to establish standards for chemical contaminants in public drinking water and "consider the best available scientific information establishing the standards."

But the delegation gets worse. Another option is for the voters with the least expertise, education, and experience to be given the responsibility, based on media or distrust of authorities, to make the complex time-consuming decision of whether to fluoridate or not and vote the unapproved prescription drug on their neighbors. Words matter and marketing by profitable industry is pitted against patients who have been harmed. To assure the public the water is safe, the Board must immediately caution cities and towns in Washington State the science has changed, it is past time to obey Federal and state law. **DO NOT ADD FLUORIDE TO TAP WATER.**

The task to simply educate the Board has been 15 years of our lives and although we have made small incremental steps, such as the Board accepting the intent of adding fluoride to public water is to mitigate or prevent a disease, the Board is still placing the profits of industry over the health of the public.

RCW 57.08.012. Authorizes water district commissioners to vote to fluoridate the water or vote to have a majority of the electors vote on a proposition to fluoridate. RCW 57.08.012 is silent regarding the determination of safety, efficacy, dosage, Good Manufacturing Practices for Pharmaceuticals, purity of the product, concentration in water, etc.

The AGO 1992 No.17,

> "2. The Legislature has authorized the Board of Health to establish, and the Department of Health to enforce, a comprehensive regulatory scheme for public water systems." The Board of Health stated: "The Board does not appear to have authority to adopt rules related to a water district deciding whether to fluoridate. The Board's authority is to regulate allowable concentration levels and method of approval of water additives." (June 9, 2010 Board Meeting Handout, page 2, emphasis added).

The Board has the authority to lower fluoride concentration added to water to the same level as mother's milk, a mean of 0.004 mg/L so that formula made with fluoridated water would be safe, or to the benchmark dose of fluoride developmental neurotoxicity, 0.2 mg/L as recommended by Grandjean (2022)[3]. The Board has authority to require additives to be pharmaceutical grade and/or provide batch assays of purity.

[3] Grandjean P, Hu H, Till C, Green R, Bashash M, Flora D, Tellez-Rojo MM, Song PXK, Lanphear B, Budtz-Jørgensen E. A Benchmark Dose Analysis for Maternal Pregnancy Urine-Fluoride and IQ in Children. Risk Anal. 2022 Mar;42(3):439-449. doi: 10.1111/risa.13767. Epub 2021 Jun 8. PMID: 34101876; PMCID: PMC9831700. Note: On a population wide basis, fluoride urine concentrations are similar to water fluoride concentration, but not as close on an individual basis.

The toxicity of fluoride is important to understand so that priority of regulation is made. Toxicity puts fluoride within the definition of **RCW 69.38.010** as a poison. Poisons are exempt from poison laws when regulated under drug laws. The Washington Board of Pharmacy determined fluoride was a legend (prescription) drug which requires a doctor's prescription. The Board should regulate fluoride keeping in mind the serious toxic risk and protect the public.

The Washington State Board of Pharmacy, Department of Health letter June 4, 2009, stated:

> "69.38.020 states that "[all substances regulated under chapters 15.58, 17.21, 69.04, and 69.50, and chapter 69.45 RCW are exempt from the provisions [of chapter 69.38 RCW]. Fluoride is a legend drug regulated under chapter 69.41 RCW. RCW 69.41.010 defines a "legend drug" as drugs "which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only." In WAC 246-883-020 (2), the Board specified that "legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the Drug Topics Red Book. " Enclosed are copies of pages 169, 342, and 690 of the 2()02 edition of the Drug Topics Red Book. Page 169 is the key to the products requiring prescription (legend drugs) and page 342 contains the fluoride products. Page 690 contains the listing of over-the-counter fluoride products, primarily toothpaste containing fluoride." (Highlight supplied)

In other words, fluoride when regulated in compliance with drug laws does not need to be regulated as a poison when used with intent to prevent human disease. When regulating fluoridation, cities and the Board must keep in mind fluoride is highly toxic and a legend drug being added to public water without patient consent, voted on by the least authoritative chemical, toxicological and pharmaceutical experts in the state.

The Board of Pharmacy Department of Health letter continues:

> "While RCW 69.41.010 restricts the dispensing of prescription drugs to practitioners, the legislature has authorized water districts to fluoridate their water supplies in RCW 57.08.012 . . By adopting a specific statute on the fluoridation of water supplies, the legislature has superseded the more general statutes in the legend drug act requiring a practitioner to dispense fluoride."

However, RCW 57.08.012 does not exempt fluoride from being regulated as much as possible under legend drug laws which require a doctor's prescription. The Board of Pharmacy does not prevent the Board of Health from lowering the concentration or requiring water suppliers from adhering to Federal laws as this petition recommends or Good manufacturing practices, purity, dosage, or/and label. No law prevents the education of the public or protection of the public from harm.

> Please provide a copy of the Board's advice, guidance, recommendations provided to cities regarding the product purity, individual patient dosage, GMP, and label.

The Washington State Legislature gave the Board of Health the task of assuring the public that water is safe and fluoridation is not safe. The Legislature did not give that task to the public, cities or public water purveyors. In order to assure the public that fluoridation is safe, please respond to the following:

#1. The Board claims and assumes fluoridation is **effective** without a single randomized controlled trial, primarily historic observations which are fraught with bias. The Board protects fluoride exposure based on endorsements from the fluoridation lobby profiting from fluoride, marketing fluoride as benefit. The FDA told the Board a decade ago, fluoridation would be "banned" if application for approval were made. The Board is not an authority to determine the effectiveness of any drug or chemical marketed with intent to prevent disease. Only the FDA CDER has that authority and the FDA CDER has not approved the ingestion of fluoride. Topical is approved with the warning, Do Not Swallow.

REQUEST: Please provide the public and Washington State Cities with quality research, published, peer reviewed randomized controlled trials of fluoride ingestion's efficacy. The Board claims efficacy, protects fluoridation as though there is efficacy, but fails to provide quality research on efficacy because the Board does not have quality research on efficacy, only observational evidence which is incomplete.

The CDC: ***"****Ingestion of fluoride is not likely to reduce tooth decay."*[i] *"For 65 years, community water fluoridation has been a safe and healthy way to effectively prevent tooth decay."*[ii] *". . . fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children…"*[iii]

The NIDR: *"An analysis of national survey data collected by the National Institute of Dental Research (NIDR) concludes that children who live in areas of the U.S. where the water supplies are fluoridated have tooth decay rates nearly identical with those who live in nonfluoridated areas"*[iv]

The NIH: Evidence for fluoridation preventing disease is incomplete.

"By 1981, it was therefore possible to propose a paradigm shift concerning the cariostatic mechanisms of fluorides in which it was argued that the predominant, if not the entire, explanation for how fluoride controls caries lesion development lies in its topical effect on de- and remineralization processes taking place at the interface between the tooth surface and the oral fluids. This concept has gained wide acceptance... With today's knowledge about the mechanisms of fluoride action, it is important to appreciate that, as fluoride exerts its predominant effect... at the tooth/oral fluid interface, it is possible for maximum caries protection to be obtained without the ingestion of fluorides to any significant extent."
SOURCE: Aoba T, Fejerskov O. (2002). *Critical Review of Oral Biology and Medicine* 13: 155-70.

"When it was thought that fluoride had to be present during tooth mineralisation to 'improve' the biological apatite and the 'caries resistance' of the teeth, systemic fluoride administration was necessary for maximum benefit. Caries reduction therefore had to be balanced against increasing dental fluorosis. The 'caries resistance' concept was shown

to be erroneous 25 years ago, but the new paradigm is not yet fully adopted in public health dentistry, so we still await real breakthroughs in more effective use of fluorides for caries prevention."
SOURCE: Fejerskov O. (2004). Changing paradigms in concepts on dental caries: consequences for oral health care. *Caries Research* 38: 182-91.

“Our analysis shows no convincing effect of fluoride-intake on caries development. . . A Bayesian analysis of multivariate doubly-interval-censored dental data.”[v]

“Since April of 1999, I have publicly decried the addition of fluoride, especially hydrofluosilicic acid, to drinking water for the purpose of preventing tooth decay.”
Hardy Limeback, BSc, PhD, DDS, Associate Professor and Head, Preventive Dentistry University of Toronto **http://www.slweb.org/limeback.html**

“Fewer fillings had been required in the nonfluoridated part of my district than in the fluoridated part.” 1997 John Colquohoun PhD, DDS **http://www.slweb.org/colquhoun.html**

“Decay is not the result of fluoride deficiency.” Aoba T, Fejerskov O. (2002). Dental fluorosis: chemistry and biology. Critical Review of Oral Biology and Medicine 13: 155-70.

“A number of recent cessation studies show that stopping fluoridation does literally nothing to increase overall dental decay.” Komarek et al, A Bayesian analysis of multivariate doubly-interval-censored dental data, Biostatistics 2005 6 pp 145-155
"it is now accepted that systemic fluoride plays a limited role in caries prevention." SOURCE: Pizzo G, Piscopo MR, Pizzo I, Giuliana G. (2007). Community water fluoridation and caries prevention: a critical review. Clinical Oral Investigations 11(3):189-93.

“the major anticaries benefit of fluoride is topical and not systemic.” SOURCE: National Research Council. (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards. National Academies Press, Washington D.C. p 13.

"Since the current scientific thought is that the cariostatic activity of fluoride is mainly due to its topical effects, the need to provide systemic fluoride supplementation for caries prevention is questionable."
SOURCE: European Commission. (2005). *The Safety of Fluorine Compounds in Oral Hygiene Products for Children Under the Age of 6 Years*. European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Consumer Products, September 20.

“The results of more recent epidemiological and laboratory studies can be summarized by stating that posteruptive (topical) application of fluoride plays the dominant role in caries prevention."
SOURCE: Hellwig E, Lennon AM. (2004). Systemic versus topical fluoride. *Caries Research* 38: 258-62.

“Current evidence strongly suggests that fluorides work primarily by topical means through direct action on the teeth and dental plaque. Thus ingestion of fluoride is not essential for caries prevention."
SOURCE: Warren JJ, Levy SM. (2003). Current and future role of fluoride in nutrition. *Dental Clinics of North America* 47: 225-43.

"[T]he majority of benefit from fluoride is now believed to be from its topical, rather than systemic, effects."
SOURCE: Brothwell D, Limeback H. (2003). Breastfeeding is protective against dental fluorosis in a nonfluoridated rural area of Ontario, Canada. *Journal of Human Lactation* 19: 386-90.

"For a long time, the systemic effect of fluoride was regarded to be most important, resulting in recommendations to use fluoride supplements such as tablets or drops. However, there is increasing evidence that the local effect of fluoride at the surface of the erupted teeth is by far more important."
SOURCE: Zimmer S, et al. (2003). Recommendations for the Use of Fluoride in Caries Prevention. *Oral Health & Preventive Dentistry* 1: 45-51.

"[F]luoride's predominant effect is posteruptive and topical."
SOURCE: Centers for Disease Control and Prevention. (2001). Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. *Morbidity and Mortality Weekly Report* 50(RR14): 1-42.

"The prevalence of dental caries in a population is not inversely related to the concentration of fluoride in enamel, and a higher concentration of enamel fluoride is not necessarily more efficacious in preventing dental caries."
SOURCE: Centers for Disease Control and Prevention. (2001). Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. *Morbidity and Mortality Weekly Report* 50(RR14): 1-42.

"Fluoride incorporated during tooth development is insufficient to play a significant role in caries protection."
SOURCE: Featherstone, JDB. (2000). The Science and Practice of Caries Prevention. *Journal of the American Dental Association* 131: 887-899.

"Current evidence suggests that the predominant beneficial effects of fluoride occur locally at the tooth surface, and that systemic (preeruptive) effects are of much less importance."
SOURCE: Formon, SJ; Ekstrand, J; Ziegler, E. (2000). Fluoride Intake and Prevalence of Dental Fluorosis: Trends in Fluoride Intake with Special Attention to Infants. *Journal of Public Health Dentistry* 60: 131-9.

"Fluoride supplementation regimens suffer from several shortcomings, the first of which may be their derivation from a time when the major effect of fluoride was thought to be systemic. Although evidence that fluoride exerts its effects mainly through topical contact is great, supplementation schemes still focus on the ingestion of fluoride."
SOURCE: Adair SM. (1999). Overview of the history and current status of fluoride supplementation schedules. *Journal of Public Health Dentistry* 1999 59:252-8.

"The case is essentially a risk-benefit issue - fluoride has little preeruptive impact on caries prevention, but presents a clear risk of fluorosis."
SOURCE: Burt BA. (1999). The case for eliminating the use of dietary fluoride supplements for young children. *Journal of Public Health Dentistry* 59: 260-274.

"Until recently the major caries-inhibitory effect of fluoride was thought to be due to its incorporation in tooth mineral during the development of the tooth prior to eruption...There is now overwhelming evidence that the primary caries-preventive mechanisms of action of fluoride are post-eruptive through 'topical' effects for both children and adults."
SOURCE: Featherstone JDB. (1999) Prevention and Reversal of Dental Caries: Role of Low Level Fluoride. *Community Dentistry & Oral Epidemiology* 27: 31-40.

"[L]aboratory and epidemiologic research suggests that fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children."
SOURCE: Centers for Disease Control and Prevention. (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. *Morbidity and Mortality Weekly Report* 48: 933-940.

"[R]esearchers are discovering that the topical effects of fluoride are likely to mask any benefits that ingesting fluoride might have... This has obvious implications for the use of systemic fluorides to prevent dental caries."
SOURCE: Limeback, H. (1999). A re-examination of the pre-eruptive and post-eruptive mechanism of the anti-caries effects of fluoride: is there any caries benefit from swallowing fluoride? *Community Dentistry and Oral Epidemiology* 27: 62-71.

"Although it was initially thought that the main mode of action of fluoride was through its incorporation into enamel, thereby reducing the solubility of the enamel, this pre-eruptive effect is likely to be minor. The evidence for a post-eruptive effect, particularly its role in inhibiting demineralization and promoting remineralization, is much stronger."
SOURCE: Locker D. (1999). Benefits and Risks of Water Fluoridation. An Update of the 1996 Federal-Provincial Sub-committee Report. Prepared for *Ontario Ministry of Health and Long Term Care.*

"Recent research on the mechanism of action of fluoride in reducing the prevalence of dental caries (tooth decay) in humans shows that fluoride acts topically (at the surface of the teeth) and that there is negligible benefit in ingesting it."
SOURCE: Diesendorf, M. et al. (1997). New Evidence on Fluoridation. *Australian and New Zealand Journal of Public Health* 21 : 187-190.

"On the basis of the belief that an adequate intake of fluoride in early life is protective against caries in later life, fluoride supplements are recommended for infants and children living in areas in which the fluoride content of the drinking water is low. However, critical reviews of the evidence have led to the conclusion that the effect of fluoride in decreasing the prevalence and severity of dental caries is not primarily systemic but exerted locally within the oral cavity. Because fluoride supplements are quickly cleared from the mouth, the possibility must be considered that they may contribute to enamel fluorosis, which is unquestionably a systemic effect, while providing relatively little protection against dental caries."
SOURCE: Ekstrand J, et al. (1994). Fluoride pharmacokinetics in infancy. *Pediatric Research* 35:157–163.

"It is now well-accepted that the primary anti-caries activity of fluoride is via topical action."
SOURCE: Zero DT, et al. (1992). Fluoride concentrations in plaque, whole saliva, and ductal saliva after application of home-use topical fluorides. *Journal of Dental Research* 71:1768-1775.

"I have argued in this paper that desirable effects of systemically administered fluoride are minimal or perhaps even absent altogether."
SOURCE: Leverett DH. (1991). Appropriate uses of systemic fluoride: considerations for the '90s. *Journal of Public Health Dentistry* 51: 42-7.

"It, therefore, becomes evident that a shift in thinking has taken place in terms of the mode of action of fluorides. Greater emphasis is now placed on topical rather than on systemic mechanisms..."
SOURCE: Wefel JS. (1990). Effects of fluoride on caries development and progression using intra-oral models. *Journal of Dental Research* 69(Spec No):626-33;

"[E]vidence has continued to accumulate to support the hypothesis that the anti-caries mechanism of fluoride is mainly a topical one."
SOURCE: Carlos JP. (1983) Comments on Fluoride. *Journal of Pedodontics* Winter. 135-136.

"Until recently most caries preventive programs using fluoride have aimed at incorporating fluoride into the dental enamel. The relative role of enamel fluoride in caries prevention is now increasingly questioned, and based on rat experiments and reevaluation of human clinical data, it appears to be of minor importance... [A]ny method which places particular emphasis on incorporation of bound fluoride into dental enamel during formation may be of limited importance."
SOURCE: Fejerskov O, Thylstrup A, Larsen MJ. (1981). Rational Use of Fluorides in Caries Prevention: A Concept based on Possible Cariostatic Mechanisms. *Acta Odontologica Scandinavica* 39: 241-249.

"It is estimated that 84% of the caries experience in the 5 to 17 year-old population involves tooth surfaces with pits and fissures. Although fluorides cannot be expected appreciably to reduce our incidence of caries on these surfaces, sealants can."
SOURCE: *Journal of the American Dental Association 1984;* 108:448.

"[E]namel surfaces with pits and fissures receive minimal caries protection from either systemic or topical fluoride agents."
SOURCE: Pinkham JR. (1999). *Pediatric Dentistry: Infancy Through Adolescence.* Third Edition. WB Saunders Co, Philadelphia.

"The type of caries now seen in British Columbia's children of 13 years of age, is mostly the pit and fissure type. Knudsen in 1940, suggested that 70 percent of the caries in children was in pits and fissures. Recent reports indicate that today, 83 percent of all caries in North American children is of this type. Pit and fissure cavities aren't considered to be preventable by fluorides, they are prevented by sealants."
SOURCE: Gray, AS. (1987). Fluoridation: Time for a New Base Line? *Journal of the Canadian Dental Association* 10: 763-765.

"The program focused on four caries-prevention techniques: sealants, a plastic-like coating applied to the chewing surfaces of back teeth and to pits and fissures on the sides of teeth (these surfaces are most prone to decay and ones which fluorides cannot protect adequately)."
SOURCE: Raloff J. (1984). Dental study upsets the accepted wisdom. *Science News*. 125(1): January 7.

It is estimated that 84% of the caries experience in the 5 to 17 year-old population involves tooth surfaces with pits and fissures. Although fluorides cannot be expected appreciably to reduce our incidence of caries on these surfaces, sealants can."
SOURCE: Scholle R. (1984). Editorial: Preserving the perfect tooth. *Journal of the American Dental Association.* 108:448.

Children attending centers showed no significant differences based on fluoride status for the total sample or other variables. Barnes GP, et al. (1992). Ethnicity, location, age, and fluoridation factors in baby bottle tooth decay and caries prevalence of Head Start children. *Public Health Reports* 107: 167-73.

#2. The Board claims fluoridation is **safe** and the Legislature is precise that the Board, not the public or cities, assure the public the water is safe**.** No Federal Authority has a single study on the safety of fluoride to the developing brain or other tissues, systems, cells or organs. The NRC 2006 report lists several risks.

REQUEST: Please provide the public and Washington State Cities with quality research in the Board's possession which persuades the Board that fluoridation is safe for the developing brain or any of the known risks.

#3. The Board claims fluoridation is **cost effective**.

REQUEST: Please provide the public and Washington State Cities with quality research that fluoridation is cost effective when treating known and undisputed adverse effects such as harm from cosmetic and functional dental fluorosis or lost wages from lower IQ are included.[4]

#4. The Board implies that even though the majority of children now show signs of too much fluoride ingestion (dental fluorosis) that children still need **more fluoride** by adding fluoride to public water.

REQUEST: Please provide the public and Washington State Cities a range of dosage which children are ingesting from all sources, total fluoride exposure, and a safe dosage of fluoride when risks are included.

#5. The **concentration of fluoride has been reduced** from 1.0 mg/L of fluoride in water to 0.7 mg/L of fluoride in water.

REQUEST: Please provide the public and Washington State Cities evidence, even observational evidence, that fluoride is allegedly still beneficial with a 30% reduction in concentration.

#6. The **tooth is highly resistant** to the migration of fluoride through the calcium rich tooth.

REQUEST: Please provide the public and Washington State Cities a mechanism of fluoride benefit. How does fluoride get from the blood through the tooth to where the caries are developing?

#7. Fluoride supplements and **other sources** of fluoride are easily obtained.

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[4] Osmunson B, Cole G, Community Water Fluoridation a Cost-Benefit-Risk Consideration, Public Health Challenges, November 7, 2024.

REQUEST: Please provide the public and Washington State Cities explanation of why these other sources of fluoride are not acceptable or inadequate?

#8. The EPA does not use any **margin of error or uncertainty factor or intraspecific variation**. : Not all humans are at a "statistical mean" in race, age, size, gender, diet, health, genetics or total toxic chemical burden of synergistic toxins.

REQUEST: Please provide the public and the Washington State Cities the margin of error or uncertainty factor or intraspecific variation the Board has selected for fluoride exposure?

#9. The Board should have evidence of the **purity of fluoride** added to public water.

REQUEST: Please provide the public and the Washington State Cities a copy of the batch assay reports, the purity, for fluoride added to water in Washington State over the last year?

#10. The CDC Division of Oral Health does not have evidence of fluoride's benefit for the fetus or infants.

REQUEST: Please provide the public and the Washington State Cities the evidence the Board has that fluoride is effective or safe for the fetus or infants?

#11. The U.S. District Court found *"It is undisputed that large numbers of susceptible individuals are being exposed each year to fluoride through fluoridation*. . . ." about 300,000 pregnant women each year, about **6,000 infants in Washington State**, are formula fed and their brains, teeth and all cells are at risk of harm.

REQUEST: Please provide the public and Washington State Cities with the Board of Health's determination of the acceptable number of children's brains which can be damaged with fluoridation based on the Boards determination of efficacy. And further, please include the acceptable risk for the other risks as listed by the NRC 2006 report (see below).

#12. Please provide peer reviewed published evidence that fluoridation is ethical when the known and probable risks are included.

Those are just a few questions the Board of Health must answer if they are going to assure safety of fluoridation.

The task of keeping up with science just on fluoridation is monumental and life-long. However, failure to protect the public is a catastrophe and could be considered a criminal act. Of context, remember a doctor's mistake is malpractice and can harm the patient or they may die. A Public Health mistake like fluoridation can harm and is harming millions.

Public health credibility is also at stake and as science changes our understanding and policy must also adapt. In our Addendum A submission, we provided slides from the NTP and they are slightly distorted (sent to me that way by the author), sorry for the poor copy. The NTP has since published the webinar which has audio along with the slides. The webinar is

shorter than the published Monograph National Toxicology Program report. The meta-analysis is yet to be published. **The Webinar: https://www.healthandenvironment.org/che-webinars/96797** Fluoride, Neurodevelopment, and Cognition: A National Toxicology Program Monograph from December 3, 2024 is critical to watch and consider.

1. **Fluoridation is not cost effective** regardless of all published claims. . . if harm to teeth and brains with just lost wages are included. **Public Health Challenges** https://doi.org/10.1002/puh2.70009
2. **The Nuffield Council on Bioethics**: *"The acceptability of any public health policy involving the water supply should be considered in relation to:*
   (i) the balance of risks and benefits;
   (ii) the potential for alternatives that rank lower on the intervention ladder to achieve the same outcome; and
   (iii) the role of consent where there are potential harms [para 7.26]."

   Fluoridation fails on all three points.

   (i) Potential harms are reported by the National Research Council in 2006 to such structures and physiologic functions as cells, teeth, skeleton, chondrocyte metabolism, arthritis, reproductive and developmental effects, neurotoxicity, neurobehavioral effects, endocrine system, gastrointestinal, renal, hepatic, immune systems, genotoxicity, carcinogenicity, and more recently concerns of potential low birth weight, miscarriage, and increased infant mortality have been raised. Safety should be assured by authorities rather than patients required to prove that they are being harmed. Randomized controlled trials, required for FDA CDER approval, safety, dosage, label and individual consent are lacking. Control of the amount of water consumption is not controlled and thus dosage is uncontrolled. Good Manufacturing Practices for Pharmaceuticals are violated.

   (ii) Alternatives which are safer include prescriptions from health care providers which control for dosage, consent, and purity. Even swallowing a pea size of toothpaste is an alternative, although the FDA advises not to swallow toothpaste. In addition, avoiding organic foods, don't wash produce, eat/drink foods high in fluoride such as black tea, wine, grape juice, mechanically deboned meat, and/or foods with fluoride post-harvest fumigant will all, and many others, cause excess fluoride exposure for many.

   (iii) Alternatives provide for consent and water fluoridation violates individual consent in the face of known harm, dental fluorosis and other risks.

   We highly disagree with the Nuffield report which suggests a vote by one's neighbors may make it ethical. Turning over decisions of pharmacology to one's neighbors is not ethical. Pontius Pilot tried washing his hands of the crime. Industry with money can market their products and gain a majority vote. Prescription drugs, including fluoride, must not be prescribed based on a popular vote.

3. **A University of Washington professor,** Dr. Charlotte Lewis, is (was) an avid promoter of historical fluoride evidence. The Board should keep in mind, in an attempt to protect fluoridation, some promoters of fluoridation have rather extreme views of both teeth and brains. In sworn deposition, Dr. Lewis testified:

Q. At this point in time, you are not prepared to say that you would withdraw your support of water fluoridation even if the evidence convinced you that it's reducing the IQ by five points in 5 to 10 percent of the population? You still would support water fluoridation at that time?

A. Well, again, because that's not the scope of what I was asked to look at, it's difficult for me to answer the question, but there are circumstances where I can imagine that that would be an appropriate trade-off.

Q. Okay. You're saying there are circumstances where I can imagine. I'm asking you based on those facts I've given you, would you or would you not withdraw your support for water fluoridation?

A. I would not withdraw my support of community water fluoridation.

AAP Spokesperson Sees IQ Loss As An Acceptable "Trade Off" For Fluoridation - Fluoride Action Network

Someone who is willing to trade IQ for ingesting excess sugar and failure to practice good oral hygiene is extremely and carelessly biased. There is no known fluoride deficiency disease. The absence of fluoride in the diet does not cause dental caries. Even if a fluoride deficiency existed, dentists can fix dental caries but not IQ loss and other developmental harm from fluoride is serious. Front matter | Fluoride in Drinking Water: A Scientific Review of EPA's Standards | The National Academies Press And excess sugar contributes to other diseases.

However, as a dentist who treated many children in the office and took some to the hospital, I am on Dr. Lewis's side with concern for the pain and suffering children can have in their mouths. Pediatricians can prescribe drugs and pull teeth, but the doctor suffers along with the patient and parents. However, fluoridation is not the answer even if fluoridation mitigates dental caries at the highest alleged benefit because brains are more important than teeth.

The sugar lobby has created the narrative that dental caries are the problem. Not so fast. The etiology (cause) for dental caries is primarily sugar, poor diet and lack of hygiene which contribute to dental caries, pain, and harm and dental caries are a sign of a bad diet and lack of hygiene. I love sugar. I'm addicted to sugar. It pains me to find fault with my bad habits.

Let’s be honest and blame sugar/diet and hygiene rather than a symptom of our bad habits. For example, we in public health can blame a person’s lung cancer for their death, but the blame should be focused on the person’s exposure to tobacco use, asbestos and pesticide exposures and other causes and contributing factors for the cancer rather than a symptom. The etiology of the pathology needs to be blamed for the disease, not a mythical, assumed, alleged, lack of an unapproved highly toxic chemical exposure.

4. Please consider additional streams of evidence at https://www.youtube.com/watch?v=d7DA02SNd5M
5. Even 0.7 ppm fluoride in water, the alleged optimal fluoride concentration in water, can harm the developing brain. Maternal Urinary Fluoride and Child Neurobehavior at Age 36 Months - PubMed Current science is overwhelmingly consistent, fluoride is harmful and alleged evidence of assumed efficacy is “incomplete.”
6. The former head of the NTP (National Toxicology Program Office of Health Assessment and Translation) made a presentation: VIDEO: Former NTP Director’s Statement on Fluoride Neurotoxicity - Fluoride Action Network
7. I was one of those who nominated fluoride's developmental neurotoxicity to the NTP for review in 2015 because the Washington State Board of Health in numerous petitions for rule change over 5 years had refused to protect the public health. 10 years later and the final second part of the report has still NOT been published. However, the draft meta-analysis is a crushing blow to fluoridation. HHS delayed and blocked release until the Court ordered the release. Why? Why did HHS block release if the release was not toxic to the policy? You can see reasons and more court history here: National Toxicology Program (NTP) Report - Fluoride Action Network

National Toxicology Program (NTP) Report - Fluoride Action Network

NTP’s Involvement in Fluoride Neurotoxicity. In 2015 the NTP solicited a request for information in the Federal Register on fluoride’s carcinogenicity, developmental neurotoxicity, and endocrine disruption. FAN submitted comments and the NTP made the decision to investigate fluoride’s neurotoxicity.. In December 2015 an “Evaluation of Fluoride Exposure and Potential for Developmental ...

fluoridealert.org

Note: the NTP report with Moderate Confidence is based on published research up to May 1, 2020, where NTP determined 18 of 19 high quality studies (and many lower quality studies) reported neurodevelopmental harm.

Subsequent to that report and between 2020, and up to 2023, NTP has an addendum reporting an additional 12 of 12 high quality studies reporting harm. Note, the Malin 2024 (link above) report is not included in the 12 of 12. The NTP is only considering one of many risks. The NTP took 10 years with the most thorough peer reviews by the fluoridation lobby and the recommendations were not about the conclusion but on clarity. At this rate, it will take centuries to carefully review all the risks of fluoride. We must now act.

8. Federal Court Rules That Water Fluoridation Poses an "Unreasonable Risk" to Children - Fluoride Action Network The Court has been highly scientific with their determination. Public funded research blocked by HHS should not take thousands of dollars in court and lawyer fees and require a court order for release. The public loses trust in authorities, especially my public health profession, when HHS public health authorities or the Board obstruct and block and manipulate science or refuse to protect the public.
   The Court found that*, "It is undisputed that large numbers of susceptible individuals are being exposed each year to fluoride through fluoridation, namely, approximately two million pregnant women, and over 300,000 exclusively formula-fed babies."*

   Washington state has about 2% of pregnant women in the USA or about 6,000 exclusively formula-fed babies, a disproportionate number are in the low socioeconomic population of moms who need to work. And most babies have both formula and mother's milk during part of their development which would also be of risk. The Court is referring to a baby after it is born.

   Before the baby is born, 100% of fetuses are affected by mothers drinking fluoridated water.

   And further, the fetus needs calcium and the baby pulls calcium out of the mother, especially during the final trimester. As the bones resorb to give the fetus calcium, fluoride is also given off from the bones and enters the fetus. Thus, girls and women who may become pregnant, (all girls and women) would be best not to drink fluoridated water at least 20 years prior to pregnancy.
9. The National research Council 2006, report for the EPA Front matter | Fluoride in Drinking Water: A Scientific Review of EPA's Standards | The National Academies Press is one of the best sources on risks from fluoride exposure and to date is still the best source on total fluoride exposure and the variation of individual fluoride exposure. Remember that not everyone drinks the same amount of water. For example, recommendation of 10 glasses of water per day for pregnant women is over 2 liters of water which has similar dosage as one liter of water at 1.5 mg/L, which the NTP report had moderate confidence of harm.

10. The past Director of the CDC's Division of Oral Health testified in sworn deposition that fluoride supplements do not benefit the fetus or infants when given to pregnant mothers.

Consider CDC Division of Oral Health does not have evidence of benefit at the same time of development the fetus is at risk of brain damage (NTP and Court.) and other cells, systems, tissues, and organs (NRC 2006).

No or little known benefit, only known risk from swallowing fluoride.

Neither the National Toxicology Program, Centers for Disease Control, the Environmental Protection Agency, the Food and Drug Administration nor the three largest fluoride manufacturers in sworn testimony under oath could provide a single study, just one study, on the safety of fluoride ingestion to the developing brain. I have not found any study in the thousands of pages received from the Board of Health under FOI request which reported safety of fluoride ingestion to the developing brain. Plenty of endorsements and observational claims, no science.

We have only touched on each stream of evidence and there is much, much more.

Bill Osmunson DDS MPH

Washington Action for Safe Water

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[i] CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22
[ii] http://www.cdc.gov/fluoridation/ Accessed 9/26/10 CDC does not determine the safety or efficacy of fluoridation.
[iii] CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22.
[iv] Chemical and Engineering News, May 8, 1989, Vol 57, Number 19.
[v] ARNOˇST KOMA´ REK∗, EMMANUEL LESAFFRE Biostatistics (2005), 6, 1, pp. 145–155
doi: 10.1093/biostatistics/kxh023

From: DOH WSBOH
Sent: 12/24/2024 10:41:30 AM
To: Davis, Michelle (SBOH),Bauman, Shay (SBOH),Noble, Ashley A (SBOH)
Subject: Fw: [EXTERNAL] Re: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

attachments\0A118998929949C6_image001.png

From: bill teachingsmiles.com <bill@teachingsmiles.com>
Sent: Thursday, December 12, 2024 12:20 PM
To: CDERPASE <CDERPASE@fda.hhs.gov>; mmakary1@jhmi.edu <mmakary1@jhmi.edu>; Michael Connett <mconnett@gmail.com>; Stuart Cooper <stuart@fluoridealert.org>; john william hirzy <jwhirzy@gmail.com>; Hardy Limeback <hardy.limeback@gmail.com>; Ellen C <ellen@fluoridealert.org>; Linda Birnbaum <birnbaum.tox@outlook.com>; David Kennedy <davidkennedydds@gmail.com>; Griffin Cole <griffincole@yahoo.com>; Team Kennedy <info@teamkennedy.com>; DOH WSBOH <WSBOH@SBOH.WA.GOV>; Gerald Steel <geraldsteel@yahoo.com>; Chris Nidel <chris@nidellaw.com>; audrey55 <audrey55@comcast.net>; Paul Connett <pconnett@gmail.com>
Cc: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

External Email

Dear PASE Staff, HHS/FDA/CDER/OCOMM, Dr. Makary, Washington State Board of Health, and All,

Is it the official position of HHS/FDA/CDER that the FD&C Act exempts the FDA CDER from regulatory oversight of drugs when diluted in public water? You have denied to even listen to science, laws and ethics (see your email below).

For example, according to the FDA CDER denial of jurisdiction, should a drug manufacturer decide to manufacture a new or existing drug, a simple dilution in tap water exempts the drug from the FD&C Act, FDA CDR NDA, Good Manufacturing Practices for Pharmaceuticals, label, dosage, or adequate research on efficacy and safety.

I, as a dentist, have made millions of dollars both selling fluoride and now I realize I was also treating fluoride cosmetic and functional harm. The fluoridation lobby is biased.

We should agree, fluoride marketed with intent to prevent disease is a drug. 21 USC 321(g)(1)(B).

1.

FDA testified to Congress that fluoride is a drug. Congressional Investigation 2001.
2.

Sodium fluoride is listed in the U.S. Pharmacopeia, etc.

3. The fluoride toothpaste label is clearly labeled, Drug Facts.

4. The Washington State Board determined fluoride is a legend drug.

5. The FDA notified 35 companies "there is no substantial evidence of drug effectiveness as prescribed, recommended or suggested in its labeling. . . Marketing is in violation of the new drug provisions of the Federal Food, Drug, and Cosmetic Act; they have, therefore, requested that marketing of these products be discontinued." Drug Therapy 1975.

6. Fluoride is not added to reduce water contamination. Fluoride is not a nutrient.

EPA: The Safe Drinking Water Act (SDWA) is precise that the SDWA prohibits the EPA from regulating drugs added to tap water.
42 USC 300g-1(b)(11) "No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water."

In an FOIA response, (HQ-FOI-01418-10) the EPA responded, "The Safe Drinking Water Act prohibits the deliberate addition of any substance to drinking water for health-related purposes other than disinfection of the water."

Steve Neugeboren, Ass. General Counsel, Water Law Office of the EPA, 2/14/2013, responded, "The FDA, remains responsible for regulating the addition of drugs to the water supply for health care purposes."

The FDA points the jurisdictional finger at the EPA, and EPA at the FDA. Hundreds of millions of Americans are harmed.

The HHS, FDA, CDERPASE confirms in their email below, you have repeatedly over the years refused to even listen to the evidence and failed to protect the public.

My request is that you reconsider your denial of a Listening Session and give us time to provide scientific, legal, and ethical evidence. Please advise where we can make an appeal if necessary.

Refusing to listen is a form of censorship.

Sincerely,

Bill Osmunson DDS MPH
Washington Action for Safe Water

From: CDERPASE <CDERPASE@fda.hhs.gov>
Sent: Wednesday, December 11, 2024 9:29 AM
To: bill teachingsmiles.com <bill@teachingsmiles.com>
Cc: CDERPASE <CDERPASE@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

Hello Mr. Osmunson,

Thank you for the additional information. As we have consistently stated publicly and through correspondence over the years, the EPA, not FDA, has the authority to regulate the use of fluoride compounds in public drinking water. You can find that information on our website (https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/does-fda-regulate-fluoride-drinking-water <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.fda.gov%2Fdrugs%2Ffreque
asked-questions-popular-topics%2Fdoes-fda-regulate-fluoride-drinking-water&data=05%7C02%7CShay.Bauman%40sboh.wa.gov%7Cf4fcb338ddf44cfb718c08dd244a9413%7C11
). We also refer to your state and local governments as the entities that decide on water fluoridation.

For these reasons, we are declining your request for a Listening Session.

Should you have further questions related to human drug products or other areas within our jurisdiction, please don’t hesitate to reach out.

PASE Staff, CDER/OCOMM

From: bill teachingsmiles.com <bill@teachingsmiles.com>
Sent: Monday, November 25, 2024 1:57 PM
To: CDERPASE <CDERPASE@fda.hhs.gov>
Cc: Michael Connett <mconnett@gmail.com>; Rick North <hrnorth@hevanet.com>; cc Reed <cici.reed1@gmail.com>; Derek Kemppainen <derekkempp@gmail.com>; Carol S. Kopf <ckopf2@optonline.net>; Ellen C <ellen@fluoridealert.org>; Doug Cragoe <cragoe@sbcglobal.net>; Jack Crowther <jack_cr3@yahoo.com>; Neil Carman <neil_carman@greenbuilder.com>; Carol Goodwin Blick <cgb@blicklabs.com>; Moms Against Fluoridation <momsagainstfluoridation@gmail.com>; Ellen C <ellen@fluoridealert.org>; Bob Runnells <wa.bob.runnells@childrenshealthdefense.org>; Hardy Limeback <hardy.limeback@gmail.com>; Stuart Cooper <stuart@fluoridealert.org>; Chris Nidel <chris@nidellaw.com>; John Mueller <jfmjr66@gmail.com>; Dawn Ewing <drdawn@drdawn.net>; dawnagal19@gmail.com; Mike Ewall <mike@energyjustice.net>; Paul Connett <pconnett@gmail.com>; Gilles Parent <gilles.parent@bellnet.ca>; David Kennedy <davidkennedydds@gmail.com>; Griffin Cole <griffincole@yahoo.com>; Jay Sanders <jay@fluoridealert.org>; audrey55

<audrey55@comcast.net>; Chris Neurath <cneurath@AmericanHealthStudies.org>
Subject: Re: [EXTERNAL] Re: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

Dear CDERPASE Staff,

Thank you for your quick response. Millions are being harmed and our intent is to stop the harm and protect the public health.

Response to your two questions.

#1. You asked, " kindly provide additional details about your organization, Teaching Smiles? Specifically, it would be helpful to know more about the organization's mission, activities, and scope of work."

Teaching smiles was an organization to teach neuromuscular, temporomandibular disorders, cosmetic dentistry and I continue to use the email address. Cosmetic dentistry morphed into toxicology and joining with the American Environmental Health Studies Project and Fluoride Action Network along with the International Academy of Oral Medicine and Toxicology, Washington Safe Water, Mom's Against Fluoridation, Food and Water Watch, the Surgeon General of Florida, RF Kennedy Jr. and you can find a list of professionals opposed to fluoridation.

Our activities involve persuading authorities to read and follow science, laws and ethics to protect the public health.

Fluoridealert.org
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsecure-web.cisco.com%2F1foDydyCtvPuBte657WdKRBe0WWpx8mJ0m-7I-7J6Sod0PVQcq2DehK_h7C4KtFZt3YBPNrwCQDIAo3JrGld-d3C5lYJ_ByxWgpDIaPq-dXa3N-jTfx5Hi8GFoOEKw7hPeivAu1mUN2tHRx4pynKnLKM-wlAp8cRyaIs51Mb4YBwtXGVbNlT3fhvDm-mcstMb694DJJSPGpd9M-kfhrUFPVlkioCFgg_fdzkq4af10L4%2Fhttps%253A%252F%252Ffluoridealert.org&data=05%7C02%7CShay.
who's website is being upgraded, and iaomt.org mission is at https://iaomt.org/about-iaomt/ <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsecure-web.cisco.com%2F109J8OJPHV5pyVKJBLDjh2nlrFzdz2olnCFYsEv0Kmlo4n2Ct1B28pm82mSviP1p2c0YPJljJZy
YLWXF5bGfpbXG4DkfbrCyjANHoxCStknvXe6AmbdBI%2Fhttps%253A%252F%252Fiaomt.org%252Fabout-iaomt%252F&data=05%7C02%7CShay.Bauman%40sboh.wa.gov%7Cf4fcb338ddf44cfb718c08dd244a9413

In brief, we are science based and focused on the harm contributed and caused by excess fluoride and mercury exposures and we encourage safer and better dental treatments.

I made a ppt with audio which will provide additional information for you
https://www.youtube.com/watch?v=d7DA02SNd5M
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.youtube.com%2Fwatch%3Fv

#2. To your question: "Additionally, we would appreciate further clarification regarding the FDA-regulated products you would like to discuss in relation to the concerns mentioned in your meeting topic and goal."

Drugs diluted in public water.

Are drugs diluted in tap water exempt from FDA CDER NDA?

Your question can have at least two directions.

A. Our focus is partly on the inappropriate regulation of FDA-products; however,

B. Our primary focus is on the total lack of regulating products the FDA is required by Congress to regulate of which the FDA CDER has failed to regulate which are causing and contributing to serious public harm.

For example, the FDA CDER has in the past suggested that FDA CDER does not regulate public water, which is the jurisdiction of the EPA under the Safe Drinking Water Act (SDWA).

And, the SDWA prohibits the EPA from adding anything to public water with intent to prevent disease in humans. EPA does not regulate the addition of drugs to tap water, EPA is prohibited.

Therefore, it appears in the view of the FDA CDER that Congress specifically left one avenue of drug manufacturing without any regulatory oversight.

If a drug manufacturer were to simply add a drop of water to their vat with or without chemicals, regardless of toxicity, purity, label, dosage, concentration, efficacy or GMP, and calls the drug a miracle drug which will treat, prevent, or cure Alzheimer disease or MS or any other disease; the drop of tap water exempts the drug from any FDA or EPA oversight. In our opinion, that is not Congress's intent. However, that is the regulatory loophole fluoridation is in.

FDA testified to Congress, fluoride is a drug.

The U.S. Pharmacopeia lists sodium fluoride as a drug.

The intent of use to prevent dental caries, a disease, places fluoride as a drug.

When the Washington State Board of Health called the FDA CDER to inquire about gaining FDA CDER approval for the fluoridation drug, the FDA CDER reportedly said if application is attempted, fluoridation would be banned. That does not sound like approval, safety, or lack of jurisdiction.

If, by some twist of imagination and speculation or point of discussion, fluoride is not a drug regulated under drug laws, then it is a poison and cities should be informed they are poisoning the public. Yet we know fluoride is a drug simply by reading the fluoride toothpaste label.

Our intent in this listening process is to protect the health of the public. Protection of the public health is our first and only mission.

Can we work together to improve the health of the public?

We do appreciate you providing us with time to review our concerns and willingness to take regulatory action. A simple letter to the state departments/boards of health informing them that the ingestion of fluoride diluted in water is not approved and for them to notify their water districts and cities to suspend, cease, manufacturing until FDA CDER NDA is approved.

Once again, the video I made for you will explain in greater detail.

Sincerely,

Bill Osmunson DDS MPH

425.466.0100

bill@teachingsmiles.com <mailto:bill@teachingsmiles.com>

We are not into conspiracies . . . we are into "follow the science and money."

From: CDERPASE <CDERPASE@fda.hhs.gov <mailto:CDERPASE@fda.hhs.gov> >
Sent: Monday, November 25, 2024 7:26 AM
To: bill teachingsmiles.com <bill@teachingsmiles.com <mailto:bill@teachingsmiles.com> >
Cc: CDERPASE <CDERPASE@fda.hhs.gov <mailto:CDERPASE@fda.hhs.gov> >
Subject: RE: [EXTERNAL] Re: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

Hello Bill,

Thank you for reaching out to our office with your meeting request and for sharing detailed information on the topic of fluoride and its potential effects. We appreciate your interest in engaging with us on this important issue.

To help us better understand your request and consider next steps, could you kindly provide additional details about your organization, Teaching Smiles? Specifically, it would be helpful to know more about the organization’s mission, activities, and scope of work.

Additionally, we would appreciate further clarification regarding the FDA-regulated products you would like to discuss in relation to the concerns mentioned in your meeting topic and goal.

Your assistance in providing this information will help ensure we have a clear understanding of your request. Please feel free to reach out with any questions or if additional context is needed.

We appreciate your time and effort in providing this information, and we look forward to your response.

PASE Staff, CDER/OCOMM

From: bill teachingsmiles.com <bill@teachingsmiles.com <mailto:bill@teachingsmiles.com> >
Sent: Sunday, November 24, 2024 4:53 PM
To: CDERPASE <CDERPASE@fda.hhs.gov <mailto:CDERPASE@fda.hhs.gov> >
Subject: [EXTERNAL] Re: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear CDERPASE,

Perhaps I missed your email and response.

I am requesting a meeting, see below.

Thank you,

Bill Osmunson DDS, MPH

From: CDERPASE <CDERPASE@fda.hhs.gov <mailto:CDERPASE@fda.hhs.gov> >
Sent: Wednesday, November 20, 2024 5:06 AM
To: bill teachingsmiles.com <bill@teachingsmiles.com <mailto:bill@teachingsmiles.com> >
Cc: CDERPASE <CDERPASE@fda.hhs.gov <mailto:CDERPASE@fda.hhs.gov> >
Subject: FW: FDA Patient Webform Request - Teaching Smiles (Bill Osmunson)

Hello Bill,

Your meeting request has been forwarded to the Professional Affairs and Stakeholder Engagement (PASE) Staff within the FDA’s Center for Drug Evaluation and Research (CDER). We acknowledge receipt of your inquiry, and our team is currently reviewing it.

A member of our team will follow up with you shortly. Please don’t hesitate to reach out if you have any additional questions in the meantime.

PASE Staff, CDER/OCOMM

From: Webform@fda.gov <mailto:Webform@fda.gov> <Webform@fda.gov <mailto:Webform@fda.gov> >
Sent: Tuesday, November 19, 2024 2:42 PM
To: ForPatients <ForPatients@fda.hhs.gov <mailto:ForPatients@fda.hhs.gov> >
Subject: FDA Patient Webform Request

Dear Sir or Madam,

Request By: Bill Osmunson

Requestor Email Address: Bill@teachingsmiles.com <mailto:Bill@teachingsmiles.com>

Requestor Phone: 4254660100

Please tell us who you are (*):

Response: Health Professional

Name of Group (if applicable):

Group's website link (if applicable):

Brief description of group or group's mission statement (if applicable):

Other (if applicable):

Question or Meeting Request: Meeting

Is Request about a Specific FDA Program: Yes

What is your request about:

- Vaccines, Blood & Biologics :
- Drug: Yes
- Medical Device:
- Disease or Health Condition :
- Multiple or Unknown :

Select an FDA program, if applicable

Multi-Product Programs:

- Patient Engagement Collaborative (PEC): Yes

Name of Disease or Condition (if applicable):
Developmental Neurotoxicity, developing brain damage, dental fluorosis, and potential harms are reported by the National Research Council in 2006 to such structures and physiologic functions as cell function, teeth, skeleton, chondrocyte metabolism, arthritis,

reproduc-tive and developmental effects, neurotoxicity, neurobehavioral effects, endocrine system, gastroin-testinal, renal, hepatic, immune systems, genotoxicity, carcinogenicity, and more recently concerns of potential low birth weight, miscarriage, and increased infant mortality have been raised.

Meeting Topic:
Harm from the over-exposure, lack of label, lack of dosage control, misbranded, adulterated, contaminated, illegal drug fluoride and FDA CDER's deferring of regulatory action.

Meeting Goal:
Requesting Regulatory Action on fluoride and fluoridation marketed and manufactured with intent to prevent dental caries.

***If a question or meeting request is sent to an incorrect mailbox and the correct point of contact is unknown, it should be sent to PatientAffairs@FDA.HHS.gov <mailto:PatientAffairs@FDA.HHS.gov> . Please add "5714" to the end of the subject line before sending the email.

***For questions or meeting requests that are incorrectly auto-routed where the correct POC is known, PatientAffairs@FDA.HHS.gov <mailto:PatientAffairs@FDA.HHS.gov> should be cc'd in the process of identifying the correct POC for tracking purposes. Please add "5714" to the end of the subject line before sending the email.